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ORIGINAL ARTICLE

A prospective, randomised study of a novel transforming methacrylate dressing compared with a silver-containing sodium carboxymethylcellulose dressing on partial-thickness skin graft donor sites in burn patients

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Key words
Altrazeal; Burns; Carboxymethylcellulose dressing; Dressing change; Pain; Silver dressings; Split-thickness skin graft donor sites; Transforming methacrylate dressing

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Abstract

This prospective, randomised study compares a new transforming methacrylate dressing (TMD) with a silver-containing carboxymethylcellulose dressing (CMC-Ag) after application to split-thickness skin graft (STSG) donor sites. This was an unblinded, non-inferiority, between-patient, comparison study that involved patients admitted to a single-centre burn unit who required two skin graft donor sites. Each patient's donor sites were covered immediately after surgery: one donor site with TMD and the other with CMC-Ag. The donor sites were evaluated until healing or until 24 days post-application, whichever came first. Study endpoints were time to healing, daily pain scores, number of dressing changes, patient comfort and physicians' and patients' willingness to use the dressings in the future. Nineteen patients had both the dressings applied. No statistically significant difference was noted in time to healing between the two dressings (14·2 days using TMD compared with 13·2 days using CMC-Ag). When pain scores were compared, TMD resulted in statistically significantly less pain at three different time periods (2–5 days, 6–10 days and 11–15 days; $P < 0{\cdot}001$ at all time periods). Patients also reported greater comfort with TMD ($P < 0{\cdot}001$). Users rated TMD as being less easy to use because of the time and technique required for application. Reductions in pain and increased patient comfort with the use of the TMD dressing, compared with CMC-Ag, were seen as clinical benefits as these are the major issues in donor site management.

Introduction

Acute wounds, such as burns and crush injuries, chronic wounds, such as venous leg ulcers, and wounds associated with necrotising tissue infection often require excision and split-thickness skin grafting (STSG). STSG donor sites can be expected to heal, with appropriate wound care, within 10–20 days (1,2) using the TIME principles (3). These donor site wounds require a moist, clean wound environment, free of cellular debris and need to be protected from external mechanical and infectious agents (2,4). A variety of dressings

Key Messages

- this prospective, randomised unblinded, non-inferiority, between-patient comparison study involving patients admitted to a single-centre burn unit who required two

skin graft donor sites compared a new transforming methacrylate dressing (TMD) with a silver-containing carboxymethylcellulose dressing (CMC-Ag) after application to split-thickness skin graft (STSG) donor sites
- no statistically significant difference was noted in time to healing between the two dressings (14·2 days using TMD compared with 13·2 days using CMC-Ag) but when pain scores were compared, TMD resulted in statistically significantly less pain at three different time periods (2–5 days, 6–10 days and 11–15 days; $P < 0{\cdot}001$ at all time periods); patients also reported greater comfort with TMD ($P < 0{\cdot}001$)
- users rated TMD as being less easy to use because of the time and technique required for application but the reductions in pain and increased patient comfort with the use of the TMD dressing, compared with CMC-Ag, were seen as being clinical benefits as these are the major issues in donor site management

are available to accommodate these requirements including moist, non-resorbable gauzes and sponges; hydrophilic and hydrogel dressings; occlusive hydrocolloid wound dressings and other interactive wound and burn dressings (classified in national and international formularies), as well as those incorporating topical antimicrobials (including polyhexamethylene biguanide, povidone-iodine and chlorhexidine), silver sulphadiazine, silver emulsions and silver barrier dressings and silicone dressings. One of the most widely used dressings, available for STSG donor sites and partial-thickness burns, is a sodium carboxymethylcellulose sheet, which can be applied to the wound bed (5,6). Aquacel Ag with Hydrofiber® (ConvaTec, Princeton, NJ) is one of the currently used dressings (7).

Transforming methacrylate wound dressing (TMD; Altrazeal, Uluru Inc., Addison, TX) is a novel dressing composed of biologically inert polymer particles of poly(2-hydroxyethyl methacrylate) and poly(2-hydroxypropyl methacrylate). These hydrophilic polymers contain a covalent methacrylate backbone with a hydroxyl aliphatic side chain (8). When applied to a moist wound bed, the sterile TMD interacts with wound exudate. Its hydration causes the particles to aggregate irreversibly and form a moist, flexible surface wound dressing, which seals the wound and conforms to the surface of the wound bed. After aggregation, capillary channels allow the transport of excess exudate away from the wound surface through a high moisture vapour transpiration rate of approximately 12 l/m^2/24 hours. The aggregated dressing contains approximately 68% water, which is similar to the water content of skin (72–74%), creating a moist wound healing environment and enhancing its biological compatibility. TMD is indicated for use in surgical wounds, exuding superficial acute wounds (such as STSG donor sites and second degree burns) as well as chronic wounds including leg ulcers, pressure ulcers and diabetic foot ulcers. Clinical experience using TMD in the treatment of diabetic foot-related necrotising fasciitis has been published, reporting a decrease in pain after application of the TMD dressings (8). This was attributed by the authors to be related to a decrease in inflammation, a cooling effect of the dressing and complete wound sealing associated with the application of TMD.

These physical and clinical properties supported the design of a prospective, randomised study to investigate the clinical outcomes and feasibility of using TMD compared with a widely used silver-containing carboxymethylcellulose dressing (CMC-Ag) in the treatment of STSG donor sites.

Methods

The study was designed as a single-centre, prospective, randomised, unblinded study involving burn patients who required STSGs and had two independent skin donor sites of approximately the same dimensions. Prior to study initiation, the protocol was reviewed and approved by the Institutional Review Board (IRB) of the University of Texas Southwestern Medical Center. Informed consent was obtained from all study patients, who were male or female, in general good health, and between the ages of 5 and 76 years. Patients were excluded if less than 3 years or more than 85 years of age, had acutely infected wounds or wounds with surrounding cellulites, a history of hypersensitivity to components of either the TMD or CMC-Ag dressing, a current clinical condition that could pose a health risk to the patient, or had a history of poor wound healing or any immune system condition that could increase the likelihood of wound irritation or infection. Furthermore, patients unable to communicate or cooperate with the investigators were also excluded from the study.

Recruitment was closed after 20 patients were enrolled and treated with the study dressings. Each patient had to have at least two split-thickness donor sites for inclusion, which were identified prospectively as 'A' or 'B'. On the day of graft surgery, one donor site was dressed with TMD and the other with CMC-Ag in a randomised, pre-allocated fashion, so that each patient served as his or her own control. A requirement was that the two donor sites had to be separated from each other by a strip of intact skin and were to be of similar dimensions.

Consenting patients underwent excision of the burn and application of the skin grafts (day 1). After general anaesthesia was administered, a solution of lactated Ringer's solution, with or without phenylephrine, was injected at the proposed donor sites. Split-thickness grafts were harvested using a dermatome (Zimmer® Air, Warsaw, IN) at a nominal setting of 0·010–0·012 inches. The grafts were then meshed at a 2:1 or 4:1 ratio. After the burn tissue was excised, the meshed skin grafts were secured to the excised wound beds using a surgical stapling device.

Before application of TMD to the donor site, the surgeon was instructed to clean the skin area with an appropriate wound cleanser to ensure that no oil-based products such as mineral oil, lotion or ointments were present. TMD was applied to the entire moist wound surface in a thin layer, with any excess on the surrounding intact skin being brushed off. The amount of dressing applied was dependent on graft size. Similarly, before application of a CMC-Ag dressing, the surgeon was instructed to clean the graft donor site area

and apply the dressing with a half- to one-inch overlap onto the skin surrounding the wound. As both dressings are incompatible with oil-based products such as petrolatum, identical wound cleansing procedure was required not only for comparison reasons but also to follow the manufacturers' directions. A secondary protective gauze dressing was applied over both dressings.

Both comparator dressings were designed to cover and protect the STSG donor area until healing without dressing change unless there was evidence of leakage, bleeding, infection or pain. Meticulous wound care and adequate analgesia were provided for the duration of the study. Patients were monitored daily as part of standard procedures whilst they were in the in-patient setting. If and when patients moved to an outpatient setting, they were monitored on alternate days at the study centre. At each visit, the investigator determined whether each skin graft donor site had healed, using the institution's standard care guidelines (i.e. >95% epithelialisation).

Subjects were questioned about pain using a 0–10 Linear Analog Scale Assessment (LASA) scale (9), with '0' being no pain and '10' being the worst imaginable pain. Similarly, patients' and investigators' satisfaction was surveyed using a 1–10 LASA scale. Additionally, 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 was sooner. If one or both of the graft donor sites were not healed by day 24, a follow-up visit (25–30 days post-surgery) was scheduled at the investigator's discretion. All dressing changes were recorded during the course of the study.

Statistical analysis

The mean number of days to healing was estimated using survival analysis methods (10). For those patients whose time to healing was not observed (lost to follow-up), time to healing was estimated based on the last visit, and the estimated survival functions, using the assumption that complete healing would occur sometime on or before day 24. The conventional log-rank comparison of survival curves was not used because the times to healing for each treatment were observed on the same patient. However, the method of imputing healing times appeared to give reasonable estimates and the matched-pairs *t*-test was used for statistical analysis. Pain scores were averaged for each patient and each donor site as follows: days 2–5, days 6–10 and days 11–15. Average pain scores at each of these three time points were compared using a mixed-model, repeated-measures ANOVA analysis that accounted for the treatments being observed on the same patient. For the patients' and investigators' satisfaction, survey questions (both based on a 1–10 LASA scale, with 1 being the worst score and 10 being the best score) and mean scores were compared using a matched-pairs *t*-test.

Results

Twenty patients (15 male and 5 female) were enrolled into the study and had the study dressings applied in accordance with the protocol; one patient was withdrawn from the study immediately after enrolment because of excessive bleeding at the donor sites on the day of surgery. Nineteen patients completed the study as planned, but seven discontinued prematurely: following an adverse event ($n = 1$), patient's request ($n = 1$), protocol violation/non-compliance ($n = 2$) and lost to follow-up ($n = 3$).

Table 1 Summary of donor site characteristics

	TMD	CMC-Ag
No. of subjects	19	19
Size (cm^2)		
Mean (±SD)	264 (±281·9)	229 (±157·3)
Median (Min–Max)	154 (36, 1008)	197 (64, 759)
Location		
Thigh	16	17
Lower leg	3	2

TMD, transforming methacrylate dressing; CMC-Ag, silver-containing carboxymethylcellulose dressing.

Patients' demographics and donor site characteristics

The ages of the 19 study patients ranged from 5 to 76 years, with a median of 36·0 and a mean of 36·6 (SD ± 16·7) years. Four were female (21%) and 15 were male (79%). Eleven patients (58%) were Caucasians, 4 (21%) African Americans, 3 (16%) Hispanic and 1 (5%) Asian. The mean (±SD) donor site size was 264 cm^2 (±281·9) for TMD sites and 229 cm^2 (±157·3) for CMC-Ag sites (Table 1). All grafts from individual patients were harvested at the same nominal thickness.

Efficacy results

When time to healing was compared between the two dressings in the 19 patients treated, no statistically significant difference was found (Table 2). With a time to healing of 14·2 days for the TMD-treated sites and 13·2 days for the CMC-Ag-treated sites, the 1-day difference with the shorter healing time for the CMC-Ag dressing was not statistically significant ($P = 0{\cdot}16$). The small sample size did not allow for conclusion of non-inferiority of the TMD (95% confidence interval: −0·5 to 2·8 days).

Pain scores at all time periods showed statistically significant differences between the two dressings, with TMD being associated with lower pain scores than CMC-Ag (Table 3). Between day 2 and day 5, the average pain score recorded was 3·7 following use of the CMC-Ag dressing compared with 1·6 after use of the TMD ($P < 0{\cdot}0001$). Similarly, for days 6–10, the average pain score was 2·6 after use of the CMC-Ag dressing compared with 0·7 after use of the TMD ($P < 0{\cdot}0001$; Table 3).

Dressing in skin graft donor sites

When inquired about comfort of the dressing at the edges, study subjects found TMD to be more comfortable than CMC-Ag (mean score of 8·6 compared with 5·9, respectively; $P < 0{\cdot}001$). Similarly, they experienced less pain when the TMD dressing came indirectly into contact with clothes or

Table 2 Mean time to healing (based on patients with healing day <24 days)

	TMD	CMC-Ag	Difference (TMD − CMC-Ag)	*P*-value*
N	17	17		
Means estimate (SE)	14·2 (0·8)	13·2 (0·7)	1·0 (0·8)	0·16
Minimum	10	9	−1	
Maximum	23	20	3	
95% Confidence interval	12·5, 15·9	11·5, 14·6	−0·5, 2·8	

TMD, transforming methacrylate dressing; CMC-Ag, silver-containing carboxymethylcellulose dressing; SE, standard error.

*Matched-pairs *t*-test with healing times imputed for four patients with censored times, as follows: for patients with healing not observed, the time to healing was assumed to be less than or equal to 24 days and was estimated using each treatment's conditional survival curve after the observed censored day. If last follow-up without healing was 4 days (subject 08) then days to healing was estimated to be 12·5 days for TMD, 11·2 days for CMC-Ag. If 9 days (subject 04) then 12·5 days was used for TMD, 12·6 days for CMC-Ag, and for 14 days (subjects 01 and 14) then 16·1 days was used for TMD, 14·6 days for CMC-Ag.

bedding compared with the CMC-Ag dressing (mean pain score of 2·1 versus 5·1; $P < 0{\cdot}001$). Table 4 summarises responses to the three subject satisfaction survey questions at the final visit.

There was no significant difference between the two dressings with regard to how well they remained in place after application as both dressings performed well (median score of 9·5 for TMD compared with 8·6 for CMC-Ag).

When asked about ease of use during application of the dressings, the surgeons found CMC-Ag to be easier to use and less time-consuming than TMD (average score of 10·0 versus 2·2; $P < 0{\cdot}001$), and therefore anticipated using CMC-Ag in the future rather than TMD (average score of 10·0 for CMC-Ag versus 1·1 for TMD; $P < 0{\cdot}001$) principally owing to the application time in the operation theatre environment.

Discussion

This study of a novel TMD compared with a CMC-Ag established that a new dressing is feasible for management of STSG donor sites.

TMD is indicated for use in surgical wounds, exuding superficial acute wounds (such as STSG donor sites and second degree burns) as well as chronic slow-healing wounds including leg ulcers, pressure ulcers and diabetic ulcers. Clinical experience using TMD in the treatment of diabetic foot-related necrotising fasciitis has been published, reporting a decrease in pain after application of the TMD dressing (8). This was attributed by the authors to be related to a decrease in inflammation, the cooling effect of the dressing and the complete wound sealing associated with the application of TMD. Indeed, immediate pain control after application of dressing is one of the most frequently observed clinical features of the TMD dressing. However, while beneficial, the exact mechanism is unknown and further research on this observation is required.

Aquacel Ag with Hydrofiber (CMC-Ag) is one of the most widely used dressings for the management of STSG (7). In addition, it is one of the most widely studied and published wound dressings. Between 2006 and 2013, six randomised controlled clinical trials (RCTs) have been conducted and published with this hydrofiber dressing containing ionic silver (11–16), with half of these RCTs having been undertaken in patients with partial-thickness burns. Caruso *et al.* (11) conducted a prospective, randomised study comparing CMC-Ag with silver sulphadiazine in the management of partial-thickness burns covering 5–40% total body surface area (TBSA). While silver sulphadiazine was associated with greater flexibility and ease of movement, the hydrofiber dressing was associated with less pain and anxiety during dressing changes. Similar observations were reported by Muangman *et al.* (14) after conducting a prospective randomised study in patients with partial-thickness burns less than 15% TBSA. Both time-to-wound closure and pain scores were significantly shorter in the CMC-Ag group during the first week of application compared with the silver sulphadiazine group. In this study, the average pain scores decreased at days 1, 3 and 7 from $4{\cdot}1 \pm 2{\cdot}1$ to $2{\cdot}1 \pm 1{\cdot}8$, and $0{\cdot}9 \pm 1{\cdot}4$, respectively. The pain reduction reported in this previous trial is similar to the results of this study. Although the LASA pain score assessments were not conducted at the same time periods, a similar trend was observable: during days 2–5, the average pain score was $3{\cdot}7 \pm 0{\cdot}3$, during days 6–10 it decreased to $2{\cdot}6 \pm 0{\cdot}3$ and finally during days 11–15 an average pain score of $1{\cdot}9 \pm 0{\cdot}4$ was recorded. The reproducibility of clinical results for the CMC-Ag dressing supports the validity of the data of this study, as the results of the CMC-Ag group reported herein correspond well with published data in burn patients (11–13).

Our study has some limitations. First, this was a small study undertaken in one specialist area. Because of the strict inclusion and exclusion criteria, it was difficult to recruit more patients. However, aside of the fact that patients served as both, intervention and control arm, this additionally resulted in a very comparable patient population. Therefore, underlying

Table 3 Average pain scores

Days		TMD	CMC-Ag	Difference (TMD − CMC-Ag)	*P*-value*
2–5	Least square means estimate (SE)	1·6 (0·3)	3·7 (0·3)	−2·1 (0·4)	<0·0001
6–10	Least square means estimate (SE)	0·7 (0·3)	2·6 (0·3)	−1·9 (0·4)	<0·0001
11–15	Least square means estimate (SE)	0·2 (0·4)	1·9 (0·4)	−1·7 (0·4)	0·0004

TMD, transforming methacrylate dressing; CMC-Ag, silver-containing carboxymethylcellulose dressing; SE, standard error.

**P*-value from mixed model repeated measures ANOVA.

Table 4 Mean subjects' response to satisfaction survey

Final visit		TMD	CMC-Ag	*P*-value*
Number of subjects with responses		17	17	
Q1—On a scale of 0–10, with 0 being not at all and 10 being very secure, did the dressing remain in place after application?	Mean (SD)	9·5 (0·9)	8·6 (1·9)	0·06
	Median	10	10	
	Min–Max	7, 10	5, 10	
Q2—On a scale of 0–10, 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 (2·3)	5·9 (1·9)6	<0·001
	Median	10	6	
	Min–Max	2, 10	2, 8	
Q3—On a scale of 0–10, with 0 being no pain and 10 being the worse pain you have ever experienced, did you notice significant pain when the dressing came into contact with your clothing or bedding?	Mean (SD)	2·1 (2·5)	5·1 (2·2)	<0·001
	Median	1	5	
	Min–Max	0, 10	2, 9	

TMD, transforming methacrylate dressing; CMC-Ag, silver-containing carboxymethylcellulose dressing; SD, standard deviation.
**P*-value from matched-pair *t*-test.

conditions did not have the ability to affect or skew the outcome. Second, our findings should be interpreted with caution, as it is difficult to transfer findings in healing of donor sites to other types of chronic wounds. However, the use of donor sites as a wound healing model provides a reproducible wound but makes healing end-point comparisons difficult for comparative treatments because donor sites are acute wounds, and of partial thickness, and are expected to heal quickly. The result of equivalent healing time points was, therefore, not unexpected. However, a major complaint made by patients who have a STSG donor site is pain with the need for comfort management, so a dressing that reduces pain and increases patient comfort is an important finding. An important extension of this study would be to determine if similar pain and comfort findings were applicable to other painful acute or chronic wounds. Milne and Serendipity (17) have reported that in a group of seven patients with venous leg ulcers, all patients reported improvements in pain levels within 15 minutes of TMD application, with a corresponding reduction in the use of oral pain medication.

One 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-ups. A number of patients did not have twice-weekly follow-up, which also reduced the precision with which the time to healing could be determined in this study. However, both donor site groups were equally affected by these protocol deviations.

Conclusion

This study has demonstrated that the new TMD can be used for the management of STSG donor sites. Compared with a conventional dressing, application of the novel dressing requires skill and is more demanding. Although no difference was noted in the time to healing between the two dressings, patients reported less pain and greater comfort with TMD ($P < 0{\cdot}001$).

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