Phase II, Non-Comparative Trial of Carboxymethylcellulose Silver Dressing Reinforced With Nylon to Treat Partial Thickness Burns

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Introduction

Carboxymethylcellulose silver dressings are effective treatments for partial thickness burns. However, these dressings need to be more pliable and conform better to wounds. A prospective, non-comparative, Phase II clinical study was conducted to assess the safety and performance of a carboxymethylcellulose silver dressing reinforced with nylon.

Methods

The dressing was used to treat superficial or mid-dermal partial thickness burns for 21 days or until healing, whichever came first. Burns covered ≥3% and ≤40% of total body surface area (TBSA) and were continuous partial thickness burns ≥1% of TBSA. The dressing was applied after initial burn care and examined for integration at 24 hours and on days 2, 4, 6, 8, 14, and 21. Once the dressing was applied, it remained in place until investigators observed clinical indications (eg, saturation, infection, leakage, shifting) that it should be removed.

The primary endpoint was safety. The classification of the severity and seriousness of AEs and their relation to the study dressing were left to the discretion of each investigator. Investigators were asked to rate the severity of an AE and to indicate whether they considered the AE serious. Secondary endpoints included healing, as measured by the percentage of patients whose study burn healed within 21 days as evaluated by re-epithelialization; functionality and dressing integrity assessed in situ and on removal; and pain/discomfort, measured in adults using the Hopkins Pain Rating Instrument (HPRI) and in children using the Face, Legs, Activity, Cry, Consolability (FLACC) instrument. Ease of use was assessed on application, during use, and upon removal.

Results

Patients' Characteristics and Disposition

Forty-two patients (33 male; mean age, 26 years; range, 1–61 years) were enrolled. The majority of burns (27, 64.3%) were scalds (Table 1), and the mean burn size was 7.0% (SD, 5.3%; range, 1%–21%). Twenty-nine patients (69%) completed the study. Of the 13 withdrawals, 9 were due to AEs, 1 patient was lost to follow-up, 2 withdrew due to protocol violation or investigator discretion, and 1 had part of the burn withdrawn (the other part was continued and healed).

Table 1. Etiology of Burn Injuries

Etiology of Burn Injuries	N	% of Total Patients
Scald	27	64.3
Flash injury	8	19.1
Flame injury	5	11.9
Contact injury	1	2.4
Other	1	2.4

Adverse Events

Thirty-two (76.2%) patients experienced AEs, 6 (14.3%) of which were considered serious by the investigators. (Table 2) The patient who died was in a motor vehicle accident after being discharged from the hospital.

Table 2. Summary of Adverse Events and Serious Adverse Events

Adverse Event	N	% of Total Patients
Total adverse events	32	76.2
Dressing-related adverse events	9	21.4
Discontinuations due to adverse events	9	21.4
Serious adverse events	6	14.3
Burn conversions	4	9.5
Infection at non-study location	1	2.4
Death (Patient died in a motor vehicle accident after being discharged from the hospital.)	1	2.4

The most common AEs were generalized itching/pruritus (8 patients, 19.0%); burn conversion (6 patients, 14.3%); hyponatremia (6 patients, 14.3%); constipation (5 patients, 11.9%); and hyperglycemia (4 patients, 9.5%). Burn conversions are generally burns that were not thought to require surgical management on initial assessment but were later determined to have met the criteria for surgical management. Accurately diagnosing and determining if a partial thickness burn is likely to convert to full thickness has been shown to be difficult even for experienced burn surgeons.[1] Further, determining how a wound will heal is a complex process influenced by additive effects such as insufficient tissue perfusion, damage by free radicals, infection, tissue desiccation, and the age and health of the patient.[2] In this study, the burns converted to deep partial thickness or full thickness after 2 to 9 days.

Discontinuations due to AEs occurred in 9 (21.4%) patients. (Table 3)

Table 3. Discontinuations Due to Adverse Events

Adverse Event	N	% of Total Patients
Conversion of burn	5	11.9
Infection at a study location	2	4.8
Death	1	2.4
Wound enlarged/deteriorated	1	2.4

Nine patients reported 9 different types of dressing-related AEs. (Table 4)

Table 4. Dressing-related Adverse Events

Adverse Event	N	% of Total Patients
Bleeding bruise/trauma to wound	1	2.4
Infection, study location (led to withdrawal)	1	2.4
Necrotic/sloughy wound	1	2.4
Pain attributed to wound	1	2.4
Burn conversion	1	2.4
Stinging of skin	1	2.4
Edema	1	2.4
Generalized itching/pruritus	1	2.4
Decreased neutrophils	1	2.4
Total	**9**	**21.4**

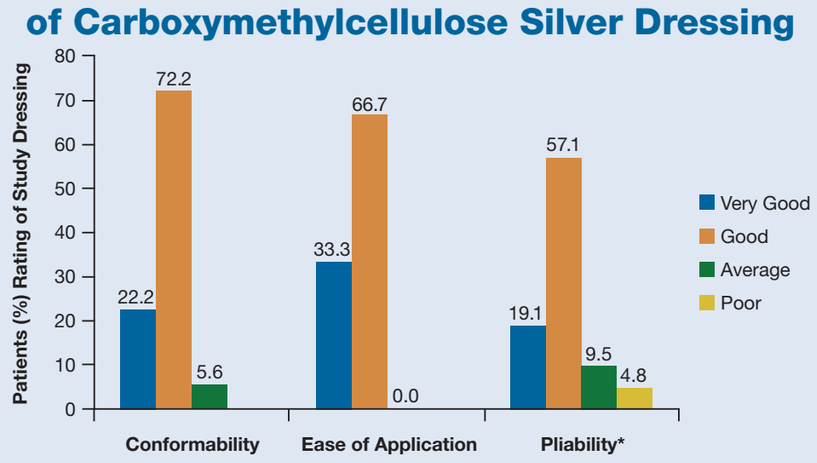
Secondary Outcomes

Twenty-eight patients (67%) healed completely, with a mean healing time of 16 days; 1 patient completed maximum study participation (21 days) without complete burn healing.

Initial ease of application was rated as "good"/"very good" in >95% of patients. Overall, 63% of dressings were considered 76%–100% integrated, and this percentage increased during the study. At removal, the dressing was intact and removed in one piece or fell off in nearly 90% of patients, was gelatinous or removed by rinsing or wiping in 5%, and either pulled apart or stuck to the burn in one place in the other patients.

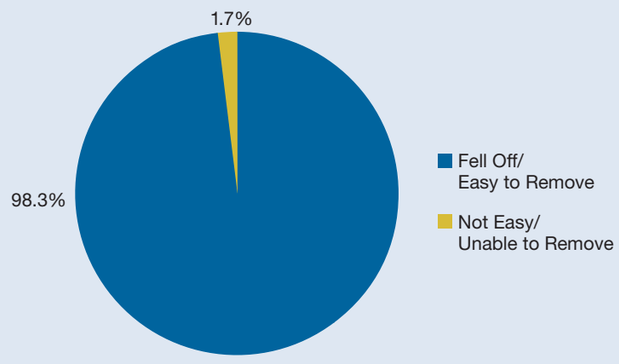
Dressing conformability was rated as "good"/"very good" at 94% of dressing changes, and dressing pliability was assessed as "good"/"very good" at >76% of evaluations. (Figure 1) Ease of dressing removal was rated as "not easy/unable to remove" in only 1.7% of evaluations. (Figure 2)

Figure 1. Conformability, Ease of Application, and Pliability of Carboxymethylcellulose Silver Dressing



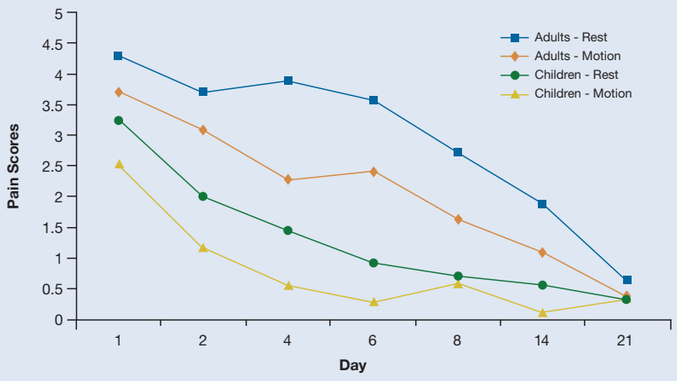
*At 24 hours. Only criteria with choice of a "poor" rating.
Responses from 9.5% of patients were not available.

Figure 2. Ease of Dressing Removal



At the end of the study, the adults' mean pain score on the HPRI decreased from baseline by 1.86 (rest) and by 1.57 (motion), and the children's mean pain score as measured on the FLACC declined from baseline by 2.42 (rest) and by 3.17 (motion). (Figure 3)

Figure 3. Mean Pain Scores for Adults (HPRI) and Children (FLACC) from Days 1–21



Conclusions

The carboxymethylcellulose silver dressing reinforced with nylon was found to be safe and well-tolerated. Both investigators and patients reported that the dressing conformed well and was very pliable; the dressing also maintained its integrity. Patients reported pain reduction at the burn site while the dressing was worn.

References

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2. Singh V, Devgan L, Bhat S, Milner SM. The pathogenesis of burn wound conversion. *Ann Plast Surg.* 2007;59:109-115.

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