CR-39: A Prospective, Internally-controlled Study to Compare the Absorbent Capability of a Hydroconductive Dressing Versus the Standard Gauze Burn Dressing on Partial Thickness Burns

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BACKGROUND

Following resuscitation and treatment of inhalation injury, the treatment of the victim of thermal injury centers around therapy and closure of the burn wound. There are four types of burn wound that require closure: 1) the superficial partial-thickness injury that can heal spontaneously by epithelialization; 2) the excised deep burn injury that requires wound bed preparation prior to closure with a skin graft; 3) the interstitial spaces in a meshed split-thickness skin graft that closes by epidermal migration; and 4) the split-thickness graft donor site that also heals by spontaneous epithelialization (Fig.1). Each of these wounds have clinical deterrents to ideal healing such as excessive exudate, bacterial bioburden, and deleterious cytokines that are produced by the thermal insult. Control of these deterrents helps to move the healing trajectory from impaired towards ideal.

Partial thickness burns affect the entire epidermis and part of the dermis with the presentation of pain and erythema, usually healing within two weeks. The ideal burn dressing should be one that maintains a moist pH-balanced wound, controls exudates, limits infections, minimal disturbance of healing tissue beneath the dressing, reduced pain to the patient, and reduced dressing changes. The standard practice for partial thickness wounds depends on the depth of the wound and the co-morbidities that the patient possesses. For superficial partial-thickness burns it is not necessary that topical antibacterial agents be used. However, at Tampa General Hospital the standard of care is the use of Silvadene® covered with a bulky gauze dressing. The frequency with which the dressings are changed is arbitrary and dictated by the volume of drainage or the physical condition of the dressing.

Recently, a new hydroconductive wound dressing, Drawtex, has been introduced and demonstrated to help control wound exudate, decrease the bacterial bioburden in experimental burn wounds, and to decrease deleterious wound cytokines such as MMP-9[1,2]. We asked the question whether this hydroconductive dressing would be useful for the care of thermal injuries. To begin to answer the question, a randomized clinical trial has been designed to compare Drawtex to our standard care for partial -thickness burns.

METHODS

This is an internally controlled study comparison of 2 wound dressing for treatment of adult partial thickness burns of scald or flame etiology. Only patients that are admitted to the burn unit and are predetermined to require burn dressings for partial thickness burns and meet all study criteria will be enrolled in the study (Table 1).

After the patient agrees to participate in the study and signs the informed consent, 2 eligible burn wounds will be chosen for the study. All patients will receive the standard pain management and wound preparation methods (cleansing, blister removal, and debridement). After initial cleaning and debridement, a thin layer of Silvadene will be applied to both study sites. The patient will receive bulky gauze dressing/burn fluff on one of their burn wounds and DrawTex on a second burn (Fig. 2). A single layer of Drawtex dressing will be applied.

Allocation of treatment of wounds sites will be done at random, using a pre-determined random assignment of treatments to the 2 defined wound regions.

Figure 1. Examples of Burn Wounds that Require Closure

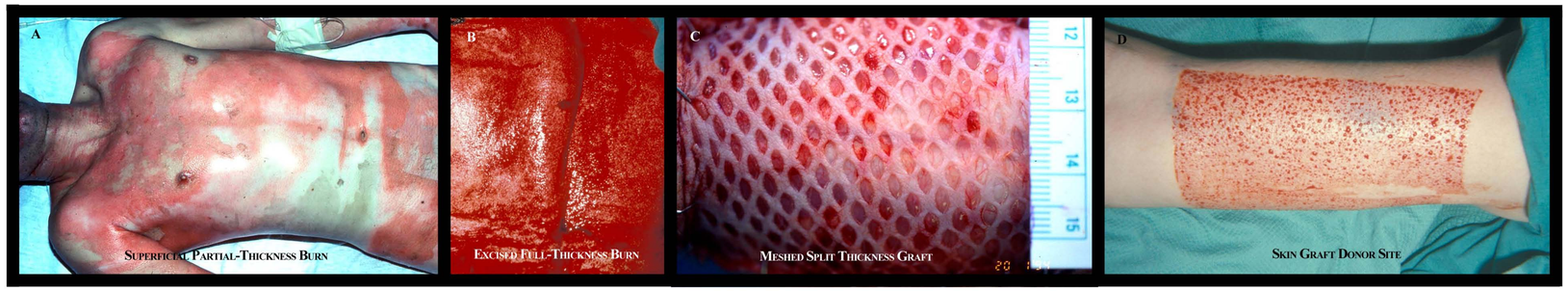
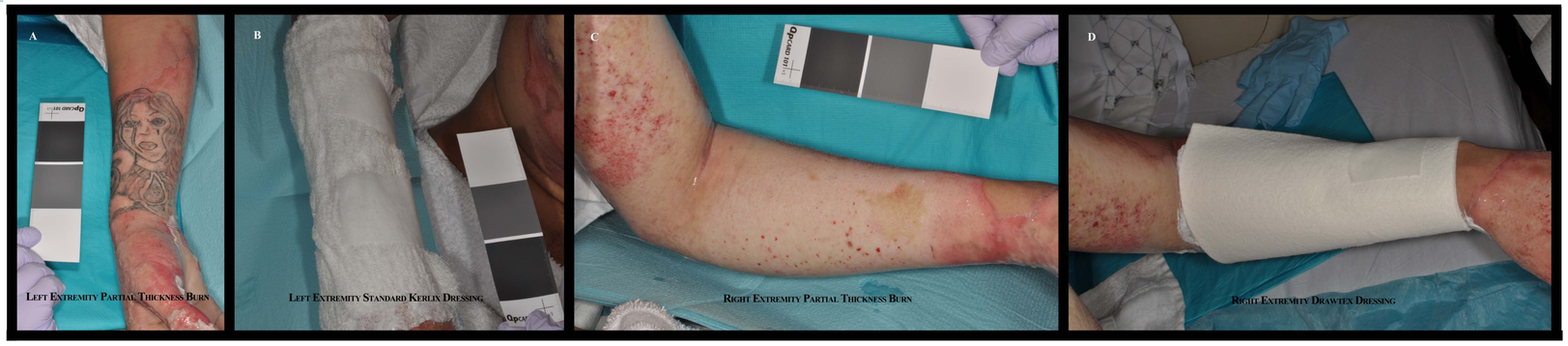


Figure 2. Application of Standard Gauze Dressing vs. Drawtex on Day 1 Partial Thickness Burns



METHODS CONTINUED

Both the bulky dressing and a single layer of Drawtex will be weighed prior to application. Every 24 hours the dressings must be changed. Both study dressings will be weighed after removal on day 1. The study wounds must be redressed in the same manner on the following day. If one of the wounds has no exudate the dressing can be changed to the investigators dressing of choice. In order to compare the dressings, their respective weights must be differentiated. The differences in weight must be obtained on day 1 and day 2.

All other non-study burn sites will be treated with our standard care, a layer of Silvadene covered with bulky gauze dressing. The wound dressings are changed every 24 hours but may be more frequent depending upon volume of drainage or the physical condition of the dressing. At each dressing change a VAS pain scale will be evaluated for each dressing site.
Wound assessments will occur until full epithelization.

Table 1. Inclusion/Exclusion Criteria

Inclusion:	Exclusion:
Patients with 2 non-contiguous second degree burns	Burns located on Head or Hands
Wound sizes of 100-320 cm^2	Burns of chemical and electrical origin
TBSA up to 25%	Clinically infected Burn (as judged by the investigator)
Burn of thermal origin	Diagnosed underlying disease(s) (e.g. HIV/AIDS, cancer and severe anaemia) judged by the investigator to be a potential interference in the treatment.
Ages 18-75	Known allergy to any of the components of the investigation products.

CONCLUSION

This randomized clinical trial is the first to evaluate the hydroconductive dressing, Drawtex, for thermal injuries. It is the first of several trials we anticipate to evaluate Drawtex in the four types of wounds associated with thermal injuries shown in Fig.1. Enrollment in this trial is ongoing. Drawtex appears to be well-tolerated. Conclusions regarding comparative pain scales or dressing weights cannot yet be determined. However, a dressing that can remove exudate, debris, bacteria, and cytokines detrimental to wound healing should be beneficial for partial-thickness burns, as well as the other types of wounds seen with thermal injuries.

REFERENCES

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