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# A phase II prospective, non-comparative assessment of a new silver sodium carboxymethylcellulose (AQUACEL® Ag BURN) glove in the management of partial thickness hand burns

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ABSTRACT

*Background:* Nylon-reinforced silver sodium carboxymethylcellulose (AQUACEL® Ag BURN) dressings were developed to be pliable and conforming for the management of partial-thickness burns. This study evaluated the AQUACEL® Ag BURN glove for the management of hand burns.

*Methods:* This 21-day, phase II, prospective, non-comparative study included 23 patients with partial-thickness hand burn of at least two fingers. The AQUACEL® Ag BURN glove was applied to one hand and could remain in place up to 21 days until clinically indicated to change the glove. Dressings were evaluated 1, 2, 4, 6, 8, 14, and 21 days after initial application. Safety was the primary study endpoint.

*Results:* Sixteen (70%) hand burns re-epithelialized fully over a mean of 15.6 days. Initial application was easy/very easy for 20 (87%) patients. Mean time for initial dressing application was 5.4 min. At final evaluation, most patients gave ratings of excellent/good for conformability (91%), overall glove performance (74%), and appropriateness of sizes (83%). Mean pain score from 0 (none) to 10 (worst imaginable) was 3.43 at baseline; during the study, mean scores were 1.15 at rest and 2.29 during movement. Of 61 glove removals, most (72%) were easy/very easy, and 12% had fallen off. Adverse events (wound site or elsewhere) occurred in 15 (65%) patients. Treatment-related adverse events were wound pain (17%), maceration (9%), and stiff fingers (4%).

*Conclusions:* The AQUACEL® Ag BURN glove was well tolerated in the management of partial-thickness hand burn. Many patients used only one glove. When glove changes were required, they were usually quick and easy.



## 1. Introduction

Partial-thickness burn is the most frequently encountered type of burn [1]. Clinical signs include blistering, erythema, edema, and pain. Partial-thickness burn disrupts the epidermis and dermis, thereby requiring acute wound care, pain control, and infection control [2]. Ideally, wound dressings should absorb excess exudate to prevent skin maceration and

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infections caused by excessive moisture. Additionally, dressings should provide a barrier against infectious microbes and should conform to the wound bed, skin, and anatomical contours.

Sodium carboxymethylcellulose (NaCMC) dressings possess these features, with the ability to form into a semi-solid gel and absorb exudate, contour to the wound bed, and trap harmful bacteria, as demonstrated *in vitro* [3,4]. Other *in vitro* data suggested that the addition of silver to the NaCMC dressing provides an additional barrier to infection [5]. In a prospective, randomized trial of patients with partial-thickness burns, a silver NaCMC dressing (AQUACEL® Ag) was associated with less pain and anxiety during dressing changes, less burning and stinging during wear, fewer dressing changes, less nursing time, fewer procedural medications, and lower costs than silver sulfadiazine [6]. In another prospective, randomized, comparative trial of patients with partial-thickness burns, changing the AQUACEL® Ag dressings every three days led to faster re-epithelialization, reduced pain scores, and lower costs of treatment than daily changes of silver sulfadiazine dressings [7].

The hand is involved in more than 80% of all burns [8]. Hand burns cover a small area but are complex wounds that require treatment at a burn center to ensure restoration of hand function and minimize scarring [8,9]. Because the hand is both a social and highly functional organ, quality of scarring and functional recovery is very important to quality of life [10]. Even a small burn to the hand can lead to loss of work and social withdrawal [11,12].

Silver NaCMC dressings reinforced with nylon (AQUACEL® Ag BURN dressings, Convatec Inc., Skillman, NJ, USA) were developed to be pliable and conforming, to provide a barrier to infection, and to reduce the need for frequent, painful dressing changes. In a separate study, a flat version of the dressing was shown to be pliable and conformed well to the wound [13]. A glove version of the nylon-reinforced silver NaCMC dressing (AQUACEL® Ag BURN glove, Convatec Inc., Skillman, NJ, USA) was developed specifically for the management of hand burn. The objective of this study was to evaluate the safety and dressing performance of the AQUACEL® Ag BURN glove in the management of partial-thickness hand burns.

## 2. Methods

### 2.1. Patient selection

This phase II, prospective, single-arm trial was conducted at three centers in the United Kingdom, two centers in France, and one center in Germany. Study participants were required to have a fresh (within 36 hours) partial-thickness hand burn that involved at least two fingers. Key exclusion criteria were as follows: age ≤5 years; hand burn that was chemical, electrical, or frostbite in origin; a poor prognosis that made it unlikely the patient would survive the 21-day study period; evidence of a deep partial-thickness or full-thickness hand burn (e.g., by laser Doppler imaging); known skin sensitivity to any of the dressing components; evidence of inhalation trauma; or fracture and/or neurological injury. Informed consent was obtained directly from patients aged >18 years and from a legally authorized representative for patients aged ≤18 years. The study was conducted in accordance with the principles of the Declaration of Helsinki.

### 2.2. Interventions

Initial burn care could include puncturing of intact blisters to drain fluid, removal of the blister roof, and cleansing of the burn and surrounding skin to remove any coagulated exudate, if appropriate. If exudate had coagulated underneath the blister, the blister and coagulate were removed.

An AQUACEL® Ag BURN glove was selected from one of four available sizes from Size 1 (smallest) to Size 4 (largest). The glove was secured at the wrist using a crepe bandage or similar retention bandage. If required, the glove could be covered with a polythene/plastic bag for protection. The glove could remain in place for up to 21 days until clinically indicated for change, such as saturation, leakage, suspected infection, or suspected change in wound depth. If the glove was saturated or leaking, it was removed and replaced with a new glove, and a new bag could be placed over the top. The glove could be moistened if it became too dry for exercises and could be replaced if there was any discomfort.

If infection or change in wound depth was suspected, the non-adherent portion of the glove was trimmed away with scissors, or if this was not possible, the glove was soaked with sterile saline and totally removed. If infection or change in wound depth was still suspected after inspection of the burn, a wound swab was obtained for bacterial culture, the burn was photographed, and the percentage of non-adherence was recorded. If infection was suspected, an adverse event form was completed. Evidence to support the diagnosis of clinical infection included the following: clinical signs/symptoms of a local wound infection (e.g., odor, purulent drainage, erythema, pain, change in appearance of wound bed); Gram stain with evidence of high numbers of bacterial cells and inflammatory cells; and culture and sensitivity. Other evidence could include fever, elevated white blood cells, cellulitis, or general malaise. If the infection warranted an alternative topical therapy, or if surgical intervention was indicated for the management of a significant change in wound depth, the patient was withdrawn from the study. If a change in therapy was not clinically indicated, a new AQUACEL® Ag BURN glove was applied and a bag could be placed over the top. If use of the AQUACEL® Ag BURN glove was continued, the patient could receive systemic antibiotics for hand burn infection and continue in the study.

Due to variations in depth, re-epithelialization and detachment was expected to occur in stages. After re-epithelialization, dried-parts of the dressing were removed by carefully probing with a gloved ''dissecting'' finger between the dressing and the wound bed. The portion of the glove that was non-adherent was trimmed with scissors. A new AQUACEL® Ag BURN glove was applied over the hand, preserving the remaining adherent glove dressing, and a bag could be placed over the top.

Study participation ended upon full re-epithelialization. If the burn had not re-epithelialized fully by day 21, the residual adherent AQUACEL® Ag BURN glove was soaked in saline and removed.