

Evaluation of Efficacy for a Hydrocapillary Dressing (XLTA) on the Treatment of Burn Wounds: A Prospective Cohort Study from South African Tertiary Burn Center

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INTRODUCTION

Burn injuries remain a significant global public health burden. In the United States alone, medical costs in addition to productivity losses due to burn injuries is estimated to be \$7.6 billion USD annually [1]. In 2021 the global prevalence of burn injuries was 248.33 million cases worldwide, with severe burns accounting for over 5% of that number [2]. Additional analyses predict a 233.4% increase in severe burns and a 142.5% increase in mild burns by 2025 [2]. Burn wound healing is complex in nature, including a multistage healing process [3]. Dressing type for these wounds can play a crucial role in the healing process.

PRODUCT OVERVIEW

The XLTA dressing aims to be an innovative new approach to the wound dressing space. The dressing is composed of 3 distinctive layers:

- **A middle hyper absorbant hydrocapillary layer** (exudate absorption and proper hydration)
- **Two outer non-adherent layers** (protect the wound, ensure patient comfort)



Figure 1. A schematic representation of the XLTA® dressing and its tri-layers.

The XLTA dressing has 3 primary proposed mechanisms of action:

- **Capillary Action:** Draws in excessive exudate, providing optimal moisture levels for epithelialization
- **Horizontal Dispersion:** Evenly distributed fluid matrix across dressing surface, prevents pooling of fluid and traps bacteria and necrotic tissue away from the wound bed
- **Positively Charged Fibers:** Attract negatively charged bacteria, cytokines, and matrix metalloproteinases (MMP's), which aid in debridement and overall help to reduce bio burden



Figure 2. Proposed mechanisms of action for the XLTA® dressing.



Image 1. Actual Image of XLTA® bandage with different weight

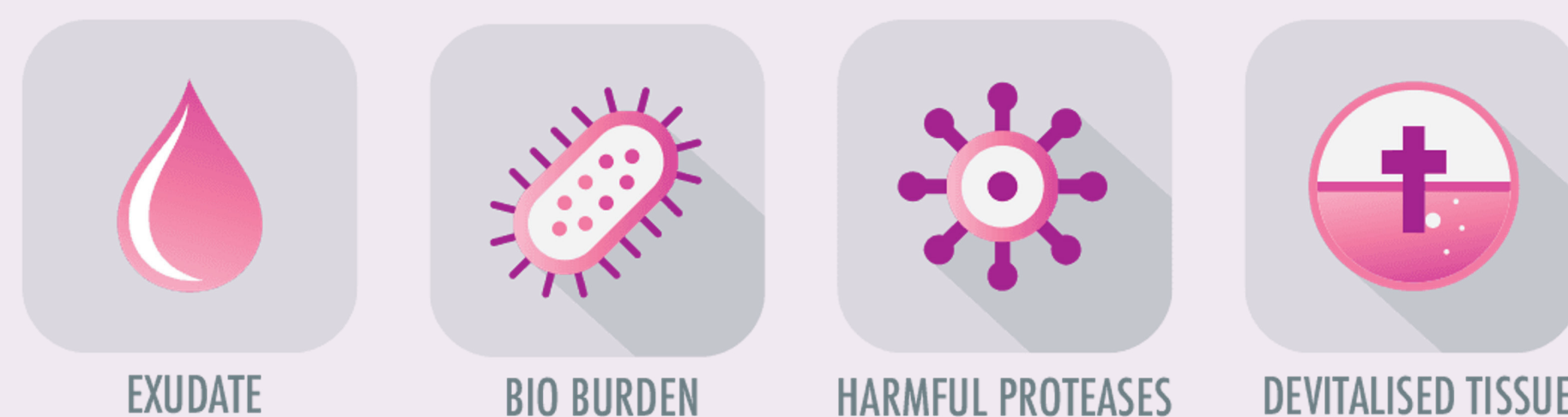


Figure 3. Benefits of XLTA® dressing as a result of mechanisms of action

Together the mechanisms of action for XLTA help the bandage to achieve:

- Excellent **exudate absorption** via capillary action
- A **reduction of bioburden** reduce the risk of biofilm
- **Sequestering of harmful proteases** away from the wound bed
- **Autolytic debridement** that supports cleaning of devitalised tissue.

CASE STUDY DESIGN AND METHODS

To investigate the efficacy and performance of the XLTA dressing, a retrospective cohort study was conducted at a tertiary burn center in South Africa. The goal was to enroll 70 patients into the study conducted from September 2021 to July 2024. Inclusion criteria for this study included patients with partial- or full-thickness burn wounds characterized with high levels of exudate. Exclusion criteria included any wounds that were infected where a bacterial bandage would have been preferred instead.

Once enrolled patient demographic data were collected upon initial evaluation, including gender, age, mode of injury, injury age, total body surface area of the injury (TBSA), time to treatment, and injury location. Additionally, this study included 10 wound assessment parameters that were analyzed: biofilm, exudate, moistness, epithelialization, slough, infection, colour, size and site, odour, and swab need (BE, ME, SIC, SOS). An initial pre-treatment wound assessment was completed, followed by a post-treatment assessment. All wound assessment parameter data were collected qualitatively based on expert visual interpretation. Wound analysis images were taken from 30 cm using an iPhone 6 in conjunction with a wound ruler. Patient-reported pain intensity was evaluated using a visual analog scale (VAS) incorporating pictorial icons to represent increasing levels of discomfort. All patient data were collected by the attending physician. The XLTA bandage was placed directly onto the wound, then a secondary dressing like Melolin was placed over it. Lastly a Kling or Crepe conforming bandage was used to wrap the wound and dressings. Patients were given various analgesics throughout their recovery as well as ketamine sedation before dressing removal.

RESULTS

A total of 62 patients were treated for various burn injuries using the XLTA dressing. The demographic of the patient population is displayed on table 1 including age, sex, mechanism of injury, wound area, wound age, and time to application.

Variable	Value
Number of patients	62
Sex (Male)	38 (61.3%)
Sex (Female)	24 (38.7%)
Mechanism: Flame	55 (88.7%)
Mechanism: Hot Water	3 (4.8%)
Mechanism: Electrical	3 (4.8%)
Mechanism: Oil	1 (1.6%)
Age (years) - Mean	35
Age (years) - Min	16
Age (years) - Max	70
TBSA (%) - Mean	27.7
Wound Age at Application (days) - Mean	27
Wound Age at Application (days) - Max	143
Applied ≤ 7 days n(%)	13 (21.0%)
Applied > 7 days n(%)	49 (79.0%)

Table 1. Demographic information summary for the patients involved

This patient demographic information gives some valuable insight into the wounds wounds and patients being treated. There is a bias towards chronic wounds, which have a higher chance of infection and are generally more difficult to treat. Additionally, an average TBSA of 29.7% demonstrated the severity of the wounds being treated

Wound Assessment	Before	After
Biofilm	Yes (29%)	No
Exudate	High (100%)	100% Less
Moisture balance	Excessive (100%)	100% Better
Epithelialization	Little (27%)	Difficult to judge. More
Slough	Yes (40%)	No
Infection	Yes (19%)	No
Colour	Predominantly red-yellow	Mostly red or pink
Size, Site	Small to larger sizes	All appear similar or smaller
Odour	Yes (3%)	No
Swab need	None	None

Table 2. Summary of pre-and post-treatment results for the 10 wounds assessment parameters

Group	McNemar's Chi-squared	P-Value
Biofilm	16.056	6.15E-05
Slough	23.04	1.59E-06
Infection	10.083	0.001496
Odor	.5	0.4795

Table 3. Summary of McNemar's Chi-squared results for biofilm, slough, infection, and odor

Patient before and after results are summarized in Table 2. This includes all BE, ME, SIC, SOS parameters. After results were compiled, statistical analysis using McNemar's Chi-squared was done. This computation analyzes categorical variables for 2 paired groups, making is ideal for before and after analysis. Additionally, this test works well with binary variables (yes/no).



Image 2. Lower leg before application (left) and 5 days later (right)

DISCUSSION

Based on the evidence provided, the XLTA hydrocapillary dressing was clinically successful in the treatment of a large variety of burn wounds. All wound assessment parameters improved following treatment with the hydrocapillary dressing. All instances of biofilm, slough, infection, and odor dropped to zero. Exudate, moisture balance, epithelialization, color, and size improved in all cases. The XLTA dressing had a positive impact on progressing the wound healing cascade in all patients. All cases demonstrated positive healing outcomes, and no negative effects were reported.

The statistical computations show strong evidence that there was improvement from the baseline analysis to the post-treatment results. The p-values for biofilm, slough, and infection are well below the 0.05 threshold, demonstrating a statistically significant difference in pre- and post-analysis. The p-value for odor was 0.4795, meaning there was no significant difference in the pre- and post-treatment results, likely due to only 2 cases of odor to begin with. With only a 3% rate of "yes" before treatment, it would be hard to demonstrate a change even with all of those cases being negative after post-treatment.

Overall, the results of the McNemar's chi-squared give strong evidence that the XLTA bandage reduces biofilm, slough, and infection after treatment with the dressing.

The XLTA bandage performed exceptionally in exudate absorption. There were no incidences of excessive exudate in any cases post-treatment, and the moisture balance of all cases improved. In previous hydrocapillary hydroconductive dressings, the mechanism of removal of slough was proposed hypothesis to be due to dehydration of the wound and matrix, causing slough to get stuck in the bandage fibers. The effect of the polyethylene layer is unknown, but mechanical debridement with these layers may be improved in the XLTA bandage. Future research aims can include this assessment to support this.

A total of 12 cases had infection at the start of the trial. After treatment, there were no instances of infection reported, demonstrating XLTA's ability to reduce infection. Evaluation of infection was based on visual assessment and no cultures were taken for analysis. Additionally, given the chronicity of most wounds, those patients with infections present were likely already on culture-specific antibiotics, thus giving inconclusive evidence as the analysis of infection was not tightly controlled. However, a few proposed mechanisms of reducing infection have some scientific rigor in their favor, as previously mentioned.

A few other observations:

- The patient demographics was well representative of the typical burn injury population
- Patient comfort was exceptional, but hard to draw conclusions on
- There may have been a slight bias towards chronic wounds

CONCLUSION

This prospective cohort study of 62 patients at a South African tertiary burn center provides strong evidence supporting the efficacy of the XLTA dressing across a range of burn wounds. BE, ME, SIC, and SOS wound assessment parameters were evaluated before and after treatment. Healing outcomes were all positive, and no negative clinical effects were reported relating to the dressing. Statistical analysis demonstrated the bandage had a positive effect in reducing biofilm, slough, and infection in those patients who presented with them before treatment. Patient comfort was reported to be exceptional, with no pain relating to the dressing itself, including dressing removal. Conceptually, this hydrocapillary bandage can perform effectively in exudate absorption, mechanical debridement, wicking away bacteria and MMPs, and creating the proper environment for rapid wound healing progression. In practice, the XLTA bandage appears to do so and demonstrates clear efficacy in treating high exuding wounds such as those presented in this study. Additional research should focus on obtaining quantitative analysis and include a side-by-side comparison with the standard of care in order to further evaluate the efficacy of the XLTA dressing.

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STUDY APPROVAL

Approval to conduct this study was granted by Health Research Ethics Committee (HREC) of the University of Stellenbosch via a biobank approval for wound care data, ID #32614.

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