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SUMMARY CLINICAL STUDY REPORT

PROTOCOL TITLE:	A 16-Day, Single Center, Randomized, Comparator-Controlled Study to Assess Wound Healing Efficacies of Different Clean, Teat, and Protect Wound Care Regimens Compared to Standard of Care and Untreated
PROTOCOL NUMBER:	CCSTOH003808 Final Version 1.0, dated 09-AUG-2021
SITE STUDY NUMBER:	C21-D154
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STUDY INITITION DATE (First Subject First Visit):	08-SEP-2021
STUDY COMPLETION DATE (Last Subject Completed):	15-OCT-2021
SPONSOR REVIEW AND APPROVAL:	**Name**: [redacted] **Signature and date:** [redacted]

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The principles of the International Council for Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP E6 (R2)) were applied to this study.

PURPOSE

The primary goal in wound care is to protect the wound from further damage and to facilitate healing by providing the optimal environment that limits infection, inflammation, and scarring. Appropriate wound dressings play an important role in providing this necessary protection and may promote restoration of skin barrier function compared to untreated wounds.[1]

Wound healing is a complex process wherein the skin surface and the underlying tissue must go through an intricate process of tissue repair. The dermis of an uncovered wound is relatively more fibroplastic, fibrotic, and scarred compared to occluded wounds, and is likely to be more inflamed and necrotic in early stages of repair. Exudate, the moisture secretion from the wound site, facilitates the healing process, by providing a variety of bioactive mediators such as enzymes, growth factors and hormones. Wound exudate may also aid in limiting inflammation by providing various immune cells with an ideal medium to destroy invading pathogens such as bacteria, foreign bodies and necrotic tissues. However, exudate in an uncovered wound can lead to scab formation, with trapped inflammatory cells, wound debris, and a layer of desiccated dermal tissue. Covering a wound with an occlusive dressing reduces scab formation and may radically alter the pattern of epidermal wound healing.

Another factor that plays an important role in wound healing is the moisture in the wound environment. As early as 1962, Winter et al., provided the first evidence that keeping wounds moist helps them heal faster compared to dry wounds.[2]

As occlusion affects both the epidermis by enhancing epithelial cell migration and the dermis by enhancing dermal collagen synthesis, maintaining a moist environment may promote the restoration of epidermal barrier function and overall wound healing while making dressing changes relatively easier. Moreover, it has been suggested that the scar left by an occlusively dressed wound is more cosmetically acceptable than that left by an uncovered wound.[3]

Moist wound healing is widely practiced by healthcare providers in the United States to enhance wound repair and recovery by protecting the wound against bacteria, creating an optimal wound healing environment, limiting reinjury and pain, and facilitating dressing changes. Hydrocolloid dressings are designed to combine the benefits of occlusion and absorbency and have been introduced in the consumer sector in various parts of the world as a non-traditional approach to treating minor wounds. However, there is an unfilled need gap in identifying the optimal hydration and occlusivity conditions to best facilitate the wound healing process with minimal cosmetic damage to the skin.

Guidelines for caring for minor cuts, scrapes, and burns are inconsistent in the literature. While cleaning and covering the wound is consistent throughout, some recommend including an antiseptic cleanser and/or antibiotic ointment. In the Handbook of Nonprescription Drugs, the American Pharmacists Association explains that in addition to irrigating wounds with saline or water for removal of debris, the use of nonprescription antiseptics is helpful in preventing secondary infections.[4] Treatment of minor wounds with topical antibiotics helps keep the wound moist, and helps prevent infection.[4,5]

More research is needed to understand the benefits of antiseptic wound cleansers and topical antibiotic ointments in the treatment of minor wounds.

This single center, randomized, comparator-controlled, 16-day clinical trial was conducted, to compare healing rates and infection protection for different treatment regimens, including an antiseptic cleanser, an antibiotic ointment, and a standard of care bandage. This study also evaluated the impact of two newly designed hydrocolloid prototype bandages on wound healing in comparison with standard of acre bandage and the different treatment regimens.

STUDY DESIGN SUMMARY

A total of 34 subjects completed study participation, with all 34 subjects included in the intent-to-treat (ITT) population. The subjects enrolled in this trial were 25- to 55-year-old males and females of Fitzpatrick skin types I-III who had uniform skin color on both volar forearms, and who had consented to participate in this clinical trial.

At Screening (Visit 1; 3 to 7 days prior to Baseline), subjects were provided with an auxiliary cleanser to use on their forearms and for all body cleansing in place of their regular body cleanser for the duration of the study.

At Baseline (Visit 2), a Sciton Er:YAG 2940 laser was used to induce eight partial-thickness (i.e. minor) wounds on the subjects' forearms (four per arm).[6] The wounds created by this method heal by the migration of epidermal cells from the dermal appendages located in the wound's base (dermal islands) and/or wound borders, and mimic minor wounds similar to real life scraped skin, typically healing in less than 16 days if left untreated.

Each test site for each subject was randomly assigned to one of the following:

Treatment code	Treatment description
A	Uncovered wound
B	Standard of Care Bandage [redacted]
C	Antibiotic Ointment [redacted]
D	Antibiotic Ointment [redacted] + Standard of Care Bandage [redacted]
E	Antiseptic Wash [redacted] + Antibiotic Ointment [redacted] + Standard of Care Bandage [redacted] (IP regimen applied for only 3 days)
F	Antiseptic Wash [redacted] + Antibiotic Ointment [redacted] + Standard of Care Bandage [redacted]
G	Hydrocolloid Pad [redacted]
H	Hydrocolloid Pad [redacted]

Each wound site [redacted] and assessed at specified intervals by clinical grading of wound healing parameters (until Day 16).

Between Baseline and Day 7, each wound site was treated with one of 8 randomly assigned treatments. Treatments included an adhesive bandage that is considered the SoC alone, a marketed antibiotic ointment alone, a marketed antiseptic wash, various regimens (combinations of antiseptic wash/bandage/ointment) and durations of use, hydrocolloid bandages, and no treatment (uncovered,

negative control). Treatments were applied/changed by an experienced staff member at the Site at specified intervals: six of the treatments were applied/changed daily from Day 1 through Day 6; one treatment was be changed only on Days 0 through 2 and the wound left uncovered after day 3.

All other treated wound sites were uncovered from Day 7 (after clinic visit) to Day 16, at which point subjects returned to the site for clinical assessments.

STATISTICAL ANALYSIS SUMMARY

The primary endpoint of this study was the Composite Healing Score, which was calculated from the clinical grading of wound healing parameters as follows:

Composite Healing Score = [general wound appearance score + smoothness score + epithelial confluence score] – [erythema score + edema score + crusting/scabbing score]

The composite healing score on a 25-point scale (-12 thru+12) is indicative of the extent of wound healing and was calculated for each wound site at each evaluation day.

Composite healing score was summarized at each time point and was analyzed within-treatment and between-treatment. The within-treatment comparison will be performed at each post-baseline time point by comparing the post-baseline scores with the baseline score (defined as the post-wound score on Day 0) within each treatment using the paired t-test. The between-treatment comparison will be performed by comparing the change from baseline (defined as post-baseline score minus baseline score) between treatments using a mixed effect analysis of covariance (ANCOVA) model.

The secondary endpoints were analyzed in a similar way as for the composite healing score, and were as follows:

- Clinical Grading of Wound Healing – Erythema
- Clinical Grading of Wound Healing – Edema
- Clinical Grading of Wound Healing – General Wound Appearance
- Clinical Grading of Wound Healing – Smoothness
- Clinical Grading of Wound Healing – Epithelial Confluence
- Clinical Grading of Wound Healing – Crusting/Scabbing

The other two secondary endpoints were the following:

- Wound Healing Process Assessment – was summarized at each time point and was analyzed at each post-baseline time point using logistic regression.
- Subject Self-assessment Questions – subject questionnaire data was summarized at each time point by treatment.

RESULTS AND FINDINGS

Primary Outcomes:

Composite Healing Score

Within-treatment analysis of the composite healing score indicated the following when compared with baseline (post-wound day 0):

- A (uncovered), B (bandage), and C (antibiotic ointment) showed a statistically significant **decrease (worsening)*** in scores at days 1, 2, 3, 4, 5, 6, and 7, and a statistically significant **increase (improvement)** in scores at day 16.
- D (antibiotic ointment + bandage), F (antiseptic wash + antibiotic ointment + bandage), and H (hydrocolloid pad [redacted]) showed a statistically significant **decrease (worsening)** in scores at days 1, 2, 3, 4, and 5, and a statistically significant **increase (improvement)** in scores at days 7 and 16.
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) showed a statistically significant **decrease (worsening)** in scores at days 1, 2, 3, 4, and 5, and a statistically significant **increase (improvement)** in scores at day 16.
- G (hydrocolloid pad [redacted]) showed a statistically significant **decrease (worsening)** in scores at days 1, 2, 3, and 4, and a statistically significant **increase (improvement)** in scores at days 5, 6, and 7, 16.

*Note that initial worsening in composite healing score was expected.

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the composite healing score, showed the following results:

- B (bandage) **performed better than**:
  - A (uncovered) at days 1, 2, 3, 4, and 16
  - C (antibiotic ointment) at days 1, 2, 3, and 16
- D (antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 2, 3, 4, 5, 6, 7, and 16
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
- F (antiseptic wash + antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
- G (hydrocolloid pad [redacted]) **performed better than**:
  - A (uncovered), B (bandage), C (antibiotic ointment), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, 16)
  - D (antibiotic ointment + bandage) at days 1, 2, 3, 4, 5, 6, and 7

  - H (hydrocolloid pad [redacted]) at days 2, 3, 4, 5, 6, and 7
- H (hydrocolloid pad [redacted]) **performed better than**:
  - A (uncovered), B (bandage), and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 1, 2, 4, 6, 7, and 16
  - F (antiseptic wash + antibiotic ointment + bandage) at days 2, 3, 7, and 16
  - D (antibiotic ointment + bandage) at days 1, 2, and 7

Secondary Outcomes:

Clinical Grading of Wound Healing – Erythema

Within-treatment analysis of the erythema score indicated the following when compared with baseline (post-wound day 0):

- A (uncovered) and C (antibiotic ointment) showed a statistically significant **increase (worsening)** in scores at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16).
- B (bandage), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage) showed a statistically significant **increase (worsening)** in scores at days 1, 2, 3, 4, 5, 6, and 7.
- G (hydrocolloid pad [redacted]) and H (hydrocolloid pad [redacted]) showed a statistically significant **increase (worsening)** in scores at days 1, 2, 3, 4, 5, 6, and 7, and a statistically significant **decrease (improvement)** in scores at day 16.

A worsening in erythema was expected on days following post-wounding.

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the erythema score, showed the following results:

- B (bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at day 16
- D (antibiotic ointment + bandage) **performed better than**:
  - A (uncovered), B (bandage), and C (antibiotic ointment) at days 4, 5, 6, and 16
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at days 4, 5, 6, 7, and 16
  - B (bandage) at days 4, 5, and 6
- F (antiseptic wash + antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) at days 4, 5, 6, and 16
  - B (bandage) at days 4 and 6
  - C (antibiotic ointment) at days 4, 6, and 16
- G (hydrocolloid pad [redacted]) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at days 3, 4, 5, 6, 7, and 16
  - B (bandage) at days 2, 3, 4, 5, 6, 7, and 16
  - D (antibiotic ointment + bandage) at days 2, 3, 5, 6, and 7
  - E (antiseptic wash + antibiotic ointment + bandage for 3 days) and F (antiseptic wash + antibiotic ointment + bandage) at days 2, 3, 5, 6, 7, and 16
  - H (hydrocolloid pad [redacted]) at days 3, 4, 5, 6, and 7
- H (hydrocolloid pad [redacted]) **performed better than**:
  - A (uncovered) at days 5, 6, 7, and 16
  - B (bandage) at days 6 and 16

  - C (antibiotic ointment) at days 6, 7, and 16
  - D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage) at day 16

Clinical Grading of Wound Healing – Edema

Within-treatment analysis of the edema score showed a statistically significant **decrease (improvement)** in scores at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16) when compared with baseline (post-wound day 0) for each wound site.

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the edema score, showed the following results:

- B (bandage), C (antibiotic ointment), D (antibiotic ointment + bandage), and E (antiseptic wash + antibiotic ointment + bandage for 3 days) **performed better than**:
  - A (uncovered) at day 3
- F (antiseptic wash + antibiotic ointment + bandage), G (hydrocolloid pad[redacted]), and H (hydrocolloid pad[redacted]) **performed better than**:
  - A (uncovered) at days 1 and 3
  - C (antibiotic ointment) at day 1

Clinical Grading of Wound Healing – General Wound Appearance

Within-treatment analysis of the general wound appearance score showed a statistically significant **increase (improvement)** in scores at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16) when compared with baseline (post-wound day 0) for each wound site.

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the general wound appearance score, showed the following results:

- B (bandage) **performed better than**:
  - A (uncovered) at days 1, 2, 3, 4, and 16
  - C (antibiotic ointment) at days 1, 2, 3, and 16
- D (antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 2, 3, 4, 5, 6, 7, and 16
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) and F (antiseptic wash + antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 2, 3, 4, 5, 6, and 7
- G (hydrocolloid pad[redacted]) **performed better than**:
  - A (uncovered), B (bandage), and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - D (antibiotic ointment + bandage) at days 2, 3, 4, 5, 6, and 7
  - E (antiseptic wash + antibiotic ointment + bandage for 3 days) and F (antiseptic wash + antibiotic ointment + bandage) at days 2, 3, 4, 5, 6, 7, and 16
  - H (hydrocolloid pad[redacted]) at days 3, 4, 5, 6, and 7

- H (hydrocolloid pad [redacted]) **performed better than**:
    - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
    - B (bandage) at days 2, 3, 4, 5, 6, 7, and 16
    - D (antibiotic ointment + bandage) at days 2, 3, and 7
    - E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 2, 3, 4, 5, 6, and 7
    - F (antiseptic wash + antibiotic ointment + bandage) at days 2, 3, 7, and 16

Clinical Grading of Wound Healing – Smoothness

Within-treatment analysis of the smoothness score showed a statistically significant **decrease (worsening)** in scores at days 1, 2, 3, 4, 5, 6, and 7, and a statistically significant **increase (improvement)** in scores at day 16, when compared with baseline (post-wound day 0) for each wound site. A worsening in smoothness was expected on days following post-wounding.

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the smoothness score, showed the following results:

- B (bandage) **performed better than**:
    - A (uncovered) and C (antibiotic ointment) at day 16
- D (antibiotic ointment + bandage) **performed better than**:
    - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
    - B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
    - E (antiseptic wash + antibiotic ointment + bandage for 3 days) at day 6
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) **performed better than**:
    - A (uncovered) at days 1, 2, 3, 5, 6, and 16
    - B (bandage) at days 1, 2, 3, 4, 5, 6, 7
    - C (antibiotic ointment) at days 1, 2, 5, 6, 7, and 16
- F (antiseptic wash + antibiotic ointment + bandage) **performed better than**:
    - A (uncovered) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
    - B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
    - C (antibiotic ointment) at days 1, 2, 4, 5, 6, 7, and 16
    - E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 4, 5, 6, and 7
- G (hydrocolloid pad [redacted]) **performed better than**:
    - A (uncovered), B (bandage), and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
    - D (antibiotic ointment + bandage) and E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 1, 2, 3, 4, 5, 6, and 7
    - F (antiseptic wash + antibiotic ointment + bandage) at days 2, 3, 5, 6, and 7
    - H (hydrocolloid pad [redacted]) at days 3, 4, 5, 6, and 7
- H (hydrocolloid pad [redacted]) **performed better than**:
    - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
    - B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
    - D (antibiotic ointment + bandage) and F (antiseptic wash + antibiotic ointment + bandage) at day 2
    - E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 2, 3, 4, 6, and 7

Clinical Grading of Wound Healing – Epithelial Confluence

Within-treatment analysis of the epithelial confluence score showed a statistically significant **increase (improvement)** in scores at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16) when compared with baseline (post-wound day 0) for each wound site (except for treatment G at day 16 [*P* = NA {not calculable}]).

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the epithelial confluence score, showed the following results:

- B (bandage) **performed better than**:
  - A (uncovered) at days 1, 2, and 3
  - C (antibiotic ointment) at days 1, 2, 3, 5, and 16
- D (antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 4, 5, 6, and 7
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 4, 6, and 7
- F (antiseptic wash + antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) at days 1, 2, 3, 4, 5, and 6
  - C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
- G (hydrocolloid pad [redacted]) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage) at days 2, 3, 4, 5, 6, and 7
- H (hydrocolloid pad [redacted]) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 2, 3, 4, 5, 6, and 7
  - D (antibiotic ointment + bandage) and E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 2, 4, 5, 6, and 7
  - F (antiseptic wash + antibiotic ointment + bandage) at days 3, 4, 5, 6, and 7

Clinical Grading of Wound Healing – Crusting/Scabbing

Within-treatment analysis of the crusting/scabbing score showed a statistically significant **increase (worsening)** in scores at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16) when compared with baseline (post-wound day 0) for each wound site, except for treatment B (bandage) at day 16. A worsening in crusting/scabbing was expected on days following post-wounding since crusting/scabbing takes time to develop.

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for the crusting/scabbing score, showed the following results:

- B (bandage) **performed better than**:
  - A (uncovered) at days 1, 2, 3, 4, 5, and 16
  - C (antibiotic ointment) at days 1, 2, 3, and 16
- D (antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
- E (antiseptic wash + antibiotic ointment + bandage for 3 days) and F (antiseptic wash + antibiotic ointment + bandage) **performed better than**:
  - A (uncovered) and B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
  - C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
- G (hydrocolloid pad[redacted]) **performed better than**:
  - A (uncovered) and C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - B (bandage), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage) at days 1, 2, 3, 4, 5, 6, and 7
  - H (hydrocolloid pad[redacted]) at days 3, 4, 5, 6, and 7
- H (hydrocolloid pad[redacted]) **performed better than**:
  - A (uncovered) and B (bandage) at days 1, 2, 3, 4, 5, 6, and 7
  - C (antibiotic ointment) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - D (antibiotic ointment + bandage) and F (antiseptic wash + antibiotic ointment + bandage) at days 1 and 2
  - E (antiseptic wash + antibiotic ointment + bandage for 3 days) at days 1, 2, 6, and 7

Wound Healing Process Assessment

Between-treatment comparisons, based on logistic regression, showed the following results:

- B (bandage), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and H (hydrocolloid pad[redacted]) **performed better than** A (uncovered) and C (antibiotic ointment)
- F (antiseptic wash + antibiotic ointment + bandage) **performed better than** C (antibiotic ointment)
- G (hydrocolloid pad[redacted]) **performed better than** A (uncovered), C (antibiotic ointment), D (antibiotic ointment + bandage), and F (antiseptic wash + antibiotic ointment + bandage)

Subject Self-Assessment Questions

Subject Assessment of Pain/Soreness

Within-treatment analysis of the subject assessment of pain/soreness score showed a statistically significant **decrease (improvement)** in scores at the following post-baseline time points when compared with baseline (post-wound day 0):

- With arm resting by side:

  - For B (bandage), C (antibiotic ointment), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), F (antiseptic wash + antibiotic ointment + bandage), and G (hydrocolloid pad[redacted]) at each post-baseline time point (days 1, 2, 3, 4, 5, 6, 7, and 16)
  - For A (uncovered) at days 1, 2, 3, 4, 5, 6, and 16
  - For H (hydrocolloid pad[redacted]) at days 2, 3, 4, 5, 6, 7, and 16

- With arm in normal motion:
  - For A (uncovered) at days 2, 4, 5, 6, 7, and 16
  - For B (bandage) and C (antibiotic ointment) at days 2, 3, 4, 5, 6, 7, and 16
  - For D (antibiotic ointment + bandage) and F (antiseptic wash + antibiotic ointment + bandage) at days 4, 5, 6, 7, and 16
  - For E (antiseptic wash + antibiotic ointment + bandage for 3 days) and G (hydrocolloid pad[redacted]) at days 3, 4, 5, 6, 7, and 16
  - For H (hydrocolloid pad[redacted]) at days 2, 3, 4, 5, 7, and 16

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for pain/soreness with arm resting by side and with arm in normal motion, showed no statistically significant difference between treatments at any time point.

Subject Assessment of Itchiness

Within-treatment analysis of the subject assessment of itchiness score showed a statistically significant **decrease (improvement)** in scores at day 16 when compared with baseline (post-wound day 0) for A (uncovered), B (bandage), C (antibiotic ointment), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage). There was no statistically significant change in scores for itchiness for G (hydrocolloid pad/[redacted]) or H (hydrocolloid pad[redacted]) at any post-baseline time point when compared with baseline (post-wound day 0).

Between-treatment comparisons, based on the mean change from baseline (post-wound day 0) for itchiness, showed that A (uncovered), B (bandage), C (antibiotic ointment), D (antibiotic ointment + bandage), E (antiseptic wash + antibiotic ointment + bandage for 3 days), and F (antiseptic wash + antibiotic ointment + bandage) **performed better than** treatment H (hydrocolloid pad[redacted]) at day 16.

Percentage of Healed

For the wound site treated with G (hydrocolloid pad[redacted]), the wound was determined as healed for 4 subjects (11.8%) at day 7, and for all 34 subjects (100.0%) at day 16.

The other wound sites were determined as healed only by the end of the study at day 16 for the following number and percentage of subjects:

- 26 subjects (76.5%) for A (uncovered)
- 32 subjects (94.1%) for B (bandage) and E (antiseptic wash + antibiotic ointment + bandage for 3 days)

- 24 subjects (70.6%) for C (antibiotic ointment)
- 33 subjects (97.1%) for D (antibiotic ointment + bandage)
- 34 subjects (100%) for F (antiseptic wash + antibiotic ointment + bandage) and H (hydrocolloid pad)

OVERALL CONCLUSIONS

Overall results from this single-center, randomized, comparator-controlled clinical trial indicate that, under the conditions of this test, wounds treated for 7 days with treatment F (Antiseptic Wash + Antibiotic Ointment + Standard of Care Bandage) showed a statistically significantly higher composite wound healing score than wounds treated for 7 days with treatment B (Standard of Care Bandage) at day 7.

Use of either hydrocolloid pad for 7 days was generally better than all other treatments. Additionally, Hydrocolloid Pad (G) was generally better than Hydrocolloid Pad (H).

Use of a bandage for 7 days (B), use of an antibiotic ointment and a bandage for 7 days (D), and use of an antiseptic wash, an antibiotic ointment, and a bandage for 3 days (E) or 7 days (F), were generally better than leaving the wound uncovered for 7 days (A) or use of only an antibiotic ointment for 7 days (C). Additionally, D, E, and F (bandage plus topical treatment[s]) were generally better than B (bandage only).