Interim Results from a Non-Comparative Clinical Investigation to Evaluate the Tolerability of a Pressure Injury Prevention Protocol with Silicone Border Super-Absorbent Polymer Dressing in Long-term Acute Care Patients

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BACKGROUND

Pressure ulcer/injury (PU/PI) is defined as localized damage to the skin and/or underlying tissue, as result of pressure or pressure in combination with shear forces[1]. The sacral region and heels region are the most affected anatomical sites, accounting for 37-53% and 19.5-35.3% of all pressure injuries respectively[2] Devices for PI prevention include specialized beds, mattresses and, more recently, dressings[3]. The three main dressings that have been researched for PI prevention are film dressings, hydrocolloid dressings, and foam dressings.

No prior investigations have evaluated dressings for PI reduction in Long-Term Acute Care (LTAC) settings. LTACs are focused on patients with serious medical problems that require intense, specialized treatment for several weeks. Such patients often transfer from intensive-care units (ICUs) in traditional hospitals.

OBJECTIVES AND HYPOTHESIS

This is an open, non-comparative, prospective, interventional, descriptive study with a main objective to assess the acceptability of the Zetuvit Plus Silicone Border wound dressing as part of a sacral pressure injury prevention protocol in LTAC setting.

Hypothesis:

- The interventional dressing is anticipated to be minimally burdensome to patients while offering benefits of reduced shear and compression forces on the sacrum
- Primary outcome was defined as patient satisfaction. Occurrence of PI and adverse events were assessed as secondary outcomes due to the anticipated low incidence in this interim analysis

METHODS

Setting

- Spaulding Rehabilitation Hospital: a 120-bed, Magnet accredited Long-Term Acute Care Hospital located in Boston, Massachusetts

Study Population

- LTAC patients meeting the following criteria were approached for consenting:
  - Identified as high risk for sacral PU development, defined by PI judgement and Braden Scale
  - Predominantly bed bound or chair bound
  - Age ≥ 18 years
  - Patient or his/her legal representative is able to understand and voluntarily sign the informed consent
- Patients were ineligible if they had a current sacral pressure or had known or suspected sensitivity to any of the components of the product being evaluated

Study Design

- Open, non-comparative, prospective Clinical Investigation to evaluate tolerability and convenience of a pressure ulcer protocol incorporating Zetuvit Plus Silicone Border dressing
- This is a descriptive study to assess qualitative endpoints, no statistical hypothesis is used for a study design

FIGURE 1: OVERVIEW OF PATIENT JOURNEY THROUGH STUDY PROTOCOL

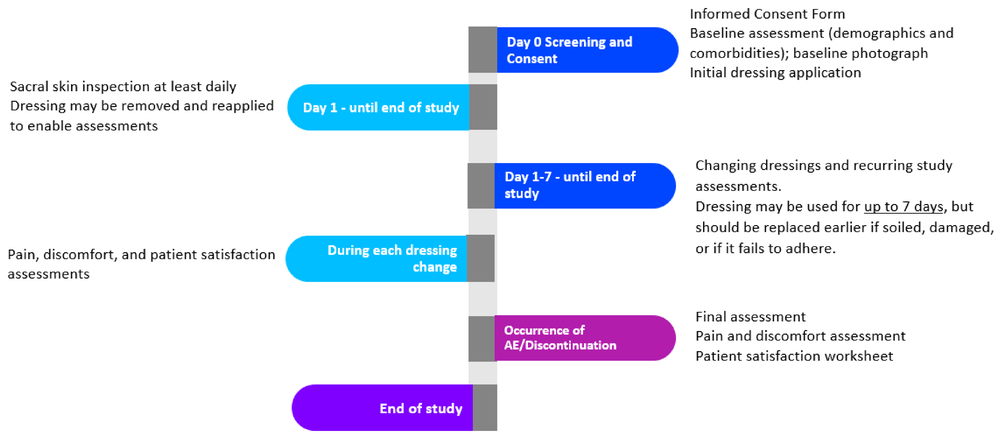
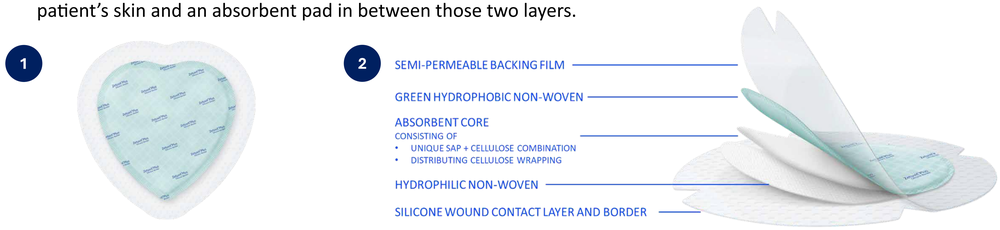


FIGURE 2: INVESTIGATIONAL DRESSING

Investigational Dressing

1. Sacral-shaped, sterile self-adhesive superabsorbent dressing with a silicone interface which allows easy application and atraumatic removal.
2. Comprises a semi-permeable polyurethane backing film, a perforated silicone layer towards the side facing the patient's skin and an absorbent pad in between those two layers.



STUDY OUTCOMES

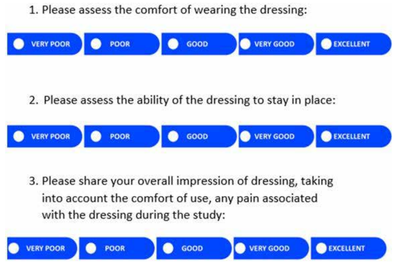
Primary Outcome

- Patient Satisfaction was assessed at 2-weeks or discontinuation/withdrawal from study

Secondary Outcome

- Sacral Pressure Injuries
  - Sacral skin was evaluated daily and documented according to standardized assessments
- Adverse events related to the dressing will be recorded by LTACH staff in patients' medical records and study eCRF from the date of screening visit by the final evaluation visit.

PATIENT SATISFACTION SURVEY QUESTIONNAIRE



INTERIM RESULTS

Accrual

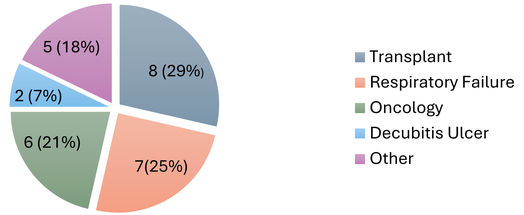
- Interim results include 28 patients out of a planned 75 patients

Characteristics of Patients:

Table 1: Distributions of Baseline Characteristics of Study Participants

Baseline Characteristics	N (%) or Median (Range)
Demographic Characteristics	
Age, Median (Min-Max)	60 (22-86)
Sex	
Male	22 (79%)
Female	6 (21%)
Baseline Braden, Median (Min-Max)	15 (13-19)
Baseline Pressure Injury Risk Factors	
Immune Deficiency	14 (50%)
Malnutrition	12 (43%)
Diabetes	8 (29%)
COPD	5 (18%)
Thyroid Disease	3 (11%)

FIGURE 3: PRIMARY DIAGNOSIS FOR LTAC ADMISSION



Follow-Up

- The average duration of use was 18 days and 6 dressing changes
- Reasons for discontinuation included discharge (n=20), request due to study burden (n=2), and request due to discomfort (n=3)

Study Outcomes:

- Patient satisfaction: 87% report good to excellent overall satisfaction
- Pressure Injuries: None observed
- Adverse Events: None observed

CONCLUSIONS

In this interim analysis of our ongoing study, sacral dressings were successfully integrated into a pressure injury prevention protocol in a high-risk population of patients admitted to a LTAC. No pressure injuries occurred in our intervention group. The intervention was reported to be tolerable by most participants. Patient accrual and follow-up will continue to further evaluate the tolerability and effectiveness of sacrum-shaped, multi-layer, silicone super-absorbent polymer dressing in the LTAC setting.

1: European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel. (Ed.), Emily Haesler. s.l. : EPUAP/NPIAP/PPPIA, 2019
2: Pressure Ulcer Risk in the Incontinent Patient: Analysis of Incontinence and Hospital-Acquired Pressure Ulcers From the International Pressure Ulcer Prevalence™ Survey. Lachenbruch C, Ribble D, Emmons K, VanGilder C. s.l. : J Wound Ostomy Continence Nurs., 2016, Vols. May-Jun;43(3):235-41.
3: Challenges in pressure ulcer prevention. Dealey C, Brindle CT, Black J, Alves P, Santamaria N, Call E, Clark M. 3, s.l. : Int Wound J., Jun 2015, Vol. 12, pp. 309-12.