A Pilot Study of a New Low Air Loss Treatment Surface in the Critical Care Setting

Jennifer Fimiani, RN, BSN, CWOCN*, Emily Cohen, RN, BSN, CWOCN*, Catherine VanGilder, BS, MT, CCRA**

Introduction

Critical care patients have a high incidence of nosocomial and community acquired pressure ulcers. Pressure redistributing surfaces are an important part of prevention and treatment of pressure ulcers. This study evaluated a new pressure ulcer treatment and prevention mattress surface which electronically senses high pressure zones and applies pressure to non-loaded areas which redistributes pressure, maximizing immersion and pressure redistribution.

Study Design

The study is an open label, prospective, observational natural history study, using a cross-sectional convenience sample. A total of 30 subjects meeting the defined inclusion criteria were placed on the Envision® surface for a minimum of 3 days, and a maximum of 7 days. The study endpoints include the following:

- Voluntary subject withdrawal.
- Completion of 3 to 7 continuous days on the Envision® surface. Note that if in the professional judgment of the clinical staff, transfer of the subject to an alternative surface after 7 days poses unnecessary risk, then the subject may remain on the surface after study exit until safe transfer can be accomplished.
- Development of a new (nosocomial) pressure ulcer of any stage, including deep tissue injury.
- Progression of an existing ulcer to a higher stage or an increase in wound volume of ≥ 25%, or an increase in the quantity of necrotic tissue in the wound bed.

Caregiver satisfaction surveys were collected, as well as patient comfort surveys.

Study Objective

The main objective of this study was to evaluate the clinical safety and effectiveness of the Envision® surface placed on the TotalCare® frame in pressure ulcer prevention and management, patient comfort, and staff acceptance in the critical care environment.

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Methods

Inclusion criteria: For inclusion, subjects must meet all of the following criteria:

- Subjects admitted to the critical care.
- Subjects are identified as being at high risk for pressure ulcer development (Braden ≤ 14)
  or who have existing pressure ulcers of any stage were sought for study participation.
- Subject or legal representative is willing and able to provide voluntary consent for study participation.
- Subject weighs between 70 and 400 pounds.
- Subject is expected to remain on the Envision® surface for at least 3 days (this is a subjective assessment).

Exclusion criteria: Subjects will be excluded from the study if they meet any of the following criteria:

- Subject has an unstable spine.
- Subject requires a pulmonary treatment mattress surface.
- Physician, subject or subject's representative declines to provide consent.

Results

Subject Demographics

Parameter	Outcome	Parameter	Outcome
Age (Mean ± SD)	63.4 ± 20 years	**Height** (Mean ± SD)	66.1 ± 4 inches
Range	23 – 88 years	**Range**	60 – 75.6 inches
Gender		**Ethnicity**	
Males	14 (47%)	African	
Females	16 (53%)	American	20/30 (66%)
		Caucasian	10/30 (33%)
Weight			
(Mean ± SD)	174.3 ± 52 pounds		
Range	104 – 288 pounds		

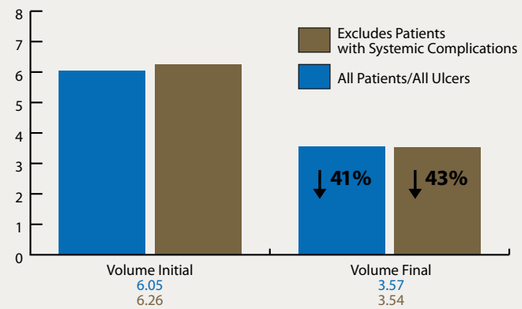
Summary of Medical Status

Parameter	Outcome	Parameter	Outcome
Urinary Incontinence	27/30 (90%)	**Neurologic Impairment**	
		Normal	4/30 (13%)
Braden Score Initial (Mean ± SD)	12 ± 1.6	Some Impairment	23/30 (77%)
		Comatose	1/30 (3%)
		Paraplegic	1/30 (3%)
Range	8 - 14	Quadriplegic	1/30(3%)

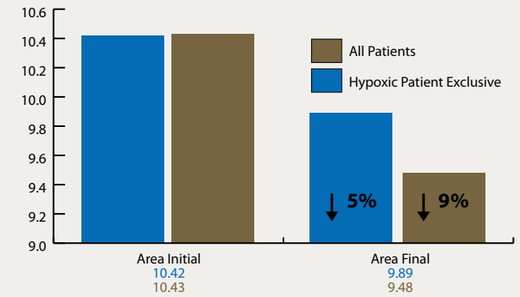
Results

1. 30 patients were enrolled.
2. Average LOS was 6 days
3. Average Braden Pressure ulcer risk score of 12 + 1.6 SD (range 8-14)
4. 27/30 (90%) had Urinary incontinence
5. 24/30 (80%) were incontinent of stool
6. Neurologic Impairment
   - Normal - 4/30 (13%)
   - Some Impairment - 23/30 (77%)
   - Comatose - 1/30 (3%)
   - Paraplegic - 1/30 (3%)
   - Quadriplegic - 1/30(3%)
7. 33 existing pressure ulcers admitted to the study
8. Stages of the ulcers (by NPUAP Staging system) were,
   - 15 Stage II
   - 9 Stage III
   - 4 Stage IV
   - 4 Unstageable
   - 1 Deep Tissue Injury
9. Ulcers decreased in volume an average of 41% if all ulcers are considered, and 43% if one patient who became significantly more hypoxic is excluded.
10. Area changes were 0.09 cm2/day if all patients are considered, and if the hypoxic patient is excluded, 0.16 cm2/day.
11. Caregivers rated the surface 4.1 on a 5 points scale (5 = extremely satisfied)

Change in Ulcer Volume



Change in Ulcer Area



Conclusions

With the National Healthcare spotlight on nosocomial pressure ulcers, the introduction of a new pressure redistribution treatment surface to a critical care setting is judicious.

By the numbers the Envision® mattress performed favorably in the following criteria:

- Decrease in Wound size 5% Area (cm2)
- Decrease in Ulcer Volume 41% (cm3)
- Staff satisfaction rating of 4.1 on a 5 point scale
- In addition, specialty clinicians found that the use of the Envision® mattress provided subjective patient interventions including
  - Pain reduction
  - Ease of Egress

To further assess the effectiveness of the mattress in this high acuity population a comparison study will be required.

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