Assessing Treatment Efficacy in Pressure Ulcers in a Real-World Post-Acute Population: Human Keratin Matrix Versus Standard of Care: A Retrospective Matched Cohort Analysis

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Abstract

Pressure ulcers cause severe complications that significantly impact healthcare systems and patient quality of life, often leading to hospitalization and death. Traditional

Standard of Care (SOC) treatments are inadequate for many patients, necessitating advanced wound care products (AWCPs), like Human Keratin Matrix (HKM).

This retrospective observational study conducts a retrospective analysis to compare the effectiveness of HKM and SOC in managing full thickness chronic pressure ulcers.

Trademarked Items:

progenacare

Methods

1. Data Collection: Retrospective observational data were gathered from electronic health records (EHRs).

2. Patient Selection: Included patients had Stage 3 or 4 pressure ulcers, failed initial Standard of Care (SOC) treatment, and were treated by a leading mobile wound care practice.

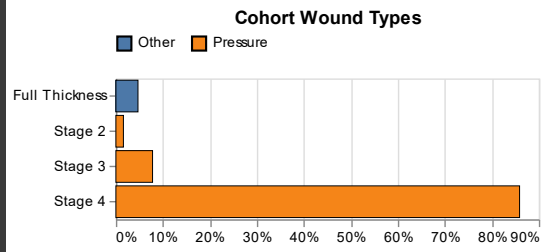
3. Study Duration: The study spanned 180 days post-treatment.

4. Cohort Selection: Patients treated with HKM were selected and matched to SOC patients using Coarsened Exact Matching (CEM).

5. Cohort Categorization: Patients were divided into two cohorts based on receiving either HKM or SOC.

6. Key Metrics: Wound closure rate and expected Percent Area Reduction (xPAR) were the main metrics.

7. Data Analysis: Employed Bayesian regression and Hurdle Gamma ANCOVA models for analysis.



The Model

Treatment Group	O_{pre}	X	O_{post}
Standard of Care (SOC)	O_{pre}		O_{post}

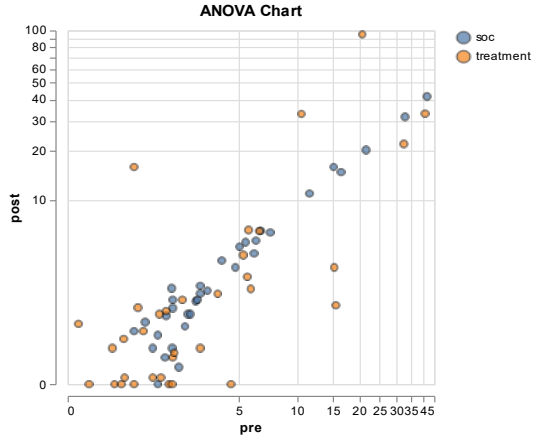
The Pretest-Posttest Control Group Design

Hurdle Gamma Model

$$
\begin{aligned}
y &\sim \text{Hurdle Gamma}(\alpha_{it}, \beta_{it}, \psi_t) \\
\text{logit}(\psi) &= \gamma_0 + \gamma_1 group_{it} \\
\log(\mu) &= \beta_0 + \beta_1 group_{it} \\
\gamma_0 &\sim \text{Normal}(0, 6) \\
\gamma_1 &\sim \text{Normal}(0, 6) \\
\beta_0 &\sim \text{Normal}(0, 5) \\
\beta_1 &\sim \text{Normal}(0, 5) \\
\psi_0 &\sim \text{Beta}(0, 1) \\
\psi_1 &\sim \text{Beta}(0, 1)
\end{aligned}
$$

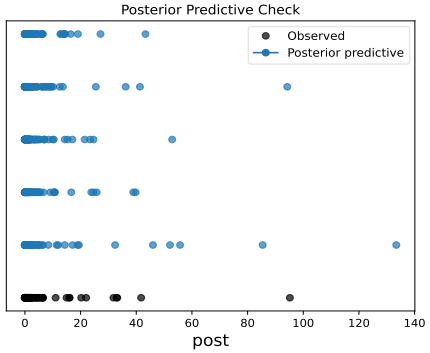
Model-fitting

The model is visualized with ANOVA chart and we can see a clear linear relationship between pre and post measurements in both groups on a symlog scale.



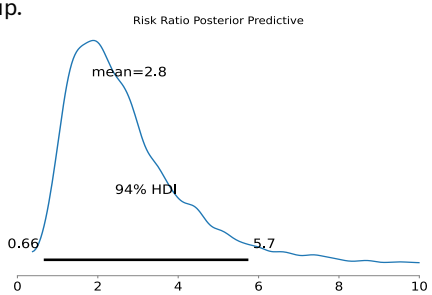
Model Checking

The model's fit was thoroughly assessed through a posterior predictive check. The results of this check revealed that the model performed well in capturing and reproducing the overall distribution and shape of the observed data. This suggests that the model is well-calibrated and capable of accurately reflecting the underlying patterns in the dataset.



Results and Discussion

The results showed that pressure ulcers treated with HKM were 2.8 times more likely to experience full wound closure than the SOC group.



The findings indicate that adding Progenamatrix to the standard of care is an effective approach for treating pressure ulcers in this challenging-to-heal population, leading to a significant improvement in the wound healing rate.