Document Title:

Statistical Analysis

Study Title:

Surgical Drape with a Releasable Acrylic Adhesive for Atraumatic Negative Pressure Wound Therapy

NCT06717308

Date: **October 10, 2024**

Title: Surgical drape with a releasable acrylic adhesive for atraumatic negative pressure wound therapy.

Statistical Analysis

Aim 1. For single-use NPWT, measures of skin irritation and injuries and pain will be analyzed using linear models to compare Comfort Release® drapes with Vac drapes while controlling for gender, age, hospital facility, and other relevant patient comorbidities. All hypothesis tests will be two-sided and p-values < 0.05 considered statistically significant. Model assumptions of normality and homogenous variance will be assessed visually using plots of the model residuals. Sample sizes of 100 patients per randomization group (n = 50 patients per randomization group from each of two hospital facilities) will allow for a standardized mean difference of 0.4 between the treatment groups to be considered statistically significant at an $\alpha = 0.05$ level with 80% power. An effect size of $d = 0.4$ is considered a moderate effect size and would translate to a mean difference of 1 unit on the Medical Adhesive-Related Skin Injury (MARSI) scoring system assuming a within group standard deviation of 2.5; and a mean difference of 4 units on the Indiana Polyclinic Combined Pain Scale assuming a within group standard deviation of 10.

Aim 2. For serial-use NPWT, measures of skin irritation and injuries and pain collected repeatedly after each drape change will be analyzed using linear mixed models to compare Comfort Release® drapes with Vac drapes. Fixed effects will include treatment group (intervention vs. control), time, an interaction between treatment group and time, gender, age, and other relevant patient comorbidities. Models will include a random effect of the patient id to control for the repeated measurements taken on patients over time. All hypothesis tests will be two-sided and p-values < 0.05 considered statistically significant. Model assumptions of normality and homogenous variance will be assessed visually using plots of the model residuals. Sample sizes of 50 patients per randomization group (from a single hospital facility) will allow for an overall standardized mean difference of $d = 0.6$ between the treatment groups to be considered statistically significant at an $\alpha = 0.05$ level with 80% power. An effect size of 0.6 is considered a moderate effect size and would translate to a mean difference of 1.5 units on the Medical Adhesive-Related Skin Injury (MARSI) scoring system assuming a within group standard deviation of 2.5; and a mean difference of 6 units on the Indiana Polyclinic Combined Pain Scale assuming a within group standard deviation of 10.

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