Button Huggie Clinical Trial Completion – Clinical Data Report

Project Title: Clinical Trial of Gastrostomy Button Securement Device
Protocol #: 18-1615
Principle Investigator: Steven L. Moulton, MD
Trial Enrollment: 175

Overview:
An IRB-approved clinical trial is being run across four major Children's Hospitals: Children's Hospital Colorado, Stanford Children's Hospital, Primary Children's Hospital, and Phoenix Children's Hospital, to test clinical outcomes and caregiver satisfaction differences between a gastrostomy button securement device (the Button Huggie) and a tape-and-gauze dressing/securement approach, commonly referred to as the "Tic-Tac-Toe" ("TTT") dressing.

Methods Summary:
Immediately after receiving an AMT MiniONE ENFit G-button, pediatric patients are enrolled in the trial and randomly assigned to either the Tic-Tac-Toe (TTT) group or the Gastrostomy Button Securement Device (Button Huggie) group. If enrolled in the TTT group, the participating family receives instructions and 8 weeks of supplies for managing the patient's new gastrostomy, using the standard tape-and-gauze dressing. If enrolled in the Button Huggie group, the participating family receives instructions and an 8-week Button Huggie supply kit for managing the patient's new gastrostomy using the Button Huggie. Each participating family is instructed to complete surveys at 2, 4, 6, and 8 weeks enrollment to gather study data.

Preliminary Results Summary:

***Dislodgements:** Dislodgement rate is the primary endpoint of the Button Huggie clinical trial. Current data from the clinical trial shows that a patient is more than 4 times more likely to experience a G-button dislodgement using the Tic-Tac-Toe method of securement, compared to using the Button Huggie. In other words, the Button Huggie reduces dislodgements by more than 77%. **This data is statistically significant**, with a ***p-value* of 0.046. The ****odds ratio* for this data is 4.41.

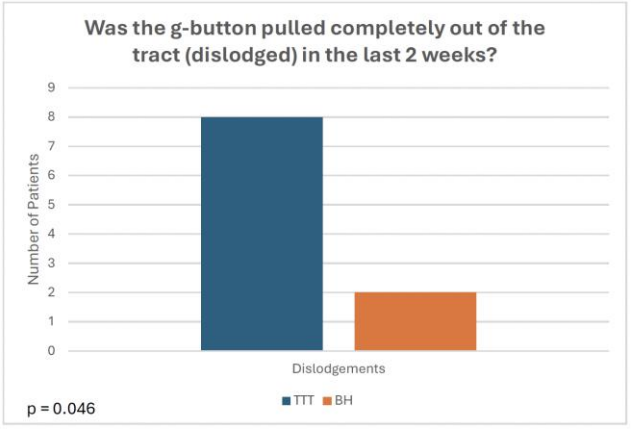


Figure 1: Number of G-button dislodgements in each study group.

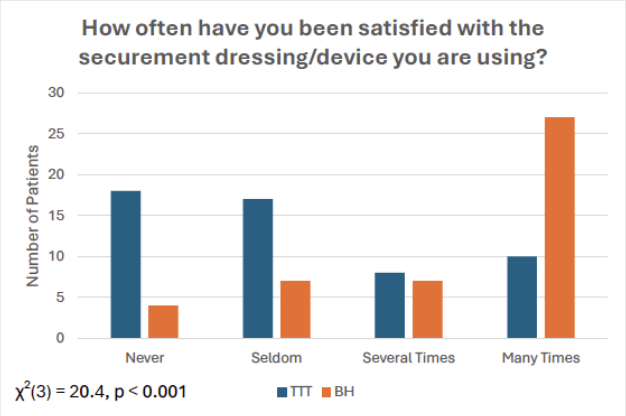
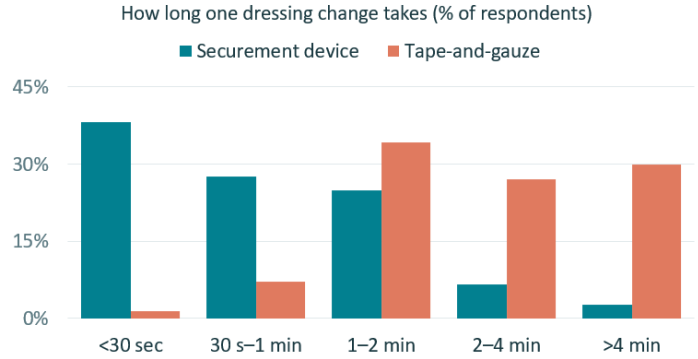


Figure 2: Self-reported caregiver satisfaction in the Button Huggie and TTT groups.

Caregiver Satisfaction: As shown in Figure 2, current clinical trial data shows that caregivers in the Button Huggie group have significantly higher satisfaction ratings compared to those in the TTT group. This data is statistically significant, with a **p-value of <0.001*. For this data, the *****chi-square value* is 20.4.

Care Time:



Thirty percent of tape-and-gauze caregivers needed more than four minutes per change — several times a day, every day.

66% vs 9%
of caregivers finished a dressing change in under a minute

Dressing change time	p<0.001
Caregiver satisfaction	p<0.001
Daily site-care time	p=0.014

Terminology:

***G-button Dislodgement:** when the G-button is completely pulled out of the patient. A dislodgement can be both dangerous and costly.

****P-value:** a p-value measures how likely it is that a result could have occurred by random chance. A low p-value (typically <0.05), is considered statistically significant, and means that is highly unlikely that the study result occurred by chance.

*****Odds Ratio:** an odds ratio is a statistic that compares the odds of an event occurring in one group versus another, taking into account the number of occurrences of said event in each group and the sample size (the number of participants) of each group.

******Chi-square Value:** the chi-square value (X^2) provides a way to test how well a sample of data matches the (known or assumed) characteristics of a larger population that the sample is intended to represent. This is known as "goodness of fit". A large chi-square value indicates a large difference between observed and expected outcomes, suggesting the differences are statistically significant.