#### Designs for a Minimal Impact Dual Access Faceplate and Smart Tie to Reduce the Risk of Tracheostomy Related Wound Complications in Children

#### Gregory Marks, MD¹; John Cronvich, BS²; Rohan Walvekar, MD¹; Joel Jones, MD¹; Michael Dunham, MD¹

<sup>1</sup> LSUHSC New Orleans, Department of Otorhinolaryngology; <sup>2</sup> Louisiana State University, Department of Engineering





# Purpose

Despite significant improvements in outcomes over the last two decades, tracheostomy remains associated with a relatively high incidence of early complications. Stomal and peristomal wound complications have been reported to occur in up to 30% of pediatric patients. In most hospitals, caretakers use cloth straps with Velcro fasteners to secure tracheostomy tubes. To estimate the amount of appropriate tension under the trach tie, the ability to insert one finger under the tie comfortably has colloquially been used. Standard objective measures of tracheostomy tie tension do not exist. Using previous literature on pressure-related ulcers and its relationship to cutaneous closing capillary pressure, our study set out to measure the relationship with tension distributed in the tracheostomy tie and the pressure exerted by the tracheostomy faceplate onto the skin.



Figure 1: Peristomal post-tracheostomy wound formation



Figure 2: Lateral neck wound formation

# Methods

IRB approval was obtained in order to use computed tomography imaging of 36 pediatric patients aging from 37 to 71 months of age. These images were then averaged and utilized to 3D print a neck model on which to base construction of the 3D printed tracheostomy tube faceplate and tracheostomy tube ties.

Design and manufacturing of materials was devised in partnership with students in the LSU School of Engineering. A conceptual prototype tracheostomy tube was manufactured via cast molding using platinum-cured silicone rubber, and the trach tie was manufactured with terephthalate polyester. Pressure sensors which conveyed real-time data to Microsoft Excel were attached to the tracheostomy tie and undersurface of the faceplate. This was clipped to the 3D-printed neck model. Faceplate pressures ranging from 0.05 psi to 0.45 psi were set on the model, and five measurements of tie tension were taken and averaged.

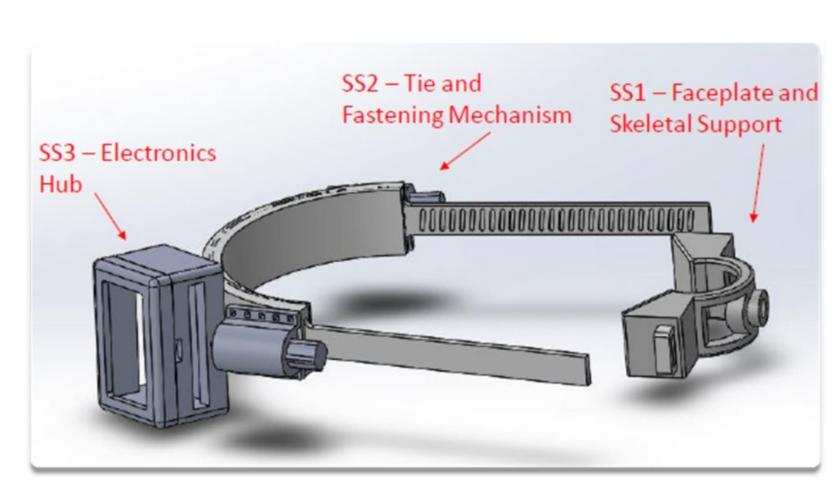
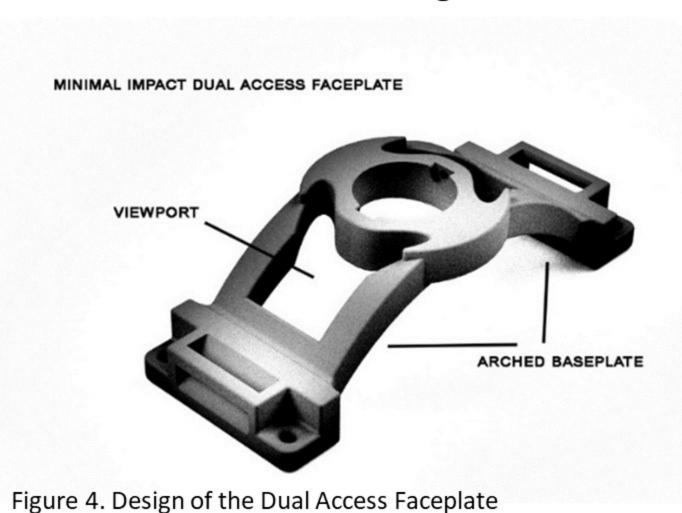


Figure 3: Original Conceptual Prototype.



#### Results

The mean trach tie tension (pound-force) was 0.0698 (SD, 0.02), 0.1198 (SD, 0.01), 0.1866 (SD, 0.02), 0.2124 (0.02), and 0.2696 (SD, 0.03), when the undersurface plate pressure (pounds per square inch) was set to 0.05, 0.15, 0.25, 0.35, and 0.45 psi, respectively. Tension applied to the tracheostomy tie (pound-force) demonstrated a strong linear correlation with the pressure (psi) applied to the undersurface of the faceplate ( $R^2 = 0.9872$ ). Neck tie tension was converted to Newtons, and plate pressure was converted to kilopascal for ease of comparison (Chart 1).

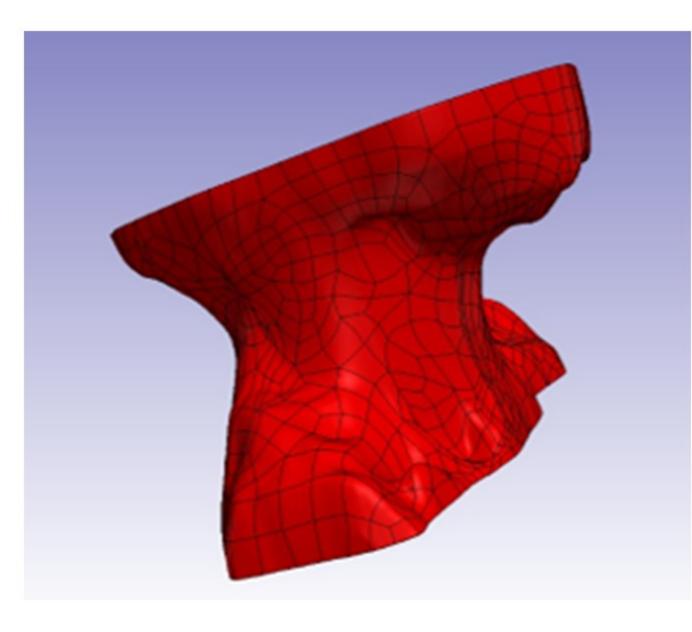


Figure 5. Computer-aided design model of neck surface topology generated from a CT scan

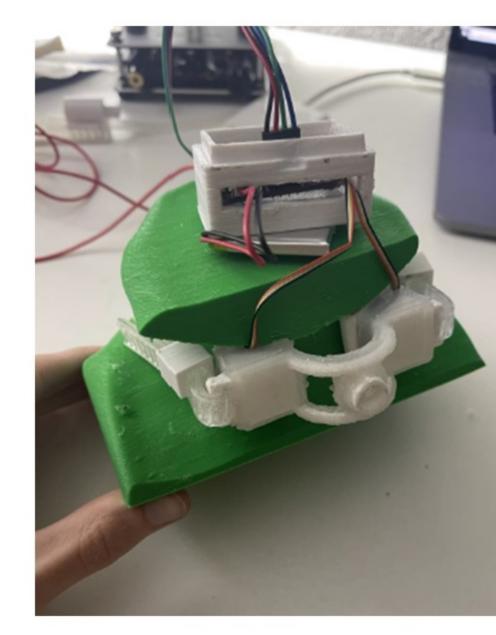


Figure 6. Testing of original prototype on 3D-printed neck model.

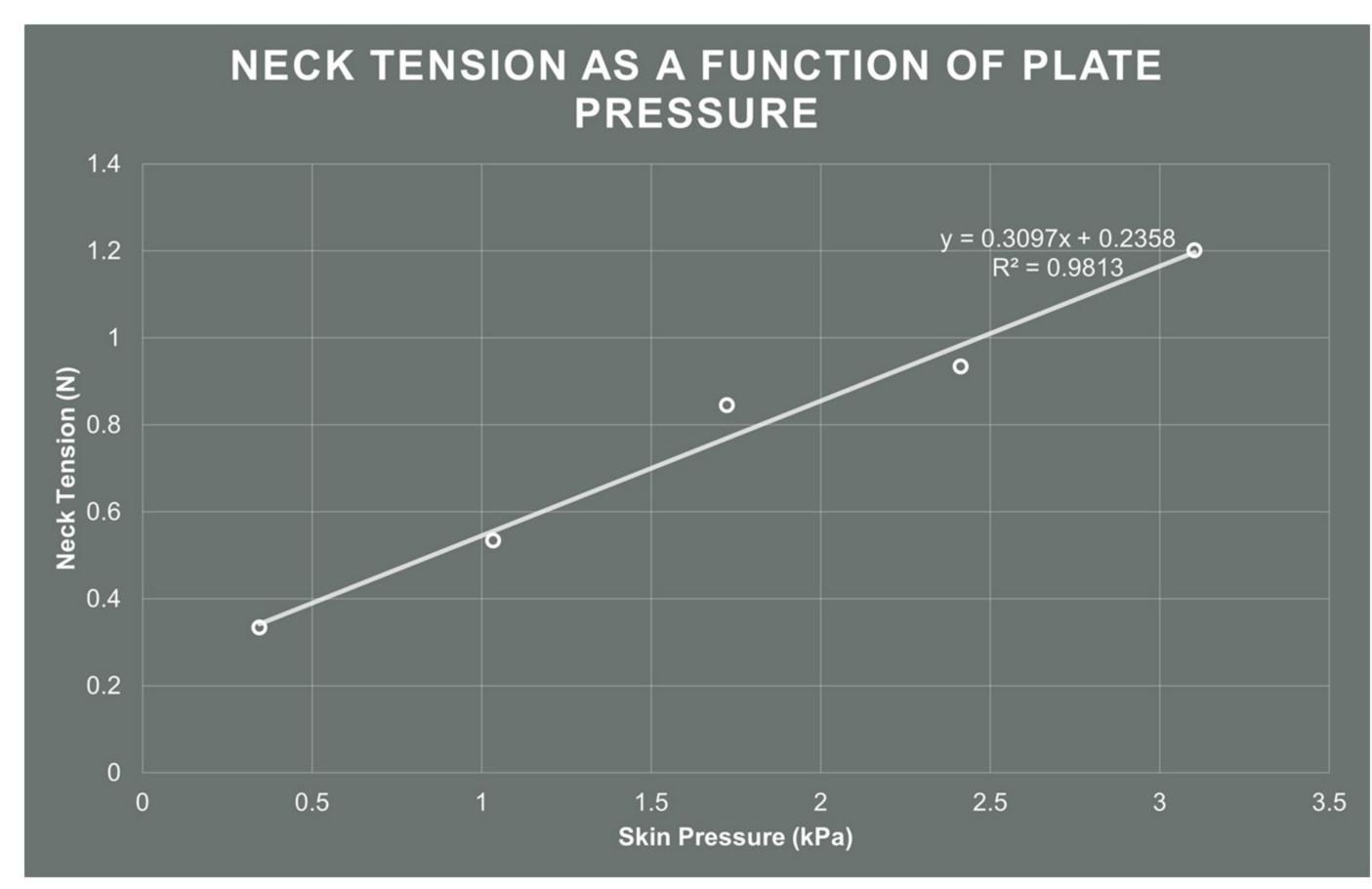


Chart 1. Neck tension as a function of plate pressure with units converted from pound-force to Newtons and pounds per square inch converted to kiloPascals.

## Discussion

Previous literature on pressure-related skin ulcers has elucidated a closing capillary pressure of 32 mmHg (4.3kPa) as an accurate surrogate for skin breakdown. While there are several studies regarding associated factors for tracheostomy-related pressure ulcers, no study has investigated the pressure related to the trach tie tightness as it is translated through the tracheostomy tube faceplate. Traditional teaching of tracheostomy tie tightness suggests being able to snuggly fit one finger between the neck and the trach tie for pediatric patients. This study is the first of its kind in investigating an objective relationship between tension of a tracheostomy tube tie as it is translated into pressure upon the patient's neck. We have demonstrated a linear relationship in the tension to pressure which can be extrapolated to further investigations regarding tracheostomy-related skin ulcerations, though this was performed on a 3D printed neck model.

This project's next phases will advance to testing on human subject's extremities for obtaining both measurements of tension and pressure as well as getting subjective measures of comfortability. Furthermore, the aim of this project is to develop improved sensor mechanisms within the tie itself to alert caretakers of tightness level as it would relate to wound complications. An additional goal is to continue refinement of the tracheostomy tube faceplate for enhanced visualization of the peristomal area for improved stomal care.

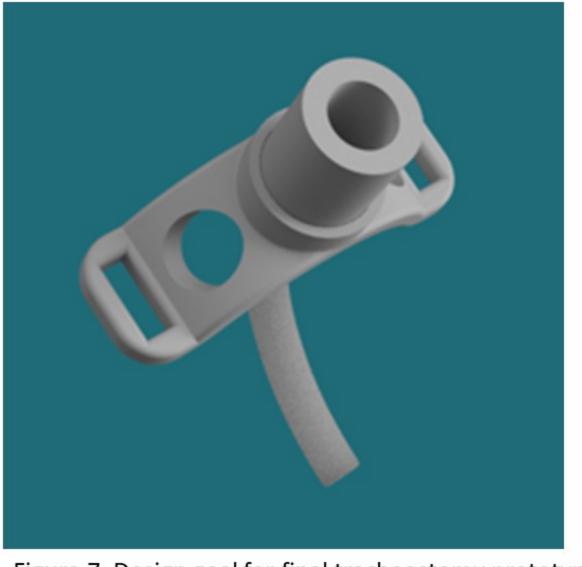


Figure 7. Design goal for final tracheostomy prototype

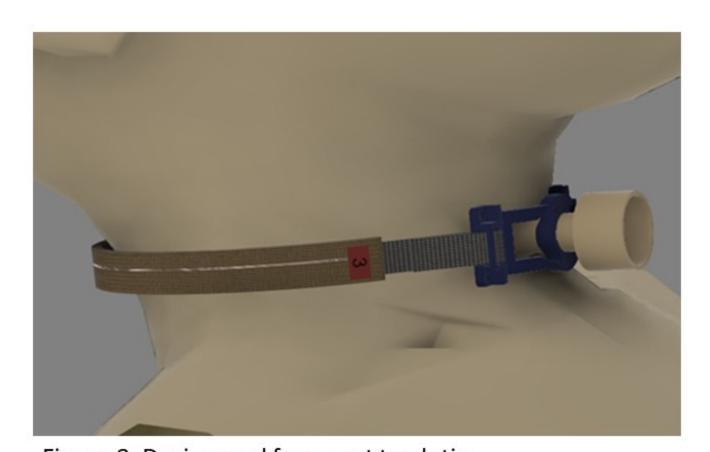


Figure 8. Design goal for smart trach tie

### Conclusions

This study establishes a model which could be used to calculate pressures applied to lateral neck skin and the peristomal region, thereby potentially determining pressure thresholds at which tracheostomy-related skin ulceration can occur. Refinements in this model are needed to develop a working prototype for future clinical evaluation.

#### References

- 1. Jaryszak EM, Shah RK, Amling J, Peña MT. Pediatric tracheotomy wound complications: incidence and significance. Arch Otolaryngol Head Neck Surg. 2011 Apr;137(4):363-6. doi:
- 10.1001/archoto.2011.33. PMID: 21502474.

  2. Hess DR, Altobelli NP. Tracheostomy tubes. Respir Care. 2014 Jun;59(6):956-71; discussion 971-3. doi: 10.4187/respcare.02920. PMID: 24891201.
- 3. Black, JM, and Kalowes, Peggy (2016). "Medical device-related pressure ulcers." Chronic Wound Care Management and Research 2016: 3 91-99. Dovepress Journal. 29 August 2016.
- Defloor T. The risk of pressure sores: a conceptual scheme. J Clin Nurs. 1999 Mar;8(2):206-16. doi: 10.1046/j.1365-2702.1999.00254.x. PMID: 10401354.
  Mervis JS, Phillips TJ. Pressure ulcers: Pathophysiology, epidemiology, risk factors, and presentation. J Am Acad Dermatol. 2019 Oct;81(4):881-890. doi: 10.1016/j.jaad.2018.12.069. Epub 2019 Jan 18. PMID: