Comparison of Negative Pressure Incision Management Systems: Impact on Simulated Incision Apposition and Assessment of Device Operational Sound Level

Pedro Maldonado, B.S., Solventum (San Antonio, TX)

Background

There are many performance aspects of Closed Incision Negative Pressure Therapy (ciNPT) systems to consider when selecting a system that best suits the needs of a given patient. For example, patients with co-morbidities are at significant risk for incisional dehiscence.[1-3] A key therapy component is helping to maintain the tissues in apposition until the healing process provides sufficient strength to withstand stress. Various ciNPT systems for the management of at-risk incisions are available and there is a continued need to articulate the differences and benefits between these systems.

A specific foam-based dressing with a skin-friendly interfacial layer designed for ciNPT was previously shown in computer models and laboratory bench models to reduce lateral incisional tension and increase appositional strength when under negative pressure (NP).[4] With the introduction of a non-foam-based dressing, there is a need to better understand the impact of different dressing designs on the biomechanics of underlying substrates.

Another aspect of ciNPT systems to consider for suiting patient needs is discreetness. Systems should operate and apply therapy with minimal disturbance to the patient including device sound level and its ability to keep noise to a minimum. A sound level comparison is needed to better understand the potential impact of this performance aspect.

Purpose

The overall objective was to evaluate two ciNPT systems, one comprised of a NP device and foam-based dressing (ciNPT-A*, **Figure 1**) and the other a NP device and non-foam-based dressing (ciNPT-B†, **Figure 2**). The evaluation consisted of multiple studies including assessment of the ability to apply appositional force to a simulated incision model and the ability to change the width of incisional space in simulated tissue.

Another study assessed operational sound levels for devices belonging to both ciNPT-A and ciNPT-B systems to compare their performance in sound level during use.

Figure 1. ciNPT-A

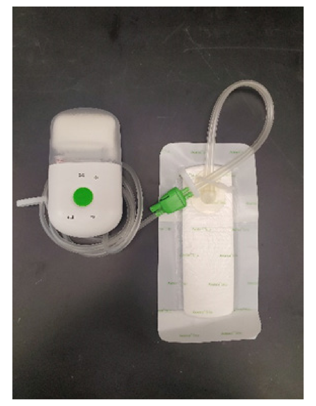

Figure 2. ciNPT-B

Methods

For the first appositional force comparison, ciNPT-A and ciNPT-B systems were tested at their factory settings (n=9 dressings/system) with each of the similarly sized dressings (absorbent length for both systems: 25 cm; width for ciNPT-A: 6.3 cm; ciNPT-B: 5 cm) centered on a simulated incision created in a multi-layered silicone model (**Figure 3**). The model contained embedded loading plates allowing measurement of appositional force acting upon the simulated incisional space. The dressing-tissue proxy substrate was placed within a tensile tester and appositional force was measured following application of NP.

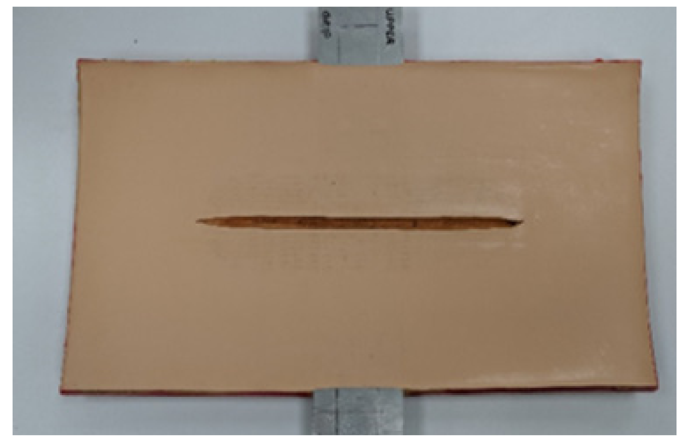

Figure 3. Appositional force model

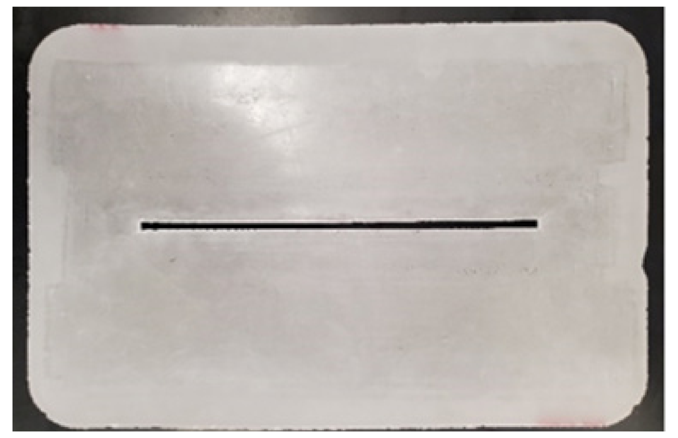

Figure 4. Incisional width model

For the second incisional width closure comparison, ciNPT-A and ciNPT-B systems were tested at their factory settings (n=9 dressings/system) with each of the similarly sized dressings (absorbent length for both systems: 15 cm; width for ciNPT-A: 6.3 cm; ciNPT-B: 5 cm) centered on a simulated incision completely penetrating a silicone sheet (**Figure 4**). The incision was covered with a thin adhesive polyurethane drape§ to isolate the incision space. The dressing-tissue proxy substrate was inverted and placed flat, exposing the backside of the incisional void for width measurement. Incisional widths at multiple locations along the void were measured prior to and after initiating NP.

For the operational sound level comparison, devices belonging to ciNPT-A and ciNPT-B systems were tested by applying therapy at factory settings while exposed to an air leak rate of ~ 18 ccm (n=3 devices/system). The sound power level emitted from each device was measured using a sound analyzer (**Figure 5**). A 2-sample t-test was used for each statistical evaluation.

Figure 5. Sound analyzer

Results

When comparing the appositional force applied to a simulated incision model, ciNPT-A achieved a greater average force of 5.987 N (± 0.77 N) when compared to 1.564 N (± 0.12 N) for ciNPT-B ($p < 0.05$) (**Figure 6**).

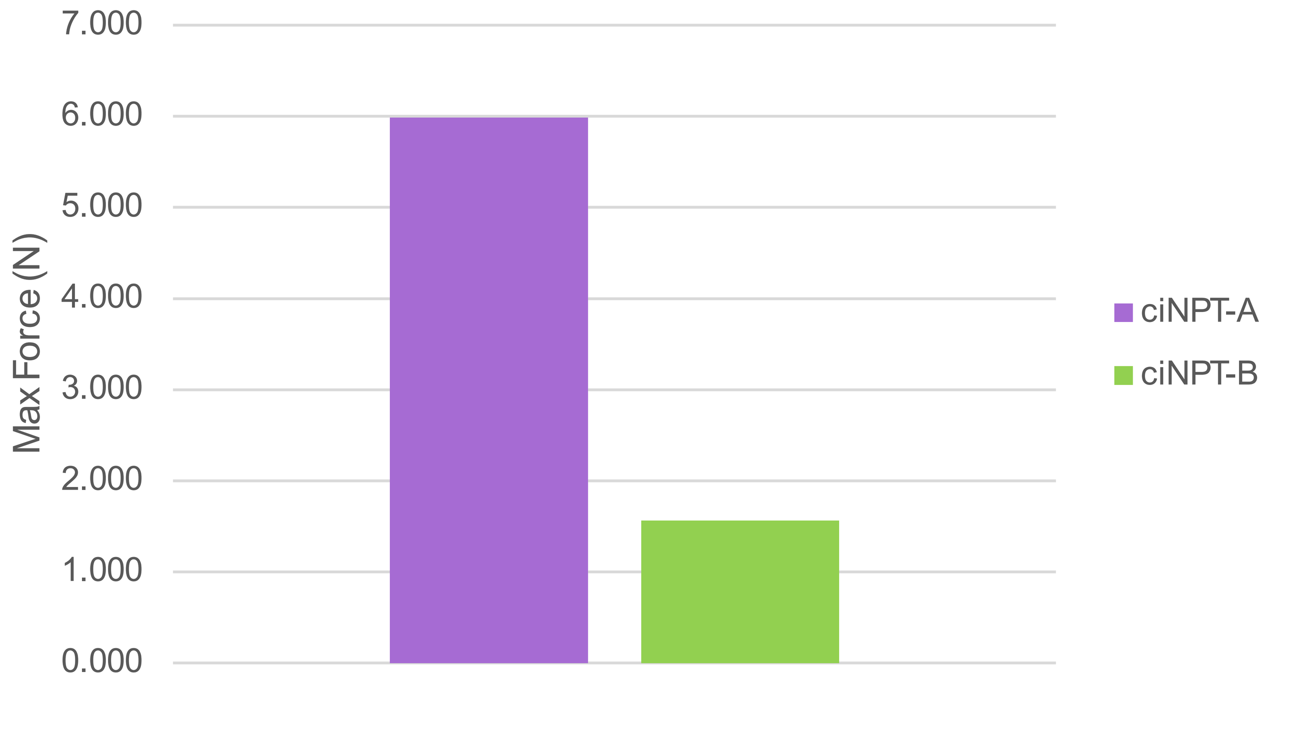

Figure 6. Mean incisional closure force

When comparing the percentage change in width of a simulated incision, ciNPT-A achieved greater average closure of -37.28% (±3.90 %) compared to -7.35% (± 1.17 %) for ciNPT-B ($p < 0.05$) (**Figure 7**).

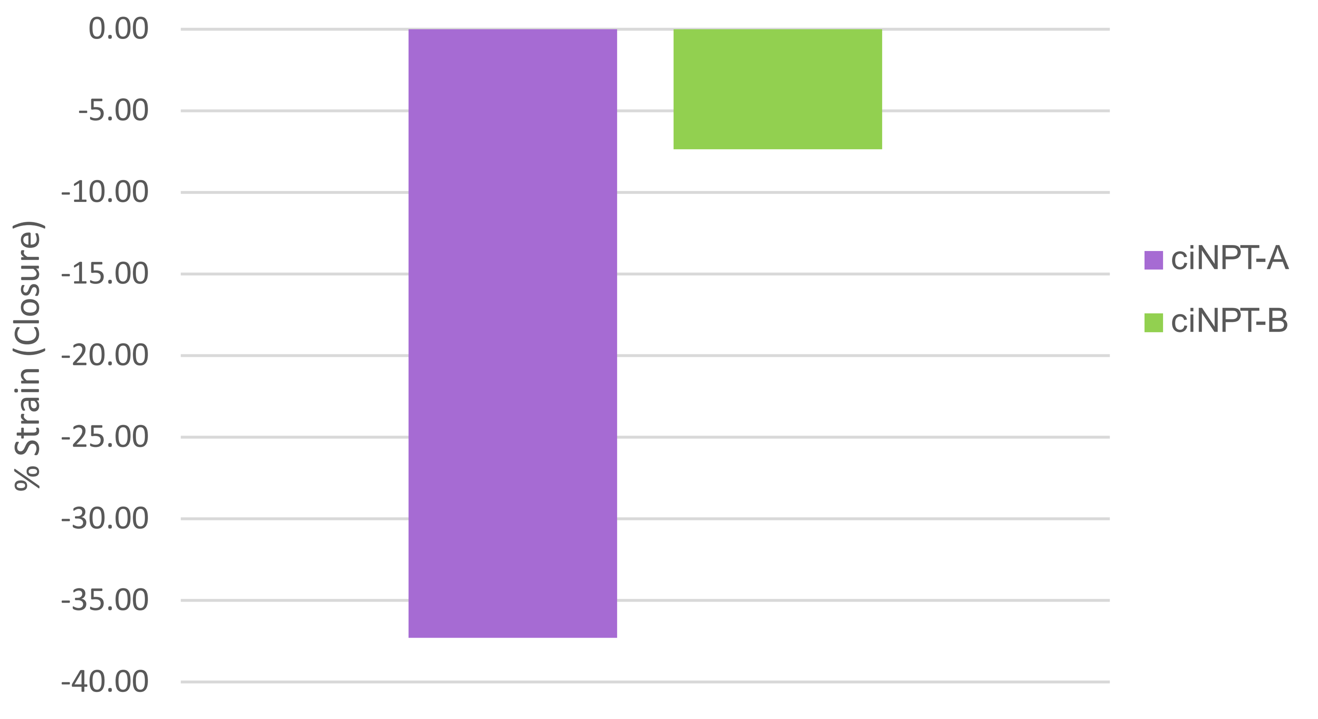

Figure 7. Mean incisional width strain (closure)

Results (Cont'd)

When comparing device operational sound level, ciNPT-A achieved a lower sound power level of 18.0 dB[A] (± 2.2 dB[A]) when compared to 27.6 dB[A] (± 3.6 dB[A]) for ciNPT-B ($p < 0.05$) (**Figure 8**). For perspective, a 10 dB increase can be perceived as a doubling in loudness by the human ear.

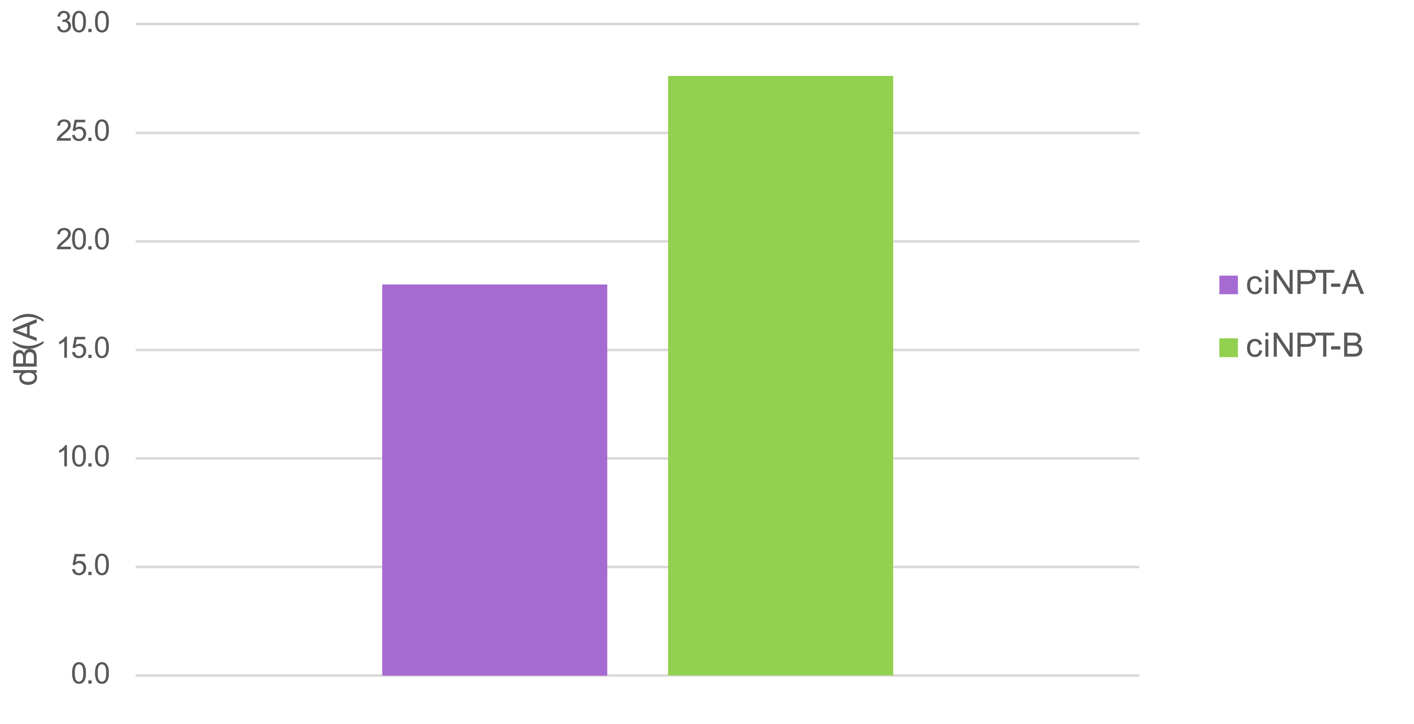

Figure 8. Mean sound power results

Conclusions

ciNPT systems are not equivalent in performance. Under these test conditions, ciNPT-A applied greater force and achieved greater percent closure when applied to simulated incision models. This may indicate greater potential for ciNPT-A to reduce lateral incisional tension and increase appositional strength of closed incisions when compared to ciNPT-B.

In addition, ciNPT-A also achieved lower device sound level when compared to ciNPT-B.

References

1. Riou JPA, Cohen JR, and Johnson HJ. *Am J Surg* 1992; 163:324-330.
2. Abbas SM and Hill AG. *ANZ J Surg* 2009; 79:247-250.
3. Wilson JA and Clark JJ. *Adv Skin Wound Care* 2004; 17(8): 428-435.
4. Wilkes RP, Kilpadi DV, Zhao Y, Kazala R, and McNulty A. *Surg Innov* 2012 Mar; 19(1): 67-75.

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NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

*3M™ Prevena™ Plus 125 Therapy Unit and 3M™ Prevena™ Peel & Place ™ Dressing (Solventum Corporation, Maplewood, MN); †Avance® Solo Therapy Unit and Avance® Solo Dressing (Mölnlycke Health Care, Göteborg, Sweden); §3M™ V.A.C.® Drape (Solventum Corporation, Maplewood, MN)

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