EFFECTS OF DYNAMIC PRESSURE ON THE GRANULATION RESPONSE IN A PORCINE EVALUATION OF NEGATIVE PRESSURE WOUND THERAPY WITH INSTILLATION AND DWELL

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Background

Negative pressure wound therapy (NPWT; V.A.C.® Therapy*) with instillation and dwell (NPWTi-d; Veraflo Therapy†) automatically cycles between 3 phases of therapy (instillation, soak, and NPWT; **Figure 1**) to create an environment that promotes healing by cleaning wounds while delivering NPWT. An earlier preclinical study compared continuous, intermittent, and dynamic negative pressure modes of traditional NPWT (as illustrated in **Figure 2**) to NPWTi-d.[1] The published work discussed NPWTi-d utilizing commercially available continuous NPWT phase (NPWTi-d-CONT) but excluded a form of NPWTi-d utilizing a dynamic NPWT phase (NPWTi-d-DPC‡). NPWTi-d-DPC is now commercially available and the experimental data from this group is being disclosed for the first time.

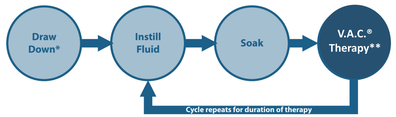

Figure 1. Phases of Veraflo Therapy (NPWTi-d; (A) 3M™ Seal Check™ Leak Detector; (B) Continuous and Dynamic Pressure Control Therapy negative pressure modes are available during the V.A.C.® Therapy phase of Veraflo Therapy).

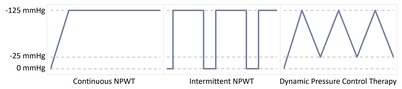

Figure 2. Illustrations of negative pressure profiles of Continuous, Intermittent, and Dynamic Pressure Control Therapy modes of V.A.C.® Therapy.

Purpose

The purpose of this study was to evaluate the granulation response of NPWTi-d-DPC, compared to other NPWT and NPWTi-d modes, in a porcine wound model.

Methods

All animal procedures were performed under a protocol approved by IACUC at the test facility. As described in detail in a previous publication,[1] a total of 10 full-thickness excisional wounds (5 contralateral pairs) were created on 5 domestic swine. Wounds were randomly assigned to one of 5 treatment groups, and dressings were applied and therapy modes set accordingly (**Table 1**). Dressings were changed on days 2 and 5. Animals were euthanized on day 7, and wound tissue was excised en bloc, formalin fixed, and processed for hematoxylin and eosin histology.

Methods (Cont'd)

Table 1. Treatment groups, dressings, and therapy settings

Treatment Group	Dressing	V.A.C.® Therapy Phase Settings	Veraflo Therapy Settings (Instillation Only)
V.A.C.® Therapy – Continuous Pressure (NPWT-CONT)	Granufoam§ Dressing	Mode: Continuous NPWT Setting: -125 mmHg	n/a
V.A.C.® Therapy – Intermittent Pressure (NPWT-INT)	Granufoam Dressing	Mode: Intermittent NPWT Setting: 5 min at -125 mmHg 2 min at 0 mmHg	n/a
V.A.C.® Therapy – Dynamic Pressure Control Therapy (NPWT-DPC)	Granufoam Dressing	Mode: Dynamic Pressure Control Therapy Setting: 3 min rise to -125 mmHg 3 min fall to -25 mmHg	n/a
Veraflo Therapy with Continuous Pressure (NPWTi-d-CONT)	V.A.C.® Veraflo Dressing¶	Mode: Continuous NPWT Setting: -125 mmHg	NPWT Time: 2.5 hr Soak Time: 5 min Instillation Solution: normal saline
Veraflo Therapy with Dynamic Pressure Control Therapy negative pressure mode (NPWTi-d-DPC)	V.A.C.® Veraflo Dressing	Mode: Dynamic Pressure Control Therapy Setting: 3 min rise to -125 mmHg 3 min fall to -25 mmHg	NPWT Time: 2.5 hr Soak Time: 5 min Instillation Solution: normal saline

Results

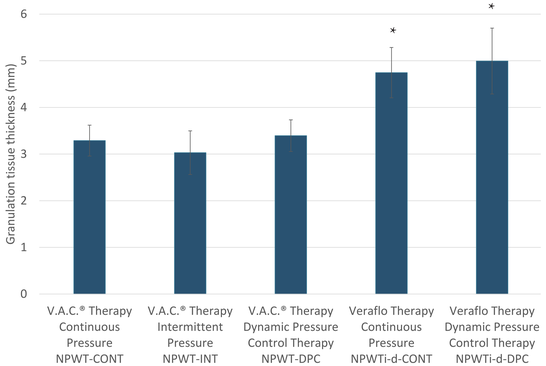

Figure 3. Graphical representation of granulation tissue thickness at day 7. (* $p < 0.05$ compared to NPWT-CONT, NPWT-INT, and NPWT-DPC)

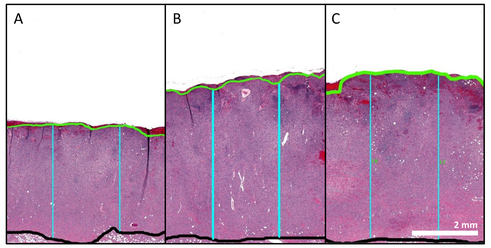

Figure 4. Representative photomicrographs of granulation tissue thickness at 7 days. (A) V.A.C.® Therapy - Continuous Pressure (NPWT-CONT); (B) Veraflo Therapy - Continuous Pressure (NPWTi-d-CONT); (C) Veraflo Therapy - Dynamic Pressure Control Therapy (NPWTi-d-DPC). Black contour indicates the base of the wound. Green contour indicates surface of granulation tissue. Blue lines indicate granulation tissue thickness measurements taken at 2 mm increments across the surface of the wound. Scale bar = 2 mm.

Results (Cont'd)

As published previously, there was no statistically significant difference in the average granulation tissue thickness between continuous (3.29 ± 0.33 mm), intermittent (3.03 ± 0.47 mm), and dynamic (3.40 ± 0.33 mm) NPWT groups; however, the average granulation tissue thickness in NPWTi-d-CONT treated wounds (4.75 ± 0.54 mm) was significantly greater than each traditional NPWT group ($p < 0.05$). Similarly, the average granulation tissue thickness of NPWTi-d-DPC treated wounds (4.99 mm ± 0.71 mm) was also significantly greater than each NPWT group ($p < 0.05$) but was not statistically greater than NPWTi-d-CONT (**Figures 3** and **4**).

Conclusions

Previous preclinical studies have suggested that Veraflo Therapy with saline utilizing continuous negative pressure exhibits faster granulation rates than V.A.C.® Therapy[1-3]. Only recently has Veraflo Therapy become commercially available with Dynamic Pressure Control Therapy, and these data suggest this increased granulation response is characteristic of this therapy mode as well. Veraflo Therapy allows for controlled delivery and removal of topical solutions to help loosen soluble debris and exudate while providing NPWT. Novel dressing configurations (V.A.C.® Veraflo Cleanse Choice Dressing# & Veraflo Cleanse Choice Complete Dressing^) in conjunction with Veraflo Therapy were recently cleared by the FDA to provide hydromechanical removal of infectious materials, non-viable tissue, and wound debris, reducing the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing. Further investigations are needed to determine whether hydromechanical cleansing and granulation with the novel dressing can be further enhanced by using a dynamic pressure mode with Veraflo Therapy.

References

1. Lessing MC, James RB, Ingram SC. Eplasty. 2013 Oct 1;13:e51.
2. Lessing MC, et al. Wounds. 2011 Oct; 23(10):309-19.
3. Leung BK, et al. Wounds. 2010 Jul 1; 22(7):179:87.

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*3M™ V.A.C.® Therapy, †3M™ Veraflo™ Therapy, ‡3M™ Dynamic Pressure Control™ Therapy, §3M™ V.A.C.® Granufoam™ Dressing, ¶3M™ V.A.C.® Veraflo™ Dressing, #3M™ V.A.C.® Veraflo Cleanse Choice™ Dressing, ^3M™ Veraflo™ Cleanse Choice Complete™ Dressing

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