Incidence of Blockage Alarms when Dressing Connector Orifices are Blocked: Comparison of Negative Pressure Wound Therapy Systems

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Introduction

- There is an ongoing need to understand the differences among various negative pressure wound therapy (NPWT) offerings in the market space.
- Some NPWT system design elements may inappropriately preclude the triggering of blockage alarms, particularly if the NPWT systems do not have wound pressure-regulating technology (PRT*).
- Blockage alarms are important in notifying the user when prescribed NPWT is not being delivered.

Purpose

- The objective of these two laboratory studies was to evaluate the ability of NPWT brands with and without PRT to trigger blockage alarms when orifices in dressing connectors were blocked.

Methods

- Study 1
  - Three units of each 3 NPWT systems with PRT (NPWT-A†, NPWT-B‡, and NPWT-C§; set at -125 mmHg; see **Figures 1-3**) and 1 NPWT system without PRT (NPWT-D**; set at -120 mmHg; see **Figure 4**) were each tested with 3 respective dressings (n=9 runs/group).
  - Testing was conducted without head height (the simulated wound with dressings and associated therapy units were level, that is, with no vertical distance between them).
- Study 2
  - Three units each of 4 NPWT systems with PRT (NPWT-A, NPWT-B, NPWT-C, NPWT-E††; see **Figures 1-3 and 5**) and 2 NPWT systems without PRT (NPWT-F‡‡, NPWT-G§§; see **Figures 6 and 7**) were each tested with 3 respective dressings (n=9 runs/group) at a setting of -125 mmHg.
  - Testing was conducted without head height.

Figure 1. NPWT-A

Figure 2. NPWT-B

Figure 3. NPWT-C

Figure 4. NPWT-D

Figure 5. NPWT-E

Figure 6. NPWT-F

Figure 7. NPWT-G

Methods (Cont.)

- The therapy units were connected to their respective dressings and pressure was monitored independently at the dressing and the canister (see **Figure 8**) under the following 3 conditions:
  - No induced blockages
  - Blockage induced in tubing near the canister (location 2)
  - Blockage induced at dressing connector orifice (location 1)
- Dressing pressures and pressures near the canister were measured for 10 minutes or until the unit had a blockage alarm, whichever occurred earlier.
- Fisher Exact test was used to statistically analyzed blockage alarm incidences and a Wilcoxon Signed Rank test was used to analyze differences from target negative pressure (NP).

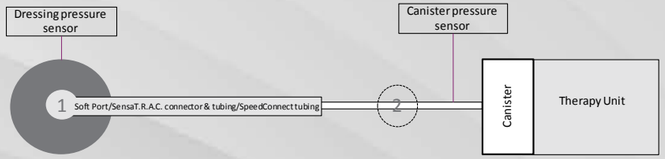

Figure 8. Experimental set-up

Results

- Study 1
  - When there was a blockage at the dressing, NPWT systems with PRT (NPWT-A, NPWT-B, NPWT-C) had blockage alarms in all 9 runs, while NPWT-D (which did not have PRT) did not have any blockage alarms (p<0.0001; **Table 1**).
  - When no blockages were present, no alarms were triggered in any of the groups.
  - Blockages were confirmed by pressure measurements at the dressing.
  - When blockages at either site were present:
    - Canister NPs associated with NPWT systems with PRT were greater than set NP, as a result of the PRT attempting to resolve low wound/dressing NP.
    - Canister NPs associated with NPWT systems without PRT were the same as set NP even when wound/dressing NP were ~0 mmHg.

Table 1. Study 1: blockage alarm incidence and measured negative pressures

Location		NPWT-A			NPWT-B			NPWT-C			NPWT-D		
1	2	Blockage Alarm (Time to alarm, s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm, s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm, s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm, s)	Dressing NP	Canister NP
○	○	0/9 (N/A)	-121.6 ± 0.4	-121.7 ± 0.4	0/9 (N/A)	-126.1 ± 0.3	-126.4 ±0.2	0/9 (N/A)	-119.9 ± 0.3	-120.3 ± 0.4	0/9 (N/A)	-123.7 ± 0.6	-124.8 ± 0.6
○	●	9/9 (106 ± 4)	-7.2 ± 2.8	-205.6 ± 39	9/9 (96 ± 4)	-7.4 ± 1.7	-217.8 ± 4.1	9/9 (90 ± 6)	-6.3 ± 1.1	-202.3 ± 5.1	9/9 (141 ± 3)	-5.4 ± 1.8	-124.9 ± 0.9
●	○	9/9 (88 ± 4)	-0.6 ± 0.2	-192.9 ± 5.3	9/9 (101 ± 3)	-1.1 ± 0.4	-195.6 ±10.0	9/9 (108 ± 5)	-0.7 ± 0.3	-170.1 ± 9.2	0/9 (N/A)	-0.3 ± 0.1	-120.8 ± 1.0

NP= negative pressure, mmHg; N/A= not applicable

Results (Cont.)

- Study 2
  - When there was a blockage at the dressing or canister, NPWT systems with PRT (NPWT-A, NPWT-B, NPWT-C, NPWT-E) had blockage alarms in all 9 runs, while NPWT-F and NPWT-G (which did not have PRT) did not have any blockage alarms (p<0.0001; **Table 2**)
  - When no blockages were present, no alarms were triggered in any of the groups.
  - Blockages were confirmed by pressure measurements at the dressing.
  - When blockages at either sites were present:
    - Canister NPs associated with NPWT systems with PRT were greater than set NP, as a result of the PRT attempting to resolve low wound/dressing NP.
    - Canister NPs associated with NPWT systems without PRT were the same as set NP even when wound/dressing NP were ~0 mmHg.

Table 2. Study 2: blockage alarm incidence and measured negative pressures

Location		NPWT-A			NPWT-B			NPWT-C			NPWT-E			NPWT-F			NPWT-G		
1	2	Blockage Alarm (Time to alarm,s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm,s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm,s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm,s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm,s)	Dressing NP	Canister NP	Blockage Alarm (Time to alarm,s)	Dressing NP	Canister NP
○	○	0/9 (N/A)	-128.9 ± 0.8	-129.3 ± 0.8	0/9 (N/A)	-126.1 ± 0.3	-126.7 ± 0.3	0/9 (N/A)	-120.1 ± 0.3	-120.9 ± 0.4	0/9 (N/A)	-123.0 ± 0.1	-123.0 ± 0.1	0/9 (N/A)	-123.7 ± 0.1	-123.7 ± 0.1	0/9 (N/A)	-123.8 ± 0.2	-123.8 ± 0.2
○	●	9/9 (94 ± 6)	-7.1 ± 1.2	-221.5 ±3.8	9/9 (86 ± 7)	-6.9 ± 1.8	-218.5 ± 6.0	9/9 (62 ± 5)	-5.9 ± 1.1	-207.5 ± 9.2	9/9 (89 ±2)	-11.4 ± 1.1	-191.2 ± 1.8	0/9 (N/A)	-12.0 ± 2.1	-123.8 ± 0.1	0/9 (N/A)	-12.8 ± 2.1	-124.1 ± 0.1
●	○	9/9 (99 ± 1)	-0.3 ± 0.0	-219.7 ± 7.2	9/9 (94 ± 4)	-0.5 ± 0.2	-208.1 ±4.6	9/9 (127 ± 5)	-0.2 ±0.0	-197.0 ± 8.8	9/9 (183 ± 3)	-0.6 ± 0.1	-202.2 ± 1.7	0/9 (N/A)	-0.2 ± 0.0	-124.2 ± 0.1	0/9 (N/A)	-0.2 ± 0.0	-124.4 ± 0.1

NP= negative pressure, mmHg; N/A= not applicable

Discussion

Blockage alarms are important in alerting the user to a potential interruption in therapy. Additional studies are needed to evaluate if prolonged interruption in delivery of prescribed NP could result in increased maceration[3] and infection[4] risks. NPWT systems with PRT had blockage alarms consistently when the dressing connector orifice was blocked, while NPWT systems without PRT (NPWT-D, NWT-F, and NPWT-G) did not even when there was an obvious blockage near the canister. Thus, different NPWT systems are not necessarily equivalent.

References

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***SensaT.R.A.C.™ Technology, †ACTIV.A.C.™ Therapy System, ‡INFOV.A.C.™ Therapy System, §V.A.C.ULTA™ Therapy System, ††V.A.C.VIA™ Negative Pressure Wound Therapy System with V.A.C. GRANUFOAM™ Dressings (KCI, an ACELITY Company, San Antonio, TX); **RENASYS™ TOUCH with Soft Port and RENAYSYS-F Foam Dressings(Smith and Nephew, plc, London UK); ‡‡NPWT PRO, §§NPWT PRO to GO with SpeedConnect™ Tubing Set and NPWT Black Foam Dressings (Cardinal Health™, Waukegan, IL)**