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Use of a Double-Lumen NPWT System With Innovative Technology Outperforms a Single-Lumen NPWT System in Accurate Delivery of Negative Pressure and Superior Fluid Removal

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Use of a Double-Lumen NPWT System With Innovative Technology Outperforms a Single-Lumen NPWT System in Accurate Delivery of Negative Pressure and Superior Fluid Removal

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Abstract

Negative pressure wound therapy (NPWT) requires 3 fundamental requirements for optimal patient safety and wound outcomes; these fundamentals include (A) accurate delivery of the set level of negative pressure to the wound bed; (B) creation of a pressure gradient between the wound bed and the waste canister to efficiently remove fluid and prevent stagnation in the tubing; and (C) maintenance of a sealed wound environment. Not all commercially available NPWT systems are designed to meet these fundamental requirements. The objective of this study was to determine the ability of 2 NPWT systems—System A (Invia Liberty; Medela AG) and System B (RENASYS TOUCH; Smith+Nephew)—to deliver a set level of negative pressure when the device was positioned at different heights in relation to the wound bed and during a simulated fluid bolus. System A is a double-lumen NPWT system with an electronically controlled feedback technology (Intelligent Pressure Control and Dynamic Exudate Removal); System B is a single-lumen system that functions through use of a controlled air leak. Regardless of device position in relation to the wound model, System A outperformed System B in its ability to dynamically respond to the sudden change in exudate volume and rapidly return to consistent delivery of the set level of negative pressure to the wound bed.

Keywords: electronically controlled feedback technology, pressure control, exudate removal, negative pressure wound therapy

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Negative pressure wound therapy has evolved from use of closed suction wall drainage systems to specific commercially available devices designed to provide a set level of negative pressure to a wound.[1-3] This evolution occurred due to the improved healing seen with application of subatmospheric pressure and removal of fluid from wounds. Negative pressure wound therapy enhances healing through 6 proposed mechanisms of action (MOA): (1) promotion of wound bed perfusion, (2) macrodeformation resulting in wound contracture, (3) microdeformation promoting granulation tissue formation, (4) fluid removal, (5) removal of potentially infectious material, and (6) creation of a moist wound environment (**Figure 1**).[1-3] Optimization of these MOA can vary depending on how NPWT systems are designed to deliver negative pressure and manage changes in wound exudate volume and viscosity.[1]

There are certain fundamental device requirements that must be met in order to maximize delivery of the MOA: (A) accurate delivery of the set level of negative pressure to the wound bed; (B) creation of a pressure gradient between the wound bed and the waste canister to efficiently remove fluid and prevent stagnation in the tubing; and (C) maintenance of a sealed wound environment.[4,5] An international consensus review on NPWT set forth by the European Wound Management Association (EWMA) assessed published findings of NPWT in wound care and further

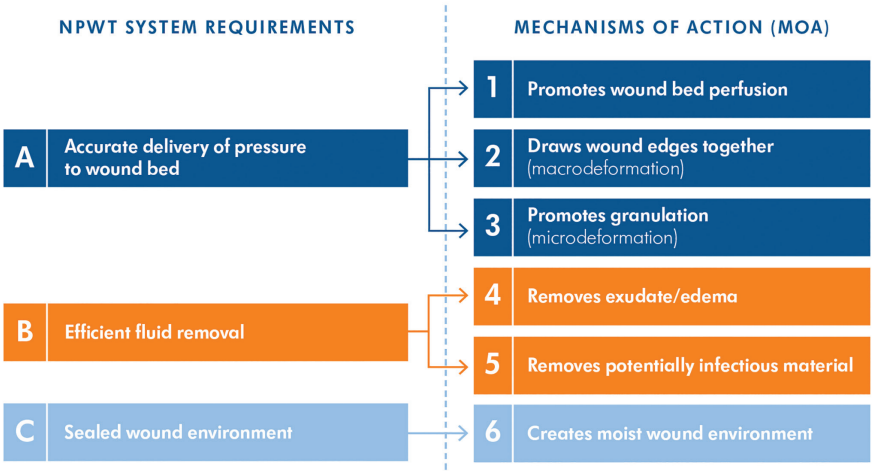

FIGURE 1. Fundamental requirements and MOA of negative pressure wound therapy (NPWT).

established that NPWT systems containing an electronically controlled feedback system to maintain set pressure to the wound bed provide the standard of care and enhance patient safety.[1] Not all systems commercially available today have the technical ability to deliver these fundamentals. Failure to deliver the fundamentals can lead to reduced outcome measures and an inability to reach the full therapeutic benefits of the therapy. Inconsistent delivery of the prescribed level of negative pressure—failure to meet Fundamental A—could result in delayed healing due to altered effects on perfusion, granulation tissue formation, and wound contraction.[6,7] Inability to maintain a pressure gradient between the wound bed and the pump results in inefficient fluid removal from the wound bed and tubing, a failure of Fundamental B. The combined effects of inconsistent pressure delivery and inefficient fluid removal can lead to stagnation of exudate on the wound and periwound skin and impede healing. Exudate from chronic, nonhealing wounds contains a higher concentration of pro-inflammatory cytokines and matrix metalloproteases (MMPs) and a lower concentration of growth factors and mitogenic activity, which adversely affect healing, and pooling of fluid can result in periwound maceration.[8-13] Systems with a continuous air leak inherently create steady airflow throughout the NPWT system and across the wound bed, which may have an adverse effect on maintaining a sealed, moist wound environment, failing to meet the requirements of Fundamental C.[14]

The majority of commercially available NPWT systems work through placement of a filler to the wound bed that is secured with an adhesive film and connected to a pump via tubing for application of negative pressure and removal of fluid from the wound bed. The tubing used can either be single or multilumen. Single-lumen NPWT systems rely on tubing with

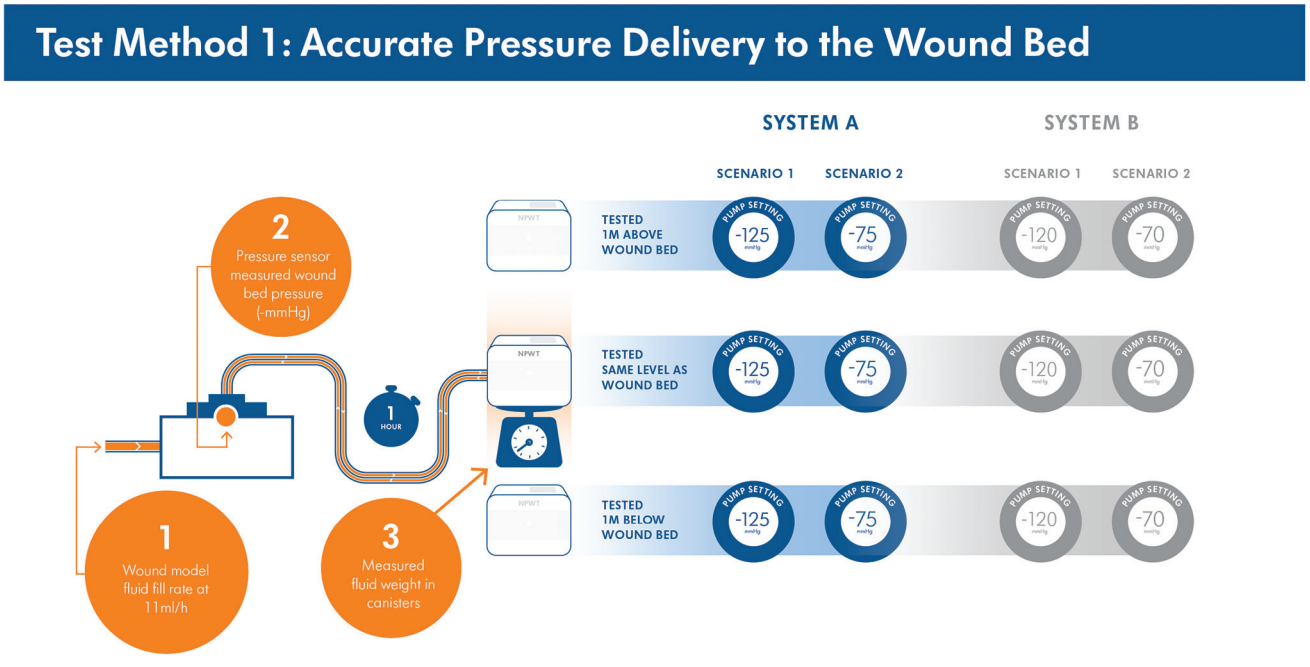

FIGURE 2. Test method 1 for System A and System B.

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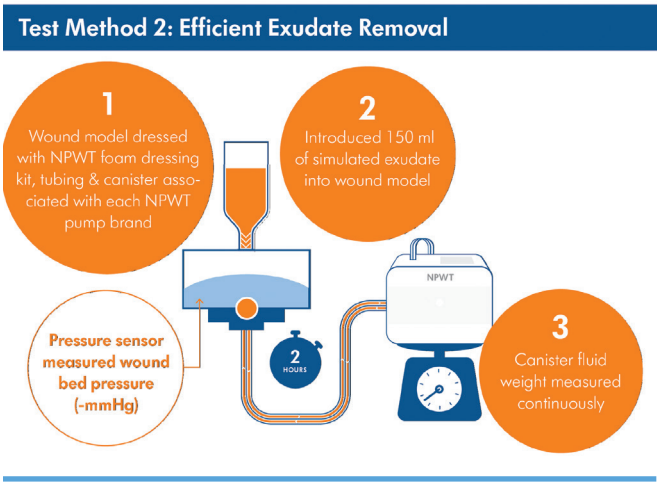


FIGURE 3. Test method 2 for System A and System B.
Abbreviation: NPWT, negative pressure wound therapy

a single-lumen that is responsible for concurrent delivery of negative pressure and removal of fluid from the wound bed. Maintenance of pressure is done through use of a controlled air leak. A continuous controlled air leak may be necessary to prevent pooling when there are changes in wound exudate volume and/or viscosity or device position in relation to the wound, resulting in a steady flow of air over the wound bed.[7] By design, single-lumen systems with a controlled air leak struggle to meet the fundamental requirements, because they are challenged to maintain a sealed, moist wound environment while also maintaining the pressure gradient required for accurate pressure delivery and fluid removal.

Negative pressure wound therapy systems with multilumen tubing that communicate directly with the pump (without controlled air leaks) isolate the functions of delivery of negative pressure and fluid removal to a respective tube, an example being a double-lumen tubing system in which the "control lumen" is responsible for delivery of negative pressure to the wound bed and the "removal lumen" is responsible for exudate removal. Multilumen NPWT systems generate a pressure gradient through use of static or dynamic airflow cycles. Airflow cycles provide a positive airflow into the control lumen(s) to maintain set pressure at the wound bed and create a pressure gradient for fluid to be removed from the wound into the canister.[7,14] Multilumen systems with an electronically controlled feedback technology containing dynamic airflow cycles have been shown to remove fluid and return to delivery of the set level of negative pressure more promptly and efficiently than NPWT systems with static airflow cycles.[7,14]

The objective of this investigation was to use a simulated wound model to compare the ability of 2 NPWT systems—System A (Invia Liberty; Medela AG) and System B (RENASYS TOUCH; Smith+Nephew)—to meet the NPWT fundamental requirements to (1) deliver set levels of NPWT to the wound bed and (2) simultaneously remove a simulated increase in wound exudate. System A is a double-lumen tubing NPWT system with an electronically controlled feedback technology (Intelligent Pressure Control and Dynamic Exudate Removal; Medela AG). System B is a single-lumen system that contains a controlled air leak.

Methods

The respective reticulated black foam dressing kits, tubing, and canisters associated with each NPWT system were utilized in the experiment. Each testing method was performed after the wound dressing was applied and therapy was initiated and allowed to reach a steady state (~10 minutes). The pressure sensors on each device confirmed when the set level of negative pressure had been reached. Testing was conducted at an independent third-party laboratory using a test protocol designed by Medela AG.

Test method 1: accurate pressure delivery to the wound bed

The method for Test 1 was performed to assess the ability of each NPWT system to accurately deliver the set negative pressure (mm Hg) at 3 different heights in relation to the wound bed (1 meter above, same level, and 1 meter below) while simultaneously removing exudate. The test was performed at –125 mm Hg and –75 mm Hg for System A and –120 mm Hg and –70 mm Hg for System B. The negative pressure settings used for System B were the closest pressure settings available on this device to the standardized settings on System A (**Figure 2**). The test method was repeated 3 times for each NPWT system at each pressure setting.

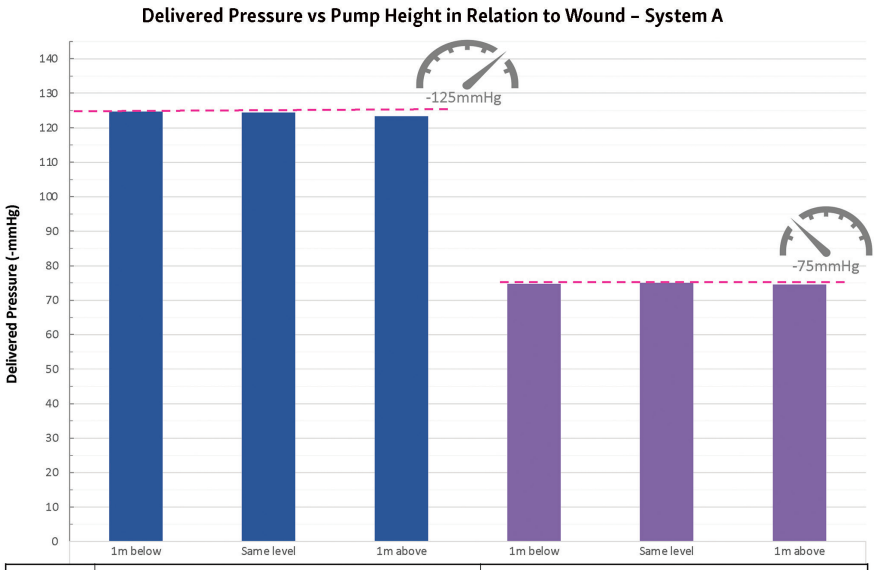
Test method 2: efficient exudate removal

The method for Test 2 was performed to assess the ability of each NPWT system to remove fluid after a sudden introduction of 150 mL of simulated wound exudate in the wound bed and determine the ability of each NPWT system to maintain the set level of negative pressure at the wound bed. The amount of simulated wound fluid removed and the pressure at the wound bed were simultaneously measured for the duration of approximately 2 hours (125 minutes). Negative pressure levels were set at –125 mm Hg for System A and –120 mm Hg for System B. The device was kept at the same level as the wound model and repeated 3 times per system (**Figure 3**).

Results

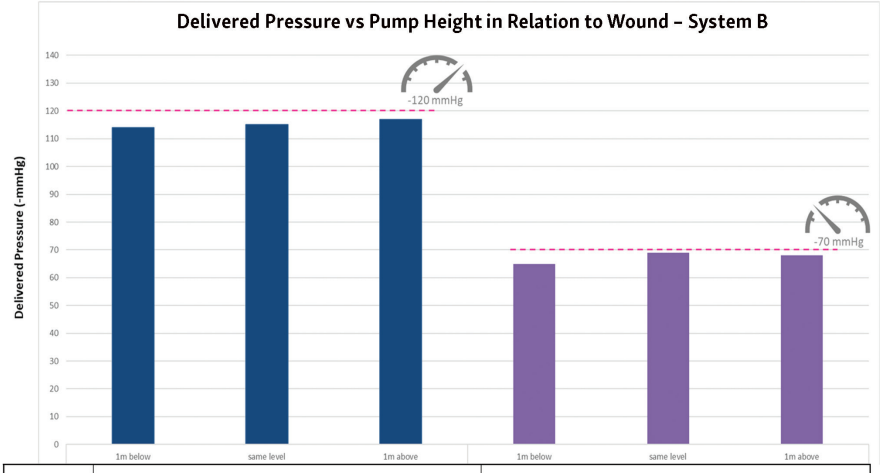
Test method 1: accurate pressure delivery to the wound bed

System A accurately and precisely delivered the set level of negative pressure to the wound model regardless of the device



	-125mmHg			-75mmHg		
	1m below	same level	1m above	1m below	same level	1m above
System A	124.7	124.4	123.3	74.7	75.0	74.5

FIGURE 4. Test method 1: delivered pressure vs pump height in relation to the wound for System A.



	-125mmHg			-75mmHg		
	1m below	same level	1m above	1m below	same level	1m above
System B	114.0	115.0	117.0	65.0	69.0	68.0

FIGURE 5. Test method 1: delivered pressure vs pump height in relation to the wound for System B.

position. System B maintained relative set pressure at the heights in the experiment. The performance of System B was least effective when the device was set at –120 mm Hg and 1 meter below the wound model. In contrast, due to the double-lumen tubing and addition of an electronically controlled feedback technology, System A maintained set pressure within 0.6 mm Hg when placed 1 meter above the wound, meeting the standard of care as defined by EWMA (**Figure 4, Figure 5**).

Test method 2: efficient exudate removal

System A removed simulated wound fluid more efficiently than System B, evacuating 89% of the fluid from the simulated bolus at the wound site into the canister and re-establishing and maintaining the set pressure of –125 mm Hg in under 20 minutes after introduction of the fluid bolus (~10 minutes). Immediately after adding the 150 mL bolus of simulated wound fluid, System A had a consistent elevation of pressure at the wound site that was within ± 10% of the set pressure. After fluid removal occurred (< 20 minutes), System A returned to a patent system and maintained the set pressure (–125 mm Hg) for the remaining duration of the test (95 minutes) (**Figure 6, Figure 7**).

System B failed to remove more than 10 mL of simulated wound exudate throughout the 125-minute experiment and showed negative pressure readings at the wound bed consistently fluctuated greater than 10 mm Hg above the set pressure level for greater than 70 minutes of the testing period. This finding demonstrates the inability of System B to maintain the set pressure or remove more than 6% of the 150 mL fluid bolus (**Figure 8, Figure 9**).

Discussion

The results from this investigation confirm the double-lumen NPWT system that contains an electronically controlled feedback technology with dynamic airflow cycles (System A) provided superior fluid management and simultaneously maintained set pressure at the wound bed as compared with the single-lumen system (System B). System A was able to dynamically respond to the sudden change in exudate volume and rapidly return the system to patency, clearing the bolus challenge in order to consistently deliver the desired pressure at the wound bed. Negative pressure wound therapy can only deliver all 6 MOA needed for optimal wound healing when the system patency is restored and set pressure is consistently delivered.[1,7,14]

To maximize healing potential, NPWT systems must be able to deliver all 3 fundamental requirements: (A) accurate

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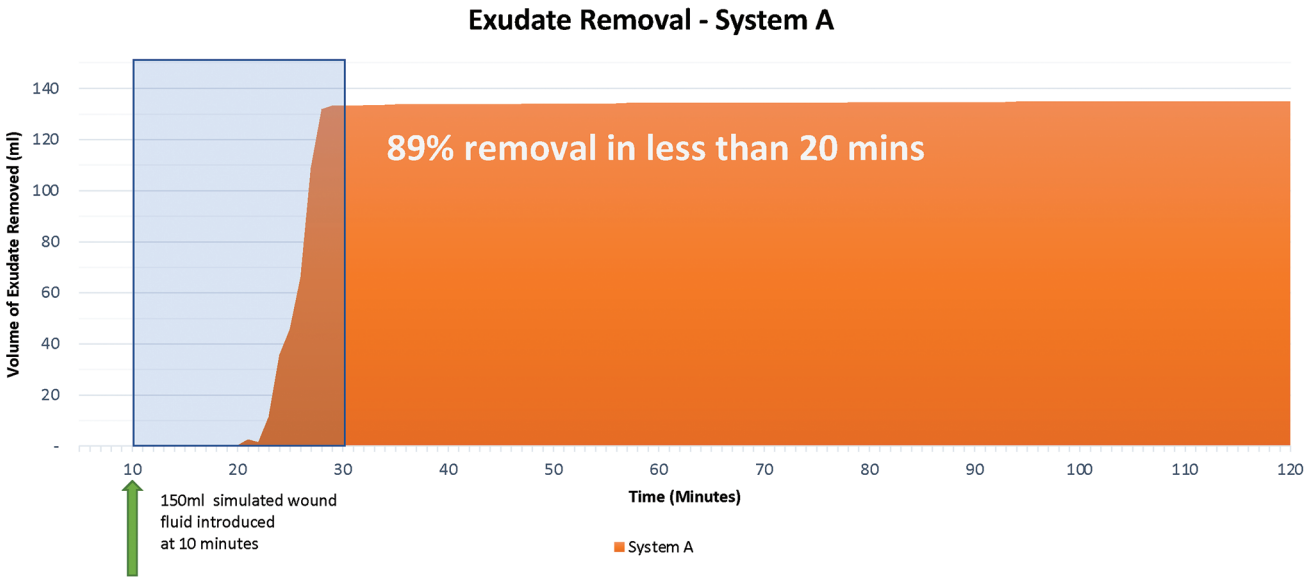

FIGURE 6. Results of test method 2: exudate removal rate for System A.

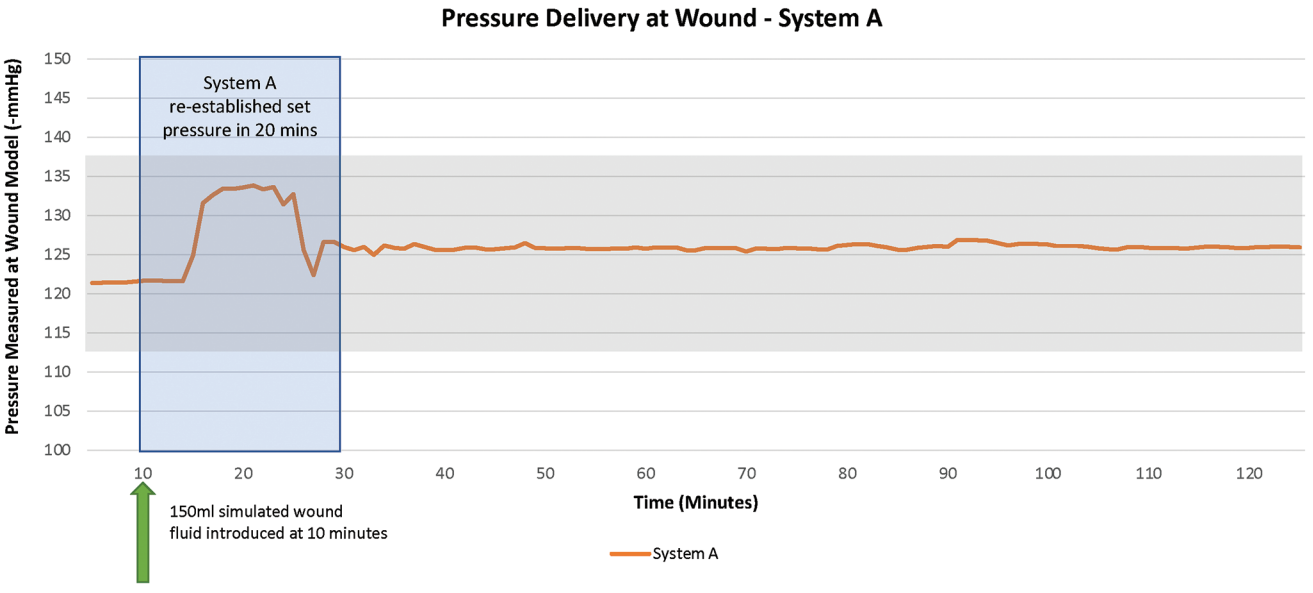

FIGURE 7. Results of test method 2: pressure delivery System A.

delivery of the set level of negative pressure to the wound bed; (B) creation of a pressure gradient between the wound bed and the waste canister to efficiently remove fluid and prevent pooling on the wound bed and stagnation of fluid in the tubing; and (C) maintenance of a sealed wound environment.[4,5] Negative pressure wound therapy systems that do not provide all 3 fundamental requirements could negatively impact the proposed MOA of NPWT and impede healing.[1] The inability to accurately deliver pressure to the wound bed (Fundamental A) may reduce the positive effects of macro- and microdeformation on the wound bed as well as wound bed perfusion. The inability to create a pressure gradient (Fundamental B) and remove fluid efficiently and expeditiously from the wound bed can lead to fluid stagnation and blockages within the tubing, likely causing the device to alarm, malfunction, and fail to deliver NPWT and remove potentially infectious material from the wound bed.[15]

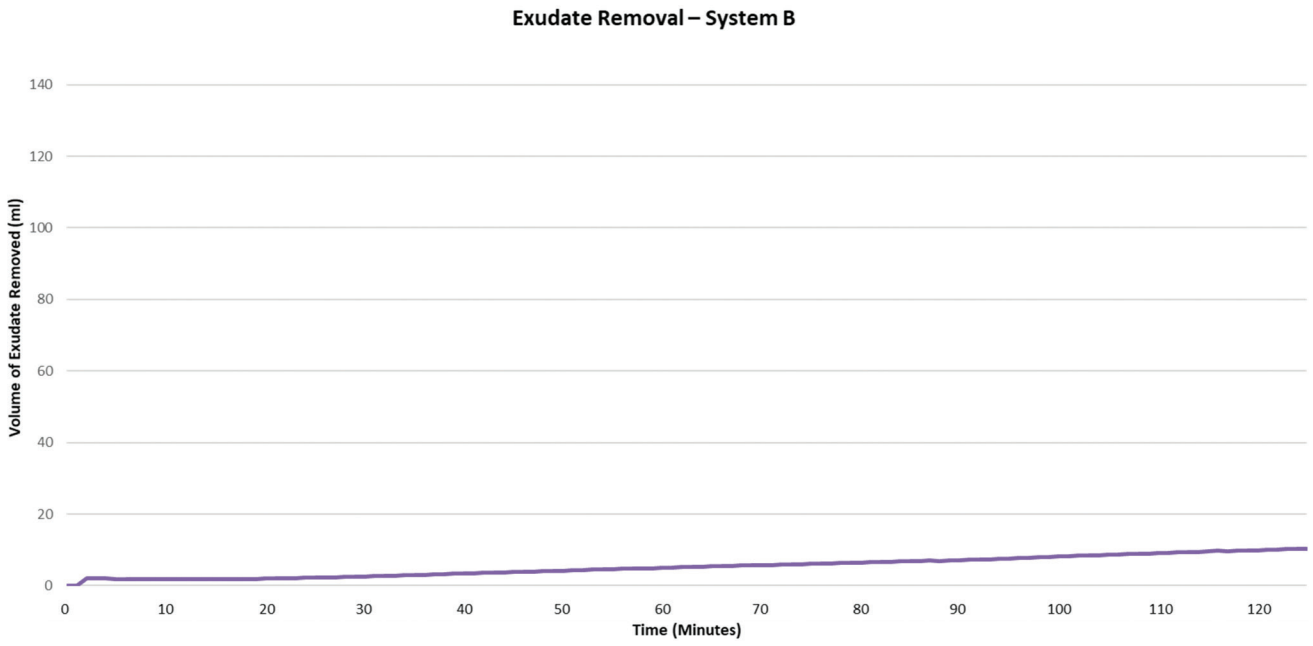

FIGURE 8. Results of test method 2: exudate removal rate for System B.

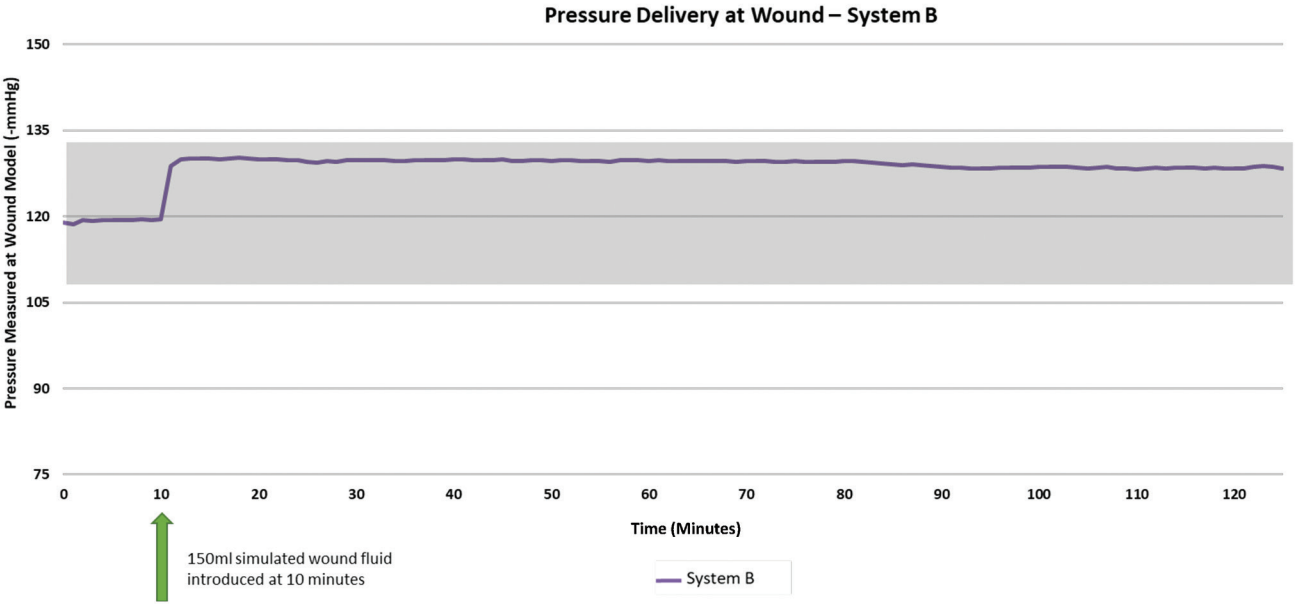

FIGURE 9. Results of test method 2: pressure delivery System B.

Exudate from nonhealing wounds has a high concentration of pro-inflammatory cytokines, proteinases, and MMP, which cause tissue damage, degradation of extracellular matrix components, lower concentration of growth factors, and inhibition of cellular proliferation and angiogenesis.[8-13] Increased presence of bacteria and neutrophils within the wound bed can also result in formation of a more viscous exudate, which can be more difficult to remove.[5] The detrimental effects of pooling exudate within the wound bed are further amplified by the increased potential for periwound maceration and damage and loss of NPWT dressing seal (ie, failure of Fundamental C).[5] Loss of this seal creates an additional force that the NPWT system must respond to, further complicating its ability to deliver the set level of negative pressure to the wound bed. Inability or loss of a system's ability to maintain

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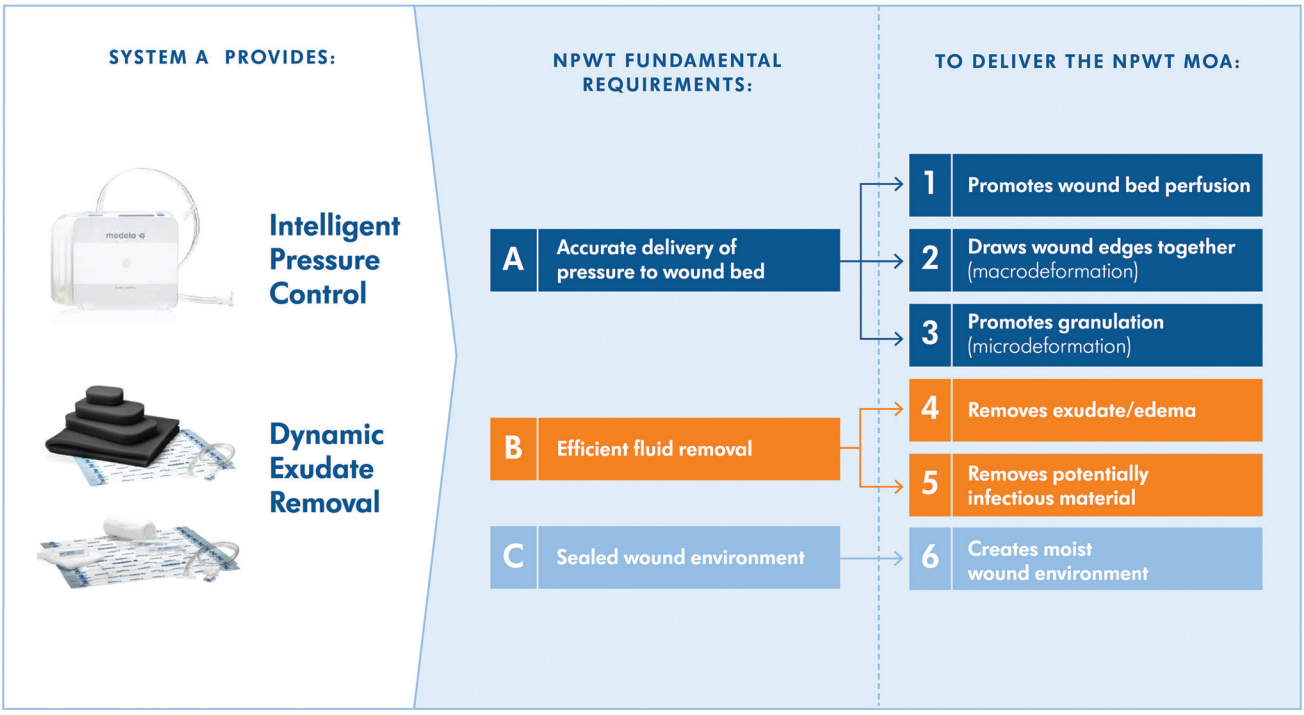

FIGURE 10. System A illustration.
Abbreviations: MOA, mechanism of action; NPWT, negative pressure wound therapy

delivery of a set level of negative pressure due to fluid stagnation and pooling can result in more frequent alarming and additional dressing changes. Depending on the time and setting in which failure of NPWT occurs (eg, during the night in the inpatient setting or when a patient is at home between outpatient or home health visits for dressing changes), these periods of time when exudate is pooling and NPWT is not being delivered could lead to additional complications. Wound worsening, infection, the need for further surgery, and graft loss, if applied, have been reported with unrecognized interruption of NPWT.[15]

Results of this study coincide with those seen in 2 previous studies[7,14] in which the same testing methods were performed for System A against 2 other NPWT systems—the first was a system with multilumen tubing and electronically controlled feedback technology with static airflow cycles (V.A.C. ULTA Therapy System; 3M)[14] and the other had dual-lumen tubing without an electronically controlled feedback technology (Cardinal CATALYST; Cardinal Healthcare).[7] Results from those 2 studies showed that System A (double-lumen tubing with an electronically controlled feedback technology) outperformed the other commercially available systems by providing prompt and efficient fluid removal and delivering consistent and accurate set levels of negative pressure to the wound bed. The electronically controlled feedback technology of System A—including Intelligent Pressure Control technology—meets the standard of care, ensuring reliable and accurate delivery of the prescribed pressure at the wound bed.[14] The Dynamic Exudate Removal technology senses changes in wound exudate volume and/or viscosity and automatically adjusts the rate of airflow cycles to optimize fluid removal and actively prevent blockages, exceeding the standard of care.[14]

Limitations

The primary limitation of this study is use of a simulated wound model to allow comparison between 2 NPWT systems. These outcomes may not be indicative of clinical performance. However, the testing methods were designed to determine the effects of common scenarios encountered, difficulty or malfunction of NPWT delivery due to position of the device in relation to the wound bed, and/or increased exudate levels often seen with changing patient conditions. The testing methods performed in this study were the same as those in previous studies.[7,14] The results of the current and 2 previous[7,14] studies demonstrate how a NPWT system with double-lumen tubing and an electronically controlled feedback technology meets the 3 fundamental requirements of NPWT. System A, an NPWT system with double-lumen tubing and an electronically controlled feedback technology outperforms other commercially available NPWT systems tested.

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Conclusions

Failure of a NPWT system to meet the 3 fundamental requirements of NPWT delivery can negatively impact the 6 proposed MOA in which NPWT promotes healing and potentially reduce the therapy's overall effectiveness.[5] Negative pressure wound therapy systems with elevated capabilities, like System A's electronically controlled feedback technology and double-lumen tubing (**Figure 10**) that can dynamically sense and respond to changing fluid volumes and viscosities, outperform other commercially available NPWT systems[7,14] and innovate the standard of care.

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