# End-users' assessment of prophylactic negative pressure wound therapy products

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**Brigid M Gillespie, Tracey Finigan, David Kerr, Gordon Lonie & Wendy Chaboyer**

## ABSTRACT

The use of negative pressure wound therapy (vacuum dressings) is increasing in surgical incisions where there is a high risk of dehiscence, seroma, and other wound healing complications. In response to the growing use of various vacuum dressings in the prophylactic treatment of surgical incisions, a product evaluation of three products was undertaken in a hospital in Queensland, Australia. In this evaluation, the three aspects of product usability were considered in a specified context of use: 1) effectiveness; 2) efficiency; and 3) satisfaction. The perspectives of the treating medical officers, nursing staff and patients were elicited. Prior to the commencement, a two-week product-specific education program was implemented. Fifteen patients were recruited, with five patients for each dressing product. The evaluation was completed in its entirety for 13/15 (86.6%) of the dressing products. The majority of surgeons and ward nurses, who used the negative pressure dressing products, recommended them. Overall, surgeons preferred the Prevena™ while nurses and patients preferenced the PICO™ product. The products evaluated here have individual features that make them appropriate to be used for certain incisional wounds. Product selection should be based on the type of surgery, the amount of wound ooze anticipated, and the level of risk associated with the incision. However, in the current economic climate, product cost will ultimately dictate product use.

*Keywords: Primary intention, vacuum therapy, stakeholder, surgical dressing, arthroplasty.*

## INTRODUCTION

Negative pressure wound therapy (NPWT), has been used to aid healing since it was first developed in the 1990s[1]. Direct application of NPWT treatment is based on a closed, sealed system that creates a vacuum (suction) to the wound surface. The wound is covered with an open-cell foam or gauze dressing and sealed with a transparent film connected by tubing to a vacuum pump that supplies either continuous or intermittent sub-atmospheric pressure. Standard negative pressure rates range between 50 and 125 mm Hg[2,3]. NPWT draws wounds closed by helping to remove interstitial fluid which contains inflammatory and potentially infectious exudates that impair healing. The precise way that NPWT promotes wound healing in surgical wounds is unclear; however, there is some limited evidence that suggests that NPWT increases perfusion of the local area and granulation tissue, thus reducing oedema, exudates and bacterial contamination[2]. NPWT is recommended for a diverse range of chronic lesions or difficult to heal wounds[2-4], and, more recently, for tenuous acute (surgical) incisions[5,6].

In response to the growing use of NPWT dressings in the prophylactic treatment of surgical incisions[6], an evaluation of three leading products was undertaken. These dressing products were assessed by end-users to identify product modifications and development for improvements. The results of the evaluation have been given as feedback to the manufacturers of NPWT devices.

## THE ROLE OF END-USERS IN MEDICAL PRODUCT DEVELOPMENT

There is growing demand for developers of medical devices to incorporate the assessment and requirements of end-users into their development processes[7,8]. Some of these demands have stemmed from the recognition that poor usability increases risks associated with medical devices[8,9]. Hence, this emphasis on patient safety has led to governmental and non-governmental bodies mandating more stringent requirements for product usability[8]. However, merely addressing the clinical needs of end-users will not guarantee success or prevent dissatisfaction or ad hoc modification of the product. Notwithstanding the imperative to maintain patient safety and optimise outcome, satisfying end-user needs must also include aspects of usability such as comfort, aesthetics, storage, portability, ease of use and learner training[8]. 'Usability' is defined in the International Organisation for Standardisation (ISO) 9241-11 as "the

extent to which a product can be used by specific users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"[10].

The value of end-user feedback in product development is acknowledged as a means of providing a better understanding of how products are developed and modified over time[9]. End-users play a vital role through providing feedback about their wants and needs, and such feedback needs to capture end-user product assessment. Other benefits of obtaining end-user assessment include improved compliance and health outcomes, and a higher level of end-user/patient satisfaction[9].

While the use of NPWT appears to be growing in some health care contexts, prior to its widespread introduction in the prophylactic management of surgical incisions, it is essential to glean the perspectives of the people who use these products. To this end, we invited end-users from three key stakeholder groups to give feedback on three single-use NPWT products manufactured by two leading companies. The results herein have been reported back to the medical device companies as a means of informing future development or modifications of these products.

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## PRODUCT EVALUATION METHODS

The goal of a product evaluation is to assess the usability of a medical device from the perspectives of end-users in order to provide practical feedback to a variety of audiences. An evaluation allows end-users to ascertain whether the product complies with industry standards in relation to its intended use, discover whether faults in the design or composition of materials are caused by accident, and compare products of a similar design and intended use[8]. In this evaluation, the three aspects of product usability (that is, effectiveness, efficiency, satisfaction) were considered in a specified context of use[10]. Effectiveness is concerned when the user is able to successfully complete a given task[9]. Efficiency may include the time taken to complete a task using the product. Satisfaction is gauged through using qualitative methods and may include aspects of comfort, aesthetics and functionality[7-9].

In this evaluation, effectiveness and efficiency[7,9] of three single-use NPWT products was considered in terms of the products' performance regarding assembly, application, wound appearance and the ability to assess the wound. The third aspect of usability, satisfaction, was considered through the qualitative feedback end-users provided based on their overall perceptions of product features and comfort when undertaking daily activities[7-9]. This evaluation was unique in that it sought to glean the perspectives of three heterogeneous consumer groups: the attending surgeon, nurse and surgical patient, all of whom had a vested interest in wound management. Table 1 shows the product specifications of the three NPWT products evaluated in relation to the indications for product use, cost, wound dressing and canister capacity, and battery life [Prevena™ (Kinetic Concepts Inc; (KCI), VAC VIA™ (KCI), and PICO™ (Smith & Nephew)].

This product evaluation was conducted in a 28-bed surgical ward of a large metropolitan hospital in southeast Queensland, Australia. From March 2012 through to October 2012, 15 patients undergoing elective primary hip or knee arthroplasty surgery consented to having one of three types of NPWT dressing products applied following skin closure in the operating room. Two wound product manufacturers provided samples of their NPWT dressing products. Prior to the commencement of the evaluation, a two-week product-specific education program, delivered by product representatives from KCI and Smith & Nephew, was undertaken for staff working in the operating room and the orthopaedic ward. The education sessions

*Table 1: Product specifications for each device*

| Product comparison | VAC VIA™ | Prevena™ | PICO™ |
|---|---|---|---|
| Manufacturer's recommendations for use | • Chronic<br>• Acute<br>• Traumatic<br>• Subacute<br>• Dehisced wounds<br>• Partial-thickness burns<br>• Ulcers (such as diabetic, pressure or venous insufficiency)<br>• Flaps and grafts | • Clean, closed incisions that continue to drain following sutured or stapled closure. | • Acute<br>• Flaps and grafts<br>• Incision sites<br>• Partial-thickness burns<br>• Subacute and dehisced wounds<br>• Traumatic<br>• Ulcers (such as diabetic or pressure) |
| Usual pressure settings | –75 mmHg to –125 mmHg | –125 mmHg | –80 mmHg |
| Usual therapy duration | 7 days | 2–7 days | 5 days |
| Therapy delivery mode | Continuous or dynamic pressure control | Continuous | Continuous |
| Cost of product | A$875 | A$395 | A$180 (excluding optional pouch) |
| Safety alarms | System fault, blockage, leakage, battery critical, therapy life exhausted | Air leak, battery critical, canister maximum capacity, system error alert, device life cycle expired | Air leak and battery critical |
| Size of canister | 250 ml | 45 ml | Drainage absorbed in dressing |
| Unit weight with empty canister | 320 g | 195 g | 27 g |
| Power source | AC and battery | Three AA lithium batteries | Two AA lithium batteries |
| Battery life | 9 hours | 5 days | 5 days |
| Dressing description | • GranuFoam™ dressing actively promotes healing<br>• Sensa TRAC™ Technology; with continuous feedback for enhanced negative pressure accuracy<br>• 3M™ Cavilon™ No Sting barrier Film (Barrier Film) helps to protect intact or damaged skin from irritation caused by urine and/or faecal incontinence, digestive juices, wound drainage, adhesives, and friction<br>• The film is colourless, transparent, and possesses good oxygen and moisture vapour permeability | • An integrated, one-piece dressing comprised of a polyurethane film with acrylic adhesive that provides adhesion of the dressing to the skin surrounding the incision and a polyurethane shell that encapsulates the foam bolster and interface layer, providing a closed system | • Silicone contact allows fluid to pass and minimise pain of removal<br>• Airlock layer maintains open airflow and allows even distribution of negative pressure across the dressing<br>• Proprietary absorbent layer moves exudates away from the wound and initiates evaporation<br>• The high moisture vapour transmission rate top film allows one-way transpiration of exudates vapour |
| | Small Spiral GranuFoam™ Dressing (cm) 7.7 x 11.2 x 1.75<br>Medium Spiral GranuFoam™ Dressing (cm) 14.5 x 17 x 1.75 | Preneva™ Patch Strip (cm)<br>2.5x15<br>10x15 | **Size (cm)**<br>10x20<br>10x30<br>15x15<br>15x20<br>20x20<br>10x40 | **Available pad area (cm)**<br>5x10<br>5x20<br>10x10<br>10x15<br>15x15<br>10x40 |

*Table 2: Stem statements for each stakeholder (Likert ratings used)*

| Surgeon's perspective | Nurse's perspective | Patient's perspective |
|---|---|---|
| 1. The dressing kit is easy to assemble | 1. I am able to adequately assess the wound | 1. The dressing feels comfortable to wear |
| 2. The dressing is easy to apply and is adherent | 2. There is little or no dressing edge lift | 2. The machine is easy to carry around |
| 3. The dressing size adequately accommodates the length of the suture line | 3. The dressing maintains an adequate seal | 3. The dressing does not cause discomfort when it is removed |
| 4. The dressing maintains an adequate seal | 4. The canister/pump is not noisy or distracting | 4. The machine is not noisy or distracting |
| 5. The dressing adequately conforms to the body surface | 5. The dressing is easily removed | 5. The dressing feels secure and intact after showering |
| 6. Is there evidence of haematoma or seroma at suture line site post-removal negative pressure device | 6. The dressing does not cause the patient discomfort when being removed | |
| 7. When the dressing is removed, the incision site is clean and dry | 8. There is minimal or no haematoma in or around incision site on dressing removal | |

were delivered via staff meetings and in-services and lasted between 20 and 30 minutes. Approval to conduct the evaluation was obtained from the hospital's Advisory Committee for New Technology and the Director of Orthopaedics.

A product evaluation form, informed by the literature on wound management and dressing characteristics was developed[11-13]. The form consisted of 36 questions and was divided into three sections that focused on the perspectives of the attending surgeon (13 questions), nurse (16 questions), and patient (7 questions). In total, there were seven questions pertinent to the surgeon and nurse, and five questions relevant to the patient. For each question, a five-point Likert scale of agreement (1='strongly disagree' through to 5='strongly agree') was used with higher scores indicating greater levels of agreement. The stem statements relevant to each stakeholder's perspective contained in the evaluation form are detailed in Table 2. Other information on the form included the operation performed, the presence of a percutaneous drain, dressing replacement in the postoperative period and receipt of product-specific education. In the evaluation form there was also a free text section for stakeholders to write their 'likes' and 'dislikes' in relation to the features of each NPWT product included in the evaluation.

## DATA ANALYSIS

Raw scores were entered into Predictive Analysis Software Package (PASW©, Version 20, Chicago, IL). Descriptive statistics were used to summarise categorical and continuous data. Categorical data included product-specific education (yes, no), type of operation (hip, knee), percutaneous drain (yes, no), and product recommendation (yes, no).The length of time the NPWT dressing remained in situ was measured by the number of postoperative days and is reported using the median and interquartile range (IQR). Stakeholders' scores for the Likert responses were summed and the mean and standard deviation (SD) used to present the results.

## RESULTS

Fifteen patients were recruited, with five patients for each NPWT product. The evaluation was completed in its entirety for 13/15 (86.6%) of the dressing products. Two patients (PICO™ and VAC VIA™ products) had to have their dressings replaced with the usual product within 12 hours after surgery because of battery failure. Consequently, results are presented for the 13 patients who completed this evaluation.

The clinical characteristics of the surgery/patient were collected. Nine (62.2%) patients had a primary hip arthroplasty, while six (46.6%) patients in this evaluation had a percutaneous drain inserted. The Prevena™ dressing was left in situ for the longest period of time, 5.6 days (IQR=1.6 days). These and other results are presented in Table 3.

Effectiveness and efficiency of the three NPWT products was evaluated relative to the extent to which each product could be used by specific users to meet their particular needs. Scores for stakeholder groups were summed and averaged for the Likert response questions (detailed in Table 2) pertaining to dressing assembly and application, wound appearance, and the ability to visualise the wound. Overall, surgeons preferred the Prevena™ (mean 29.0, SD 4.0), while nurses and patients preferenced the PICO™ (mean 31.4, SD 4.9 and mean 19.4, SD 4.0 respectively). These results are detailed in Table 4.

*Table 3: General characteristics across 13 surgeries where NPWT was applied*

| Characteristic | n | % |
|---|---|---|
| Product education | 8 | 61.5% |
| Type of surgery | | |
| Hip | 9 | 69.2% |
| Knee | 4 | 30.8% |
| External percutaneous drain | 6 | 46.2% |
| Drain exit site outside dressing parameter | 4 | 66.6% |
| Preoperative shave | 2 | 15.4% |
| Product recommendation | | |
| Ward nurse | 9 | 69.2% |
| Surgeon | 10 | 75.9% |
| | **Median** | **IQR** |
| Number of postoperative days NPWT product left in situ | | |
| VAC VIA™ | 4.7 | .97 |
| Prevena™ | 5.6 | 1.6 |
| PICO™ | 3.5 | .57 |

Usability in relation to satisfaction was qualitatively assessed in the free text section of the evaluation form. Stakeholder groups were invited to make comments about their 'likes' and 'dislikes' for the particular NPWT product they used. From the perspectives of the surgeons, wound appearance and cost were important considerations. Nurses commented about the product-specific education required and the lack of ability to visually assess the wound. For patients, comfort, the size of the pump and the provision of a pouch needed to carry it defined their levels of satisfaction. These qualitative comments are illustrated in Table 5.

## DISCUSSION

To our knowledge, this is the first product evaluation that has specifically focused on aspects of usability[7-9] in relation to three single-use NPWT products designed for tenuous surgical incisions. While it is not intended to be a piece of research, the approach that we have taken was rigorous as it was informed by the literature on surgical wound management and NPWT. Additionally, the roll-out of the evaluation was preceded by a product-specific education program to ensure consistency in product application and postoperative management. Both shortcomings and areas for product improvement were noted, in addition to user-friendly or aesthetic features. The results of this evaluation, taken into context, suggest that all NPWT products evaluated achieved the purposes for which they were intended; thus they demonstrated acceptable usability.

Feedback from the attending surgeons about product usability was generally positive, with around 75% recommending a NPWT product. Surgeons' comments in regard to suture line appearance and dressing adherence were favourable. Ease of application was an important aspect of efficiency, with some surgeons stating that applying the VAC VIA™ was "fiddly". Overall it appeared that surgeons preferred the Prevena™ dressing product. The Prevena™ dressing product has been specifically designed for high-risk surgical incisions that are likely to drain during the postoperative period. In surgeries such as primary hip and knee arthroplasty, wound ooze is common, and to some extent, expected, in the early postoperative period[6]. Therefore, selection of this NPWT product may be appropriate depending on the patient and the type of surgery. Surgeons also commented on the cost of the NPWT products. Such concerns reflect the ongoing debate around the cost of using NPWT over conventional dressing products[14,15]. While some research shows that using NPWT products may be cost-effective in reducing patient's length of hospital stay[2,14], full economic evaluations are scarce, but are urgently needed alongside clinical trials to test product efficacy.

Nearly 70% of the nurses exposed to a NPWT product believed that it demonstrated acceptable usability, and recommended their use. However, nurses main concerns centred on the inability to visualise the wound, making it difficult to assess. Best practice guidelines advocate for the surgical dressing to be left in situ for at least the first 48 hours where possible[16,17]. The product manufacturers (KCI, Smith

*Table 4: Total scores for each stakeholder group for each NPWT dressing product evaluated (n=13)*

| | | | VAC VIA™ (n=4) | | Prevena™ (n=5) | | PICO™ (n=4) | |
|---|---|---|---|---|---|---|---|---|
| **Stakeholder** | **Number of questions** | **Possible score** | **Mean** | **SD** | **Mean** | **SD** | **Mean** | **SD** |
| Surgeon | 7 | 7-35 | 26.0 | 2.8 | 29.0 | .70 | 28.0 | 2.1 |
| Nurse | 7 | 7-35 | 26.2 | 3.5 | 29.4 | 4.0 | 31.4 | 4.9 |
| Patient | 5 | 5-25 | 15.0 | 2.1 | 17.8 | 3.8 | 19.5 | 4.0 |

*Table 5: Qualitative comments from stakeholders in relation to each NPWT product*

| Stakeholder | VAC VIA™ (n=4) | Prevena™ (n=5) | PICO™ (n=4) |
|---|---|---|---|
| Surgeon | • More fiddly to apply than the other NPWT products<br>• Product battery not charged, trial ended<br>• Cost prohibitive<br>• Dressing adheres to skin well | • Cost prohibitive<br>• Happy with wound appearance and suture line<br>• Extra sticky plastic supplied if seal is not achieved | • Easy to apply<br>• Happy with wound appearance<br>• Ease of use and compact<br>• Cost prohibitive |
| Nurse | • Unable to visualise wound<br>• Size of canister is bulky<br>• Education needed to change the unit<br>• Canister is quiet | • Unable to visualise wound<br>• Bulky, no pouch for mobilising<br>• No incidents or alarms noted<br>• Education needed to change the unit | • Unable to visualise wound<br>• Attachment to pump broke, pump disconnected from tubing<br>• Compact pump |
| Patient | • Machine is bulky to carry<br>• No case with machine, difficult to move around<br>• Comfortable to wear but range of movement is reduced (knee) | • Machine is a bit bulky to carry around<br>• No carry case supplied | • Comfortable to wear<br>• No pouch |

& Nephew) of the NPWT devices used in this evaluation recommend that the dressing be left in situ for up to seven days in order to obtain optimal wound healing. This guidance is given contingent on the type of surgery and the location of the incision. Nurses preferred the PICO™ dressing product over the other NPWT dressings because of the compact design of the pump. Unlike the Prevena and VAC VIA™, the PICO™ does not have a canister for the collection of haemoserous ooze. The PICO™ dressing is capable of absorbing up to 50 ml of fluid. The product manufacturer (Smith & Nephew) recommends that the dressing should be changed when there is up to 50% strike-through on the dressing. As such, use of the PICO™ product may be limited to surgical incisions where minimal wound ooze is anticipated. However, in this evaluation, the amount of wound ooze did not impact on any aspect of usability.

Generally, product evaluations do not seek the input from the patient end-user as these individuals do not make purchasing decisions[9]. Yet, as end-users, patients should be given the opportunity to provide feedback on usability. For patients in this evaluation, size and portability of the canister or pump were important aspects of usability as they mobilised following surgery, with overall preferences going to the PICO product. The lack of a carry case to accompany the NPWT product appeared to detract from the overall appeal. Some patients who had knee arthroplasty reported that their range of movement was somewhat restricted with the VAC VIA™ because of the bulky nature of the dressing. The VAC VIA™ device has a canister that can accommodate up to 250 ml of wound ooze, and while it is designed to be used on surgical wounds, it may be more appropriate to use in wounds where there is moderate exudate expected.

Only around 60% of nurses and treating surgeons who were exposed to the NPWT products attended the education sessions on the use of these devices. The importance of training everyone involved in the use of new products cannot be understated and impacts on end-users perceptions of usability. The success of a clinical device in delivering its promised outcomes largely depends on the end user's ability to operate the device according to the manufacturer's instructions[9]. Although a two-week product-specific program was delivered to operating room staff, surgeons and the nurses who worked on the ward, some staff who were exposed to the NPWT products during this evaluation did not have the opportunity to attend. In spite of the roll-out of the product-specific program, the busy nature of the clinical setting limited the numbers of nurses and doctors who attended. Of those nurses who were able to attend, the majority anecdotally reported that they had not been exposed to these disposable NPWT products prior to the evaluation.

## LIMITATIONS

We recognise that this product evaluation has several limitations. Firstly, the number of evaluations conducted for each NPWT product may be insufficient for end-users to adequately assess the product features. The NPWT dressing products were supplied by the two manufacturers free of charge and were specifically intended for this evaluation. Nevertheless, we selected stakeholders who could offer different insights into usability based on effectiveness, efficiency and satisfaction, to establish whether the NPWT product met their specific purposes and needs. Secondly, although a product-specific education program was undertaken for a two-week period prior to the evaluation, it was not long enough to capture all potential end-users. Consequently, the lack of product familiarity in some instances may have influenced end-users perceptions of the NPWT products being evaluated. Thirdly, this evaluation was based on self-report data, and, therefore, is subjective. Fourthly, in terms of assessing usability, we did not measure the length of time required to apply or remove the NPWT dressing, or the number of errors made during dressing application. Nor did we measure incisional pain experienced by patients. These measures of efficiency and satisfaction could be incorporated into subsequent evaluations. Finally, we evaluated three NPWT products; nonetheless there are other products of a similar nature available that we did not include. Our decision to evaluate the particular products herein was based on their emergent use in the hospital facility where this evaluation was conducted.

## CONCLUSIONS

Generally it appears that the NPWT products featured in this evaluation met the criteria that define 'usability'[10]. Usability tests are especially valuable for identifying problems or shortfalls that stakeholders might not otherwise be aware of. We sought the perspectives of three heterogeneous stakeholder groups, and gave their feedback to the product manufacturers. Clearly, eliciting end-user perspectives is a crucial step in the continuing refinement of any medical device. As such the feedback provided by nurses and doctors as health care professionals should be considered during various stages of product development. The products that we evaluated have individual features that make them suitable for use in certain types of surgical incisions. Product selection should be based on the type of surgery, the amount of wound ooze that is anticipated, and the level of risk associated with the incision. Ultimately, product cost will dictate the products that will be purchased in the current economic climate.

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## CONFLICTS OF INTEREST

The authorial team declares that they have no conflict of interests.

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