Review of an independent audit into the clinical efficacy of VACUTEX™

Michelle Deeth

Abstract

An independent report was completed and analysed by Pharmaceutical Research Associates International in August 2001 (Pro-Tex, 2001). This company provides a service to carry out independent project work and research studies within the healthcare sector. The project involved 73 tissue viability nurses and 93 patients, whereby the performance of VACUTEX™ capillary action wound dressing was assessed on both acute and chronic wounds. The audit takes into account the varying cultures across England and Wales and demonstrates this rapid method of comparing previous dressings used on a multitude of wound types, with analysis focusing on the versatility and efficacy of the VACUTEX™ capillary action wound dressing. This article reviews the findings of the audit.

In recent years, numerous products have been developed for the treatment of various wound types. As a result of the many variances and multiple factors associated with individual wound care management, the use of standard products for given wound types remains unspecified. Therefore, the choice of dressing is highly subjective and is often influenced by dressing cost and availability, wound type, wound site, the stage of wound healing, and specific individual patients' needs (Pudner, 1996; Bale and Jones, 1997; Flanagan, 1998).

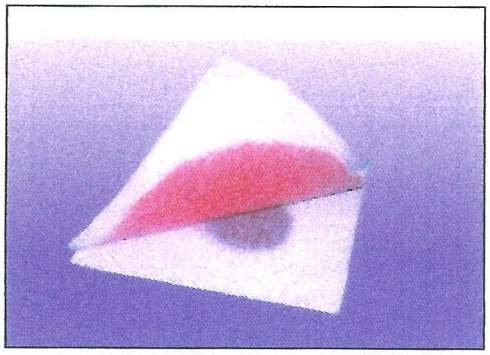

Figure 1. VACUTEX™ locks and distributes fluid within a central layer. The contact layer prevents exudate from 'spreading' across the wound site and avoids maceration. Accelerated capillary action 'pulls' interstitial fluid from the wound bed.

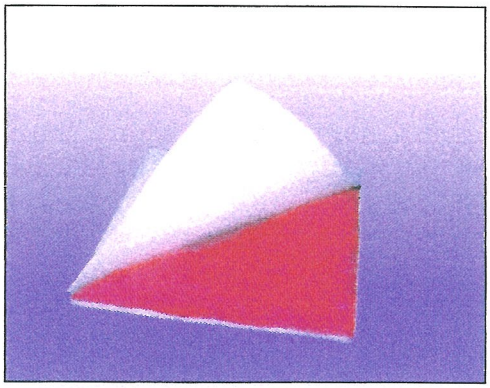

Figure 2. The third layer of the dressing remains dry until saturation occurs within the central layer. Exudate 'wicks' laterally throughout the central layer until saturated.

There is a general lack of independent evidence to support why any one product takes presidence over another. Cannavo et al (1998) suggest that there remains insufficient evidence from clinical trials to support decision making in wound care.

Bux and Malhi (1996), on presenting the results of a wound management audit performed in an NHS trust, revealed that the correct choice and use of dressings was made in only 20% of cases, with wide variations between wound care products.

The addition of any new wound care product to the range currently available must have the potential to reduce the inherent subjectivity in

Table 1. VACUTEX™ sizes

5 cm x 5 cm
10 cm x 10 cm
10 cm x 15 cm
10 cm x 20 cm
15 cm x 20 cm
20 cm x 20 cm
10 cm x 100 cm
20 cm x 100 cm

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Table 2. Wound types and wound locations treated with *VACUTEX™*

Wound type	Description (if given)	Location	Number of patients assessed	Number of patients improved following *VACUTEX™* treatment	Percentage of patients improved following *VACUTEX™* treatment
Leg ulceration	Leg ulcer/venous leg ulcer/chronic leg ulcer	Lower leg	19	18	95
	Necrotic/sloughy	Lower leg	3	3	100
	Not given	Ankle	3	3	100
	Not given	Foot	1	1	100
Leg ulceration total			**26**	**25**	96
Pressure ulceration	Not given	Sacrum	5	5	100
	Not given	Sacrum and other (ankle, heel, hip, knee)	4	4	100
	Not given	Buttock/hip/thigh	3	3*	100
	Not given	Back	1	1	100
	Diabetic	Foot	2	2	100
Pressure ulceration total			**15**	**15**	**100**
Surgical interventions	AAA repair/ hysterectomy/ laparotomy/dehisced scars or wounds/ removal CAPD catheter/ appendectomy/ infected umbilical hernia wound	Abdomen/ abdomen, groin, penile/scrotum	24	24	100
	Pilonidal sinus/ laparotomy/dehisced wound/hip replacement	Buttock/hip/ sacrum/anus	8	8	100
	Trauma/amputation/ knee replacement	Leg — including leg, groin, knee, lower leg, foot and toe	6	6	100
Surgical interventions total			**38**	**38**	100
Other		Lower leg/heel/toe	5	5	100
		Sacrum	2	2*	100
		Hip/buttock/back	3	3	100
		Scalp	1	1	100
		Abdomen	1	1	100
		Hands	1	1	100
		Not given	1	1	100
Other total			**14**	**14**	100

*Information missing on patients. Source: Pro-Tex (2001); AAA = abdominal aortic aneurysm; CAPD = continuous ambulatory peritoneal dialysis

> The wound contact layer (reversible) is able to lift and transport exudate, and/or necrotic/sloughy tissue. The middle layer prevents "strikethrough" by allowing exudate to move into, and wick laterally, across the centre, thereby removing exudate from the wound interface and the surrounding skin...

wound care management, rather than complicate further the choice for practitioners.

However, a study by Boxer and Maynard (1999) consisting of a self-administered questionnaire used to survey registered nurses working in hospital and community services in a large Australian city, revealed that registered nurses (a total of 140 questionnaires were returned) had a significant role in chronic wound management but that they relied primarily on their own experience and that of their colleagues.

With the focus on increased efficacy of wound care products, the purchaser and the Government are concentrating on cost-effective care and measurable outcomes in treatment. Cost-effective management of wounds is a complex matter and should focus on not only short-term costs to healing, but also the long-term costs (Roberts, 1998).

Current guidance on the use of debriding agents and specialist wound care clinics for difficult to heal surgical wounds, issued by the National Institute for Clinical Excellence (NICE, 2001), recommends that:

> 'The choice of debriding agent for difficult to heal surgical wounds should be based on impact of comfort, odour control, and other aspects relevant to patient acceptability, type, and location of wound, and total cost. In addition, there should be enhanced education of healthcare workers, patients and carers, and the sharing of clinical expertise in the provision of specialist wound care services.'

This article discusses a novel and relatively new approach to obtaining data in wound care. This method of obtaining data has offered patients presenting with a diverse range of both acute and chronic wounds a useful tool to structure systematically and uniformally appropriate information for analysis, while demonstrating the versatility of *VACUTEX™* (to be referred to as the trial dressing) in the healing of a diverse range of wound types on any location of the human body.

VACUTEX™ CAPILLARY ACTION DRESSING

VACUTEX™ is a three-layered, rapid capillary action dressing, manufactured in the UK by Pro-Tex Capillary Dressings Ltd. Polyester filaments and poly/cotton fibres are constructed and manipulated, creating a three-phase multidirectional capillary action.

The wound contact layer (reversible) is able to lift and transport exudate, and/or necrotic/sloughy tissue. The middle layer prevents 'strikethrough' by allowing exudate to move into, and wick laterally, across the centre, thereby removing exudate from the wound interface and the surrounding skin (*Figures 1* and *2*) (Russell et al, 2001).

In an unpublished independent report completed at the Surgical Testing Materials Laboratory (STML, 2001), tests demonstrated the absorbency by wicking of the trial dressing to be four times quicker than a leading hydrofibre and three times faster than a leading hydrocellular foam.

The reverse layer of the dressing 'pulls' exudate from the saturated middle layer, enabling the dressing to be applied in layers for managing large amounts of exudate. The fused, low-adherent outer layers prevent microfibres from being shed into the wound.

VACUTEX™ is non-interactive and non-impregnated and is indicated for most wounds, both acute and chronic (Deeth and Pain, 2001). The only contraindication to using *VACUTEX™* is arterial bleeds and in extremely vascular, bleeding fungating wounds. This is because of the pulling effect that the dressing's capillary action creates within the dressing. *VACUTEX™* can be obtained in several sizes, as shown in *Table 1*, and can be cut into several shapes to suit each individual wound.

METHODOLOGY

During the independent clinical review (Pro-Tex, 2001), 73 wound care nurses throughout England and Wales, both within the hospital and community setting, were trained in the use of the trial dressing by nurse advisers employed by Pro-Tex Capillary Dressings. Ninety-three patients were recruited with a variety of acute and chronic wounds for treatment with the trial dressing. The wound types and wound location of the patients included in the audit are summarized in *Table 2*. All tissue viability nurse specialists involved in the audit used their own clinical expertise and protocols to individually define, and interpret their knowledge and understanding of what they classified as a difficult to heal wound.

A clinical review questionnaire was completed for each participating patient. The results from each separate questionnaire were entered to a single spreadsheet for ease of reference and analysis (Pro-Tex, 2001). The clinical review took the form of wound assessment and management, which included photographs, general visual observation, and wound measurement to describe how improvement was measured. The definition of improvement to the wound was left to the discretion of the nurses' own clinical judgment, although it is recognized that this method has a degree of subjectivity.

The methodology was designed to enable the results to be aimed at addressing the key points, as recommended by NICE, for the use of debriding agents and specialist wound care clinics in the treatment of difficult to heal surgical wounds. These considered:

- *Patient acceptability:* the acceptability of the trial dressing compared to other wound care products
- *Type and location of wound:* a list of the range of wound types and the variety of locations of wounds successfully treated with the trial dressing
- *Cost:* an assessment of the alteration in the number of dressing changes performed with the trial dressing compared, where possible, to other treatments.

RESULTS

The results of the audit are summarized below. The spreadsheets containing the individual results for each patient can be found in full in the report (Pro-Tex, 2001).

The audit found that 79% of wounds ($n=73$) showed improvement within 5 days of using the trial dressing. In 30% ($n=22$) of these patients, wound healing was noted as early as after 1 or 2 days. The remaining patients experienced improvement within 1–2 weeks. When addressing patient comfort, 48% ($n=45$) of the patients considered the trial dressing to be 'very comfortable', with 43% of the patients ($n=40$) considering it to be 'comfortable' (*Figure 3*).

The trial dressing claims to have the ability to reduce odour by locking it within the middle layer of the dressing. The nurses' assessment and comments from the patients suggest that the trial dressing does have a positive effect on wound odour levels (Pro-Tex, 2001). Six per cent of patients ($n=6$) reported a total reduction in malodour, while the remaining patients who had a malodorous wound reported an improvement in the containment of odour.

Nursing use of the trial dressing was favourable, with only 4% ($n=3$) of the nurses reporting the trial dressing as not easy to use (*Figure 4*).

The frequency with which the trial dressing was changed, compared to the frequency with which previously used dressings were changed, was summarized for each patient participating in the clinical review (*Figure 5*). Fifty per cent ($n=40$) of the patients (13 patients were excluded because of missing data) experienced a reduction in the number of required dressing changes with the trial dressing compared to previously used dressings, thus showing cost-effectiveness.

DISCUSSION

Overall, it was felt by the tissue viability nurse specialists that the trial dressing would be a valuable additional tool to the armoury of dressings currently available for wound care. The trial dressing is extremely versatile within wound management and can be used across a broad range of wound types (Deeth and Pain, 2001), as has been shown in *Table 2*.

Ease of nursing use has a direct bearing on patient comfort, and was therefore considered an important measure of patient acceptability. The idea of tailoring a dressing

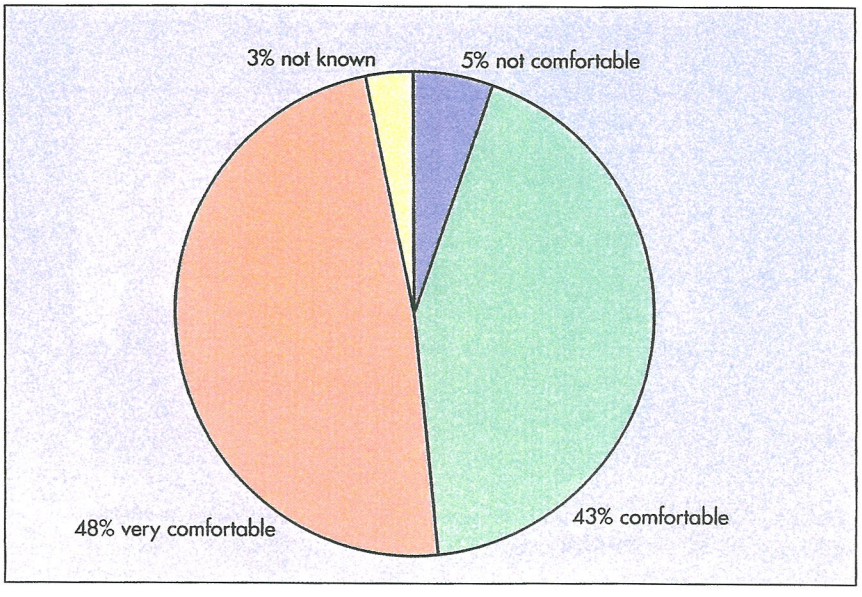

Figure 3. Patient comfort in relation to VACUTEX™. Source: Pro-Tex (2001).

to meet the specific needs of a wound and the patient is a new concept, but the results are seen to be favourable.

The rapid capillary action of the trial dressing that was noted during the clinical review would support the contraindications that the trial dressing should not be used on arterial bleeds or heavily bleeding wounds. Within the field of wound care, there continues to be a lack of evidence to support decision making in product choice. A good audit method to assist in gaining the evidence to subsequently inform future research studies can only be seen as a move in the right direction for researchers (Gold et al, 1996).

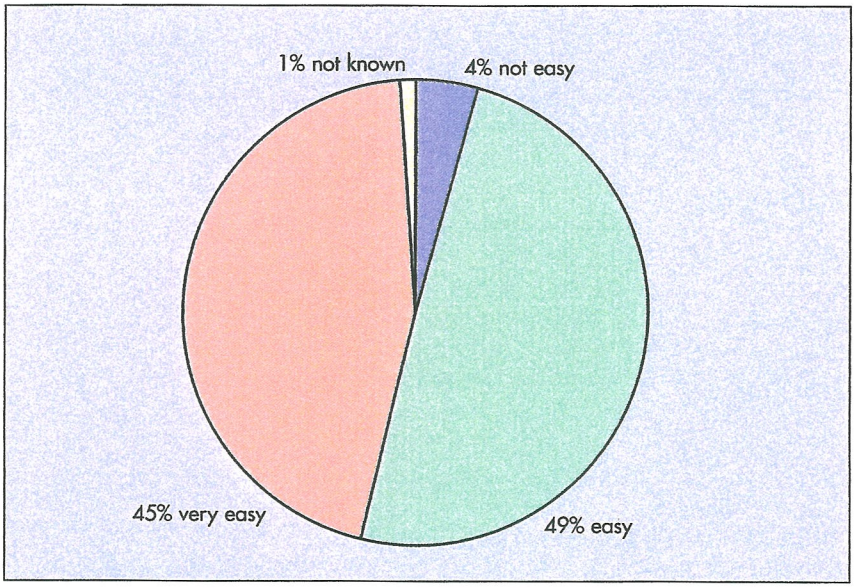

Figure 4. Ease of nursing use in relation to VACUTEX™. Source: Pro–Tex (2001).

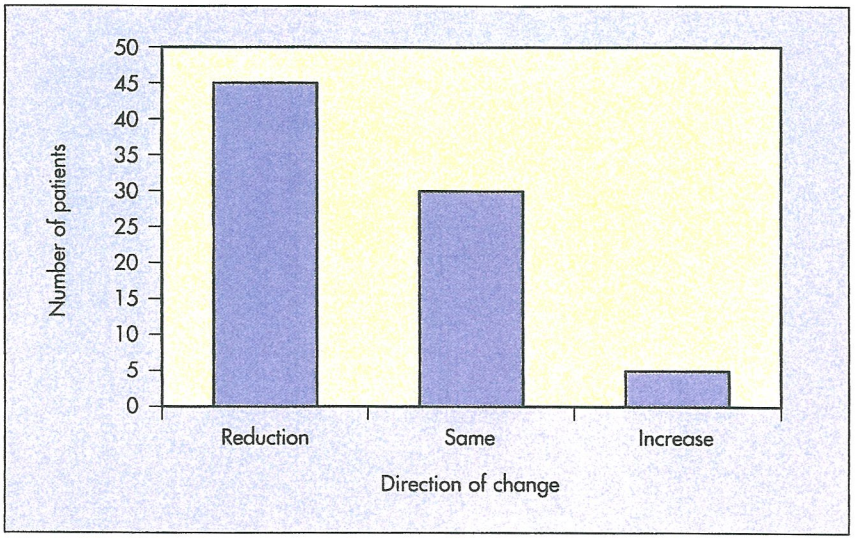

Figure 5. Alteration in the number of dressing changes (VACUTEX™ vs other dressings). Note: 13 patients excluded because of missing data. Source: Pro-Tex (2001).

The implications of the results of this audit support the inherent subjectivity associated with dressing selection; in addition, it has been shown that there is a need for education and training programmes aimed at individuals with a responsibility for wound care in order to ensure the appropriate use of the trial dressing.

The audit highlighted future areas of study, which include the effects of the trial dressing on infected wounds.

LIMITATIONS OF THE AUDIT

The method of collecting data for the audit described in this article was used to gain a snapshot of the efficacy of the trial dressing within the clinical setting. When carrying out a simple randomized controlled study with a large sample size, the number of subject variables are reduced by the inclusion/exclusion criteria. This will limit the number of patients who can be entered into the study. However, as this was an audit, there were no formal inclusion/exclusion criteria. The only criteria for inclusion was that the wound had previously proved difficult to heal with other wound care products.

The audit described in this article focuses on a much more subjective approach, allowing clinicians to interpret by their own experience what is happening within the wound. It is accepted that as a result of these limitations, the results of the audit are very much based on the individual assessment and the opinion of the nurse. Every practitioner will describe what they 'perceive' to be happening to a wound differently and there is no provision within the audit to guard against this problem.

It is accepted by the author that this method lacks the rigor of a randomized control trial which remains the gold standard in research (Moher et al, 1996), but it still offers practitioners reliable and valid information and could be viewed as a starting point to inform future studies.

CONCLUSION

The clinical review audit demonstrated a high patient acceptability of the trial dressing as measured by improvement in the wound, comfort, nursing ease of use, and odour

reduction. The diversity of wound types and locations were treated successfully with the trial dressing and it was also shown to have the potential to be cost-effective.

The wound care nurses involved in the audit claimed that the trial dressing has a potentially valuable role in the field of wound management. As the clinical review form for data collection was designed in conjunction with the nurses who took part in this audit user error was minimized and it ensured that only essential information was obtained. BJN

Pro-Tex Capillary Dressings Ltd would like to acknowledge and thank Mair Fear for her assistance in the production of the clinical review form for the above audit.

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KEY POINTS

- This article describes a review of an independent audit using a unique approach to data collection to demonstrate the performance of *VACUTEX™* capillary dressing in both acute and chronic wounds.
- The tissue viability nurses within the audit found *VACUTEX™* to be a versatile and able to be used across a broad range of wound types.
- There was high patient acceptability of *VACUTEX™* in terms of improvement in the wound, comfort, nursing ease of use, and odour reduction.