An evaluation of Versiva® XC® gelling foam dressing and its effect on wound-related quality of life

The selection of an inappropriate dressing regimen can result in moderate to heavily exuding wounds having a negative impact upon the patient's skin and quality of life. However, before integrating a new dressing into a wound formulary, the clinician responsible must ascertain the product's quality and cost-effectiveness through appropriate research. This article features a 50-patient evaluation of Versiva® XC® gelling foam dressing, which combines a foam construction with Hydrofiber® technology in a thin easy-to-use dressing, and its effect on wound-related quality of life in patients with wounds of differing aetiology.

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KEY WORDS
Wound care
Quality of life
Exudate
Cost-effectiveness
Wound dressings

The process of evaluating a wound dressing before its inclusion in a wound formulary is familiar to many tissue viability/wound specialist nurses, pharmacists and procurement officers. However, there is a dearth of evidence to support the use of products (Vermeulen, 2005).

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When it comes to the provision of evidence, randomised controlled trials (RCTs) are seen as the gold standard. However, RCTs limit the types of wound aetiologies and patient groups that can be studied and can therefore provide a narrow view of a dressing's performance.

Examination of a broad cohort of patients with several wound aetiologies can provide a much more comprehensive view and reduce the work of the specialist when it comes to choosing an appropriate dressing.

An improved quality of life, for example, having a wound dressing that does not stain clothing, is often greatly appreciated by patients.

This article details an evaluation of Versiva® XC® gelling foam dressing (ConvaTec), which was trialed on a cohort of 50 patients with a variety of wound aetiologies. It provides evidence of the dressing's effect on pain and odour from the patient's perspective as well as examining its fluid-handling capability, frequency of change required, conformability and ease of application of the dressings from the clinician's point of view.

Moderate to highly exuding wounds continue to provide a huge challenge to the skill of the managing clinician and the impact of an exuding wound upon the patient's quality of life is well documented (Harding et al, 2000).

Clinicians should remember that wound healing may not be the primary aim of care, especially from the patient's point of view. An improved quality of life, for example, having a wound dressing that does not stain clothing, is often greatly appreciated by patients.

Evidence

Before integrating any dressing into a wound formulary, the clinician responsible, be it a tissue viability nurse (TVN), wound specialist, pharmacist or procurement officer, must decide on the product's quality and cost-effectiveness by reviewing the available evidence.

Wound dressings are expensive and all clinicians are subject to budget constraints, indeed an integral part of any clinician's role involves allocating resources wisely to provide quality healthcare — this applies to wound management as much as any other specialty.

The National Institute of Health and Clinical Excellence (NICE) provides evidence on treatments,

products and medicines to guide clinicians' practice. It utilises the quality-adjusted life years measurement (QALY), a measurement of disease burden, which uses factors such as pain levels, mobility and mood, to calculate how many years a product would add to a patient's life and thereby its cost-effectiveness, i.e. how much does one wound dressing cost per QALY (NICE, 2008).

The QALY method takes into account that the cost of a wound dressing includes not only the retail price, but also the nursing time involved — a valuable commodity and one that is insufficiently recognised (Harding et al, 2000). The QALY method can help clinicians avoid, for example using inexpensive dressings, which manage exudate poorly and require changing on a daily basis, over more expensive products, which manage wound exudate well and only require changing twice weekly.

In addition to examining the quality and cost-effectiveness of each wound dressing, a clinician should also investigate the evidence to determine whether or not the product achieves the manufacturer's claims. Much is made of the lack of evidence available to support wound dressings, especially in the form of RCTs. However, it could be argued that RCTs provide very little in the form of useable information for the clinician who has to manage chronic wounds (unless specific wound aetiology is under investigation) as these wound types are often excluded from RCTs (Timmons, 2008).

The difficulty of recruiting patients with wounds of a similar size and with similar co-morbidities onto an RCT is immense. Also, vascular supply and nutritional status play a significant role in wound healing; however, locating a significant number of patients with similar vascular and nutritional status could take years.

Professor Rawlins (2008), Chair of NICE, recently stated that: 'Hierarchies of evidence should be replaced by accepting — indeed embracing — a diversity of approaches. This is not a

Patient's date of birth		**Wound details**	
Gender	M / F	Wound size	
Medical history		Wound site	
Cardiac		Length (cm)	
COPD		Breadth (cm)	
Diabetes type 1		Depth (cm)	
Diabetes type 2		Volume (if known)	
Rheumatoid			
Other conditions		**Wound assessment**	
Allergies		Healing continuum	
		Infection continuum	
Treatment history		Exudate continuum	
Previous primary dressing			
Previous secondary dressing		**Investigations**:	
Frequency of dressing change		Ankle brachial pressure index	
		Haemoglobin	
Versiva® XC® performance		Temperature	
Size of product used		White cell count	
Time taken to apply (minutes)		Wound swab	
Ease of application			
Other dressings used in combination		**On removal of Versiva® XC® was the patient's skin affected?**	
Did patient experience pain?		Skin stripping	Y / N
During dressing application?	Y / N	Reactive hyperaemia	Y / N
Once the dressing was applied?	Y / N	Rash	Y / N
During dressing removal?	Y / N	Maceration	Y / N
Did the dressing conform to the wound?	Y / N		
		Was odour present?	
Did the dressing leak before dressing change occurred?	Y / N	Dressing odour?	Y / N
		Wound odour?	Y / N
Did the wound change while being treated with Versiva® XC®?			
Better	Y / N		
Same	Y / N		
Worse	Y / N		

Figure 1. The evaluation form.

plea to abandon RCTs and replace them with observational studies ... it is a plea to investigators to continue to develop and improve their methodologies.'

Clinicians and researchers should work together to examine when RCTs are appropriate and when other forms of investigation, such as the systematic review of case reports, could highlight other areas of care.

Versiva®XC® gelling foam dressing

Versiva® XC® gelling foam dressing combines foam product construction with Hydrofiber® technology (which many healthcare professionals are familiar with in the form of AQUACEL® [ConvaTec]) in a thin, easy-to-use dressing. Unlike some traditional foam dressings, which

absorb fluid into the air pockets of the foam structure, Hydrofiber® technology absorbs fluid into the interior of the fibres, causing them to swell and merge with each other to form a cohesive gel. This gelling action is specific to the area where fluid is absorbed — where there is no fluid, the fibres remain dry.

Because fluid is absorbed and retained within the fibres rather than just being taken into air gaps or pockets between fibres or inside a foam, the fluid is effectively retained when pressure is applied.

Versiva® XC® gelling foam dressings are available in both adhesive and non-adhesive formats and come in square, heel and sacral shapes.

Versiva® XC® gelling foam dressing is indicated for moderate to heavily exuding acute or chronic wounds.

The evaluation

The authors of this evaluation observed the wounds of 50 patients aged between 52–100 years using a systematic evaluation to determine the effectiveness of Versiva® XC® gelling foam dressing in dealing with some specific quality of life factors including:

- Wound aetiology
- Dressing frequency
- Conformability and ease of application
- Patient comfort
- Adverse reactions
- Perception of odour
- The dressing's use in diabetic patients
- Healing continuum.

The patients' wound aetiologies included pressure ulcers, leg ulcers, traumatic injuries and complex surgical wounds. Patients with diabetes were not excluded (as is often the case with RCTs that do not have diabetic patients as their focus), as the authors felt it vital that a wound dressing should be able to demonstrate its effectiveness upon a range of wound aetiologies, including the most challenging.

Similarly, a range of wound sites were included in order to test the

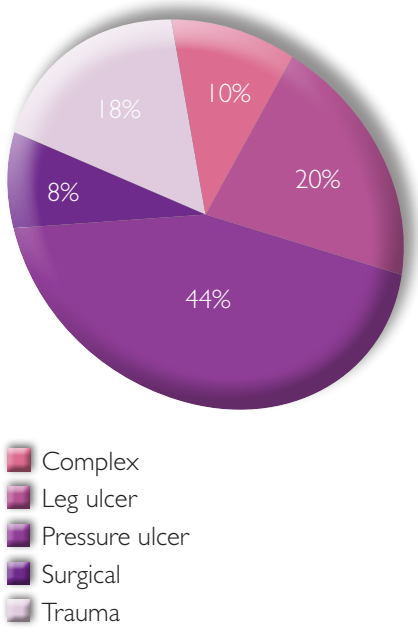

Figure 2. Aetiologies of the wounds in the study.

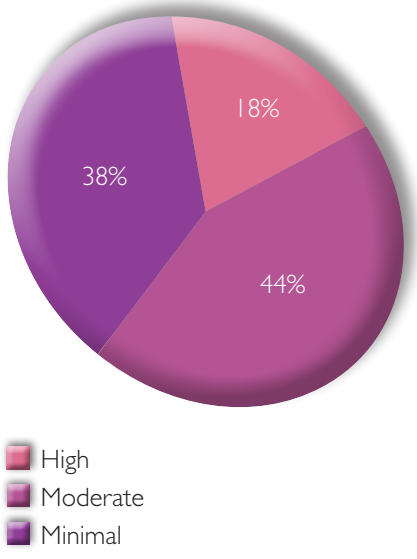

Figure 3. Volume of exudate.

conformability of the wound dressing, since any dressing that does not demonstrate conformability can restrict clinicians' options in practice.

The patients were drawn from both primary and secondary healthcare settings across three different sites:

- Hospitals in Aberdeen
- Community settings in Hull
- Hospitals in Epsom and Carshalton.

The patients were selected by the clinicians, on the basis that they had a wound, which was producing exudate. The patients were then assessed and treated by the clinicians and nursing staff within the hospital setting or in the community. Evaluation forms were completed on a secure electronic database after each wound review.

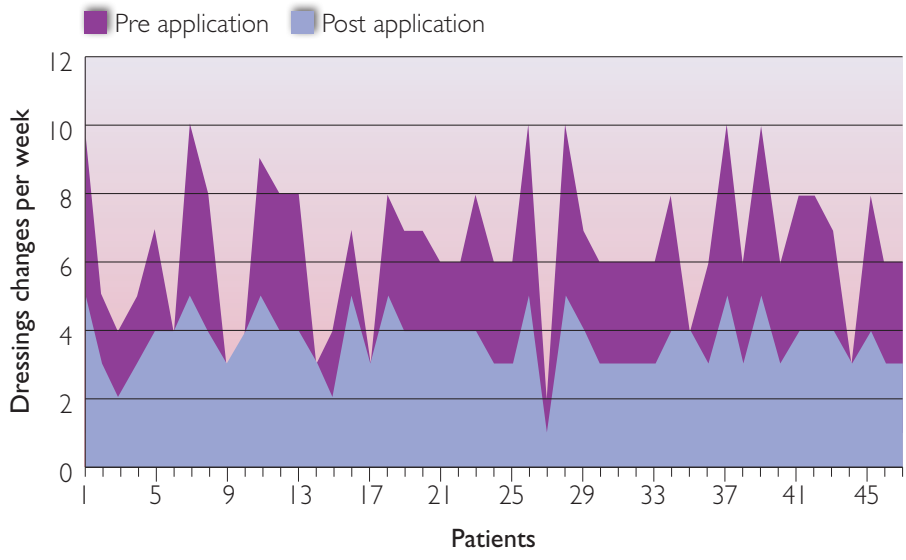

Figure 4. Frequency of dressing changes pre and post use of Versiva® XC® gelling foam dressing.

The clinicians involved in this audit were provided with the full range of Versiva® XC® dressings, including the adhesive, non-adhesive, square, heel and sacral-shape versions.

On completion of the study the clinicians met to discuss the results and systematically review each patient in order to identify if any patterns arose, e.g. whether the dressing performed when used on moist or heavily exuding wounds. They also discussed whether there were any difficulties with the dressings, i.e. were they conformable to the wound area?

Evaluation form

Performing an extensive evaluation of a wound dressing can provide vital information. However, it is vital that any evaluation is not only acceptable for patients with regard to pain management and exudate control, but also uncomplicated for clinicians to apply.

The evaluation form used in this evaluation (*Figure 1*), helped investigators to focus on factors important for both patient and clinician.

Results

Wound aetiology

A number of patients with different wound aetiologies and with both acute and chronic wounds were evaluated (*Figure 2*). Traumatic injuries included skin tears and lacerations — injuries common in older people due to the fragility of ageing skin.

Leg ulcers of all aetiologies were included as the dressing was evaluated for exudate management, comfort and conformability, all of which can be difficult to manage in lower leg ulcers.

In order to observe whether the wound bed continued to progress and whether dressing change frequency could be reduced, which would result in time savings for clinicians and reduced dressing changes for the patient, wounds were included regardless of the volume of exudate being produced. *Figure 3* demonstrates the volumes of exudate produced by the wounds in the evaluation:

- High volumes of exudate: nine wounds (18%)
- Moderate volumes of exudate: 22 wounds (44%)
- Minimal volumes of exudate: 19 wounds (38%).

Dressing frequency

Figure 4 demonstrates that there were significant reductions in the change of dressing frequency in the majority of patients observed.

Conformability and ease of application of dressing

The dressing shapes predominantly used in this evaluation were the adhesive square Versiva® XC® gelling foam dressings (*Figure 5*). These were occasionally used in areas of the body that would not be immediately obvious, i.e. the sacral area in patients for whom the sacral dressing did not conform, however, the investigators assessed that these dressing shapes were the most appropriate for the individual wound involved.

The majority of investigators found the Versiva® XC® gelling foam dressings 'very easy' to apply (*Figure 6*), however, with two patients the investigators found it 'difficult' to apply the adhesive heel dressings and on five occasions investigators found it 'difficult' to apply the adhesive square dressings. None of the investigators found the Versiva® XC® gelling foam dressings 'very difficult' to apply.

The majority (76%) of investigators found the Versiva® XC® gelling foam dressings conformable to the wound and peri-wound area (*Figure 7*).

Patient comfort

Patients were asked whether they experienced any pain or discomfort on application, removal or while wearing the Versiva® XC® gelling foam dressings (*Figure 8*). The vast majority did not experience any pain or discomfort, although six patients (12%) did complain of pain on either application, removal or during wear. However, only one patient complained of pain both while wearing the dressing and on its removal — all other patients complained of pain only once, either on application or during wear/removal of the dressing.

Adverse reactions

Figure 9 illustrates that six patients (12%) experienced both leakage of

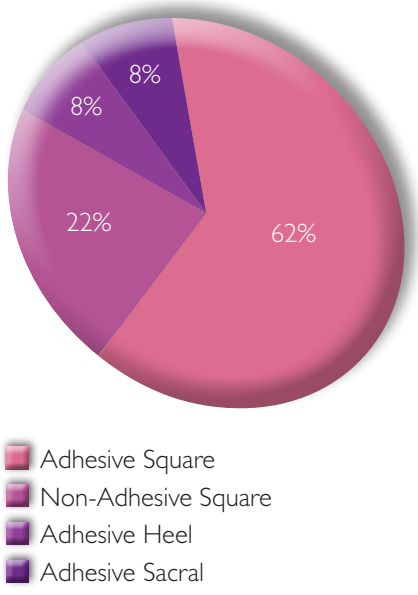

Figure 5. Types of Versiva® XC® gelling foam dressing evaluated.

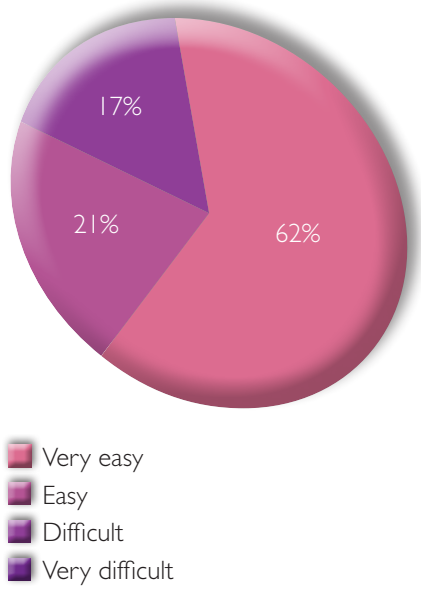

Figure 6. Ease of application.

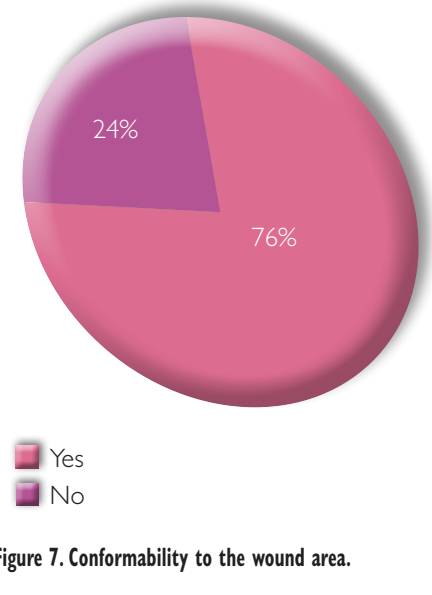

Figure 7. Conformability to the wound area.

exudate and skin maceration while wearing the Versiva® XC® gelling foam dressing. This could be due to clinicians' unrealistic expectations of the dressing as despite these patients' wounds being assessed as producing high volumes of exudate, no absorbent primary dressing was applied, which may have been beneficial (Cooper et al, 2009). Only one patientexperienced an apparent skin reaction due to sensitivity.

Perception of odour

During the evaluation, 12 patients perceived an odour emanating from their wound — six of these felt there was an odour emanating from the dressing (*Figure 10*).

Patients with diabetes

Six patients with diabetes were included in the evaluation and their wounds either improved or remained the same (*Figure 11*).

Wound healing continuum

Wound healing was not the primary aim of the evaluation, however where possible wound volume was measured in order for both clinicians and patients to determine whether using Versiva® XC® gelling foam dressing had a positive effect on healing (*Figure 12*). Fourteen patients' wounds (28%) decreased in size, 19 (38%) remained unchanged, seven (14%) were lost to follow-up and three (6%) appeared to worsen.

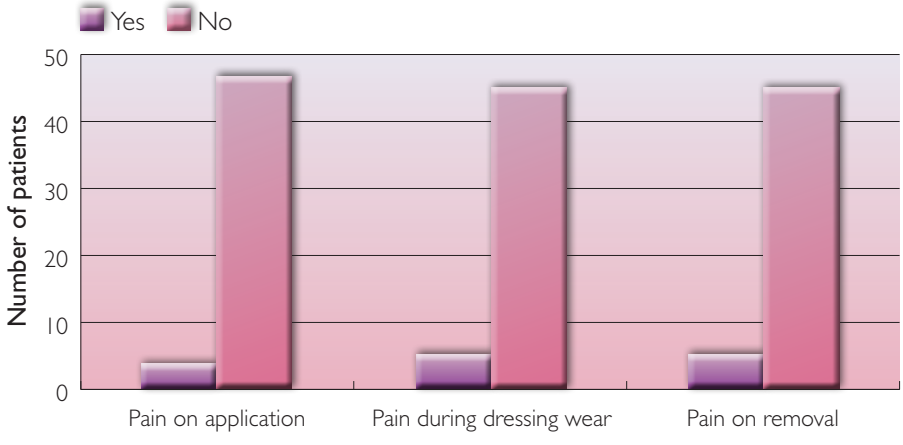

Figure 8. Patient's pain experience.

Discussion

One of the difficulties highlighted in this evaluation was a lack of training for some clinicians in using the dressing. Not including training for all of the clinicians may have resulted in some of the problems encountered with application of the dressing, unrealistic expectation of wear time and the absence of a primary absorbent dressing (Cooper et al, 2009).

Patients have differing body shapes and dressing evaluations should include a section where investigators can record such information, for example an obese or cachectic patient will test a dressing's ability to conform, both to the wound itself and the patient's body shape. In this evaluation, 76% of clinicians found the Versiva® XC® gelling foam dressing conformable — the same percentage found the dressings either 'very easy' or 'easy' to apply.

However, 14% of clinicians found the dressings did not conform well to the patient's body and a further 14% reported that the Versiva® XC® gelling foam dressings were 'difficult' to apply, highlighting again the training issues vital for a comprehensive evaluation.

Six patients (12%) experienced

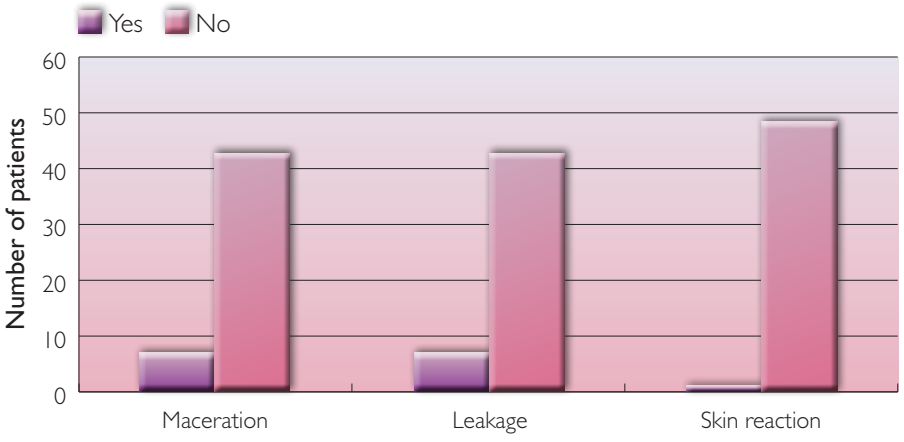

Figure 9. Adverse skin reactions.

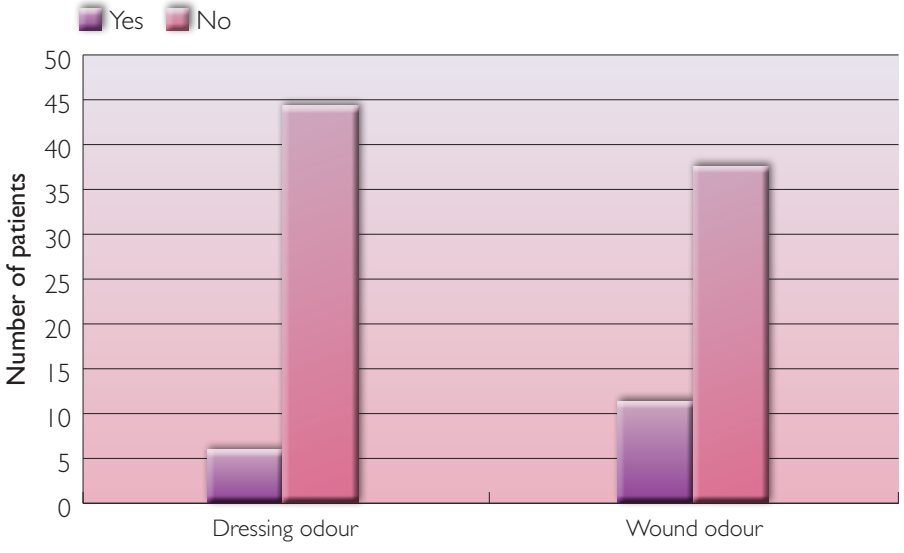

Figure 10. Perception of odour.

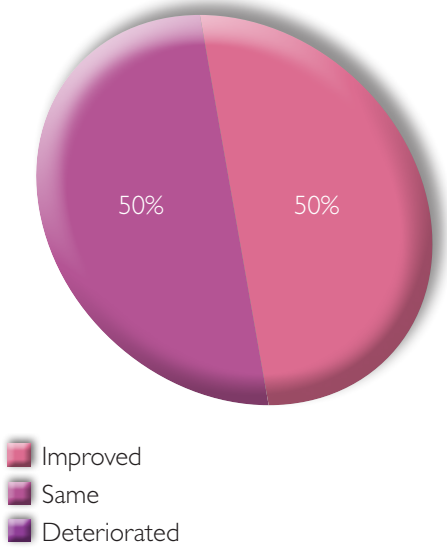

Figure 11. Status of diabetic wounds following use of Versiva® XC® gelling foam dressing.

both leakage of exudate and maceration of their peri-wound skin. These patients all had high levels of exudate indicating that the dressing was not replaced promptly when saturated. This would appear to be a training issue as all six patients were recruited by the same clinician. It is vital that the appropriate size dressing is used and also that it is changed when indicated, i.e. when saturated with exudate — if a saturated dressing is left *in situ* this can lead to skin maceration.

One patient (2%) experienced an apparent skin reaction to the border of the Versiva® XC® gelling foam Adhesive dressing.

Twelve patients (24%) perceived an odour, with six [12%] of these believing the odour was coming from the dressing rather than the wound. This is an unfortunate result as patients are naturally self-conscious about any perceived or real odour.

While the vast majority of patients (44) did not experience any pain or discomfort when using the Versiva® XC® gelling foam dressing, two patients (4%) reported pain on application, three (6%) complained of discomfort on wearing the dressing and two (4%) reported discomfort on removal.

However, on closer inspection of the evaluation forms it transpired that only one patient complained of pain on more than one occasion and that most of the patients complained of pain on either application, wear or removal, but not all three. This suggests that either the patient's pain management fluctuated (either due to their own self-assessment of pain or due to timing of analgesia) or the pain was caused by the investigator's inexperience in using the dressings.

Patients complaining of pain were all attended by district nurses who found the dressings non-conformable and experienced difficulty in application. This reinforces the need to collaborate with the manufacturer to ensure appropriate training is provided before using any new product.

Six patients (12%) with diabetes were included in the evaluation and their wounds either improved or remained the same. In addition, the Versiva® XC® gelling foam dressings were found to be conformable, an attribute vital in managing diabetic wounds. Bulky or creased dressings can apply pressure to the diabetic wound area and lead to deterioration.

During the evaluation, 14 patients' wounds (28%) decreased in size, 19 (38%) remained unchanged, seven patients (14%) were lost to follow-up and three wounds (6%) appeared to worsen. This deterioration was due either to the wound increasing in size

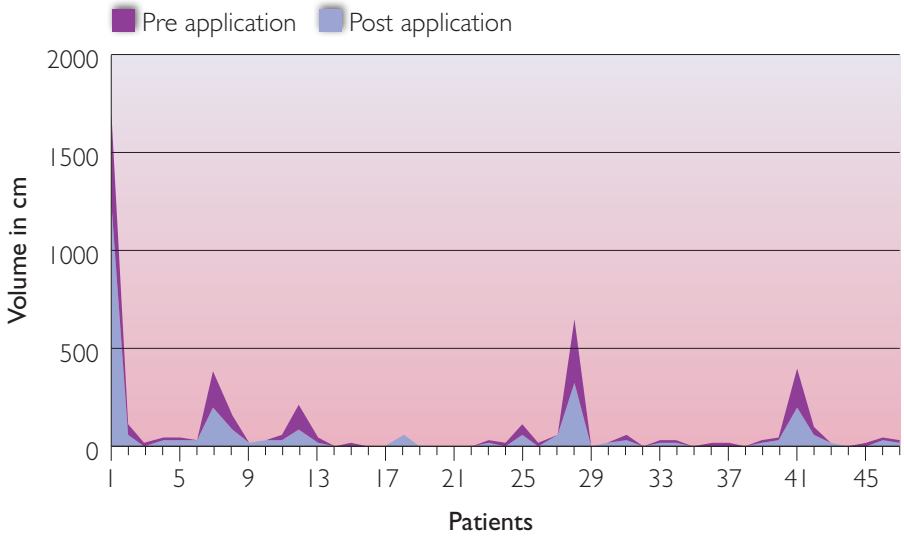

Figure 12. Wound volume pre and post application of Versiva® XC® gelling foam dressing.

after debridement or deterioration in the patient's condition rather than any problem with the Versiva® XC® gelling foam dressings (as evidenced by the clinicians' documentation).

Although there were instances when wounds appeared to deteriorate due to exudate leakage and the associated maceration, it is possible that clinicians did not change the dressings with sufficient frequency or had unrealistic expectations of the dressing's fluid handling capability.

Conclusion

This evaluation has provided some valuable information about the Versiva® XC® gelling foam dressing, which will enable clinicians to determine whether or not it will be of use in their practice.

The range of patients and wounds included in this evaluation will be familiar to most TVNs and will help them decide whether to include the dressing in their wound formularies. This is in contrast to an RCT, which would take far longer to achieve, would be limited to perhaps one wound aetiology and where the presence of comorbidities might exclude the very patient group in whom clinicians are most interested.

This evaluation has highlighted very clearly that before any wound dressing evaluation any clinicians inexperienced in using the dressing should undergo a period of training to ensure the product is fairly evaluated and that no bias is introduced due to lack of knowledge or experience.

One valuable finding of the evaluation is the necessity to record a patient's body shape and weight as one investigating team experienced difficulties in the application of Versiva® XC® gelling foam dressing. While the problem may have been a training issue, the problem may equally have arisen due to an obese or grossly debilitated patient.

When asked, the vast majority of patients described Versiva® XC® gelling foam dressing as comfortable and did not complain of odour. Perhaps more wound dressing evaluations should include overall patient satisfaction, with clinicians considering patients' opinions — after all patients may have valid suggestions about the care of their wounds.

Since none of the patients in this evaluation experienced an increase in dressing change frequency, Versiva® XC® gelling foam dressing clearly has a good fluid-handling capability and depending on appropriate training is likely to prove conformable and easy for the vast majority of clinicians to apply. WUK

Key points

- Exuding wounds can be difficult to manage.
- Evaluation of a wound dressing should also consider the patient's experience of the dressing.
- Prior to evaluation of a wound dressing, all participating staff should be fully trained in how to use the dressing.
- Evaluating one dressing through examining its impact on a large group of patients can produce valuable information regarding the dressing's efficacy.

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