

# From the laboratory to the leg: Patients' and nurses' perceptions of product application using three different dressing formats

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## Abstract

Leg ulcers (for example, venous, arterial or mixed aetiology ulcers) produce a significant burden for the patient, their family and health services because of slow healing and chronic recurrence requiring intensive wound products and nursing time. The mainstay of treatment for venous ulcers is compression therapy to address the underlying cause of chronic venous hypertension. Many wound products have been trialled to improve the efficacy of leg ulcer healing. A key part of product development is evaluation of product acceptability for patients and nurses. This study examined the user acceptability of three new types of keratin wound dressings during development. A convenience sample of 23 patients, with leg ulcers of differing aetiology, were recruited from a nurse-led, community-based Wound Management Clinic in New Zealand using inclusion/exclusion criteria. Patients and nurses were asked to complete a structured questionnaire at each dressing change and provide comments on each product. The results showed that both patients and nurses preferred all of the dressings over previous products. For the gel and the foam, the preference was virtually unanimous for both nurses and patients. For the matrix, the preference was still strong (82% for patients and 64% for nurses) and for those nurses who did not prefer the matrix, the main reasons were that it was more difficult and time-consuming to apply. Comments on usability have enabled the company to improve the matrix's structure to address these issues. This study has highlighted the importance of patients and nurses being involved in product testing to ensure the product meets criteria of comfort, duration, timeliness, ease of use and overall preferability.

*Keywords: Wounds, chronic; bandages and dressings; product evaluation; questionnaire; clinical effectiveness*

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## Introduction

Leg and foot ulcers, whether from venous, arterial or mixed aetiologies, cause considerable and prolonged distress for patients, with pain being a common symptom<sup>1-3</sup>. Often ulcers become infected, resulting in offensive odour and further wound deterioration<sup>4</sup>. These symptoms can engender unhappiness, social isolation, restricted mobility and negatively affect the person's quality of life<sup>5</sup>. Venous leg ulcers are thought to affect up to 3.5% of the general population<sup>6</sup>, with women having more lower limb ulcers than men, outnumbering them by a ratio of more than 2:1<sup>7</sup>. They produce a significant burden for the patient, their family and the health service because of slow healing and chronic recurrence, therefore needing intensive wound care products and nursing time<sup>4</sup>. The cost of treating leg ulcers not only involves the cost of the product and the nursing time to redress the ulcer, but includes any hospital stay, home health costs, risks and costs of complications<sup>6</sup>.

Compression therapy to address the underlying cause of chronic venous hypertension is the current mainstay of treatment for venous leg ulcers<sup>8</sup>. However, many new wound care products have been developed and trialled over the

last 20 years to improve the efficacy of leg ulcer healing. A key part of product development is evaluating the product acceptability for both patient and nurse<sup>4</sup>. Key criteria for the patient are: comfort, staying in place, fitting in with footwear and lifestyle, easy removal, time taken for the dressing, and overall satisfaction rating<sup>9,10</sup>. The nurse is interested in these criteria but also that the product is available in different sizes, is easy to use, has minimal adverse effects and can be used appropriately with compression therapy<sup>9</sup>. Evaluating the acceptability of a product by surveying patients' and nurses' views is a crucial part of product testing. As specialist wound care nurses are experienced in using a variety of products to treat complex wounds, they provide valid evaluation of new products. The aim of this study was to examine the user acceptability for patients and nurses for three new types of keratin wound dressing and with the concurrent involvement of the manufacturer as part of the product development.

## Background to the wound dressing product

The wound dressing products evaluated contain keratin, which is a naturally occurring protein found extensively in hair, skin and nails. Natural ingredients, based on intact keratin proteins, designed and manufactured by Keratec, are currently used as active ingredients in a wide range of personal care formulations and dietary supplements. Measurement of keratin performance has provided strong indication of the potential benefits of the application of keratin in a wound environment and has established the safety of using keratin for wound treatment<sup>11,12</sup>. In particular, *in vivo* studies have suggested that intact, keratin, protein-based products can stimulate cellular migration into a wound to improve the speed of wound healing<sup>13</sup>. This encouraging evidence formed the basis to develop keratin into wound dressings and to study both the acceptability of the product and the efficacy of the dressings for wound healing<sup>14</sup>.

## Research aims

To gather user perceptions and feedback on the acceptability of these new dressings, the following aims were identified:

- To identify the perceptions of wound care nurses about the keratin wound care dressing.
- To identify the perceptions of patients who are receiving wound dressings for leg ulcers, about the keratin dressings.
- To compare perceptions of nurses and patients regarding existing dressings with keratin dressings.
- To provide a guide for future keratin dressing development by taking into account user preferences.

## Methods

### Sample

The keratin dressings were used on a convenience sample of 23 patients presenting to a nurse-led Wound Management Clinic in a community-based nursing service in Christchurch, New Zealand. Patients attending the Wound Management Clinic were approached to take part in the study and they gave written informed consent. The study was approved by the Regional Ethics Committee. Patients were selected with a range of non-infected chronic venous, arterial and diabetic wounds, with varying levels of wound exudate. Exclusion criteria included: a wound infection, patients less than 18 years old and those patients unable to remain in the trial for 12 weeks. The study ran for 12 weeks, with recruitment in the first four weeks. Criteria for patient withdrawal were developed as follows: patients who developed significant infection in the wound were withdrawn until the infection was resolved. Any significant deterioration of the wound was reported promptly to the principal investigator and the patient was withdrawn. If the patient left the Wound Management Clinic for any reason, then they were withdrawn. However, all patients enrolled in the study completed the trial period.

### Dressing types

The keratin dressings used were termed 'gel', 'matrix' and 'foam'. The gel was used for dry to moderate levels of exudate, the matrix for light to heavy exudate and the foam for moderate to heavy exudate. The choice of dressings was at the discretion of the wound clinic nurse and training was provided in keratin product selection. The change of dressing was the only change made to the treatment, except when the ulcer became infected. If the patient developed an infection, other appropriate dressings were used until resolution, when the keratin dressing was reintroduced. There were seven nurses involved in the study and they were experienced, specialist wound care nurses.

### Questionnaires

Two questionnaires were developed specifically for this study, using similar questions for both the patients and nurses. The questions used key indicators, such as ease of application, comfort, patients' adherence to treatment and ease of removal, which are common to other studies<sup>9,15</sup>. Patients were asked to complete the questionnaire at each clinic visit after the dressing change. The questionnaire consisted of nine questions using a four-point rating scale and comments about the dressing and how they found it (Table 1, Questions 1–9).

The nurses' questionnaire was completed after each dressing change and was in two parts. The first part collected additional

Table 1. Percentage of nurses' and patients' views on keratin gel.

	Much less/little less preferable		Little more/much more preferable	
	Nurse	Pt	Nurse	Pt
Q1. Overall, how preferable was the new dressing compared to the old one?	1	7	98*	89*
	Very difficult/difficult to apply		Very easy/easy to apply	
Q2. Overall, how easy was the dressing to apply?	0	1	100	99
	Disagree/strongly disagree		Strongly agree/agree	
	Nurse	Pt	Nurse	Pt
Q3. The patient appeared to find keratin dressing was comfortable to have in place	6	5	94	93*
Q4. It took less time for the dressing to be done (compared to previous ulcer dressing)	7	11	93	87*
Q5. It took more time for the dressing to be done (compared to previous ulcer dressing)	99	77	1	19*
Q6. The patient knows how to look after their dressing	0	0	100	99*
Q7. The dressing stayed in place well	2*	0*	97	99
Q8. I would be happy to use the dressing again	1*	3*	97	96
Q9. For repeat dressings: I found that the keratin dressing was easy to remove	3*	8*	86	86

Note: \* indicates some questions omitted and totals not 100%

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clinical information about the type of ulcer, the product used before the study, the keratin product and the secondary dressing being used. The second part asked the nurses' opinions about the keratin dressing using the same questions as the patients. This provided comparability between users and increased the validity of the study. Nurses had open-ended questions to complete, firstly to comment on usability of the dressing, especially in relation to comfort, desiccation, maceration, trauma, eczema, sensitivity and conformability. The second question asked "What improvement/ alterations/ additions would you like to see with regard to keratin dressings?" This provided qualitative data to highlight individual perceptions and these responses were analysed using thematic analysis. Questionnaires were analysed for both patients' and nurses' perceptions of the dressings overall and separately for each dressing type.

## Results

### Patient and nurse characteristics

There were 23 patients with venous and mixed arterial/venous ulcers enrolled in the study, yielding 272 nurse

questionnaires and 255 patient questionnaires. Although the efficacy of the dressing products was not being researched, 77% showed improvements in their wounds and 18% healed completely. This low healing rate reflects that many patients entered the study with recalcitrant wounds, which were complex and failing to heal, despite compression therapy. Some of the wounds did not heal as expected due to infection; however, infection control monitoring showed there was an identical infection rate in non-trial patients both at the clinic and in the community. The nurses who took part were all experienced wound clinic nurses.

### Patient and nurse summary for all dressing types

Overall, 91% of patients and 86% of nurses preferred or very much preferred the keratin dressings. Thirty-five per cent of nurses and patients overall chose "very much preferred" for the keratin dressings compared to other dressings they had used. Even allowing for a positive bias towards the trial dressings, this result is clinically significant. The gel and foam dressings were considered easy to apply or remove and, compared to other dressings, were quicker to change. The

Table 2. Percentage of nurses' and patients' views on keratin foam.

	Much less/little less preferable		Little more/much more preferable	
	Nurse	Pt	Nurse	Pt
Q1. Overall, how preferable was the new dressing compared to the old one?	5	2*	95	97
	Very difficult/difficult to apply		Very easy/easy to apply	
Q2. Overall, how easy was the dressing to apply?	4	4	96	96
	Strongly disagree/disagree		Strongly agree/agree	
	Nurse	Pt	Nurse	Pt
Q3. The patient appeared to find keratin dressing was comfortable to have in place	4*	4	94	96
Q4. It took less time for the dressing to be done (compared to previous ulcer dressing)	10*	16*	89	82
Q5. It took more time for the dressing to be done (compared to previous ulcer dressing)	89*	71*	8	21
Q6. The patient knows how to look after their dressing	0*	1*	99	98
Q7. The dressing stayed in place well	2*	0*	95	98
Q8. I would be happy to use the dressing again	1*	0*	95	98
Q9. For repeat dressings: I found that the keratin dressing was easy to remove	5*	6*	86	90

Note: \* indicates some questions omitted and totals not 100%

most noticeable results were that the keratin dressings were considered comfortable and stayed in place well.

The results in Table 1 indicate a similarity overall between the patients' and nurses' views on the gel product in Questions 2, 3, 4, 6, 7, 8 and 9. In Question 1, 98% of nurses preferred the gel overall compared to 89% of patients. For Question 5, more patients (19%) saw the product as taking more time compared to the nurses (1%).

The results in Table 2 indicate a similarity overall between the patients' and nurses' views on the foam product except Question 5. For Question 5, more patients (21%) saw the product as taking more time compared to the nurses (9%).

The results in Table 3 indicate a wider range of views for the matrix dressing compared to the others. There was similarity overall between the patients' and nurses' views on the matrix product in Questions 3, 7, 8. For Question 1 more nurses (33%) didn't prefer the matrix dressing compared to the patients (14%). In Question 2 more nurses (34%) saw the matrix as more difficult to apply compared to patients (9%). In relation to Question 4, more nurses (46%) disagreed the matrix took less time compared to the patients' view (27%). This view is supported in Question 5, where 41% of the nurses agreed it took more time compared to 32% of the patients. This could

be linked to the nurses' view (13%) in Question 9 that the matrix was not easy to remove. Comments on the matrix dressing did identify some usability problems and this may have influenced the nurses' views on application, removal and time taken.

### Comments on dressing from nurses

The nurses were asked to comment on the dressing and any improvements or alterations they would like to see made. This is an important part of product testing, as often in-trial modifications are needed and can be re-evaluated straight away. Comments indicated that the gel product worked well, it was easy to use and no immediate changes to the product were indicated. Regarding the foam dressing, some in-trial modifications to the backing improved the absorbency and decreased the small amount of lateral maceration that was occurring. Although not a major problem, it would be better to make the foam dressing slightly softer, especially at the edges. Comments about the matrix dressing indicated that product should be altered to dissolve more quickly and completely. The product was too dry and rigid out of the packet and required immersion in water to soften it and improve usability. There were several comments regarding the need for an antimicrobial product in the range.



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Table 3. Percentage of nurses' and patients' views on keratin matrix.

	Much less/little less preferable		Little more/much more preferable	
	Nurse	Pt	Nurse	Pt
Q1. Overall, how preferable was the new dressing compared to the old one?	33*	14*	64	82
	Very difficult/difficult to apply		Very easy/easy to apply	
Q2. Overall, how easy was the dressing to apply?	34*	9	66	91
	Strongly disagree/disagree		Strongly agree/agree	
	Nurse	Pt	Nurse	Pt
Q3. The patient appeared to find keratin dressing was comfortable to have in place	7*	9	90	91
Q4. It took less time for the dressing to be done (compared to previous ulcer dressing)	46	27	53	72
Q5. It took more time for the dressing to be done (compared to previous ulcer dressing)	55	62	41	32
Q6. The patient knows how to look after their dressing	0*	14*	99	84
Q7. The dressing stayed in place well	3*	3*	93	96
Q8. I would be happy to use the dressing again	4*	0*	93	97
Q9. For repeat dressings: I found that the keratin dressing was easy to remove	13	3*	87	91

Note: \* indicates some questions omitted and totals not 100%

## Discussion

There is a wide range of products to promote moist wound healing and the sheer variety can be overwhelming for nurses<sup>4</sup>. It is crucial that both nurses and patients evaluate new products, as each perceives different factors to be important. Nurses are concerned with ease of application and removal, as this may affect wound healing and time taken. Patients are also concerned about comfort, wearability and the ability to complete daily living activities<sup>15</sup>. All three products were rated positively overall by both nurses and patients. There was an overall similarity between the nurses' and patients' perceptions in the areas of usefulness, comfort, time taken, and product preference for the gel and foam products. However, the matrix ratings showed a wider range of views. The matrix was preferred less by 33% of nurses, it was more difficult to apply and took more time. These ratings were supported by the nurses' comments on improving the matrix dressing and the company is making improvements to its composition. When asked if they would be happy to use the matrix dressing again, 93% of the nurses

agreed, indicating a positive response towards the product. The patients found the matrix dressing comfortable, so their preference for this dressing remained high. In summary, this study has provided very important product information for the manufacturer on the acceptability of three new wound dressings.

## Limitations

Although the study provided some very useful data on the products, there were a number of limitations. Firstly, perceptions of new things are influenced by the 'novelty' effect, where a person may be enthusiastic or sceptical about a new product and this may influence their perceptions and behaviours<sup>16</sup>. Perceptions (either positive or negative) held by the researcher or the nurse may influence the views of patients and vice versa. Patients with chronic leg ulcers may be more optimistic about a new product because they hope it will be effective. However, one factor that may mitigate this 'novelty' effect was the study duration of 12 weeks. Having a longer trial is supported by researchers<sup>9,15</sup>, who indicate that

a six-week trial is not long enough for a thorough evaluation of product acceptability.

Another factor to consider was that the previous dressings used on patients were not documented consistently. Within the Wound Clinic, moist wound healing and compression bandaging is the standard treatment for patients with venous ulcers. However, patients referred from other providers may have experienced adherent dressings and so keratin would definitely be more preferable.

The questionnaire covered criteria (for example, comfort, ease of application and so on) that have been evaluated in other product testing research<sup>9,15</sup>. Piloting the questionnaire before use may have indicated a three-point rating scale (for example, less comfortable, about the same and more comfortable) was more objective than a four-point rating scale, which was open to individual interpretation. Researchers<sup>15</sup> have discussed how some criteria (for example, patient adherence to the treatment protocol) are difficult to assess with any degree of objectivity.

## Implications for practice

This study has highlighted the importance of patients and nurses being involved in new product testing to ensure the wound product meets the criteria of comfort, duration, timeliness, ease of use and overall preferability. Feedback has led to modifying the matrix dressing, to improve the product. Ongoing user feedback is crucial to the applicability of the product to different skins, types of wounds and practice contexts.

## Conclusion

Many new wound care products have been developed and trialled over the last 20 years to improve the efficacy of leg ulcer healing. A key part of product development is to evaluate the product acceptability for patients and nurses. Patients are concerned with comfort, the dressing staying in place, fitting in with footwear and lifestyle, easy removal, time taken for the dressing and overall satisfaction rating. Nurses also have to consider ease of application and removal, as this may affect wound healing and time taken. The results showed that both patients and nurses preferred all of the dressings over the respective previous products. For the gel and the foam, the preference was virtually unanimous for both nurses and patients. For the matrix, the preference was still very strong (82% for patients and 64% for nurses) and for the minority of nurses who did not prefer the matrix, the main reasons were that it was more difficult and time-consuming to apply. These ratings were supported by the nurses' comments and the manufacturer is making improvements to its composition. However, the patients found the matrix

dressing comfortable, so their preference ratings were high. In summary, this study has provided very important product information for the manufacturer on the acceptability of three new wound dressings.

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