Wound management using a superabsorbent foam dressing: outcomes of a post-CE-mark primary care clinical evaluation

KEY WORDS
- Comfort and conformability
- Exudate management
- Foam superabsorbent dressing
- Product evaluation

In this post-CE-mark evaluation of 74 patients with wounds of various aetiologies thirty-eight (71.6%) wounds closed or showed a reduction in surface area compared with baseline. Seventy-seven per cent of patients and clinicians stated that the dressing was considered to be either 'good' or 'very good' in terms of exudate management.

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In a previous article, Glover (2014) presented feedback from a series of meetings convened to discuss the challenges of assessing and describing wound exudate, and the ability of both foam and absorbent dressings to manage exudate. Participants were asked to outline what they believed to be the characteristics of both genres of dressing based on their clinical experience (Glover, 2014).

After this discussion, the participants were given a CE-marked bordered foam absorbent dressing, KerraFoam® Gentle Border (KFGB) to examine. At the time the meetings were held, this dressing was available on the market but the manufacturers, Crawford Healthcare Ltd (UK), wanted to improve its properties; they planned to use the identified positive characteristics of foam and superabsorbent dressings, the identified exudate management challenges, and participants' previous experiences of the dressing as a basis for improvement.

The reformulated dressing is listed in the Drug Tariff as a foam dressing but is unusual in that it combines both foam and superabsorbent layers. Thus, it absorbs and retains (locks in) exudate (Stephenson et al, 2014), maintains a moist wound environment, and helps reduce risk of skin maceration. In addition, other reported benefits include (Crawford Healthcare, 2014):

- Lateral wicking technology which increases capacity and wear-time
- A soft silicone adhesive contact layer which prevents painful dressing changes and skin stripping
- Conformability to skin surface
- Comfortable to wear

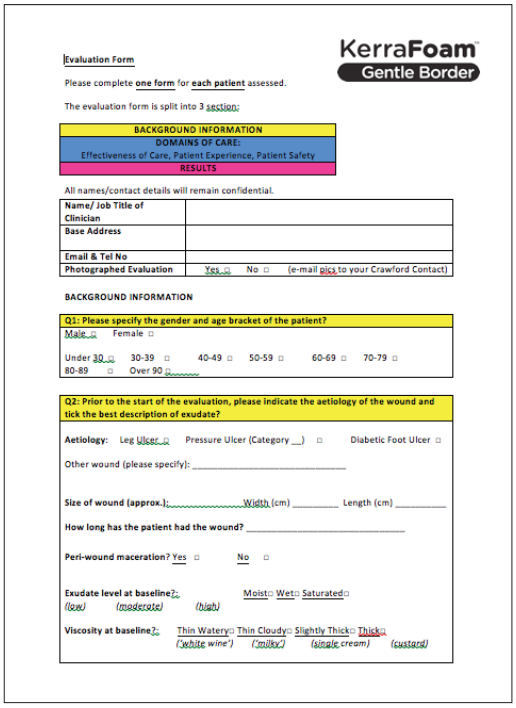
Following this reformulation and the reintroduction of KFGB to the market (with CE mark), a post-marketing surveillance study was undertaken in the form of a service evaluation. Such studies are not comparative, rather they focus on the reported benefits of the dressing to determine if these are met. Thus, while the previous dressings the participants used are recorded, no formal comparison is undertaken.

METHODOLOGY

Thirty clinicians (district nurses and tissue viability nurses) from primary care organisations across the UK participated in the evaluation and reported on 74 patients. The clinicians, some of whom were participants in the meetings discussed earlier, were asked to identify patients with open, exuding wounds previously treated with a different silicone foam dressing, who met the clinical indications (moderate to severely exuding wounds, burn wounds) for use of KFGB.

The primary objective of this evaluation was to determine, according to clinician opinion, the dressing's exudate handling properties and thus it's potential to prevent periwound maceration. Other parameters assessed — wear time, patient satisfaction with the dressing and how they felt it compare with their previous dressing, and clinician satisfaction — were secondary outcomes.

Crawford Healthcare trained clinicians to complete the evaluation form and requested they use the dressing for 4 weeks or until healing, whichever was sooner. The evaluation tool allowed consistent reporting in all parameters using both open and



Evaluation Form

KerraFoam Gentle Border

Please complete one form for each patient assessed.

The evaluation form is split into 3 section:

BACKGROUND INFORMATION
DOMAINS OF CARE:
Effectiveness of Care, Patient Experience, Patient Safety
RESULTS

All names/contact details will remain confidential.

Name/ Job Title of Clinician	
Base Address	
Email & Tel No	
Photographed Evaluation	Yes □ No □ (e-mail pics to your Crawford Contact)

BACKGROUND INFORMATION

Q1: Please specify the gender and age bracket of the patient?

Male □ Female □

Under 30 □ 30-39 □ 40-49 □ 50-59 □ 60-69 □ 70-79 □
80-89 □ Over 90 □

Q2: Prior to the start of the evaluation, please indicate the aetiology of the wound and tick the best description of exudate?

Aetiology: Leg Ulcer □ Pressure Ulcer (Category __) □ Diabetic Foot Ulcer □

Other wound (please specify): _____

Size of wound (approx.): _____ Width (cm) _____ Length (cm) _____

How long has the patient had the wound? _____

Peri-wound maceration? Yes □ No □

Exudate level at baseline?: Moist□ Wet□ Saturated□
(low) (moderate) (high)

Viscosity at baseline?: Thin Watery□ Thin Cloudy□ Slightly Thick□ Thick□
("white wine") ("milky") (single cream) (custard)

Figure 1. The first page of the Product Evaluation form.

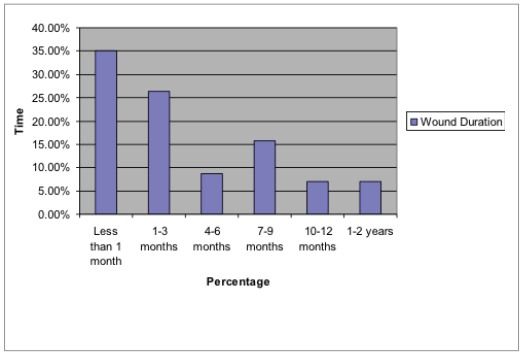


Figure 2. Wound duration.

closed categories; it had been reviewed by a number of independent third parties so data could be comprehensively captured and quantified (*Figure 1*).

Descriptive statistical tests were performed upon the reported data to explore associations between patient demographics, wound aetiology and presentation, and outcomes. All tests were performed using the chi-square test within SPSS 17.0 (SPSS Inc); a p value of under 0.05 was considered to reflect a statistically significant difference. For ease of interpretation, the chi-square test results have been shown simply as the p value.

As this was a service evaluation, research and ethics committee approval was not required, although approval was given by each centre's respective management teams. Local guidelines and procedures were adhered to, including the use of compression therapy where appropriate, although this was not captured in the study.

Clearly, the approach to an evaluation is different to that of a randomised controlled trial; this evaluation was not managed or overseen by a clinical research monitor, which may account for some of the data loss despite follow-up from the company. However, this data loss also reflects its generation as an evaluation rather than a research study; this was a real-time study in primary care.

Baseline parameters

The patient demographics were as follows:

- Gender was reported for 74% (n=55) of patient participants; 55% (n=30) were male, 45% (n=25) female
- Age was reported for 85% (n=60) of patient participants; 55% (n=33) were aged under 70, 45% (n=27) over 70 years old.

Wound assessment

- Seventeen different types of wound were treated; leg ulcers (n=23, 53.5%) were the most common, followed by pressure ulcers (26%, n=11) and diabetic foot ulcers (n=9, 21%) (*Table 1*)
- Wound aetiologies were not equally present in older (over 70 years) and younger patients; most leg ulcers and skin tears occurred within the older patients (x^2=14.71, df (degree of freedom)=4, p<0.01)
- The distribution of wound types was not influenced by gender (x^2=5.44, df=4, p=0.24).
- Wound surface area was reported for 78% (n=58) of patient participants; this ranged from 0.25 cm^2 to 300 cm^2. For analysis these were categorised as large or small (area over and under 10 cm^2 respectively), with 29 wounds in each category
- Wound duration was reported for 77% (n=57) of patient participants (*Figure 2*). Duration varied according to aetiology — leg ulcers were more likely to have been present for over four months (x^2=10.53, df=4, p<0.05), although no association with either the age or gender of the patient was noted. There was a trend for wound size to be larger in leg ulcers and pressure ulcers and smaller in skin tears (x^2=7.91, df=4, p=0.09)

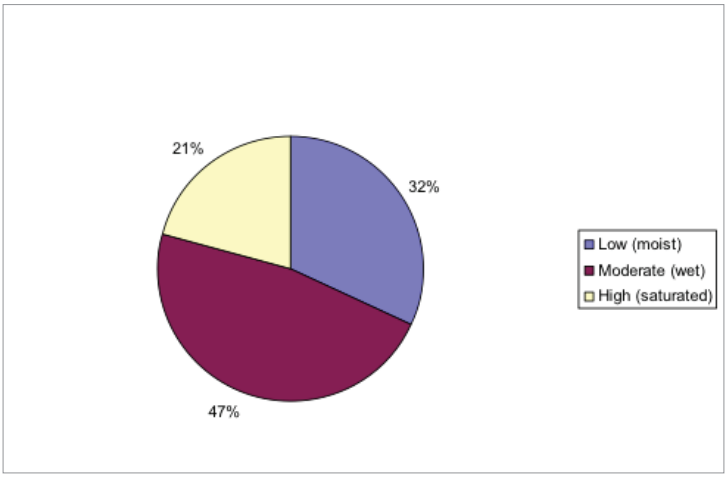


Figure 3. Baseline exudate levels.

Table 1. Reported wound aetiology

Wound type	Number
Leg ulcer	23
Pressure ulcer	11
Diabetic foot ulcer	9
Pin site	1
Skin tear	6
Moisture lesion	1
Surgical wound	4
Abdominal wound	2
Bilateral leg wet eczema	2
Epidermolysis Bullosa	1
Skin graft	2
Traumatic wound	4
Topical ulcer	1
Burn	1
Amputation site	1
Friction burn	1
Nicorandil ulcer	1
Total	71
Missing	3

- Wound size was not related to the age of the patient but interestingly, wounds tended to be smaller in males and larger in women (x^2=6.79, df=1, p<0.01). It is not clear how to interpret this result.

Wound exudate

- Baseline exudate levels were reported on all patients (*Figure 3*). Wounds were typically described as being wet with exudate (47.3%, n=35), with exudate described as either thin and watery (36%, n=27), or thin and cloudy (36%, n=27)
- Periwound skin maceration was observed in 27 (36%) the 74 patients assessed
- Wound exudate was heavier in older wounds (x^2=6.2, df=2, p<0.05), in leg ulcers, pressure ulcers and diabetic foot ulcers (x^2=15.84, df=48, p<0.05); light exudate was associated with skin tears
- Where exudate was present its viscosity was lighter in both young wounds (x^2=7.85, df=3, p<0.05) and in small wounds (x^2=19.99, df=3, p<0.001), whereas exudate viscosity was thicker in leg ulcers, pressure ulcers and diabetic foot ulcers (x^2=22.09, df=12, p<0.05).

Dressings used prior to study

Patients experienced a wide range of other dressing products (*Table 2*); for analysis, these were condensed to Allevyn Gentle Border (Allevyn GB), Mepilex Border and Other. The frequency of dressing changes was grouped into at least every day, 2 to 3 times a week and weekly. Allevyn GB and Mepilex Border dressing changes were more frequent where wounds were larger (x^2=7.08, df=2, p<0.05) or where peri-wound skin maceration was present (x^2=6.78, df=2, p<0.05). Trends approaching statistical significance were noted where Allevyn GB and Mepilex Border were often used with female patients, Mepilex Border more often used where the exudate viscosity was watery and thin, and Allevyn GB used with watery and cloudy exudate.

Other dressing changes prior to KerraFoam GB use were related to the level of exudate with more frequent changes were exudate levels were high (x^2=12.65, df=4, p<0.05). No association was observed between the frequency of dressing change and wound size, aetiology, patient age or gender, the age of the wound the presence of per-skin maceration and the viscosity of wound exudate.

RESULTS

Wound assessment

- Figure 4 shows the wound status for the 72% (*n*= 53) completed evaluations. Thirty-eight (71.7%) patients had their wounds close or reduce in surface area during the evaluation
- Positive outcomes (healing or size reduction) were strongly related to the age of the wound, with younger wounds more likely to have a good outcome (healing, reduction in area) (x^2=12.81, df=1, p<0.001)
- There was no relationship between outcome and patient age or gender, wound type and size, the presence of peri-wound maceration at baseline or exudate level or type at baseline.

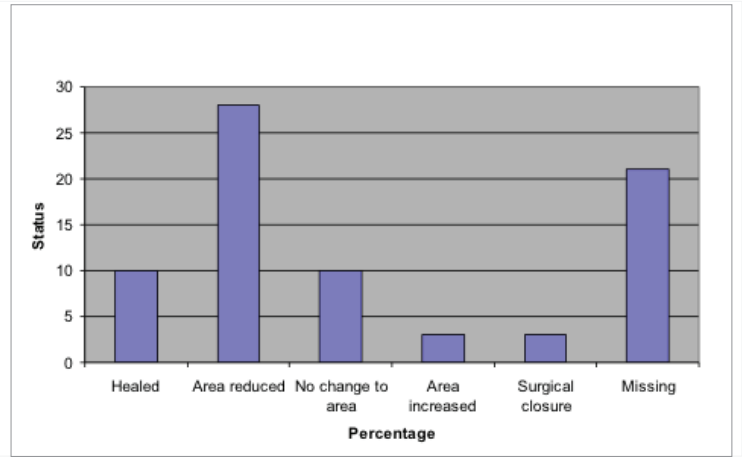


Figure 4. Wound status at study end.

Peri-wound maceration

Post-evaluation, the number of patients with periwound skin maceration had reduced from 27 to nine, the number of patients reported to have wet or saturated wounds reduced from 50 to 17, while the presence of slight to thick slough diminished from 19 to eight patients. Other secondary outcome parameters are outlined in *Figure 5*. Due to denominator changes from the 'before' to 'after' group in each wound appearance group, comparisons were left as descriptive numerical changes.

Clinicians also reported other positive signs in the wounds — less pain (*n*=7), more granulation tissue (*n*=15), reduced size (*n*=28) and a more healthy looking wound in 19 cases.

Negative changes post evaluation of KerraFoam GB were rare, with one and three reports of increased pain and wound size respectively, and two reports of both reduced granulation tissue and a less healthy looking wound. The observations reported by clinicians may not reflect patient numbers as the clinicians were free to select all of the changes present in the wound both positive and negative.

Patient and clinician satisfaction

Clinician and patient satisfaction with the KerraFoam GB dressing was reported. In 56/72 (90.3%) reports, the dressing was considered to be either good or very good in terms of exudate management.

While this was not a formal comparator study, patients and clinicians were asked their opinion

Table 12 Wound dressings applied prior to KerraFoam GB use

Drressing	Number
Allevyn Gentle Border	12
Mepilex Border	19
Tegaderm Foam	4
Inadine/KerraMax	3
Inadine	1
Allevyn	1
Cosmopore	1
Mepore	3
KerraLite Cool	1
Cutimed Sorbact/Promogran/KerraMax Care	1
New wound no previous dressing	4
Opsite	1
Bandage	1
Gauze/crepe	1
Aquacael/Tegaderm	1
Gauze/Mepore	1
Pads/Tubigrip	1
Biatain Silicone	2
Mepitel One/KerraMax Care/Comfifast/KLite	1
Total	59
Missing	15

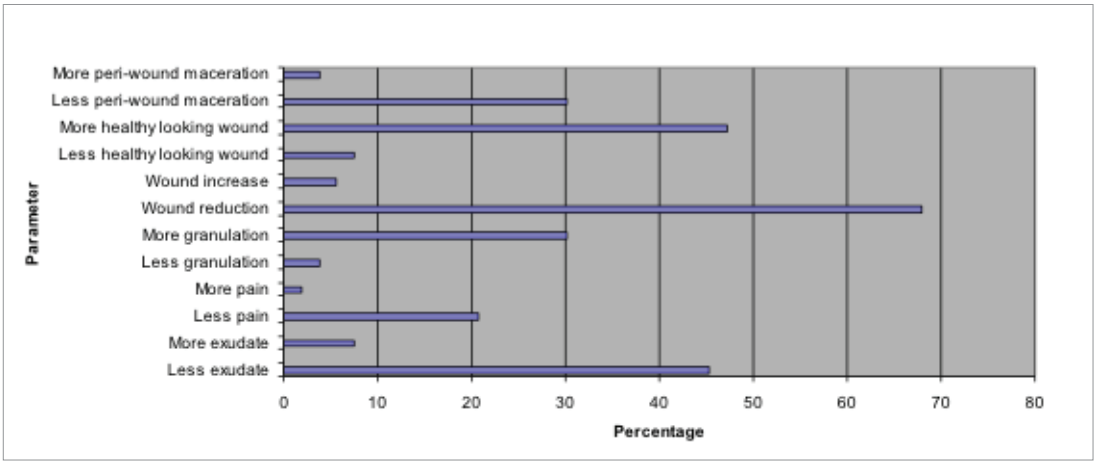


Figure 5. Secondary Parameters at Study End.

on the previous dressing they had experienced and how it rated against the study dressing. For patients the dressing was considered to be as or more comfortable in 65/72 (90.3%) of cases and as or more convenient in 60/71 (84.5%) of cases

Clinicians rated the dressing on eight parameters; feel, comfort and conformability, ability to 'lock away' exudate, patient acceptability, wear time, ability to help heal a wound and its fluid handling properties. Clinicians were free to select as many options as they felt applied to the dressing. Comfort was the most commonly reported response (*n*=36) followed by its ability to lock exudate (*n*=26) and the high acceptability to patients (*n*=22). The options least selected by clinicians were the feel of the dressing (*n*=11), the long wear time (*n*=12) and its ability to help heal wounds (n=16) (*Figure 6*).

Where clinicians were unwilling to use the dressing again (and where negative comments were offered) only three challenges were reported on more than a single occasion — poor retention (*n*=12), unexpected changes in the wound (*n*=3) and increased pain associated with an adverse reaction to the dressing (*n*=2).

Based upon these positive comments, the dressing was considered to have met or exceeded expectations in 51/68 (75.0%) of cases and clinicians would be happy to use the dressing again in 57/70 (81.4%) of cases.

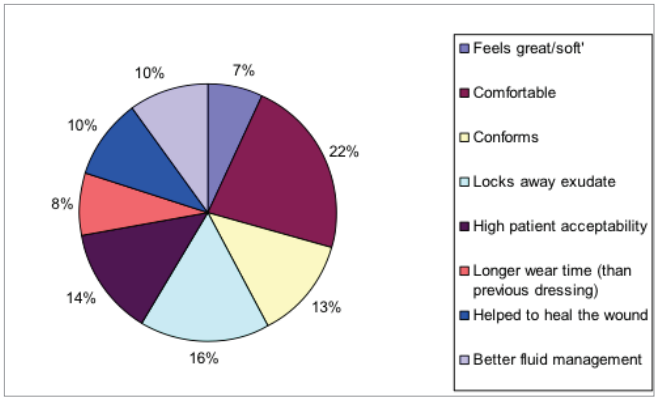


Figure 6. Clinician Reported Parameters

Dressing wear time

- Clinicians were asked to evaluate the dressing for a maximum of 4 weeks or until healing. However, KFGB was used for between 1 and 76 days with 10 evaluations ongoing at the time of data analysis. It is difficult to explain this anomaly; it may be due to incorrectly entering start and finish dates, or for other reasons. Again, as this was an evaluation, data collection was not monitored formally.
- Mean length of KerraFoam GB use was 16 days (standard deviation [sd] 12.75 days) with the median length of product use being 14 days
- Of the 72% (*n*= 53) of completed evaluations, the KerraFoam GB dressing was changed between one and thirty-nine times (mean dressing changes per patient 8.7 [sd 8.4] median dressing changes 6.5). The data indicate that the KerraFoam GB dressing was changed on average 0.57 times per day (sd 0.36) giving a change of dressing around every 2 days
- Eleven patients were able to have their wounds dressed at longer intervals between changes when dressed with KerraFoam Gentle Border

while 55 patients experienced the same frequency of dressing changes through their evaluation of the KerraFoam dressing as they had with the previous dressing.

DISCUSSION

A number of trends were seen between the presence of peri-skin maceration, exudate level and type and wound characteristics; for example peri-wound maceration was more commonly reported in older wounds (x^2=8.34, df=1, p<0.01), in pressure ulcers (x^2=18.32, df=4, p=0.001) and in big wounds (x^2=5.37, df=1, p=0.02).

Wound exudate was heavier in older wounds (x^2=6.2, df=2, p<0.05), in leg ulcers, pressure ulcers and diabetic foot ulcers (x^2=15.84, df=48, p<0.05) with reduced exudate levels seen in skin tears. There was no association between the level of exudate and the age of the wound. Where exudate was present its viscosity was lighter in both young wounds (x^2=7.85, df=3, p<0.05) and in small wounds (x^2=19.99, df=3, p<0.001), whereas exudate viscosity was thicker in leg ulcers, pressure ulcers and diabetic foot ulcers (x^2=22.09, df=12, p<0.05). There were no relationships between wound characteristics such as exudate level and viscosity and patient age or gender.

In the UK, practitioners have wound management products to choose from. Many dressings of various genres (hydrocolloid, foam, alginate, etc) are available from a range of manufacturers. Theoretically, this should make the job of wound management relatively simple; however, knowing which of the dressings is most clinically effective in each genre or between genres can be difficult. This is due to the inherent difficulties in undertaking gold-standard studies such as the randomised controlled trial (RCT). The European Wound Management Association (EWMA) Patient Outcome Group have argued that the randomised controlled trial (RCT), whereby a single intervention is investigated until the primary outcome is achieved, is difficult in wound care because it may be clinically indicated that intervention is no longer the appropriate method of treatment, even though the primary outcome, healing for example, has not been achieved (Gottrup et al 2010).

However, the Cochrane Wounds Group (Bell-Syer et al, 2009) argued that many wound care treatments have been inadequately evaluated using inappropriate study designs, poorly conducted trials and small samples. The group went on to suggest that researchers should address these issues rather than using observational research designs to evaluate wound management product effectiveness, and that there is no reason why RCTs should not be used (Bell-Syer et al, 2009).

To address such difficulty, White (2010) suggests a pragmatic approach in which real-world evidence can be determined from service evaluation data, since such patient populations are both meaningful and representative. In addition, no inclusion or exclusion criteria are required with this approach. Product reviews can help to determine tolerability, effect and patient safety parameters, and to identify side effects. Real-life evaluations on patients in practice provide information on the benefits of a product and its optimal use. This approach is supported by the Healthcare Quality Improvement Partnership (Brain et al, 2011), which suggests that provided an appropriate policy is in place, practitioners can evaluate a treatment or technique that is understood to be safe and effective but new to the organisation, or an existing treatment or technique that is to be adapted for new purposes.

A plethora of evidence generated by wound product reviews exists (McKeeney 2011, Meaume et al 2005, Walker et al 2014, Meuleneire 2009), and organisations are producing internal guidance on the undertaking of wound dressing product reviews (Basingstoke, Southampton and Winchester District Prescribing Committee, 2013; South Western Region, 2012).

Limitations

Various limitations are noted in this evaluation. Participating clinicians were not asked to specify the aetiology of leg ulcer wounds, nor whether or not compression was used.

In addition, as this was not a formal comparative study, rather a product evaluation, a certain amount of clinical and patient subjectivity is inherent when considering the parameters of healing rate, and patient comfort using KFGB and the previous dressing. However, this does not detract from the outcomes.

While there are gaps in the data reported, the robustness of the evaluation's design is evidenced by the identification of anticipated trends; for example, dressing changes pre-use of KFGB were

influenced by high exudate levels, and as anticipated, fewer were required using the KFGB. A number of statistically significant results and trends were observed within the analysis. These included:

- Wound duration varied by wound aetiology, with leg ulcers more likely to have been present for over 4 months ($p<0.05$)
- Wounds tended to be smaller in males compared with females ($p<0.01$)
- Periwound skin maceration was more commonly reported in older wounds, in pressure ulcers and in large wounds ($p<0.01$). Other wounds had less or no peri-wound maceration
- Wound exudate was heavier in older wounds, in leg ulcers, pressure ulcers and diabetic foot ulcers ($p<0.05$) compared with other wounds treated
- Where exudate was present, its viscosity was lighter in both young wounds and in small wounds, whereas exudate viscosity was thicker in leg ulcers, pressure ulcers and diabetic foot ulcers. However, describing exudate accurately is problematic (Glover, 2014), so ascertaining exactly what 'lighter' or 'thicker' mean is difficult
- Dressing changes prior to KFGB use were related to the level of exudate, with more frequent changes when exudate levels were high. Dressing changes using KFGB were less frequent
- Positive outcomes (healing or size reduction) were strongly related to the age of the wound, with younger wounds more likely to have a good outcome compared to wounds of a longer duration
- Following the use of KFGB, peri-wound maceration was reduced compared with the condition of the skin before the evaluation began ($p<0.02$). This observation may simply reflect the progress of the wound over time, but alternatively it may mark superior removal of fluid from the periwound area compared with previously used foam dressings.

CONCLUSION

The data suggest that KFGB was used successfully in most instances, with positive outcomes achieved for the majority of patients. Where the dressing was less successful, the main issue appeared to be retention of the dressing, but the cases where this was reported were few.

The potential for improved fluid management with KFGB should be explored in a comparative study where wounds of a similar age are dressed with KFGB or foam dressings commonly used before the evaluation.

While these preliminary observations require validation in future comparative studies, this service evaluation shows that KFGB could be added to a formulary as requires fewer dressing changes (particularly where exudate levels are high, is comfortable and conformable and is largely pain-free upon removal). WUK

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