The CONTOP multinational study: preliminary data from the UK arm

Linda Russell (on behalf of the UK investigators)

Abstract

Background: This study presents the preliminary findings of UK data from a larger international outcomes evaluation of a silver-releasing foam dressing, Contreet Foam Dressing™ (manufactured by Coloplast A/S). *Objective:* To carry out a comparative outcomes assessment of clinical performance of Contreet Foam *vs* local best practice in the treatment of chronic wounds. *Method:* This study was comparative, open, prospective, parallel, and block-randomised. A total of 82 patients were included and were recruited from chronic wound clinics. Patients were randomised to a 4-week treatment period with either Contreet Foam or local best practice. *Results:* Findings indicate that Contreet Foam has greater ease of application and removal (p=0.0003), enhanced fluid absorption (32% *vs* 56% leakage), leakage control (p=0.0032), odour reduction, and prolonged wear time (4.2 *vs* 3.4 days), and a 50% relative reduction in wound area from baseline during the study. *Conclusion:* These preliminary results support faster wound healing with Contreet Foam *vs* best local practice.

KEY WORDS

Chronic wounds
Silver dressings
Wound healing
Outcomes research
Contreet Foam Dressing

Clinical research produces much needed evidence of comparative product or procedural safety and efficacy. However, the scientific rigor that makes such studies valuable as support for clinical decision-making also isolates them from normal practice, because participants are usually carefully selected based on rigid and specific inclusion criteria. This may mean that the challenging 'real-world' wounds are not included in such studies (Bolton et al, 2004). To assess both the efficacy and effectiveness of a treatment or intervention, a combination of clinical research and outcomes research may lead to more applicable evidence-based wound management.

This study uses an outcomes approach as described by Rapier (1996). Therefore, inclusion of data from patients with wounds seen in everyday clinical practice situations, rather than data from carefully selected patients seen in a more traditional clinical trial, was allowed. Consequently, to obtain clinically- and statistically-significant data, large patient numbers are required. Results originating from outcomes research should be viewed within the context of a wide range of evidence that includes safety studies, randomised clinical trials, and economic evaluations. This allows practitioners to make more informed choices based on a range of information when deciding which new treatments to implement in clinical practice.

The Medicines and Health Care Products Regulatory Agency in Clinicia (2004) suggests that trials for medical device manufacturers should aim to demonstrate that a device works as intended in the appropriate environment, under typical conditions. A medical device must function safely and effectively in the real world. The use of an outcomes research approach is best suited to demonstrate this effectiveness. The results of this study should be evaluated in the light of available clinical trials (Karlsmark et al, 2003; Jorgensen et al, 2005; Rayman et al, 2005) and economic evaluations (Scanlon et al, 2004) on Contreet Foam.

The findings of this UK study represent one country in a larger international study evaluating Contreet Foam. Currently, 619 patients have been included over a period of 18 months, in the international study from specialist wound care clinics in Germany, the UK, Denmark, Italy, Switzerland, Belgium, Slovenia, Brazil and Canada. It is anticipated that the final number of patients recruited to this study should increase towards a target of 1000 over the next 12 months.

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The study is of a rolling nature and is concluded in some countries, including the UK. The data presented here are preliminary UK results with conclusions based upon this information. The early publication of these findings has been undertaken to bring valuable information to the practitioner as early as possible.

Aims

The UK study aimed to carry out an outcome evaluation of clinical performance, and quality of life of an antibacterial, sustained, silver-releasing hydro-activated foam dressing, Contreet Foam (manufactured by Coloplast A/S), *vs* local best practice in the treatment of chronic wounds with delayed healing. The focus was on the following primary endpoints: reduction in relative ulcer area, and assessment of wound odour and leakage.

Study design

The study was designed as a comparative, open, prospective, parallel, block-randomised, international evaluation using an outcomes approach. A total of 82 patients were included in the UK study and were recruited from 12 chronic wound clinics.

Patients were randomised, using a computer-generated list in sealed envelopes, to a 4-week treatment period using either Contreet Foam or local best practice. Contreet Foam is a soft hydrophilic polyurethane foam containing silver as an integral part of its matrix. The silver ions are present in a form that is readily hydro-activated in the presence of fluid or wound exudate with sustained silver-release up to seven days (Larsen, 2002; Lansdown, 2003). Local best practice is comprised of a range of dressings seen in everyday clinical practice in the UK. These dressings varied depending on the practice in each centre in the study. Local wound management protocols ranged from the use of dry dressings to dressings promoting moist wound healing, e.g. hydrocolloids, hydrogels, and alginates (*Table 1*). Antimicrobial dressings, and those promoting moist wound healing, were by far the most frequently used primary dressing types. Wound management was performed in accordance with local protocol and guidelines in order to reflect everyday practice. Compression bandaging was used when indicated for patients with venous leg ulcers in accordance with local guidelines. All practitioners likely to be involved in the care of the patients within clinics and in home-care settings were informed by letter that the treatment assigned by randomisation in the clinic should be adhered to during the 4-week study period. All dressings were changed when judged necessary by the wound care practitioners.

All treatments were carried out in accordance to the manufacturer's instructions for use. The treatment period was four weeks and participants attended the wound clinic at one-week intervals. Patients with chronic wounds, exhibiting delayed healing and producing medium to high levels of exudate, e.g. leg ulcers, pressure ulcers (EPUAP grade II and III; EPUAP, 1999) and diabetic foot ulcers (grade I to III Wagner classification; Wagner, 1981) were included. However, other wound types, such as donor sites and postoperative wounds were included. Wound exudate levels were quantified using Schulze's definitions (2001); i.e. moderately exuding wounds were classified as requiring dressings every second day with a conventional dressing or every third day with a modern absorbent dressing. Heavily exuding wounds were defined as requiring daily or more frequent dressing changes with a conventional dressing or every second day with a modern

Table 1
Classification of wound dressing in the local best practice group

Classification of wound dressing	n=39
MWH-High exudate	49%
Foam/alginates/hydrogel/hydrofibre	n=19
MWH-Low exudate	5%
Hydrocolloid /film	n=2
Traditional	2%
Gauze	n=1
Antimicrobial dressings	44%
(65%, n=11 silver dressings; 35%, n+6 other active dressings)	n=17

Table 2
Inclusion and exclusion criteria

Inclusion criteria	Yes	No
Moderately to highly exuding ulcer		
18 years of age or older		
The ulcer is characterised by at least 1 of the 5 options		
Please indicate characteristics (You may tick more than one)		
1. Delayed healing due to bacteria[a]		
2. Wound with risk of infection[b] (suspected or existing)		
3. Discolouration of the granulation tissue[c]		
4. Clinically infected ulcer[d]		
5. Full foul odour		
These three questions must be answered by 'yes' to allow the patient to be included		

Exclusion criteria	Yes	No
Pregnant or lactating		
Ulcer depth more than 0.5 cm		
Known hypersensitivity or allergy to any content of the dressing used in the study		
Gangrene (diabetic ulcer grade 4 or 5 in the Wagner classification)		
Pressure ulcers grade I or IV		
All questions must be answered by 'no' to allow the patient to be included		

a. Reports of less than 0.5 cm ulcer reduction over the past 4 weeks, no change or an increase in the volume or surface area of the ulcer over the past 4 weeks.
b. E.g. diabetic foot ulcers or sacral pressure ulcers.
c. Granulation tissue that is pale, dusky, or dull in colour, as well as granulation tissue that is dark, deep red.
d. Requiring treatment with systemic antibiotics. Treatment at the discretion of the physician.

Table 3

Baseline characteristics of the patient population

	Contreet Foam (n=43)	Standard care (n=39)
Age (mean years+/-SD)	73 years (+/-11.5)	72 years (+/-12.9)
Gender (%male/female)	47% male/53% female	41% male/59% female
Baseline wound size (median cm^2 +/- SD)	20.4(+/-126)	16.0 (+/-53.6)
Duration of wound (mean years +/-)	2.4 (+/-3.9)	2.5(+/-3.8)

absorbent dressing (Schulze et al, 2001). Wound dimensions were measured using greatest length and greatest width. The inclusion and exclusion criteria are listed in *Table 2* and were relatively unrestricted in order to obtain data relevant to everyday clinical practice.

Statistical considerations

A sample size calculation, based on 80% power and difference of means $\delta=(\frac{\mu_1-\mu_2}{\rho})$ assuming a standard deviation using a two-group t-test, provided a target of 272 subjects per treatment group (O'Brien and Muller, 1983).
To ensure adequate recruitment, and allowing for a drop-out rate of 15%, an arbitrary target of over 600 was set. All data collection forms were completed by the research nurses at the participating clinics. The statistical analyses were carried out using the validated statistical software SAS version 8.12. The obtained data was analysed as intention to treat (ITT) using the chi-square test, Wilcoxon signed rank test, Mann-Whitney's U test and student's t-test (Altman, 1992). The level of significance used was $\alpha=0.05$. P-values less than 0.05 are stated as non-significant (ns) in the results section.

Ethics

This study was carried out in accordance with the requirements of the Declaration of Helsinki (World Medical Association, 2005). Ethics approval was obtained according to the current guidelines from the appropriate research ethical committees (Multi-Centre Research Ethics Committees) and research and development departments at the individual sites where the research was undertaken. Participants were given both verbal and written information about the clinical evaluation and a consent form was signed before recruitment to the study. They were also informed of their right to withdraw from the study at any time and given 24 hours to make a decision.

Results

A total of 82 patients were included in the UK study. Of these patients, 43 were randomised to the Contreet Foam group and 39 patients to the local best pratice group. Seven patients in the Contreet Foam group withdrew during the study including one patient, where ulcer deterioration was reported as an adverse event, four due to insufficient treatment effect, one was admitted to hospital and one developed an MRSA infection. Two patients in the local best practice group withdrew during the study including one patient, where severe inflammation was reported as an adverse event and the other due to excessive leakage of exudate from the dressing. The baseline characteristics of the patient population in the Contreet and local best practice groups are presented in *Table 3*.

As expected when using a randomised study, the patient population was equally distributed in terms of wound type and location (*Figures 1a and b*), with no statistically significant differences between the two treatment groups at study commencement (*Table 3*). The most common wound types were leg ulcers (81% in the Contreet Foam group and 78% in the standard care group) located on the lower leg or ankle (*Figures 1a and b*). Some patients in the local wound management group were treated with two or more dressings simultaneously. The classification of dressings used in the local best practice group is shown in *Table 1*.

Healing and wound bed appearance

The median relative wound area from baseline in the Contreet Foam group decreased in size by 50% compared to 25% in the non-Contreet group over a 4-week period of treatment (*Figure 2*). A literature review by Flanagan (2003) indicates that percentage of area reduction is an important indicator in differentiation between healing and non-healing wounds. It concludes that a 20–40% reduction of wound area between 2–4 weeks is likely to be a reliable predictive indicator of healing, the efficacy of this has particularly been demonstrated for venous leg ulcers (Flanagan, 2003). From these considerations, it can be suggested that a relative wound area reduction of 25% in the standard care group indicates that the wounds in this group are not responding as well to treatment. Conversely, a 50% relative wound area reduction shows that patients in the Contreet Foam group are responding particularly well to treatment, indicating that Contreet Foam is more effective in promoting wound closure ▸▸

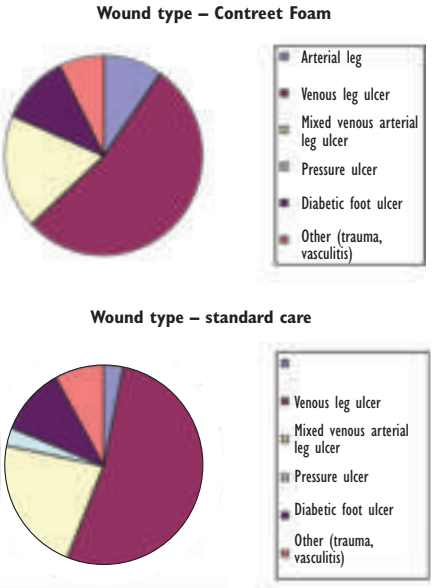

Figure 1a. Wound type for Contreet Foam and local best practice groups.

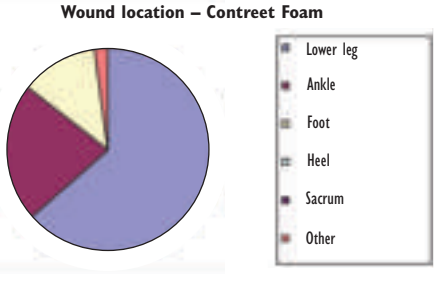

Figure 1b. Wound location for Contreet Foam.

and healing than the dressings used in the local wound management group.

The progress of healing during the study was assessed by nurse researchers using a subjective ordinal scale and the results are shown in *Figure 3*. A total of 5% (n=2) of patients in the Contreet group healed completely during the four weeks of the study compared to 3% (n=1) in the local best practice group. In the Contreet Foam group, 42% of the patients (n=18) experienced 'marked improvement' compared to 28% (n=11) in the local best practice group.

Exudate management

The amount of exudate in chronic wounds can be a barrier to healing (Enoch and Harding, 2003). Due to their inflammatory state, chronic wounds often produce copious amounts of exudate, and this may be increased further in wounds that are heavily colonised or infected by bacteria (Enoch and Harding, 2003). It is recognised that excessive exudate production can be detrimental, causing maceration and excoriation of the surrounding skin and may lead to infection, increased odour and hypersensitivity (Schulze et al, 2001).

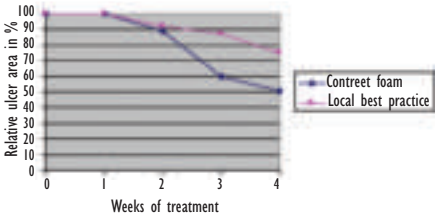

Figure 2. Median relative ulcer area.

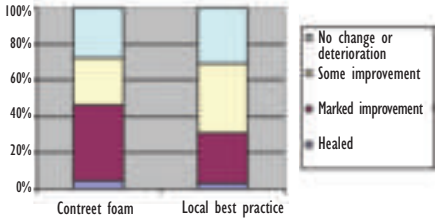

Figure 3. Wound progress over 4 weeks (subjective assessment by practitioner.

Table 4
Reasons for dressing change (participants could have more than one reason)

	Contreet Foam	Standard care
Leakage	32%	56%
Saturation with exudates	22%	25%
Max. wear time exceeded (according to instructions for use)	39%	25%
Other	19%	11%

The exudate level produced by wounds in this study was assessed by nurse researchers by visual inspection using a 4-point verbal rating scale. This method has been shown to correlate with objectively measured exudate production (measured by weighing used dressings) (Karlsmark et al, 2004). This study shows a non-significant reduction in exudate level in the Contreet Foam group, which was not observed in the local best practice group. This could be due to a decreased bacterial load resulting from sustained silver release from the Contreet Foam. *Figure 4* shows the exudate level of the wounds in the two treatment groups during the study.

Dressing performance

Large volumes of uncontrolled exudate may cause leakage from dressings and staining of the patient's clothes. This can cause considerable distress and limit patient activities, which can have a major psychosocial impact on both patients and carers (Naylor, 2002). Leakage was the main reason for dressing change in 32% of the patients in the Contreet Foam group, compared to 56% in the local best practice group suggesting that the use of Contreet Foam is likely to improve the patient's overall quality of life (ns). The mean wear time for Contreet Foam was found to be 4.2 days compared to 3.4 days in the local best practice group (*Figure 5*). Although the difference is slightly less than a full day, in clinical practice this suggests that wounds dressed with Contreet Foam require fewer dressing changes. This should save both the nurses' and patients' time and reduce the amount of dressings needed over a given treatment period. The main reasons for dressing changes during this study are listed in *Table 4*.

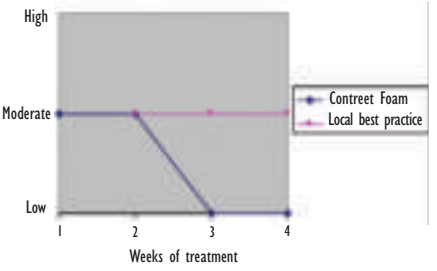

Figure 4. Exudate level.

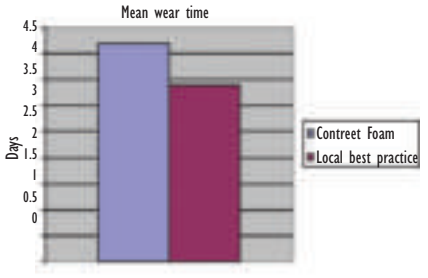

Figure 5. Mean wear time for Contreet Foam and local wound management group.

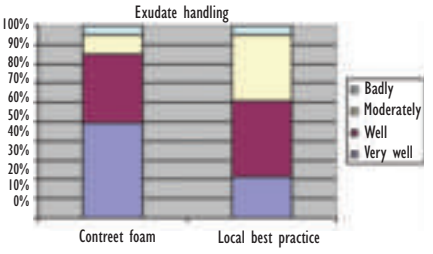

Figure 6. Assessment of exudate handling (subjective assessment by local practitioner.

The results show that more than half of the patients in the local best practice group experience leakage compared to less than a third in the Contreet Foam group (ns). *Figure 6* demonstrates to what extent the dressings in each treatment group were capable of handling wound fluid.

The exudate handling was measured on a 4-point ordinal scale by the nurses and a statistical significant difference was found between the two treatment groups in favour of Contreet Foam suggesting more controlled exudate handling in this group (p=0.0032). The condition of the peri-ulcer skin is seen in *Figures 7* and *8* which show how the condition of the skin surrounding the ulcer improved in the Contreet Foam group during the 4-week evaluation period.

After four weeks, the condition of the peri-ulcer skin was normal for approximately 40% of the patients treated with Contreet Foam compared to 31% of the patients in the local best practice group. A reduction in erythematous peri-ulcer skin of 62% of cases was observed in the Contreet Foam group compared to a reduction of 12% in the local best practice group (ns).

The overall ease of dressing application and removal in the two treatment groups was assessed by the research nurses and rated on a four-point ordinal scale. Ease of dressing application ($p=0.0003$, Mann-Whitney's U test) and removal ($p<0.0001$, Mann-Whitney's U test) was rated as 'very easy' in the Contreet Foam group compared to 'easy' in the standard care group. This demonstrates statistical significance for both dressing application and removal when using Contreet Foam compared to local best practice.

Use of systemic antibiotics

In the UK, chronic wound patients receive significantly more antibiotics than matched non-wound patients (Howell-Jones et al, 2005). The increasing level of bacterial resistance to traditional antibiotics and the isolation of organisms with minimal antibiotic sensitivity are stimulating the current interest in silver products in chronic wound care (Driver, 2005). Silver ions are biocidal at very low concentrations due to the ability of microbial cells to absorb and concentrate silver from very dilute solutions (Thomas, 2004). By using silver dressings on critically colonised wounds, or, preventively on wounds in danger of infection, it can be hypothesised that the use of antibiotics may be reduced in the long term. The prescribing pattern of systemic antibiotics in the two treatment groups during the 4-week study period is presented in *Figure 9*.

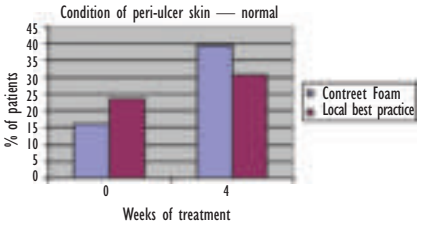

Figure 7. Condition of peri-ulcer skin — normal.

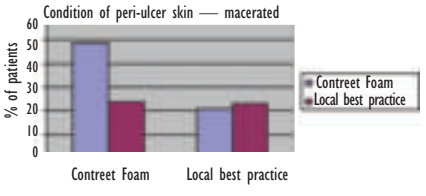

Figure 8. Condition of peri-ulcer — maceration.

The data clearly shows a reduction in systemic antibiotic treatment of 63% (n =7, dropped to 2) in the Contreet Foam group over the 4-week treatment period, compared to a minor reduction of 4% (n=7, dropped to 6) in the local best practice group. These results suggest that Contreet Foam may reduce the use of systemic antibiotics in patients with chronic wounds.

Wound odour

Malodorous wounds have a big impact on the patients' psychological state and social life. In some cases, patients refuse to leave the house or block offers of help and visits to their homes, whereas others are nauseated by the smell of the wound and lose their appetite (Benbow, 1999). One of the main reasons for offensive odour in a chronic wound is multiplication and colonisation of bacteria (van Toller, 1994). At commencement of the study, some wound odour was noted by nurses in both treatment groups. However, after the first week of treatment the odour disappeared in the Contreet Foam group, whereas no odour reduction was detected in the local best practice group until after the third week (*Figure 10*).

The rapid disappearance of odour observed in the Contreet Foam group compared to the local best practice group could indicate that the sustained silver release from Contreet Foam eliminates bacteria from the wound surface faster.

Conclusion

These preliminary results point to clinically important findings for chronic wound care. The combination of silver with absorbent foam, as in Contreet Foam, has been found to have a number of significant benefits. Notably, a reduction of 50% in median relative wound surface area was achieved in the Contreet Foam group compared to 25% in the local best practice group during the 4-week treatment period. This suggests that the chronic wounds in this study respond better to treatment with Contreet Foam than to a variety of local wound care treatments. Contreet Foam exhibited a superior fluid handling capacity resulting in fewer dressing leakages and improved skin condition. It also performed more effectively in the patient-related quality of life parameters that were assessed during this study. The dressing wear time was approximately one day longer in the Contreet Foam group than in the local best practice group, which should save nursing and patient time, as well as reduce the amount of dressings required over a given treatment period as also seen in the study by Scanlon et al (2004).

Contreet Foam is in this study evaluated against local best practice which can be identified as a weakness of the study. However, the reason for this is that wound care is not, and never will be, standardised or consistent in clinical practice. It is important to investigate what the treatment outcomes are in everyday clinical practice. ▸▸

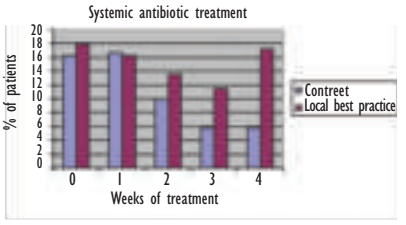

Figure 9. Systemic antibiotic treatment.

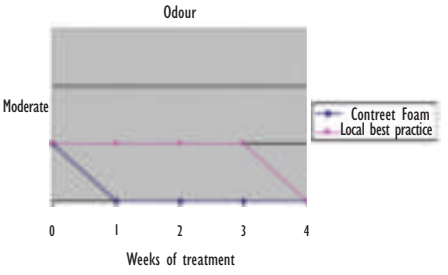

Figure 10. Wound odour.

In a classical, clinical, randomised study, Contreet Foam has been shown to be an effective treatment, reducing wound area over a 4-week period by 45%, while showing excellent exudate handling and odour reduction properties (Price et al, 2004; Scanlon et al, 2004; Sibbald et al, 2004). These findings have been confirmed in this outcomes study which has evaluated patients with chronic wounds in real-life settings. This study provides evidence that Contreet Foam may reduce the need for systemic antibiotics to treat local infection in chronic wounds.

This UK sample of 82 patients is a subset of the larger international Contreet Foam study which will be reported on in Autumn 2005. These UK results are very encouraging as they already demonstrate enhanced fluid absorption, leakage control, odour reduction and prolonged wear time of Contreet Foam. This suggests that Contreet Foam has several important patient-related quality of life benefits, which will hopefully become clear when the results of the multi-national study are analysed. **WUK**

Acknowledgements

Investigators: Mr Asit Kumar Kar, Consultant Surgeon, Scunthorpe General Hospital, Scunthorpe; Caroline Farrant, Wound Care/ Lymphoedema Clinical Nurse Specialist, Amesbury Health Centre, Amesbury; Denese Freshwater, Specialist Nurse for Wound Care, Bedford Primary Care Trust, Bedford; Pam Kirby, Lead Nurse Vascular/ Tissue Viability Team, Nurse Lead Outpatient Clinic, Kings Mill Hospital, Nottinghamshire; Linda McCauley, Clinical Nurse Specialist, Hurst Road Clinic, Walthamstow; Purnima Rishi, Lead Podiatrist in Diabetes, Warrior House Health Centre, Castle Point and Rochford NHS PCT, Essex; Linda Russell, Tissue Viability Nurse Specialist, Queen's Hospital, Staffordshire; Adrienne Taylor, Tissue Viability Nurse, Salford Royal NHS Trust, Hope Hospital, Salford; Nicci Kimpton, Tissue Viability Nurse, St Lawrence's Hospital, Bodmin; Gill Wicks, Tissue Viability Specialist Nurse, Trowbridge Community Hospital, Adcroft Street, Trowbridge; Robin Cooper, Wound Care Specialist, Shakespeare House Health Centre, Basingstoke; Leslie Robinson, Vascular Nurse Practitioner, Cumberland Infirmary, Carlise

Key Points

- A study was carried out to compare the dlinical performance of Contreet Foam *vs* local best practice in the treatment of chronic wounds.
- Preliminary findings support faster wound healing with Contreet Foam than with best local practice.

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