Randomised clinical trial comparing Hydrofiber and alginate dressings post-hip replacement

- **Objective:** To compare the performance of Hydrofiber and alginate dressings used in the treatment of primary hip arthroplasty wounds.
- Method: Patients were randomised into one of two groups, receiving either a Hydrofiber or an alginate dressing. Outcome measures, assessed by daily observations, included skin damage (erythema, blisters and skin injuries) and the dressing's ability to handle exudates. Photos of the dressing and the skin area around wounds were taken. Patients noted skin problems, discomfort at mobilisation and pain at dressing removal.
- **Results:** In the alginate group, there were fewer blisters in the wound area compared with the Hydrofiber group (7% versus 18%, p=0.03). During dressing removal, fewer patients in the alginate group reported pain than patients in the Hydrofiber group (2.1% versus 15%, p=0.01).
- Conclusion: We recommend the use of both dressings following total hip arthroplasty, although the alginate would be our first choice, as we found fewer blisters when using alginate dressings as opposed to Hydrofiber dressings.
- Conflict of interest: None.

blister; erythema; skin injury; wound care; patient comfort; osteoarthritis of the hip

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ollowing arthroplasty, the surgical wound is commonly clean and heals without complication.¹ However, when using implants, infection control is a critical concern.² Wounds with implants provide a favourable environment for microbial colonisation, and problems that can be dependent on differences in standard of care, such as blistering, persistent leakage and infection are commonly reported.²,³ The occurrence of blistering in orthopaedic wards varies greatly, from 2.3% to 60%.¹,⁴ Blisters may cause prolonged hospital stays, multiple dressing changes and possibly increase the risks of superficial and deep infection.¹,²,²,+7

A huge range of dressings are available for surgical wounds, with different dressing types giving different results in terms of skin problems, exudate handling and patient comfort. Wear times also vary, and numerous dressing changes might lead to a higher prevalence of infection.⁸

Trials comparing 'active' modern dressings, such as alginate and Hydrofiber, with 'passive' conventional wound dressings, such as gauze and central pads, often conclude that modern dressings are the better option as wound healing may be enhanced in a moist environment.^{9–11}

When used on chronic ulcers or wounds left to heal by secondary intention, Hydrofiber dressings have been shown to be easier to apply and remove, less adherent to the wound bed, have better wear times and cause less pain on dressing removal when compared with alginate dressings.12 However, the results of studies on their use on clean surgical wounds left to heal by primary intention are more diverse. One trial did not find any significant differences in patient comfort and wound complications between Hydrofiber and a central pad dressing (Mepore, Mölnlycke Healthcare, Gothenburg, Sweden),13 whereas other trials found the Hydrofiber dressing was superior to a central pad (Mepore) and a non-woven dressing (Cutiplast, Smith & Nephew, Hull, UK) in terms of blister rate and patient comfort following lower limb arthroplasty.^{2,14} Modern dressings cost more than conventional dressings and to defend their use, we need to be able to show that they produce better clinical results in terms of skin status and comfort.

In our hospital, we carried out an internal audit of wound care post-hip arthroplasty, where standard care involved the use of a conventional dressing (Mesorb, Mölnlycke Healthcare, Gothenburg, Sweden) covered with self-adhesive fabric (Mefix, Mölnlycke Healthcare, Gothenburg, Sweden). Although the deep infection rate after 30 days was low (0.4%), the blister/skin injury rate was 42%, which caused us concern. Changing the conventional dressing to an alginate dressing resulted in a significant reduction in blister/skin injury rate, from 42% to 15%, and improved patient comfort.¹⁵

Reported advantages of Hydrofiber dressings over

alginates, led us to consider changing to a Hydrofiber dressing.12 However, as we found no randomised trials compared these two types of dressing in an orthopaedics context, we planned this large randomised trial before making the decision. When searching for relevant randomised trials, our search strategy was to look for medical subject headings (MeSH) by performing simple searches in Medline, for 'blisters and hip', 'dressings and hip', 'Hydrofiber', 'hydrofibre' and/or 'alginate'. Furthermore, we searched in Medline, PubMed, Embase, British Nursing, Cochrane, Clinical Evidence and Google Scholar, combining the MeSH terms 'wound healing', 'arthroplasty', 'replacement', 'hip', 'hip prosthesis', 'prosthesis implantation', 'coxa', 'lower limb arthroplasty', 'hip fracture', 'dressing', 'bandages', 'adhesives', 'blister', 'skin blisters', 'bulla', 'bullous lesions', 'skin injury', 'erythema', 'alginates', 'tegaderm alginate', 'tegagen alginate', 'calcium alginate', 'sorbsan', 'kaltogel', 'kaltostat', seasorb', 'algosteril', 'melgisorb', 'algisite', aquacel', 'Hydrofiber' and 'hydrofibre' with 'and/or'. Some MeSH terms were combined with '/ae' (ae = adverse effects), for instance 'adhesives/ae', to narrow the search to negative effects of the glue in dressings.

The null hypothesis was that there is no difference in skin status or in the risk of wound complications following use of these two dressings.

Materials and method Setting and recruitment of participants

All patients admitted for primary hip arthroplasty between January and November 2008 at Kysthospitalet i Hagevik, an orthopaedic hospital in Norway, were eligible for inclusion in the trial. The only exclusion criterion was reluctance to participate.

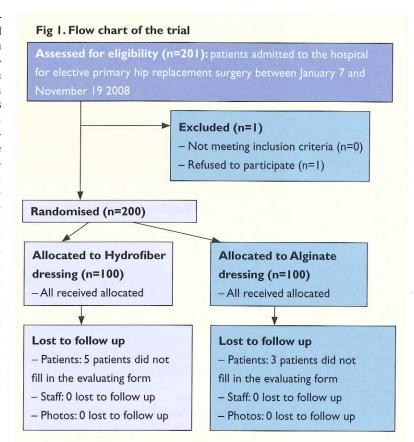
On admission, patients received verbal and written information about the trial from hospital staff; those who participated gave written, informed consent. Approval was granted by the regional ethics committee (registration number: 221.07)

Randomisation procedure

Patients were randomised to receive either a Hydrofiber dressing (Aquacel, ConvaTec, Skillman, NJ, US) or an alginate dressing (Tegaderm Alginate*, 3M, Bracknell, UK). Two members of hospital staff, who were in no other way connected to the trial, prepared the same number of cards with either 'Aquacel' or 'Alginate' written on them, and then put them into opaque sealed envelopes. Randomisation took place in the operating theatre, after incision, when the scrub nurse randomly chose and opened one of these sealed envelopes.

Blinding

Patients were blinded to the dressing they received. Total blinding was not possible among staff as there is a slight visual difference between the two dressings.



Interventions

In theatre, patients received either a Hydrofiber dressing (10x10cm) or an alginate dressing (10x10cm or 10x20cm), both of which were folded to achieve a three-layer deep dressing in accordance with the manufacturer's instructions. Both dressings were covered with the same adhesive polyurethane film (Mepore, Mölnlycke Healthcare), and care was taken to apply this without tension. The film, which was in contact with the skin outside the wound area, protects the primary dressing from environmental contamination. Its transparency enables inspection of both wound exudate and the surrounding area.

- **Hydrofiber** Hydrofiber (Fig 2) is a sterile, non-woven sheet of sodium carboxymethyl cellulose. The dressing is a primary contact layer, and on contact with wound exudate its fibres produce a cohesive gel that provides a moist wound environment¹²
- Alginate Alginate (Fig 3) is a sterile, non-woven sheet made from the calcium salt of alginic acid. When in contact with wound exudate or serous fluid, the insoluble calcium alginate is partially converted to soluble sodium salt, and a hydrophilic gel is produced, creating a moist wound environment.¹²

During the trial period, 15 surgeons conducted the hip arthroplasties, always working in consultant/resident pairs. There were no obvious differences in com-

*During 2007 the name of this dressing was changed from Tegagen Alginate to Tegaderm Alginate.

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Fig 2. Hydrofiber dressing applied in the operating theatre. The Hydrofiber dressing is white, the covering film and its borderline can barely be glimpsed, and the marker line shows the inner edge of the drape that has just been removed

petence between the surgeons. Table 1 provides further information on baseline characteristics. The exit wound of the suction drain was positioned away from the main wound, and dressings were applied separately to the main wound and the suction drain sites. This made it possible to remove the drain after about 24 hours without disturbing the wound dressing.

Outcome measures

• Clinical staff-evaluated outcomes Hospital staff filled in an evaluation form on each day of the patients' hospital stay. Observations were documented in evaluation forms and with photos. These photos, which were taken in the operating theatre before and after dressings were applied and on the first or second postoperative day, were used in the measurement of wound area and to observe changes in skin status during the hospital stay, when patients left the hospital, and at the outpatient clinic 3 months after the operation.

A sterile marker pen was used to mark the edges of the Steri-Drape before its removal in theatre. It was noted on the evaluation form whether or not there was any skin damage under the drape's adhesive.

Skin damage was registered as erythema, blisters or skin injury, and the size of the skin damage was classified as small (1–2cm), medium (2–5cm) or large (>5cm). This was measured with planimetry on sizeadjusted photos (using the dressing as object of known size). The location of skin damage was recorded in two groups, proximal and distal. The first author looked at all photos to verify the collected data about skin status on the evaluation forms.

To define the skin damage, we used the pressure ulcer classification from the International Classification of Diseases (ICD–10, L89). This defines erythema as 'the ulcer appears as a defined area of persistent redness', and skin blister or skin injury as 'the ulcer appears as skin loss involving epidermis, dermis or both'. ¹⁶



Fig 3. Alginate dressing applied in the operating theatre. The alginate dressing is white, the covering film and its borderline can barely be glimpsed, and the marker line shows the inner edge of the drape that has just been removed

The treatment protocol stipulated that if the amount of exudation exceeded the absorption capacity of the dressing, or a leakage occurred, then the dressing should be removed. In such cases, it was replaced with a conventional dressing, such as a central pad (Mepore), with the observation period ending with the removal of the active dressing. Otherwise, dressings were routinely removed after showering on the day of discharge from hospital. (This was the only time that the dressings were moistened before removal.)

A governing nurse supervised each of the two wards in which the patients were located. All of the nurses and nurse students were thoroughly trained in skin evaluation and data collection. In general, they followed the hospital's written protocol for wound care and dressing change. The students always worked with an experienced nurse.

• Patient-evaluated outcomes All patients filled in an evaluation form at dressing removal. Its focus was to report pain, itching, burning and discomfort during use of the dressing, and pain at dressing removal. Results were recorded as yes/no, and on a 10-point visual analogue scales (VAS) where 0 = no problems and 10 = unbearable problems.

Patients received in-depth advice on how to interpret and fill in the form. For example, they were told that the term 'pain' related solely to pain resulting from the dressing usage and did not include pain during mobilisation. Similarly, they were told that the term 'burning pain' referred solely to such a dressing-related sensation, felt under the dressing.

Sample size

It was determined that 100 subjects were needed in each group to provide 80% power to detect a 15% difference in the proportion of patients with skin damage (with a two-sided type 1 error of 5%), assuming 10% had skin damage in the least affected

group. The chance of detecting a one-point difference in mean VAS pain scores (0–10cm), with an assumed standard deviation of 2cm, was 94%.

Statistical analysis

Differences in outcome measures between the treatments were investigated using the chi-square test with continuity correction for proportions (categorical variables) and the independent samples Student's t-test for mean values (continuous variables). Where appropriate the Fisher's exact test was used to test group differences for categorical variables. Multiple linear and logistic regression analyses were also performed to adjust for possible imbalances between the groups regarding age and dressing length in size, but these gave only negligible differences in results. The proportion of unchanged dressings by postoperative day in the Hydrofiber and alginate group was calculated using the Kaplan-Meier method¹⁷ and differences tested with the log rank test. There were no censored observations.

Results were considered statistically significant when p values were less than 0.05. All analyses were performed using the statistical program package SPSS 17.0 (SPSS Inc., Chicago, IL).

Results

Of the 201 patients asked to participate in the study, 200 agreed to take part. Participants had a mean age of 64.2 years (± 12.1), and the majority were women (60.5%). Table 1 shows participants' baseline characteristics; most variables were comparable in the two groups. All patients had surgery for osteoarthritis of the hip. The patient trajectory through the study is illustrated in Fig 1. All of the evaluation forms filled in by staff were completed, and photos were taken of all patients. However, eight patients did not return their patient evaluation forms.

Clinical staff-evaluated outcome measures

Skin status was better among patients in the alginate group (75/100 had no recorded damage) compared with the Hydrofiber group (59/100 had no recorded damage) (p=0.02), mainly due to a lower proportion of blisters (Table 2).

The area of damaged skin was larger in the Hydrofiber group (11% was categorised as 'large') than in the alginate group (3%), but this was not statistically significant (p=0.05). Overall, 38% of skin damage comprised blistering and 48% erythema, and the majority (61%) of damaged areas were defined as 'small'.

The locations of the skin damage are given Table 3. No skin damage was found under any of the active dressings. Nearly all cases of skin damages were located proximally (92.3%), with no differences between groups (p=1.0). Similarly, there was no significant difference between the groups in relation

Table I. Baseline characteristics for patients with primary hip arthroplasty by dressing type

	Hydrofiber (n=100)	Alginate (n=100)
Age: mean (SD)	66.5 (12.3)	62.0 (11.4)
Sex: female/male	64/36	57/43
Body mass index (kg/m²): mean (SD)	26.8 (4.4)	26.3 (3.9)
Diabetic	5	6
Dressing/latex allergy	0	5
Steri-strips	57	64
Skin staples	7	8
Sutures	36	28
Surgical incision length (cm): mean (SD)	19.1 (4.5)	18.5 (4.9)
Dressing length in size (cm): mean (SD)	24.0 (4.6)	22.5 (4.7)
Surgery time (minutes): mean (SD)	126.1 (28.7)	124.2 (29.7)
Drain removed first postoperative day (n)	87	88
Incision, lateral/post lateral (n)	16/84	8/92
Hospital stay (days) (mean; SD)	8.71 (4.1)	8.05 (3.2)

Table 2. Clinical staff evaluated skin status after primary hip arthroplasty by type of dressing

	Hydrofiber (n=100)	Alginate (n=100)	p value
Erythema (%)	17	15	0.8*
Blister (%)	18	7	0.03*
Skin injury (%)	6	3	0.3**
Total (%)	41	25	0.02*

*Pearson chi-square test with continuity correction **Fisher's exact test

to skin damage and the area covered by the film dressing and the Steri-Drape. Over half of the cases of skin damages were located where the Steri-Drape had been removed, and the majority were found at the edge of the film dressing.

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Table 3. Clinical staff observation of skin damages by type of dressings after primary hip arthroplasty

	Hydrofiber (n=41)	Alginate (n=25)	p value
	No. (%)†	No. (%)†	
Edge of the film dressing	10 (23)	12 (41)	0.1*
Edge of the film dressing and under Steri-Drape	25 (55)	11 (41)	0.4*
Under film dressing and under Steri-Drape	2 (4)	0 (0)	0.5**
Under film dressing	4 (18)	2 (17)	0.9**

^{*}Pearson chi-square test with continuity correction

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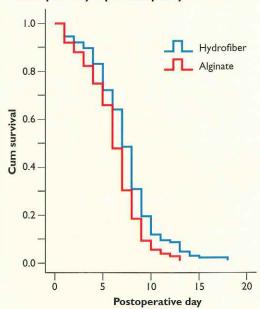
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Fig 4. Removal of dressings for patients after primary hip arthroplasty



Kaplan-Meier estimates of the proportion of unchanged dressings in the Hydrofiber and alginate groups. A log-rank test for equality of the survival distributions gave a p value of 0.004.

Of the 18 blisters in the Hydrofiber group, 14 were found at the edge of the film dressing and beneath the Steri-Drape (where it had been removed in theatre). In the alginate group, only 1 of 7 blisters was found at this location.

Fifty three per cent of skin reactions were reported

during the first 3 postoperative days. There was no statistically significant difference in these early skin reactions between the Hydrofiber (56/100) and alginate (48/100) groups (p=0.7). In the photos taken 3 months post-surgery, there was no erythema, but blisters and skin injury were still visible as shadows.

The mean time until the first dressing change was 6.1 days (\pm 2.8) in the alginate group and 7.2 days (\pm 3.2) in the Hydrofiber group (p=0.01). Fig 4 shows the proportions of unchanged dressings in the two groups by postoperative day. Twenty patients in the Hydrofiber group and 29 patients in the alginate group had their dressings removed before hospital discharge. With adjustment for age and dressing size, the logistic regression model showed this difference was statistically significant (p=0.01). There was no difference in the amount of exudation (p=0.9), mean surgery time (p=0.2) or the proportion of patients with dressing/latex allergy (p=0.7) in patients with and without skin damage.

Patient-evaluated outcome measures

There were no significant differences in mean scores for pain, itching, burning pain or discomfort between the two groups while the dressings were being used. During dressing removal, fewer patients in the alginate group reported pain compared with the Hydrofiber group, and patients in the alginate group reported a lower mean VAS score than those in the Hydrofiber group (Table 4). Among the patients with a baseline VAS score of over 0, the mean score was 1.9 in the Hydrofiber group versus 0.9 in the alginate group. Overall, there was no correlation between occurrence of skin damage and pain at dressing removal (p=0.1).

Discussion

Wound healing problems following hip arthroplasties have a multifactoral aetiology. The importance of surgical technique and soft tissue handling is well known among surgeons. However, there is less awareness of the potential benefits of modern dressings and the importance of good technical skills when applying/removing dressings (skin tension, trapping irritating chemicals, epidermal stripping).

The trial showed positive patient outcomes with both the alginate and the Hydrofiber dressing. The main differences between the two were that patients in the alginate group had better skin status and reported less pain during dressing removal than patients in the Hydrofiber group. Moreover, the Hydrofiber dressings were kept *in situ* 1.1 days longer than alginate dressings before removal, which may indicate that the former absorbed excessive exudate better, but the collected data of amount of exudation were equal between the dressings.

Skin damage from drapes, tapes and dressings is a common problem, and postoperative blistering

^{**}Fisher's exact test

[†]Total number of remarks on skin status.

seems to be a key to wound care difficulty after hip arthroplasty. Blisters/injuries require additional dressings, take extra nursing time and may delay discharge. Patients experience discomfort and are at increased risk of developing local infections related to impaired skin integrity. The original dressing was left on as long as possible or until the patients left the hospital. A mean time of 6-7 days until the first change of dressings seems to be longer than most other trials, which makes direct comparison difficult.1,14 A trial from Finland presented 24% skin damage for the Hydrofiber dressing within 3 days postoperatively after arthroplasties.3 Since about half of the skin damages in our trial were observed during the first 3 postoperative days, this seems support our findings. On the other hand, our blister/ injury rate for Hydrofiber dressings seems to be higher than in two other trials of orthopaedic patients, which reported a blister rate of 2.3-2.4% after a median wear time of 4 days.^{1,2} However, these trials included both hip and knee arthroplasty, and in our experience the occurrence of blisters after knee arthroplasty are rare.

The blister/injury rate for alginate dressings might vary as a number of different brands of alginates with different characteristics are available. However, we have not found other trials reporting blister/injury rates for alginate dressings. In the present trial, 25% of the patients given alginate dressings had skin damages, and of these 10% were blisters and skin injury. Tegaderm Alginate seems to be one of the best alginates in terms of absorbency and dressing characteristics. ¹⁸⁻²³

The type of dressing appears to be the primary cause of postoperative blistering, as the rate of blistering varies according to the dressing in use.2,5,24-26 Koval reported that the type and duration of surgery had more effect on postoperative blister formation than the type of dressing.7 Other factors that may be responsible for blisters are oedema following surgery, skin changes in the patients, dressings applied over a joint in movement, as well as the elasticity of the tape. 4,8 In the present trial all baseline characteristics of patients were fairly similar. Furthermore, all patients had a primary hip arthroplasty with about the same duration of surgery, postoperative oedema and rehabilitation. Neither surgery time nor dressing/latex allergy had any influence on the frequency of blistering. Great care was also taken in applying both the dressings and the covering film without tension. Significant differences are found in characteristics and blistering of some film dressings,5 but in the present trial both the drape used in the operating theatre and the film covering the active dressing postoperatively were identical in the two patient groups. However, the majority of the blisters were found under or at the edge of the film, which underlines the importance of carefully choosing the cover

Table 4. Patient evaluation of pain, itching and discomfort by type of dressing after primary hip arthroplasty

	Hydrofiber*	Alginate*	p value
Pain from the dressing during mobilisation†	95; 0.34 (1.0)	95; 0.42 (1.2)	0.6†
Itching under the dressing†	94; 0.87 (1.6)	96; 0.87 (1.6)	I†
Burning pain under the dressing†	94; 0.54 (1.2)	96; 0.50 (1.3)	0.8†
Discomfort by use of the dressing†	94; 0.59 (1.1)	97; 0.56 (1.2)	0.9†
Pain at removal of the dressing Yes (%)	93; 15	97; 2.1	0.01‡
Painscore at removal of the dressing§	93; 0.57 (1.3)	97; 0.21 (0.5)	0.01†

*Results are presented as number; mean (SD),

† Student t-test, Pearson chi-square test with continuity correction

Fisher's exact test

§ Measured on a visual analogue scale

of the active dressing. In our trial, more than half of the blisters were located where the Steri-Drape had been removed. Moreover, all blisters found were also under or at the edge of the covering film. Removal of Steri-Drapes may cause epidermal stripping which may contribute to blister formation, but there was no such visible skin damage in the present trial.

Some issues seem to affect dressing performance. These relate to the dressing application technique. When the skin is stretched or there is oedema, the fibres of the dressing are stretched, creating tension at the skin-dressing interface. There was no skin damage under the active dressings in the present trial. The fact that the majority of the skin damage were found at the edge of the film for both dressings may indicate that the tension at the interface skin and the edge of the dressing with covering film is of great importance. Postoperative oedema or absorbed exudate in the dressing may add to the tension.

The majority of the skin damage in our trial had a proximal location (92.5%), and this is in accordance with other trials.^{4,24} This may be because movement, and therefore the tension at the film-skin interface, is highest in the proximal part of the hip joint.

The ability to absorb excessive exudate is another important property of dressings. The difference in time until the first dressing change seems to be of minor importance in the present trial. Patients are usually discharged after about 4 days, which is sooner than these dressings ought to be changed. The decision to change a wound dressing in the present trial was based on the clinical judgement of the

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We would like to thank the staff at Kysthospitalet i Hagevik for their co-operation in the trial. nursing staff when there seemed to be a danger of leakage. Therefore, some dressings may have been changed prematurely or left on for too long. Modern dressings require fewer dressing changes, and this may lead to a more stable healing environment with less disruption to healthy granulation tissue.

Although patient comfort was good with both dressings, the patients who were managed with Hydrofiber dressings experienced more pain on dressing removal, compared with those managed with alginates. However, this difference, measured on a VAS scale, is only just within the limits of what is regarded as the minimum clinically significant difference (0.9-1.3 units).27-29 When patients were asked on a yes/no basis, 'Was it painful to have the dressing removed?', the answer was 'yes' for 2.1% of the alginate group and 15% of the Hydrofiber group. This difference may be due to differences in tension, resulting from the dressing characteristics (for instance their material or fibres) or dressing functions (such as the ability to contain exudates or prevent adhesions to the wound area). In a randomised trial of surgical wounds left to heal by secondary intention, patients evaluated the alginate as significantly less painful, and nurses found it easier to remove than saline-soaked gauze.30

Strengths and weaknesses of the trial

Strengths of the trial have been the high number of randomised participants, the identical surgical procedure used, the identical film covering the active dressing as well as the documentation by taking photos. One weakness of the trial has been that the decision to remove the dressings was done by a staff nurse, even though this was done according to standardised criteria. A further weakness is the fact that the assessment of the photos was made by one of the authors and not of an independent and blinded researcher or dermatologist.

One should also be aware that as multiple statistical tests have been carried out on the collected data, it is possible that false significances have been found.

Conclusion

Hydrofiber and alginate dressings are both recommended following primary hip arthroplasty. The alginate group had statistically fewer blisters and better patient comfort during removal, and the alginate will therefore be our first choice of dressing. This randomised trial has both strengths and weaknesses that may have influenced the results. Further research is needed to verify whether there are clinical differences between these dressings.



Bulletin board

The first double-blind RCT in wound care

esults of the 'Challenge' randomised controlled trial (RCT) show that UrgoStart foam dressing has superior efficacy to a control.

The RCT, which will be submitted for publication, included 187 patients with venous leg ulcers, and compared UrgoStart (formerly known as UrgoCell Start TLC), a foam dressing containing the protease inhibitor NOSF, with the same dressing without NOSF.

After 2 months of treatment, the healing rate in the UrgoStart

group was twice as fast as that in the neutral foam dressing group. Urgo says this indicates that UrgoStart performs better in terms of healing times and quality of life.

Activa Healthcare launches new debridement system

ebrisoft is a new and easy-to-use active debridement system that its manufacturer claims can debride wounds in minutes.

According to Activa, Debrisoft removes wound debris, necrotic material, slough and exudate with a single swipe. They say it can even remove longstanding hyperkeratotic tissue from surrounding skin, while allowing newly formed granulation tissue and epithelial calls to remain intact.

The product is said to debride wounds in 2–4 minutes. It is soft and flexible, and is designed to bind to wound debris, locking it into its fibres.

The system is easy to use and can be disposed of as normal clinical waste, leaving a clean wound to be dressed as usual.

Sue Johnson, Lead Nurse, Wound Care, Doncaster and Bassetlaw Hospitals NHS Founda-

The editor welcomes information on resources, organisations and new products. These should be emailed to jwc@ markallengroup.com