A small study in healing rates and symptom control using a new sheet hydrogel dressing

• **Objective:** This study set out to investigate the pain control and absorptive properties of a new sheet hydrogel dressing (ActiFormCool, Activa).

• **Method:** This was a simple evaluation involving 20 wounds. Compression was used when appropriate, although each patient receiving compression had used short-stretch bandages before entering the study.

• **Results:** Pain was reduced from an average of 8.65 to an average of 3.75, where 10 represents the worst pain possible and one represents no pain. Exudate reduction was assessed by the number of dressing changes required each week. The dressing-change rate reduced from an average of 2.8 times weekly to an average of 1.3 times weekly. Skin condition improved in all three cases in which the surrounding skin had been a problem before the study. Over a four-week period, two wounds healed, four healed by 90% and two by 80%, with an overall average healing rate of 46%.

• **Conclusion:** ActiFormCool provides an optimum wound-healing environment, reduces pain and absorbs fluid, making it an excellent alternative to loose hydrogels.

• **Declaration of interest:** This study was funded by Activa Healthcare.

**Wound healing** is a complex biological process, and practitioners need to be aware of factors that may adversely affect it.\(^1\) Dressings, in particular, can have a profound effect on the repair process and quality of life.\(^2\) Hydrogel dressings are popular because they are effective, comfortable, easy to use, cost-effective and control wound-surface hydration.\(^3,4\)

This article describes the investigation of ActiFormCool (Activa), a new concept in sheet hydrogel dressings in terms of pain control, exudate absorption and debridement.

**Wound management challenges**

Wound bed preparation is a term for the promotion of wound closure through the diagnosis and correction of systemic and local factors that may delay healing.\(^5\) Preparing the wound bed for healing, particularly in necrotic or bacteria-laden, sloughy, non-healing chronic wounds, is a major challenge. Both the necrotic tissue and the slough must be debrided to progress healing. The simplest and possibly safest, although slowest, form of debridement is autolysis. Once slough is removed, the dressing must retain a moist environment. Hydrogel dressings can do both as they donate fluid into the wound.\(^6\)

However, a balance must be struck between maintaining a moist wound environment and preventing periwound maceration from excess exudate, particularly under compression therapy.\(^7\)

**Symptom control**

Patients rarely view their wounds as the primary problem — they are more likely to be concerned with associated effects such as pain, fluid loss, malodour and reduced quality of life.\(^8\) Ideally, the chosen dressing will also:

• Reduce pain — ‘dry’ dressings create a drawing effect on the wound and increase pain
• Control malodour through the removal of slough and through anti-odour components such as charcoal
• Absorb fluid.

**ActiFormCool sheet hydrogel**

The ActiFormCool sheet hydrogel has been designed to:

• Maintain a moist environment
• Cool painful wound sites without reducing the potential for healing
• Retain its position over the wound to enable easy handling during application.

**Moist wound healing**

Although no reliable operational definitions exist of what is too little or too much wound surface moisture, the water-vapour transmission rate is a reliable measure of a dressing’s capacity to retain moisture and provide an environment that supports healing,\(^9\) or to allow passage of vapour through the dressing’s surface to support a highly exuding wound.

Coats et al.\(^1\) found that, in sheet hydrogels, a large drop in skin temperature was only achieved when...
References
2 Kerstein, M.D. Moist wound healing, the clinical perspective. Ostomy Wound Man 1995; 41: 5-7.
6 Hampton, S., Coil ins, F. Hydrogel wound dressings: moist environmentlO as the moisture ‘bathes’ nerve endings, thereby reducing pain. ActiFormCool moistens the wound and cools inflamed tissues, effectively reducing pain11 due to the noxious inhibitory control.12 The temperature then climbs to an optimum condition to promote wound healing.13 This is believed to be a unique feature of this sheet of hydrogel. Normothermia is 37°C plus or minus 1°C. The body’s core temperature is 37°C, but the interior of wounds is often cooler, and can be as low as 33°C or 34°C.14

ActiFormCool dressing
ActiFormCool dressing comprises a two-sided, clear, transparent hydrogel formed around a supporting blue polyethylene matrix. The gel contains approximately 70% water, and is permeable to water vapour, gases and small protein molecules, but is impermeable to bacteria. Provided the dressing is not allowed to dry out, it will not adhere to underlying tissue on removal. If the dressing does dry out, it is easily rehydrated to prevent tissue damage.

The dressing comes in three parts:
- Base liner, removed before the dressing is applied
- Hydrogel centre
- Top liner, which can be left in situ or removed, or left as required, depending on the amount of exudate loss (remove liner) or the dryness of the wound (leave liner in place).

When the dressing is applied to dry wounds without its top film cover, the top liner may be left in place to provide occlusion and a lower moisture vapour transmission rate, so that adherence is not a problem. An alternative method is to apply an adhesive film over the sheet hydrogel to retain moisture and prevent adherence (as can occur with all absorbent dressings). If, however, fluid management is required, the top liner may be removed to allow a greater moisture vapour transmission rate and increased management of exudate (Fig 1).

Method
A simple evaluation was the chosen. While large randomised controlled trials are believed to be the gold standard of research and the NHS Executive advocates their use for providing evidence of clinical effectiveness, they are not necessarily the best research method for some areas of clinical practice, particularly as they have very strict criteria which do not allow for development of any dressing potential.

Exclusion criteria
- Moribund patients
- Patients with clinically infected wounds (defined by pyrexia, cellulitis and a positive swab result)
- Refusal to take part in the study.

Inclusion criteria
- Any patient with a chronic wound
- Treatment for leg and foot ulceration with or without compression bandaging
- Wound demonstrating little evidence of healing to date. Average wound duration was nine months to two years, with a minimum of six months.

Measurement, evaluation and analysis
On entry into the study, the following baseline measurements were recorded:
- Demographic data
- Cognitive status
- Wound status and aetiology
- Wound duration
- Previous wound dressing history
- Medical status
- Patient profile.

Wounds were photographed at inclusion and then weekly thereafter.

Original dressings used were recorded but, as this was an evaluation and dressing types (Aquacel [hydrofibre] [ConvaTec], Algipan [hydrofibre], Aquacel [hydrofibre], Aquacel [hydrofibre]) were variable, it was not considered an advantage to compare them with the sheet hydrogel.

Eighteen patients were assessed for the study, but only 16 patients with 20 wounds were evaluated as two patients withdrew before the trial began after changing their mind about participation. Wounds comprised leg ulcers and foot ulcers.

Study participants were recruited from nursing homes, private referrals and district nurses. Each was provided with a full explanation and consent was obtained. All participants were given the opportunity to discuss their individual wound problems and helped to develop their own individual aims and helped. These were then used to assess whether the dressing was clinically effective.

Each leg ulcer was re-assessed for venous/arterial insufficiency using Doppler. Each patient had been assessed previously as part of their usual care, and no changes were found. If venous insufficiency was indicated, orthopaedic wool and short-stretch compression was applied over the dressing, although
this had been current practice for these patients.

The ActiformCool dressings were applied by removing the base liner and then placing the hydrogel sheet face down onto the wound. This remains in place without the need to handle the dressing. The top liner is removed only if required.

Application of a secondary dressing to the remaining wounds was left to the discretion of the nurse. All nurses were qualified in wound care and confident in the selection of secondary dressings.

Pain was assessed by the patients on a recognised scale of 1–10, where 10 is the worst possible pain and 1 is no pain. The scale was 10cm in length and was provided on a laminated card.

Evaluation comprised five to seven assessments over four to six weeks (depending on the patient’s individual requirements) or to healing, whichever occurred first.

As the results were positive for healing, it was felt to be ethical to continue using the dressings for some patients after the study. Therefore, after the trial period ended two subjects were followed up for one month. Data for these two patients are included in this paper but only for the first six weeks. The results of the extended treatment are not given here.

During the study, we wanted to gather knowledge on how the dressing could or should be used in order to investigate its potential for the manufacturer. Therefore, an action research approach was used, comprising:

- Planning
- Taking actions
- Evaluating the results of the action or undertaking relevant fact-finding
- Re-planning, in line with the results.

This process is used by practitioners to study problems scientifically in order to guide, correct and evaluate their decisions and actions. It is a fancy way of saying ‘let’s study the research, to make changes to the study as it progresses’ and to make changes to the use of the dressing as necessary.

Analysis relied on a Fisher’s exact test of pain and exudate comparisons before and after the use of the test dressing.

Results

Pain

At the start of the study 15 subjects reported pain scores ranging from 10 (worst pain imaginable) to three, with one subject reporting a level of 10 in both ulcers, another reporting nine and two reporting eight in all of their ulcers if they had more than one. The total pain scale number was 173, with an average pain scale of 8.65. The type of pain reported ranged from venous pain to vasculitis, and all subjects reported the pain as being in the wound rather than around it or in the foot.

At study completion eight subjects reported pain ranging from 10 (worst pain imaginable) to three. The total pain scale number was 30, with an average pain scale of 3.75, with an overall reduction from an average of 8.65 to 3.75.

A Fisher’s exact test found that pain scores were significantly lower after treatment with the ActiFormCool dressing (p<0.01).

One subject who described the original pain as 10 on admission to the study experienced a reduction to three in the first week and then to zero, where it remained to the end of the trial.

Exudate management

At baseline 13 wounds had high exudate and seven had medium exudate (Fig 2). No wound had low exudate. The researcher made a subjective assessment of the level of exudate, based on how often the dressing was changed and how wet it was at each change. Dressing changes ranged from daily to twice weekly, with an average of 2.8 times weekly.

At completion one subject had high exudate, nine subjects had medium exudate and eight had low exudate (Fig 3). The medium exudate levels had increased but this was due to the drop of some subjects from high to medium. Two subjects reduced to zero exudate.

At this time dressing changes ranged from twice weekly to weekly, with an average of 1.3 times weekly, representing a halving in change times.

Based on these figures a Fisher’s exact test found that exudate levels were significantly reduced at the end of the study (p<0.025). Therefore, ActiForm-
The dressing is easily cut to size when wounds require moisture. Cool either successfully reduced exudate levels or had a greater capacity than the previous dressings to absorb exudate.

The dressing capacity was very noticeable, as were the changes in the dressing's colour (Figs 4–6). The dressing absorbed the colour of the wounds, but appeared to reduce in colour as the wound malodour reduced.

Skin condition
The removable film cover provided users with a choice. When the wound was excessively wet, the film cover was removed, enabling a higher vapour moisture transfer rate and a longer wear time. In drier wounds, the film cover was left on, promoting a moist environment for optimum healing. This protocol was developed with the assistance of the district nurses and nursing home nurses as part of the action research aspect of the study.

Skin condition improved in all three cases in which maceration and hyperkeratosis had been a problem before the study.

Healing
During the study period (four to six weeks), two subjects healed completely, four healed by 90% and two by 80% within the four weeks. The rest continued to the sixth week. There was an overall healing rate of between 0% and 100%, with an average of 46%.

Use of compression
Eleven subjects received compression therapy while using ActiFormCool. The dressing continued to absorb fluids under the bandage, and no problems were identified.

Ease of use on awkward areas
ActiFormCool has a ‘clingy’ base that holds onto the skin. This enables ease of use, particularly when applying the dressing as it remains in place, enabling secondary dressings or bandages to be applied single handedly with ease.

Discussion
A small evaluation such as this can only demonstrate a dressing’s healing potential and is not proof of efficacy. However, the Fisher’s exact test results demonstrated significant differences in pain and exudate levels.

The exudate control was unexpected. Although the study set out to assess exudate levels, the substantial absorptive capacity of this hydrogel sheet was not anticipated.

The reduction in wound colour suggested bacteria were absorbed into the dressing. Indeed, wound colonisation reduced in three wounds. Bacteria have their own individual colour and all richly colour the fluid in a wound bed. The presence of serous-coloured fluid and a reduction in the amount of exudate means that bacterial loading is reduced. However, this was not proven in this study and requires further investigation.

The evaluation suggests that the dressing can be used under compression bandaging and cut to the wound size. In addition, it indicates that the surface film should be left in place when placed on a dry wound and removed when placed on a wet wound.

Conclusion
ActiFormCool provides an optimum wound healing environment, reduces pain and absorbs fluid, making it a successful alternative to loose hydrogels when preparing the wound bed to heal.

The dressing was easy to use and pain-free to remove. It helped reduce wound pain, absorbed well and was suitable for both wet and dry wounds. All of the wounds studied responded well to the dressing.

This small study, therefore, demonstrates that ActiForm Cool was clinically effective. The figures demonstrate its excellent healing potential.

While the study was not large, it did demonstrate significant differences in pain and exudate reduction as well as the potential to facilitate healing in these wounds.