Pain management in leg ulcers using ActiFormCool™

Stephen R Young, Sylvie Hampton

Abstract

Background: In addition to its impact on quality of life, wound pain may result in a physiological stress response leading to delayed healing. Two recent audits of the sheet hydrogel wound dressing ActiFormCool™ have indicated that it can be effective in managing chronic wound pain. *Objectives:* To confirm and extend these earlier findings by exploration of the hypothesis that patients using ActiFormCool™ hydrogel dressing will experience less pain during wear time. *Methods:* Fifty one patients were assessed for wound pain, exudate, comfort and healing status before and during wound management with ActiFormCool™. Overall pain and the individual types of pain classified as 'ache', 'burn', 'sharp' or 'stinging' were assessed. *Results:* Statistically significant reduction of ache, burn or sharp pain types was found when ActiFormCool™ was used to replace other dressings. Improvements in healing were observed for 46 of the study wounds with reduction in exudate and improved comfort for those patients with 'Painful' or 'Uncomfortable' wounds. *Conclusions:* Results of the audit confirmed earlier findings. ActiFormCool™ produced a statistically significant reduction in wound pain with a resulting improvement in patient comfort. *Declaration of interest:* This study was funded by Activa Healthcare.

KEY WORDS

ActiFormCool™
Chronic wound
Comfort
Exudate
Pain

The diversity of wound management choices currently available makes this an exciting and rapidly expanding field of care. However, wound management is often undertaken by health care professionals who have not received sufficient training in this speciality (King, 2000). Undoubtedly, this results in the inadvisable or inappropriate use of wound dressings (Bux and Malhi, 1996). Each dressing is specifically designed for a purpose, with the primary function being to prepare the wound bed for healing, and this requires a knowledge of the complications and physiological responses that occur in a wound with each different dressing type. Pain is one of the common complications of wound healing and its assessment remains an integral part of wound diagnosis as well as local wound management (Sibbald, 2003). Unfortunately, this remains a largely neglected area (Gould, 1999).

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ActiFormCool™ is a second-generation sheet hydrogel dressing that is possibly able to address the issue of pain in wounds. Two pilot studies have suggested that pain is reduced when ActiFormCool™ is applied (Hampton, 2004; Collins and Heron 2005). It would be extremely costly and difficult to prove the efficacy of any dressing in pain control due to the variables such as different types and aetiologies of pain. Nevertheless, a small series of case studies, undertaken to identify the position of ActiFormCool™ in wound care (Hampton, 2004), identified that pain was significantly reduced after application of ActiFormCool™. The study had asked for a subjective assessment of pain from the patient using an analogue scale of one (no pain) to 10 (worse pain imaginable). It identified that the patients assessed their wound pain as an average of 8.65 before ActiFormCool™ was applied and this was reduced to 3.75 after application. The decrease in pain associated with the use of ActiFormCool™ was shown to be significant at a level of $p<0.01$ using the Fishers Exact Test. The author therefore decided to undertake an audit in collaboration with nurses in the UK in order to confirm or refute the results from the earlier studies.

A second audit was performed with 69 patients throughout the UK and the clinical evaluation was of 13 patients with 16 wounds. The results were presented at the Wounds UK Conference 2004, in Harrogate. This audit demonstrated that 67% of patients had stinging, burning and sharp pain with an average pain score of 6.4 before application of ActiFormCool™. In confirmation of Hampton's case study findings (Hampton, 2004), pain was reduced to an average score of 3.8 when ActiFormCool™ was applied. However, as this was not a randomised controlled trial, the findings would undoubtedly be questioned. Therefore, the author decided to investigate further, using a similar audit protocol to that used previously.

The Audit investigation

Pain is complex with multiple causes and no single dressing could possibly reduce pain in all painful wounds. Therefore, the objectives of this audit were to establish

Table 1
Key parameters assessed during the audit

The Audit investigated	Rationale for the investigation
Pain levels	This was subjectively identified on a 1–5 visual analogue scale with 1 = no pain, and 5 = worst pain imaginable
The type of pain	There are many reasons for pain in ulceration and these are not always due to the wound itself, but to arterial insufficiency or other reasons. It is important to begin to identify when the pain occurs and whether different types of pain can be assisted by applying ActiFormCool™
Exudate	Exudate can cause pain (through maceration of the skin, which is similar to a burn) or it can cause a mental anguish which has similar physical stress reactions to pain
Healing	A healed wound will be less likely to be painful, and therefore, a faster healing rate is important for quality of life through a reduction in pain

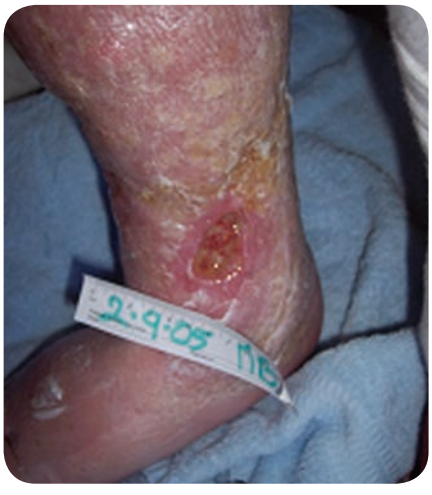

Figure 1. Venous leg ulcer causing extreme early morning pain.

the effectiveness of ActiFormCool™ hydrogel sheet dressing in reducing pain in painful leg ulcers and to establish what particular types of pain could be reduced (*Table 1*). It is intended that the results shall be used as the basis for a group of specialist nurses to design a pain tool specifically for leg ulcers. Each patient in the audit was already being provided with ActiFormCool™ as part of their general care, before the audit and, therefore, no changes to care provision were made.

Background to the pain investigation

Pain is often ignored in wound healing or passed over as a symptom of the type of wound involved. The result is often erroneous beliefs such as 'venous leg ulcers are never painful' or 'arterial leg ulcers are only painful when the leg is elevated'.

The patient who is in pain may have delayed wound healing as pain may cause a physiological stress response that can affect the delivery of oxygen and nutrients to the wound (Hampton and Collins, 2003). Pain is the result of a complex sequence of physiological and psychological events with the release of histamine and prostaglandin playing a large role in the painful outcome. There are different types of nerve fibres and pain receptors: each receptor acts at differing speeds of conduction, leading to dissimilar experiences of pain sensation. Burning pain may be the result of polymodal C fibre nociceptor stimulation and pricking pain due to the stimulation of A_δ nociceptors. Therefore, it was important to establish whether ActiFormCool™ could decrease pain in all or certain pain types.

Melzack and Wall (1984) suggested the 'gate theory' where they postulated that the potential of large diameter afferents and small diameter afferents are different. The relative amounts of neural activity received by these different neurones determines the output to higher brain centres. The smaller diameter afferents can increase the perceived pain. However, if activity in the larger diameter afferents is increased, perceived pain is decreased. Therefore, an increase in activity in the larger afferents can 'close the gate' and reduce pain. The use of transcutaneous electrical nerve stimulation (TENS) applies this theory in practice through stimulation of the larger diameter afferents. This explanation gives credence to the 'old wives' method of dealing with pain: if a child falls and hurts their knee and mother rubs or kisses it better, the pain appears to abate. However, TENS has a greater success rate in reducing neurological pain and may not be of value in painful wounds.

Sources of wound pain

Wounds are often painful for a variety of reasons. Leg dependency in venous ulceration may cause pain because as hydrostatic pressure increases, the leg becomes increasingly oedematous and the potential for pain increases. Conversely, leg elevation in venous ulceration may increase pain as in the case of the patient in *Figure 1* where her venous pain became unbearable at 2am every morning. Treatment with compression also increased the pain but the use of analgesics as a method of pain control allowed the treatment to continue. Atrophy blanch is also a particularly painful dermal condition associated with venous ulceration that can be seen as white patches around the ankle and calf.

Ischaemic pain is either acute or chronic and can be extremely painful. Ischaemia can be a result of intermittent claudication, poor blood delivery in the large arteries or small arterioles, or due to unrelieved pressure. It can result in increasing pain when the leg is elevated because blood supply to the feet will be decreased. Ischaemia can lead to arterial ulcers

that are very painful and difficult to heal. However, some arterial ulcers are not painful and others may increase in pain when legs are dependent. Ischaemia can lead to vasculitic ulceration in patients with rheumatoid arthritis or to foot ulcers in patients with diabetes.

Some ulceration may be due to vasculitis when the blood supply is not reaching the dermis (*Figure 2*). The pain from vasculitis has been described as 11 on a scale of 1–10 with 10 described as the 'worst pain you could suffer' (Hampton and Collins, 2003).

Wounds may be painful because the wound bed is exerting pressure on the wound margins, causing pain in the nerve supply surrounding the wound. Venous leg ulcer pain experienced during compression bandaging is poorly understood (Nemeth et al, 2004) and often bandaging is stopped due to this lack of understanding.

Wound dressings

Dressings can also increase pain in wounds, particularly when a hydrophilic dressing is applied, or a dressing that adheres to the wound bed where movement or removal of the dressing can increase pain potential. Alginates, sugar paste, foams or dispersion technology can all increase pain in an already dry and painful wound. In contrast, a moist dressing would 'bathe' nerve endings to reduce pain (Flanagan, 1997).

Bacteria

Some bacteria may cause wounds to feel painful. *Pseudomonas aeruginosa* is a difficult pathogen to treat because antibiotics are largely ineffective and it can be responsible for many deaths in hospitalized patients (Hancock, 1997). It is the experience of the author (Hampton) that *Pseudomonas aeruginosa* can also be a prime cause of pain and certainly, clinical infection will nearly always increase wound pain.

Pain management

Patients who identify pain related to leg ulcers, when questioned, may report that the pain is in the ulcer, around the ulcer, or elsewhere in the leg and is not always related to the ulcer site. Leg ulcer pain that is described as 'burning' usually responds well to non-steroidal inflammatory drugs (Emflorgo, 1999), although it should be remembered that non-steroidal anti-inflammatory drugs can limit the production of prostaglandins which, in turn, will affect wound healing. If the pain is described as 'throbbing', the patient may require opiates, and tingling, smarting, or stinging pain may require anti-epileptic drugs (Emflorgo, 1999). Dressing removal that is painful may require nitrous oxide and oxygen to allow painless dressing changes. The most common pain descriptors used in research are 'aching,' 'stabbing', 'sharp,' 'tender,' and 'tiring.' Often 'burning' pain is the result of too much wound fluid which macerates the wound and the surrounding tissues.

Pain has a physiological response that causes vasoconstriction, reducing blood delivery to the wound bed, increasing pain, and delaying wound healing. Therefore, analgesia must be the second consideration and dressings first in reducing wound pain; in other words, a dressing such as a hydrocolloid, film dressing or hydrogel should be used that will 'bathe' the painful nerve endings. 'Dry' dressings such as alginates, foams, and cadexomer pastes and osmotic dressings such as sugar paste, may increase pain initially when the 'pull' of the new dressing causes the nerve endings to be stimulated. Generally, this initial pain will decrease within half an hour when the dressing becomes moistened.

Chemical mediators, such as bradykinin, histamine, serotonin and prostaglandins which are released following injury, are associated with both pain and inflammation (Rice, 1994). The effect on pain can be reduced through the use of analgesia that reduces the production of prostaglandins (NSAIDs, aspirin, etc). However, as prostaglandins are promoters of the inflammatory process and influence cell activity by acting as messengers between cells, any reduction in their production can have an adverse effect on healing.

Haines et al (1997) suggest that chronic pain is a major health problem and produces many demands on health-care resources. Wound pain has been a major problem for a long time and, apart from analgesia, is poorly addressed. Many patients will refuse analgesia because they are concerned about side effects such as feeling less in control. Moist dressings may reduce pain, but to date, there is no dressing available that is designed to deal with wound pain and drugs that may assist (e.g. lignocaine) are, unfortunately, not

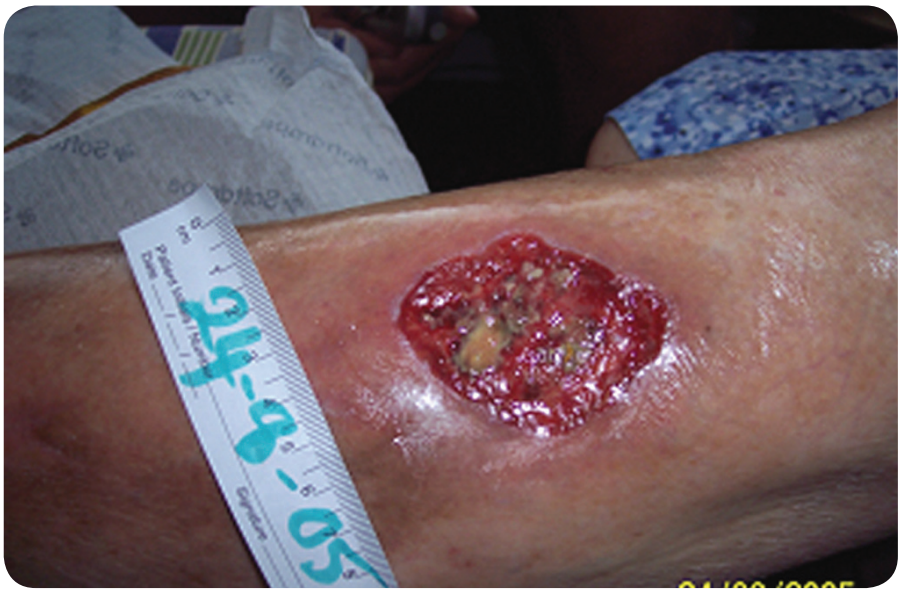

Figure 2. An acutely painful vasculitic ulcer.

Table 2
Effect of ActiFormCool on wound pain: individual pain types

Type of pain	No of patients	Patients reporting reduction due to treatment	Rating reduction attributable to ActiFormCool 95% confidence limit
Ache	15	12	1–3 levels
Burn	12	12	1–3 levels
Sharp	11	10	1–2 levels

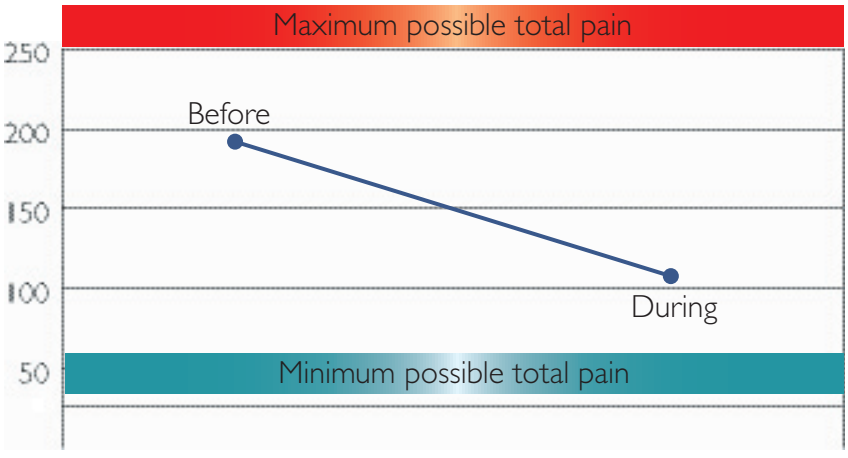

Figure 3. Effect of ActiFormCool™ on wound pain: total pain. Data points represent the sum of pain scores for the assessment of 50 patients' wound pain on a visual analogue scale of 1–5 before and during treatment with ActiFormCool™ (1 = no pain, 5 = the worst pain imaginable).

licensed for wound care. Nevertheless, the single most important aspect of pain control is to identify the causative factor and rapid, multidimensional treatment is urgent and vital.

Pain relief may be improved by reducing sensitisation of nociceptive pathways caused by tissue injury. Such a reduction depends mainly on inhibition of local inflammatory changes and the relationship between duration of nociceptive block and nociceptive input (Pedersen et al, 1996) and there is a potential that ActiFormCool™ may dampen the inflammatory response that creates pain. If ActiFormCool™ can contribute to wound management with pain reduction then it is important that this is further investigated.

Study aims

The aim of this audit was to substantiate earlier studies that had demonstrated the potential efficacy of ActiFormCool™ in wound pain relief and improvement of healing. This was achieved by exploration of the hypothesis that patients using ActiFormCool™ hydrogel dressing as a primary dressing will experience less pain during wear time, improved healing and therefore, increased quality of life. The primary objective of the study was to evaluate the effect of ActiFormCool™ on wound pain with the effect on healing, comfort and exudation as secondary objectives.

Methods

Audit forms were sent to 35 nurses throughout the UK with 27 returning the completed audit form. The results were from 51 patients with chronic ulcers of the leg or foot. All ulcers had previously been treated with another dressing but were being treated with ActiFormCool™ on the day of the audit. The longest period of use was greater than 3 months and the shortest period was 7 days. Methodology and data recorded for this audit were essentially the same as that used in the previous study (Hampton, 2004) and are given in summary form here.

Pain assessment

The patients were asked to assess their wound pain before and after treatment with ActiFormCool™ using a linear visual analogue scale. They were asked to score their pain where one = no pain and 5 = the worst imaginable. Patients were also asked to define the type of pain as either 'ache', 'burning', 'sharp' or 'stinging'.

Dressing comfort

Both patients and nurses were asked to give their opinion of ActiFormCool™ comfort during wear and upon removal. Their responses were rated as painful, uncomfortable, comfortable or very comfortable for the purpose of analysis.

Wound healing improvement

Although assessment of healing was not a primary objective of this audit, it presented an opportunity to ascertain whether the nurses observed any improvement in response to the use of ActiFormCool™. The nurses were asked to make a subjective judgement on whether there was any improvement in the wound healing status by selecting one of the statements about the healing status of the wound : 'showed improvement', 'no improvement', 'not sure', 'healed' or 'ActiFormCool™ discontinued'.

Exudate levels

Nurses were asked to categorise the levels of wound exudation as 'copious', 'medium', 'minimal' or 'none' for each wound when managed with the previous dressing and with ActiFormCool™.

Results

Pain assessment

Overall pain

Fifty complete before and after pain assessments were available for statistical analysis. If the scores for all patients in the audit are added together, the highest total score that could be obtained for all subjects is 250 and the lowest possible total score that could be obtained for all

Table 3
Effect of ActiFormCool on healing

Healing classification	Subject numbers	
Showed improvement	46	90%
Healed	1	2%
No improvement	3	5.8%
Not sure	1	2%
Discontinued	1	2%

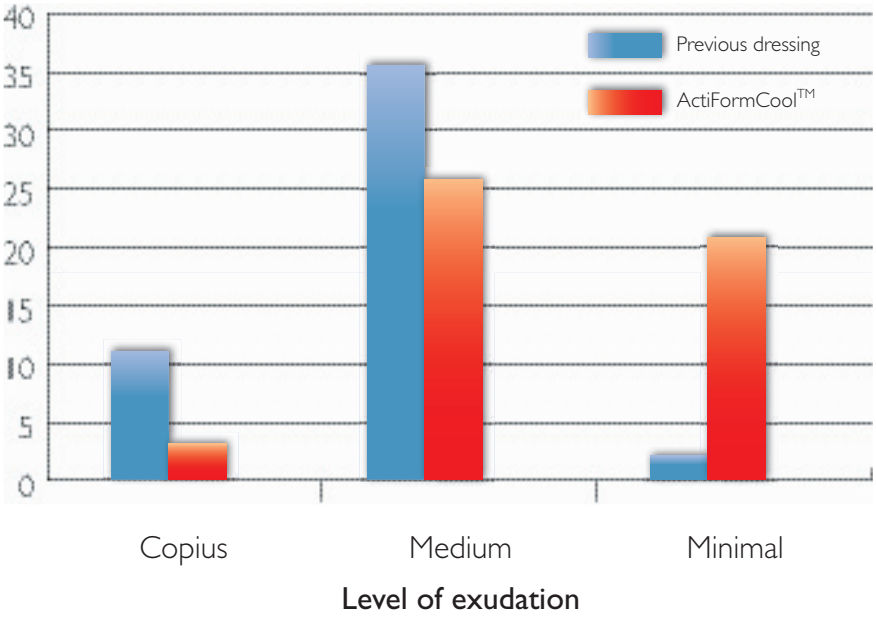

Figure 4: Comparison of exudate levels ActiFormCool™ vs previous dressing.

subjects is 50. In this study a total value of 194 was found for pain before use of ActiFormCool™ which fell to 111 after treatment with ActiFormCool™ (*Figure 3*). The total difference between groups was therefore 83 with a mean difference of 1.66+0.306/patient with a p value <0.001 assessed by the t test. Use of this precise value for the mean difference is open to criticism as the values used for analysis were not continuous being discrete values between 1 and 5 in increments of one. The statistically significant average pain reduction observed after treatment with ActiFormCool™ was in the range of 1.354–1.966. In reality this should be translated as a reduction of 1–2 ratings on a linear scale of one to 5.

Type of pain

Design of the audit allowed pain to be stratified into 4 types. Of these three, ache, burn and sharp gave sample sizes large enough for statistical analysis (*Table 2*). The sample size was too small to perform analysis on the sting type pain group.

The majority of wounds exhibiting ache, burn and sharp types of pain demonstrated a reduction in pain in response to the use of ActiFormCool™. The data indicated that a statistically significant minimum of one level of pain reduction can be expected and this could be up to three levels for ache and burn types of pain. The wide range calculated (1–3) is a consequence of the small sample size in each group after stratification by pain type.

Wound healing improvement

The subjective nurse classification of healing status for all wounds after application of ActiFormCool™ is shown in *Table 3*. For analysis purposes, the assumption was made that a positive result could be accepted when the final assessment was classified as either 'showed improvement' or 'healed'. Conversely, 'no improvement' or 'not sure' were classified as negative results. On this basis, a sign rank test was considered appropriate. For the sample size of 50, there are 46 positive responses and 4 negative. The probability of obtaining this pattern by pure chance is much less than 0.001 so it may be safely concluded that ActiFormCool™ did generate an improvement in comfort. This finding has to be tempered with the knowledge that the nurse assessment of healing status in this study is subjective.

Dressing comfort

Comparative data was available on 37 patients and was evaluated as a series of analyses using the sign rank test. Of the total responding patients, 17 recorded a difference in the level of comfort after ActiFormCool™ application, all of which were an improvement.

Patients with an initial 'painful' classification

Six patients initially had wounds classified as 'Painful' and 5 recorded improved comfort after ActiFormCool™ was applied. This was a significant result ($p<0.01$) but due to the low sample size, the 95% confidence limits encompass improvements from nil to a move to 'very comfortable'. One can conclude that for this type of wound there will be a response to treatment however no assurance can be given as to how effective the response will be. A larger sample size would be required to define this.

Patients with an initial 'uncomfortable' classification

Seven patients initially classified their wounds as 'uncomfortable' and all recorded a positive effect in moving to 'comfortable' or 'very comfortable' ($p<0.01$). The sample size again was

small and the confidence limits (95%) only allow a conclusion that one would expect such a move. Thus, on average, patients rated as uncomfortable will experience an improvement in comfort level and move to either comfortable or very comfortable with ActiFormCool™ application.

Patients with an initial 'comfortable' classification

This was the largest group with 23 patients, five of whom recorded a change in comfort level, all of which were positive. This number is not statistically significant. The one remaining patient was classified as 'very comfortable' and no change was recorded.

These data indicate that on average, ActiFormCool™ can improve the comfort level of patients with uncomfortable or painful conditions but, unsurprisingly, is unlikely to improve comfort levels for patients who already rate their condition as 'comfortable' or 'very comfortable'.

Exudate levels

The result of comparing exudate levels before and during treatment with ActiFormCool™ were similar for this and the previous two audits. In all three cases, the numbers of patients with 'high' and 'medium' exudate levels were reduced and the numbers with 'minimal' or no ('none') exudate increased with ActiFormCool™. The changes identified in the present study are shown in *Figure 4*.

If the exudate data is ranked as copious > medium > minimal > none, all patients except one recorded either a zero or positive (improved) response to ActiFormCool™. Analysing the differences in response using the sign rank test gives a significance level of $p < 0.01$ that the pattern is not due to random error. Thus it is possible to conclude that, on average, the use of ActiFormCool™ did reduce exudate levels. Applying confidence limits to these data shows that with 95% confidence there could be a reduction in exudate class of between 0 and one rating.

Discussion

Three studies auditing the effect of ActiFormCool™ on the parameters of pain, exudate, comfort and malodour associated with chronic wounds have now been performed. The latest audit of 51 patients reported here confirms the results of the previous two, and has allowed a statistical analysis of the findings. Although the audit was based on very subjective data, it was possible to demonstrate a significant improvement in pain levels when ActiFormCool™ was used on painful wounds. The results of this audit confirm those of the earlier two studies and extend the positive findings to an aggregate total of 133 patients. Overall pain was reduced and the individual types of pain classified as 'ache', 'burn' or 'sharp' were each significantly reduced. As well as pain reduction, improvements were observed in healing status for 46 of the study wounds with reduction in exudate and improved comfort for those patients with 'painful' or 'uncomfortable' wounds.

Further work is required in order to attempt to identify why ActiFormCool™ is successful in reducing pain, and a randomised controlled trial would be useful in this context. However, undertaking RCTs in painful wounds does mean that one group of patients would receive treatment that does not assist with pain and raises difficult ethical considerations when applying the criteria of an RCT. In the meantime, it would be extremely useful if other researchers could undertake a similar audit to extend and compare results.

It is hoped that the types of pain identified within this audit will be used as a basis for the local pain group to design a pain tool for leg ulcers. This may ultimately lead to the development of guidelines for the treatment of particularly painful wounds. WUK

Key Points

- Wound pain causes a physiological response that can have a negative effect on healing.
- Pain is a common complication of wounds but is a largely neglected area of wound care.
- Three studies have shown ActiFormCool dressings to have a significant effect on pain reduction for many patients with painful leg ulcers..

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