A clinical in-market evaluation of an alginate fibre dressing

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Abstract

Practice nurses working in GP surgeries are responsible for caring for patients with both acute and chronic wounds. The management of wounds is challenging and it is important to achieve and maintain an optimum healing environment. Practice nurses play an integral part in managing both acute and chronic wounds within a community setting, it is essential that they can make informed decisions as to which products to use. A clinical in-market evaluation of 23 patients was carried out to assess the performance of ActivHeal Aquafiber® in clinical practice. Overall, the dressing performed well in respect of fluid handling and durability. The dressing addressed patient needs in terms of easy application and removal, prevention of leakage and wound progression.

Key words: Wound healing ■ Delivery of healthcare ■ Wound infection ■ Health expenditures

Practice nurses (PNs) working in some GP surgeries have traditionally been responsible for caring for patients with both acute and chronic wounds. Many health centres have dedicated wound care clinics, but the majority of patients seen by PNs are by appointments booked within general treatment clinics. As a result, the face-to-face contact time is limited.

There are no published data that demonstrate the percentage of time PNs spend on wound care, or the numbers of patients with wounds treated by PNs. However, as a PN, the author has observed that patients with wounds who require treatment tend to be in the following categories:

■ They have been discharged from hospital following surgery and require wound assessment and management including suture or staple removal
■ Minor surgery has been undertaken by the GP in primary care, and the patient requires follow-up wound care
■ They are patients with chronic wounds who are able to, and prefer to, attend the surgery instead of a hospital
■ They are patients with minor injuries who prefer to attend the GP surgery rather than A&E at the local hospital.

Probst et al (2014) identified recent changes in healthcare, where there was a ‘shift of services’ (Probst et al, 2014: S8) from secondary to primary care and an increased demand for wound care services. These changes have started to impact on PNs as the number of acute wounds increases as patients undergoing surgical procedures in secondary care are more likely to receive these as a day case, or may have an early discharge from hospital. In addition, the introduction of GP contracts in 2004 encouraged GPs to undertake ‘enhanced services’ (Probst et al, 2014: S12) which include minor surgical procedures such as excisions and incisions of skin lesions, biopsies and toenail surgery (British Medical Association, 2012), all of which can impact on the caseload of the PN.

Acute wounds are those that heal within a recognised timescale with no complications, progressing through the recognised stages of coagulation, inflammation, proliferation and epithelialisation to healing (Dowsett and Newton, 2005). However, delayed healing is a risk factor even for minor wounds that are thought to have become stuck at a certain stage, usually in the inflammatory stage (Enoch and Price, 2004). Recognised intrinsic and extrinsic factors such as medication, poor nutrition, significant concomitant illness such as diabetes, substance abuse and infection can influence wound chronicity (Vowden, 2011).

While the number of patients attending for the treatment of acute wounds is likely to increase, there is also the burden of chronic wounds that have to be managed within the community setting (Gottstrup et al, 2013). Non-healing wounds have become a significant problem with an estimated cost in excess of 3–4% of the healthcare budget in the UK (Posnett et al, 2009). Anecdotally, organisational changes and the increasing workload of district nurses in some areas have resulted in patients with wounds who are able to mobilise being referred to the clinics undertaken by PNs.

The challenge for PNs is to provide a quality service for patients who require treatment for acute and chronic wounds. As such they are required to deliver effective wound care within a busy clinic appointments system where time is limited. In this clinical environment, the most effective way to manage wounds includes the following: knowledge of the wound-healing process, documentation so that wound assessment and progress can be recorded effectively, having access to a limited number of products and knowledge about them, being able to identify when the wound is not progressing and having access to advice from a tissue viability nurse specialist.

At a patient’s initial visit to the author’s GP surgery, time is...
allocated for a full patient assessment where factors that can delay healing are identified. This time is used to advise the patient on diet, exercise, and hygiene as well as to provide information on what to expect as the wound progresses, how to identify infection and possibly how to replace any dressings if they are participating in care. Educating patients about their health and wellbeing gives them an important opportunity to have some control over what happens to them (Wounds International, 2012).

The most appropriate dressing is then selected to facilitate healing. This will be dependent on the condition of the wound bed, the level of exudate, the infection status and patient requirements following a full wound assessment.

**Background**

The management of wounds is a challenge and it is important to achieve and maintain an optimum healing environment (White and Cutting, 2006; Benbow, 2011). A thorough holistic assessment and management of the wound is the key to effective wound care. The priority is to optimise the patient’s potential for healing through, for example, correcting identified nutritional deficiencies, maintaining good hygiene and encouraging mobilisation (Benbow, 2011). Assessment will establish causation, tissue types and exudate levels and will assist in addressing patient concerns. Wellbeing has been explored and has been described as a dynamic matrix of factors including physical, social, psychological and spiritual and cultural (Wounds International, 2012). The international consensus document *Optimising Wellbeing in People Living with a Wound* highlights the importance of collaboration between clinicians and patients, to optimise wellbeing, improve or heal the wound, alleviate and manage symptoms and ensure both clinicians and patients are fully engaged in this process (Wounds International, 2012). Precise, individual and timely wound assessment underpins effective clinical decision making, enabling appropriate goals to be documented for the management of the wound in order to reduce morbidity and costs (Posnett et al, 2009).

Clinicians involved in wound care should possess the essential skills required to plan, implement and evaluate care on an individual basis (Cook, 2011). The Nursing and Midwifery Council (NMC) states that care delivered must be based on the best available evidence or best practice, with every registered practitioner possessing the knowledge and skills for safe and effective practice (NMC, 2015). The NMC also adds that practitioners must be able to recognise their limitations and undertake appropriate learning and practice activities that maintain and develop competence and performance.

In order to improve the quality of care for patients attending the surgery with wounds, a process of professional development was introduced to ensure that the PN (the author was the only PN at the surgery at the time of the evaluation) involved in wound care had the knowledge and skills to implement up-to-date research-based practice. The PN had access to a dedicated clinical support nurse from the company Advanced Medical Solutions (AMS) who provided both clinical and education support to the practice, providing theoretical knowledge of the wound-healing process and treatment options using a university-approved education package within the wound care clinics. AMS has developed a wound care educational package that has educational endorsement from the University of Chester and covers all aspects of wound care and its management (AMS, 2013a) for health professionals. This provided the PN with access to a flexible way of learning, allowing her to challenge existing practice and build on her knowledge and skills to make informed decisions on patient care. The aim of providing an educational resource is to ensure that both clinician and patient achieve maximum benefit from the package, with the clinician developing appropriate skills and improved outcomes and experience for the patient (Forder, 2011).

**Product review**

As PNs have an integral part in managing both acute and chronic wounds within a community setting, it is essential that they can make informed decisions as to which products to use. An in-market clinical evaluation was undertaken in the author’s wound care clinic. The use of alginate dressings was selected for review because of the high number of wounds on which they were used.

A clinical in-market evaluation of 23 patients was carried out to assess the performance of ActivHeal Aquafiber® in clinical practice. The primary objective was to evaluate the performance of the dressing in providing the optimum environment for healing. The secondary objectives were to evaluate the product, including ease of application and removal, and patient and clinician satisfaction.

Hydrofibre and alginate dressings are frequently used, because they are easy to use, are effective at managing wound exudate and are relatively low-cost (Griffin, 2014). Alginites have been used within the wound care environment since the early 1940s (Clarke, 2012) and are still considered to be complex versatile dressings, particularly for the management of wounds where there is excess exudate (Thomas, 2000a). There are a number of alginate products available, all of which are derived from seaweed, but there are differences between the type of seaweed, consistency of the dressing and performance (Thomas, 2000b). This has been attributed to the differing ratios of mannuronic and guluronic acid (the acids derived from the seaweed) that can influence the presentation of the dressing and the consistency of the gel when the dressing becomes wet (Clarke, 2012).

Alginites are applied to the wound as a fibre sheet, rope or ribbon, which becomes a soft gel once exudate has been absorbed into the product as a result of ‘an ion-exchange reaction’ between the calcium ions in the dressing and sodium ions in serum or wound fluid (Thomas, 2000c). The release of calcium ions into the wound bed is also thought to stimulate the cytokines and subsequently to encourage wound healing (Thomas, 2000c).

ActivHeal Aquafiber is a highly absorbent, conformable, non-woven gelling alginate fibre dressing with a reinforced layer hidden within the mannuronic fibres, which gives the fibrous dressing greater wet strength. When the dressing fibres come into contact with exudate, they swell and form a soft cohesive gel dressing that provides an ideal moist environment required to support wound healing (Hawkins, 2010). It has the ability to absorb exudate vertically into the dressing, reducing...
the risk of maceration and damage to the peri-wound skin or to the wound itself (Timmons, 2008; Ousey et al, 2011). In vitro studies have demonstrated its ability to absorb a large amount of wound exudate with in vitro studies indicating this to be 23 g of fluid per 100 cm² of dressing over a 24-hour period. This is equivalent to other fibrous dressings available (Kesteven et al, 2012).

ActivHeal Aquafiber is indicated for use as a primary dressing for acute and chronic wounds and full-thickness and partial-thickness burns, where there is moderate to heavy exudate (Hawkins, 2010). The dressing also has a high wet tensile strength, so that it can be removed intact and minimises the risk of leaving any fibres within the wound (Kesteven et al, 2012); leaving dressing fibres behind can be problematic as they could become a focus for infection (Timmons, 2008).

As with the majority of alginate products, it requires a secondary dressing, which should be selected according to the level of exudate, peri-wound skin condition and patient preference (Morris, 2006). Aquafiber also has haemostatic properties and therefore can also be used to control minor bleeding (Thomas, 2000a). The product is CE marked which states that it can be used on bleeding wounds as a haemostat (AMS, 2013b). This makes it an ideal product to use following some minor surgical procedures undertaken within the primary care environment in GP surgeries.

Method
A prospective evaluation was conducted to investigate the clinical performance and acceptability to patients and clinicians of ActivHeal Aquafiber dressing. The primary objective was to assess the clinical performance of the product in providing the optimum environment for healing. This was determined by progression to healing looking at reduction in wound size and increase in the percentage of viable tissue in the wound bed.

The secondary objectives of the evaluation included observing the effectiveness of the dressing in managing wound exudate and the impact on the peri-wound skin condition, the ease of application and removal and acceptability to clinician and patient.

The need for ethical approval was investigated but not required, as the dressing was evaluated as part of the standard care delivered within the practice. Local guidance for product evaluations was followed. The GPs gave permission for the product evaluation to take place. All clinicians were supported by offering specific guidance on the recommendations for use of the dressing, as recommended in the product leaflet (AMS, 2013b), and patients were treated in accordance with the instructions for use and data were collected without any changes to treatment protocol.

The evaluation was conducted in accordance with basic ethical principles such as informed consent and consent for photography. Confidentiality was maintained at all times and patients were identified only by an allocated study number, sex and their age in years.

A convenience sample of patients who attended the surgery over a 6-month period who required treatment with an alginate dressing was planned. Patients were required to be over 18 years of age and able to understand and consent to participating in the evaluation. The patients also had to be compliant with treatment, have no suspected or known sensitivity to alginate dressings and present with a wound that was assessed as appropriate for ActivHeal Aquafiber by the PN. Wounds where there was insufficient exudate to require a fibre dressing were excluded from the evaluation.

A bespoke evaluation form was used to record information on the patient’s coexisting illnesses, wound aetiology, size and location, status of the wound bed, peri-wound skin condition and exudate level. This was completed at the start of the evaluation, before ActivHeal Aquafiber was applied to the wound, and for up to 4 weeks of continuous use. The evaluation was completed at each wound assessment and dressing change over the 4-week period. Wound photography was also used to record wound progression, and to support the written data. Dressing products that had been used before using ActivHeal Aquafiber were also documented, as was the frequency of dressing change during the evaluation period.

At the initial assessment where ActivHeal Aquafiber was introduced, the wounds were measured and photographed at a minimum of weekly intervals. This enabled the data to be collated to provide clinical evidence relating to wound progression and the achievement of patient outcomes.

At the end of each patient evaluation, the performance of the dressing was rated by the clinician, based on her experience and comments made by the patients during the treatment. The clinician was given a list of preset criteria, which included ease of application and removal, whether it was comfortable for the patient to wear, the ability of the dressing to remain on the wound and maintain a moist environment. The clinician was required to rank her experience and observation on a scale of 1-5 (1 being excellent and 5 poor).

No statistical analysis was planned for the evaluation because it was anticipated that the patient numbers would be too low to generate any significance. Data were analysed using a simple spreadsheet to provide information on patient demographics, wound information and clinician’s assessment on dressing performance.

A total of 23 patients were recruited into the evaluation of which 70% (n=16) were female and 30% (n=7) were male, with ages ranging from 25 to 71 years (mean 49.8 years). A range of different wound aetiologies were included, with surgical wounds being the most prevalent (Table 1).

A total of 61% of patients (n=14) had coexisting illnesses which can have a negative impact on healing. Of the 23 patients, 26% (n=6) had a diagnosis of diabetes.

Results
The outcome of the evaluation demonstrated that ActivHeal Aquafiber had been used according to the manufacturer’s instructions as a primary dressing. Of the 23 patients, 35% (n=8) were recorded as having used Aquafiber on the wound at the start of treatment, with the remaining 65% (n=15) observed to have been changed from an alternative product; for 40% of these patients (n=6) this was the alternative alginate available on the wound care formulary.

The choice of secondary dressing and frequency of
dressing change was determined by the clinical assessment of the wound in relation to exudate level, patient comfort or pain and condition of the wound and peri-wound skin condition. On 70% of patients (n=16), an adhesive foam dressing was used as a secondary dressing, with an alginate combination dressing or bandage being the product of choice for 13% (n=3). The PN chose the secondary dressing following an assessment of the surrounding skin and the position of the wound. Data on the secondary dressing used were missing for 17% of patients (n=4). The choice of secondary dressing may have impacted the effectiveness of exudate management, frequency of dressing change and patient comfort.

At the initial assessment undertaken before using ActivHeal Aquafiber, the size of the wounds was recorded and varied from 0.6 cm² to 50 cm², with 30% (n=7) recorded as having a cavity. For the purpose of data analysis, they were categorised into five groups according to the size. Data were excluded for two patients as it was missing for one patient and recorded as there being multiple wounds for a second.

Figure 1 demonstrates the range of wound sizes, at the start and end of the evaluation period, where it was recorded that 11 patients had healed. In the remaining 10 patients, all of the wounds had decreased in size, with no cavities reported.

The condition of the wound bed was recorded at the start and end of the evaluation period for all patients (n=23). None of the patients included in the review were observed to have necrotic tissue in the wound, but 74% (n=17) were reported to have slough present. Table 3 shows the percentage of viable tissue (epithelial and granulation) recorded at the start and end of the evaluation period. At the start of the evaluation six patients were assessed as having 100% viable tissue in the wound bed (all of which was granulation tissue). This increased to 18 patients at the end of the evaluation, of which 11 had healed (100% epithelial tissue) and the remaining 7 were reported to be free of slough.

A wound assessment was performed to evaluate the progression of the wound, to highlight any elements that may delay wound healing and to evaluate the effect of the current treatment objectives (Ousey and Atkin, 2013). Practitioners who care for patients with wounds need the necessary skills to accurately assess and understand the result of an assessment, allowing development of an appropriate, evidence based treatment plan (Ousey and Cook, 2012).

Although alginites are not always the first choice for wound debridement within the clinic, ActivHeal Aquafiber is often used to remove superficial soft slough from the wound bed, in wounds where exudate management is a priority and an absorptive dressing is required. As the dressing forms a gel it provides an environment that aids in the facilitation of autolysis of devitalised tissue (Hawkins, 2010). In this evaluation it was observed to effectively facilitate autolytic debridement of soft slough, and assist in preparing the wound bed to heal in the majority of patients.

All of the patients had a wound where the level of exudate was assessed as moderate or high by the PN using clinical judgment at the start of the evaluation. Peri-wound skin maceration was observed in 13% of patients (n=3). A total of 22% of patients (n=5) had wounds with a clinical diagnosis of infection, and were treated with systemic antibiotics.

| Table 1. Wound aetiologies included in the evaluation |
|----------------------------------------|------------------|
| Wound type                      | Number of patients |
| Diabetic foot ulcer             | 2                |
| Abscess                        | 2                |
| Leg ulcer                      | 1                |
| Skin tear                      | 1                |
| Self harm—laceration           | 2                |
| Pilonidal sinus                | 1                |
| Surgical wound                 | 14               |

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All of the patients had a wound where the level of exudate was assessed as moderate or high by the PN using clinical judgment at the start of the evaluation. Peri-wound skin maceration was observed in 13% of patients (n=3). A total of 22% of patients (n=5) had wounds with a clinical diagnosis of infection, and were treated with systemic antibiotics.
At the end of the evaluation, 96% of patients (n=22) were recorded as having low or no exudate, with the remaining patient documented as having a moderately exuding wound. There were no reported new infections after treatment with ActivHeal Aquafiber, and only one incidence of peri-wound skin maceration.

Overall the dressing performed well in respect of fluid handling and durability. The clinical performance of the dressing met the clinician’s expectations of a fibre dressing. The dressing addresses patients’ needs in terms of easy application and removal, prevention of leakage and wound progression.

While acknowledging the limitations, such as lack of control of external bias, internal validity, the lack of a comparative data group and the small sample size, the evaluation can provide interesting clinical data on the patient groups.

**Case studies**

**Case study 1**

The patient initially presented on 5 July 2013 (Figure 3) with a recurrent swelling to her buttock and following surgery was discharged for dressing changes from the PN. Treatment aims initially were to promote granulation tissue growth and provide absorption for exudate. The wound bed tissue type was 100% granulation with moderate exudate levels. ActivHeal Aquafiber was applied to absorb exudate, provide an optimal healing environment at the wound bed and reduce maceration to surrounding tissue. ActivHeal foam adhesive was applied as a secondary dressing to assist in exudate management and secure the primary dressing.

By 8 July, the wound dimensions had decreased, there was less exudate and granulation tissue was present at the wound bed (Figure 4). The patient was happy with the wound progress and found the dressing comfortable to wear. The peri-wound area was healthy and intact. By 22 July, the wound had reduced again in size, dressing changes were now only once weekly and there was less exudate (Figure 5). The patient was happy with the wound progress.

**Case study 2**

Following surgery on 1 February 2013 the patient presented to the PN with a surgical wound on 1 May (Figure 6). The wound had previously been managed using an alginate-based dressing. Past medical history stated that the patient had peripheral vascular disease, coronary heart disease and cardiac abnormality. The treatment aims initially were to promote granulation tissue growth and provide absorption for exudate. The wound bed tissue type was 100% granulation with moderate exudate levels. ActivHeal Aquafiber was applied to absorb levels of exudate, promote cell reproduction at the wound bed and reduce maceration to surrounding tissue.

Eight wound assessments were completed and the wound had progressed through the wound healing continuum to be fully epithelialised and healed by 15 June. Figure 7 shows the wound on 1 June. Throughout the reassessment period, exudate levels were moderate and dressing changes occurred three times a week. Aquafiber was used as a primary dressing to absorb exudate and promote healing. ActivHeal foam adhesive was applied as a secondary dressing to assist in exudate management and secure the primary dressing.

**Budgetary implications**

Wounds not only have an effect on patient outcomes, they can also be a drain on resources; wound care is estimated to cost the NHS £1.4–2.1 billion each year, representing up to 4% of total NHS expenditure (Dowsett and Shorney, 2010). At a time when cost saving has become an increasing priority within the NHS, wound management is an area where it is possible to lower the financial burden of care, as dressing selection can offer the opportunity to reduce expenditure without reducing the quality of care. The clinical in-market evaluation undertaken with ActivHeal Aquafiber suggests that there is potential for cost savings. It was impossible to calculate exactly, but the author noted that:
Case study 2

The frequency of dressing change was the same as with other fibre dressings previously used, such as Sorbsan and Aquacel. The unit price per dressing for ActivHeal Aquafiber is less than other similar products on the Drug Tariff, such as Sorbsan and Aquacel (Drug Tariff, 2015). The clinical outcomes observed in this uncontrolled evaluation suggest that, when used as part of a programme of care (also including a patient assessment and identification of comorbidities that can affect healing), Aquafiber can provide an optimal environment for wound healing. There were no reported incidences such as new wound infections, which could increase the cost of care substantially. In addition, complications such as peri-wound skin maceration decreased indicating that there may be a reduced requirement for skin-protecting products.

A recent investigation by Powys Health Board undertook an evaluation to consider the performance indicators of different wound care products and choose the best care pathway for the patients. The Health Board took costs into consideration and selected treatments that offered savings without compromising quality and care for its patients. The results highlighted that by challenging its current practice and using a different gelling fibrous dressing of Aquafiber instead of a hydrofibre dressing, significant cost savings could be achieved without diminishing the quality of care provided (Griffin, 2014).

As a result of the author’s evaluation, ActivHeal Aquafiber became the fibrous dressing of choice at the author’s GP surgery.

Conclusion

The outcome of the clinical in-market evaluation suggests that ActivHeal Aquafiber may be suitable for use in PN wound care clinics. Although this was an uncontrolled study that observed the outcome of using the dressing within standard practice, all patients demonstrated an improvement in wound status, with 11 progressing to healing. It was considered easy to use by the clinician and acceptable to patients. It also performed well with a range of secondary dressings.

Clinicians who provide wound care face many challenges, one of which is the effective management of exudate levels. The selection and appropriate use of dressings is important. Inappropriate management can lead to increased demands on time and resources, and can result in delayed healing and further complications. In general practice, clinics run by PNs are often stretched to capacity, so the treatment of exuding wounds needs to be effective and efficient.

Alginate dressings have been identified as an effective product for exudate management, and this simple evaluation of ActivHeal Aquafiber when used within the PN clinic demonstrated that it was easy to use, acceptable to both clinicians and patients and provided a suitable environment for wound progression in the majority of patients.

One of the challenges facing the NHS is to improve the quality of care for patients, adapt to changing healthcare demands and to improve the productivity of the service (NHS England, 2014). PNs have a proactive part to play in improving the quality of service for patients who attend clinics for wound care treatment, and recommending service developments to meet the challenges within the NHS.

By using the services offered through a commercial partnership and using wound care products effectively, the service delivery was improved. The use of low-cost but clinically effective dressing products also contributed to cost containment. The ActivHeal Aquafiber dressing performed well in the evaluation in terms of fluid handling and managing exudate, and met both patient and clinician expectations of a fibre dressing.

Conflict of interest: this article was supported by Advanced Medical Solutions.


Enoch S, Price P (2004) Cellular, molecular and biochemical differences in the pathophysiology of healing between acute wounds, chronic wounds...
PRODUCT EVALUATION

KEY POINTS

- The number of patients requiring treatment of acute wounds in primary care is likely to increase.
- A clinical in-market evaluation of 23 patients was conducted to assess the performance of ActivHeal Aquafiber.
- Practice nurse play an integral part in managing both acute and chronic wounds within the community.
- The clinical performance of the dressings evaluated in this study met the clinicians’ expectations of a fibre dressing.
- The dressings evaluation provide an environment that aids the facilitation of autolysis of devitalised tissue.