Case report series of Actilite Protect®:
an eight-patient clinical evaluation

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INTRODUCTION

The specialty of wound care is one that has expanded exponentially in modern times with a plethora of theories and technologies, including wound bed preparation, the role of proteases, negative pressure wound therapy (NPWT), and an almost bewildering array of dressing formulations, from antimicrobials to larval-based products. However, for the clinician on the ground who may not have time to appraise all the theory — or indeed afford all of the new technologies — there is still a high premium placed on having a range of wound care dressings that can be used on a variety of wounds, are simple to use, patient-friendly, and — increasingly important in this day and age — cost-effective (Chandan et al, 2009).

To this end, Advancis Medical offers a series of dressing options for the clinician to choose from depending on the patient's needs, whether this be a primary non-adherent foam dressing for use under compression (Advazorb®); a soft silicone wound contact layer that protects the periwound skin (Silflex®); or a superabsorbent dressing that can be used to manage excess exudate production (Eclypse®). The aim is for the breadth of this product range to meet clinical need and improve patient outcomes.

However, an area as diverse as wound care demands constant innovation and to further meet the needs of patients, Advancis Medical has created Actilite Protect®, a dressing that combines the silicone, foam and honey technology found across the company's wound care range to create one unique dressing.

ACTILITE PROTECT®

Faced with a growing incidence of chronic and acute wounds, clinicians need practical solutions as well as theories. Fortunately, among the advances borne out of our greater understanding of wounds are new dressing technologies designed to combat some of the conditions that lead to poor healing, as well as the symptoms that cause such distress for patients. Actilite Protect® (Advancis Medical) is one such dressing. Comprising a hydrophilic foam dressing with a soft silicone wound contact layer and border, it also contains medical grade Manuka honey and a Manuka oil dissolvable film.

Upon contact with exudate, the film forms a 'gel-like' substance absorbing exudate while maintaining the moist wound healing environment crucial to wound healing. Simultaneously, the honey/oil contained within the dressing directly penetrates the wound, working to combat the action of harmful bacteria. Actilite Protect is designed for use on the full range of wounds, including chronic leg ulcers, pressure ulcers, diabetic ulcers and infected wounds, as well as acute skin tears and post-surgical wounds.

HONEY

Medical grade honey (a specifically manufactured product that is sterilised to remove impurities or potential bacteria) has been shown to have many applications in wound care, particularly when used as part of a dressing's composition. Honey has a gentle debriding effect on a wound, creating a moist wound environment that facilitates autolysis by drawing fluid from the wound through powerful osmotic action, while simultaneously rehydrating devitalised tissue (Gethin and Cowman, 2008; Evans and Mahoney, 2013). Honey's broad spectrum of action against bacteria has been widely reported and its antibacterial action can even have an effect on resistant strains of bacteria such as meticillin-resistant *Staphylococcus Aureus* (Wahdan, 1998). It has also been able to kickstart healing in wounds that have been previously unresponsive to antibiotics (Dunford, 2000). Honey has been shown to be effective on a variety of different wound types including venous leg ulcers, pressure ulcers, burns, surgical wounds, necrotising fasciitis and oncological wounds (White, 2005a).

Honey's wound care properties

Anti-inflammatory

The antioxidants in honey produce an anti-inflammatory effect that reduces the amount of exudate, slough and devitalised tissue in the wound bed (Bradbury et al, 2014). It also acts against the over-inflammation that can impede healing, while simultaneously promoting angiogenesis (Bainbridge, 2013).

Antimicrobial properties

Honey is typically made up of 80% sugar and 17% water. The sugar binds the water molecules making it impossible for microbes to use them. An enzyme which is added to the honey as it matures — glucose oxidase — converts some of the glucose to gluconic acid which creates a hostile environment that is too acidic for microbes to thrive (White, 2005a). This conversion also produces hydrogen peroxide which acts as a broad spectrum antiseptic (White, 2005a). Honey can prevent the formation of *Pseudomonas aeruginosa* biofilm i*n vitro* in laboratory studies, as well as inhibiting and

disrupting established biofilm (Cooper et al, 2014). There is also a suggestion that using honey is less likely to result in the development of resistant strains of bacteria: a widespread problem that has happened as a result of the over-use of antibiotics (European Wound Management Association [EWMA], 2014).

Promotes debridement in sloughy and necrotic wounds and creates a moist wound environment

Honey promotes autolytic debridement by providing a moist wound environment and through the possible activation of proteases (Molan, 2009). The high sugar content and low water levels in honey produce an optimal moist environment for wound healing by exerting an osmotic effect that can draw excess moisture away from the wound (Molan, 2009).

Reduces or eliminates wound malodour

Wound dressings that contain honey are particularly suited to malodorous wounds that have local infection (White 2005b). Honey stops the production of ammonia and other odorous products of bacterial decomposition in necrotic wounds (White and Molan, 2005). It also debrides devitalised tissue and reduces bioburden and any accompanying smell (Bradbury et al, 2014).

Stimulation of healing

Honey promotes the production of cells that promote healing and the growth of new tissue.

CASE REPORTS

Advancis Medical was the first company in the UK to introduce medical grade Manuka honey into wound care dressings and it has since developed a wealth of expertise and knowledge in producing innovative honey-based products. This case report series explores the use of Actilite Protect over a predetermined time period in a range of wounds. The evaluations provide an overview of Actilite Protect's action on non-healing wounds. Both the outcomes and clinician/patient feedback show that this dressing is a worthy addition to the healthcare professional's wound care toolkit, from a clinical, quality of life and health economic perspective.

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The evaluations detailed in this case report series were undertaken by:

Sarah Mancini, clinical director, Clinical UK Ltd (*cases 1–2*)

Jackie Stephen-Haynes, professor and consultant nurse in tissue viability, Birmingham City University and Worcestershire Health and Care Trust (*cases 3–8*)

Rosie Callaghan, tissue viability nurse specialist, Worcestershire Health and Care Trust (*cases 3–8*)

CASE REPORT 1

This case shows how the introduction of a honey-based foam dressing into the treatment of a leg ulcer managed to improve the condition of the wound bed.

The patient was a 45-year-old woman who had developed a leg ulcer above the right malleolus, which had been present for one year. She was a non-smoker and had no underlying conditions that might have affected wound healing, although she did have limited venous return due to previous trauma to the area.

Nurse visits to treat the patient's wound had varied from twice- to once-weekly, but there had also been periods when she did not see nurses for some months. Various treatment options had been tried, including iodine and non-adhesive dressings.

Figure 1.
The wound at presentation showing white maceration around the edges.

Figure 2.
Wound showing reduced maceration.

Wound progress

During the evaluation an Actilite Protect dressing was used. The dressing has a three-in-one structure (foam, Manuka honey and a silicone wound contact layer), which was considered useful in this patient.

At initial presentation, the wound measured 3x3cm and was 2cm deep. There was white maceration around the wound site and the wound bed itself was dark yellow/red with some over-granulation. Critical colonisation was also evident (*Figure 1*).

After one week of treatment with Actilite Protect, the white maceration around the wound site had reduced. Granulation had increased and there was evidence of further epithelialising tissue. The depth of the wound had reduced to 1cm and there were no longer any signs of critical colonisation (*Figure 2*).

At the end of week two there was further granulation and epithelialisation. The periwound skin was healthy and the wound had improved generally, although the dimensions remained the same as at the end of week one.

No other dressing was used in conjunction with the Actilite Protect, which was rated by the clinician as very easy to use, apply and remove, as well as being atraumatic to the wound bed and periwound skin. The dressing conformed well to the wound with no pain on application and removal. It was also intact on removal and remained in place as long as expected with no rolling of the edges.

The clinician also felt that the dressing's Manuka honey film layer helped to prevent infection in the wound and that overall the dressing had aided healing, providing a moist healing environment with a natural honey component.

The patient also found the dressing comfortable, and, although she did experience a little pain with its use, she was satisfied with the overall treatment.

CASE REPORT 2

In this case a honey dressing was used on a 71-year-old patient's toe ulcer, helping to close the wound and reduce the bioburden, as well as staying intact on removal.

The patient was a 71-year-old man who lived in a care home. He had an ulcer behind his large toe — this consisted of a small broken area with localised infection which had been present for 1–2 months. The patient's nutritional status was poor and he had been using systemic antibiotics for some weeks before starting the evaluation.

Historically, the patient had not wanted to engage with healthcare professionals but became interested in the evaluation after finding out that it featured a natural product — the Manuka honey incorporated into the structure of Actilite Protect.

Wound progress

During the evaluation an Actilite Protect dressing was used, partly for its antimicrobial action.

On presentation, the wound was locally infected and red with inflammation. It measured 5x5cm and was 1mm deep. After one week of using Actilite Protect there was some reduction in inflammation and the wound had begun to close. Although it was still vulnerable, there were no signs of infection. At the end of week two the wound site remained closed and was on course to heal.

The clinician rated Actilite Protect as very easy to use, both in terms of application and removal. It was atraumatic to the wound bed and periwound skin and conformed very well to the wound.

The patient did not report any pain throughout the course of the evaluation and the dressing remained intact on removal, staying in place as long as expected with no rolling of the edges.

At the end of the evaluation, the dressing had contributed to wound closure and helped to reduce the bioburden. However, infection was still present and antibiotics were required. The patient rated the dressing as very comfortable and was very satisfied with the treatment and lack of pain.

Overall, the clinician was pleased with the outcomes achieved by using Actilite Protect on this patient's ulcer.

CASE REPORT 3

This case shows how a honey-based foam dressing tackled the infection present in a patient's leg ulcer, as well as helping the wound heal and reducing exudate volumes.

Figure 1.
Wound at the outset of the evaluation.

The patient was an elderly woman who was residing in a care home. She had diabetes and a poor nutritional status and had smoked in the past.

The ulcer on her lower leg had been present for six weeks with dressings being changed every two days because of excessive exudate. She had been given systemic antibiotics before the evaluation, but did not take any during this two-week trial of Actilite Protect. At presentation, the wound bed exhibited 100% granulation tissue and the wound itself measured 4x3cm. There were signs of critical colonisation and the periwound area was red. The patient rated her wound pain as '6' on a 10-point scale where '10' indicated the worst pain.

Wound progress

Actilite Protect (10x10cm) was used in conjunction with Sorbaderm® No-sting Barrier Film (Aspen Medical) with the dressing being changed every three days. After one week, the wound had reduced in size to 4x2cm with an island of epithelialisation, however there were still signs of critical colonisation and the patient's pain levels remained high.

By the end of week two, the wound had reduced in size to 2x2cm. The critical colonisation had resolved and the pain had reduced to a rating of '2', with the dressing now being changed every four days. The clinician noted that the dressing was atraumatic to the wound bed and almost atraumatic to the periwound skin, although the clinician did mention that the adhesive remover may have helped with this. The dressing conformed well to the wound and there was no pain on application, although there was some on removal. The dressing stayed intact as well as remaining in place as long as expected, with no rolling at the edges.

At the end of the two-week evaluation the clinician concluded that Actilite Protect had tackled the infection effectively and helped the wound to heal (*Figures 1–3* show the wound's improvement). The dressing made a great difference to the appearance of the wound bed, with healing noted and exudate and pain levels both reduced. The three-in-one structure of the dressing (foam, Manuka honey and a silicone wound contact layer) was appreciated by the clinician and it was considered cost-effective and easy to apply. Overall, the clinician reported that Actilite Protect was very easy to use and easy to remove.

The patient found the dressing very comfortable and was very satisfied with the treatment, particularly the reduced pain levels.

Figure 2.
Wound reducing in size.

Figure 3.
Towards the end of the evaluation the wound exhibited reduced exudate volumes.

CASE REPORT 4

This case features a patient with two connected sacral wounds that reduced in size and severity when treated with a honey-based foam dressing.

Figure 1.
The connected wounds at presentation.

This patient was a 78-year-old female non-smoker without any underlying conditions, although her nutritional status was described as poor. The sacral abscesses had been present for two weeks and were being dressed by her regular nurses before she agreed to join the Actilite Protect evaluation. No systemic antibiotics were used before or during the evaluation.

Wound progress

At presentation, the patient had two sacral wounds, which were found to be connected when probed (*Figure 1*). The wound bed comprised 100% slough and the joint area of the two wounds measured 4x3cm. There were signs of local infection, the periwound skin was reddened, and the patient rated her pain as '8' on a scale of 1–10, where '10' was the worst pain.

The dressings were being changed every three days before the switch to Actilite Protect. As well as Actilite Protect (10x15cm), the clinicians also applied Sorbaderm® No-sting Barrier Film (Aspen Medical) to the periwound skin throughout the two-week evaluation.

After a week of treatment with dressing changes being performed every three days, the wounds had merged into one and the slough had become 'runny' (*Figure 2*).

The overall wound dimensions had not changed, there were still signs of local infection and the periwound skin was still red. However, the pain was much reduced and the patient now rated it as '2' on the 10-point scale.

By the end of the second week the wound's dimensions remained the same but the wound bed comprised 100% granulation tissue and the redness of the periwound skin was greatly reduced *(Figure 3)*. There were no signs of infection and the patient's pain levels had reduced to '0'.

The clinicians chose to carry on using Actilite Protect even after the evaluation was completed because it had worked so well at reducing the inflammation (*Figure 4*).

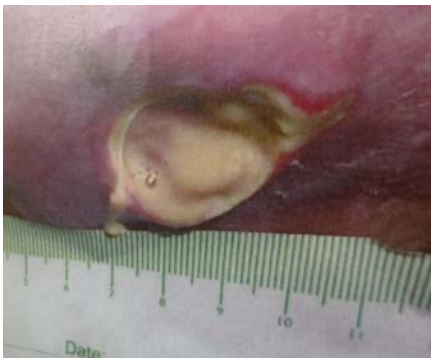


Figure 2.
After one week of treatment with Actilite Protect, the two wounds had merged and the slough had become 'runny'.

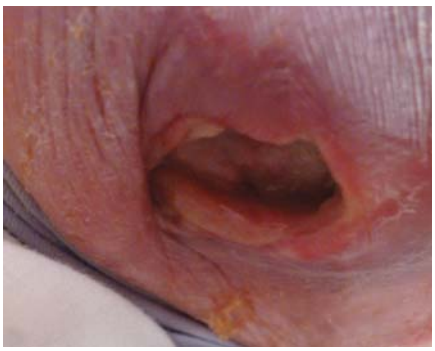


Figure 3.
At the end of week two there was 100% granulation in the wound bed.

At the end of the evaluation period the clinician was asked to rate Actilite Protect on a scale of '1' (very easy) to '5' (very difficult), and gave it a score of 1. As well as being rated easy to use and apply and very easy to remove, the clinician also noted that Actilite Protect was atraumatic to the wound bed throughout the dressing's wear time. With regard to conforming well to the wound, the clinician rated it '3' out of '5', as it was found to fit the shape of the patient's body well.

The patient did not experience any pain due to the use of Actilite Protect — this was also true of removal, with no analgesia being required. The dressing remained intact on removal and stayed in place while in use with no sign of rolling.

The clinician stated that Actilite Protect's dissolvable film of Manuka honey made a great difference to the condition of the periwound skin, helping to reduce inflammation as well as contributing to the healing of the wound itself. The clinician also appreciated the dressing's three-in-one action (foam, Manuka honey and a silicone wound contact layer), as this made dressing changes easier. The patient reported that the dressing was very comfortable. She had experienced no pain from the wound once the inflammation had reduced and she was very satisfied with the treatment.

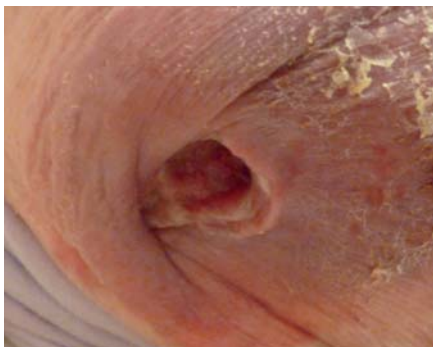


Figure 4.
During the trial the inflammation was greatly reduced.

CASE REPORT 5

This case details how a honey-based dressing was used as an all-in-one treatment option in the case of patient with a foot ulcer.

Figure 1.
Wound at week one showing 100% granulation in the wound bed.

This patient was an 82-year-old former smoker who was living in a care home. He had an ulcer on the side of his left foot that had been present for one week and measured 2x1cm with 100% granulating tissue in the wound bed (*Figure 1*).

The patient tested negative for diabetes after a blood test and his ankle brachial pressure index (ABPI) was also measured and found to be normal, with a clear signal indicating a lack of arterial involvement.

Overall, there was no underlying medical condition that might have delayed healing. The periwound skin was also healthy and he was not experiencing any pain.

Wound progression

Actilite Protect (10x10cm) was used to cover the wound, and, although the clinician reported that this size initially seemed too large, the dressing did conform well to the wound. While the dimensions of the wound did not change dramatically over the two-week evaluation period, it did show signs of improvement (*Figures 2* and *3*).

Figure 2.
The wound showing an increase in epithelialisation.

Dressings were changed every four days throughout the evaluation and were reported to be easy to use and to remove, being rated '3' on a five-point scale for ease of application, with '1' indicating very easy removal and '5' very difficult removal. The dressing was atraumatic to the wound bed and the periwound skin and the patient did not experience any pain during application or removal.

Over the evaluation period, the dressing remained intact on removal and stayed in place as long as expected, with no rolling at the edges. The clinician felt that the dressing had positively contributed to wound healing and that it was easy to use because of its all-in-one composition (foam, Manuka honey and a silicone wound contact layer).

However, the clinician did comment about the sizes available, saying that smaller-sized dressings would be a useful option.

The patient found the dressing very comfortable to wear and was very satisfied with the pain-free treatment he had received during the two-week evaluation.

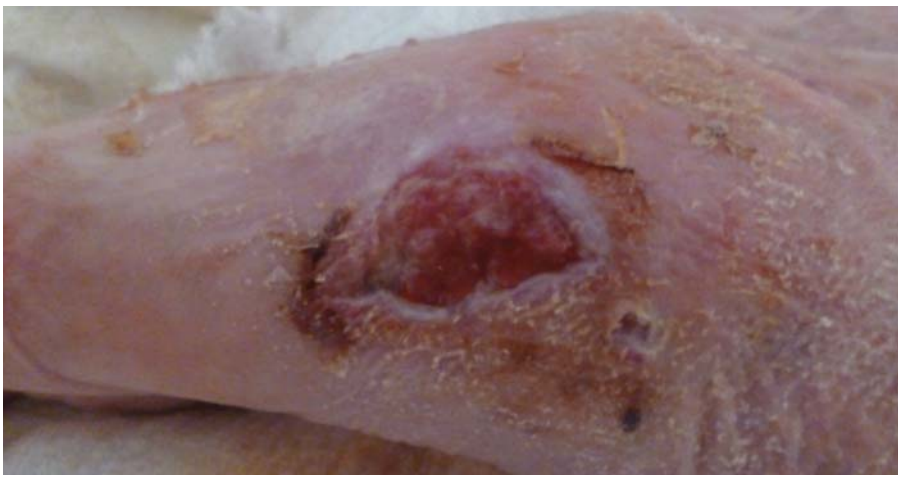


Figure 3.
The wound at week two, showing further granulation.

CASE REPORT 6

This case features an ankle ulcer that had developed significant slough and required frequent dressing change.

The patient in this case was a 96-year-old woman who lived in a care home. Her nutritional status was poor and she also had diabetes, but was a non-smoker. Due to the pressure ulcer that had developed on her ankle she had been prescribed systemic antibiotics by her GP and was referred to tissue viability. The wound had been present for four weeks and was being treated daily by the staff at the nursing home. The ulcer itself measured 2x1cm and the wound bed exhibited thin, yellow slough, although there were no signs of infection (*Figure 1*). The periwound skin was healthy.

Wound progression

At presentation the dressing was being changed daily and this was reduced to every three days during the evaluation period. Actilite Protect (10x10cm) was used without a secondary dressing. The clinician felt that the size was possibly too big for the wound, but still rated the dressing as very easy to use and remove, and easy to apply.

The wound's dimensions did not change throughout the evaluation but by the end of week one the slough was lifting and by week two there was no slough at all, with the wound bed having developed 100% granulation tissue (*Figure 2*). The patient's pain was rated as '3' on a 1–10 scale, where '1' indicated a 'complete lack of pain' — this rating reduced to '2' after one week of treatment with Actilite Protect.

The dressing was atraumatic to the wound bed and the periwound skin and conformed very well to the wound. There was no pain during wear and removal, and no analgesics were required.

The dressing remained intact on removal and it stayed in place longer than expected, although it did roll at the edges. The care home staff needed to be persuaded to change the dressing less frequently (every three days), as they had been used to daily changes.

The clinician felt that the Manuka honey element of the dressing helped to treat infection and slough, and that the dressing made a positive contribution to healing. Overall, the clinician was very happy with the dressing.

When the patient was asked about the dressing she said that she found it comfortable and pain-free — overall she declared herself satisfied with the treatment she had received.

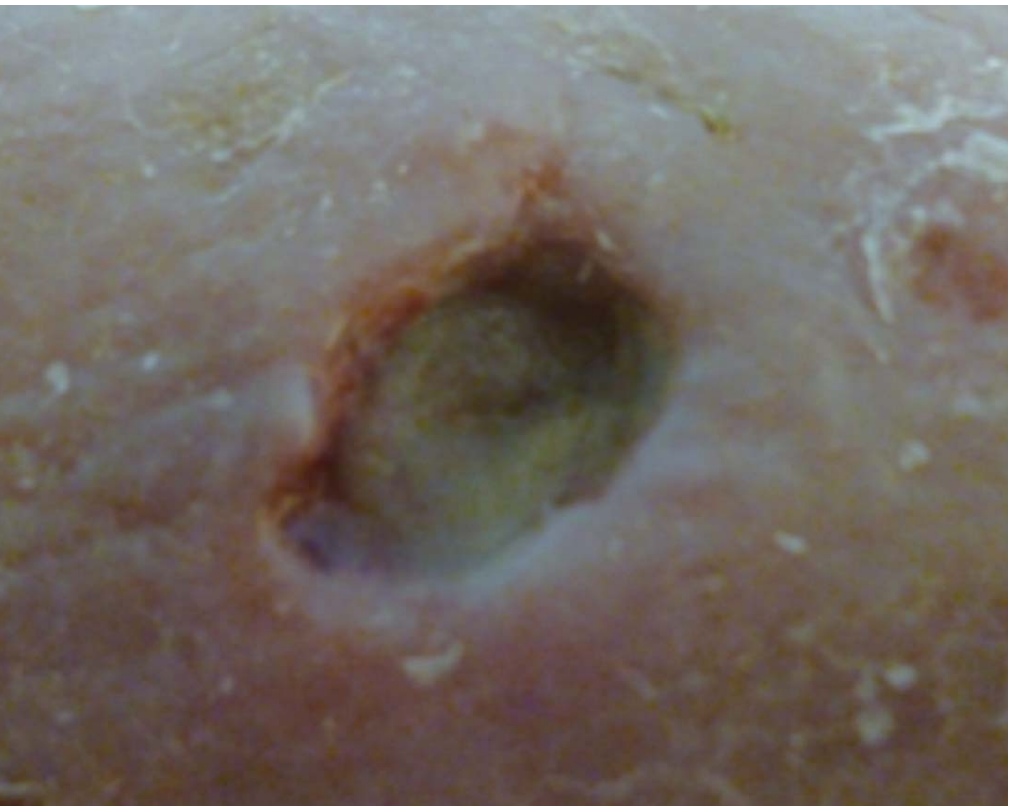


Figure 1.
The ulcer at presentation showing slough in the wound bed.

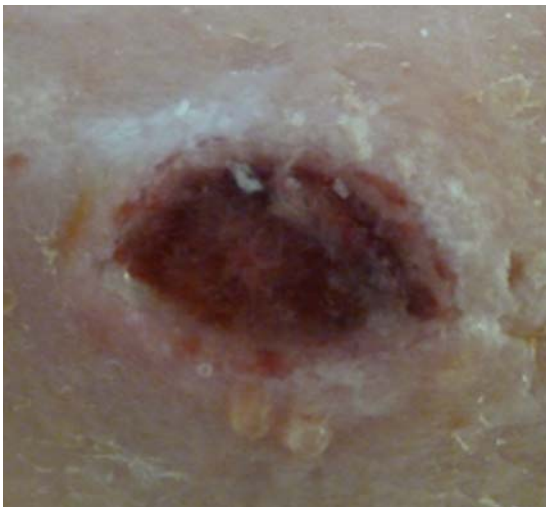


Figure 2.
At week two, the wound demonstrated 100% granulating tissue.

CASE REPORT 7

This report looks at the case of a patient with an infected non-healing pressure ulcer, detailing how a honey-based dressing reduced the size of the wound and resolved the infection.

Figure 1.
Wound after one week of treatment with Actilite Protect.

This patient was an 82-year-old woman who was being cared for in a nursing home and who had developed a pressure ulcer on the side of her left foot that had been present for six months. She was a non-smoker, but her nutritional status was described as poor and, although she did not have diabetes, this was being checked three-monthly because of the wound's very slow healing rate.

At the time of presentation, the ulcer was being dressed with Sorbsan® (Aspen Medical) every two days, with a foam dressing as a secondary dressing and a protective barrier applied to the periwound skin.

Wound progress

It was decided to use Actilite Protect on the patient's wound because of the potential benefits — Manuka honey for antimicrobial debridement; a foam layer for exudate management; and a silicone outer layer to protect the fragile periwound skin and assist with atraumatic removal.

Sorbaderm® No-sting Barrier Film (Aspen Medical) was used along with Actilite Protect (10x10cm), although the clinician commented that she would have used a 5x5cm dressing had this size been available.

Figure 2.
Healed wound after two weeks of treatment.

At presentation, the wound consisted of 100% granulating tissue and measured 1x1.5cm — it was described by the clinician as critically colonised. The periwound skin was red but the wound itself was not causing the patient any pain. After one week of treatment the tissue was still 100% granulating, but the wound size had reduced to 1x1cm (*Figure 1*).

After following the new dressing regimen for two weeks, the clinician rated Actilite Protect as very easy to use, apply and remove (rating all three categories as '1' on a five-point scale where '1' was 'very easy' and '5' was 'very difficult'). The dressing was rated as atraumatic to the wound bed and the periwound skin. At the end of the trial, the dressing was being changed every five days rather than every two days, and after two weeks of treatment the wound had completely healed (*Figure 2*). The clinician stated that the infection that had been preventing the wound from healing had been resolved through the action of the dressing's Manuka honey dissolvable film.

The clinician stated that dressing changes were pain-free and that there was no need for local analgesia. The dressing remained intact upon removal and stayed in place during wear and its conformability was considered to be very good. The edges of the dressing had rolled-up, however and the clinician stated that the use of oval-shaped dressings on that particular part of the foot could be used to prevent this.

When asked about the new dressing, the patient reported that it had been very comfortable and that she was very satisfied with the treatment (rating it '1' on a scale where '1' was 'very satisfied' and '5' was 'dissatisfied'). She also reported that the treatment had been pain-free.

Whereas the previous two-dressing regimen had failed, the clinician stated that Actilite Protect positively contributed to the wound's eventual healing.

CASE REPORT 8

In this case, a trauma to the shin resulted in a wound that required exudate management and an antimicrobial dressing.

Figure 1.
Unhealed skin tear on the patient's lower shin.

Figure 2.
The wound reducing in size as treatment with Actilite Protect progresses.

This patient was a 74-year-old woman who was being cared for in a nursing home. She had an unhealed skin tear on her lower shin caused by a trauma to the leg that had occurred four weeks previously. Before the evaluation it had been treated with a foam dressing that was changed every two days.

The patient had a poor nutritional status but no underlying medical conditions and she was a non-smoker. Antibiotic s were not used either before or during the evaluation.

Wound progress

During the evaluation an Actilite Protect dressing (10x10cm) was used, as the foam can absorb mild-to-moderate exudate and the Manuka honey is a natural antimicrobial, which can help with debridement — both qualities that the clinician thought might help with this particular wound. The dressing also has an atraumatic silicone wound contact layer designed for pain-free removal.

After two weeks of treatment the clinician rated the product as '2' on a scale of 1–5 for ease of use, where '1' was 'very easy' and '5' was 'very difficult' — the dressing was also found to be easy to apply and remove (both rated '2' on the five-point scale). The dressing was considered to be atraumatic to the wound bed and the periwound skin (rated '4' where a score of '5' was considered 'atraumatic'), and it was reported to have conformed well to the wound. The dressing remained intact upon removal and stayed in place as long as had been expected, without the edges rolling.

Figure 3.
The wound demonstrating growth of granulation tissue and further reduced size.

During the two-week evaluation there had been no pain on application or removal and there was no need for analgesia during dressing changes. In fact, no pain was reported throughout the entire evaluation. When the patient was asked about the new dressing regimen, she rated it as very comfortable and was satisfied with the dressing's performance (rating it '2' on a five-point scale where '1' was 'very satisfied').

By the end of one week of treatment the wound bed consisted of 50% granulation tissue and by the end of two weeks this had risen to 100%. The wound, which measured 10x5cm upon presentation and was reported to have critical colonisation, healed after being dressed with Actilite Protect every three days.

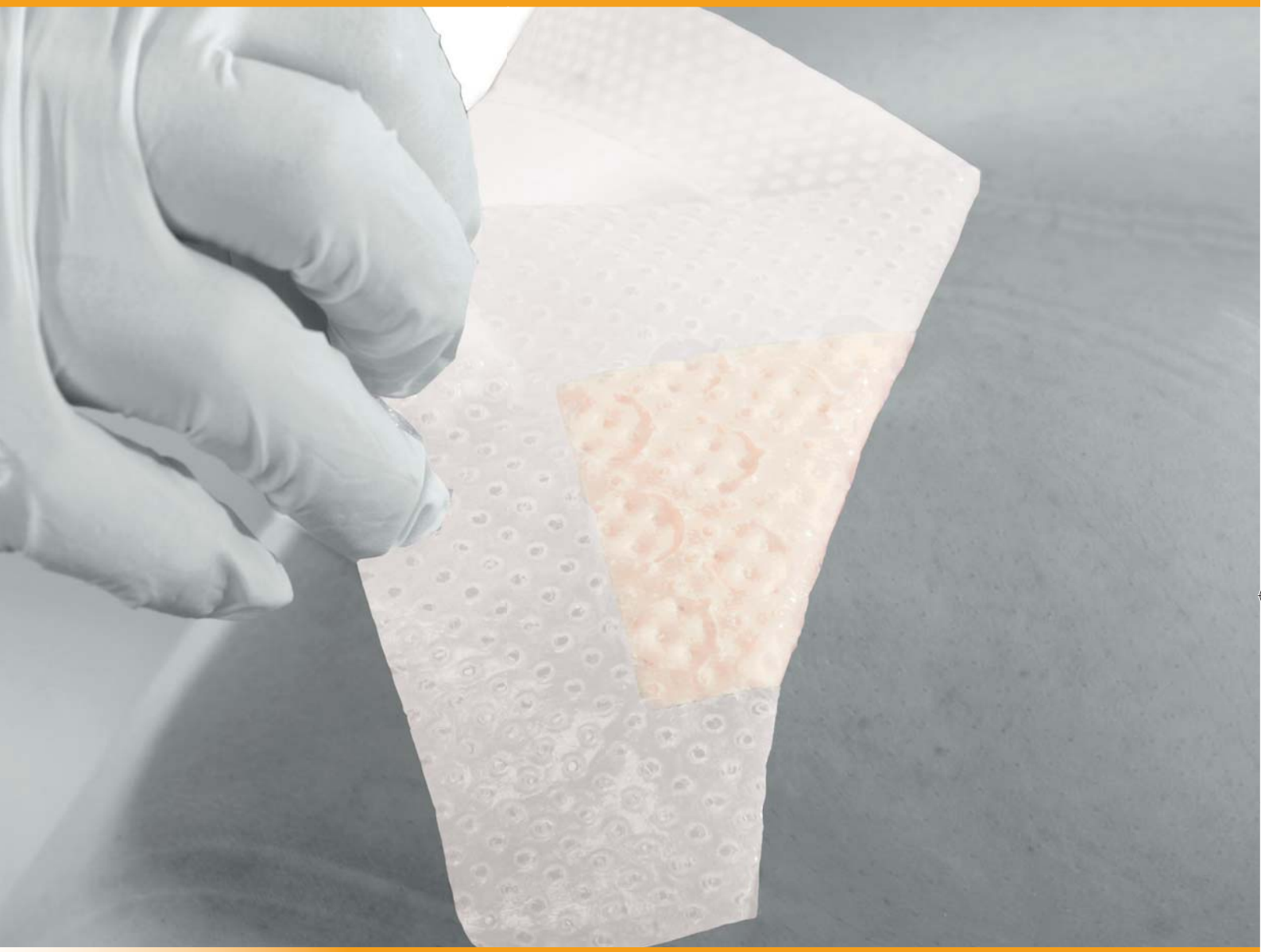
The periwound skin did develop signs of maceration during the evaluation, and the clinician commented that it would be necessary to use barrier protection on the periwound area.

The clinician was unable to say whether the Manuka honey in the dressing had treated any infection, although she did state that the product had positively contributed to the wound's healing. She was particularly impressed by the fact that Actilite Protect is a single dressing that does not require a secondary dressing, and felt that this made it easier to apply.

The clinician did express some concerns abo ut the shape of the dressing and suggested that an oval shape would prevent any rolling of the edges when using it on awkwardly positioned wounds (such as on the buttocks).

Actilite Protect®

The first time 3 dressings have been combined



Wound healing as nature intended

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