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A real-life clinical evaluation of a next-generation antimicrobial dressing on acute and chronic wounds

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A real-life clinical evaluation of a next-generation antimicrobial dressing on acute and chronic wounds

• **Objective:** To assess the effectiveness of a new, next-generation antimicrobial dressing (AQUACEL Ag+ dressing) in facilitating healing in a variety of hard-to-heal wounds that may have been compromised by infection and/or biofilm.

• **Method:** This was an international, multi-centred, real-life, non-randomised evaluation involving patients with a wide variety of slow-, non-healing or deteriorating chronic and acute wounds. There were no strict inclusion or exclusion criteria and the clinicians were asked to use their discretion in the selection of patients. The clinicians continued to use their standard protocol of care but replaced their existing primary wound-contact dressing with the next-generation antimicrobial dressing (NGAD) for up to 4 weeks. Clinicians could extend the treatment period if this was deemed clinically appropriate. Baseline assessments included wound bed characteristics, exudate level, indicators of wound biofilm, and signs and symptoms of infection. At the final assessment, the investigators reported the wound size, wound bed characteristics, and exudate level.

• **Results:** A total of 121 patients were recruited into the original evaluation, of which eight were excluded for incomplete data sets. Most wounds (73; 64%) were either venous leg ulcers (59; 52%) or diabetic foot ulcers (14; 12%). At baseline, the wounds of (26; 23%) patients were slowly improving, 65 were stagnant (58%) and 22 (19%) were deteriorating. Just under three-quarters (74%) of the wounds had suspected biofilm (criteria including failure of a wound to heal, lack of response to topical and systemic antimicrobial agents, or the presence of slimy substances on the wound surface). Following the evaluations, the average wound closure achieved for all wounds was 72.6%, 19 (17%) wounds healed, 47 (42%) achieved at least 90% wound closure, and 71 (63%) achieved at least 75% closure. The average treatment period was 4.1 weeks; 35 wounds were treated with the dressing for more than 4 weeks. Cost analysis indicated that potential antimicrobial dressing cost reductions of approximately 30% were realised using the NGAD.

• **Conclusion:** This real-life, non-randomised evaluation provides encouraging evidence that the NGAD may have a role to play in facilitating wound progression towards healing by helping to eliminate the biofilm barrier.

• **Declaration of interest:** M. Walker, D. Metcalf, D. Parsons and P. Bowler are all employees of ConvaTec Ltd. Aysha Mendes da Mata is an independent writer and Annemarie Brown is an independent clinician, both received a fee and support from MA Healthcare to write up the evaluation using data supplied by ConvaTec.

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biofilm; wound healing; chronic wounds; leg ulcers; debridement; AQUACEL Ag+; wound dressings

Research into the pathogenesis of non-healing wounds has revealed the increasingly complex and ever-challenging task of achieving closure in these wounds. The impact of intrinsic and extrinsic factors such as wound aetiologies and chronicity, ischaemia, comorbidities, medication, infection and the negative effects of prolonged inflammation are well documented.[1–4] More recently, however, attention has focused on wound biofilm to explain why some wounds do not heal.

Although microbial bioburden has long been recognised as a potential barrier to wound healing, biofilm is now being considered as a key microbial impediment.[1,5–7] Biofilm involves surface-attached microbial communities encased within, and protected by, a self-produced extracellular polymeric substance (EPS).[6] This barrier, often described as 'slime', protects the microorganisms from external threats by blocking the action of antimicrobial agents, such as antibiotics and antiseptics, and inflammatory cell components. In addition, polymicrobial communities within a wound can

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interact and communicate with each other in order to maintain a competitive advantage over the host.[8] Biofilm has been implicated with impaired granulation-tissue formation and epithelialisation, and persistent inflammation in wounds.[5,6,9]

There is now substantial evidence to support the existence of biofilm in chronic wounds.[6,10–15] In the light of this emerging evidence, the authors of the original TIME concept, to assess the management of chronic wounds through good wound bed preparation by assessing tissue; infection/inflammation; moisture imbalance; and edge of wound assessment, have highlighted the need to amend the framework to incorporate the clinical management of biofilm.[3,7]

Currently, best management strategies for biofilm removal include regular sharp debridement, vigorous cleansing, and appropriate use of systemic antibiotics and/or topical antimicrobial agents.[1,3,12,16–19] However, biofilm is known to re-form quickly after debridement,[7,20–22] and can tolerate the effects of antimicrobial agents and the immune system.[6,23–25] Many clinicians would find the prospect of undertaking regular sharp debridement in everyday clinical settings challenging.[26] This led Ammons[1] to suggest there is a need for additional methods of removing wound biofilm, including wound dressings.

A novel, next-generation antibacterial dressing (NGAD) utilising Hydrofiber technology has been developed that is able to effectively manage exudate in addition to managing key local barriers to wound healing, namely biofilm and infection.[4] The three interactive components of the dressing (ionic silver the antimicrobial component, a metal chelator and a surfactant which facilitates biofilm disruption) work synergistically to both disrupt biofilm and expose microorganisms within biofilm to the microbicidal action of ionic silver.[27–29]

This paper describes an international, multi-centre, real-life, non-randomised clinical product evaluation, undertaken to provide additional evidence to support previously published *in vitro* and *in vivo* data on the NGAD.[27–30] It aimed to assess the dressing's effectiveness in promoting healing in hard-to-heal wounds that may have been compromised by infection or biofilm.

Methods

In this clinical evaluation, patients with slow-, non-healing or deteriorating wounds were recruited from 33 health-care facilities across 15 countries between May and October 2013. The recruiting clinicians were all experienced in tissue viability and podiatry, and had previous experience with Hydrofiber wound dressings. While there was no strict inclusion or exclusion criteria, the clinicians were asked to use their discretion in the selection of patients with wounds that were failing to demonstrate any significant progression towards healing.

As the product had gained regulatory clearance for clinical use in all of the countries involved, no ethical committee approval was required.[31] Since this was not a clinical research study, written informed consent was not essential, but verbal consent was obtained between clinician and patient before starting the study. Product safety has previously been demonstrated in a 42-patient, non-comparative clinical study in non-healing chronic venous leg ulcers.[32]

Treatment

Clinicians were requested to continue treating their patients with their own standard protocol of care but to replace their previously used primary wound contact dressing with the NGAD for up to 4 weeks and/or as deemed clinically appropriate. The principal aim of this evaluation was to assess wound progression through the application of this new primary dressing and it is acknowledged that variations in protocols of care would be expected from country to country. However, each clinician was primarily asked to evaluate each wound before and after treatment with the NGAD.

Baseline assessment

A standard evaluation form was used for each patient to record basic demographic information, as well as details of any relevant medical history, conditions and treatment, and the following information relating to their wound:

- Type of wound
- Location of wound
- Duration of wound (0–3 months; 3–6 months; >6 months)
- Volume of wound (greatest length x greatest width x depth)
- Status of wound (slow-healing, stagnant or deteriorating)
- Tissue types present in the wound bed (% of necrotic tissue, slough, granulation tissue and suspected biofilm)
- Level of exudate (low, moderate, high)
- Signs and symptoms of infection (i.e. pain, erythema, oedema, heat/warmth, malodour, purulent exudate, biofilm, discolouration of granulation tissue, friable granulation tissue[18,19,33,34]
- Condition of surrounding skin (healthy, macerated, dry/eczematous)
- Previous treatments used.

Patients with three signs of clinical infection were considered to be at risk of infection and those with ≥4 signs were considered to be clinically infected.[33–35] Indicators of biofilm included failure of a

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Fig 1. Number of participants by country

wound to heal (over a period of weeks to months), lack of response to topical and systemic antimicrobial agents, recurrent infections or the presence of slimy substances on the wound surface.[36,37]

Interim assessment

At each dressing change the following information was recorded:

- Signs and symptoms of infection (as baseline) including suspected biofilm
- Exudate management (subjective rating: excellent, good, fair, poor)
- Pain (ongoing and at dressing change as measure on 0–10 VAS scale).[38]

Final assessment

At the final assessment, the following information was recorded to assess healing progress over the course of the evaluation:

- Wound progress (decrease/increase in size)
- Volume of wound (as baseline)
- Condition of the surrounding skin (improved/same/deteriorated)
- Tissues present in wound bed (as baseline with the addition of epithelial tissue)
- Exudate level (as baseline).

Healing was defined as 100% epithelialisation with no drainage.

Cost analysis

Potential cost savings that could be achieved with the use of the NGAD were estimated. In order to do this, all wounds in the evaluation were classified at baseline and at endpoint according to one of following wound health states identified by:[32]

- Healed: skin is intact
- Improved: wound is progressing towards healing
- Same: wound is neither healing nor deteriorating
- Deteriorating: wound is increasing in size, exudate or odour and surrounding skin is deteriorating.

Harding *et al.*[32] determined and defined these categories (as well as one category not used in the present evaluation for severe wounds that are infected or have complications requiring hospitalisation) on the basis that they are distinct and clinically relevant—a theory that had been tested and confirmed in a pilot study in 2000. The authors then estimated antimicrobial dressing treatment costs for each of these stages of wound healing using NHS prices, the Drug Tariff, the British National Formulary and National Reference Costs (2009). A standardised data-collection

Table 1. Evaluation sample patients by wound type and duration

Ulcer type	No. of patients	Mean age (years) (range)	Wound duration* 0–3 months	3–6 months	>6 months
VLU	59	72 (44–92)	13	9	37
DFU	14	70 (42–87)	7	2	5
Traumatic wound	9	68 (30–90)	5	2	2
PU	9	74 (23–88)	2	5	2
Other:					
• abscess	7	59 (25–88)	3	1	3
• cellulitis	2	25 and 41	1	–	1
• inflammation	1	46	1	–	–
• radiation	1	76	1	–	–
• rectal	1	88	–	–	1
• tumour	1	59	–	–	1
	1	68	–	1	–
SSI†	5	60 (59–68)	5	-	-
Postoperative wound	5	43 (28–76)	2	1	2
Amputation	4	63 (58–69)	2	2	1

* Results refer to number of patients
† SSI was not defined
VLU = venous leg ulcer; DFU = diabetic foot ulcer; PU = pressure ulcer; SSI = surgical site infection

instrument was used to collect data for a total of 827 weekly observations and any planned treatment between visits. The health states (defined as healed; progressing; static; deteriorating and severe) were found to be clinically meaningful in that costs were found to be similar within health states, and as might be expected, wounds were shown to become more costly to treat as they increased in severity.[32]

Estimated costs for antimicrobial dressings from Harding *et al*.[32] were then applied to the wounds in the present evaluation, based on wound health states at baseline endpoint. It should be noted that estimations were based on the same antimicrobial dressing costs (2009) as used by Harding *et al*.[32]

Table 2. List of comorbidities

Allergies
Arterial/venous hypertension
Cellulitis
Chemotherapy
Chronic obstructive pulmonary disease (COPD)
Coronary arterial disease
Diabetes/diabetic neuropathy
Dialysis
Dementia
Depression
Gout
Hormone therapy
Hyperlipidaemia
Hypertension
Hypothyroidism
Ischaemia
Lymphoedema
Muscular dystrophy
Neuropathy
Obesity
Obstructive sleep apnea
Oedema
Osteoporosis/osteoarthritis
Parkinson's
Phlebitis
Poly pharmacy
Pulmonary tuberculosis
Pulmonary vascular disease
Pyroderma gangrenosum
Rectal cancer
Rheumatoid arthritis

Results

Sample

A total of 121 patients were recruited into the evaluation. This was reduced to 113 patients for evaluation as eight were withdrawn due to incomplete data sets.

Patients

The final sample (n=113) consisted of 53 males and 60 females with a median age of 69 (mean: 67; range: 23–92; Table 1); however, one patient age was not specified. The majority of patients were from Poland (24%; n=27) and Canada (20%; n=23; Fig 1). Full details are given in Fig 1. Many patients presented with additional comorbidities (49%) such as diabetes, rheumatoid arthritis and obesity, which could potentially contribute to impair wound healing;[39,40] see Table 2 for a full list of recorded comorbidities. More than half of the sample presented with venous leg ulcers (VLUs) (52%; n=59; Table 1). All wound types are given in Table 1. Wound types were further categorised by wound duration, which was classed as 0–3 months, 3–6 months or >6 months (Table 1).

Baseline measurements

At baseline, the wounds of 26 patients (23%) were considered to be improving (for example, slow healing or showing minimal signs of improving but were not considered static or stagnant), 65 were stagnant (58%) and 22 (19%) were deteriorating. The number of wounds with clinical signs of infection is shown in Fig 2.

In total, 62 wounds had three clinical signs of infection at baseline, 56 of which also had suspected biofilm (90% of subgroup; 50% of total); 44 had four clinical signs of infection, of which 39 also had suspected biofilm (89% of subgroup; 35% of total); and 22 had five or more clinical signs of with suspected biofilm (100% of subgroup; 19% of total) (Fig 3).

At baseline patients were on a range of different antimicrobial treatments (Fig 4). The most common antimicrobial treatment was silver dressings 31 (27%) followed by antibiotic (22) and iodine solution (17; Fig 4).

Final evaluation measurements

In 35 patients, at the clinicians' discretion, the NGAD was applied for more than 4 weeks because of the wound healing progress observed, hence at least one wound reported healed within 5 weeks. Fig 5 highlights the mean time to healing across the wound types evaluated.

Quantitative wound closure

Of the 113 wounds included in this clinical evaluation, 107 (95%) either healed or improved by the end of the treatment period, and the average

Fig 2. Number of patients with clinical signs of infection at baseline

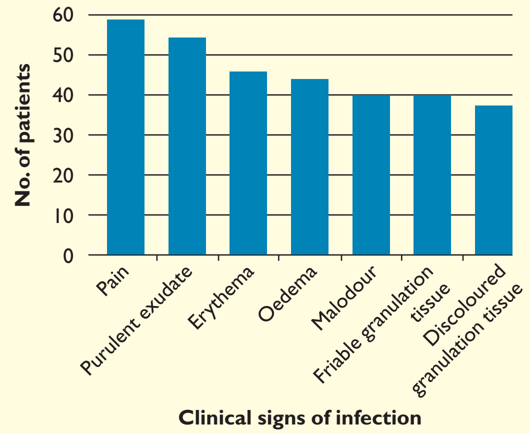
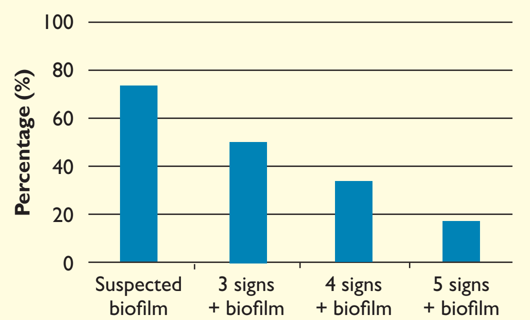


Fig 3. Percentage of patients with suspected wound biofilm and/or three or more clinical signs of infection and suspected biofilm



wound closure achieved was 72.6% (as measured by wound volume reduction). Nineteen wounds (17%) healed completely, 47 (42%) reduced in size by at least 90%, and 71 (63%) achieved at least 75% wound closure (Fig 6). Of the six (5%) wounds that did not improve, two (2%) stayed the same and four (4%) increased in size. Of the 39 wounds in the 0–3 month baseline duration category, 11 (28%) completely healed, 27 (69%) improved by an average of 85% and one (3%) increased in size. Of 22 wounds in the 3–6 months category, three (14%) healed completely, 17 (77%) improved by an average of 75%, and two increased in size (9%). Of the 52 wounds in the >6 months category, five (10%) healed, 44 (85%) improved by an average of 67%, two (4%) remained the same and one (2%) increased in size. Wounds that increased in size were most frequently associated with aggressive debridement of devitalised, necrotic tissue.

Marked reductions in wound size were observed at the end of the treatment period, irrespective of baseline wound duration and wound type (Fig 7). While the treatment period ranged from 1-8 weeks, the average treatment period for this evaluation was 4.1±1.7 weeks (mean±standard deviation).

Wound-bed quality

After application of the NGAD, there was a decrease in the amount of necrosis and slough observed, as well as increases in the percentage of granulation and epithelial tissue compared with baseline (Fig 8).

There was a general reduction in exudate levels during the course of the evaluation (Fig 9). At baseline, 86 wounds (83%) had high or moderate exudate levels, decreasing to 30 (32%) at the end of the evaluation. Only 18 (17%) wounds had low exudate levels at baseline, whereas this number increased to 63 (68%) by the evaluation end. However, it should be noted that data on exudate levels were missing for up to 20 wounds (18%) throughout the evaluation period. The calculated percentages take into account that the number of exudate evaluations was different from baseline (104 evaluations) and study end (93 evaluations).

Overall, the condition of the surrounding skin improved over this evaluation period in 109 (96%) evaluated patients (Figure 10). No clinical conditions of the surrounding skin were recorded by clinicians for the remaining four patients. At base-

Fig 4. Number of patients undergoing antimicrobial treatments at baseline

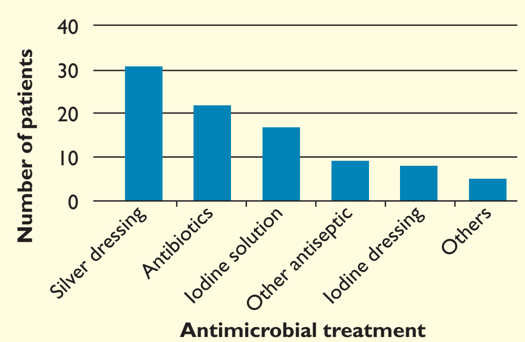


Fig 5. Mean time to healing across wound types

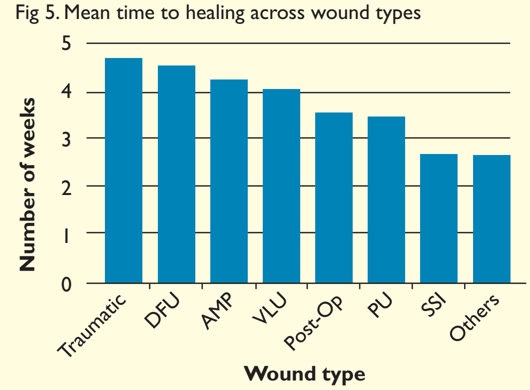
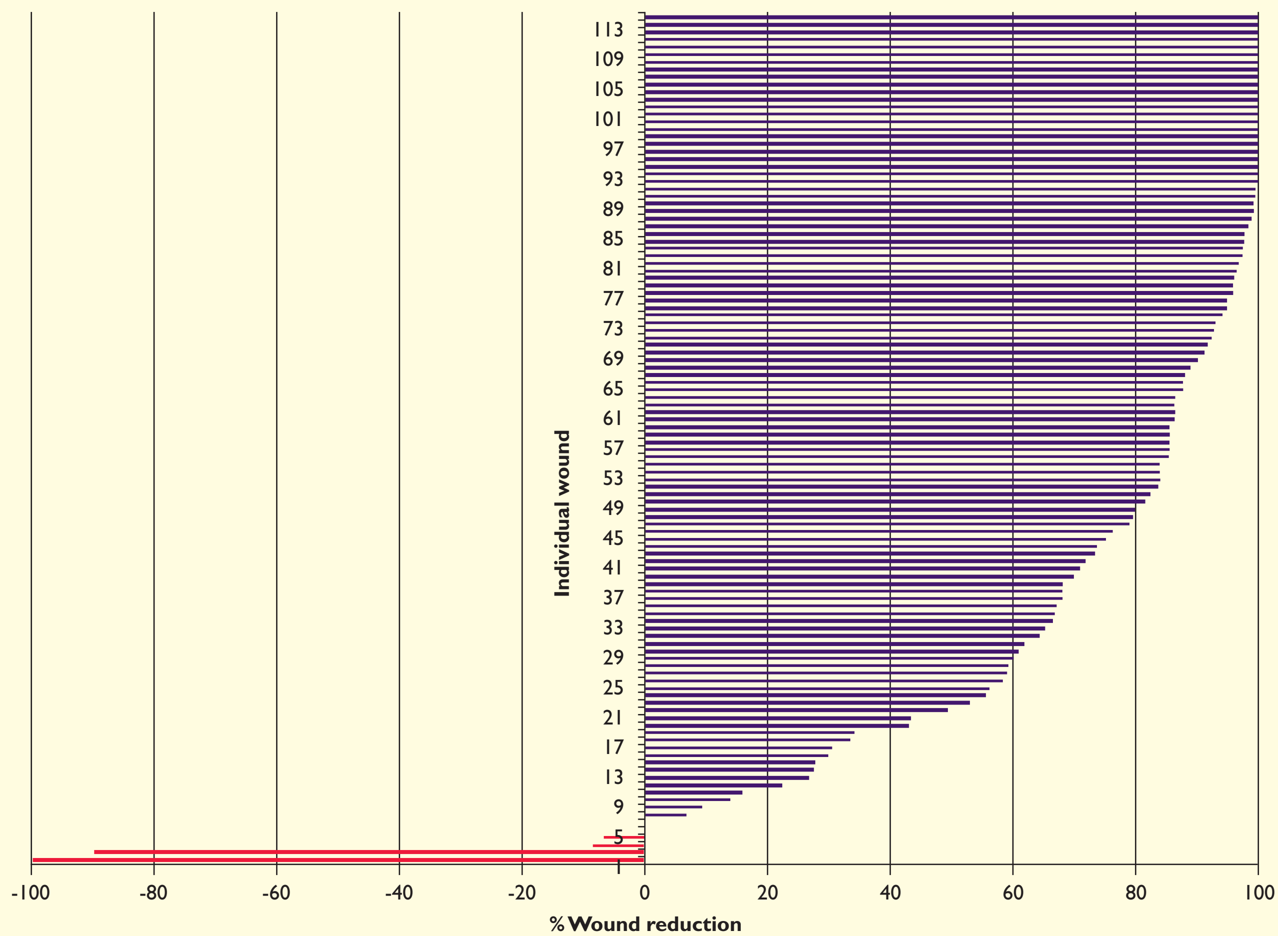


Fig 6. Percentage decrease (■) or increase (■) for each wound in the evaluation



line, 47 patients' (43%) wounds were reported as macerated or wet surrounding skin, 29 wounds (27%) as having dry/eczematous surrounding skin, and 33 (30%) as having healthy skin. At the evaluation endpoint, only 6% of the wounds were observed to still have dry/eczematous surrounding skin conditions.

Cost analysis

Potential cost savings were achieved using the NGAD, based on the general shift of wounds from the more costly 'deteriorating' and 'same' categories, to 'improved' or 'healed'. Table 3 compares weekly antimicrobial primary dressing costs estimated[32] for each wound type, per baseline duration category, at baseline and at endpoint. For patients with wounds in the 0–3 month category, the baseline weekly cost of £104.09 reduced to £62.09 following use of the NGAD, a reduction of £42.00 per patient per week. For wounds in the 3–6 month category, the weekly cost fell from £100.46 to £83.88, a reduction of £16.58 per patient per week. For wounds in the >6 month category, the weekly cost fell from £116.02 to £81.49, a reduction of £34.53 per patient per week. As over 50% of the wounds evaluated were of >6 months' duration, these data suggest that the use of the NGAD might achieve potential cost savings when used in non-healing wounds. Table 3 displays the cost estimates of treating wounds by duration in their different health states at baseline and after treatment with the NGAD.

Discussion

This clinical evaluation set out to assess the effect of the NGAD, when incorporated into standard clinical practices, on a diverse range of deteriorating, static or slowly improving wounds that were likely to be impeded by infection or suspected biofilm, in patients from clinical settings across Europe and Canada. It was a real-life evaluation, in that it involved a large number of patients (n=113), from a variety of health-care facilities, who were invited to recruit patients at their own discretion and regardless of aetiology, using the sole inclusion criterion that wounds must be failing to progress as expected. In this way, the evaluation reflects day-

Fig 7. Average wound size reductions by duration and wound type from evaluation baseline to endpoint

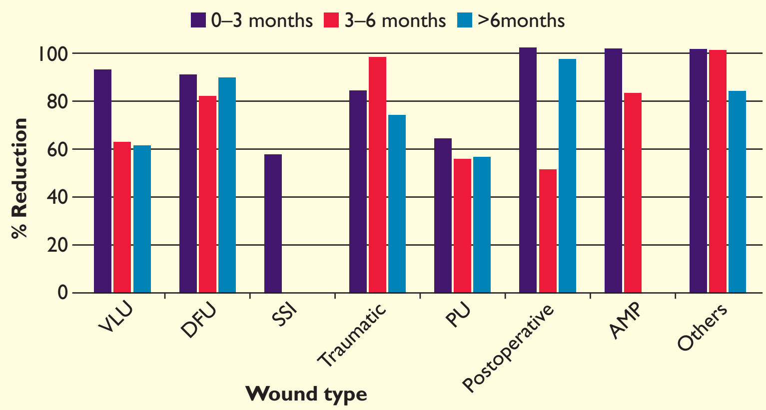


Fig 8. Increase in granulation tissue (baseline versus evaluation end) and reduction in necrosis, slough plus improvement in re-epithelialisation

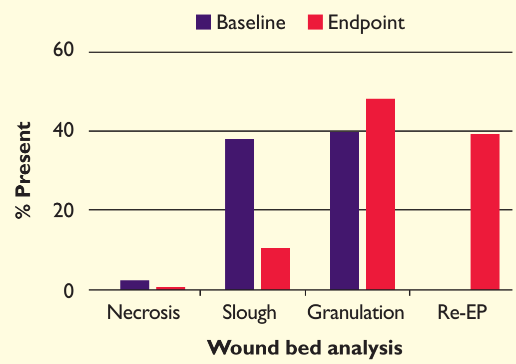
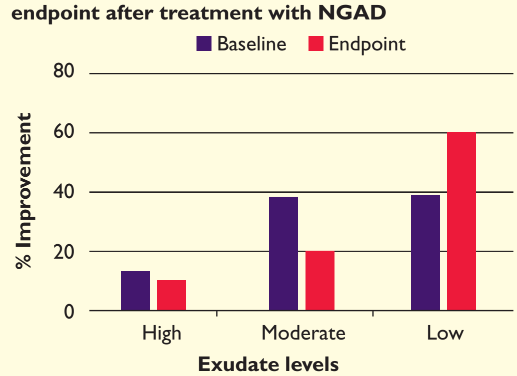


Fig 9. Changes in exudate level at base line and endpoint after treatment with NGAD



to-day practice, where clinicians make clinical judgments about dressing selection, based on individual patient requirements. The findings therefore give a pragmatic insight into the clinical outcomes that might be expected following the use of the NGAD in everyday practice.

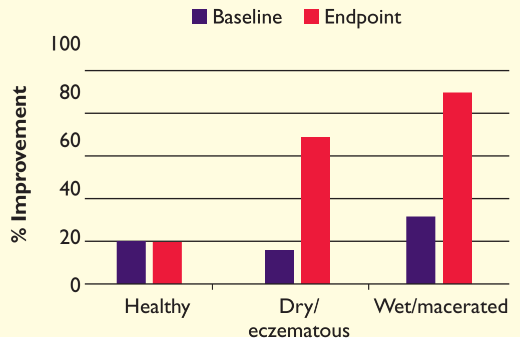
At baseline, indications were that previously used antimicrobial agents (including systemic antibiotics and silver and iodine topical agents) were having little impact on wound progression. Following the introduction of the NGAD, considerable improvements in wound progression were observed, irrespective of wound type and duration. Of particular note was that 19% of the 113 wounds included in this evaluation healed completely, and 76% were associated with an improved healing status in an average treatment period of 4.1 weeks. Additionally, the number of patients experiencing moderate to high exudate levels decreased from 75% at baseline to 27% at the end of the evaluation, and an improvement in peri-wound skin was observed in 64% of patients. Since biofilm was suspected in a majority of the wounds evaluated (based on wound appearance, lack of wound progression, lack of response to topical and systemic antimicrobial agents[36,37] the overall favourable response to the NGAD observed indicates that it may have a role to play in reducing biofilm and subsequently allow chronic wounds to progress towards healing. The improvements in granulation tissue formation and epithelialisation observed following use of the NGAD in this evaluation mirror observations made in a validated and robust wound biofilm animal model.[30]

However, it is important to consider that this was a non-controlled evaluation that reflects the reality of day-to-day clinical practice. The only inclusion criteria were that wounds were failing to progress as expected, with clinicians also being asked to note signs of infection and biofilm. However, in our opinion, the large number of comorbidities experienced by the recruited patients and the wide range of antimicrobial products used previously, to which the wounds had failed to respond, are strong indicators that the wounds were chronic and that the NGAD was used as indicated.

It is widely accepted that a chronic wound is one that does not proceed to heal, as expected, within three months.[41] With this is mind, we categorised the wounds, based on their baseline wound duration, as either 0–3 months, 3–6 months and ≥6 months. While the wounds in the 0–3 month category could be regarded as 'acute', they were only included in the evaluation if they were not progressing as expected (that is, were deteriorating, static or healing slower than anticipated).

Since the 1970s, biofilm has been implicated in a variety of chronic clinical conditions characterised by recurrent infections and tolerance to antimicrobial agents.[42] While the concept of wound biofilm is widely accepted, there is still debate as to whether it is possible to determine if a biofilm is present in the wound.[43] There is further controversy over whether wound biofilm may be seen with the naked eye, with some proposing that its

Fig 10. Improvement in skin conditions



presence may be indicated by visual and non-visual signs,[18,19,36,37] and others proposing that sophisticated laboratory techniques are required to confirm biofilm presence without the use of a biofilm detection method, as yet, unavailable to clinicians.[19,36,37,43,44] However, it should be noted that in addition to visible signs of suspected biofilm, in this evaluation, wounds were also considered to be biofilm-positive if they had experienced recurrent infection, and/or if there was poor response to topical and systemic antimicrobials.

The NGAD incorporates design features to facilitate healing in problematic wounds by disrupting biofilm and subsequently exposing associated micro-organisms to the killing effect of ionic silver. Indeed, *in vivo* research has demonstrated that it is able to remove macroscopic biofilm and support epithelialisation to a significantly greater extent than Telfa AMD (a PHMB-containing gauze dressing) and a non-silver-containing Hydrofiber dressing.[30] The results presented here contribute further to the growing pool of evidence for the NGAD.

Biofilm-related infections have been reported to account for annual costs in the region of $94 billion in the US, and soft-tissue infections (for example diabetic foot ulcers) are considered to be one of the major biofilm-associated diseases.[45] Observations of improvement in wound progression following the use of the NGAD enabled potential antimicrobial dressing cost savings to be calculated based on a recently published wound care costing methodology.[32] Considering all 113 wounds included in this evaluation and the associated wound progression, a weekly, dressing-inclu-

Table 3. Cost estimates by baseline wound duration and wound status at baseline and endpoint[32]

Wound duration	No. of wounds	Weekly antimicrobial dressing cost per wound	Total weekly antimicrobial dressing cost	No. of wounds	Weekly antimicrobial dressing cost per wound	Total weekly antimicrobial dressing cost
	Baseline			**Endpoint**		
0–3 months						
Healed	0	£0.00	£0.00	12	£6.04	£72.48
Improved	13	£87.59	£1138.67	25	£87.59	£2189.75
Same	18	£100.27	£1804.86	0	£0.00	£0.00
Deteriorating	7	£159.45	£1116.15	1	£159.45	£159.45
Total	38	£104.09	£3955.42	38	£62.09	£2359.42
3–6 months						
Healed	0	£0.00	£0.00	1	£6.04	£6.04
Improved	9	£87.59	£788.31	21	£87.59	£1839.39
Same	11	£100.27	£1102.97	0	£0.00	£0.00
Deteriorating	2	£159.45	£318.90	0	£0.00	£0.00
Total	22	£100.46	£2210.12	22	£83.88	£1845.36
>6 months						
Healed	0	£0.00	£0.00	6	£6.04	£36.24
Improved	4	£87.59	£350.36	45	£87.59	£3941.55
Same	36	£100.27	£3609.72	1	£100.27	£100.27
Deteriorating	13	£159.45	£2072.85	1	£159.45	£159.45
Total	53	£116.02	£6149.06	53	£81.49	£4318.97

Participating clinicians:

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sive cost saving of 29.1% per patient (£107.04 baseline cost, versus £75.85 with the NGAD included) was observed. Further clinical and cost-effectiveness studies are required to support these initial observations.

Limitations

This evaluation has several limitations. There was no standardised treatment protocol, other than the incorporation of the NGAD into existing best practice. As a result, a variety of different cleansing agents and secondary dressings were used, introducing a range of variables to the evaluation. This reflects the real-life context of the evaluation, as additionally treatment periods were also left to the clinicians' discretion. In addition, the clinical evaluation form did not stipulate how to measure wound depth, or define surgical site infection, while exudate levels and the condition of the peri-wound skin were assessed differently at baseline and at the end of the evaluation.

Given the widespread acknowledgement of the clinical manifestations of biofilm in a diversity of clinical infections and its tolerance to antimicrobial strategies, it is likely that the majority of wounds included in this clinical evaluation were not healing as a consequence of biofilm involvement. Noticeable wound progression following implementation of the NGAD in a majority of cases was likely due to its ability to reduce the impact of biofilm. However, further controlled clinical research is required to confirm these findings.

Conclusion

The NGAD is a new antimicrobial dressing designed to effectively manage wound exudate, infection and biofilm. Of the 113 patients included in this evaluation, 74% had wounds with suspected biofilm. Following an average treatment period of 4.1 weeks, the majority of wounds had either healed or improved (n=107; 94.7%). This clinical evaluation provides good preliminary evidence of the benefits of the NGAD for non-healing chronic and acute wounds that may be impeded by suspected biofilm, although randomised studies are needed to substantiate this. ■

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