Do AQUACEL® Ag+ Extra ™ dressings improve the outcomes of hard to heal wounds presenting with infection or suspected biofilm, what is the perceived ease of use and patient tolerability of these dressings?

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Introduction

Wound infection continues to be challenging for people with a wound, their families and health care professionals.1 Wound infection can lead to prolonged wound healing, with only 45% of chronic wounds healing where infection is identified or suspected . Wound infection can lead to multiple health service visits and increased hospital admission duration or frequency.2 When a wound is hard-to-heal, the interruption in the healing process is largely associated with the presence of tenacious biofilm.4 It is increasingly acknowledged that a majority, if not all, non-healing wounds contain biofilm which is a key barrier to healing4, with evidence suggesting up to 78.2% of non-healing wounds have a biofilm present.5The management of non-healing wounds comes at significant economic cost with £5.6 billion of the annual spend on wound care in the UK associated with the cost of unhealed wounds.2 Prolonged healing negatively impacts quality of life outcomes for the person with a wound and their family.3 Accurate and timely identification of the signs and symptoms of wound infection and biofilm alongside effective management are critical in improving the quality of life of those living with hard to heal wounds.1

Method

We recruited 29 patients, a total of 41 wounds from 7 clinical settings, with hard-to-heal or infected wounds for this prospective multi-centre, product evaluation of the routine clinical practice using AQUACEL® Ag+ Extra ™ and Ribbon dressing. Recruitment was undertaken via consecutive enrolment by the treating health care professional(s), (HCP). Wounds were dressed in line with the patient's current treatment plan, with the only change being the use of AQUACEL® Ag+ Extra ™ and Ribbon dressing used as the primary contact layer. Dressing intervals were decided by the HCP according to clinical need, over a period of *4* weeks. Results and wound photography were recorded via a Clinical Management Review Form completed by the HCP at the end of the 4 weeks.

A questionnaire was used to collect information on patient experience of comfort during wear time, removal without trauma and clinician experience. Information was collected in relation to , but not limited to, if would they like to use the dressing again, did the dressing stay in position, what effect the dressing had on malodour from the wound if originally present? Wound outcomes including changes in wound bed tissue type presentation , bacterial burden , presence of biofilm , exudate levels and peri wound skin optimisation.

Inclusion and exclusion criteria

All patients attending the participating centres were recruited in consecutive order if they were already receiving best practice wound intervention but continued to experience a hard to heal or infected wound. Exceptions were patients who had a diagnosis of osteomyelitis, deemed not suitable for the investigation according to the investigator's judgement, had a known allergy/hypersensitivity to any of the components of the dressing, were pregnant or breast-feeding.
As part of the analysis process 4 review forms (7 wounds) were excluded from the final data set for reasons such as , other health or wound care interventions were introduced during the review period, the patient care setting changed, or the patient was discharged from the case load interrupting the continuity of the review.
This resulted in a total of 25 patients and 34 wounds included in the final data set.

Patient and wound information

Data has been reported and analysed as counts and percentages (N, %) for categorical variables.

The mean age of patients recruited is 71.2 years, gender was recorded at 50% Female(n=17/34) , 38.23 % Male(n=13/34 and 11.77% not recorded(n=4/34).

Cofounders, contributing environmental factors and underlying aetiologies were identified for patients as part of a past medical history and existing management plan, including but not limited to, diabetes, hypertension , chronic heart disease, malignancy, chronic kidney disease, nutritional status and smoking status. Additional, best practise, supporting therapies such as compression therapy, pressure relieving devices and systemic therapies were identified and included as a baseline for patients recruited.

Patient and wound information

Wound aetiology and status were recorded at the recruitment stage and at the 4-week interval. Wound types included Venous Leg Ulcers and Pressure Ulcers categorised as Unstageable and Category 4 by the respective HCPs.

The average duration of wound presentation is 2.3 years.

At the start of the review 50% (n=17/34) of wounds were recorded as static, 35.2%(n=12/34) deteriorating and 14.7% (n=5/34) progressing. (See table 1) With 41.17% (n=14/34) showing clinical signs of infection and 97.06 % (n=33/34) assessed as having suspected biofilm present. (See table 2a) Levels of exudate were recorded as 11.76 % (n=4/34) high , 67.64% (n=23/34) moderate and 20.58% (n=7/34) low. (See table 3a and 3b) exudate levels have been compared respectively (See table 3c)

Wound bed presentation based on visual assessment of tissue type was recorded at the start of the review and reassessed at the 4-week interval. Predominant tissue types have been compared respectively.(See tables 4a and 4b)

Wound status initial assessment
N=17/34 static wounds

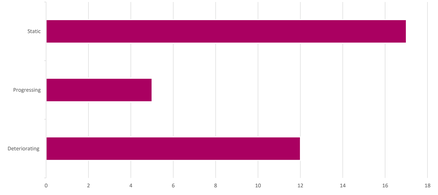

Table 1

Initial assessment tissue type and exudate level

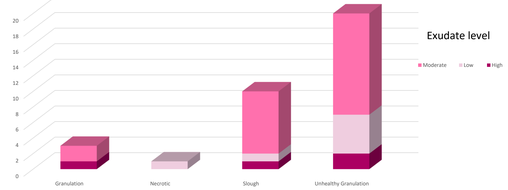

Table 3a

Initial assessment predominant tissue type
N= 31/34 Devitalised tissue /Unhealthy Granulation

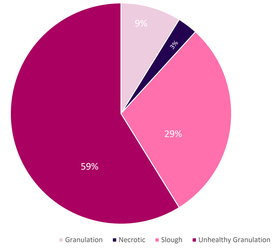

Table 4a

Initial Assessment N = 33 / 34 with signs of infection / biofilm

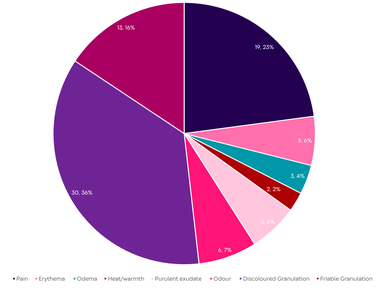

Table 2a

Suspected biofilm presence and exudate level

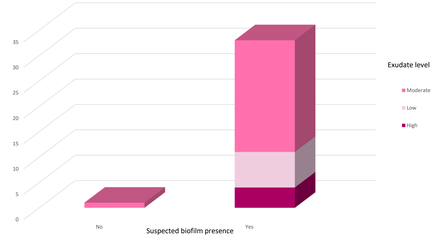

Table 3b

References: 1. International Wound Infection Institute (IWII) Wound Infection in Clinical Practice. Wounds International. 2022.. 2 Guest JF, Fuller GW, Vowden PCohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013BMJ Open 2020;10:e045253. doi: 10.1136/bmjopen-2020-045253. 3Wounds UK. Best Practice Statement: Improving holistic assessment of chronic wounds. London: Wounds UK, 2018. Available to download from: www.wounds-uk.com. 4. Murphy C, Atkin L, Swanson T, Tachi M, Tan YK, Vega de Ceniga M, Weir D, Wolcott R. International consensus document. Defying hard-to-heal wounds with an early antibiofilm intervention strategy: wound hygiene. J Wound Care 2020; 29(Suppl 3b):S1–28. 5. Malone M, Barjnsholt T, McBain AJ, James GA, Stoodley P, Leaper D, Tachi M, Shultz G, Swanson T, Wolcott RD "The prevalence of biofilms in chronic wounds: A systematic review and meta-analysis of published data" Journal of Wound Care, 2016 Jan 2;26(1):20-25.5

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Results

Final Assessment
N = 9 / 34 with signs of infection / biofilm

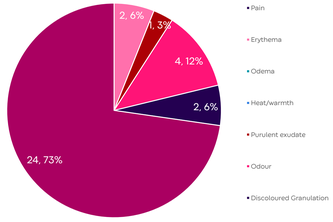

Table 2b

Final assessment
Predominant tissue type
N= 26/34 Granulation / Epithiliasation

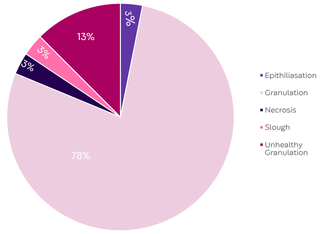

Table 4b

Final assessment
Exudate level and Tissue type correlation

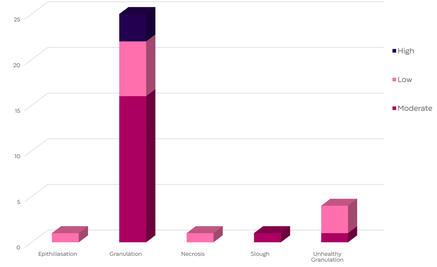

Table 3c

Wound status final assessment
N= 32/34 Improved

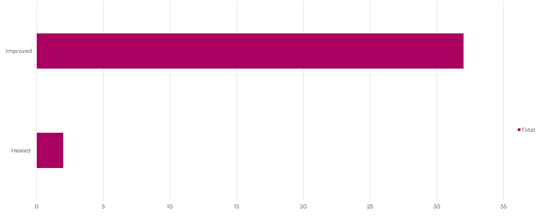

Table 5

Discussion

Dressings have been developed that are highly absorbent and exudate-retaining, such as carboxymethylcellulose (CMC), many with silver to control bioburden. AQUACEL® Ag+ Extra ™ was designed specifically for biofilm with 'MORE THAN SILVER' technology, where the active ingredients benzethonium chloride (BEC) and ethylenediamine tetra acetic acid (EDTA) work synergistically together with ionic silver to bring antibiofilm action by disrupting and destroying biofilm.7 These results correspond with existing literature that AQUACEL® Ag+ Extra ™ dressings are effective for hard-to-heal wounds where infection and biofilm are a barrier to healing.8

It was further noted in the analysis that peri wound skin management was assessed at initial and final stages with data showing no signs of peri wound maceration or deterioration at final assessment with 100% HCP satisfaction in the ability for AQUACEL® Ag+ Extra ™ to effectively absorb and retain exudate under compression therapy applied at 20mmHg and 40mmHg.

Further analysis could be applied to the reduction in wound size from initial assessment to final assessment at the 4-week interval. There were notable decreases in the number of dressing changes at the final assessment point with scope for further cost analysis to assess the positive impact this could have on health care spend in relation to HCP time and resources and patient experience and quality of life.

Health Care Professional and Patient experience

HCP feedback overall performance
compared to previous dressings used

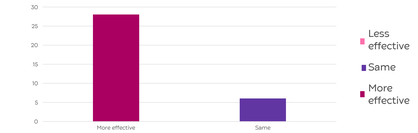

Table 6

Ability to remain intact on removal

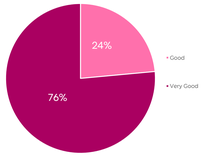

Table 8

Comfort of dressing application
N=27/34 Very Good

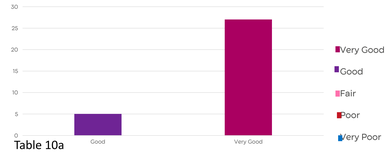

Table 10a

Ability to manage odour
N=29/34 Very good or Good

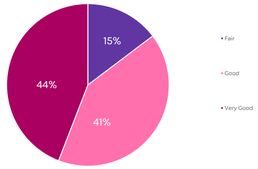

Table 7

HCP satisfaction of exudate
management Absorption and Retention

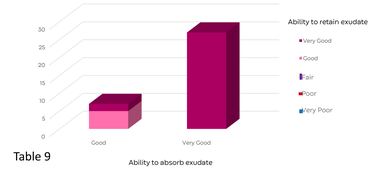

Table 9

Atraumatic removal
N=29/34 Very Good

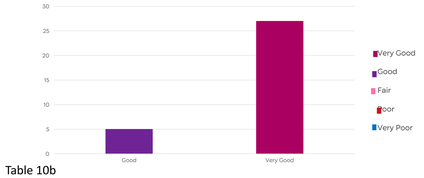

Table 10b

Conclusion

A key aspect of the care of hard-to-heal wounds is overcoming the factors that delay healing, such as infection and biofilm[6] Results from this review of clinical performance and outcomes using real-world evidence demonstrates the positive impact of AQUACEL® Extra ™ Ag+ dressing for wounds that are infected or suspected to have biofilm present.

- All participants in the cohort entered the evaluation with a wound that was hard to heal or infected as per the inclusion criteria.
- All patients had already been receiving best practice wound care interventions according to their individual needs prior to recruitment addressing any cofounding considerations in the differences between wound types.
- The results of this review demonstrated AQUACEL® Ag+ Extra ™ dressing to be effective in the management of wound infection and biofilm where a presence of suspected biofilm was reduced by 69.40 % and infection by 66.64% during the review period. (See table 2b)
- Management of the wound bed was assessed by the recording of tissue type presence. Improvements were seen with 73.53 % (n=25/34) of wounds presenting with healthy granulation by week 4 opposed to the presence of unhealthy granulation or devitalised tissue (slough/necrosis) for 91.17% (n=31/34)of wounds at the start of the review resulting in 94.12 % (n=32/34) of the wounds improved and 2 wounds healed. (See tables 4a, 4b and 5)
- Number of wounds with reported malodour at the start of the evaluation was subjectively recorded by the HCP. Clinicians provided feedback on the ability of AQUACEL® Ag+ Extra ™ to effectively manage malodour during the evaluation period with 100 % HCP satisfaction. (See table 7)
- HCP satisfaction was established at 100% in the ability for AQUACEL® Ag+ Extra ™ dressing to effectively manage exudate in respect of absorption, retention and protection of the peri wound skin. Be atraumatic in its application and one-piece removal from the wound. 82.35% of HCPs found the overall performance of AQUACEL® Ag+ Extra ™ dressing more effective when compared to the previous dressing with 100% of HCPs reporting they would continue to use AQUACEL® AG+ Extra ™ dressing and recommend it to others. (See tables 8 and 9)
- Patient feedback shows 100% satisfaction in AQUACEL® AG+ Extra ™ dressing supporting patient comfort during application , wear time and removal. (See tables 10a and 10b)

References: 6. Mori Y, Nakagami G, Kitamura A et al. Effectiveness of biofilm-based wound care system on wound healing in chronic wounds. Wound Repair Regen 2019; 27(5):540–547. 7 Metcalf DG, Bowler PG. Clinical impact of an anti-biofilm Hydrofiber dressing in hard-to-heal wounds previously managed with traditional antimicrobial products and systemic antibiotics. Burns Trauma 2020; 8:tkaa004. 8 Metcalf DG, Parsons D, Bowler PG. Clinical safety and effectiveness evaluation of a new antimicrobial wound dressing designed to manage exudate, infection and biofilm. Int Wound J 2016;14(1):203–213.

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