Wound Hygiene Protocol incorporating an antibiofilm gelling fibre dressing: Real-world impact in hard-to-heal wounds in patients receiving antibiotics

Background/Aims: This study evaluated the effect of a 4-step wound care strategy, the Wound Hygiene Protocol (cleanse, debride, refashion, dress), incorporating Aquacel Ag+ Extra dressings, on hard-to-heal wounds in patients receiving systemic antibiotics.

Methods: This was a subgroup analysis from a larger real-world evaluation (April 2021 to December 2022).

Results: Data from 229 wounds in 219 patients (median age: 73) were analysed. The most frequently observed wound types were venous leg ulcers (24%) and pressure injuries (18%). Hard-to-heal wounds (<6 months, 72%; 6–12 months, 10%; >12 months, 18%) improved after a median treatment duration of 33 days. Local infection, determined by the HCP according to international consensus criteria, decreased from 74% to 4% ($p<0.001$). At baseline, 37% of wounds were static and 26% were deteriorating; by final assessment, only 2% remained static (1%) or deteriorating (1%), while the majority showed a positive trajectory, with 74% improved and 24% healed. Mean wound volume reduced by 81% ($p<0.001$) with significant decreases in exudate levels ($p<0.001$) and clinically suspected biofilm ($p<0.001$).

Conclusion: The Wound Hygiene Protocol with Aquacel Ag+ Extra dressings significantly improved outcomes in hard-to-heal wounds in patients receiving antibiotics whose wounds had previously not responded to antibiotic therapy, and may support antibiotic stewardship.

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Key words
- Antibiotic stewardship
- Biofilm
- Hard-to-heal wound
- Infection
- Wound Hygiene

Hard-to-heal wounds, defined as wounds that do not transition through the normal phases of healing in a timely manner (Grey et al, 2006), are often characterised by the presence of microorganisms that increase infection risk, delay healing and often lead to administration of systemic antibiotics by health care professionals (HCPs; Ovington, 2003; Rahim et al, 2017). Between 2013-2015, 16.4% of UK antibiotic prescriptions were for wound care (Dolk et al, 2018). While appropriate use of antibiotics can improve wound outcomes, inappropriate and overuse of antibiotics contributes to rising antimicrobial resistance (AMR; Sutton and Ashley, 2024). In the US, 30% of all antibiotic prescriptions in 2010/2011 were deemed unnecessary (CDC, 2016). AMR is estimated to cause 700,000 deaths annually, projected to increase to 10 million by 2050, highlighting the urgent need to reduce unnecessary antibiotic use (Interagency Coordinating Group on Antimicrobial Resistance, 2019). In line with International Wound Infection Institute (IWII) guidance on antimicrobial stewardship, aligning wound care practices with antimicrobial stewardship (optimising antimicrobial use to improve patient outcomes and limit resistance) is essential to address AMR and minimise antibiotic use (Swanson et al, 2022).

Approximately 78% of hard-to-heal wounds (those that do not respond to standard of care as expected (e.g. compression, offloading, moisture management)) contain biofilm (Malone et al, 2017). Biofilm is defined as communities of microorganisms embedded in a matrix of extracellular polymeric substances which protect microorganisms from antibiotics, antiseptics and the host immune response (James et al, 2008). Biofilm elicits a suboptimal host inflammatory response (chronic infection), and is a precursor of local infection (acute infection; Hurlow and Bowler, 2022). Together, this has been found to increase infection risk four-fold ($p=0.0001$; Jain et al, 2024). Hard-to-heal wounds are often characterised by mixed

Declaration of interest: Authors are employees of, and hold stock in, Convatec Ltd.

microbial populations including antibiotic-resistant bacteria and phenotypically tolerant microorganisms in biofilm form (Bowler et al, 2020), which can lead to the failure of antibiotics (Gurjala et al, 2011; Metcalf and Bowler, 2013).

It is recognised that wound healing outcomes are influenced by a complex interplay of systemic and local factors. However, early and proactive wound care strategies incorporating the physical removal and disruption of biofilm are widely advocated, as this may reduce microbial burden, reduce infection risk, and create a more favourable environment for healing (Darvishi et al, 2022). The implementation of a structured and standardised approach targeting biofilm remains a key component of antimicrobial stewardship, to reduce reliance on systemic antibiotics.

The Wound Hygiene Protocol is a 4-step regimen incorporating biofilm management, that can be administered early, safely and consistently by any HCP in any clinical setting. The Wound Hygiene Protocol was developed by an international panel of wound care specialists and promotes healing by reducing or removing unwanted materials (microorganisms, biofilm, devitalised tissue and debris) from the wound and preventing the re-formation of biofilm (Murphy et al, 2019; 2020; 2021). The Wound Hygiene Protocol consists of the following consecutive steps:

1. Cleanse the wound and periwound skin
2. Debride
3. Refashion the wound edges
4. Dress the wound.

As biofilm tolerates antibiotics (Bowler et al, 2020), the Wound Hygiene Protocol may support antimicrobial stewardship by reducing inappropriate and ineffective use of antibiotics, which is the focus of this exploratory, post-hoc analysis. Antibiofilm dressings have previously been reported to be effective at facilitating the healing of hard-to-heal wounds unresponsive to standard antimicrobial agents, including antibiotics (Metcalf and Bowler, 2020; Whiteley, 2023).

The inaugural Wound Hygiene data-guided activity aimed to evaluate the real-world effectiveness of the Wound Hygiene Protocol on hard-to-heal wounds when administered across different clinical settings (Torkington-Stokes et al, 2024).The aim of this exploratory, post-hoc analysis was to evaluate the impact of the Wound Hygiene Protocol on wound out-comes in patients receiving systemic antibiotics as part of their standard of care.

Materials and methods

Design

This exploratory, post-hoc analysis focuses on patients receiving systemic antibiotics from a broader, prospective, real-world evaluation of hard-to-heal wounds managed with the Wound Hygiene Protocol across six European countries (Spain, Italy, UK, Poland, Netherlands, Portugal; Torkington-Stokes et al, 2024). Between April 2021 and December 2022, data were captured electronically by participating HCPs using a Wound Hygiene Protocol data collection form. HCPs were invited to participate in educational training on implementing the Wound Hygiene Protocol in clinical practice over a recommended 4-week period, adjusted based on wound progression. Further details are available in Torkington-Stokes et al (2024).

Objectives and endpoints

The primary objective of this exploratory, post-hoc analysis was to evaluate the impact of the Wound Hygiene Protocol incorporating Aquacel Ag+ dressings (Convatec Ltd, Deeside, UK; marketed as Aquacel Ag Advantage dressings in the US) on hard-to-heal wounds in patients receiving antibiotics at baseline.

Primary endpoints

Primary endpoints were:

- Changes in local wound infection status
- Overall wound status
- Wound volume.

The presence of local infection was determined by the HCP according to international consensus criteria (Haesler et al, 2019) and included:

Classic signs of local infection:

- Erythema
- Local warmth
- Swelling
- Purulent discharge
- Delayed healing
- New or increasing pain
- Increasing malodour.

Subtle signs of local infection:

- Hypergranulation
- Bleeding friable granulation tissue
- Epithelial bridging
- Pocketing granulation tissue
- Wound breakdown and enlargement
- Increased exudate.

Wound volume was calculated by measuring the longest length and widest width using a disposable sterile ruler and deepest depth using a probe. This was performed at baseline and final assessment by the same HCP, who had attended an education and training event on how to implement the Wound Hygiene Protocol in clinical practice prior to commencing implementation of the Wound Hygiene Protocol.

Secondary endpoints

Secondary endpoints included:

- Changes in suspected biofilm
- Exudate levels.

The presence of suspected biofilm was determined using the international consensus criteria (Haesler et al, 2019) and included:

- Failure of appropriate antibiotic treatment
- Recalcitrance to appropriate antibiotic treatment
- Recurrence of delayed healing on cessation of antibiotic treatment
- Unresponsiveness to antimicrobial therapy
- Delayed healing despite optimal wound management and health support
- Increased exudate/moisture
- Low level chronic inflammation
- Low level erythema
- Poor granulation/friable hypergranulation
- Secondary signs of infection.

Participants

Eligible patients were ≥18 years of age with a hard-to-heal wound, defined as a wound that failed to respond to standard of care, and were being treated with systemic antibiotics as part of their standard treatment plan. Exclusion criteria included ongoing chemotherapy/radiotherapy, end-of-life management, active spreading wound infection, wounds probing to bone, or osteomyelitis as determined by the clinician.

Statistical analyses

The primary null hypothesis was that implementation of the Wound Hygiene Protocol with Aquacel Ag+ Extra dressing at Stage 4 does not result in any characteristic changes in wounds in patients being treated with antibiotics. Changes in categorical characteristics were tested using the McNemar-Bowker test.

Changes in wound volume were evaluated using a non-parametric Wilcoxon signed-rank test. Wounds missing width, length or depth data were excluded from the wound volume analysis. For absolute change in wound volume, all wounds with baseline depth including zero were included to account for some cases where wounds appeared to enlarge before progressing (e.g. positive autolytic debridement). For percentage change in wound volume, wounds with zero depth at baseline were excluded.

Data completeness was assessed for all variables. Where data were not recorded by the HCP, values were classified as missing. The number of missing observations is indicated where relevant.

Ethical approval and patient consent

The original evaluation (Torkington-Stokes et al, 2024) was a service evaluation analysing real-world healthcare outcomes following implementation of the Wound Hygiene Protocol without changes to standard practice. Ethics committee review was confirmed as not required by the local participating healthcare institutions.

Patient selection and data collection were conducted in a routine healthcare setting by the HCP using the Wound Hygiene Protocol data collection form. Written informed consent was obtained locally from the patient, by the HCP, according to local requirements.

Table 1. Patient demographics.

	Patients (n=219)
Patient age, median (range)	73 (19-98)
Sex, n (%)	
Female	115 (52.5%)
Male	102 (46.6%)
Missing	2 (0.9%)
Country, n (%)	
Spain	74 (33.8%)
Italy	56 (25.6%)
Poland	50 (22.8%)
United Kingdom	25 (11.4%)
The Netherlands	8 (3.7%)
Portugal	6 (2.7%)

Confirmation of consent was documented on the Wound Hygiene Protocol data collection form and stored on a secure Convatec Google Cloud Platform (Google Inc, US).

Results

Patients and baseline statistics

A total of 229 wounds from 219 patients receiving antibiotics at baseline were analysed. Median patient age was 73 years (range, 19–98). Patients were recruited from six countries, with the largest proportions from Spain (34%), Italy (26%) and Poland (23%) [Table 1].

Most HCPs were general nurses (56%) or nurse practitioners (35%). Community clinics were the most common setting (27%), followed by patient homes (24%), outpatient clinics (19%), and hospitals (17%) [Table 2].

Venous leg ulcers (24%) and pressure injuries (18%) were the most frequent wound types, followed by diabetic foot ulcers (11%) and surgical wounds (9%), with additional wound types also represented [Table 3]. Wound duration was 3-6 months in 14% of cases, 6-12 months in 10%, and >12 months in 18%. New wounds (<7 days) accounted for 7%, 7-14 days for 8%, 2-4 weeks for 12%, 4-8 weeks for 16% and 2-3 months for 15% [Table 3]. Cleansing agents used on periwound skin and the wound bed are reported separately [Table 3]. Antiseptics (periwound: 29%, wound: 40%), saline (periwound: 47%, wound: 41%), and surfactant solution (periwound: 35%, wound: 56%) were the most frequently used in both areas.

Alongside systemic antibiotics, 39% of patients also received topical antimicrobials. The most frequently used were silver-containing dressing (22%), iodine-containing products (10%), and topical antibiotics (3%), with other agents used less commonly. Frequently used named products included Aquacel Ag Extra (11%), Betadine (4%), and Atrauman® Ag (4%). Adjunct therapies were also common, including analgesics (31%), compression bandaging (22%) and compression hosiery (10%) [Table 4].

Local infection status

Following a median treatment duration of 33 days (range 2–198), local wound infection decreased from 74% at baseline to 3% of all wounds and 4% of all non-healed wounds at final assessment (95% reduction; $p<0.001$). Non-infected wounds increased from 18% to 69% of all wounds (86% of all non-healed wounds; Figure 1).

Wound status

At baseline, 11% of wounds were progressing, 37% were static and 26% were deteriorating [Figure 2A]. At final assessment, 74% had improved and 24% had healed. Only 1% remained static and 1% were deteriorating [Figure 2B].

Wound volume

Baseline mean (SD) wound volume was 96.7 (258.1) cm^3. At final assessment mean wound volume had reduced by 81% to 19.7 (107.4) cm^3 ($p<0.001$) [Table 5; Figure 3].

Biofilm suspicion and exudate levels

Suspected biofilm (Haesler et al, 2019) decreased from 81% of wounds at baseline to 17% at final assessment (79% reduction; $p<0.001$; Figure 4).

At baseline, most wounds had moderate (41%) or high (37%) exudate. At final

Table 2. Healthcare professionals and clinical settings.

	Wounds (n=229)
Healthcare professional, n (%)	
General nurse	128 (55.9)
Advanced HCP/nurse practitioner	80 (34.9)
Physician	9 (3.9)
Podiatrist	7 (3.1)
Other	2 (0.9)
Missing	2 (0.9)
Healthcare assistant	1 (0.4)
Clinical setting, n (%)	
Community clinic	61 (26.6)
Patient home	55 (24.0)
Outpatient clinic	43 (18.8)
Hospital	38 (16.6)
Post-acute facility	16 (7.0)
Care home	6 (2.6)
Physician office	6 (2.6)
Other	4 (1.7)

assessment, this had decreased to 22% and 3%, respectively ($p<0.001$; Figure 5). Wounds with no or low exudate increased from 2% to 15% and 18% to 41%, respectively ($p<0.001$; Figure 5).

Discussion

In this exploratory, subgroup analysis of a real-world evaluation of hard-to-heal wounds in patients receiving antibiotics at baseline, management with the standardised Wound

Table 3. Baseline wound characteristics and cleansing agents used.

		Wounds (n=229)	
Wound type, n (%)			
Leg ulcer		79 (34.5)	
	Venous		54 (23.6)
	Arterial		4 (1.7)
	Mixed		16 (7.0)
	Unknown		5 (2.2)
Pressure ulcer/injury		41(17.9)	
	Stage 2		1 (0.4)
	Stage 3		19 (8.3)
	Stage 4		14 (6.1)
	Unstageable		2 (0.9)
	Deep tissue injury		5 (2.2)
Diabetic foot ulcer		26 (11.4)	
Surgical wound		21 (9.2)	
	Closed		7 (3.1)
	Open		5 (2.2)
	Dehisced		9 (3.9)
Traumatic wound		19 (8.3)	
Cavity wound		11 (4.8)	
Skin tear		16 (7.0)	
	Type 2		5 (2.2)
	Type 3		11 (4.8)
Other		16 (7.0)	
Wound duration, n (%)			
<7 days		16 (7.0)	
7–14 days		19 (8.3)	
2–4 weeks		27 (11.8)	
4–8 weeks		37 (16.2)	
2–3 months		34 (14.8)	
3–6 months		31 (13.5)	
6–12 months		22 (9.6)	
>12 months		41 (17.9)	
Missing data		2 (0.9)	
Cleansing agent (periwound skin), n (%)			
Antiseptic		66 (28.8)	
Saline		107 (46.7)	
Surfactant solution		80 (34.9)	
Soap and water		11 (4.8)	
Water		52 (22.7)	
Cleansing agent (wound), n (%)			
Antiseptic		92 (40.1)	
Saline		93 (40.6)	
Surfactant solution		127 (55.5)	
Soap and water		4 (1.8)	
Water		24 (10.5)	

Table 4. Previous additional antimicrobial agents and wound therapies.

		Wounds (n=229)	
Antimicrobial agent, n (%)			
Silver		51 (22.3)	
	Aquacel® Ag Extra™		25 (10.9)
	Atrauman® Ag		8 (3.5)
	UrgoClean Ag		4 (1.7)
	Mepilex® Ag		2 (0.9)
	Other silver		12 (5.2)
Iodine		22 (9.6)	
	Betadine		9 (3.9)
	Inadine		2 (0.9)
	Other iodine		11 (4.8)
Topical antibiotic		6 (2.6)	
Enzyme gel		3 (1.3)	
	Flaminal®		2 (0.9)
	Other Enzyme gel		1 (0.4)
Hypochlorous acid		3 (1.3)	
	Eusol		2 (0.9)
	Microdacyn		1 (0.4)
Octenidine		3 (1.3)	
	Octenisept®		3 (1.3)
Chlorhexidine		1 (0.4)	
DACC		1 (0.4)	
	Sorbact®		1 (0.4)
Additional wound therapies, n (%)			
Antibiotics		229 (100)	
Analgesics		72 (31.4)	
Compression bandaging		50 (21.8)	
Compression hosiery		23 (10.0)	
Equipment (e.g. pressure relieving/offloading device)		15 (6.6)	
Other		19 (8.3)	

Figure 1. Infection status at baseline and final assessment.

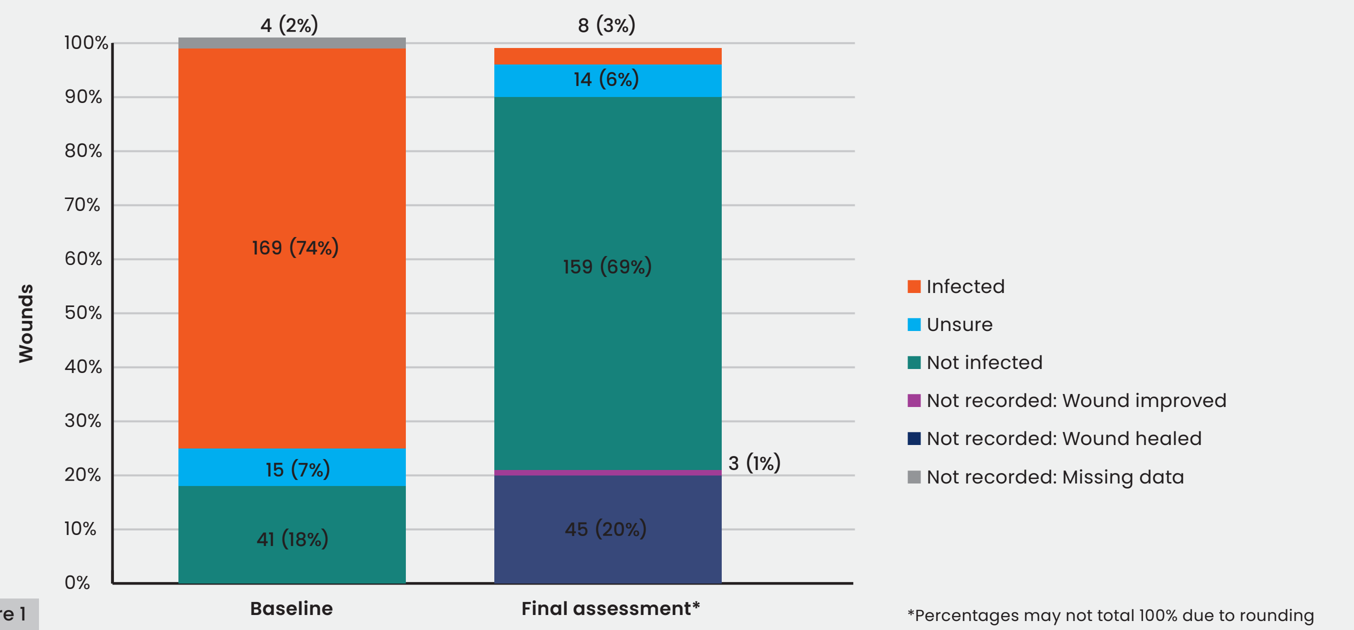

Figure 1

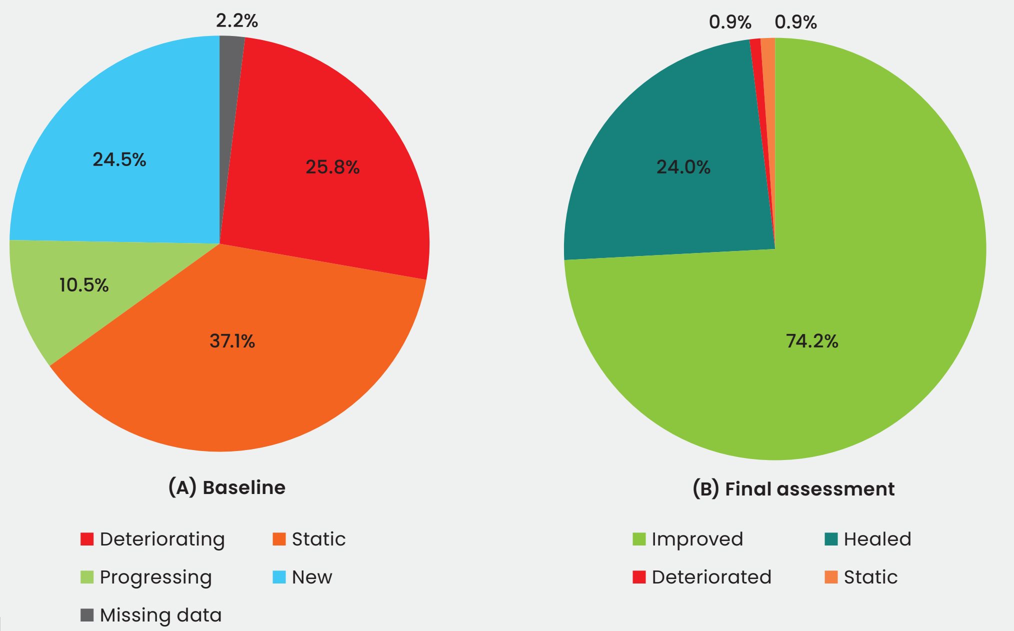

Figure 2

Figure 2. Wound status at baseline (A) and at final assessment (B).

Table 5. Change in wound volume.				
Wounds (n=229)				
Parameter	Baseline	Observed value	Change from baseline	Percentage reduction from baseline
Wound volume (cm^3)				
n	222	221	219	186
Mean (standard deviation)	96.7 (258.1)	19.7 (107.4)	-77.6 (224.5)	80.7 (27.2)
Median	13.8	0.009	-7.9	93.2
Interquartile range	1.4, 59.6	0.0, 4.2	-48.0, -0.69	69.2, 100.0
Range	0.0, 2,100.0	0.0, 1,500.0	-1,929.0, 12.0	-66.7, 100.0
95% confidence interval	–	–	-107.5, -47.7	76.8, 84.6
P value	–	–	<0.001	<0.001

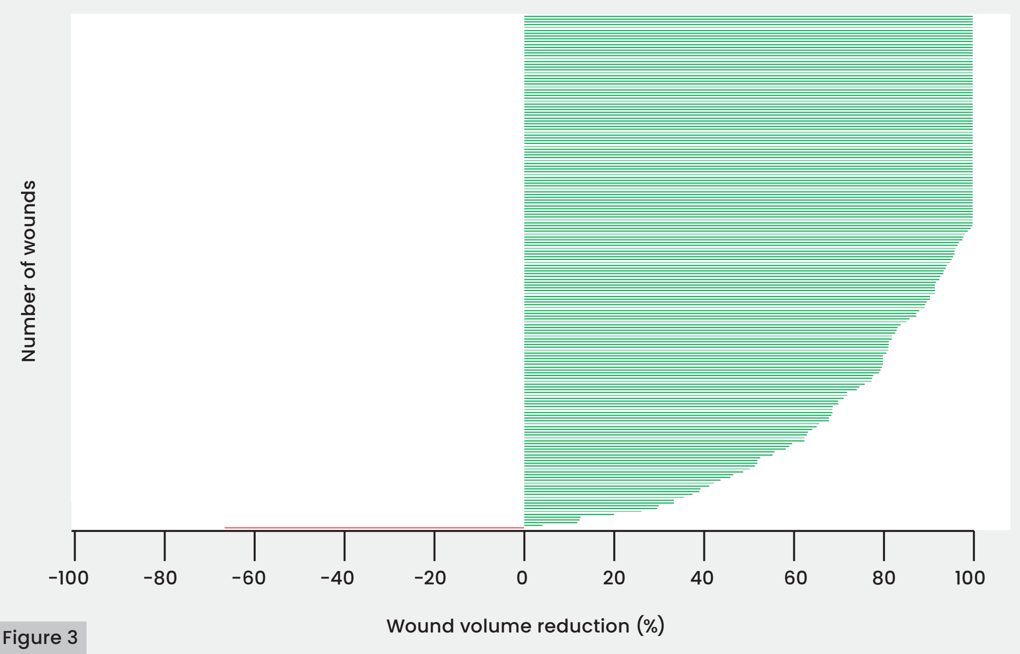

Figure 3

Figure 3. Waterfall plot of percentage reduction in wound volume for all wounds with depth at baseline (n=186).

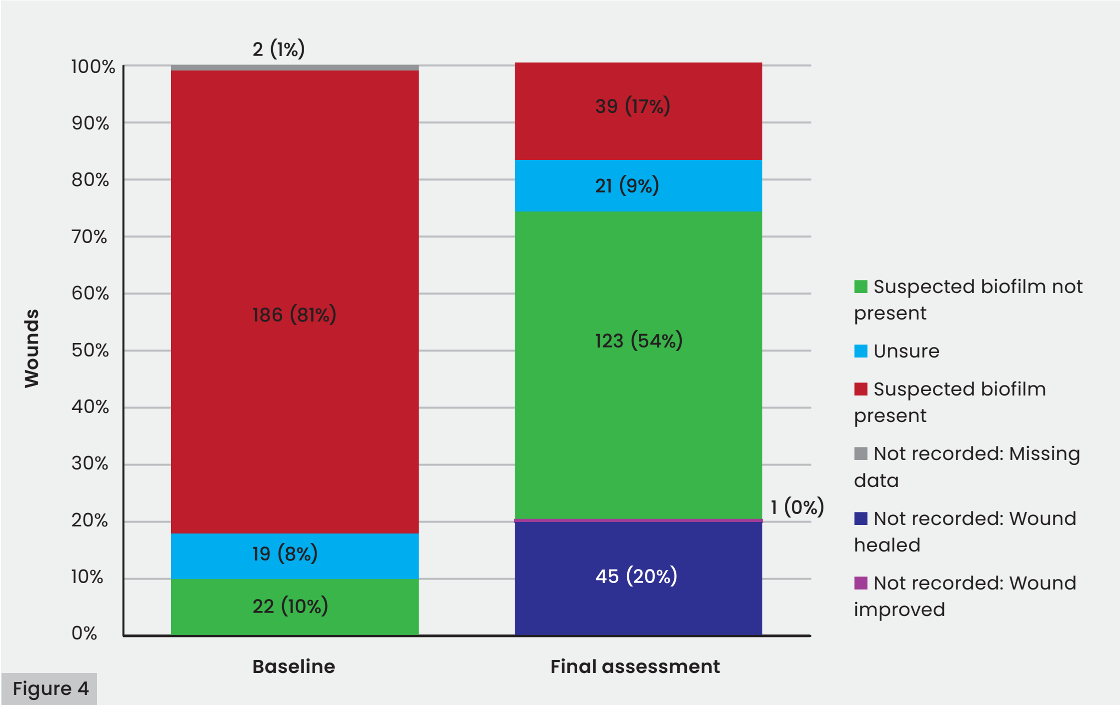

Figure 4. Suspected biofilm at baseline and final assessment.

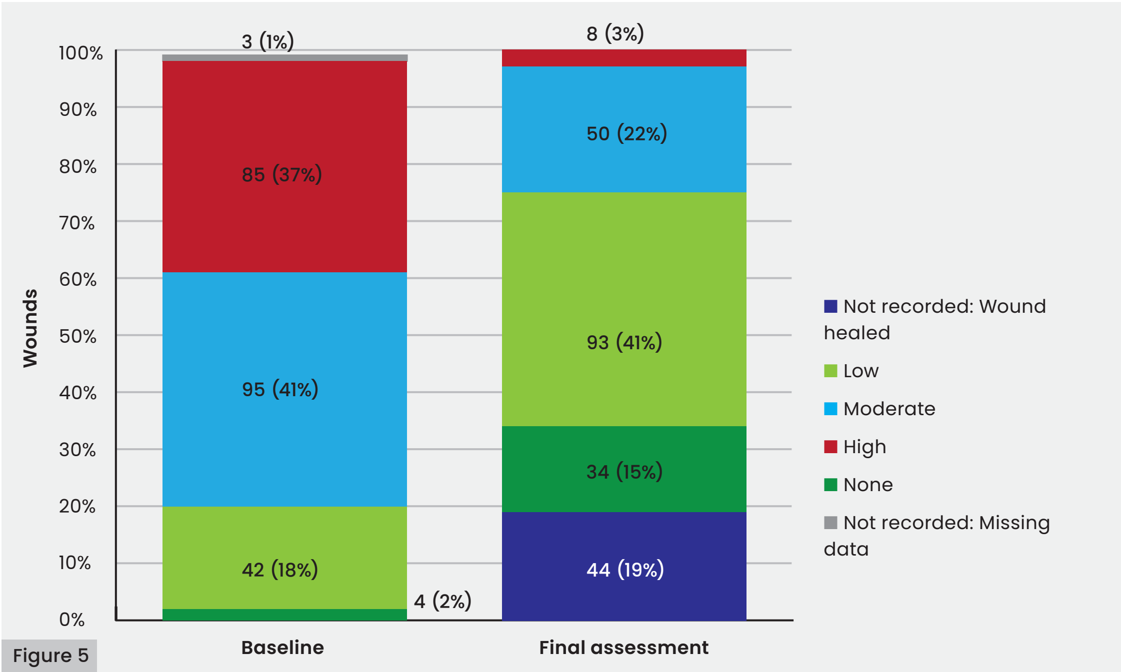

Figure 5. Exudate levels at baseline and final assessment.

Hygiene Protocol incorporating Aquacel Ag+ Extra dressings (marketed as Aquacel Ag Advantage dressings in the US) for a median of 33 treatment days, was associated with significant reductions in local infection, wound volume, suspected biofilm, and exudate levels. Local infection resolved in nearly all (95%) baseline infected wounds and most wounds improved or completely healed, from a population in which more than half were static or deteriorating at baseline, in addition to being impeded by local infection.

To our knowledge, this is the first published analysis of patients receiving systemic antibiotics within in a wound care programme applying an internationally recognised biofilm-based standard of care, the Wound Hygiene Protocol (Murphy et al, 2019; 2020). Previous studies suggest Aquacel Ag+ Extra dressings support healing in hard-to-heal wounds (Walker et al, 2015; Metcalf et al, 2016), though outcomes may vary depending on prior standard of care. The present analysis demonstrates the value of standardising care through a structured, protocol-driven approach focused on periwound and wound bed preparation, incorporating the appropriate use of antimicrobials to reduce variation in clinical practice.

Aquacel Ag+ Extra dressings may promote

wound healing by reducing biofilm, as shown in multiple in vitro studies (Bowler and Parsons, 2016; Parsons et al, 2016; Suleman et al, 2020, Meredith et al, 2023; 2024). In the current cohort, despite prior use of a variety of antimicrobial dressings and systemic antibiotics, 74% of wounds were diagnosed as infected at baseline. Following treatment, only 3% were diagnosed as infected and wound volume was significantly decreased, suggesting management with the Wound Hygiene Protocol incorporating Aquacel Ag+ Extra dressings was more effective than previous approaches.

There are several strengths to this analysis including the large sample size and diverse clinical characteristics, providing valuable real-world insight into outcomes of hard-to-heal wounds in patients receiving antibiotics. The results of this analysis support the use of the Wound Hygiene Protocol in this high-risk population.

There were several limitations of this analysis, including variations in cleansing and debridement techniques, as well as differing clinical expertise. It is difficult to determine the impact of such variation on the positive wound outcomes seen in this analysis. As this was non-comparative, it is difficult to isolate the effect of the Wound Hygiene Protocol, antibiotics and natural healing trajectory of the wound. However, it is notable that most wounds included in this analysis were previously static or deteriorating despite standard of care and antibiotics. The diagnosis of local infection and suspicion of biofilm were not laboratory-confirmed and were determined by HCP visual assessment, possibly leading to the introduction of human error. However, this reflects real-world practice where definitive tests are unavailable (Haesler et al, 2019). Future investigations should compare treatment strategies in a controlled clinical environment to reduce confounding factors and potential sources of bias.

Conclusion

The Wound Hygiene Protocol is a promising standard of care for hard-to-heal wounds that addresses local barriers to healing, such as biofilm. This exploratory, post-hoc analysis suggests that the Wound Hygiene Protocol, incorporating antibiofilm dressings, complements antibiotic therapy and may support antibiotic stewardship. Future directions include enhanced data collection for further insight into the efficacy of different methods and products used at all Wound Hygiene Protocol steps, as well as sub-analyses on different wound types, wound care settings and geographies. ●

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