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Improving outcomes for patients with hard-to-heal wounds following adoption of the Wound Hygiene Protocol: real-world evidence

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research

Improving outcomes for patients with hard-to-heal wounds following adoption of the Wound Hygiene Protocol: real-world evidence

Objective: To evaluate the impact of a four-step biofilm-based wound care strategy, Wound Hygiene Protocol (WHP: cleanse, debride, refashion, and dress), on hard-to-heal wounds.

Method: This was a prospective, real-world analysis of hard-to-heal wounds managed with the WHP that incorporated Aquacel Ag+ (Convatec Ltd., UK) dressings. Data were captured electronically between April 2021 and December 2022. The primary endpoint was change in wound volume from baseline to final assessment.

Results: A total of 693 wounds in 669 patients (median patient age: 74 years) were included in the analysis with a median treatment time of 31 days. Most health professionals were general nurses (50%) or nurse practitioners (38%). Patient homes (27%) and community clinics (27%) were the most common clinical settings. Venous leg ulcers (26%) and pressure ulcers/injuries (17%) were the most common wound type. Duration was >12 months in 21% of wounds. At baseline, the mean wound volume was 57.8cm³. At the final assessment, mean wound volume was 17.2cm³, corresponding to an 80% reduction from baseline; p<0.001). At baseline, 66% of wounds were static or deteriorating. At final assessment, this had decreased to 5%, and 94% had improved or healed. Exudate levels were moderate or high in 69% of wounds at baseline which decreased to 25% at final assessment (p<0.001). Suspected biofilm and local wound infection decreased from 79% and 43%, respectively, at baseline, to 18% and 3%, respectively, at final assessment (p<0.001 for both).

Conclusion: The WHP is a new proposed standard of care that successfully treated hard-to-heal wounds by addressing the key local barriers to wound healing.

Declaration of interest: RT-S and DGM are employees of Convatec Ltd., UK. Knowledge- and skill-based training delivered to health professionals prior to study initiation was funded by Convatec Ltd.

biofilm • hard-to-heal wounds • real-world analysis • wound • wound care • wound dressing • wound healing • wound hygiene

Despite recent advances in wound care (e.g., negative pressure wound therapy and bioactive dressings), the number of hard-to-heal wounds is rising.[1–7] With a global prevalence of ~1.9 per 1000, it is predicted that the incidence will increase with the ageing population.[1–3,8] Hard-to-heal wounds are defined as wounds that do not transition through the normal phases of healing in a timely manner.[9] They are associated with a significant reduction in health-related quality of life and place a great burden on healthcare systems.[3,10–13] In the UK, the annual National Health Service cost of wound management in 2017/2018 was £8.3 billion; £2.7 billion and £5.6 billion were associated with managing healed and unhealed wounds, respectively.[8] Moreover, wound care accounts for 2–4% of healthcare expenditure in Europe and costs $28 billion USD per year in the US.[11–14]

Among wound care specialists, the term ‘hard-to-heal’ has been increasingly favoured instead of ‘chronic’, as the latter suggests that such wounds are lifelong and that the local barriers to healing (i.e., biofilm) cannot be overcome with appropriate care.[15,16] Additionally, to healthcare payers, the term ‘chronic’ can suggest that such wounds are long-term and unresolvable, thus potentially discouraging allocation of resources to effectively address healing.[15,16] Biofilm is a self-produced matrix of extracellular substances consisting of communities of microorganisms and has long been implicated as a barrier to healing in hard-to-heal wounds.[17,18] A recent multivariate logistic regression analysis of risk factors associated with hard-to-heal wound infection found that there was a four-fold higher chance of infection due to biofilm-forming organisms, resulting in hard-to-heal wounds compared to non-biofilm producers (p=0.0001).[19] The physical removal of biofilm is therefore a vital step in facilitating wound

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healing that must be routinely performed with additional measures to reduce its re-formation.[20] Wound care is multidisciplinary and involves a variety of health professionals (HPs) such as nurses, physicians, podiatrists and surgeons, with varying degrees of skill and training in wound management. Therefore, there is a need for standardised biofilm-based wound care to optimise patient outcomes.

The Wound Hygiene Protocol (WHP) was developed by an international panel of wound care specialists to provide a four-step standardised approach to biofilm management and wound care. The protocol is comprised of four steps that are performed consecutively and consistently at each patient visit:[15,16,21]

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

Its core principle is to kickstart healing by removing or minimising all unwanted materials (biofilm, devitalised tissue and foreign debris) from the wound, address any residual biofilm, and prevent its re-formation.[15,21] The WHP allows for biofilm-based wound care to be administered early, safely and consistently by any HP in any clinical setting. It may also promote antimicrobial stewardship by helping to reduce inappropriate and ineffective use of antibiotics.

As the first significant Wound Hygiene data-guided activity, the objective of this study was to collect clinical evidence to evaluate the real-world effectiveness of the four-step protocol of care on hard-to-heal wounds when administered across different clinical settings.

Method

Study design

This was a prospective, real-world analysis of hard-to-heal wounds managed with the WHP in different wound care settings across Spain, Italy, the UK, Poland, the Netherlands and Portugal. Between 1 April 2021 and 31 December 2022, data were captured electronically using a WHP data collection form by participating HPs. Knowledge- and skill-based training was delivered to HPs on how to implement the WHP in clinical practice over a recommended period of four weeks, or earlier if wound closure occurred, or longer if clinical judgement dictated. A detailed description of assessments at baseline and the end of the implementation period is outlined in Table 1.

Objectives and endpoints

The study objective was to evaluate the impact of the WHP that incorporated Aquacel Ag+ Extra/Ag Advantage dressings (Convatec Ltd., UK) on the progression (moving positively along the healing trajectory) of hard-to-heal wounds. The primary endpoint was change in wound volume from baseline to final assessment. Wound volume was estimated by measuring the length and width using a disposable sterile ruler and depth using a probe. Secondary endpoints included qualitative

Table 1. Key study assessments. X indicates which assessment/procedure was performed at baseline and/or final assessment

	Baseline	Final assessment
Patient consent	X	
Demographics	X	
Inclusion/exclusion criteria	X	
Medical history	X	
Concomitant medications	X	
Patient mobility	X	
Wound characteristics		
Location	X	
Duration	X	
Type	X	
Size (volume)	X	X
Classification	X	X
Tissue types	X	X
Periwound skin condition	X	X
Exudate level	X	X
Biofilm assessment	X	X
Local wound infection assessment	X	X
Pain level	X	X
Previous dressings	X	
Additional therapies	X	
Overall wound status	X	X
HP questionnaire		X

HP—health professional

Table 2. Patient demographics

	Wounds (n=693)
Patient age, median (range)	74 (18–101)
Sex, n (%)	
Male	310 (45)
Female	380 (55)
Missing data	3 (0.4)
Country, n (%)	
Italy	197 (28)
Spain	178 (26)
UK	144 (21)
Poland	116 (17)
The Netherlands	52 (8)
Portugal	6 (1)

Table 3. Health professionals and clinical settings

	Wounds (n=693)
Health professional, n (%)	
General nurse	349 (50)
Advanced HP/nurse practitioner	260 (38)
Physician	36 (5)
Podiatrist	27 (4)
Healthcare assistant	8 (1)
Other	7 (1)
Missing data	6 (1)
Clinical setting, n (%)	
Patient home	190 (27)
Community clinic	186 (27)
Outpatient clinic	124 (18)
Hospital	98 (14)
Post-acute facility	62 (9)
Care home	20 (3)
Physician office	13 (2)
Other	7 (1)
Missing data	1 (0.1)

HP–health professional

changes in exudate levels, suspected biofilm, and signs of local infection.

The presence of suspected biofilm was determined by HPs using a set of criteria[22] outlined on the WHP data collection form that 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; and secondary signs of infection.

The presence of local wound infection was also determined according to criteria[22] outlined on the WHP data collection form and included classic signs (erythema, local warmth, swelling, purulent discharge, delayed healing, new or increasing pain, and increasing malodour) and subtle signs (hypergranulation, bleeding friable granulation tissue, epithelial bridging and pocketing granulation tissue, wound breakdown and enlargement, and increased exudate).

Study participants

Eligible patients were ≥18 years of age with a hard-to-heal wound, defined as a wound that has failed to respond to evidence-based standard of care (SoC).[15]

Table 4. Baseline wound characteristics

Wound type, n (%)	Wounds (n=693)
Leg ulcer	**272 (39)**
Venous	183 (26)
Arterial	11 (2)
Mixed	50 (7)
Unknown	28 (4)
Pressure ulcer/injury	**120 (17)**
Stage 1	0 (0)
Stage 2	28 (4)
Stage 3	50 (7)
Stage 4	32 (5)
Unstageable	1 (0.1)
Deep tissue injury	9 (1)
Diabetic foot ulcer	66 (10)
Surgical wound	**59 (9)**
Closed	11 (2)
Open	15 (2)
Dehisced	33 (5)
Traumatic wound	81 (12)
Cavity wound	16 (2)
Malignant wound	4 (1)
Moisture lesion	4 (1)
Weeping oedema	4 (1)
Skin tear	**33 (5)**
Type 1	3 (0.4)
Type 2	9 (1)
Type 3	21 (3)
Other	34 (5)
Wound duration, n (%)	**Wounds (n=693)**
<7 days	56 (8)
7–14 days	47 (7)
2–4 weeks	92 (13)
4–8 weeks	95 (14)
2–3 months	95 (14)
3–6 months	88 (13)
6–12 months	74 (11)
>12 months	143 (21)
Missing data	3 (0.4)
Additional wound therapies, n (%)	**Wounds (n=693)**
Antibiotics	230 (33)
Compression bandaging	203 (29)
Analgesics	149 (22)
None	131 (19)
Other	111 (16)
Compression hosiery	64 (9)
Equipment (e.g., pressure relieving/ offloading device)	61 (9)

Patients were excluded if they were receiving chemotherapy/radiotherapy or end-of-life care, had actively spreading wound infection or osteomyelitis as determined by the clinician, or had wounds that probed to bone.

Statistical analyses

The primary null hypothesis for this analysis was that implementation of the WHP with Aquacel Ag+ Extra dressing at Stage 4 does not result in any wound characteristic changes. A non-parametric Wilcoxon signed-rank test was used to determine if there was a statistically significant reduction in wound volume from baseline to final assessment. Wounds with missing data on area (width or length) or depth were excluded from the wound volume analysis. For absolute change in wound volume, wounds with any recorded baseline wound 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 wound depth at baseline were excluded from the analysis. For categorical data, the change was tested using the McNemar–Bowker test.

Ethical approval and patient consent

This was a service evaluation with real-world analysis of healthcare outcomes following implementation of a protocol of care that did not involve change to standard practice. Ethics committee review was confirmed as not required by the local participating healthcare institution.

Patient selection was defined by the HP and data collection was completed in a routine healthcare setting by the HP using the WHP data collection form. Written informed consent was obtained from the patient, at the local level by the participating HP, according to local requirements. Confirmation of consent was documented on the WHP data collection form, stored on a secure Convatec Google Cloud Platform (Google Inc., US).

Results

Patients and baseline wound characteristics

A total of 693 wounds in 669 patients were included in the analysis, with a median treatment duration of 31 days (range: 2–200 days). The median age of patients was 74 years (range: 18–101 years), and the proportion of males and females was similar (Table 2). Most patients were from Italy (28%), Spain (26%) and the UK (21%) (Table 2), and the majority of HPs were general nurses (50%) or nurse practitioners (38%), followed by physicians (5%) and podiatrists (4%) (Table 3). Patient homes (27%) and community clinics (27%) were the most common clinical setting, followed by outpatient clinics (18%), hospitals (14%) and post-acute facilities (9%) (Table 3). Venous leg ulcers were

Fig 1. Waterfall plot of percentage reduction in wound volume (number of wounds=501)

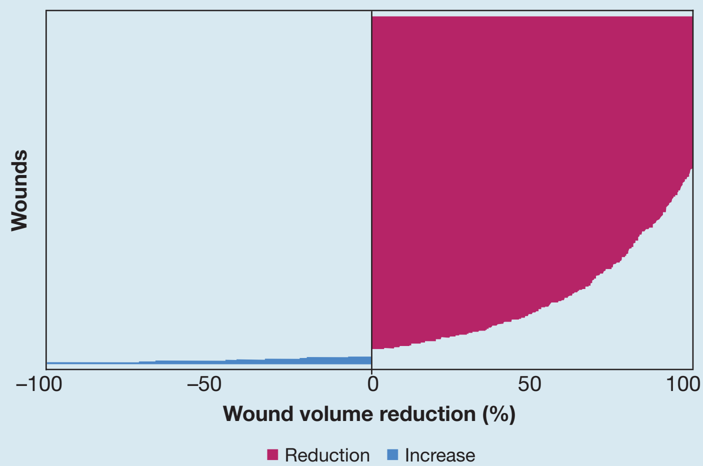
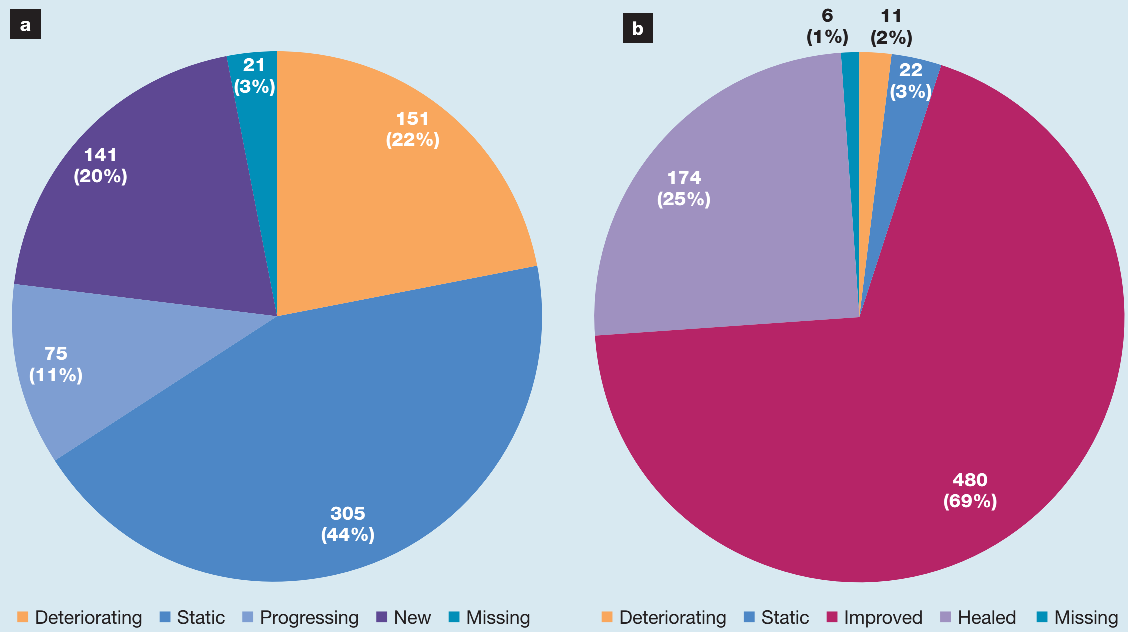


Table 5. Change in wound volume

Parameter	Baseline	Observed value	Change from baseline*	Percentage reduction from baseline†
	Wounds (n=693)			
Wound volume (cm³)				
n	661	658	646	501
Mean±SD	57.8±184.0	17.2±187.5	-41.3±243.6	79.8±31.0
Median	4.5	0.0	-3.0	95.7
Interquartile range	0.1, 25.0	0.0, 1.80	-20.4, 0.0	70.0, 100.0
Range	0.0, 2100.0	0.0, 4500.0	-1929.0, 4500.0	-100.0, 100.0
95% CI‡	–	–	-60.1, -22.5	77.1, 82.6
P-value§	–	–	<0.001	<0.001

Wounds with missing area (width or length) or height data were excluded from the wound volume analysis. *Wounds with any recorded baseline wound depth including zero were included. †Wounds with zero wound depth at baseline were excluded. ‡95% CI for mean change/percentage reduction from baseline. §Based on one sample Wilcoxon signed-rank test. CI—confidence interval; SD—standard deviation

Fig 2. Wound status at baseline **(a)** and at final assessment **(b)**



the most common wound type (26%), followed by pressure injuries/ulcers (PIs/PUs) (17%), traumatic wounds (12%) and diabetic foot ulcers (DFUs) (10%) (Table 4). The duration of wounds was >12 months in 21%, and the most common additional therapies were antibiotics (33%), compression bandaging (29%) and analgesics (22%) (Table 4).

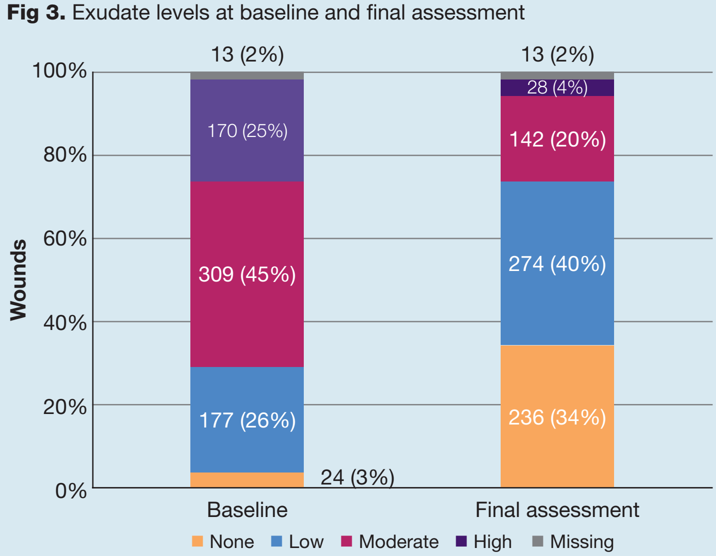
Wound size

At baseline, the mean±standard deviation (SD) wound volume was 57.8±184.0cm^3 (Table 5). At final assessment, the mean wound volume was 17.2±187.5cm^3, corresponding to a mean reduction of 41.3±243.6cm^3 and an 80% mean reduction from baseline (p<0.001) (Table 5; Fig 1). The median (range) wound volume was 4.5cm^3 (0.0–2100.0cm^3) at baseline and was 0.0cm^3 (0.0–4500.0cm^3) at final assessment (Table 5). A 100% reduction in wound volume was observed in 43% (216/501) of wounds (Fig 1).

Wound status

At baseline, only 11% of wounds were progressing; 44% of wounds were static and 22% were deteriorating (Fig 2a). At final assessment, most wounds had improved from baseline (69%) or healed (25%). Only a small proportion of wounds were static (3%) and deteriorating (2%) at final assessment (Fig 2b).

Fig 3. Exudate levels at baseline and final assessment



Exudate levels

At baseline, exudate levels were moderate or high in 45% and 25% of wounds, respectively. At final assessment, this had decreased to 20% (moderate exudate) and 4% (high exudate) (p<0.001; Fig 3), corresponding to 56% and 84% reductions in the proportion of wounds with moderate or high exudate level, respectively. The proportion of wounds with no exudate or low exudate levels increased from baseline (3% and 26%, respectively) to final assessment (34% and 40%, respectively) (p<0.001; Fig 3).

Biofilm and infection status

Suspected biofilm decreased from 79% of wounds at baseline to 18% at final assessment (77% reduction; p<0.001) (Fig 4). Local wound infection diagnosis decreased from 43% of wounds at baseline to 3% at final assessment (93% reduction; p<0.001) (Fig 5).

Discussion

In this real-world analysis of hard-to-heal wounds, management with a standardised WHP that incorporated Aquacel Ag+ dressings was associated with a statistically significant decrease in wound volume, exudate levels, suspected biofilm, and local infection after a median of 31 treatment days. Nearly all wounds had improved or healed from a population in which two-thirds were static or deteriorating at baseline (including leg ulcers, PUs/PIs and DFUs), demonstrating a shift to a positive healing trajectory. To our knowledge, this is the first wound care programme that has implemented an internationally recognised biofilm-based SoC.[15,16]

While previous studies have evaluated the impact of treatment with Aquacel Ag+ on hard-to-heal wounds,[23,24] study designs enabled clinicians to adopt their own SoC for wound bed preparation, thus introducing variation in practice that may have influenced results. The present data demonstrates the effectiveness of the WHP in standardising periwound and wound bed preparation pre-dressing application, thus reducing variation across diverse clinical settings and different HPs, as well as highlighting the importance of biofilm reduction at each step.

In this analysis, Aquacel Ag+ was the common dressing applied at Step 4. While each step of the WHP aims to reduce overall bioburden, the use of Aquacel Ag+ dressings has been shown to reduce biofilm in numerous in vitro studies.[25–30] A variety of antimicrobial dressings were used on wounds prior to implementing the WHP, yet 66% were static or deteriorating at baseline. At the final assessment, only 5% of wounds were static or deteriorating and 94% of wounds had progressed or healed.

A key strength of our analysis includes the generalisability of our findings due to the large sample size, inclusion of a variety of wound types, clinical settings, locations and HPs. Additionally, as the study population represents a prospective consecutive cohort (i.e., patients that met the eligibility criteria were included from onset), these results can be considered strong evidence in support of the WHP.

Fig 4. Suspected biofilm at baseline and final assessment

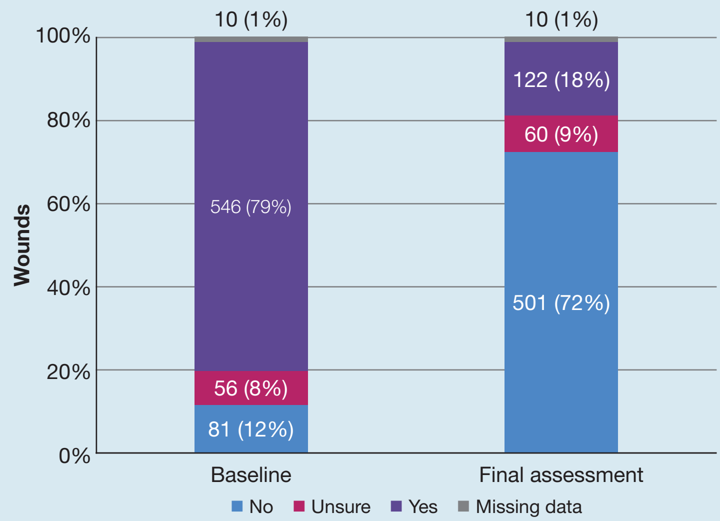
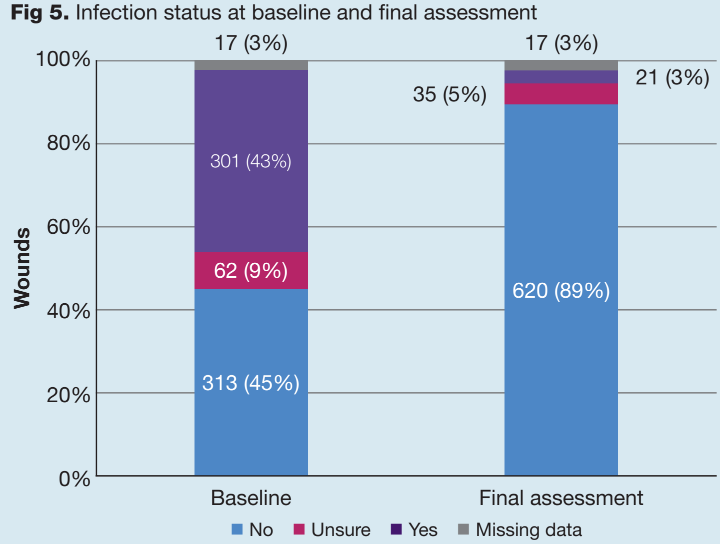


Fig 5. Infection status at baseline and final assessment



Limitations

Limitations of this analysis include differences in cleansers and debridement techniques, as well as HPs with different skill levels, making it difficult to ascertain the impact they had on the positive wound outcomes. Similarly, the single-arm nature of this analysis makes it difficult to distinguish between the effect of the WHP versus the natural healing trajectory of the wound. However, this analysis included hard-to-heal wounds, the majority of which were static or deteriorating, despite standard therapies. Furthermore, the presence of biofilm and local infection were not laboratory-confirmed (as no definitive tests exist for either), and were determined by HPs with varying levels of clinical expertise.

Conclusion

The WHP is a new proposed SoC that successfully treats hard-to-heal wounds by addressing key local barriers to healing (i.e., biofilm). Incorporation of an antibiofilm dressing may further facilitate wound healing by helping to reduce overall bioburden. Future directions include studies in Asia

Reflective questions

- What is biofilm and what role does it play in hard-to-heal wounds?
- What are the four steps of wound hygiene?
- How does implementation of a biofilm-based wound care strategy facilitate wound healing?

and the US and enhanced data collection for further insight into the efficacy of different methods and products used at all WHP steps, as well as sub-analyses on different wound types, wound care settings and geographies. JWC

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