

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

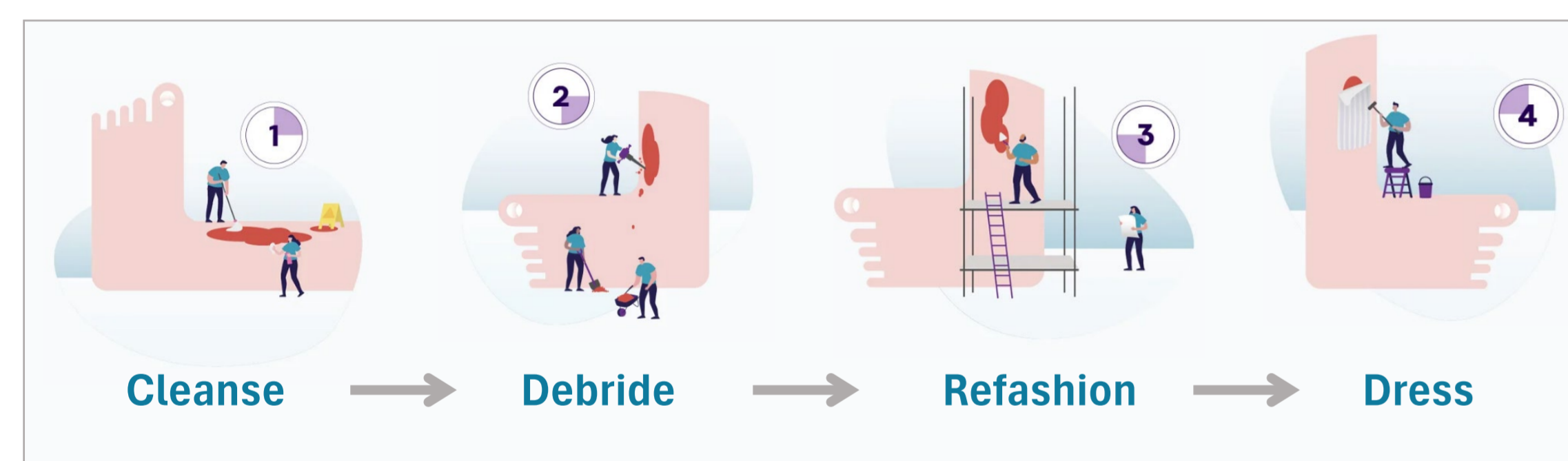
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Background

- Hard-to-heal wounds are a major challenge to healthcare systems globally¹:
 - Estimated prevalence of 2.21 per 1,000 population²
 - Associated with reduced patient health-related quality of life and substantial economic burden^{3,4}
- Bioburden has long been implicated in hard-to-heal wounds⁵:
 - At least 78% of hard-to-heal wounds estimated to have biofilm⁶
 - Biofilm can protect microorganisms from antibiotics, antiseptics and the host immune response⁵
- Wound Hygiene is 4-step standardized approach to biofilm management and wound care (Figure 1)⁷⁻⁹:
 - Developed by an international panel of wound care specialists
 - Allows biofilm-based wound care to administered early, safely, and consistently in any clinical setting

Figure 1. Wound Hygiene: antibiofilm protocol of care



Objective

To evaluate the impact of Wound Hygiene (incorporating an advanced antibiofilm gelling fibre dressing*) on hard-to-heal wounds

Methods

- A prospective, real-world analysis of hard-to-heal wounds managed with Wound Hygiene
- Patients were enrolled from different wound care settings across Spain, Italy, the United Kingdom, Poland, the Netherlands, and Portugal
- Between 01 April 2021 and 31 December 2022, patients were managed with Wound Hygiene (incorporating a CMC dressing containing ionic silver, EDTA and BEC*) for approximately 4 weeks or as deemed clinically appropriate
- The primary endpoint was change in wound volume from baseline to final assessment
- Secondary endpoints were qualitative changes in exudate levels, suspected biofilm, and signs of local infection

Results

- A total of 693 wounds were included in the analysis (Table 1 and Table 2)
- After a median treatment time of 31 days, there was a statistically significant 80% mean reduction in baseline wound volume (p<0.001) (Table 3 and Figure 1)
- At the final assessment, most wounds had improved (69%) or healed (25%), and only a small proportion were deteriorating (22% → 2%) or static (44% → 3%) (Figure 2)
- There was an increase in the proportion of wounds with no (3% → 34%) and low (26% → 40%) exudate (p<0.001) (Figure 3)
- There was an increase in the proportion of wounds without suspected biofilm (12% → 72%) and without infection (45% → 89%) (Figure 4 and Figure 5) (p<0.001)

Table 1. Patient demographics and clinical settings

	Wounds (N=693)
Patient age, median (range)	74 (18–101)
Sex, n (%)	
Male	310 (45)
Female	380 (55)
Missing	3 (0.4)
Country, n (%)	
Italy	197 (28)
Spain	178 (26)
United Kingdom	144 (21)
Poland	116 (17)
The Netherlands	52 (8)
Portugal	6 (1)
HCP, n (%)	
General nurse	349 (50)
Nurse practitioner	260 (38)
Physician	36 (5)
Podiatrist	27 (4)
Healthcare assistant	8 (1)
Other	7 (1)
Missing	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	1 (0.1)

Table 2. Baseline wound characteristics

	Wounds (N=693)
Wound type, n (%)	
Leg ulcer	272 (39)
Venous	183 (26)
Arterial	11 (2)
Mixed	50 (7)
Unknown	28 (4)
Pressure ulcer/injury	120 (17)
Diabetic foot ulcer	66 (10)
Surgical wound	59 (9)
Traumatic wound	81 (12)
Cavity wound	16 (2)
Malignant wound	4 (1)
Moisture lesion	4 (1)
Weeping oedema	4 (1)
Skin tear	33 (5)
Other	34 (5)
Wound duration, n (%)	
< 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 therapies, n (%)	
Antibiotics	229 (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)

Table 3. Change in wound volume (cm³)

	Baseline n = 661	Final assessment n = 658	Change from baseline* n = 646	Percentage reduction from baseline† n = 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

Figure 1. Percentage reduction in wound volume

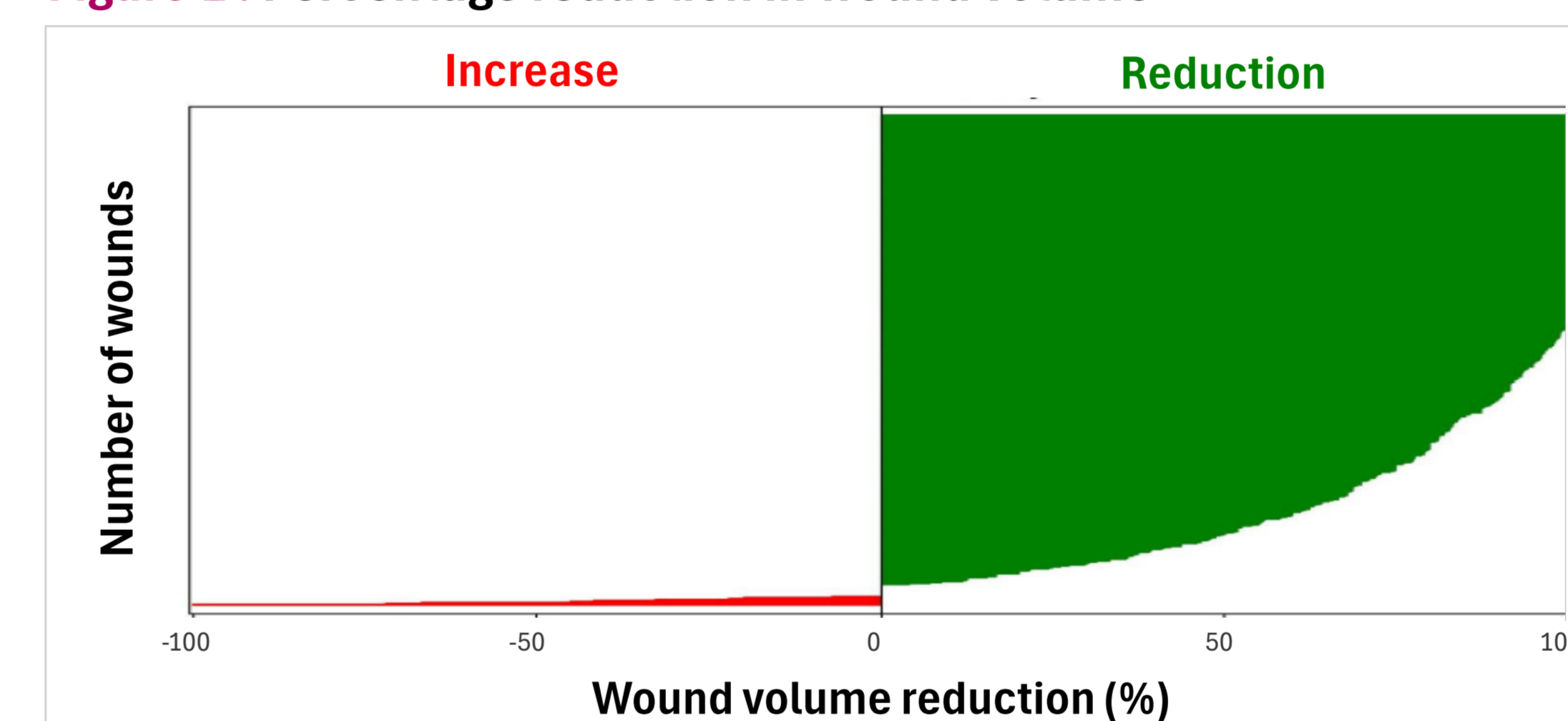


Figure 2. Wound status

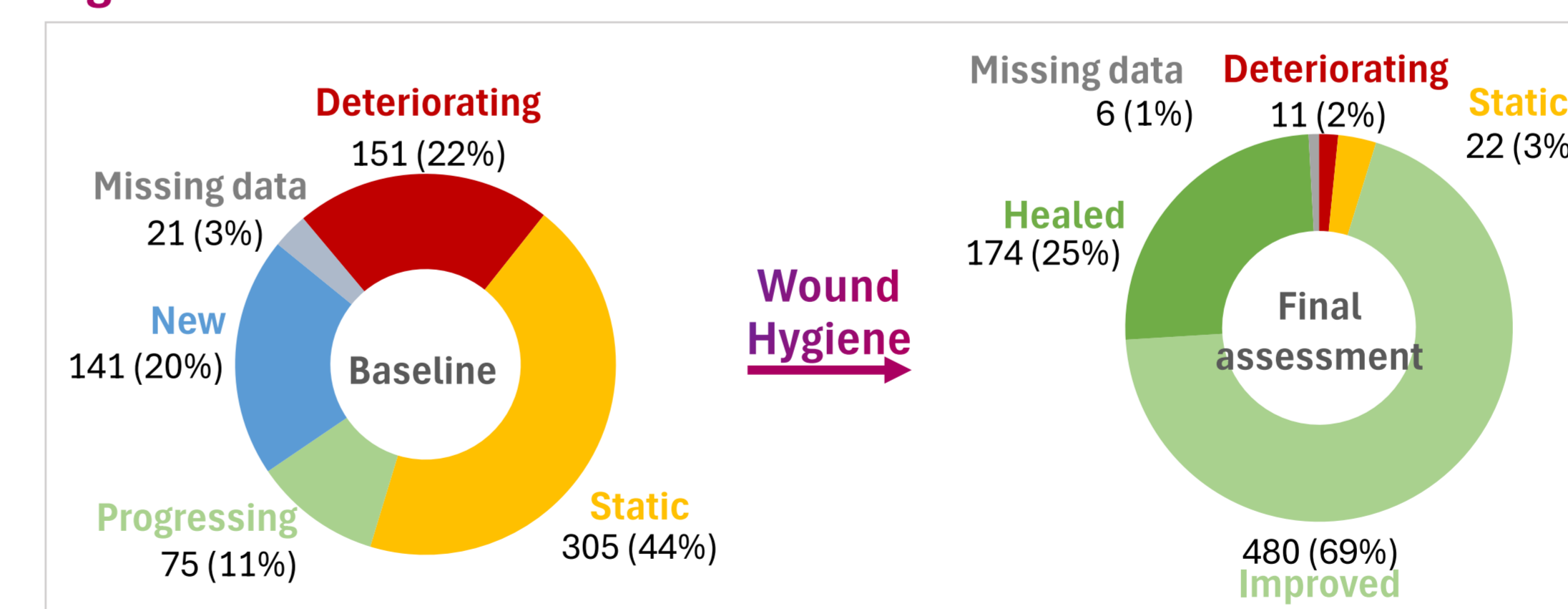


Figure 3. Wound exudate

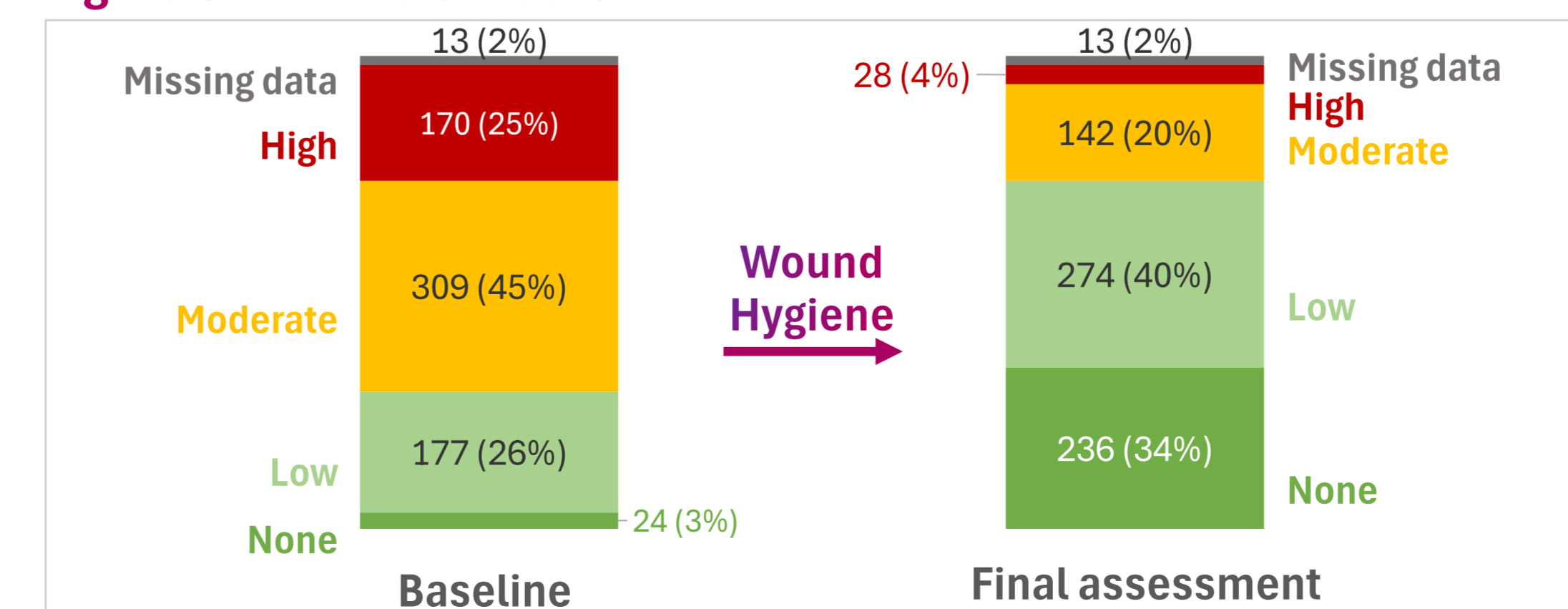


Figure 4. Suspected biofilm¹⁰

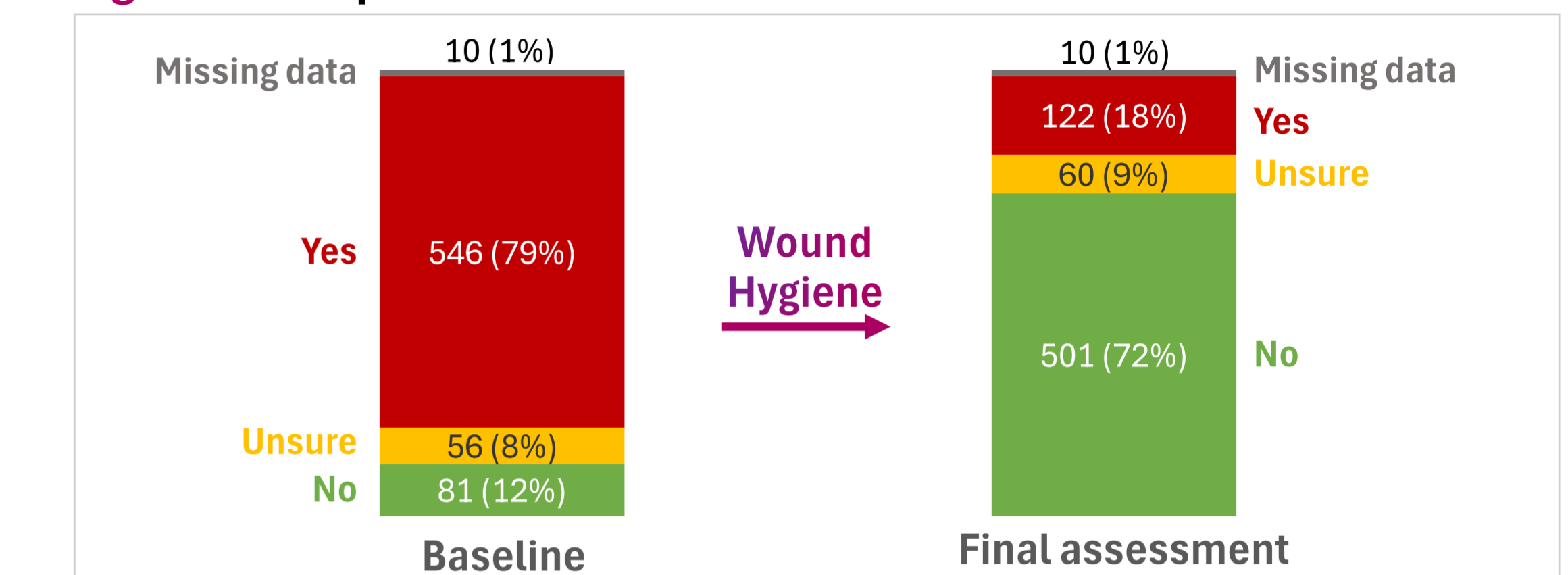
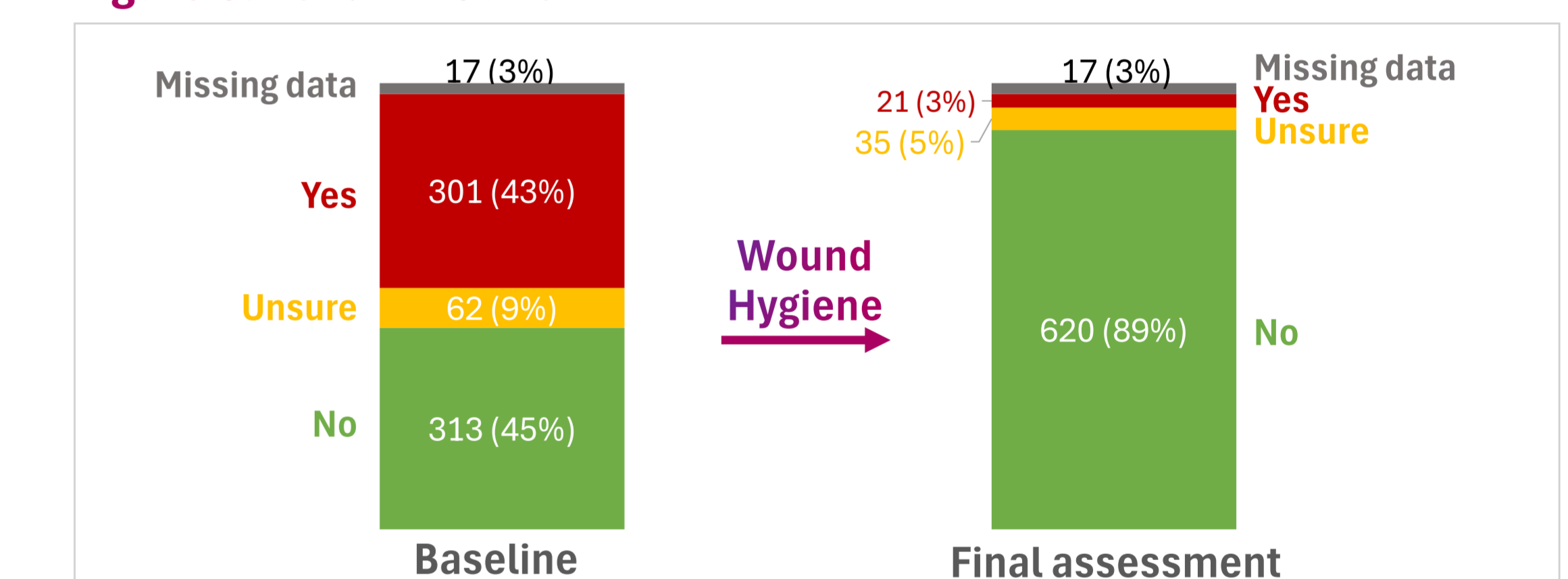


Figure 5. Local infection¹⁰



Discussion

- Wound Hygiene addresses a key local barrier to healing (i.e., biofilm) and can help minimize variation in biofilm-based wound care across different clinical settings
- Incorporation of an advanced antimicrobial gelling fibre dressing dressing may further facilitate wound healing by helping to reduce overall bioburden
- From participating HCPs responses (n=693), nearly all would routinely adopt Wound Hygiene in clinical practice (99%) and would continue to use (97%) or recommend (99%) the antibiofilm dressing

Conclusion

Management of hard-to-heal wounds with Wound Hygiene (incorporating an advanced antibiofilm gelling fibre dressing*) was associated with statistically significant reductions in wound volume and qualitative reductions in exudate, suspected biofilm, local and infection

References & Footnotes

1. Rice JB et al. *Diabetes Care* 2014;37(3):651–658. 2. Martinengo L et al. *Ann Epidemiol* 2019;29:8–15. 3. Olsson M et al. *Wound Repair Regen* 2019;27(1):114–125. 4. Chan B et al. *J Wound Care* 2017;26(Suppl 4):S4–S14. 5. James GA et al. *Wound Repair Regen* 2008;16(1):37–44. 6. Malone M et al. *J Wound Care* 2017;26(1):20–25. 7. Murphy C et al. *J Wound Care* 2020;29(Sup3):S1–S26. 8. Murphy C et al. *J Wound Care* 2019;28(12):818–822. 9. Murphy C et al. *J Wound Care* 2021;30(7):582–590. 10. Haesler E et al. *J Wound Care* 2019;28(Sup3b):S4–S12.
 *AquaCel® Ag+ Extra™ (AquaCel Ag Advantage in the United States).
 Abbreviations: CMC; carboxymethylcellulose; BEC; benzethonium chloride; EDTA; ethylenediaminetetraacetic acid; HCP; healthcare professional