

BACTERIAL INFECTION IN DFUS

DFU infections are the initiating event in more than 85% of diabetes-related lower limb amputations.¹

Diabetes weakens the immune response and associated comorbidities (e.g., neuropathy) can **mask the clinical signs and symptoms (CSS) of infection**, delaying diagnosis.^{2,3}

Elevated bacterial burden is known to prolong healing and increase the risk of infection.⁴

Objective diagnostic measures are required to identify regions of chronic pathogenic bacteria and facilitate its thorough removal.

OBJECTIVES

1 Determine the **sensitivity of IWGDF criteria for detecting DFUs with elevated bacterial burden.**

2 Investigate how **adding fluorescence imaging to the DFU assessment regime** affects bacterial detection sensitivity.

Post-hoc analysis of 138 DFUs from a prospectively powered, multi-center FLAAG clinical trial:



Clinician assessment

IWGDF criteria; CSS+ if at least 2 of the following: swelling, erythema, local pain or tenderness, increased warmth, purulent discharge.



Biopsy and microbial analysis

Quantitative microbial analysis (CFU/g) and speciation (TOF MS).



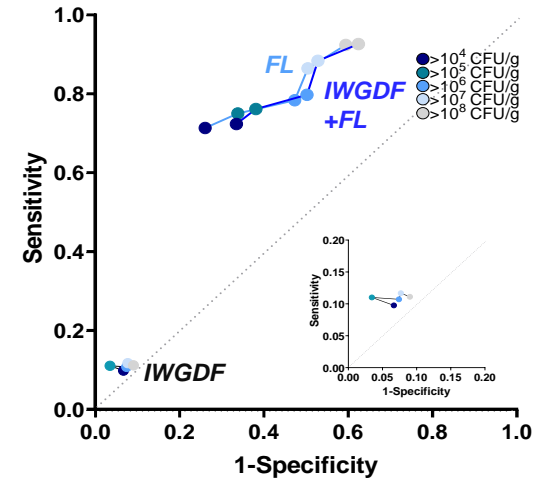
Point-of-care fluorescence imaging

MolecuLight was used to detect areas of elevated bacterial burden (most gram positive, gram negative, aerobic and anaerobic pathogens) at loads >10⁴ CFU/g.

PREVALENCE AND DETECTION OF CIBL IN 138 DFUS

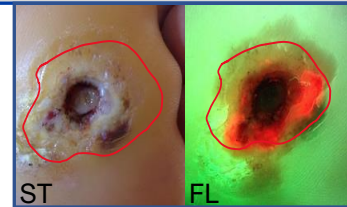
94% of DFUs containing bacteria had loads greater than 10⁴ CFU/g.

- 84% of DFUs had **fluorescence indicating bacteria outside of the wound bed**, mostly confined to a ring of callused tissue in the periwound.
- ROC curves (right) show that all five **IWGDF criteria were poor predictors of bacterial loads** in wounds (>10⁴ CFU/g), and this did not improve as bacterial loads increased (up to 10⁸ CFU/g).
- Fluorescence imaging boosted the sensitivity across all bacterial loads above 10⁴ CFU/g**; for example, to 92.6% (p<0.0001), up from 11.1% using IWGDF criteria alone in wounds with >10⁸ CFU/g.

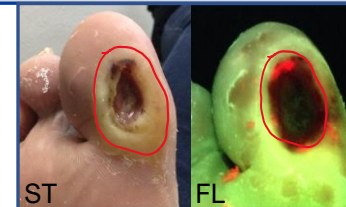


Receiver operator characteristic (ROC) curves. Diagonal grey dotted line denotes 'line of chance'.

○ Periwound (~2 cm from wound edge) ● Porphyrin-producing bacteria >10⁴ CFU/g ● Tissue (e.g. collagen, elastin)



Total bacterial load:
2.3 x 10⁸ CFU/g
IWGDF criteria:
None



Total bacterial load:
1.1 x 10⁹ CFU/g
IWGDF criteria:
None

Bacterial Load	IWGDF Criteria ¹					≥2 Criteria (CSS+)	Red/cyan fluorescence
	Swelling	Erythema	Pain	Warmth	Purulent discharge		
10 ⁴ – 10 ⁵ CFU/g	21.4%	0%	0%	0%	0%	0%	42.9%
10 ⁵ – 10 ⁶ CFU/g	20.0%	12.0%	0%	12.0%	0%	0%	64.0%
10 ⁶ – 10 ⁷ CFU/g	16.7%	4.2%	4.2%	0%	0%	0%	58.3%
10 ⁷ – 10 ⁸ CFU/g	20.6%	14.7%	8.8%	8.8%	2.9%	2.9%	82.4%
>10 ⁸ CFU/g	11.5%	15.4%	11.5%	11.5%	7.7%	7.7%	92.3%



CHRONIC INHIBITORY BACTERIAL LOAD (CIBL)

“Chronic presence of bacterial microorganisms in a wound or its surrounding tissue at loads which can damage tissues and be inhibitory to healing, as well as requires clinical intervention, with or without presence of clinical symptoms..”

The prevalence, distribution, and pathogenic nature of bacterial burden in DFUs is grossly underappreciated. This underappreciation is likely due to both: (1) a lack of reliable methods for identifying the presence and locations of bacteria in wounds, and (2) the absence of a clinical definition for such a finding in *asymptomatic* patients.

As a result of the findings in this study, **we propose new terminology, CIBL, to define the presence of bacteria at a subclinical level that is distinct from infection, but nevertheless requires clinical intervention.**

IMPACT ON BACTERIAL-INFECTION MANAGEMENT

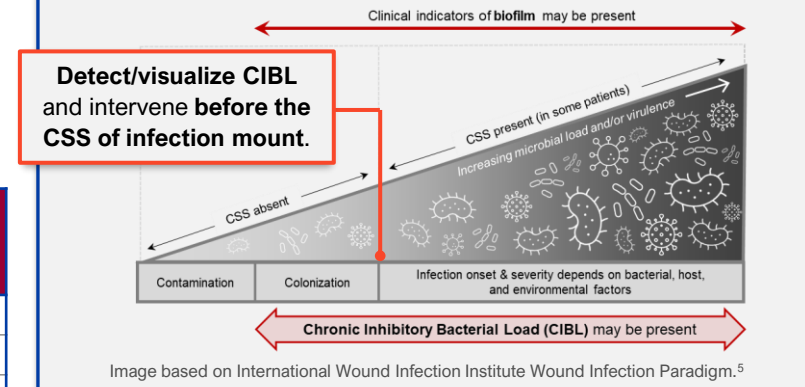


Image based on International Wound Infection Institute Wound Infection Paradigm.⁵



Poster
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References