



# Illuminating the Evidence

## Publication Summary

Rennie MY *et al.* *Journal of Wound Care* (2017).\*



MolecuLight®

### Point-of-care fluorescence imaging predicts the presence of pathogenic bacteria in wounds: a clinical study

Multi-site clinical trial finds that regions of red fluorescence are predictive of bacterial loads  $\geq 10^4$  CFU/g in 100% of study wounds



#### Study Design

- The MolecuLight *i:X* Imaging Device illuminates wounds with 405 nm violet light, causing fluorescence signals to be emitted from tissues and bacteria. Most bacterial species appear red on MolecuLight *i:X* fluorescence images due to a red-fluorescent endogenous by-product of their metabolism, porphyrins.
- Multisite, prospective, single blind clinical trials (clinicaltrials.gov #NCT02682069, #NCT03091361) were conducted to determine the positive predictive value (PPV) of red fluorescence on MolecuLight *i:X* images for detecting bacteria in wounds.
- 60 lower limb chronic wounds (47 DFUs, 12 VLUs, 1 amputation) were imaged for bacterial fluorescence using the MolecuLight *i:X* Imaging Device. Regions positive for red fluorescence were discretely sampled using either biopsy or curettage, to correlate red fluorescence signals to bacterial presence.
- Biopsy samples were analysed via gold standard quantitative polymerase chain reaction (qPCR); curettage samples were analyzed via semi-quantitative culture analysis.



#### Key Results

- The PPV of red fluorescence on MolecuLight *i:X* images was 100%, regardless of sampling method, analysis technique, or study site. No false positives were detected.

Bacterial Load in Regions of Red Fluorescence

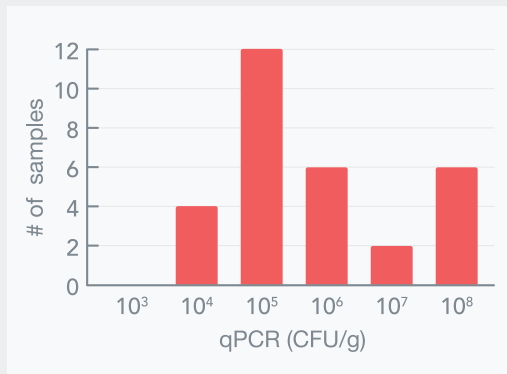


Figure 1: Total bacterial load quantified via 16S qPCR of biopsied regions of red fluorescence (n=30).

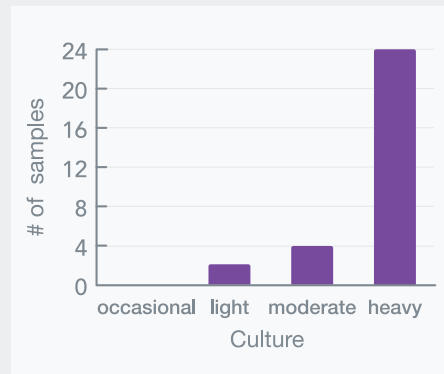


Figure 2: Bacterial load reported from culture analysis of curettaged regions of red fluorescence (n=30).

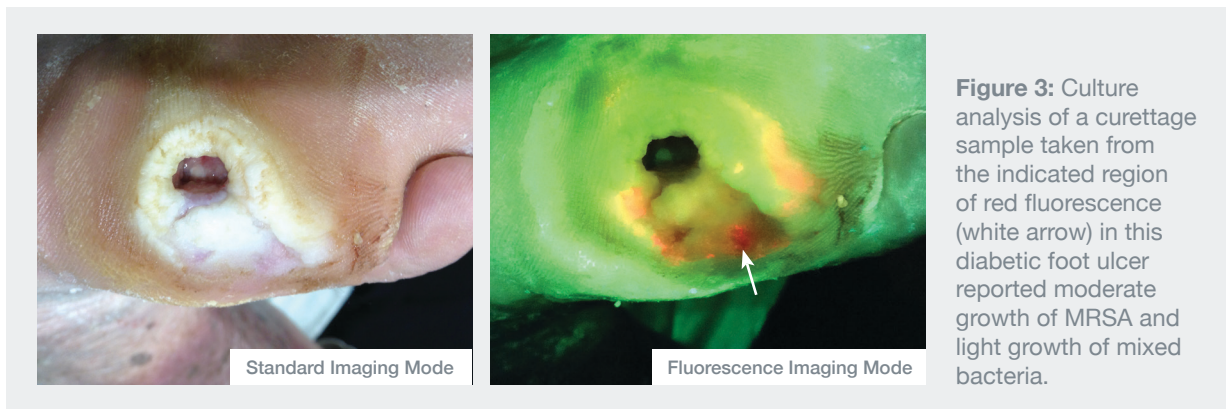


## Illuminating the Evidence (continued)



### Key Results (continued)

- Total bacterial loads detected as red fluorescence in this study ranged from  $10^4$  -  $10^8$  CFU/g. Total load was  $\geq 10^5$  CFU/g in 87% of wounds accessed via qPCR. Culture analysis reported moderate growth or higher of at least one bacterial species in 93% of samples taken from regions of red fluorescence.
- The red fluorescence signal appeared very bright in some wounds, suggesting bacterial presence near the surface, while in other wounds blush red or pink suggested subsurface bacterial presence.
- *Staphylococcus aureus* was the most prevalent pathogen detected (23/60 wounds); Methicillin-Resistant *Staphylococcus aureus* (MRSA) was detected in 7/60 wounds. Other species detected included *Enterobacter cloacae*, *Proteus mirabilis*, *Klebsiella pneumoniae*, and *Citrobacter koseri*.



**Figure 3:** Culture analysis of a curettage sample taken from the indicated region of red fluorescence (white arrow) in this diabetic foot ulcer reported moderate growth of MRSA and light growth of mixed bacteria.



### Conclusion

Fluorescence guided sampling (curettage or biopsy) in regions of red fluorescence on MolecuLight *i:X* images positively predicts the presence of pathogenic or opportunistic bacteria at loads of clinical concern ( $\geq 10^4$  CFU/g). The lack of false positives in this study suggests that fluorescence guidance, in combination with subsurface sampling techniques, could entirely eliminate the risk of false negative wound sampling. Real-time information on the presence and location of bacterial burden within or around wounds could influence treatment decisions at the point of care.



### Study Citation

\*Rennie MY, Lindvere-Teene L, Tapang K, and Linden R. Point-of-care fluorescence imaging predicts the presence of pathogenic bacteria in wounds: a clinical study. *Journal of Wound Care*, 2017. 26(8): p. 452-460.

