



Illuminating the Evidence

Publication Summary

Blackshaw EL *et al.* *Journal of Wound Care* (2018).*



MolecuLight®

Efficacy of an imaging device at identifying the presence of bacteria in wounds at a plastic surgery outpatients clinic

Results of this clinical study demonstrate that MolecuLight *i:X*™ fluorescence images were more sensitive than clinical signs and symptoms in detecting bacterial pathogens in the wound



Study Design

- The MolecuLight *i:X* imaging device illuminates a wound with safe violet light, causing endogenous 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 by-product of their metabolism, porphyrins. *Pseudomonas aeruginosa* fluoresces cyan.
- This was a single-centre, prospective, observational study of 17 plastic surgery outpatient wounds (burns, trauma, skin cancer excisions, postoperative wounds, ulcers) testing the device’s potential to improve standard practice. Patients were excluded if their wound was not amenable to a swab sample.
- At a routine clinic visit, patient wounds were examined by a clinician, and any clinical signs and symptoms of infection (CSS) were noted (e.g. pain, heat, malodour, swelling, purulent exudate). A standard image was taken of the wound, after which the room was made dark and the MolecuLight *i:X* Imaging Device was used to acquire a fluorescence image.
- The wound was sampled via swabbing (Z-technique) and sent to the hospital laboratory for semi-quantitative culture testing using standard microbiology laboratory techniques.
- Device efficacy was determined by comparing the presence of bacterial fluorescence on images (red or cyan fluorescence) to microbiology results. Four cases are described in detail.



Key Results

- Sensitivity of fluorescence images for identifying bacterial loads of concern was 100%, compared to 63 % sensitivity of clinical signs and symptoms (**Figure 1**). Accuracy of fluorescence images for identifying bacterial loads of concern was 92%, compared to 82 % accuracy of clinical signs and symptoms.

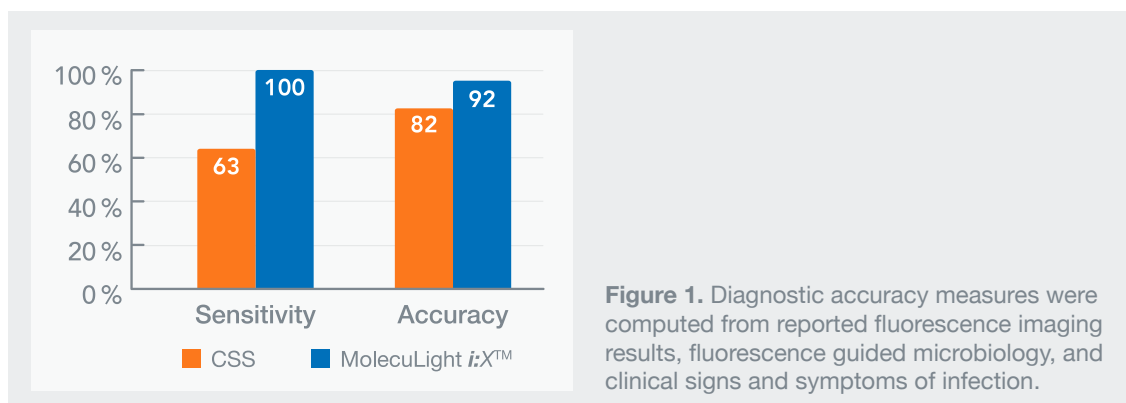


Figure 1. Diagnostic accuracy measures were computed from reported fluorescence imaging results, fluorescence guided microbiology, and clinical signs and symptoms of infection.



Illuminating the Evidence (continued)



Key Results (continued)

- Three asymptomatic patients were flagged as bacteria-positive on fluorescence images, with culture reports confirming significant bacterial levels. In at least one of these cases, the information from fluorescence images triggered a referral for treatment of infection.
- Only five study patients exhibited CSS. All five had bacteria positive fluorescence images (red or cyan) and significant levels of bacterial growth on cultures.
- In total, there were eight wounds positive for significant bacterial growth on cultures. *Staphylococcus aureus* was the most prevalent bacterial species detected, followed by *Pseudomonas aeruginosa* and coliforms. Fluorescence images correctly identified regions positive for bacterial fluorescence in each of these eight wounds.



Conclusion

The strong correlation between fluorescence images and microbiology in this study demonstrated the potential benefit of the MolecuLight *i:X* Imaging Device for point of care bacterial detection. The device was non-contact, quick to use, and the real-time information on bacterial presence provided greatly reduced waiting time for microbiology results. Potential was identified for this fluorescence imaging device to guide sampling and to aid clinicians in the diagnosis and management of wound infections.



Notes

Diagnostic accuracy measures presented in **Figure 1** were computed directly from the reported fluorescence imaging results, microbiology, and clinical signs and symptoms of infection for each study wound, using standard formulas. Though this graph accurately represents this study's data, these metrics were not computed in the publication. Statistical comparisons were not performed.



Study Citation

*Blackshaw EL and Jeffery SLA. Efficacy of an imaging device at identifying the presence of bacteria in wounds at a plastic surgery outpatients clinic. *J Wound Care*. 2018; 27(1): 20-26.

