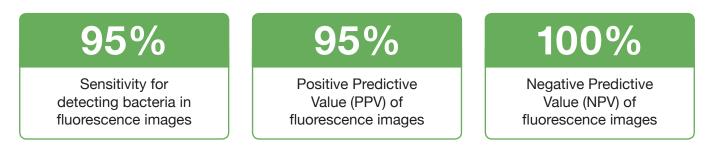
# Efficacy of a Bacterial Fluorescence Imaging Device in an Outpatient Wound Care Clinic: A Pilot Study



## Hurley CM et al. Journal of Wound Care (2019)\*

This independent study demonstrates the accuracy and ease of use of the MolecuLight *i*:*X*<sup>®</sup> fluorescence imaging device to detect pathogenic bacteria and measure wound size. The real-time information about the wounds enabled guided treatment selection and monitoring at the point-of-care.

## Study reports the following:



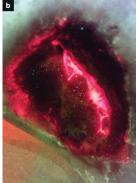
# Study Design

- The MolecuLight *i*:X<sup>®</sup> imaging device uses safe and non-invasive violet light to visualize the location of potentially harmful levels of moderate-to-heavy bacteria in wounds at point-of-care, by detection of endogenous red (most bacteria) and cyan (*Pseudomonas aeruginosa*) fluorescent bacterial signals
- An independent, single-center, prospective observational study was conducted in an outpatient plastic surgery wound care clinic to assess the accuracy and ease of use of the wound imaging device in detecting pathogenic bacteria
- Fluorescence images and 50 swabs were acquired from 33 wounds. A swab was performed on regions of the wound where the imaging device detected red or cyan fluorescence to assess bacterial growth, species and sensitivity of the imaging device

# **Key Results**

- The instant and accurate measurement of wound size and bacterial fluorescence using MolecuLight *i:X* was useful in documenting progression of chronic wounds and guiding treatment decisions
- Bacterial fluorescence imaging enabled targeted swabbing of the wound bed, limiting potential for false negative swab results



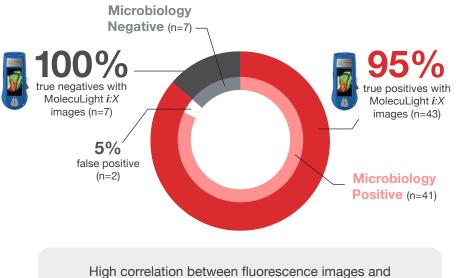


Standard Image

Fluorescence Image Bacteria at loads >10<sup>4</sup> CFU/g fluoresce red

- Nine unique bacteria species were identified in the fluorescence positive wound regions, with *Staphylococcus aureus* being the most common
- Fluorescence imaging prompted discovery of secondary wound infection below normal skin, promoting timely delivery of antibiotics and limiting delays associated with swab culture analysis
- Use of the MolecuLight *i:X* imaging device identified *Pseudomonas aeruginosa* in a wound bed lacking typical signs of *Pseudomonas* (e.g. greenish tinge, odor), enabling swift initiation of *Pseudomonas*-targeted treatment

#### **Microbiological Confirmation of Fluorescence Findings**



High correlation between fluorescence images and microbiology resulted in **sensitivity** and **positive predictive value of 95%** and **negative predictive value of 100%** based on comparison of 50 unique swabs and fluorescence images

### Conclusion

Use of the MolecuLight *i*:*X* handheld imaging device provided a simple, non-invasive and accurate method of detecting potentially pathological bacteria in wounds at the bedside. The real-time information provided through fluorescence imaging enabled documentation of wound progression and aided in clinician decision-making on the use of antibiotics and specialized dressings.

### **Study Citation**

\* Hurley CM, McClusky P, Sugrue RM, Clover JA, Kelly JE. Efficacy of a bacterial fluorescence imaging device in an outpatient wound care clinic: a pilot study. J Wound Care. July 2019. 28(7): p.438-443 PMID: 31295094

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The MolecuLight *i*:X<sup>™</sup> Imaging Device has received FDA De Novo clearance, please see https://us.moleculight.com/ for USA specific intended & indications for use. The MolecuLight i:X<sup>™</sup> Imaging Device is approved by Health Canada and has CE marking for sale in Canada and the European Union.

