Clinical Evaluation of Fluorescence Imaging in Positively Predicting the Presence of Bacteria in Chronic Wounds at the Point-of-Care

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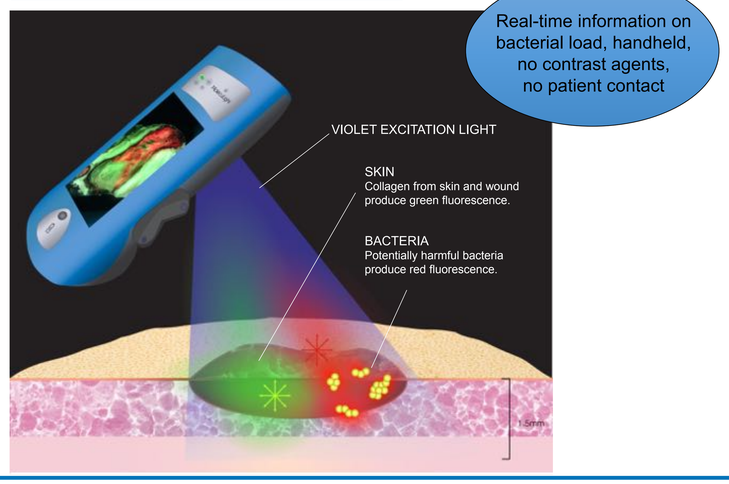
Introduction:

- Clinical diagnosis of infection in chronic wounds involves assessment of signs and symptoms based on visual inspection and microbiological cultures. This process is subjective and delayed culture results often prevent prompt treatment.
- Fluorescence imaging has recently been introduced as a new method to visualize the presence of potentially harmful bacteria in wounds in real time at the bedside using a non-contact, hand-held device[1,2].
- 405 nm excitation of tissue together with 500-545 and 600-665 nm emission filters is used to detect and localize bacterial-produced porphyrin molecules, which fluoresce red while illuminated by the device. In contrast, illuminated tissues fluoresce green.
- Multicenter clinical studies (www.clinicaltrials.gov registry: NCT02682069) were performed in Canada and the United States to evaluate the positive predictive value (PPV) of red fluorescence imaging for detecting bacteria in wounds.

Methods:

- 43 subjects (n = 16 USA, n = 27 Canada) with chronic wounds were imaged by standard photography followed by fluorescence imaging using the MolecuLight ***i:X***™ Imaging Device.
- Wounds with positive areas of red fluorescence were sampled using either biopsy (analyzed via qPCR) or curettage (analyzed via semi-quantitative culture and sensitivity testing) to correlate red fluorescence signals to bacterial presence.
- A red fluorescence signal from a discretely sampled area of the wound resulting in a microbiologically-confirmed presence of bacteria was defined as a true positive result.
- PPV was calculated as PPV=True Positive/(all samples).

Point-of-care Fluorescence Imaging



Results:

Red Fluorescence of Bacteria Imaged in Real-time

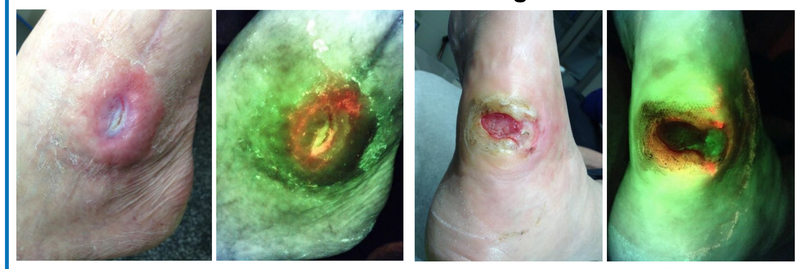
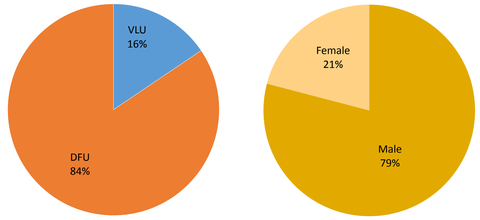


Figure 1. Example MolecuLight ***i:X*** images of chronic wounds taken in standard (ST-Mode) and fluorescence mode (FL-Mode). Bacterial presence was confirmed via targeted sampling of regions with red fluorescence.

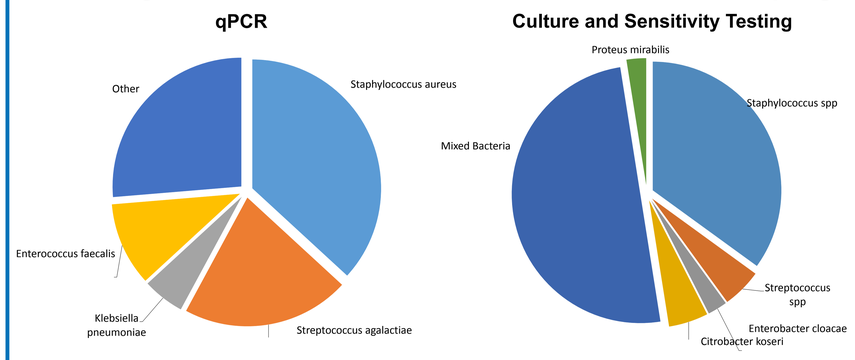
Wound Types and Patient Demographics



Summary of Sampling Data

	USA	Canada
PPV	100 %	100 %
n	16	27
Sampling Method	Biopsy	Curettage
Microbiological Analysis	qPCR Bacterial load ≥ 10^5 CFU/g	Culture and Sensitivity Bacterial load ≥ moderate/heavy
Prevalent Pathogens	*Staph. aureus* – 44 % *Streptococcus* – 25 %	*Staph. aureus* – 48 % Mixed Bacteria – 70 %
Polymicrobial Colonies	38 %	44 %

Pathogens Detected* from Red Fluorescence Guided Sampling



* Pathogens sum to >100% due to polymicrobial colonies

Conclusions:

- Real-time fluorescence imaging with the MolecuLight ***i:X***™ Imaging Device positively predicts the presence of potentially harmful bacteria in wounds at clinically significant levels.
- PPV of the device was 100% irrespective of health care infrastructure, microbiological analysis technique or user training across US and Canadian centers.
- When combined with clinical best practice, fluorescence imaging of wounds offers clinicians real-time information on bacterial presence and distribution which can guide early interventions to reduce bioburden and promote wound healing.

References

1. DaCosta RS et al. PLoS One. 2015 Mar 19;10(3):e0116623.
2. Wu YC et al. International Wound Journal. 2016 Aug;13(4):449-53.

The MolecuLight ***i:X***™ Imaging Device is approved by Health Canada (Medical License #95784) and has CE marking (Certificate #G1160292355002) for sale in the European Union. US FDA De Novo approval pending - the MolecuLight ***i:X***™ Imaging Device is not available in the US.

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