Prospective clinical evaluation of fluorescence imaging in positively predicting the presence of *Pseudomonas aeruginosa* in chronic wounds

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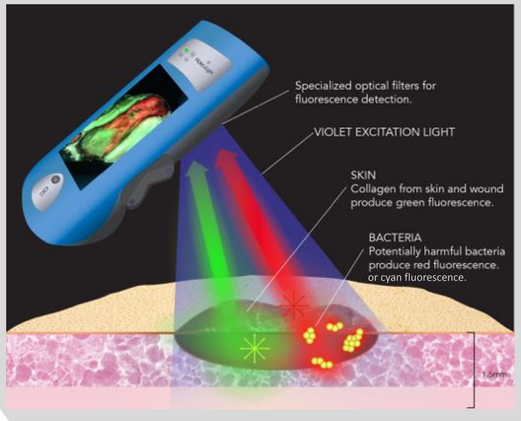
INTRODUCTION

- Real-time, point-of-care detection of critical bacterial colonization relies primarily on subjective visual inspection and clinical signs and symptoms. Confirmation via microbiological cultures can delay immediate treatment.
- When wounds are illuminated by violet light, most pathogenic bacterial species emit a red fluorescence signal due to the production of porphyrins, while *Pseudomonas aeruginosa* uniquely emits a cyan (bluish-green) fluorescence signal due to the production of pyoverdine[1].
- Fluorescence imaging was recently shown to detect red fluorescence from porphyrin producing bacteria (e.g. *S. aureus, E. coli, S. marscecens, A. baumannii*) in wounds with a positive predictive value (PPV) of 100%[2].
- This prospective single-centre clinical study (clinicaltrials.gov registry: NCT03290690) was performed to evaluate the PPV of cyan fluorescence observed on fluorescence images in predicting the presence of *P. aeruginosa* in chronic wounds.

METHODS

- Chronic wounds on a lower limb were imaged by standard photography followed by fluorescence imaging using a handheld fluorescence imaging device[3].
- Regions of the wounds exhibiting cyan fluorescence (n = 8 to date) were discretely sampled using curettage for semi-quantitative culture analysis to correlate cyan fluorescence signals to the presence of *P. aeruginosa*.
- A cyan fluorescence signal from a discretely sampled area of the wound resulting in a microbiological confirmation of the presence of *P. aeruginosa* was defined as a true positive result.
- PPV was calculated as PPV = True Positive/(all samples).

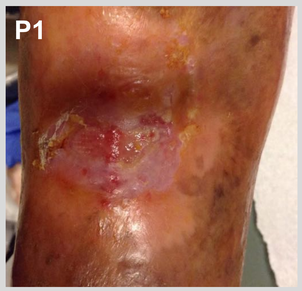
BACTERIAL FLUORESCENCE IMAGING



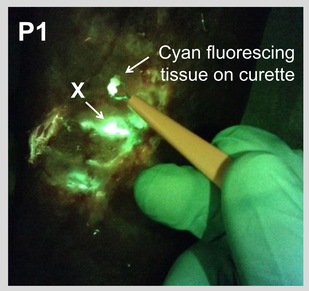
RESULTS

- **The positive predictive value of cyan fluorescence for detecting the presence of *P. aeruginosa* was 100%**. No false positives were detected.
- Regions of cyan fluorescence detected bacterial loads of light (25%), moderate (37%), and heavy growth (37%) of *P. aeruginosa*.

Cyan Fluorescence of *P. aeruginosa* Imaged in Real-time



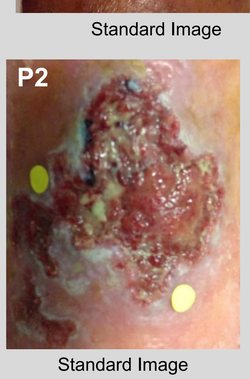
Standard Image



Fluorescence Image

Example standard and fluorescence images of study wounds. Bacterial presence was confirmed via curettage sampling of regions exhibiting cyan fluorescence. The site of curettage sampling is denoted by an X.

Note: Yellow stickers, when shown, are for the device's wound measurement feature; they are not required for bacterial imaging. P = patient.



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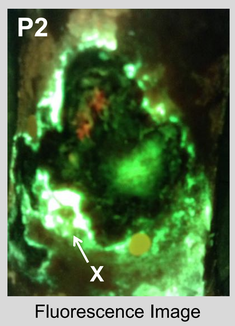
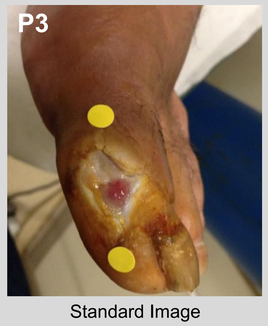


Fluorescence Image



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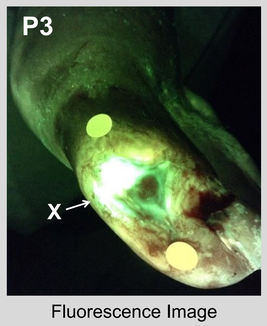
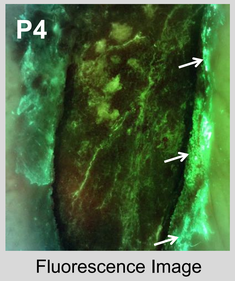
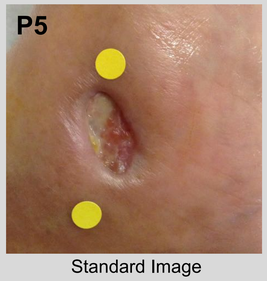


Fluorescence Image

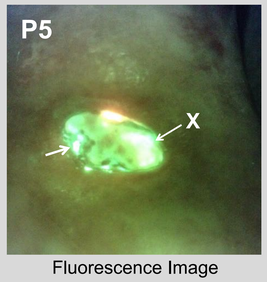
Standard Image



Fluorescence Image

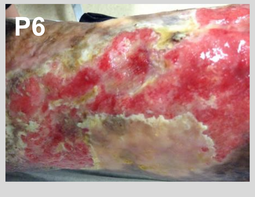


Standard Image

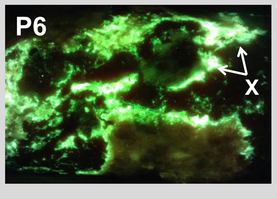


Fluorescence Image

Standard Image

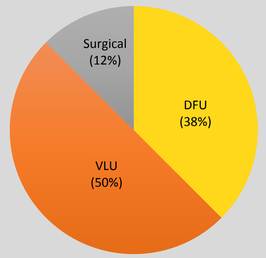


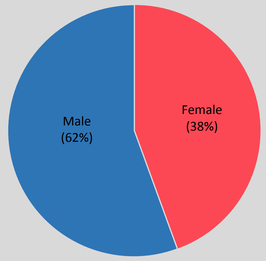
Fluorescence Image



RESULTS

Wound Types and Patient Demographics





VLU = venous leg ulcer; DFU = diabetic foot ulcer

CONCLUSIONS

- Real-time fluorescence imaging positively predicts the presence of *P. aeruginosa* in wounds at clinically significant levels.
- *P. aeruginosa* is a unique wound pathogen with response to wound treatments quite unlike other pathogenic bacteria commonly seen in wounds[4]. Delays from culture or other microbiological analysis can therefore lead to inappropriate selection of wound therapies.
- Detection of *P. aeruginosa* at the bedside via safe, fast fluorescence imaging facilitates selection of antimicrobials specifically targeting this pathogen.
- In summary, when combined with clinical best practice, fluorescence imaging of wounds guides clinicians to specific, local or systemic, therapies to combat pathogenic *Pseudomonas aeruginosa*, which would otherwise impede wound healing.

References

1. DaCosta R et. al, Point-of-care fluorescence imaging for real-time sampling and treatment guidance of bioburden in chronic wounds: first-in-human results. PLoS One, 2015.

2. Rennie MY et. al, Point-of-care fluorescence imaging predicts the presence of pathogenic bacteria in wounds. J Wound Care, 2018.

3. MolecuLight *i:X*

4. Sader et. al, P. aeruginosa antimicrobial susceptibility results from 4 years of the international network for optimal resistance Monitoring, 2017.

Disclaimer

This work has been made possible by a research grant from MolecuLight, Inc, the sponsor of this clinical study.

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