Use of a bacterial fluorescence imaging system to target wound debridement and accelerate healing: a pilot study

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This prospective longitudinal study evaluated use of the MolecuLight ***i:X***® fluorescence imaging system to:

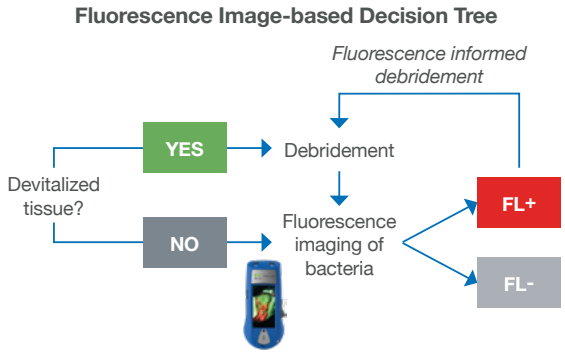
(1) inform location and extent of debridement
(2) monitor bacterial burden in and around lower extremity wounds over a 12-week period
(3) measure wound area over time

Background

- Proliferation of bacteria at loads >10^4 CFU/g contributes to delayed wound healing[1].
- Wound bed preparation, which includes cleaning and debridement, is performed to reduce bacterial load and remove devitalized tissue. However, without immediate information on the extent and persistence of bacteria, bacterial burden will remain and slow or stop the healing process.
- The MolecuLight ***i:X*** is a point-of-care fluorescence imaging device that provides immediate information on the presence and location of moderate-to-heavy bacterial loads (>10^4 CFU/g) in wounds and surrounding tissue[2-4] to aid in detection and removal of bacteria.

Design

Eleven lower extremity wounds were imaged weekly over a 12-week period to collect information on bacterial fluorescence and wound area measurement. Workflow performed by the clinician is described below.



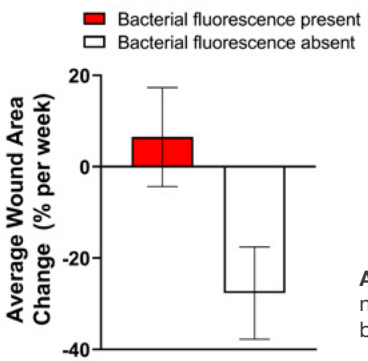
At each weekly visit, the wound was assessed for devitalized tissue and then underwent fluorescence imaging of bacteria.

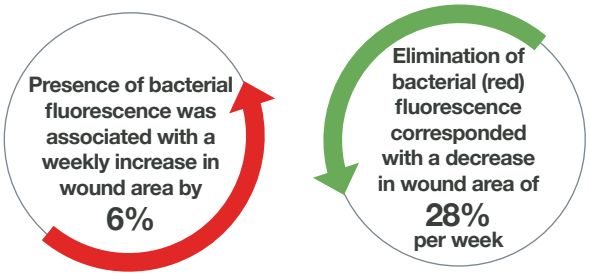
Presence of devitalized tissue or fluorescence from bacteria (FL+) prompted debridement. Fluorescence images informed extent and location of debridement to eradicate bacterial fluorescence.

Imaging procedure was repeated after subsequent debridement and additional debridement was performed when FL+.

Persistence of fluorescence from bacteria prompted changes to dressing selection or use of antimicrobials to target elimination of bacteria.

Results





Average weekly change in wound area. All wounds, by chance, began the study on a non-healing trajectory. The bar graph represents average weekly change in wound area when bacterial fluorescence was present (red) or absent (open bar).

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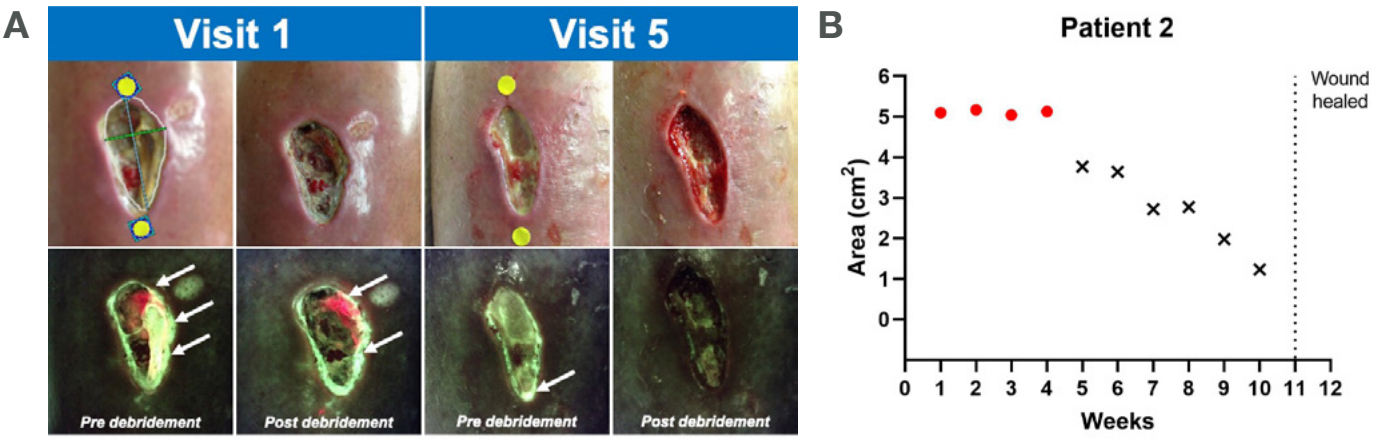

Patient 2, trauma in lower right leg. The wound was open for 13 weeks prior to participating in the study. **(A)** At Visit 1, bacterial (red and cyan) fluorescence was observed (white arrows), prompting debridement. Fluorescence information guided further debridement and use of antimicrobials over the next 4 weeks. By visit 5, bacterial (red) fluorescence had resolved and corresponded with a dramatic shift in healing trajectory. **(B)** Presence of bacterial (red) fluorescence (red circles) was associated with no change or increase in wound size while absence of bacterial fluorescence ('x') resulted in a decrease in wound size indicative of a positive healing trajectory.

- Prior to study participation, wounds had an average duration of 16.5 weeks. At initial assessment, 10/11 wounds were positive for bacterial (red or cyan) fluorescence. Bacterial fluorescence was observed in the periwound region in 81% of wounds and in 64% of wound beds. Both regions were targeted with debridement.
- The information provided by fluorescence imaging on bacterial load and location at point-of-care supported medical necessity for additional debridement in most wounds assessed.
- Elimination of bacterial fluorescence from wounds resulted in a decrease in wound area associated with a healing trajectory (>25% decrease in wound area over 4 weeks).
- Over the course of the study, all wounds where fluorescence signal from bacteria was eradicated (n=6) went on to heal within 2-6 weeks.

Conclusion

In this longitudinal prospective observational study, fluorescence imaging informed the extent of debridement, application of antimicrobial therapies, and selection of appropriate secondary dressings that led to elimination of bacteria in all wounds that completed the study.

Fluorescence-guided treatment facilitated a switch to a healing trajectory in wounds when a bacterial fluorescence signature was no longer present.

Clinical reflection

In this study, fluorescence imaging and digital wound measurement provided documented evidence of wound healing progress. ***What information do you currently use to determine whether a wound is on a positive healing trajectory?***

References
1. Xu et al. Bacterial load predicts healing rate in neuropathic diabetic foot ulcers. *Diabetes Care* (2007) **2.** Rennie et al. Point-of-care fluorescence imaging predicts the presence of pathogenic bacteria in wounds: a clinical study. *J Wound Care* (2017) **3.** Hurley et al. Efficacy of a bacterial fluorescence imaging device in an outpatient wound care clinic: a pilot study. *J Wound Care* (2018) **4.** Serena et al. Real-time bacterial fluorescence imaging accurately identifies wounds with moderate-to-heavy bacterial burden *J Wound Care* (2019)

The MolecuLight *i:X*® Imaging Device has received FDA 510(k) clearance, and is approved by Health Canada and has CE marking for sale in Canada and the European Union.