

# Conclusions

# New Dimensions in Wound Diagnosis and Management

## Results

Number of Wounds Cleansed		
Initial periwound fluorescence	Periwound fluorescence after saline cleanse	Periwound fluorescence after modified NaOCl
10/10	10/10	3/10

## Conclusions

- Bacterial (red and/or cyan) fluorescence was present in the periwound area in 100% of wounds. The fluorescence persisted after initial, standard of care cleansing with saline.
- This is concerning given that red fluorescence equates to a bacterial load of  $10^4$  CFU/g or higher (i.e. moderate/heavy bacterial loads)<sup>4</sup>.
- 30% of wounds required debridement after cleansing with a modified sodium hypochlorite (NaOCl) solution\*
- Thus, results of this study demonstrate that bacteria is located outside of the wound bed, and poses a cross-contamination risk. Current best cleansing practices using saline:
  - do not maximize removal of bioburden, and
  - leave behind an unacceptably high bacterial load ( $\geq 10^4$  CFU/g) that is considered detrimental to wound healing<sup>5</sup>
- Incorporation of bacterial fluorescence imaging into routine wound care resulted in more aggressive cleansing. This specifically targeted regions of bioburden, and indicated to the clinician if additional therapy (e.g. debridement) was required to fully eliminate the bioburden.
- Results highlight the potential of bacterial fluorescence imaging to dramatically improve current cleansing practices by enabling point-of-care, bioburden based decision making on when cleansing is sufficient, and when additional techniques are required to remove bioburden.

## References

- International Best Practice: Wound Management in DFUs. Wounds International, 2013.
  - DaCosta RS et al. Point-of-Care Auto-fluorescence Imaging for Real-Time Sampling and Treatment Guidance of Bioburden in Chronic Wounds: First-in-Human Results, PLoS ONE, 2015.
  - Ottolino-Perry et al. Improved detection of wound bacteria using autofluorescence image-guided wound sampling in diabetic foot ulcers. International Wound Journal, 2017
  - Rennie MY et al. Point-of-care fluorescence imaging positively predicts the presence of pathogenic bacteria in wounds at loads  $\geq 10^4$  CFU/g: a clinical study. J Wound Care (submitted).
  - Edwards R and Harding KG. Bacteria and wound healing. Curr Opin Infect Dis. 2004.
- \*Anasept® Antimicrobial Skin & Wound Cleanser, Manufactured by Anacapa Technologies, Inc.
- \*\*The bacterial fluorescence imaging device used in this study is manufactured and sold by MolecuLight, Inc.

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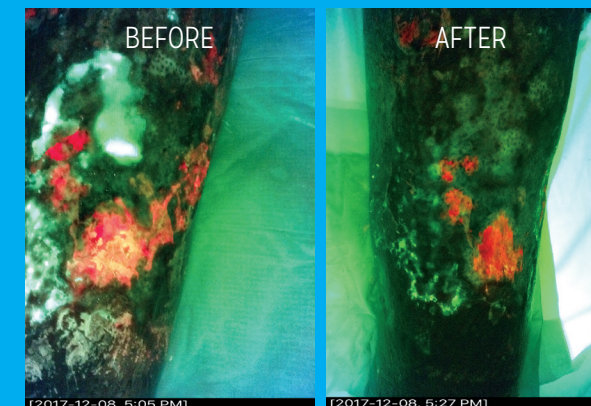
## Diagnosis:

Bacterial fluorescence, a unique and novel method of determining, in real time, bacterial bioburden and activity of bacterial species.<sup>1,2,3,4</sup>

## The MolecuLight i:X<sup>+</sup>

is an innovative, hand-held device which allows clinicians diagnosing and treating skin wounds to visualize fluorescence in wounds.

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ANTIMICROBIAL SKIN & WOUND CLEANSER AND GEL



## Management:

The use of Anasept® Antimicrobial Skin & Wound Cleanser in the reduction of wound bioburden and elimination of certain bacterial species is confirmed by bacterial fluorescence.

<sup>†</sup>The MolecuLight i:X is manufactured by MolecuLight, Inc. 425 University Avenue, Suite 700 Toronto, ON, M5G 1T6 Canada. The MolecuLight i:X™ imaging device is approved by Health Canada (Medical License #95784) and has CE marking (Certificate #G1160292355002) for sales in Canada and the European Union. The MolecuLight i:X™ Imaging Device has received FDA De Novo clearance. Please see <https://us.molecuLight.com> for USA specific intended and indications for use.

<sup>1</sup> DaCosta RS et al. Point-of-Care Auto-Fluorescence Imaging for Real-Time Sampling and Treatment Guidance of Bioburden in Chronic Wounds: First-in-Human Results, PLoS ONE, 2015.  
<sup>2</sup> Ottolino-Perry et al. Improved detection of wound bacteria using autofluorescence image-guided wound sampling in diabetic foot ulcers. International Wound Journal, 2017  
<sup>3</sup> Rennie MY et al. Point-of-care fluorescence imaging positively predicts the presence of pathogenic bacteria in wounds at loads  $\geq 10^4$  CFU/g: a clinical study. J Wound Care (submitted).  
<sup>4</sup> Hill-Douglas et al. Shifting focus: implications of periwound bacterial load on wound hygiene. Infectious Disease and Critical Care Internal Medicine, Vancouver Coastal Health.



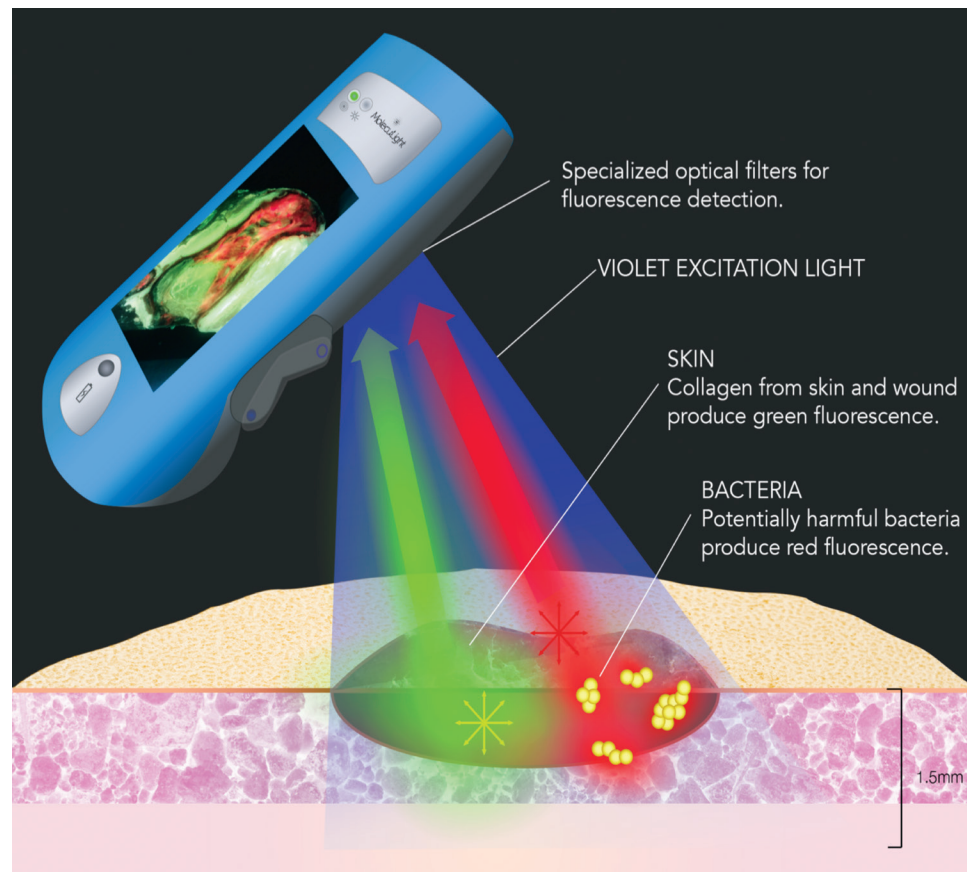
# Bacterial Fluorescence Imaging

# Shifting Focus: Implications of Periwound Bacterial Load on Wound Hygiene

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## Introduction

- Wound cleansing is the most ubiquitous method to maintain optimal wound hygiene as it is available at all clinical settings and skill levels.
- The periwound is often a neglected area, but serves as a source for microbial recontamination if not adequately cleansed.
- Fluorescence imaging has been used to visualize fluorescing bacteria in real-time at the bedside using a non-contact device<sup>2-4</sup>.
- This study reports the use of bacterial fluorescence imaging to assess bioburden in the wound and periwound area to optimize wound hygiene using a commercially available modified sodium hypochlorite (NaOCl) solution\*, compared to standard practice.



Fluorescence images were used to assess presence of bioburden after each cleansing step and determine the region to target further cleansing or debridement if cleansing did not eliminate the bioburden.

## Methods Bacterial Fluorescence Imaging

When excited by 405 nm violet light, tissues fluoresce green while bacteria fluoresce red (e.g. Staphylococcus aureus) or cyan (e.g. Pseudomonas aeruginosa).

This enables real-time, point-of-care detection and localization of bioburden ( $\geq 10^4$  CFU/g) within and around wounds<sup>2-4</sup>.

Bacterial fluorescence imaging was incorporated into assessment of 10 wounds of mixed etiology (e.g. DFU, VLU, SSI, PU).<sup>\*\*</sup>

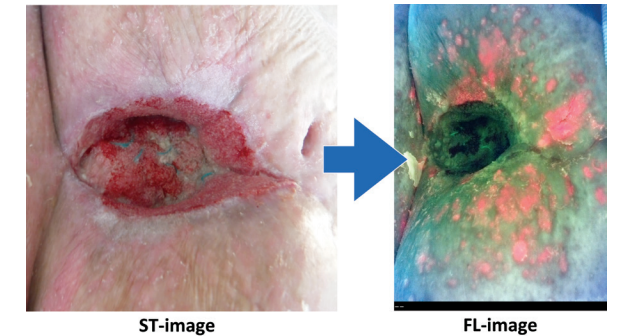
Fluorescence imaging was performed at baseline, after cleaning with saline and after cleaning with a modified sodium hypochlorite (NaOCl) solution\*.

## Results

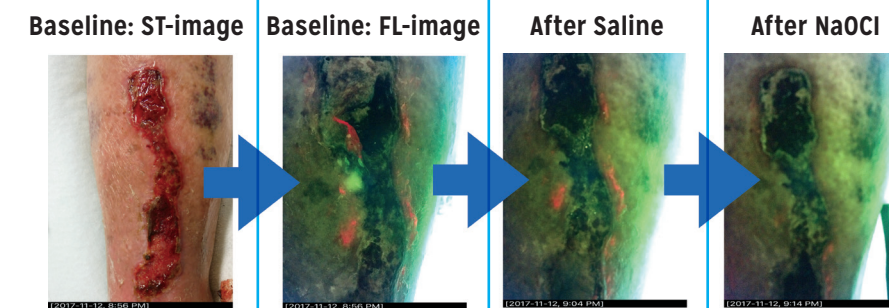
Visualization of bacterial load can be incorporated into routine wound care to optimize wound hygiene by guiding targeted cleansing. Standard practice cleansing with saline was performed on 10 wounds in this study.

### Case 1:

- 72 year old male treated with NPWT after midline surgery complication
- Distinct odor observed at the time of assessment
- Swab obtained from the wound bed prior to fluorescence imaging were negative for bacterial growth
- Red fluorescence indicates presence of bacteria



Based on fluorescence images after initial saline cleanse, in which bacterial (red) fluorescence was present in 100% of wounds, clinician chose to more aggressively cleanse all 10 wounds using a modified sodium hypochlorite (NaOCl) solution\*, specifically targeting regions of bioburden. 3 cases are demonstrated.

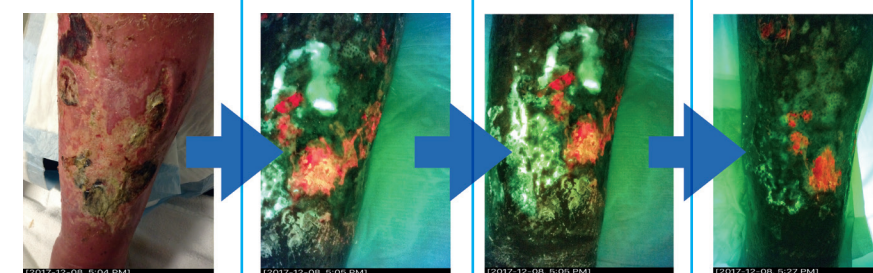
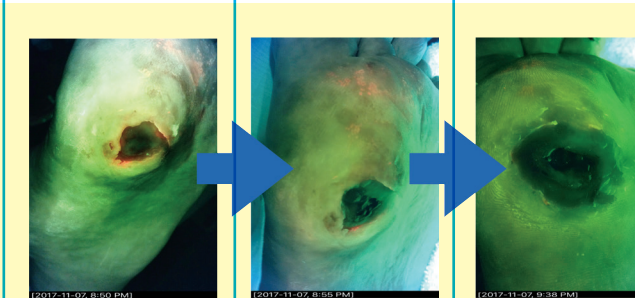


### Case 2:

- Saline cleanse was moderately effective in removing red fluorescent bacteria
- NaOCl cleanse successfully removed red fluorescing bacteria

### Case 3: DFU

- Red fluorescing bacteria present at the wound bed and periwound site.
- Saline cleanse did not eradicate fluorescent bacteria
- NaOCl cleanse successfully removed all red fluorescence



### Case 4: VLU with necrosis

- Cleansing with saline did not remove cyan or red fluorescing bacteria
- NaOCl was very effective on cyan fluorescing bacteria
- Red fluorescence remained after NaOCl cleanse and the patient required debridement