Prospective clinical study on the efficacy of bacterial removal with mechanical debridement in and around chronic leg ulcers assessed with fluorescence imaging



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This study demonstrates the utility of the MolecuLight *i*:X[®] imaging device to provide immediate feedback on effectiveness of standard mechanical debridement used to reduce bacterial burden in and around venous leg ulcer wounds.

Background & Study Design

- Mechanical debridement of the wound is one of the most common methods to remove devitalized tissue and reduce bacterial colonization.
- However, without objective information on the presence of bacteria in the wound, it is challenging to determine whether the extent and location of debridement is sufficient to reduce bacterial burden.
- The MolecuLight *i*:X imaging device offers the possibility of real-time visualization of moderate-to-heavy loads of bacteria (≥10⁴ CFU/g).
- In this prospective study, the MolecuLight *i:X* was used on 25 venous leg ulcers (VLU) to evaluate effectiveness of debridement. Images were captured before and after debridement.
- Bacterial-positive area was quantified using image processing software to determine the percentage of wound bed or surrounding region with red fluorescence indicative of bacteria at loads ≥10⁴ CFU/g^{1,2}.

Imaging with the MolecuLight *i:X* showed:



of VLU periwound area was colonized by high bacterial loads pre-debridement 99%

Reduction of bacterial signal in the wound bed after debridement 36%

of periwound bacterial signal is left behind after standard debridement in VLUs (without the guidance of fluorescence)

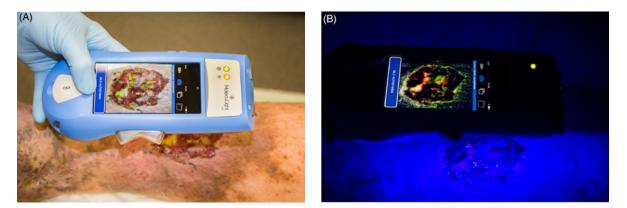


Figure 1: Example of how a standard image (A) and fluorescence image (B) are captured using the MolecuLight *i:X*. Standard and fluorescence images were taken before and after debridement to provide immediate feedback on efficacy of debridement to resolve bacterial burden.

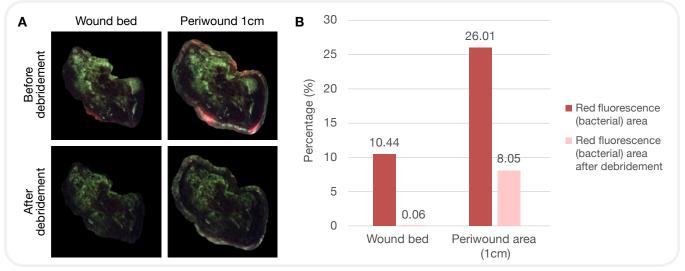


Figure 2: Analysis of red fluorescence (bacterial) area of a wound. Representative fluorescence images (A) captured before (top row) and after (bottom row) debridement. (B) Comparison of quantified red fluorescence (bacterial) wound areas before (red bars) and after (pink bars) debridement.

Results & Conclusion

- Fluorescence imaging using the MolecuLight *i*:X enabled quick, reliable, non-contact visualization of wound regions colonized by bacteria.
- VLU periwound bacterial presence was more prevalent, area-wise, than wound bed bacterial presence. This phenomenon was increasingly present in larger VLUs.
- Prior to debridement, bacterial-positive signals were present across 10% of the wound bed region and 26% of the periwound region.
- A single mechanical debridement was highly effective in reducing bacterial signal in the wound bed, which is where clinicians typically target their treatment.

Standard debridement *without fluorescence guidance* **left behind 36% of periwound bacterial signal, indicating these regions of high bacterial load are routinely missed by standard debridement.** Attention to the wound edge is a key element of wound bed hygiene. These bacterial loads may continue to delay healing and can re-contaminate the wound bed.

Reflection Question

The MolecuLight *i*:X imaging device enables point-of-care visualization of the presence and location of moderate-to-heavy^{1,2} loads of bacteria. *How can this diagnostic imaging information be used to optimize effectiveness of debridement?*

Study Citation

Moelleken M, Jockenhofer F, Benson S, Dissemond J. Prospective clinical study on the efficacy of bacterial removal with mechanical debridement in and around chronic leg ulcers assessed with fluorescence imaging. Int Wound J. 2020.

References

1. Rennie MY et al. J Wound Care, 2017 2. Serena TE et al. J Wound Care, 2019

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The MolecuLight *i*:X[®] 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[®] Imaging Device is approved by Health Canada and has CE marking for sale in Canada and the European Union.

