

Utility of Bacterial Fluorescence in the Application of Cellular Tissue Products

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Background

Cellular and tissue-based products (CTPs) are applied to improve wound closure in non-healing wounds. Certain CTPs provide a biological scaffold to facilitate re-epithelialization, while others provide growth factors or cytokines to stimulate natural healing processes.

Factors that prevent CTPs from successfully integrating:

- Infection
- Shearing and excessive tension
- Hematomas and seromas
- Poor vascularity and oxygenation

Infection and bacteria above a certain threshold is one of the top causes of CTP failure.

The presence/absence of autofluorescence signals indicating bacterial burden above 10⁴ CFU/g have been associated with skin graft and healing outcomes after CTP application.¹⁻³

Methods

We present **interim results from a prospective case series** exploring the association of bacterial fluorescence signals with venous and diabetic ulcer outcomes following CTP therapy.

- Fluorescence imaging informed wound bed preparation ahead of CTP application.
- Wound area measurements were captured digitally using MolecuLight i:X.

CTP IS APPLIED

- Bacterial fluorescence imaging* to inform wound bed prep & immediately before application

1, 2, and 3 WEEKS LATER

- Assessment of signs of early CTP integration (granulation tissue, epithelialization)

4 WEEKS LATER

- Wound area reduction (WAR) is assessed
- Optional bacterial fluorescence imaging*

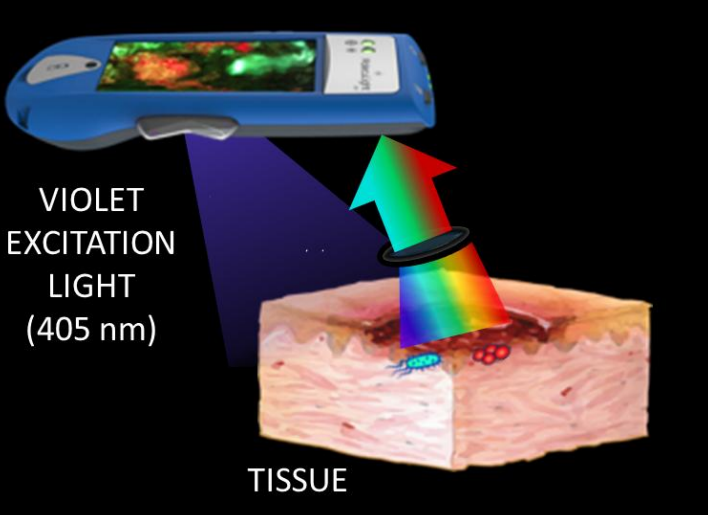
Primary Outcome Measure:

- 40% wound area reduction at 4-weeks

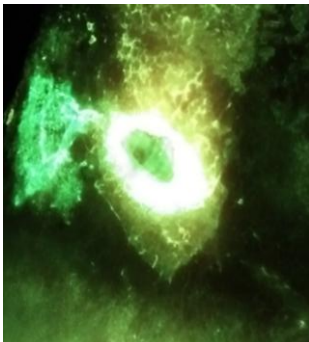
Secondary Outcome Measure:

- Improved granulation & epithelialization during follow-up

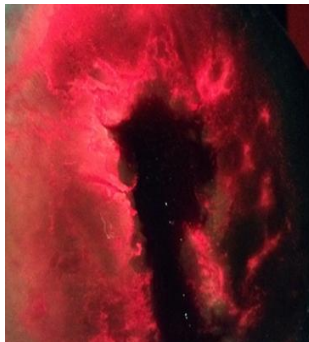
Principles of bacterial fluorescence imaging



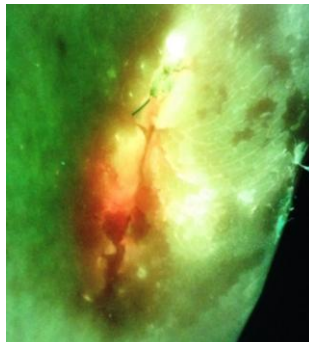
*MolecuLight i:X, MolecuLight Inc.



Cyan fluorescence (blue/green halo) indicates *Pseudomonas aeruginosa*



Red fluorescence indicates most Gram positives, negatives, aerobes and anaerobes



Yellow fluorescence indicates subsurface bacteria (mix of green signals from normal tissue with red)

Results

INTERIM ANALYSIS:

13 patients

- Chronic, longstanding DFUs (n=5) and VLUs (n=8).
- Most patients were white males (69%) with adequate circulation to the affected extremity (92%).
- Most patients suffered from diabetes mellitus (62%), peripheral vascular disease (85%), chronic venous insufficiency (62%).

Baseline Fluorescence

- 10 of 13 (77%) of wounds presented with bacterial fluorescence. However, only 6 (46%) were fluorescence (+) following cleansing and debridement immediately prior to CTP application.

Primary Outcome

- 9/13 wounds were followed to at least 3 weeks post-CTP application.
- 0 of the 4 fluorescence (+) wounds achieved 40% WAR.
- 4 of the 5 fluorescence (-) wounds achieved 40% WAR.

Secondary Outcomes

- 1 of 4 (25%) fluorescence (+) wounds showed evidence of improved granulation and epithelialization.
- 3 of 5 (60%) of fluorescence (-) wounds showed evidence of improved granulation and epithelialization.
- One wound [fluorescence (+)] showed improved granulation but not epithelialization.



Preliminary Observations

- Wounds with **no evidence of bacterial fluorescence at the time of CTP application tended to achieve greater WAR**, with improved granulation and epithelialization as compared to fluorescence positive wounds.

CASE EXAMPLES:

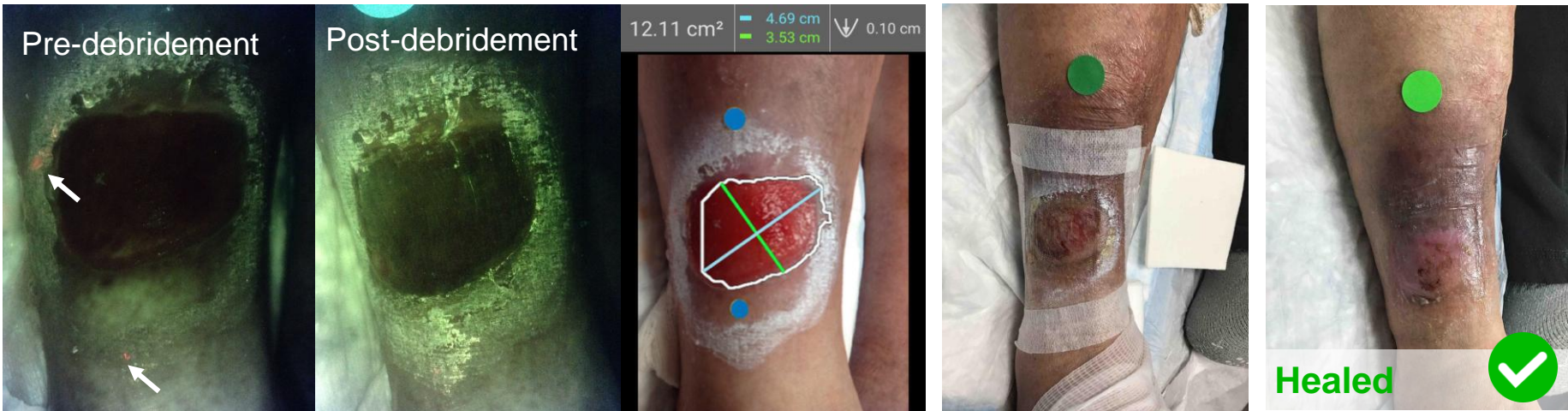
Case 1: Fluorescence negative wound heals within 2 weeks

- 82 y.o. male with chronic right leg venous ulcer of approximately 1 year duration.
- Comorbid with diabetes mellitus (circulation to affected extremity is adequate), hyperlipidemia, peripheral vascular disease, chronic venous insufficiency, and coronary artery disease.
- Compression therapy with adequate compliance.

Graft Bed Preparation:

- Nonviable tissues and small regions of red bacterial fluorescence were removed via mechanical debridement and antibacterial wash, both informed by fluorescence imaging.
- Apligraf skin substitute applied (9.5 cm²).

Home Care: Secondary dressing changes provided by home care nurse, keep wound veil in place.



CTP Application

Wound Area: 12.1 cm²

Debridement effectively removes regions of red fluorescence at wound edges (white arrow)

1-Weeks S/P

Epithelialization and granulation improving.

2-Weeks S/P

Wound healed

Case 2: Fluorescence positive wound increased in size

- 80 y.o. female with chronic left leg ulcers of approximately ~3 years duration.
- Underlying chronic venous hypertension, bilateral edema of lower extremities (Stage 2), AFib.
- Compression therapy with adequate compliance.

Graft Bed Preparation:

- Mechanical cleansing with Vashe® & mechanical gauze debridement followed by curettage debridement were used to remove bioburden and devitalized tissues. Post-procedurally, fluorescence imaging demonstrated a reduction in bioburden, though some did remain.
- Affinity skin substitute applied (2.96 cm²).

Home Care: Keep area dry & maintain wound veil in place until next F/U. At-home care provided 3x per week by wound care nurse.



CTP Application

Wound Area: 2.9 cm²

Red (white arrow) and cyan (yellow arrow) fluorescence at wound edges

2-Weeks S/P

Skin substitute still present on wound bed

4-Weeks S/P

Wound Area: 5.1 cm²

Red and heavy cyan fluorescence persists at wound edges (arrows)

References: [1] Al-Jalodi O, Sabo M, Patel K, et al. Efficacy and safety of a porcine peritoneum-derived matrix in diabetic foot ulcer treatment: a pilot study. J Wound Care 2021, 30, S18-S23. [2] Hanson-Viana E, Rojas-Ortiz JA, Rendón-Medina MA, Luna-Zepeda BL. Bacterial fluorescence imaging as a predictor of skin graft integration in burn wounds. Burns 2024, S0305-4179(24)00122-0. [3] Aung B. Can Fluorescence Imaging Predict the Success of CTPs for Wound Closure and Save Costs? Today's Wound Clinic 2019,13:22-25.