List of Key Publications on MolecuLight Platform Technology

100+ PUBLICATIONS

3500+ PATIENTS

The MolecuLight ***i:X*** and **DX** are FDA-cleared, handheld wound imaging tools that produce digital wound measurements and standard and fluorescence images which detect bacteria that is linked to infection and the disturbance of the healing process[1-2]. This improvement in bacterial detection frequently alters clinical decision making about wound care.

Below is a global bibliography of peer-reviewed research on MolecuLight.

Please visit our website for more information:
https://us.moleculight.com/publications/

All references (in blue) are hyperlinked to the journal entries

Best Practices & Health Equity

Guidelines

Guidelines for Point-of-Care Fluorescence Imaging for Detection of Wound Bacterial Burden Based on Delphi Consensus
Oropallo A. *et al.* Diagnostics, 2021

32 wound care experts collaborated in a Delphi consensus to develop guidance for bacterial fluorescence imaging. Recommendations cover imaging workflow, patient selection criteria, and when and how often to use this technology.

Clinical Trial
Post-hoc Analysis
n=350

SAWC Award Winning

Skin Pigmentation Impacts the Clinical Diagnosis of Wound Infection: Imaging of Bacterial Burden to Overcome Diagnostic Limitations
Johnson J. *et al.* J Racial Ethn Health Disparities 2023

Significant inequities in wound infection assessment for people of color were evidenced through clinical data, where harmful bacteria were more often missed versus patients with lighter skin tones. MolecuLight fluorescence imaging improved bacterial detection across all skin tones, especially enhancing sensitivity on dark skin tones by 12-fold to bridge this gap.

Practice Perspectives

Bacterial Fluorescence Imaging to Address Racial Inequities in Wound Infection Assessment
Andersen, CA *et al.* Adv Skin & Wound Care 2024

This publication highlights MolecuLight as an essential tool for a more equitable wound care practice. The authors view MolecuLight as uniquely positioned to enhance clinical decision-making, thereby improving healing outcomes and reducing costly complications. This benefit is critical for underprivileged minority populations who are at a substantially higher risk of poor health outcomes.

Outcomes & Cost-Effectiveness

Randomized Control Trial
n=56

The Use of Point-of-Care Bacterial Autofluorescence Imaging in the Management of Diabetic Foot Ulcers: A Pilot Randomized Controlled Trial
Rahma, S. *et al.* Diabetes Care 2022

RCT evidence that MolecuLight imaging dramatically improved DFU healing outcomes. Wound healing rates doubled at 12-weeks (45% vs. 22%) and the presence/absence of bacterial fluorescence reliably predicted the degree of wound closure.

Retrospective Study
n=167

SAWC Innovation Spotlight

Improving Wound Healing and Infection Control in Long-term Care with Bacterial Fluorescence Imaging

Kelso, MR *et al.* Adv Skin & Wound Care 2024

A retrospective review across 55 long-term care facilities showing that MolecuLight significantly improved pressure injury outcomes compared to standard care alone. Patients treated with MolecuLight experienced a 71% higher healing rate, healed 28% faster, were 1.4 to 1.8 times more likely to heal, and experienced 75% fewer complications.

Retrospective Study
n=229

thebmjawards
Finalist 2021

Routine fluorescence imaging to detect wound bacteria reduces antibiotic use and antimicrobial dressing expenditure while improving healing rates: Retrospective analysis of 229 foot ulcers

Price, N. *et al.* Diagnostics 2020

A "before and after" cohort study showing that fluorescence imaging reduced antibiotic and antimicrobial dressing needs and wound care costs while improving foot ulcer healing rates (39% to 48%).

Clinical Trial
n=27

EWMA Award Winning

Integrating Point-of-Care Bacterial Fluorescence Imaging-Guided Care with Continued Wound Measurement for Enhanced Wound Area Reduction Monitoring

Derwin, R. *et al.* Diagnostics 2024

Fluorescence imaging predicted wound area reduction based on bacterial presence, with persistent bacterial loads correlating to worse outcomes. MolecuLight digital wound measurements were significantly more accurate than manual measurements (23% overestimation with ruler).

Prospective Study
n=236

SAWC Award Winning

Diagnosis and treatment of the invasive extension of bacteria (cellulitis) from chronic wounds utilizing point-of-care fluorescence imaging

Andersen, A. *et al.* International Wound Journal 2021

MolecuLight imaging prevented the need for intravenous antibiotics and hospitalization in 100% of wound-related cellulitis cases by aiding in early diagnosis and bacterial source control.

Prospective Study
n=11

SAWC Award Winning

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

Cole, W and Coe S. J Wound Care 2020

MolecuLight imaging provided real-time guidance for debridement and antibiotic selection in chronic lower extremity wounds. Removal of bacterial fluorescence signals was associated with reduced wound areas.

Clinical Trial
n=40

Point-of-care autofluorescence imaging for real-time sampling and treatment guidance of bioburden in chronic wounds: first-in-human results

DaCosta, RS *et al.* PLoS One 2015

The first-ever human clinical trial on bacterial fluorescence imaging demonstrated accurate detection of high bacterial loads and improved healing outcomes.

Wound Hygiene and Debridement

Clinical Trial
n=71

An objective comparative study of non-surgical cleansing techniques and cleanser types in bacterial burden management

Oropallo, A. *et al.* International Wound Journal 2024

This study used MolecuLight fluorescence imaging to objectively identify the most effective cleansing methods and solutions for wound care. The findings provide valuable insights for developing evidence-based wound cleansing protocols.

Retrospective Study
n=1000

AAWC Award Winning

Lights, fluorescence, action—Influencing wound treatment plans including debridement of bacteria and biofilms

Jacob, A *et al.* Int Wound J 2023

A real-world multisite study of 1000 wounds showed that fluorescence imaging frequently revealed harmful bacterial presence missed during routine inspection. Providers changed their course of clinical action over half the time, most commonly extending hygiene/debridement or targeting debridement to MolecuLight positive areas.

Clinical Trial
n=151

How effective is simple mechanical wound debridement in reducing bacterial colonisation? Results of a prospective clinical study

Moelleken, M *et al.* Int Wound J 2024

MolecuLight enhanced mechanical wound debridement by visualizing bacterial presence, enabling targeted removal and significantly reducing bacterial load.

Clinical Trial
n=25

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

Moelleken, M *et al.* Int Wound J 2020

MolecuLight imaging revealed the inadequacy of standard debridement highlighting the need for objective visualization of bacterial burden.

Clinical Trial
n=28

A novel debridement device for the treatment of hard-to-heal wounds: a prospective trial

Al-Jalodi, O *et al.* J Wound Care 2021

Fluorescence-targeted mechanical debridement using MolecuLight safely reduced bacterial loads with minimal patient discomfort, yielding results comparable to sharp debridement.

Burn Wounds

Clinical Trial
n=38

Bacterial fluorescence imaging as a predictor of skin graft integration in burn wounds

Hanson-Viana, E. *et al.* Burns 2024

Fluorescence imaging was a highly accurate method for assessing recipient sites and predicting skin graft take/loss outcomes among burn patients. By informing better decision-making surrounding grafts, MolecuLight imaging may lead to better outcomes.

Review

Diagnosing burn wounds infection: The practice gap & advances with MolecuLight bacterial imaging

Farhan, N. *et al.* Diagnostics 2021

This review summarizes evidence demonstrating the benefits of fluorescence imaging for burn wound assessment, with a focus on improved bacterial detection.

Retrospective Study
n=178

Assessing Pediatric Burn Wound Infection Using a Point-of-Care Fluorescence Imaging Device

Turner, E *et al.* J Burn Care Res 2024

MolecuLight significantly improved the accuracy of identifying wound infections in pediatric burn patients compared to visual assessment alone, in turn better informing wound management at the point-of-care.

Prospective Study
n=14

Imaging of bacteria in burn wounds treated with split thickness grafts in MEEK/MESH technique: a pilot study with first experiences in clinical wound evaluation with autofluorescence

Alawi, SA *et al.* Handchir Mikrochir Plast Chir 2019 (Article in German)

MolecuLight imaging reliably predicted burn wound infections following split-thickness skin grafting, with positive and negative predictive values of 82% and 90%.

Prospective Study
n=14

Utility of MolecuLight *i:X* for managing bacterial burden in pediatric burns

Farhan, N *et al.* J Burn Care Research 2020

First study to show that fluorescence imaging can visualize clinically significant bacterial burden in pediatric burn wounds and is easily incorporated into routine pediatric burn wound assessment.

Observational Study
n=20

The use of the MolecuLight *i:X* in managing burns: a pilot study

Blumenthal, E *et al.* J Burn Care Research 2018

Compared to standard examination, MolecuLight fluorescence imaging offered a superior method for detecting bacterial burden in burn wounds, allowing for targeted swabbing of bacterial-laden regions within large wounds.

Sampling and Antimicrobial Stewardship

Clinical Trial
Post-hoc Analysis
n=78

Use of fluorescence imaging (FL) to optimize location of tissue sampling in hard-to-heal wounds

Serena, TE *et al.* Front Cell Infect Microbiol 2022

Fluorescence imaging objectively guided clinicians to bacterial hotspots, yielding higher bacterial loads and more reliable microbial profiles.

Observational Study
n=31

Improved detection of clinically relevant wound bacteria using autofluorescence image-guided sampling in diabetic foot ulcers

Ottolino-Perry, K *et al.* Int Wound J 2017

MolecuLight-targeted sampling demonstrated superior accuracy versus Levine swabbing in detecting high bacterial loads, also identifying a greater diversity of bacterial species within wounds.

Implementation Study
n=26

Use of a Fluorescence Imaging Device to Detect Elevated Bacterial Loads, Enhance Antimicrobial Stewardship, and Increase Communication Across Inpatient Complex Wound Care Teams

DasGupta, T *et al.* Wounds 2022

MolecuLight imaging enhanced communication and collaboration between wound care teams, leading to improved assessment accuracy and standardized treatment interventions.

Commentary

Antibiotic Misuse in Wound Care: Can Bacterial Localization through Fluorescence Imaging Help?

Caputo, WJ *et al*. Diagnostics *(Special Issue)* 2022

Fluorescence imaging provided actionable insights on bacterial burden, enabling informed and localized treatment decisions that reduced antibiotic overuse.

Surgical Wounds

Clinical Trial
n=80

Bacterial autofluorescence in infected perineal wounds: A prospective cohort study

Okeahialam NA *et al.* Diagn Microbiol Infect Dis 2022

This study demonstrated the high diagnostic accuracy (83% sensitivity, 90% specificity) of bacterial fluorescence imaging in detecting clinically significant bacterial burden in perineal wounds, enabling informed treatment decisions at the point-of-care.

Prospective Study
n=55

The clinical progression and wound healing rate of dehisced perineal tears healing by secondary intention: A prospective observational study

Okeahialam NA *et al.* Eur J Obstet Gynecol Reprod Biol 2022

Perineal tear wounds with bacterial fluorescence exhibited delayed healing compared to non-colonized wounds, with fluorescence being a statistically significant predictor of this delay.

Clinical Trial
n=58

Uncovering the high prevalence of bacterial burden in surgical site wounds with point-of-care fluorescence imaging

Sandy-Hodgetts, K *et al.* Int Wound Journal 2021

Standard assessment missed high bacterial loads in most surgical wounds referred to specialists. MolecuLight imaging significantly improved detection, demonstrating its potential to optimize post-surgical care.

Retrospective Study
n=4

Multidisciplinary Strategies With Real-Time Fluorescence Images and Negative Pressure Wound Therapy to Manage Organ/Space Surgical Site Infection in Transplanted Kidneys

Chen, CH *et al.* Annals Plastic Surgery 2023

MolecuLight imaging provided a novel and effective method that supports standard of care in managing organ/space surgical site infections after kidney transplantation.

Advanced Therapies

Clinical Trial
n=11

Efficacy and safety of a porcine peritoneum-derived matrix in diabetic foot ulcer treatment: a pilot study

Ai-Jalodi, O *et al*. J Wound Care 2021

The presence or absence of red or cyan on bacterial fluorescence images accurately predicted the success or failure of DFU healing after acellular matrix product placement.

Case Series
n=11

Fluorescence imaging guided dressing change frequency during negative pressure wound therapy: a case series

Raizman, R J. Wound Care 2019

MolecuLight imaging through NPWT dressings provided objective bacterial monitoring to better inform dressing change frequency and optimize resource utilization.

Validation

Clinical Trial
n=350

Diagnostic accuracy of point-of-care fluorescence imaging for the detection of bacterial burden in wounds: Results from the 350-patient FLAAG trial

Le, L *et al.* Adv Wound Care 2021

A multi-site trial validating MolecuLight fluorescence imaging demonstrated significant improvement in detection of bacterial burden compared to standard assessment. 69% of treatment plans were informed by fluorescence imaging.

Clinical Trial
Post-hoc Analysis
n=138

Point-of-care fluorescence imaging reveals extent of bacterial load in diabetic foot ulcers

Armstrong, DG *et al*. Int Wound J 2023

This study reveals the limitations of relying on clinical signs and symptoms for detecting harmful bacteria in DFUs. The concept of "chronic inhibitory bacterial load" (CIBL) is introduced, with MolecuLight imaging vastly improving its detection for better wound care.

Clinical Trial
n=28

Rapid diagnosis of *Pseudomonas aeruginosa* in wounds with point-of-care fluorescence imaging

Raizman, R *et al.* Diagnostics 2021

Cyan detected on MolecuLight fluorescence images reliably predicted presence of *Pseudomonas aeruginosa* with a PPV of 93%. Less than 20% of wounds with *Pseudomonas* exhibited the 'classic' symptoms of this pathogen.

Clinical Trial
n=50 and n=22

SAWC Award Winning

Use of a bacterial fluorescence imaging device: wound measurement, bacterial detection, and targeted debridement

Raizman, R *et al.* J Wound Care 2019

Wound measurement accuracy was validated at >95% using the MolecuLight ***i:X*** device, and fluorescence imaging before and after standard debridement revealed persistence of bacterial fluorescence in 100% of DFUs.

Case Series
n=20

Instantly evaluating bacterial infections on skin ulcers in an Asian population using a fluorescence-emitting device

Kurokami, Y *et al.* J Cutan Imminol Allergy 2023

This study validated fluorescence imaging for detecting bacterial burden in diverse wound types, extending its application to an Asian population for the first time.

Clinical Trial
n=33

Efficacy of a bacterial fluorescence imaging device in an outpatient wound care clinic: a pilot study

Hurley, CM *et al.* J Wound Care 2019

MolecuLight imaging demonstrated a sensitivity of 100%, specificity of 78%, PPV of 95% and NPV of 100% for identification of pathologic bacteria in wounds.

Prospective Study
n=60

Point-of-care fluorescence imaging predicts the presence of pathogenic bacteria in wounds: a clinical study

Rennie, MY *et al.* J Wound Care 2017

MolecuLight-guided curettage or biopsy sampling positively predicted bacterial presence in wounds at potentially harmful levels, entirely eliminating the risk of false negative sampling.

Clinical Trial
n=19

Real-time bacterial fluorescence imaging accurately identifies wounds with moderate-to-heavy bacterial burden

Serena, TE *et al.* J Wound Care 2019

This pilot study set the stage for the larger, 350-patient FLAAG clinical validation trial.

Clinical Trial
n=43

A prospective multi-site observational study incorporating bacterial fluorescence information into the UPPER/LOWER wound infection checklists

Hill, R and Woo, K. Wounds 2020

All wounds positive for UPPER/LOWER were also positive with MolecuLight. In many cases the fluorescence information added a third check to the UPPER/LOWER score, turning a negative diagnosis of infection into a positive one.

Observational Study
n=14

Efficacy of an imaging device at identifying the presence of bacteria in wounds at a plastic surgery outpatients clinic

Blackshaw, EL *et al.* J Wound Care 2018

In this validation study, clinicians found that MolecuLight was easy to use and greatly reduced the time taken waiting for microbiology results.

Species Detected, Biofilm & Other Preclinical Studies

Pre-clinical

Detection of bacterial fluorescence from *in vivo* wound biofilms using a point-of-care fluorescence imaging device

Lopez, AJ *et al.* Int Wound J 2021

The first study to demonstrate detection of bacterial biofilm in mouse wound models using bacterial fluorescence imaging.

Pre-clinical

In vitro detection of porphyrin-producing wound bacteria with real-time fluorescence imaging

Jones, LM *et al.* Future Microbiol 2020

Fluorescence imaging visualized porphyrin production from 28 bacterial species (Gram +, Gram -, aerobic, anaerobic), including those in biofilm.

Pre-clinical

A shell-less hen's egg test as infection model to determine the biocompatibility and antimicrobial efficacy of drugs and drug formulations against *Pseudomonas aeruginosa*

Warncke P *et al.* Int. J. Pharmaceutics 2020

MolecuLight imaging visualized in real-time pseudomonal infection progression and treatment efficacy in a shell-less hen's egg model.

MolecuLight®

Point-of-Care Imaging Systems for
Bacterial Detection and Digital Wound Measurement

MolecuLight *i:X*®

MolecuLight**DX**™

moleculight.com

[1] Hurlow J, Bowler PG. Acute and chronic wound infections: microbiological, immunological, clinical and therapeutic distinctions. *J Wound Care*. 2022;31(5):436-445.
[2] Rahim K, Saleha S, Zhu X, Huo L, Basit A, Franco OL. Bacterial Contribution in Chronicity of Wounds. *Microb Ecol.* Apr 2017;73(3):710-721.

Indications for Use: The MolecuLight device is intended for use as a handheld imaging tool that allows clinicians diagnosing and treating skin wounds, at the point-of-care, to: (i) View and digitally record images of a wound, (ii) Measure and digitally record the size of a wound, and (iii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light. The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads >10^4 CFU per gram as compared to examination of clinical signs and symptoms alone. The MolecuLight device should not be used to rule-out the presence of bacteria in a wound. The MolecuLight device does not diagnose or treat skin wounds.

Some studies included explore uses beyond FDA clearance and most have not been reviewed by the FDA. MolecuLight sometimes provided devices or financial support, and its employees may have been involved in the research.