Accuracy and intra-user variability of a wound area measurement software

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INTRODUCTION

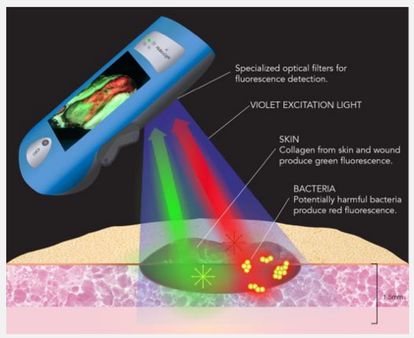
- Accurate, rapid tracking and documentation of wound size is an important component of wound care.
- Size has traditionally been determined using a wound ruler to measure wound length and width. However, this approach frequently overestimates wound area and is difficult to consistently measure when wound shape changes.
- Wound area measurements provide a more accurate description of changes in wound size over time.
- This study validated a wound area measurement software that tracks wound area, length, and width.

METHODS

MolecuLight *i:X* Wound Imaging Device

- Wound measurement: Automatic detection of wound boundaries, option for manual boundary delineating, measurement of wound area (cm^2), length and width (cm), or vertical and horizontal (cm).
- Bacterial fluorescence imaging: when excited by 405 nm violet light, tissues fluoresce green while bacteria fluoresce red (porphyrin-producers) or cyan (pyoverdine-producing *Pseudomonas aeruginosa*), enabling real-time detection of bacteria (loads ≥ 10^4 CFU/g)[1,2,3].

Wound Measurement



Bacterial Fluorescence Imaging

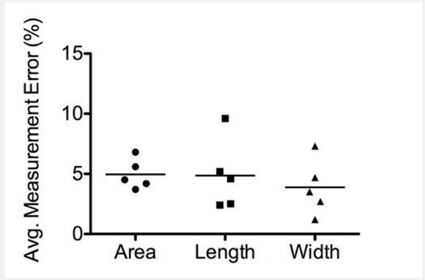
Assessment of Measurement Accuracy and Inter-User Variation

- Benchtop measurement testing of five wounds of known dimensions was performed by 10 trained users.
- Users placed either one or two yellow calibration stickers near the wound in the camera's field of view, took an image, and pressed the "measure" button to trigger immediate automatic wound border detection and overlay of area, length, and width on the saved wound image.
- Deviation from known dimensions and intra-user variation was computed.

RESULTS

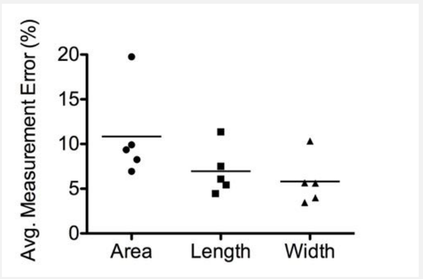
Measurement Accuracy ≥ 5% (2 stickers)

Benchtop measurement testing of five wounds of known dimensions was performed by 10 trained users.



Benchtop testing revealed that when two calibration stickers are used, as is recommended, average measurement error for wound area, length, and width all were within 5% of known values, thus were highly accurate.

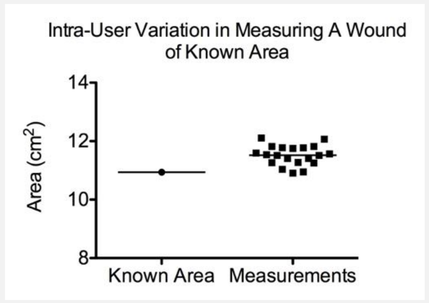
Measurement Accuracy ≥ 15% (1 sticker)



As expected, average measurement error for wound area, length, and width increased to 6-15% when only a single sticker was used.

Intra-User Variation (Measurement Repeatability)

To assess repeatability, a single trained user measured the same wound of known area 20 times. Measurements were made using 2 MolecuLight Wound Measurement Stickers.



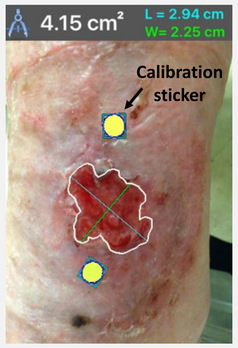
Standard Deviation = 0.34; COV = 2.94%

- Intra-user coefficient of variation (COV) was < 3%, thus wound measurements were highly repeatable.

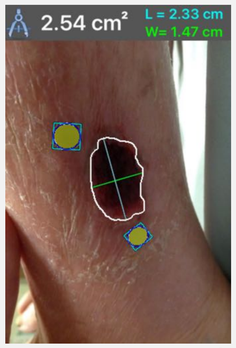
CLINICAL USE

- Clinical evaluation was performed on 15 patients with diverse wounds (size range: 0.3 to 17 cm^2). Wound area generated by the MolecuLight i:X device was compared to clinician made wound ruler measurements.

Symmetrical Wounds

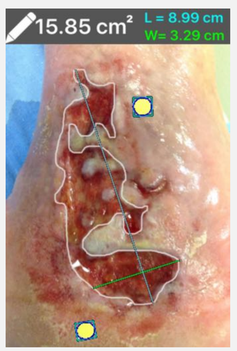


Area measurement (4.15 cm^2) in accord with clinician's wound ruler LxW measurement (2.5 x 2.5 cm = 5 cm^2).



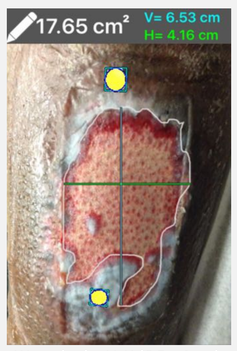
Area measurement (2.54 cm^2) in accord with clinician's wound ruler LxW measurement (2.2 x 1.2 cm = 2.64 cm^2).

Irregularly Shaped/Challenging Wounds

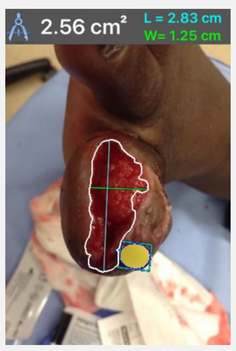


Wound ruler LxW (9 x 4 cm) was unable to capture wound's irregular shape, therefore overestimated wound area by 2.3 fold.

Using a ruler, clinician forced to measure as two separate wounds, which is more difficult to track over time.



Wound ruler VxH (6.5 x 4 cm) was unable to capture wound's irregular shape, therefore overestimated wound area by 47%.



Example using one calibration sticker, due to difficult wound location. Wound ruler LxW (2.9 x 1.2 cm) overestimated wound area by 42%.

CONCLUSIONS

- These results demonstrate the accuracy and consistency of the dimensions produced by this wound measurement software.
- **Accuracy: The use of 2 MolecuLight Wound Stickers produced an average wound area measurement error of ≤ 5%**, when the image is taken with MolecuLight Wound Stickers in the plane of the wound. When a single sticker was used, error increased to 6-10%.
- Use of two stickers enables the measurement algorithm to better correct for plane inaccuracy which may be created via suboptimal user placement of the stickers or suboptimal user placement of the imaging device.
- Clinically, area measurements (cm^2) calculated from wound borders were in tight accord with wound ruler predictions, except in the case of wounds with irregular wound boundaries, where automated area measurements were far superior.

IMPLICATIONS FOR PRACTICE

- **This software can now be confidently deployed in clinical practice, improving wound measurement accuracy, tracking of wound size over time, and documentation.**

REFERENCES

1. 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.
2. Ottolino-Perry et al. Improved detection of wound bacteria using autofluorescence image-guided wound sampling in diabetic foot ulcers. International Wound Journal, 2017
3. Rennie MY et al. Point-of-care fluorescence imaging positively predicts the presence of pathogenic bacteria in wounds at loads ≥ 10^4 CFU/g: a clinical study. J Wound Care (submitted).

Rouge Valley HEALTH SYSTEM

MolecuLight

The MolecuLight ***i:X***™ Imaging Device is approved by Health Canada (Medical License #95784) and has CE marking (Certificate #G1160292355002) for sale in the European Union. US FDA De Novo approval pending - the MolecuLight ***i:X***™ Imaging Device is not available in the US.