Reliability of a Novel 3D Wound Measurement Device

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Introduction

Chronic wounds affect approximately 1-2% of the population in developed nations, with the majority of that cost being spent on wound care products.[1-3] A key component of wound care is the collection of objective data on wound size and composition. Clinicians must be able to track wound progression over time in order to determine treatment effectiveness and the necessity for alternative interventions.[4-6] Percent change in ulcer size after 4 weeks is a robust predictor of wound healing at 12 weeks.[7] There is a clear need for a 3-dimensional wound assessment solution that is accurate and reliable; it also has to integrate seamlessly with the clinical workflow through intuitive interface and portability.

6.5 Million	Americans Affected [1]
$25 Billion	Dollars Spent on Treatment [1]
5%	Increase every year on spending [2]
0	Gold Standard for Wound Assessment

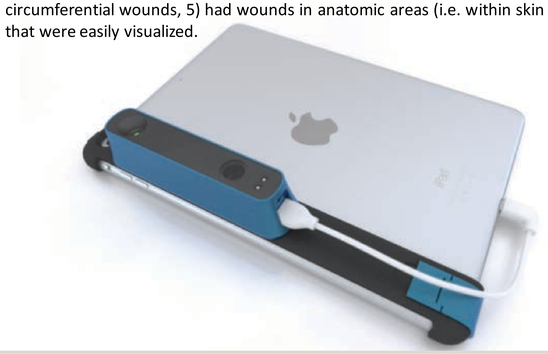
Methods

A prospective reliability study review was performed on patients with chronic wounds in a clinical setting to evaluate this 3-dimentional wound measurement device (3DWM). **Device:** iPad fitted with a 3D structure sensor, with integrated software that performs wound border segmentation using the interactive Graph Cuts algorithm implemented by Boykov et. al.[8,9]

Primary endpoint: establish the inter- and intra-rater reliability of the 3DWM device. Inter-rater reliability is the reliability of measurements conducted at different times by the same rater (15 min interval, same rater); Inter-rater reliability is the reliability of independent raters' measurements (two independent raters).
Secondary endpoints: comparing measurements to (a) digital planimetry and (b) manual metric measurements.

Analysis: conducted in R. 3DWM device measurements were compared to digital and manual measurements using the Wilcoxon Signed Rank test.
Power: Detect a test-retest correlation of at least 0.55. Using the Bonferroni correction to account for multiple comparisons, 31 wounds needed for 80% with 10% attrition.

Inclusion: Patients 1) were aged 18 or older, 2) were willing to participate and give consent, 3) did not have external fixation devices, 4) did not have circumferential wounds, 5) had wounds in anatomic areas (i.e. within skin folds) that were easily visualized.



Results

Forty-five wounds from a total of 31 patients
Excluded: patients with external fixation device (1), patients with circumferential wounds (5), wound in their skin folds (3).

Intra-rater ICC values were very high for length, width, area, and volume and low for depth. **Inter-rater** ICC values were very high for length, width, and area, and moderate for volume and depth.

Correlation between 3DWM, digital planimetry, and manual metric measurement were nearly 1:1 for area, length, and width.

Absolute values for area did not vary significantly between digital planimetry and 3DWM. Area measures were significantly different between manual metric and 3DWM. Wound area was overestimated by manual metric measurement in 41 of 45 wounds studied (91.11%).

Summary of estimates for wound measurements using the 3DWM

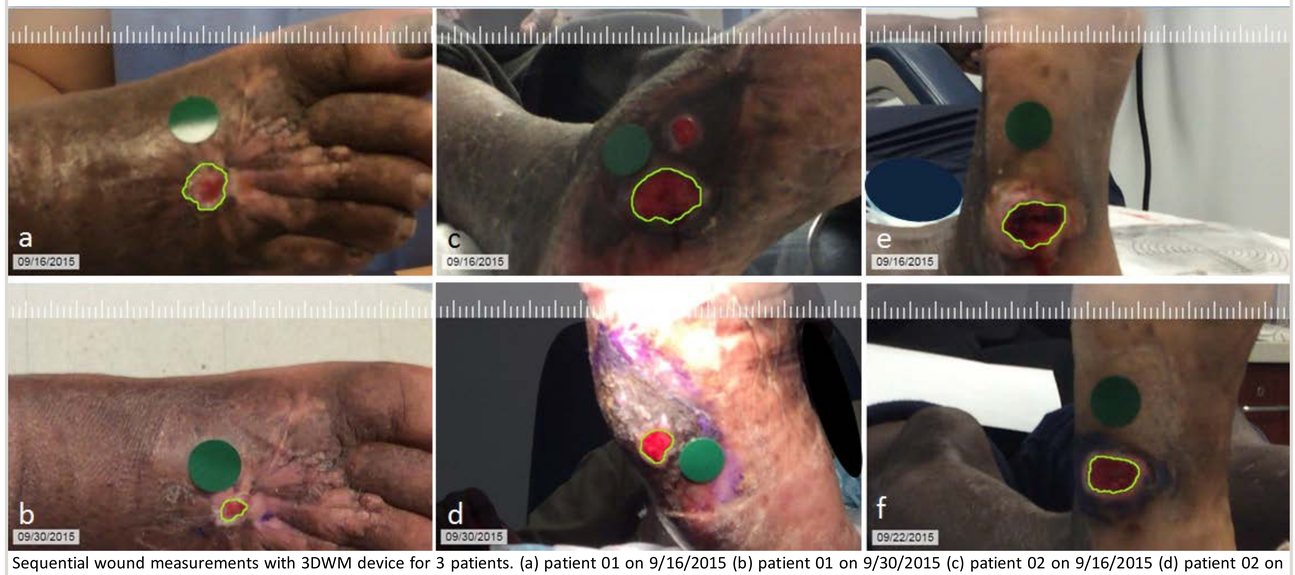
	Intra-rater Estimate	Intra-rater Confidence Interval	Inter-rater Estimate	Inter-rater Confidence Interval
Length	0.997	[0.995, 0.998]	0.997	[0.995, 0.998]
Width	0.995	[0.991, 0.997]	0.995	[0.991, 0.997]
Depth	0.360	[0.079, 0.588]	0.649	[0.441, 0.791]
Area	0.998	[0.997, 0.999]	0.999	[0.998, 0.999]
Volume	0.888	[0.806, 0.937]	0.696	[0.511, 0.82]

Correlations between 3DWM and other

	3DWM vs. Digital Planimetry	3DWM vs. Manual Metric
	Correlation	**Correlation**
Area	0.997	0.996
Length	0.997	0.990
Width	0.988	0.987
P-value	$<2.2*10^{-6}$	

P-values obtained from the Wilcoxon Signed Rank Test

	3DWM vs. Digital Planimetry	3DWM vs. Manual Metric
Area	0.911	$2.797* 10^{-8}$
Length	0.001	0.4728
Width	0.001	*0.1192*



Sequential wound measurements with 3DWM device for 3 patients. (a) patient 01 on 9/16/2015 (b) patient 01 on 9/30/2015 (c) patient 02 on 9/16/2015 (d) patient 02 on 9/30/2015 (e) patient 03 on 9/16/2015 (f) patient 03 on 9/22/2015

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Discussion

- The 3DWM device is an accurate and reliable method of measuring wounds
- Its performance is superior to manual measurements and comparable to more accurate methods such as digital planimetry
- 3DWM device eliminates the calibration errors of digital planimetry as it does not require a reference
- It provides a true 3D model of the wound rather than an estimate based off a 2D projection
- Measurements can be obtained without having to manipulate the wound
- Easy to integrate into clinic workflow

Limitations

Device-dependent
- Differences in sensor orientation
- Inability to visualize wound borders in the presence of inadequate lighting
- The failure to accurately measure small wounds (<4cm^2)

Device-independent
- Certain wound locations; i.e. posterior leg
- Certain wound types; i.e. tunneling, circumferential, requiring external fixation

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Acknowledgements

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The authors have no conflicts of interest for this study.

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