

Accuracy and repeatability of area measurements on large areas of erythema using an electronic wound measurement device (SilhouetteMobile™)

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Background

Previous reports, based on laboratory and clinical research, have demonstrated the accuracy of an electronic wound assessment device (SilhouetteMobile™, ARANZ Medical Limited, Christchurch, New Zealand) on wounds¹⁻⁶. To date the measurements have been on wounds and models less than 100cm² in size. This research sought to evaluate the measurement accuracy of the device on anatomical models representing large acute bacterial skin infections. Accurate measurement of such lesions has importance in clinical practice and clinical trials.

Aim

To assess the accuracy and repeatability (intra- and inter-rater variability) of SilhouetteMobile™ on large surface areas of modeled erythema.

Method

Six tracings of known area, ranging in size from approximately 150cm² to 900cm² were placed on various sites on a mannequin (face, forearm, thigh, leg, abdomen, buttocks).

Three raters measured each lesion three times, resulting in a total of nine measurements per lesion.

SilhouetteMobile™ was used to capture all the data. The three raters were unaware of the actual area of the lesions and they were not aware of the results of their own or other raters' measurements during data capture.



Figure 1: The tracings after application to the mannequin. Top row, left to right: face, forearm, buttocks. Bottom row, left to right: abdomen, medial thigh (saphenous vein) (above), lateral thigh (below).

Results

Table 1 and Figure 2 show the results for the three measurements per rater, for the three raters, across the six wounds. Table 2 and Figure 3 show the percentage error, which is calculated by dividing the difference between the measurement and the true area by the true area.

Rater:	Measurements (cm ²)					
	Face	Forearm	Thigh, Med.	Abdomen	Buttocks	Thigh, Lat.
1	156.7	238.7	276.8	524.1	598.6	877.2
	155.8	236.6	281.2	524.3	593.5	898.1
	152.8	236.0	281.5	517.4	598.5	877.9
2	149.8	242.6	282.5	538.0	586.0	897.8
	152.8	244.0	285.3	525.0	571.2	877.7
	149.9	240.1	281.8	530.5	578.9	891.5
3	157.6	241.7	278.0	515.2	604.7	901.1
	156.0	239.3	279.7	531.2	585.8	906.2
	150.8	238.3	282.4	518.5	598.4	922.1
Actual area:		153.4	239.1	277.0	527.3	579.4
		896.0				

Table 1: Measurements of the six 'lesions'.

Rater:	Measurements (% error)					
	Face	Forearm	Thigh, Med.	Abdomen	Buttocks	Thigh, Lat.
1	0.8%	-0.2%	-0.1%	-0.6%	3.3%	-2.1%
	0.2%	-1.0%	1.5%	-0.6%	2.4%	0.2%
	-1.7%	-1.3%	1.6%	-1.9%	3.3%	-2.0%
2	-3.6%	1.5%	2.0%	2.0%	1.1%	0.2%
	-1.7%	2.1%	3.0%	-0.4%	-1.4%	-2.0%
	-3.6%	0.4%	1.7%	0.6%	-0.1%	-0.5%
3	1.4%	1.1%	0.4%	-2.3%	4.4%	0.6%
	0.4%	0.1%	1.0%	0.7%	1.1%	1.1%
	-3.0%	-0.3%	1.9%	-1.7%	3.3%	2.9%
Largest		-3.6%	2.1%	3.0%	-2.3%	4.4%
Average		-1.2%	0.3%	1.4%	-0.5%	1.9%
Std dev		1.9%	1.1%	0.9%	1.4%	1.7%

Table 2: Percentage error of the measurements.

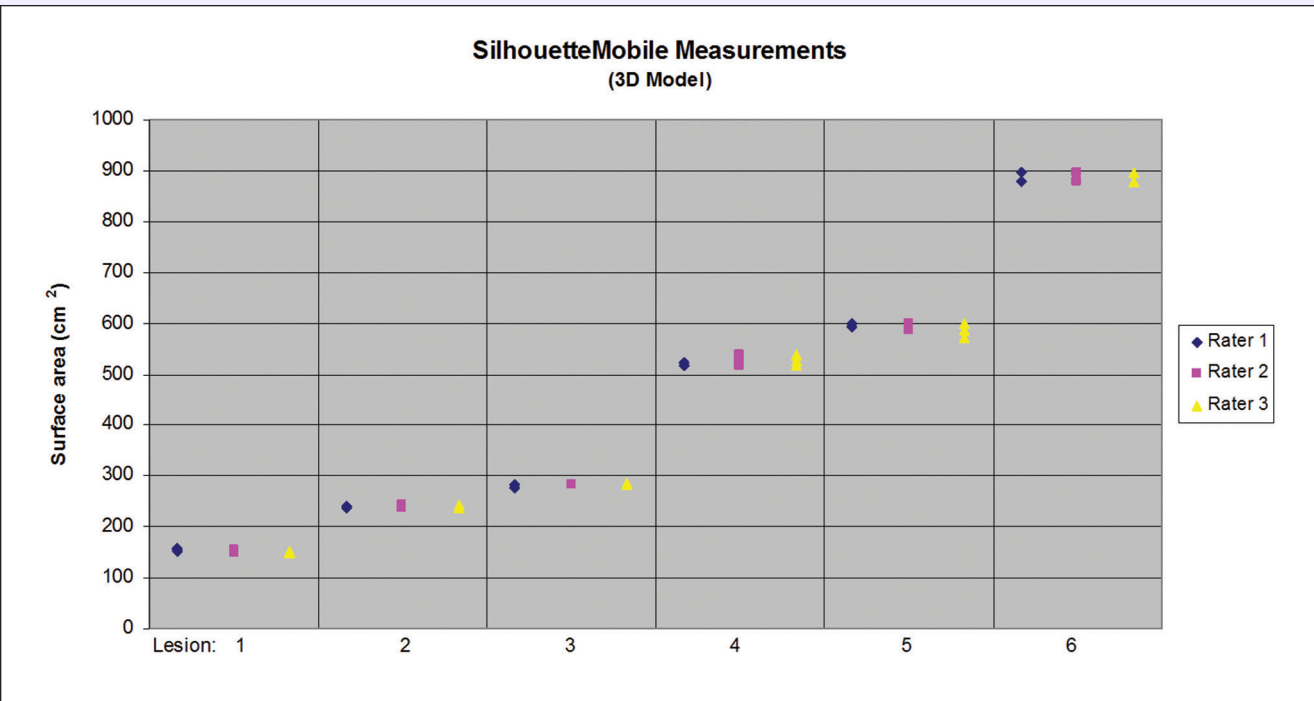


Figure 2: Measurements of the six 'lesions'.

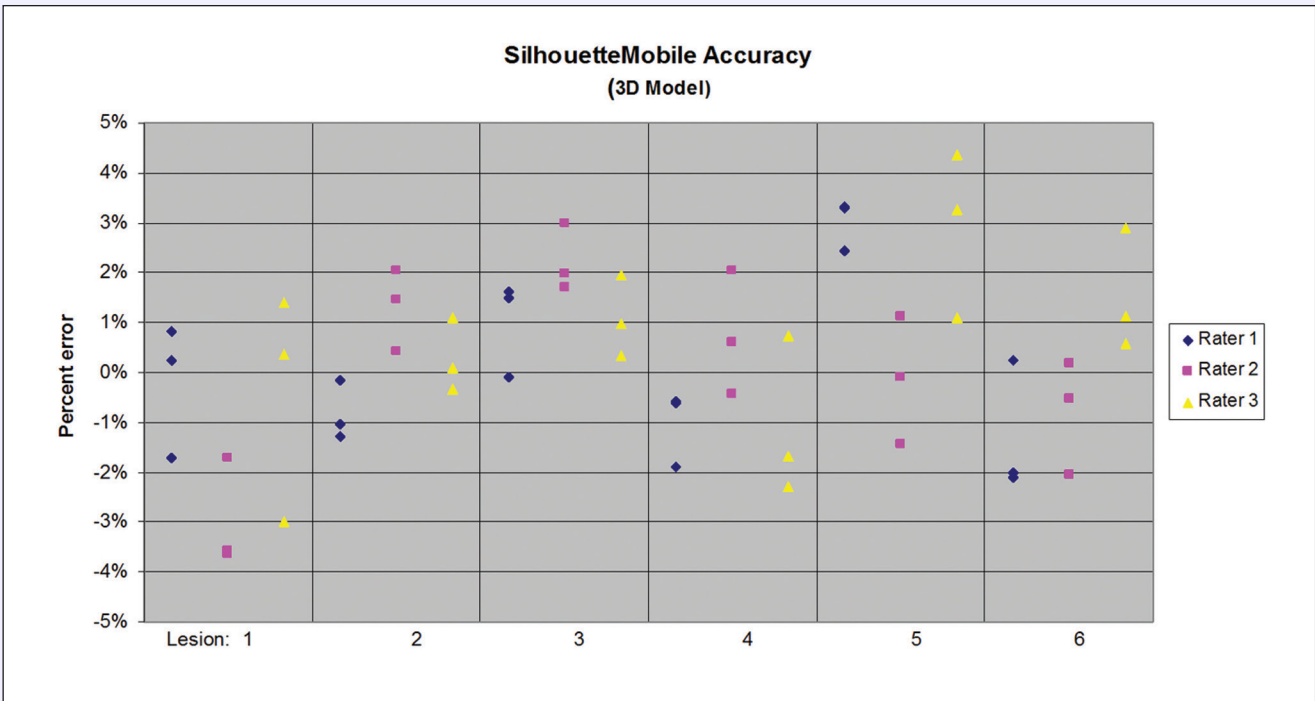


Figure 3: Percentage error of the measurements.

Percentage error	
Largest	4.4%
Average	0.3%
Standard deviation	1.8%

Table 3: Largest, average and the standard deviation of the percentage errors.

Lesion location	Area Measurements				
	Mean Area (cm ²)	Intra-Rater		Inter-Rater	
		Var. (cm ²)	CV (%)	Var. (cm ²)	CV (%)
1. Face	153.6	6.6	1.7	5.7	1.6
2. Forearm	239.7	3.0	0.7	6.6	1.1
3. Medial thigh	281.0	5.1	0.8	3.6	0.7
4. Abdomen	524.9	43.1	1.3	29.4	1.0
5. Buttocks	590.6	52.0	1.2	106.7	1.7
6. Lateral thigh	894.4	122.2	1.2	183.2	1.5

ICC (%)	99.94
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Table 4: Mean, Variance, Coefficients of Variation and ICC.

System Accuracy

The largest, average and the standard deviations of the percentage errors were calculated for each lesion and are shown in Table 2, and summarized across all lesions in Table 3.

The 95% confidence level for the percentage error indicates that we would expect a single measurement to be within -5.2% and +6.3% of the true value.

System Repeatability

All measurements generated by each rater were used to calculate the variances between raters (inter-rater) and within raters (intra-rater) for the lesions. From these variances the coefficients of variation (CV) for inter- and intra-rater sources were calculated as the standard deviation (square root of the variance attributable to intra- or inter-rater sources) over the mean, expressed as a percentage (%). These results are shown in Table 4.

The overall reliability (combining inter- and intra-rater variability) of the device measurement was then calculated and represented as the intra-class correlation coefficient (ICC). Here the ICC represents the percentage of the total variation among all the measurements which is due to actual differences in lesion size; and the balance represents variability due to measurement error (inter- and intra-rater); a perfect value of 1.00 would indicate that there is no measurement error. The ICC is also presented in Table 4.

Conclusion

From these measurements, Silhouette's inaccuracy (or bias) in area measurement was 0.3%. Furthermore, it was found that any single measurement is likely to be within approximately 6% of the true value 95% of the time for the types of lesions that were being modeled in this study.

The repeatability (precision) associated with the three raters (inter-rater variability) and variation between repeat measurements by the same rater (intra-rater variability) was <2%. This would indicate that repeated measurements over time, even by different raters, are likely to detect very small changes over time as a lesion changes in size and dimensions.

Overall, SilhouetteMobile™ was found to be an accurate, non-contact method for measuring large areas of modeled erythema.

References

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Contact Information

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What is Silhouette?

Wound measurement is essential in assessing the progress of wound healing. The most commonly used tools include wound tracings, width and length measurements, and digital photography. These methods have been useful in clinical practice but have limitations. Such limitations include lack of accuracy, difficulty of use, and often entail wound contact. More advanced equipment tends to be bulky, heavy and expensive.

To address these short-comings, ARANZ Medical Limited (Christchurch, New Zealand, www.aranzmedical.com) has employed its experience in medical image processing and laser scanning, developing a wound assessment and information management system, Silhouette™.

SilhouetteMobile™, the point-of-care data capture device, combines a digital camera and structured lighting in the form of two laser beams to automatically correct for image scale and skin curvature, allowing rapid and accurate measurements of the wound surface area and depth. The scanner unit plugs into a standard Personal Digital Assistant (PDA) to form a highly portable acquisition device that can be easily held and operated using a single hand.

Comprehensive reports can be generated on the PDA from the collected data. Documentation can include photographic records, serial wound measurements, and other pertinent data, and is customizable for a specific healthcare provider. The report can be emailed for teleconsultation purposes, or archived for long term storage.

SilhouetteCentral™, a database for longer-term storage of collected wound information, stores and manages all information collected by SilhouetteMobile™ in one central location. Assessment details can be reviewed and edited remotely. Clinicians can review wound data via the internet using a web interface.

Silhouette™ is used in clinical trials, hospital inpatient and outpatient care, long term care facilities, wound care centers and home health agencies.

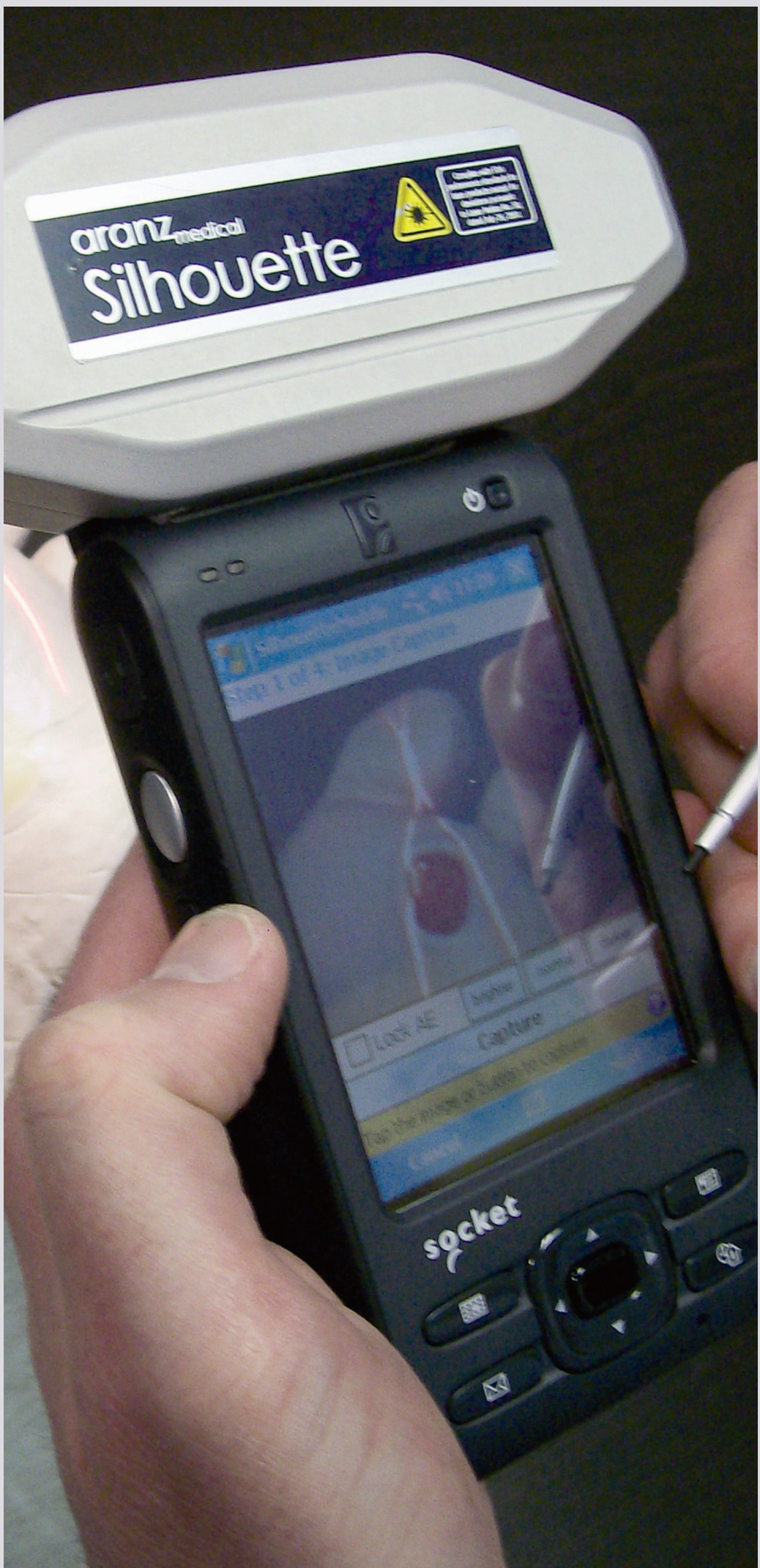


Figure 4: SilhouetteMobile