Surviving Cancer Without Compromising Lifestyle

Technical Report

Improved efficacy of XiTRON Hydra 4200 bioimpedance device using dual-tab electrodes

1. Background

Bioimpedance analysis is an easy to use, portable and non-invasive tool for use in the assessment of body composition parameters [1]. The accuracy of any estimation from a bioimpedance measurement is very much contingent upon accurately and reliably locating the precise electrode sites to record the appropriate impedance measurements [2].

One of the largest factors influencing the measured impedance of the body is the length of electrically participating tissue through which the current flows. The current is applied to the body and impedance measured via the application of electrodes on the skin. Therefore the distance between the electrodes is important. A 1 cm displacement of the electrode can result in a 2% change in measured impedance [3]. In-house studies conducted by ImpediMed have demonstrated a 5% change in raw impedance values per centimetre of displacement.

The placement of single tab electrodes in line with two anatomical reference points potentially introduces error due to the natural variations in anatomical structure in the patient population. In an attempt to control the errors created by variable electrode placement, ImpediMed has designed a dual-tab electrode to maintain a fixed distance between electrodes. The addition of the indicator line on the new dual-tab electrodes allows operators to repeatedly place the electrodes more reliably in relation to an anatomical reference point.

2. Methods

Bioimpedance data was collected on the XiTRON Hydra 4200 bioimpedance spectroscopy device using both standard XiTRON single electrodes and the ImpediMed dual-tab electrodes. The term standard electrode refers to the current electrodes supplied with the device, part number IS4000. The term dual-tab electrode refers to the ImpediMed dual-tab electrode part number IU02GELTC. These electrodes have a fixed 5 cm spacing from midpoint to midpoint of the electrode gel [2].

Two subjects were tested on five separate occasions over a two week period. Each subject was assessed by two operators. The measurements were made using the XiTRON Hydra 4200 in accordance with the Instructions for Use. The single electrodes were positioned by each operator using anatomical markers of the dorsal surface of the hand and foot between the bony protuberances that form the wrist and ankle joint respectively and at the distal metacarpals and metatarsals respectively as described by Lukaski [4] **(See Figure 1)**. The dual-tab electrodes were positioned with the head of the electrode with the green line on the dorsal surface of the wrist/ankle between the bony protuberances that form the wrist/ankle joint and the tail of the electrode running down towards the fingers/toes electrode **(See Figure 2)**.

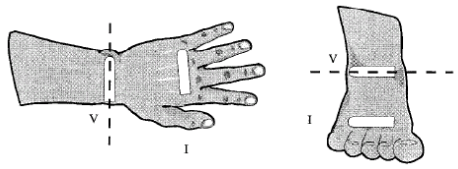

Figure 1

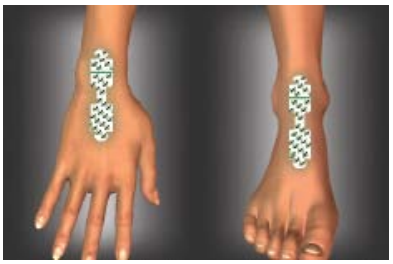

Figure 2

Whole body measurements were assessed using the right side (dominant for both subjects). Each measurement was repeated three (3) times for each electrode placement.

3. Results

3.1. Performance

The impedance values measured using the standard XiTRON electrodes and the Impedimed dual-tab electrodes were compared using the student's t-test ($\alpha = 0.05$), see Table 1. Results show that the mean of measurements made with the XiTRON and Impedimed electrodes (when used according to the Instructions For Use as detailed above) were not significantly different for the two tailed tests ($P(T \leq t) > 0.8$). This suggests that measurements made with the Impedimed dual-tab electrodes are statistically similar and can be used interchangeably.

Table 1 - Student's T Test for Equivalence

Parameter	P(T≤t)
Z10	0.935
R0	0.818
Rinf	0.970

In addition, high correlation between the XiTRON and Impedimed electrodes were found.

Table 2 - Correlation

Parameter	r
Z10	0.987
R0	0.989
Rinf	0.978

These results highlight the substantial equivalence in performance of the XiTRON standard electrodes and Impedimed dual-tab electrodes.

3.2. Variance

Two parameters were considered:

1) The variance of impedance (Z) and clinical data for each operator over the 5 days of testing was calculated. The variance (σ) is a measure of the spread of data from the average of the 5 days of measurement.

   The variances over the 5 days of the standard and dual-tab electrodes were calculated and compared. The reduction in variance achieved when using dual tab electrodes can be calculated as a percentage according to Equation 1. Table 3 summarises the average decrease in variance (%) achieved through the use of the dual-tab electrodes.

Variance Reduction = $\frac{100(\sigma_s^2 - \sigma_d^2)}{\sigma_s^2}$ **Equation 1**

2) The difference between operators was calculated for each day and averaged over the 5 days. The difference between operators gives an indication of the similarity of performance when multiple operators use a device.

   The average difference between operators was calculated and compared for standard and dual-tab electrodes. The decrease in operator difference achieved when using dual-tab electrodes can be calculated as a percentage according to Equation 2. Table 3 summarises the decrease in difference between operators when using dual-tab electrodes.

$$\textit{Decrease in Operator Difference (\%)} = \frac{100(\overline{OpDiff}_s - \overline{OpDiff}_d)}{\overline{OpDiff}_s} \qquad \textbf{Equation 2}$$

Table 3- XiTRON Standard and Impedimed Dual-Tab Electrode Comparison

Parameter	Average Variance Reduction[1]	Average Decrease in Operator Difference[2]
Z10	29%	27%
R0	28%	29%
Rinf	28%	26%

4. Conclusions

Results show that the use of dual-tab electrodes can improve longitudinal tracking by decreasing the variance between impedance measurements over consecutive visits. This study shows that intra-operator variance can be reduced by up to 29%.

Dual-tab electrodes have also been shown to reduce the error introduced by multiple operators. A decrease in operator difference of up to 29% can be achieved with the use of dual tab electrodes. A reduction in inter-operator measurement differences will lead to more reliable and reproducible results in a multi-operator environment.

The findings of this study demonstrate that the dual-tab electrodes manufactured by ImpediMed offer a more reliable, reproducible method of body composition analysis using bioimpedance devices. It is recommended that ImpediMed dual-tab electrodes are used for bioimpedance readings taken with the XiTRON Hydra 4200.

5. References

1. Kyle, U.G., et al., *Bioelectrical impedance analysis-part II: utilization in clinical practice.* Clin Nutr, 2004. **23**(6): p. 1430-53.
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3. Ellis, K.J., et al., *Bioelectrical impedance methods in clinical research: a follow-up to the NIH Technology Assessment Conference.* Nutrition, 1999. **15**(11-12): p. 874-80.
4. Lukaski, H.C., et al., *Assessment of fat-free mass using bioelectrical impedance measurements of the human body.* Am J Clin Nutr, 1985. **41**(4): p. 810-7.