Correlation and Validation of Body Composition Analyzers (i Series) with Dual Energy X- ray Absorptiometry (DEXA)

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Abstracts: This paper presents the development and evaluation of the i Series BIA (bioelectrical impedance analysis) device (models i20, i25, i30, i35, i50, i55), by MEDIANA Co., Ltd. The device utilizes a tetra-polar electrode method incorporating 8-point electrodes to improve the accuracy and reliability of body composition analysis. This paper employs a multi-frequency segmental measurement method with a wide range of measurement frequencies from 1 kHz to 1000 kHz. In comparing the correlation between Dual Energy X-ray Absorptiometry (DEXA) and BIA devices for fat-free mass (FFM) and muscle mass measurements, the results demonstrated a high correlation, with a coefficient of determination (R) of 0.984 for fat-free mass and 0.983 for muscle mass, respectively.

Keywords: Dual-Energy X-Ray Absorptiometry (DEXA), Bioelectrical Impedance Analysis, Tetra-Polar Electrode Method, 8-Point Electrodes, Segmental Measurement, Multi-Frequency Analysis.

1. INTRODUCTION

Obesity poses a significant threat to health and is associated with various diseases such as coronary artery disease, hypertension, and stroke as well as respiratory disorders including sleep apnea [1-3]. Traditional methods for evaluating obesity, such as waist circumference and other body measurements, have limitations in providing comprehensive clinical insights. For accurate measurement of visceral fat, the most widely used method is Computed Tomography (CT) which offers the advantage of clearly distinguishing between visceral and subcutaneous fat. However, drawbacks include higher radiation exposure and significant cost.

The current gold standard method being used is DEXA, which stands for "Dual-Energy X-ray Absorptiometry." This technique involves the passage of two very low-energy X-ray beams with differing energies through the body, allowing for the measurement of bone mineral content, lean mass, and fat mass. Due to its high accuracy, DEXA has been adopted as a replacement for underwater densitometry in many laboratories. DEXA offers advantages such as greater subject safety, ease of measurement, and high accuracy. However, limitations include the cost of the equipment, the need for regular equipment standardization, and a potential decrease in accuracy for individuals weighing over 150 kg. The radiation exposure during measurement is significantly lower than that of chest X-rays, and the error in body fat measurement is approximately 1.7%. It does have other limitations as well. DEXA involves ionizing radiation exposure, which raises concerns related to safety, especially with regard to repeated or pediatric assessments. Furthermore, DEXA measurements can be influenced by variations in hydration status and soft tissue composition, potentially leading to inaccuracies in the results [4].

Bioelectrical impedance analysis (BIA) is a technique for measuring body hydration using electrical methods. In the case of healthy individuals, the component of Fat-Free Mass (FFM) contains a certain amount of water, making BIA a valid method for deriving FFM. The measurement of body hydration using whole-body BIA has been widely employed as a means of analyzing body composition since the studies by Hoffer (1969) and Thomasset (1962) [5-6]. The fundamental principle of BIA assumes the body to be an electrically conductive object composed of resistance and capacitance elements, representing the non-fat tissues, organized into a cylindrical conductor. Additionally, adipose tissue acts as an insulator, impeding the flow of current, while lean tissue, consisting of water-containing electrolytes, facilitates efficient electrical conduction.

Research on BIA was initiated by Thomasset (1962), who employed electrical resistance as an indicator of total

body water content, with later studies such as Hoffer (1969) demonstrating a correlation (r=0.92) between total body resistance and total body water content. Moreover, the impedance index (Height^2/ Impedance) showed a close relationship with the volume of the electrical conductor, which was utilized for estimating body water and FFM. Building upon these numerous research findings, the BIA method for assessing body composition is currently widely utilized due to its advantages of being easy, rapid, non-invasive, relatively cost-effective, and suitable for both long-term monitoring and periodic measurements, making it a valuable tool in the field of body composition evaluation.

Bioelectrical Impedance Analysis (BIA), on the other hand, offers a non-invasive and radiation-free alternative, making it a safer option for certain populations and longitudinal studies. Additionally, BIA devices are generally more portable and convenient, allowing for easier data collection in a wider variety of settings. Therefore, considering the drawbacks of DEXA, BIA presents itself as a promising alternative for body composition analysis in situations where safety, practicality, and accessibility are paramount.

Specifically, electrical conductivity is directly proportional to water and electrolyte content. Muscles, being highly hydrated, exhibit superior electrical conductivity, while fat, with lower water content, displays reduced conductivity [6]. The BIA **i** Series (models i20, i25, i30, i35, i50, i55), developed by MEDIANA Corporation, is a medical device that measures body composition by applying alternating currents to biological tissues and measuring the resulting impedance and its relationship with body tissues.

This study aims to investigate the correlation between the body composition analysis results obtained from the **i** Series and those from DEXA. Additionally, it seeks to validate the effectiveness and accuracy of the **i** Series. This research attempts to assess the potential clinical applications of the **i** Series and verify its reliability and precision through a comparison with DEXA. The findings of this study are expected to offer significant insights into the prevention and management of obesity-related disorders.

2. Participant selection criteria

Participants in this experiment were selected based on the following criteria.

- Subjects were healthy people without any medical history that could affect the experiment and were selected in a balanced way considering the gender ratio and age distribution.

- Only those who voluntarily signed the consent form were selected as subjects, and children and adolescents under the age of 19 were required to have the signature of a legal representative.

The following subjects were excluded.

- Pregnant or lactating women

- Any person who refused to be exposed to trace amounts of radioactive material

- Any person who had difficulty standing unaided or if the clinical trial was judged to be difficult due to poor physical condition

- Persons with implanted metal or implantable medical devices such as pacemakers or stents

- People with contagious diseases or wounds on the palms or soles

Table 1 shows the basic statistical results such as gender, age, weight, height, and BMI of the participants.

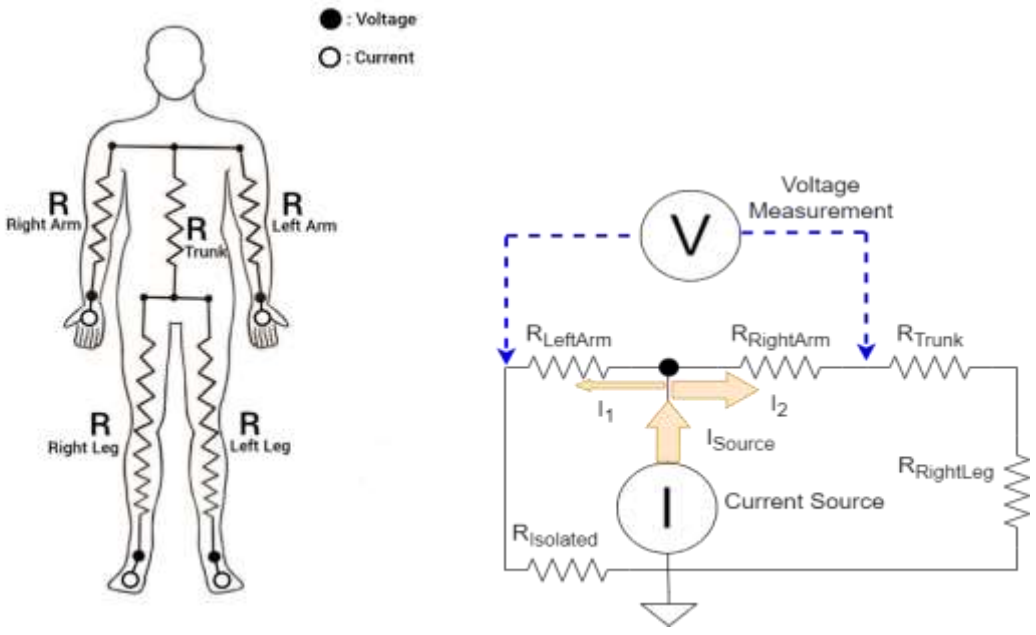
Table 1. Participant's body information

		Distribution of Age						
		3~10	11~18	19~29	30~39	40~49	50~59	60~
Male	N	**4**	**11**	**33**	**24**	**19**	**15**	**9**
	Height(cm)	122.8±14.5	170.5±9.4	176.4±6.5	173.5±4.9	172.8±5.7	167.5±7.1	167.5±4.7
	Weight(kg)	28.6±12.8	72.6±20.4	74.9±12	78.6±14.1	73.5±9.7	69±4.8	69.2±10.3
	BMI(kg/m2)	17.8±3.6	24.8±5.8	24.1±3.7	26±4.1	24.6±3.1	24.7±2.1	24.6±2.5
Female	N	**3**	**18**	**30**	**14**	**29**	**21**	**9**
	Height(cm)	128.9±12.3	161.3±4.3	159.4±4.3	159.3±5.1	159±5.5	155.7±4.7	154.7±5.1
	Weight(kg)	30±6.4	57.4±9.9	58.1±8.3	58.4±9.1	59.6±9.5	58.7±6.9	58.5±6
	BMI(kg/m2)	17.8±0.4	22.1±3.8	22.9±3.3	23±3.4	23.6±3.5	24.2±2.8	24.5±2.4

N: number of participants

3. Body Impedance Analysis

Body impedance analysis was conducted with the subject in a vertical position with a pair of electrodes for current injection and voltage sensing placed on the palms and soles, respectively, after cleansing the electrode attachment sites with moistened tissues to eliminate any foreign substances on the skin. The temperature and humidity in the laboratory were maintained at a constant level during the measurement process. Each clinical trial participant was measured twice to assess reproducibility. The **i** Series device was utilized in both tetrapolar and eight-polar electrode configurations. The measurement principle of the tetrapolar electrode configuration is as follows [7].



(a) **(b)**

Figure 1. Eight-polar (a) and Tetra-polar electrode(b) configuration with electric circuit with values determined by example

For the purpose of illustration, all body resistances were set to 500Ω ($R_{LeftArm}$, $R_{ReftArm}$, R_{Trunk}, $R_{RightLeg}$) and the open portion of the circuit was endowed with a relatively high resistance value of 1 M ohm ($R_{Isolated}$). It is assumed that a current of $200\mu A$ (I_{Source}) is supplied from the current source. The sum of resistances in the right loop is 1500Ω, while the sum of resistances in the left loop amounts to 1.0005 M ohms, consequently causing the most current to flow through the right loop. In this example, the current I_1 flowing through the left loop is almost $0\ A$ and the current I_2 flowing through the right loop is nearly $200\mu A$. This methodology permits measurement of voltage across individual segments, and upon division by current, facilitates the measurement of resistance values.

$$V_{RightArm} + V_{LeftArm} \approx V_{RightArm} + 0 = V_{RightArm}$$

$$\frac{V_{RightArm}}{I_{source}} = R_{RightArm}$$

By substituting the values in the example above, the right arm resistance value can be obtained as follows.

$$\frac{0.1V}{200\mu A} = 500\Omega = R_{RightArm}$$

The utilization of multi-frequency technology in BIA helps to overcome limitations associated with single-frequency methods and provides a more comprehensive, accurate, and adaptable approach to assessing body composition [8]. The i Series includes multi-frequency analysis technology with measurement frequencies at 1kHz, 5 kHz, 10kHz, 50 kHz, 100 kHz, 250kHz, 500 kHz and 1000 kHz.

The Fig.2 is the BIA used in this experiment, which is a product developed by MEDIANA Co., Ltd

(a) i25 (b) i35 (c) i55

Figure 2. The i Series body composition analyzer by MEDIANA Co., Ltd

4. Dexa Measurement

The assessment of body composition using DEXA was conducted through the Bone Density Measurement Center at Severance Hospital, Yonsei University, and utilized the Horizon W equipment (Hologic Inc., USA). DEXA was employed to measure fat-free mass, body fat mass, muscle mass, and bone mineral content, which serve as reference values. The measurements were performed on the same day as the body impedance measurements.

DEXA measurements provide results categorized into overall body composition and regional body composition. For the overall body composition, the entire body was measured and the corresponding results were generated. In the case of regional body composition, qualified specialists adhered to predetermined protocols to partition the body into trunk, right arm, right leg, left arm, left leg, and head segments, subsequently providing measurements for each segment.

A multiple regression analysis was conducted to evaluate the correlation between the measurements obtained from the **i** Series and DEXA methods. The following evaluation criteria were employed:

- Trunk Fat-Free Mass
- Fat-Free Mass of the Left Arm and Right Arm
- Fat-Free Mass of the Left Leg and Right Leg
- Total Fat-Free Mass, Total Muscle Mass, and Bone Mineral Content
- Segmental Mass and Segmental Muscle Mass

The regression analysis aimed to assess the relationships between the measurements acquired using the **i** Series and DEXA methods for the specified evaluation criteria.

5. Statistical Analysis

In addition to investigating differences in trunk fat-free mass based on weight or height, certain variables related to fat-free mass, such as impedance index associated with volume, density of trunk fat tissue based on age, gender differences in fat percentage according to sexual characteristics, tissue density variations by race, and fat density based on submersion, can serve as independent variables in the regression equations. This study utilized the independent variables of weight, impedance index, age, and gender, as selected through a stepwise selection method. The selected independent variables were impedance index, weight, and gender [8].

Double cross-validation was conducted in order to determine the applicability of regression equations derived from the study population to groups not participating in the experiment. The double cross-validation involves dividing the study population into two groups (Group A and Group B). The regression equation for predicting trunk fat-free mass was developed based on Group A data, assuming that Group B did not participate in the experiment. This equation was then applied to Group B data to assess the accuracy and error of the predicted trunk fat-free mass in comparison to DEXA, a standard method. Conversely, a regression equation based on Group B data was established and applied to Group A to evaluate the accuracy and error compared to the standard method, thus validating the potential applicability to non-participating groups.

Validity coefficients (R) and standard errors of the estimation (SEE) for predicted fat-free mass values in relation to the standard method (DEXA) were compared through the double cross-validation process, by substituting Group A data into the Group B prediction equation and vice versa. Based on the observed similarities from the double cross-validation, the two groups were combined into one, and a predictive equation for trunk fat-free mass based on

impedance values was formulated. The validity of this model was examined, ensuring that the regression equation adhered to the regression hypothesis and that the validity of the prediction equation was established. The validity of the body composition prediction equation was evaluated by comparing it with body composition measurements obtained using DEXA, which is considered the gold standard for body composition assessment. The prediction equation was derived through regression analysis between measured values such as weight, height, body impedance, and body composition as determined by DEXA. By comparing the correlation between the estimated body composition values derived from the prediction equation and the body composition values measured by DEXA, the effectiveness of the body composition prediction equation was assessed.

In the clinical trial results, the key body composition components (muscle mass and fat-free mass) estimated through the body composition measurement algorithm exhibited a high correlation with the reference equipment, DEXA, with an R-squared value exceeding 0.983. Moreover, a strong correlation was observed between the measurement of visceral fat in cross-sectional areas obtained through abdominal computed tomography and the estimated body water content through isotope dilution, further validating the accuracy of the developed algorithm.

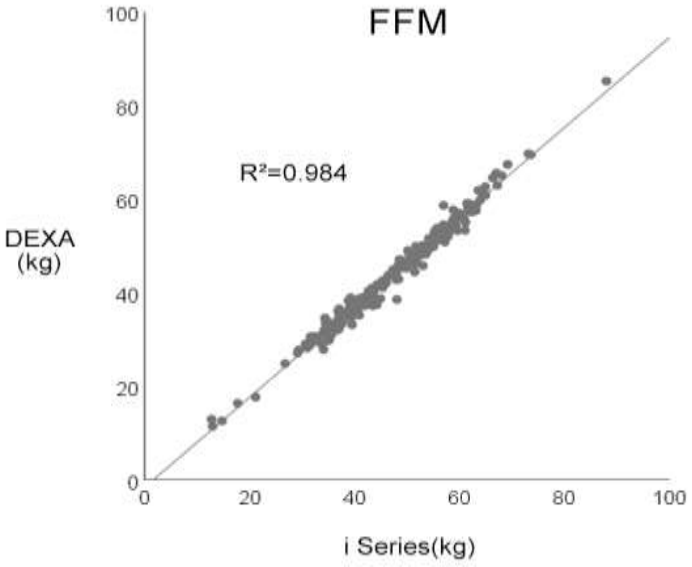


Figure 3. Cross validation of FFM measured on DEXA and BIA i Series.

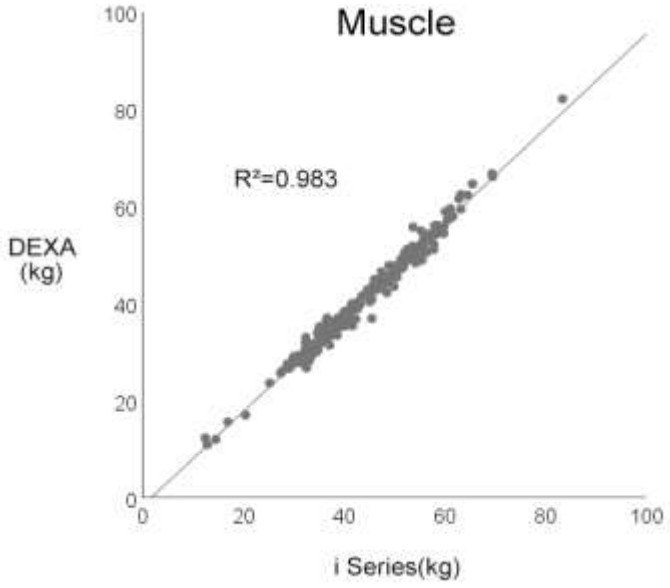


Figure 4. Cross validation of muscle measured on DEXA and BIA i Series

Multiple regression analysis was performed to analyze the correlation between the body composition measured by the **i** Series device and the body composition measured by DEXA, and the linearity of the result was confirmed. The body composition values calculated by the MEDIANA body composition analyzer **i** Series device were compared and analyzed with those calculated by DEXA (Horizon W, Hologic Inc., USA). The clinical trial was conducted at “Wonju Severance Christian Hospital”.

CONCLUSION

The objective of this clinical trial was to establish the safety of the **i** Series body composition analyzer device and validate the accuracy of its measurement algorithm. The clinical trial yielded compelling outcomes, revealing a strong correlation between the body composition estimates derived from the measurement algorithm and the reference DEXA measurements, with an $\mathbf{R^2}$ value of 0.983. Similarly, a significant correlation was established with the estimation of body water content. Based on these findings, it is evident that MEDIANA's **i** Series body composition analyzer exhibits performance and efficacy consistent with its intended purpose of use.

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