

Construction and standardization of cost-effective, sensitive, and portable bioimpedance phase angle monitoring device

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ABSTRACT

Background: The availability of acute phase sensitive electronics has increased the interest in the use of bioelectric impedance to simulate human body compositions in the field of human nutrition, human biology, physiology, and sports medicine and clinical medicine. **Objective:** The cost of the instrument which is available in the market is high though it is sensitive and accurate. The aim of the study is to develop a portable, accurate, sensitive, and cost-effective bioimpedance phase angle monitoring device. **Materials and Methods:** The shift is quantified geometrically as the angular transformation of the ratio of the reactance (X_c) to the resistance[®] or the phase angle (\emptyset). The instrument is developed with resistance, capacitance, an internal circuit, electrodes, wires, and a display monitor. **Results:** The instrument is developed and calibrated. We got the phase angle values of male ($n = 25$) and female ($n = 15$) are $7.3 \pm 0.28^\circ$ ($n = 15$) and $6.83 \pm 0.30^\circ$ and the average being $7.05 \pm 0.37^\circ$ ($n = 40$). The cost for the development of the instrument was around 5000/-. **Conclusion:** The cost of the instrument will be around 4000/- when developed in commercial basis. The instrument will be portable, sensitive, and cost-effective compared to the existing instrument.

Key words: Bioimpedance phase angle, Calibration, Development, Standardization, Validation

INTRODUCTION

The principle of bioimpedance has been introduced in the 1950s. The availability of acute phase sensitive electronics has increased interest in the use of bioelectric impedance to simulate human body compositions in the field of human nutrition,^[1,2] human biology,^[3] physiology,^[2,4,5] and sports medicine.^[6] The monitoring of phase angle to assess the morbidity and mortality of certain grievous diseases, such as AIDS with or without tuberculosis, liver cirrhosis, pancreatic cancer, and colorectal cancer,^[7-11] was conducted in western countries. Lower phase angles appear to be consistent with low reactance and equal either cell death or a breakdown in the selective permeability of the cell membrane. There is a significant difference in phase angle between healthy and disease states. The phase angle increases with improving clinical status.

Phase angle depends on the cell membrane integrity and body cell mass. The cost of the instrument which is available in the market is high though it is sensitive and accurate.

We needed a cost-effective, portable, and sensitive instrument to check the prognosis of many widespread diseases such as tuberculosis^[12] and some dreaded disease such as cancer.^[8] The instrument developed by us may serve the purpose at low cost.

Bioelectric impedance (z) measured in ohms is the square root of the sum of the square of resistance[®] and reactance (X_c) or

$$Z^2 = \sqrt{R^2 + X_c^2}$$

Moreover, it is frequency dependent. Bioelectric resistance is the pure opposition of a biological conductor to the flow of an alternating electric current, whereas reactance is the resistive effect due to

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capacitance produced by tissue interfaces and the cell membrane. Capacitance, or the storage of electric charge by a condenser, causes the current lag behind the voltage creating phase shift. The shift is quantified geometrically as the angular transformation of the ratio of the reactance (X_c) to the resistance[®] or the phase angle (θ). The geometrical relationship among impedance, resistance, reactance, and phase angle of an electrical current are illustrated in Figure 1.

At very low frequency (f_1), the capacitive component of the system is effectively an open circuit so that the reactance is equal to 0 and measured impedance (Z) is purely resistive (R_0). As the frequency increases in proportion to the resistance causing phase angle to open until as maximum is reacted at a critical frequency (f_c) specific to the system. Beyond the critical frequency, the reactance begins to decrease in proportion to the resistance with increasing frequency.

Most biological systems are highly conductive and phase angle at a critical frequency is small. Variation among the individuals among phase angle at a fixed frequency could be due to differences in the capacitive (capacitance) behavior of the tissue associated with the cell size, membrane permeability, intracellular component or fat mass or distribution of body fluids. A design of the instrument is provided (Figure 2). After developing the instrument, it is calibrated with standard bioimpedance instrument.

MATERIALS AND METHODS

Using the following discrete electronic components, two circuits were built:

- a. 50 KHz sine wave oscillator
- b. Phase angle measuring circuit

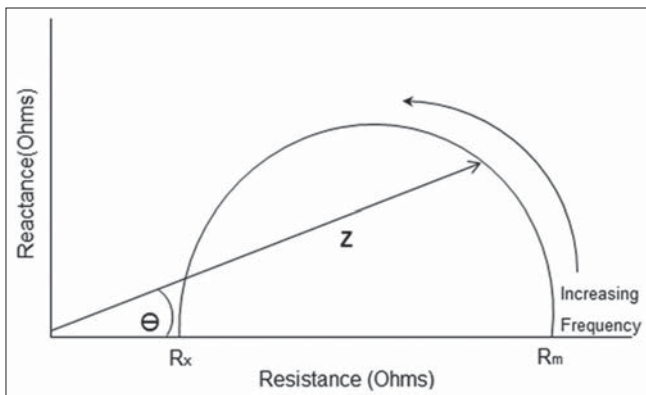


Figure 1: Diagram of the graphical derivation of the phase angle (arctan); its relationship with resistance (R), reactance (Xc), impedance (Z), and the frequency of the applied current

- c. Electrodes and wires
- d. Digital display monitor.

With these above, we assembled the instrument. Then, the instrument was validated against Quad scan instrument (BODYSTAT Quadscan 4000) kept in Nutrition Division of Physiology Department of St. John’s Medical College, Bengaluru. The cost of the development of the instrument was 5000/-. The cost of the instrument will be around 4000/- when developed in commercial basis.

Construction of the monitoring device

The instrument is built using two blocks, the first circuit which generates sine wave oscillations at 50 KHz frequency and the second one measure the phase angle. It has standard four electrodes out of which two are used for injecting current (<1 mA) and two are used to measure phase angle (as depicted in the diagram). The two injecting electrodes and two measuring electrodes were used assuming the body is bilaterally symmetrical. The phase angle is directly displayed in degrees in an LCD monitor.

About 40 healthy subjects were chosen from the student community and general population in the age group of 18-50 years at private hospitals Bengaluru, Nellore, and Ghaziabad India. 25 subjects were males and 15 were females. Ethical clearance was obtained from the Institute’s Ethical Clearance Review Board. Informed consent was obtained using a specially designed consent form. After an overnight fast, the subjects were made to lie down supine on a bed in the metabolic lab of the Narayana Medical College, Nellore and research lab of Rama

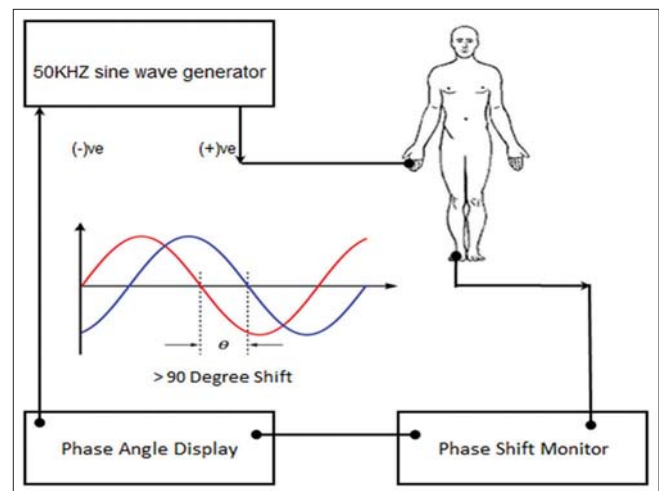


Figure 2: Design for the tetraelectric-bioimpedance phase angle monitoring device and its actual display

Medical College, Ghaziabad for 10 min. History of any pacemaker or orthopedic hardware implant was taken along with the history of food intake and recent exercise.

The subjects were asked to separate their legs for 30-40°. Any jewelry on the person was removed. Ordinary electrocardiography electrodes were used under aseptic conditions. Electrodes were applied on the right side with injecting electrodes placed on the dorsum of hand and feet on the metacarpal and metatarsals, respectively. The reading electrodes were placed between the medial and lateral malleoli of the same side. The reading electrodes of the wrist were placed between radial styloid and ulnar prominence of the wrist. The distance between injecting and reading electrodes was 5 cm.

The subjects were asked not to move when the instrument was measuring the bioelectrical impedance. A single measurement was taken. In the case of erroneous readings, the electrodes were re-applied, and the measurement was repeated. Phase angle was calculated by the monitoring device.

Calibration

The instrument is calibrated for phase shift in the range of 0-10° (working range) using known values of resistance-capacitance network.

RESULTS

Using our instrument as shown in Figure 3, we got the values in males ($n = 25$) $7.3 \pm 0.28^\circ$ and in females ($n = 15$) $6.83 \pm 0.30^\circ$, respectively, as evident in Figure 3 which is similar to the values in Indian population,^[5] and the overall average being $7.05 \pm 0.37^\circ$ ($n = 40$). A paired t -test was conducted, and Pearson correlation of -0.123 was observed between male and female.

DISCUSSION

Phase angle is a marker of cell and cell membrane structure and functional status. A low phase angle has been associated with an impaired outcome in tumor diseases such as pancreatic cancer, colorectal cancer, and lung cancer as well as HIV/AIDS, liver cirrhosis; on dialysis, pulmonary tuberculosis, bacteremia, and sepsis.^[6-10,13] The Phase angle reflects the status of cell to the cell membrane. It can be considered as a global marker of health. Any change in tissue physiology should produce changes in the tissue electrical properties.^[14] Reduced phase angle indicates a decreased ionic conduction with the loss of dielectric mass. The

standardized phase angle is an independent predictor of impaired functional and nutritional status.

Phase angle is calculated by finding reactance divided by resistance (ratio) and taking the arctangent of that ratio. Phase angle normally expressed in degrees. The energy of all living things comes from cells that consume oxygen and nutrients and expel carbon dioxide and waste. The quantity and efficiency of cells directly affect phase angle. The outer boundary of the cell is a plasma membrane of phospholipid molecules that are dielectric to form an electrical capacitor when a radio frequency signal is introduced to the cells environment. Capacitance is fundamental to any human phase angle measurement, the higher the capacitance, the greater the phase angle. An elite athlete world has a higher phase angle than a sedentary person. It has been well documented that phase angle declines with disease, age, and reduced activity level. The phase angle values for males and females were $7.43 \pm 0.98^\circ$ and $7.05 \pm 1.58^\circ$, respectively, in Indian population.^[5]

In our instrument, we got the values of male and female were $7.3 \pm 0.28^\circ$ and $6.83 \pm 0.30^\circ$, respectively, which is similar to the values in Indian population and the overall being $7.05 \pm 0.37^\circ$.

The sex-related differences found in the study of Barbosa-Silva *et al.*^[15] were not found in some previous studies. Baumgartner *et al.*,^[6] in the first study of phase angle and body composition, found no significant difference in phase angle values between sex and age groups. Selberg and Selberg^[7] also found no significant difference in phase angle values by sex in healthy subjects, probably because of their very small sample size (74 adults and 48 subjects aged <18 years in Baumgartner *et al.*'s study and 50 subjects in Selberg and Selberg's study) and consequent lack of power. This difference, however, was found in larger studies of healthy adults and a hemodialysis population.^[7,16]

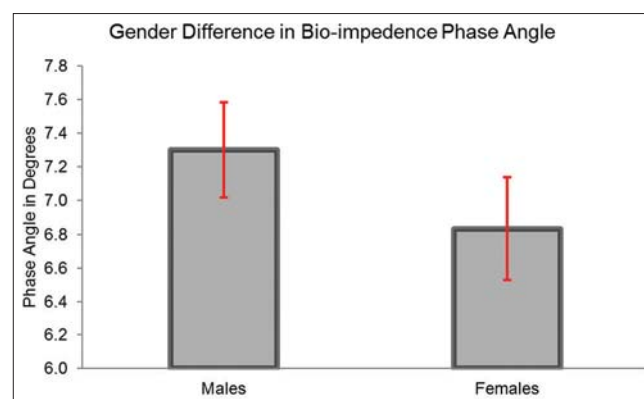


Figure 3: Bioimpedance phase angle with mean and standard deviation in males ($n = 25$) and females ($n = 15$)

Buffa *et al.*^[17] also showed a significant decrease in phase angle with age in healthy elderly subjects, and Kyle *et al.* found the same age and sex differences in 2740 healthy adults.

The prognostic role of the phase angle is easier to assess if standardized values are used. Standardized phase angles on the positive side of the scale (i.e., values greater than the mean) are expected for healthy subjects. Sick individuals (e.g., cancer patients) are expected to have negative standardized phase angles (i.e., values lower than the mean), which become increasingly lower with a worsening prognosis. The use of standardized phase angles is likely to produce better results than is the use of a single population reference value for identifying high-risk persons.

CONCLUSION

We developed the instrument as portable, sensitive, cost-effective compared to other existing instruments which are very expensive. We validated the instrument against an existing and functioning instrument. The bioelectrical data of the sample agreed well with the normal reference values of the Indian population though a larger sample size is required to be more discrete.

In the country like India, we have limited resources and a large population to diagnose and investigate we can use this instrument as a screening tool in the patients presenting with very common diseases such as tuberculosis and cancer. This instrument is portable, sensitive, and cost-effective for screening the mass for the diseases which were already investigated and established.

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