Minimum Detectible Changes Associated with Tissue Dielectric Constant (TDC) Measurements as Applicable to Assessing Lymphedema Status

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Minimum Detectible Changes Associated with Tissue Dielectric Constant (TDC) Measurements as Applicable to Assessing Lymphedema Status

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Running Title: Minimal Detectible Change of TDC Measurements
ABSTRACT

Background: Tissue dielectric constant (TDC) measurements are increasingly being used as a tool to help characterize lymphedema features, detect its presence and assess treatment related changes. Although the underlying physics of this technology has been well described in the literature there has been little systematic study of in vivo reliability aspects. A central unanswered question is the minimal detectable change (MDC) or difference that, with a given level of confidence, may be ascribed to this technology. Our goal was to address this issue using test-retest measurements from which intraclass correlations (ICC) and MDC could be estimated.

Methods and Results: Forty volunteers (20 females) aged 19-61 years with body mass indices of 14.7-47 Kg/m^2 and body fat percentages of 12.0-48.9% were evaluated. Two measurers (M1 and M2) used two different TDC measuring devices (multiprobe and compact) to measure TDC in triplicate sequentially and bilaterally at three locations; anterior forearm, hand palmer mid-thenar eminence and dorsum mid-web. These measurements were made by each measurer twice constituting test-retest values (T1 and T2). From these measurements ICC\textsubscript{2,1} and MDC at 95% confidence were determined for each site and probe for absolute TDC values and for inter-side ratios. MDC values for absolute TDC ranged from 2 to 9 TDC-units and for inter-side ratios ranged from 5.3 to 8.0% depending on site and probe. ICC\textsubscript{2,1} values ranged from 0.765 to 0.982.

Conclusions: The MDC values herein documented may be used to provide guidance to aid interpretation of measured TDC changes or differences in a clinical environment.
CONDENSED ABSTRACT

Tissue dielectric constant (TDC) measurements are used to characterize lymphedema features, detect its presence and assess treatment-related changes. We sought to estimate the minimal detectable change (MDC) ascribable to this technology. Forty volunteers were evaluated with a test-retest design to determine intraclass correlations (ICC$_{2,1}$) and MDC. Two measurers used a multiprobe and compact device to measure TDC bilaterally on forearm, hand palm and dorsum. MDC for absolute TDC ranged from 2 to 9 TDC-units and for inter-side ratios ranged from 5.3 to 8.0% depending on site and probe. These values may be used to guide interpretation of TDC changes.

KEY WORDS

Lymphedema Measurement
Tissue Dielectric Constant
Measurement Reliability
Minimum Detectible Change
Minimum Detectible Difference
INTRODUCTION

Tissue dielectric constant (TDC) measurements are increasingly being used as a tool to help characterize lymphedema features \(^1\)-\(^4\), detect its presence \(^5\)-\(^7\) and assess treatment related changes \(^8\)-\(^13\). Furthermore, such measurements have shown practicality in a range of pathological conditions \(^14\)-\(^22\) and have been used to study applied aspects of skin physiology \(^23\)-\(^27\). Although the underlying physics and principle of operation of this technology has been well described in the literature \(^28\)-\(^33\) there has been surprisingly little systematic study of in vivo reliability aspects \(^34\). Because of its use to assess changes in lymphedema status resulting from various forms of therapy and other conditions the question of measurement reliability becomes increasingly important. A central question in this regard relates to the minimal detectable change or difference that, with a given level of confidence, may be ascribed to this technology. Our goal was to address this issue by performing test-retest measurements using two different TDC measuring devices from which intraclass correlations (ICC) and minimum detectible changes (MDC) could be estimated thereby providing a guide to aid interpretation of measured TDC changes or differences in a clinical environment.

METHODS

Subjects

A total of 40 adult volunteers (20 females and 20 males) participated in this research study. Subjects were recruited from medical students, faculty, staff and family via word of mouth resulting in a range of ages (19-61 years), body mass indices (14.7 – 47 Kg/m\(^2\)), body fat percentages (12.0 – 48.9 \%) and total body water percentages (38.0-62.2\%). Respective means
and standard deviations (SD) were 26.3 ± 6.4 years, 26.0 ± 6.1 Kg.m², 25.5 ± 9.1 % and 54.0 ± 5.9%. After explaining the study to potential participants, and if they agreed to participate, they signed a consent form that was approved by the University institutional review board (IRB) and a time for participation was scheduled. The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. To be eligible for participation, potential subjects needed to be at least 18 years of age with no history of arm or hand edema or lymphedema or any current skin condition that might impact the planned measurements. The study was conducted from January through July of 2018 at Nova Southeastern University.

**Measurers**

TDC measurements (described subsequently) were done by two medical students who prior to this study had no experience using the TDC measuring devices. Operational procedures were explained by the senior author (HNM) and they had an opportunity to utilize the devices with HNM as a subject with feedback provided regarding technique during a one-hour training session. Subsequently, the two measurers, denoted as M1 and M2, as part of their experience development made all protocol measurements on five test subjects who would not be part of the main study. The test data was reviewed by HNM for consistency with a primary criterion that at least 80% of all triplicate measurements demonstrated a coefficient of variation of 5% or less. This criterion was achieved by both measurers.
**Initial Study Procedures**

Upon entry into a dedicated experimental room, subjects removed their shoes and socks and stood on a body composition scale (Tanita Ironman BC558, Segmental Body Composition Monitor) to measure their weight, body water percentage, total body fat percentage, and individual body compartment fat percentages. Each subject self-reported their age, height, and dominant hand. After this they sat on a padded chair to which an arm rest was attached across the front so that they could comfortably rest their arms. Room temperature and humidity were recorded at the start of measurements. Thereafter the tissue dielectric constant (TDC) measurement protocol was initiated.

**Tissue Dielectric Constant (TDC) Measurement**

Two different TDC measuring devices were used, both manufactured by Delfin Technologies (Kuopio, Finland). One was the MoistureMeterD using a 2.5 mm effective depth measuring probe and the other was the more recently available compact version referred to as the MoistureMeter Compact. TDC measurements were obtained by placing the probe surface perpendicularly on the subject’s skin with firm but gentle contact pressure. Measurements were done in triplicate sequentially and bilaterally at three standardized locations; 1) the anterior forearm 5 cm distal to the antecubital fossa, 2) the center of the hand palmer thenar eminence and 3) the hand dorsum mid-web **between the thumb and index finger that was not over bone.** The triplicate measurements at each site were done by alternating between sides sequentially, starting with the dominant side. The order of the measurements was hand dorsum to hand palmer to forearm. After placing the probe on the skin, a measurement takes
about 5 seconds. Anatomical sites were chosen to be inclusive of sites used related to lymphedema and other TDC-related measurements.2-6, 24, 27.

The physics of TDC measurements is well described in the literature28, 32, 33, 35. Briefly, a very low intensity 300 MHz signal is transmitted from the probe in contact with the skin and penetrates the skin to varying depths depending on the probe used. Some incident energy is reflected to a processing unit. In the multiprobe device it is a separate unit and in the compact device it is self-contained. Based on information from the reflected wave the processor calculates the real part of the complex permittivity of the composite tissue being sampled. This value is the TDC that has a value strongly dependent on the relative amount of water in the sampled tissue. The effective penetration depth depends on the probe design and in the present case the multiprobe effective penetration depth was approximately 2.5 mm whereas the compact device used has a penetration depth of about 2 mm. Effective penetration depth has been defined as that depth at which the incident energy falls to 37% of its surface value29.

**Procedure**

Two measurers (M1 and M2) and one data recorder participated in the protocol. The procedure was for M1 to do the complete measurement set first using the compact probe with M2 not present in the experimental room. After M1 completed the first measurement set M1 left the room and M2 entered and completed the 1st measurement set with the compact probe. This process was then repeated with the measurers using the multiprobe. The combined process of measuring with the compact and multiprobe was then repeated so that M1 and M2 both completed two completed measurement sets, the first designated as time 1 (T1) and the 2nd as time 2 (T2). At no time during the measuring process were M1 and M2 in the
experimental room at the same time and neither knew of the values obtained by the other. Room temperature and relative humidity of the room was 22.3 ± 1.0°C and 52.6 ± 4.1%.

**Analyses**

The minimum detectable change or difference (MDC) is the smallest change or difference that should be interpreted as being real and was calculated at the 95% confidence level using the equation \( \text{MDC}_{95} = 1.96 \times \text{SEM} \times \sqrt{2} \). SEM is the standard error of the measurement with \( \text{SEM} = \text{SD} \times \sqrt{1-\text{ICC}} \), where SD is the standard deviation of the complete data set for T1 and T2 measurements and ICC is the intraclass correlation. For the present design the appropriate generalized ICC is \( \text{ICC}_{2,1} \) calculated based on a two-way random effects model for absolute agreement as \( \text{ICC}_{2,1} = (\text{MS}_S - \text{MS}_E)/[\text{MS}_S + (K-1)\text{MS}_E + K(\text{MS}_T - \text{MS}_E)/n] \). In this equation \( \text{MS}_S \) is the subject mean square, \( \text{MS}_E \) is error means square, \( \text{MS}_T \) is the trials (within) mean square, \( n \) is the number of independent measurements, and \( K \) is the number of measurers. All statistical analyses were done using SPSS version 16. ICC and MDC values were determined for the absolute TDC measurements at each site and for each probe and also for the inter-side ratios. Interarm ratios of TDC measurements have been shown to be essentially independent of a person's handedness.
RESULTS

TDC Values

Table 1 summarizes absolute TDC values and key ratios for each anatomical site measured by both measurers using the multiprobe 2.5 mm depth probe and the compact probe. Initial comparisons of TDC values measured on dominant and nondominant sides during first and second measurement sets (T1 and T2) showed very similar values with no statistically significant difference (p>0.3) between sides or measurement times. Thus, each value in the table includes data of the combined sides and times for a total of 160 measurements (40 subjects x 2 sides x 2 measurement times). The main findings with respect to measured TDC values are as follows.

1. For both measurers and for both probes TDC values were significantly different among anatomical sites (p<0.001) with the forearm having the least TDC value and the hand palm showing the greatest TDC value.

2. TDC values recorded by the compact probe was statistically different from that recorded by the multiprobe probe at all sites and for both measurers. However, the main difference between probes was recorded at the forearm where the compact probe TDC values exceeded the multiprobe by an average of 16.3% for measurer 1 (M1) and by 16.6% for measurer 2 (M2). At the hand sites the difference between probe values was less than 5% at the hand dorsum and less than 2% at hand palm.

3. There was an overall statistically significant difference (p<0.001) in TDC values measured by M1 and M2 at each site with percentage differences ranging from 2.0 to 4.3% for the multiprobe and 2.2 to 5% for the compact probe.
**Intraclass Correlation Coefficients (ICC\(_{2,1}\)) and MDC for Absolute TDC Value**

Table 2 summarizes ICC and MDC values for absolute TDC values for each anatomical site measured by both measurers using the multiprobe 2.5 mm depth probe and the compact probe. The main findings with respect to measured TDC values are as follows.

1. ICC\(_{2,1}\) values had a wide range which when averaged between M1 and M2 had a minimum of 0.765 at the hand dorsum when using the multiprobe and a maximum value of 0.982 at the forearm using the compact device. The corresponding largest and least minimum detectible differences are 9 and 2 TDC units respectively.

2. For both the multiprobe and the compact probe the least MDC is observed for measurements on the forearm (4 and 2 TDC units respectively) and greatest for measurements on hand dorsum (9 and 4 units respectively).

3. For each anatomical site measured the compact probe yielded a smaller MDC value than for the multiprobe.

**Intraclass Correlation Coefficients (ICC\(_{2,1}\)) and MDC for Inter-arm TDC ratios**

Table 3 summarizes ICC and MDC values for dominant to nondominant side TDC ratios for each anatomical site measured by both measurers using the multiprobe 2.5 mm depth probe and the compact probe. The main findings with respect to TDC ratios are as follows.

1. Average inter-arm ratios ranged from 0.985 – 0.986 on the hand palm to 1.000-1.008 on the hand dorsum with all values not differ significantly from a value of one.

2. For both probes and most anatomical sites the intraclass correlations were less compared with corresponding values determined for absolute TDC values (table 2)
The average MDC for ratios ranged from 0.053 to 0.080 corresponding to MDC% ranging from 5.3% to 8.0% depending on anatomical site and probe used.

DISCUSSION

A main goal of this study was to provide useful estimates of the minimally detectible difference or change (MDC) that could be reliably taken to represent a real difference or change when measuring TDC. This undertaking was triggered by the fact that TDC measurements have been widely used and are increasingly being used in a variety of research and clinical studies but until now there has not been a systematic determination of the associated MDC. Without such clarification interpretation of findings is unnecessarily hindered.

The anatomical sites chosen for these measurement and assessments were those that are often used in the evaluation of upper limb edema or lymphedema. So that strictly speaking it is to these sites (forearm and hand) that the MDC estimates apply. Further, because the test subjects were specifically chosen to be free of lymphedema for this reliability study, the extent to which the determined estimates directly apply to persons with lymphedema is unspecified. However, they importantly serve as a lower bound on expected MDC values.

In making these assessments two different TDC measuring devices were utilized. One was a multiprobe device capable of accommodating different probes that measure to differing tissue depths. The other was a compact device that is contained in single hand-held device that measures to a single tissue depth. These devices, which are made by the same manufacturer, differed in construction and the depth to which they measured. The multiprobe measured to an effective depth of about 2.5 mm as specified by the manufacturer whereas the compact probe
measured to a depth of about 2 mm as previously determined. These two probes are the
ones that are most widely reported in use within the literature.

The fact that absolute TDC values recorded at the forearm were greater when measured
using the compact probe was confirmed via the present measurements, with the compact
yielding a value about 4.2 TDC units higher at the forearm. This difference is likely since
measuring deeper will include more low-water content subcutaneous fat to be included in the
measured volume. The effect would be a lower TDC reading for the 2.5 mm probe.

However for the forearm this difference is about 16.5% whereas a prior study
reported a difference of about 5.6%. There are several possibilities that may account for
this difference. In the prior report the percentage difference was based on the mean
difference divided by the average of the values determined by the two probes. In the present
study the divisor in the calculation was the value of the 2.5 mm depth. This was used to
determine the percentage that the compact exceeded the multiprobe. If percentage
difference between the two measurements were determined for the present study a value of
14.2% would be calculated. Another factor that may account for the difference relates to the
absolute value determined using the multiprobe. In the present study absolute TDC values
measured with the compact probe (31.9 ± 3.5) on the 40 subjects (half female and half male)
was similar to that previously reported (31.1 ± 2.6) measured on 64 subjects, also half female
and half male. However, the multiprobe TDC values measured in the present study were less
than previously measured (27.6 ± 4.3 vs. 29.4 ± 2.7). Such a difference might account for
some of the discrepancy and would occur if the current subjects had a greater fraction of
hypodermal fat within the measurement volume of the multiprobe. Since this was not measured this plausible reason must for now remain speculative.

Contrastingly, average TDC values at the hand differed by less than 1.0 TDC unit. The smaller probe-related difference might reflect structural differences inherent among anatomical sites. However, despite differences in absolute values measured between probes at the forearm, interarm ratios computed as dominant / nondominant side TDC values, proved to be remarkably similar at all sites (table 2). This suggests that use of either probe would yield comparable results when assessments of interarm ratios were the parameter of interest.

The MDC values summarized in tables 2 and 3 provide the main reliability outcome of the present study. Because some research and clinical applications may utilize absolute TDC differences whereas others may use inter-side ratios, MDC are needed separately for each application. The results for the absolute values analysis demonstrate that MDCs are dependent the anatomical site being evaluated and on the probe being used. For all sites measured, the compact probe had the least MDC value that ranged from 2 TDC units at the forearm to 4 TDC units at the hand dorsum.

At each site the multiprobe demonstrated a greater MDC value that ranged from 4 TDC units at the forearm to 9 TDC units at the hand dorsum. The explanation for the difference in MDC values between these two probes is speculative but probably involves at least two factors. The standard compact device has an included pressor sensor, not present in the multiprobe device, that might allow for a more uniform application pressure which in turn may have yielded a greater intraclass correlation value. Additionally, because the compact probe measures to a lessor depth than the multiprobe, minor differences in contact pressure during
the measurement might have less effect on the measured TDC value. This follows since a lessor depth measurement probe includes proportionately more of the homogeneous high-water content dermal region as opposed to possibly including different proportions of dermis and low-water content hypodermis as would be the case for the deeper measurement probe.

In contrast to probe-dependent MDC differences associated with absolute TDC values, probe differences in MDC were less clear as applied to inter-arm TDC ratios (table 3). The compact probe average MDC was less than for the multiprobe at forearm and hand palmer but greater at the hand dorsum. Overall the MDC value for interarm TDC ratios ranged 0.053 to 0.080. These MDC values may be used for lymphedema assessments in two separate ways. When comparing a prior measured inter-arm ratio to a measurement taken later or after treatment, a change in ratio needs to be greater than the MDC values specified in table 3 to be considered a possibly real change. For example, if a pre-surgery inter-arm ratio (at-risk / contralateral) of 1.065 were measured at the forearm, using the multiprobe, then anything less than a subsequently measured ratio less than 1.065 + 0.080 or 1.145 should not be considered as a real change at the 95% confidence level. If the compact probe were being used, its smaller MDC leads to a threshold of $1.065 + 0.067 = 1.132$. Similar calculations could be done for other anatomical sites of interest.

MDC values determined for interarm ratios may also help specify threshold ratios to detect lymphedema. Such thresholds have been calculated as those values that exceed normal reference ratio averages by at least 3 SD. For forearm these range between $1.26^{2,4}$ and $1.29^{38}$ and for hand dorsum are 1.23 for a 2 SD threshold or 1.32 for a 3SD threshold$^{39}$. Threshold values based on the present more limited data set and calculated using the 3 SD threshold
using site-dependent and probe-dependent MSD values added, ranged between about 1.23 and 1.27, values similar to those previously reported.

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AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist
REFERENCES


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<td>Forearm Anterior</td>
<td>27.4 ± 4.3</td>
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<td>36.4 ± 6.6</td>
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<td>45.8 ± 5.3</td>
<td>45.0 ± 4.3</td>
<td>0.991 ± 0.103</td>
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Table 1. **Tissue Dielectric Constant (TDC) Values**

Entries are mean ± SD of combined dominant and nondominant side TDC values measured at times 1 and 2 constituting 160 measurements for each entry. P-values refer to comparisons of multiprobe vs. compact probe. Differences in TDC values among and between sites are significant (p<0.001) for probe and measurer. Differences in values between measurers at all sites for each probe is also significant (p<0.001). M2/M1 is the ratio of TDC values measured by measurer 2 (M2) divided by those of measurer 1 (M1). CP/MP is the ratio of compact to multiprobe TDC values.
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<td></td>
<td>1.59</td>
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Table 2. Reliability parameters based on test-retest of absolute TDC measurements

Abbreviations: ICC<sub>2,1</sub> = intraclass correlation, SEM = standard error of measurement, MDC = minimal detectible change or difference, M1 and M2 = measurers 1 and 2, AVERAGE = average of M1 and M2 parameters with value in parentheses the MDC value rounded up to the next whole number.
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Table 3. Reliability parameters based on test-retest of TDC ratios

Parameters based on dominant to nondominant side ratios. Abbreviations: ICC,1 = intraclass correlation, SEM = standard error of measurement, MDC = minimal detectible change or difference, M1 and M2 = measurers 1 and 2, AVERAGE = average of M1 and M2 parameters. DOM/NDOM is dominant to nondominant side TDC ratio ± (SD). THRESHOLD is defined as the mean ratio + 3 SD + MSD for a given site and probe.