LYMPHEDEMA ASSESSMENT BY LOCAL TISSUE WATER AND INDENTATION RESISTANCE

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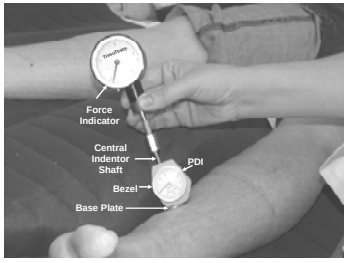
BACKGROUND and GOALS

Changes in both tissue water and tissue resistance to indentation accompany limb lymphedema but the relationship between these changes, if any, is unclear. Because lymphedema-related changes are not generally uniform within a limb it is useful to be able to noninvasively assess these parameters locally at sites of clinical interest. Local tissue water (LTW) is quantifiable using the tissue's dielectric constant (TDC) since its value increases with relative tissue water content. TDC measurements have been reported to be useful for routine clinical assessments. However, a corresponding handheld clinical assessment tool to routinely quantify corresponding local tissue indentation resistance (TIR) in a way that does not depend on device orientation (gravity-independent) is not widely available. Thus, the research goals were to:

1) Develop a simple portable device for routine clinic assessment of TIR in patients with lymphedema,
2) To determine if LTW and TIR were related and
3) To determine the effect of a single manual lymphatic drainage (MLD) treatment on these parameters.

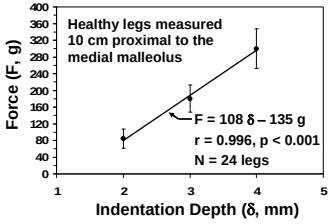
TISSUE TESTER DEVICE



The device has a force meter coupled to an indentor and penetration depth indicator (PDI). The PDI has a circular 29.5 mm diameter base plate with a central 10.5 mm diameter opening through which the a 10 mm diameter indentor passes.

Indentation depth depends on force applied and resistance of the tissue. The PDI zero is set with the device placed vertical on a hard surface by rotating the PDI indicator bezel to indicate zero indentation. Accuracies of the force and penetration indicators are ±5 g and ±0.1 mm respectively. Calculated surface contact pressure of the indentor is 93.6 mmHg per 100 g applied force. For brevity, the complete tissue testing device (force indicator and PDI) will subsequently be referred to as tissue tester.

HEALTHY VOLUNTEERS



Indentation force of both legs of 12 healthy volunteer subjects was determined for penetration depths of 2, 3 and 4 mm. As shown by the above graph indentation force was linear with respect to indentation depth (bars = ± 1 SD). TDC values for these subjects (mean ± SD) are shown in the table.

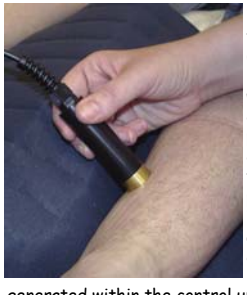
PATIENTS WITH LYMPHEDEMA

	Subjects	Patients (N=18)		
		Pre-treatment	Post-treatment	%Change
Force (g)	316± 38	401 ± 123†	331 ± 98**	-21.5 ± 17.1
TDC	28.6±1.6	35.9 ± 8.3†	32.6 ± 8.0**	-9.1 ± 6.9
Girth (cm)		35.3 ± 7.3	34.3 ± 7.2**	-3.0 ± 2.3

† p<0.001 compared to subjects, ** p<0.001 compared to pre-treatment

TDC, tissue resistance (force) and girth measurements were made at a calf site visually identified as having the greatest swelling in 18 persons with leg lymphedema (22 legs) before and after a single MLD session. TDC was measured in triplicate and the average of the three readings used to characterize the site's tissue water. Each TDC measurement takes about 10 seconds once the probe is touched to the skin. Tissue resistance was then measured at the same site using the tissue tester by indenting to a standardized indentation depth of 4 mm and recording the force required to achieve this indentation. The force meter holds the indentation force value for easy reading. The results (above table mean ± SD) shows that tissue resistance and tissue water are greater in lymphedematous legs compared to subject's legs and that all parameters are significantly reduced by a single MLD treatment. Force shows the greatest percentage reduction. Despite treatment-related reductions in both indentation force and TDC there was no correlation between the changes in these parameters as assessed via Pearson's correlation value (r= -0.067). There was also no discernible correlation between indentation force and TDC values for either the control subjects or for the patients

TDC MEASUREMENTS



TDC was measured with the MoistureMeter-D, (Delfin Technologies Ltd, Kuopio Finland, www.delfintech.com). It consists of a cylindrical probe connected to a control unit that displays the TDC value when the probe contacts the skin. The physics and principle of operation has been well described[3-5]. In brief, a 300 MHz signal is generated within the control unit and is transmitted to tissue via the probe in contact with the skin. The portion of the incident electromagnetic wave that is reflected depends on the dielectric constant of the tissue, which itself depends on the amount of free and bound water in the tissue volume through which the wave passes. For reference, pure water has a value of about 78.5. The effective penetration depth of the probe used was 2.5 mm.

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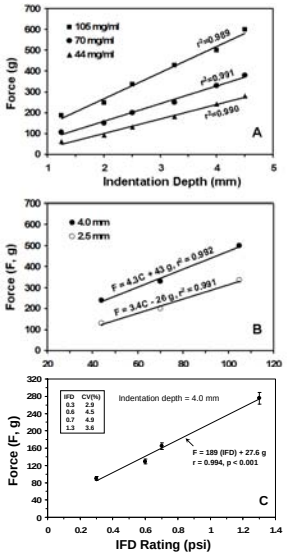
IN VITRO TISSUE TESTER RESULTS

Indentation-force characteristics were determined using gels of varying water content and consistency. Gel concentrations were prepared by mixing gelatin (Knox™) with distilled water to achieve gelatin concentrations of 44 mg/ml, 70 mg/ml and 105 mg/ml. Freshly prepared, stirred and fully dissolved gelatin of each concentration was poured into eight 21 mm deep by 42 mm wide wells in a pan containing 24 individual wells. Total volume placed in each well was 25 ml. The pan was then placed in a refrigerator overnight at 4ºC and removed after 12 hours for testing.

For each concentration the tissue tester was used to produce indentations to a depth of 1.25, 2.0, 2.5, 3.25, 4.0 and 4.5 mm and the force for each was recorded. Each test was done on a separate well (6 wells per concentration) to avoid possible alterations of the gel due to a prior compression. Results indicate force is linear with indentation for each concentration (A) and with concentration for different indentation depths (B). Tests were also done on polyurethane foam blocks of different indentation force displacement (IFD) ratings as specified by the American Society of Testing Materials. This rating is based on measurements of the force required to compress a material 25%. Tissue tester evaluations were done using 2.5 cm thick, 4 by 4 cm square blocks with IFD ratings of 0.3, 0.5, 0.7 and 1.3 psi where higher ratings correspond to greater required compression force. Indentation tests to 4.0 mm, done for each IFD rating 12 times showed indentation force linear with IFD rating (r=0.994) with coefficients of variation for all IFD ratings less than 5%. (C).



SUMMARY AND CONCLUSIONS

Tissue tester device: With respect to the tissue tester, it was shown that a rather simple handheld device can be easily used clinically to rapidly assess tissue resistance to localized compression thereby obtaining an index of underlying tissue mechanical properties. Typically the measurement can be done in less than 10 seconds and does not depend on gravity for operation so it can be applied to tissue at any orientation and can be used on any body part surface.

Effects of Leg Lymphedema on Measured Parameters: As compared to legs of subjects without lymphedema, the presence of leg lymphedema was associated with 1) a significantly greater tissue resistance as judged by the indentation force and 2) a greater local tissue water as judged by the greater tissue dielectric constant

Effects of MLD therapy: With respect to effects of therapy, the data showed that a single MLD treatment resulted in a significant reduction in tissue resistance as judged by reduced indentation force and also resulted in a significant reduction in local tissue water as judged by the reduction in tissue dielectric constant

Interpretation of Findings: Our interpretation of the present findings is that an MLD-related tissue softening accounts for the force reduction whereas fluid movement out of the interstitial space accounts for the TDC reduction. Since these changes were not correlated, the findings suggest that measurements of both local tissue resistance and tissue water can provide useful independent information as to the lymphedematous status and its potential change with therapy.