Noninvasive measurement of the stiffness of tissue in the above-knee amputation limb

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Abstract—In order to characterize the mechanical properties of the soft tissue in above-knee amputations, nine subjects were measured with a Doppler ultrasound system. Measurements were made at four locations: anterior, posterior, lateral, and medial. The characterizations included tissues up to 2.5 cm deep. The average posterior moduli are significantly greater than the anterior and lateral parameters. No significant difference was found among moduli from the medial zone compared to other areas. Superficial tissue had a significantly higher modulus than the tissue beneath. A simple method for transducer placement produced repeatable results. The present technique proved to be useful with patients in good health, and with no severe residual limb complications. The information generated with the ultrasonic device may aid in prosthesis fitting and will be used in a Computer-Aided Design (CAD) system as well as in other clinical applications.

Key words: above-knee amputation, CAD/CAM, Doppler ultrasound, prosthesis fitting, residual limb complications, tissue characterization.

INTRODUCTION

Prosthetists measure tissue stiffness to help determine the condition of an amputated limb. By assessing the tissue condition, they decide how to shape the socket. Traditionally, these judgments have been subjective. Published guidelines aid in assessing the amount and condition of soft tissue in the amputated limb; however, these are qualitative descriptions of the tissue, such as “soft” or “average” (10). These types of measures are sufficient for an experienced prosthetist, but a new prosthetist may not find it easy to make the required judgment. Additionally, recent developments in Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) for prosthetic fitting have fostered the need for the quantification of many of the parameters that formerly were measured intuitively by the prosthetist.

Our research in CAD has included the development of a tissue modulus measurement device. The device collects data that can be used in the calculation of a measurement of stiffness, the Young’s or elastic modulus. The resulting numerical value can be incorporated into computer applications. If a CAD system is not used, the device gives the prosthetist a specific value on which to base socket rectification. Both the experienced and inexperienced prosthetist will have an objective measure as a guide in fitting a socket.

A device that measures mechanical properties of the tissue could be useful in other clinical applications. For example, because tissue ulceration may begin below the skin surface, mechanical changes occur in the tissues before they become
apparent to the patient or clinician (7). A device that could measure small changes in the mechanical properties of the tissue would allow timely treatment of pressure areas, promote a higher degree of awareness in patients susceptible to ulceration, and possibly prevent further deterioration.

Another use of such a system could be in determining levels of muscle conditioning. If exercises to build muscle mass or tone were prescribed, a change in modulus of the tissue would indicate changes in the muscle, and provide a measure of the effectiveness of the treatment.

The equipment developed in the CAD project must be tested thoroughly to determine the normal ranges of tissue moduli, the differences in moduli for “fatty” as opposed to “muscular” tissue, and the differences in moduli relating to sex, age, weight, time since amputation, cause of amputation, and other relevant variables. The purpose of this preliminary study was to determine the present capabilities of the system and identify areas of improvement that would make the system more useful clinically.

Mechanical properties of tissue are of significant interest to the medical community. Many investigators have studied and tested different types of tissues, but the mechanical characteristics of human tissue, especially muscle and other soft tissues, are incompletely tabulated at this time. In vivo tissues are nonlinear, inhomogeneous, anisotropic materials which exhibit many complicated behaviors such as creep, stress-relaxation, and hysteresis (2,4,9).

Additionally, most studies of human tissues have concentrated on static or dynamic testing of cadaver parts. Generally, these tests were conducted to the tissue’s failure point. Ultimate strength values are useful in finding replacement materials when needed; however, they provide little insight into the behavior of the tissue during normal use in the body.

Though more difficult to measure, the elastic modulus of the tissue is of more interest for socket design than is the ultimate strength of the soft tissue. In this regard, some elastic modulus values have been presented. On a basic level, the Young’s modulus of elastin (the primary component in elastic body tissues) is approximately 600 kPa, and that of collagen is 1,000 MPa (3). Ligaments have moduli in the 400-600 MPa range (1,11). These values were all measured on tissues along their long axis, i.e., for tendons, ligaments, and muscles, along their line of action; and for skin, parallel to its surface. In many loading conditions, especially in the prosthetic fitting, the loads are transverse to the line of action, such as the pressures which compress: a) the legs and buttocks while sitting; b) the bottom of the foot inside the shoe while standing; and, c) the residual limb inside its socket while standing. Body tissues are anisotropic: their mechanical characteristics are not the same in all directions, and so tensile strengths or even elastic moduli measured along the length of the tissue provide incomplete insight into the mechanical behavior of the tissue during different loading situations.

Moreover, much of the research reported in the literature has been completed on isolated tissues; that is, generally muscle was tested with fat removed (4). Ligaments and tendons, though sometimes tested with small sections of bone, were usually separated from their surroundings. Body fluids and normal spaces between tissues were not included. It is very difficult to project the mechanical behavior of the system using data collected from isolated components.

In order to measure the elastic modulus of a live tissue in its functional position, an ultrasonic measurement device was developed (8). Ultrasound is noninvasive, painless, familiar to clinicians and many patients, and ultrasonic devices are widely available.

**METHODS**

The modulus of elasticity was measured on the residual limb tissue of nine adult males with above-knee amputations. All amputations were performed at least one year prior to this study. In this preliminary study, subjects were not categorized according to age, cause of amputation, or crutch usage. These variables should be investigated separately in subsequent studies.

Each subject sat in a sling apparatus over the measurement equipment. An opening in the sling accommodated the subject’s residual limb, which hung vertically into the transducer apparatus (Figure 1).

Moduli were measured with a pulsed Doppler ultrasonic device (8). This device is similar to the type of ultrasound apparatus commonly used for measuring blood velocity (5,12). Normally, these
instruments measure the phase of the returning signal. When a sinusoidal acoustical waveform (pulse) is applied to the tissue, the returning wave has changed in phase after hitting the target particle. This phase shift is measured by a quadrature phase detector and is directly proportional to the distance from the transducer. As the target moves, the phase of the corresponding signal also changes. Therefore, the movement of the target can be “tracked” by continuously monitoring the phase of the returning signal.

Because the residual limb tissue is virtually motionless when placed in the measurement device, it is necessary to move the tissue in order to measure displacement. This motion, or “perturbation” of the tissue is accomplished by pushing on the surface of the skin with the head of the measurement device (see Figure 2). This head contains the ultrasound transducer, which also moves during the perturbation. The head is curved to fit the contour of the leg and is 5 cm in diameter, so that a relatively large area, compared to the size of the transducer, is moved for measurement. This movement of a large amount of tissue causes behavior which can be described as a “flow” of tissue, similar to the fluid flows that the Doppler normally measures. In this manner, a nearly uniform motion of the tissue surrounding the transducer takes place, with the exception of the extremities of the measurement field. The outermost and innermost layers generally compress more than does the middle section of the soft tissues because of their juxtaposition with significantly harder materials (the measurement head on the skin surface, and the bone on the inner part of the tissue). These sections are not considered in the data analysis. The tissue in the measurement region is compressed slightly to keep the tissue in contact with the transducer, but this compression is assumed to have a negligible effect on the results.

For measurement, the frequency and amplitude of motion had to be optimized for accurate data collection at the ultrasound probe frequency. The transducer frequency used was 10 MHz, with a pulse repetition frequency of 4 kHz. The perturbation
Figure 2.
Ultrasound transducer and head of perturbation device.

frequency was set to 8 Hz and the amplitude of the head motion was 0.25 cm. This optimized the motion for measurement and was comfortable to the subject because the tissue deformation was small.

An Apple IIe computer was used for data acquisition and data analysis. The peak displacements of the motion cycle were located by sampling the output displacement signal every 10 milliseconds. A running average of peaks was calculated and randomly sampled. If the value did not vary for a total of at least five samples, the value of the displacement was recorded and the depth was changed to measure the next target. If the samples did not match, the measurement process continued until five consecutive equal values were obtained. The depth resolution varied with increasing depth. The highest resolution occurred between 0.5 and 1.5 cm, and the lowest after 2 cm. The poorest resolution was at approximately 0.1 cm. This is consistent with the usual behavior of 10 MHz Doppler devices (6).

After the displacement data were acquired, they were plotted on displacement-versus-time curves (Figures 3 and 4). Values were drawn from these curves for use in the modulus equation:

$$ E = 1.5\rho\omega^2 \frac{U_2(X_3 - X_1)}{U_1 - U_2} \frac{U_2 - U_3}{X_3 - X_1} \frac{X_3 - X_2}{U_2 - U_3} $$

where $\omega$ is the frequency of cyclic displacement of the tissue,
$\rho$ is the tissue density, 1.1 gm/cm$^3$,
$X_i$ is the ith depth in the tissue,
and $U_i$ is the motion amplitude at depth $X_i$.

This equation uses three representative displacements measured by the Doppler system (represented by $U_1$, $U_2$, and $U_3$), and their corresponding depths ($X_1$, $X_2$, and $X_3$) to calculate the modulus. The modulus also depends on the density of the tissue, which is considered to be a constant, and the frequency of the applied motion to the tissue, 8 Hz.
Equation [1] was theoretically derived from the laws of physics, and further details concerning this derivation, as well as the sensitivity to the assumptions of constant density and homogeneity, have been published previously (6).

Because the modulus equation (Equation [1]) uses only three data points from the whole data set, the modulus depends upon which points are chosen. Often, stray points occur because of movement of the subject or large inhomogeneities in the measurement field (such as scar tissue or large blood vessels), and these points tend to change the calculated modulus. These values are not correct, because the modulus should depend only on the material tested, and the choice of any three points from one data set should yield the same modulus. To minimize the effect of erroneous points, the data were “smoothed” to fit the exponential curve of the form \( y = Ce^{-kx} \), where \( C \) and \( k \) are characteristic constants of the particular curve, determined from the data. This form was chosen because an ideal elastic material would produce an exponentially decaying curve. Using this smoothing technique, the modulus varies only slightly when different sets of three points are chosen, eliminating dependence upon point choice. The modulus, then, is only related to the characteristics of the curve, how quickly or slowly it decays.

Repeatability tests were performed before any subject testing began. For convenience, modulus readings were taken on the largest surface of the lower leg (over the gastrocnemius muscle) of one subject. Although these values are not comparable to data from the residual limbs of amputees, the experimental and analytical techniques were the same, and so the tests are valid for checking the repeatability of the measurement technique.

For this evaluation, five sets of readings were taken without removing the apparatus. Because the equipment is intended to be used to measure the same region of a patient on several occasions throughout the patient’s treatment, it is necessary to be able to replace the instrument in approximately the same location without marking the skin. It would be convenient to estimate the location of previous readings without referring to anatomical landmarks. To test the repeatability of measurements taken in this manner, the perturbator was removed and then, with no markings made or measurements taken, replaced for five more readings. The entire procedure was repeated again (i.e., five more measurements). One week later, five final measurements were taken in the same region to insure that the values were repeatable from day to day as well.

Once repeatability was ascertained, subject testing was performed. Measurements at four areas of the residual limb were taken on each subject. These were: a) an anterior position of the residual limb over the rectus femoris muscle group; 2) a posterior position over the semitendinosus muscle group; 3) a medial area where there appeared to be the least amount of developed muscle present; and, 4) a lateral zone approximately 180 degrees from the medial measurement point. Each zone was approximately halfway between the distal and proximal ends of the residual limb. These areas varied slightly on each subject due to different residual limb sizes and shapes, scar tissue, and muscle condition. However, an attempt was made to place the transducer at the regions of interest as consistently as possible.

After all data were collected, they were manually compiled and analyzed for variance in modulus values between locations and depths. Significant differences were determined using standard two-tail \( t \)-tests and \( F \)-tests with the significance level set at 0.01.

![Figure 3](image_url)

Displacement data from Doppler ultrasound system.
During the analysis, it was recognized that at times the perturbator device did not contact the skin well due to unusual contours of the residual limb, movement of the patient, or loosening of the bracket. In these cases, the data set appears unusually “flat,” and yields an abnormally high modulus value. In order to exclude these errant readings, all values that deviated from the mean by over 100 percent were discarded. Nine such points were eliminated from a total of 103 modulus values.

RESULTS

Resulting data were plotted on displacement versus depth graphs (see Figure 3). These are easily comparable for different measurements, a stiffer material giving a generally flatter curve, and a less-stiff material resulting in a more sharply declining curve.

While examining the data, it was noticed that many of the curves had a relatively flat section followed by a sharp decline. This is easily seen in Figure 4, with the first section ending at approximately 1.16 cm. So that this characteristic was not simply “smoothed out” during the data analysis, a two-curve method of analysis was adopted. In this procedure, the data set is divided into two sections: the modulus for each section is calculated, and, using the two previous moduli, a weighted modulus is determined for the entire curve. The point at which the curve is divided is determined via a computer program which sets the division point when the slope changes significantly. The average division point was 0.86 cm ± 0.3 cm.

Data collection included displacements from 0 to approximately 3 cm. In order to eliminate zones of nonuniform displacement and poor resolution, data were discarded from 0 to 0.2 cm and beyond 2.5 cm. Often the data naturally ended before 2.5 (this will be discussed later); the average endpoint for all the data was 2.15 cm ± 0.33 cm.

Repeatability testing

In order to show that the results of the testing were acceptably repeatable among trials, the four groups of five readings taken at separate test times were compared using an F-test analysis of variance. This showed that there were no significant differences among any of the groups, regardless of having removed and replaced the equipment. These data are shown in Table 1.

Table 1.
Reliability.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial 1</td>
<td>26.25</td>
<td>33.53</td>
<td>28.96</td>
</tr>
<tr>
<td>Trial 2</td>
<td>30.74</td>
<td>23.84</td>
<td>28.23</td>
</tr>
<tr>
<td>Trial 3</td>
<td>23.48</td>
<td>23.65</td>
<td>28.63</td>
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<tr>
<td>Trial 4</td>
<td>25.96</td>
<td>22.08</td>
<td>31.88</td>
</tr>
<tr>
<td>Trial 5</td>
<td>29.33</td>
<td>18.55</td>
<td>33.42</td>
</tr>
<tr>
<td>Average</td>
<td>27.15</td>
<td>24.33</td>
<td>30.22</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>2.89</td>
<td>5.57</td>
<td>2.30</td>
</tr>
</tbody>
</table>

Amputee testing

Differences in moduli at various locations were determined and are presented in Table 2.

Weighted modulus values for the anterior, posterior, medial, and lateral areas were tested for variance, again with a standard F-test. This procedure showed there were significant differences between the groups. In order to determine which group or groups were different, a least-significant difference $t$-test for several means was performed.
Table 2. Average moduli by group.

<table>
<thead>
<tr>
<th></th>
<th>Anterior</th>
<th>Lateral</th>
<th>Posterior</th>
<th>Medial</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Data Pts.</td>
<td>7</td>
<td>8</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Average</td>
<td>57.9</td>
<td>53.2</td>
<td>141.4</td>
<td>72.3</td>
</tr>
<tr>
<td>Standard Deviation =</td>
<td>31.1</td>
<td>30.5</td>
<td>79.1</td>
<td>45.5</td>
</tr>
</tbody>
</table>

1st Curve

| No. of Data Pts. | 34 | 30 |
| Average          | 117.6 | 59.1 |
| Standard Deviation = | 63.0 | 74.0 |

2nd Curve

This test showed that the posterior modulus (mean value 141.4 kPa ± 79.1) was significantly higher than the anterior (57.9 kPa ± 31.1), and the lateral (53.2 kPa ± 30.5) values. Although it is also higher than the medial group (72.3 kPa ± 45.5), it was not significantly so.

Differences were determined for the first part of the curve, which corresponds to the superficial tissues, versus the second part of the curve, the tissue beneath. It was found that the first curve (average modulus 117.6 kPa ± 63.0) was significantly stiffer than the underlying tissue (average modulus 59.1 kPa ± 74.0).

**DISCUSSION**

**Repeatability**

The results of the repeatability tests indicate that it is reasonable to estimate the location of the last measurement for subsequent readings as long as the same approximate position is used. Refined equipment may be more sensitive to slight variations in modulus, in which case more accurate placement of the transducer will become necessary. For this test, however, the method was found to give acceptable repeatability.

**Amputee data**

One of the most striking features of the data was the high variance of each group. Because in this study no age, weight, patient condition, or other demographic distinctions were made, it is reasonable that the data would be highly varying. Despite this, the results show interesting trends. The posterior muscles were, in general, the stiffest. Although they were not significantly different from the medial readings, it is believed that this is probably due to the relatively small sample size of the test, and that further testing would probably distinguish the two groups.

The significance of this finding is difficult to assess. It is possible that the manner of walking which most amputees adopt uses the posterior muscles more than other areas. This could be useful, as prostheses change and improve, in determining which devices alter the gait the most, and which configuration is most acceptable. Is it desirable to have this outcome, or should all the muscles be used more fully? This information could also be useful to determine if a patient is learning to walk appropriately, once the desired modulus distribution has been determined. Unfortunately, it is not known whether posterior stiffness is an acquired muscle condition, or if the posterior muscles have a normally higher modulus. There have not yet been any measurements of the changes in muscle stiffness of the various locations over time (i.e., as the amputee becomes used to walking in the prosthesis). If, in fact, the higher posterior moduli were acquired after the amputation, this would be reflected in a study of modulus changes of the residual limb areas over time.

As for modulus variation throughout the depth of the tissue, the results show that the most superficial, 0.5 to 1.1 cm depth, tissue is stiffer than the tissue beneath it. The first layers of tissue are generally fatty, and those beneath are muscular. This configuration should give a lower modulus to the superficial tissue and a higher value for the muscle; the exact opposite was found. Skin has a relatively high tensile modulus, so the skin's confining effect on the upper tissue levels may have caused this unexpected result. This is an interesting effect, because normally a prosthesis will interact more with the superficial layers of tissue, and the behavior of the superficial layers will have a great effect on the function and fitting of the prosthesis.

Another interesting outcome in this study was that although the ultrasound monitored the motion of the tissue to a depth of 2.5 cm, most of the data were truncated before that point, regardless of the
depth of tissue in the person's residual limb. Although there was much more tissue than 2.5 cm on most patients, the data set was automatically shortened before this. The truncation point of each data set was determined by a computer algorithm which finds the point where the data no longer are reasonable. Each set decays to a certain point and then begins to increase. This increase is physically impossible and is believed to be an artifact of the collection process. It may be caused by a large inhomogeneity in the tissue, such as a boundary where muscles slip relative to each other, or where a large blood vessel is located in the measurement field. Also, in deeper tissues it is difficult to obtain a clear ultrasound signal. It may be possible that it is simply too difficult to collect good data in deeper tissues using current ultrasound equipment.

SUMMARY

The ultrasound technique for measurement of Young's modulus was found to be repeatable, and the measurement and analysis techniques were refined. Preliminary results on nine male subjects with above-knee amputation showed that the posterior muscles have the highest modulus, and the superficial tissues (first 0.5 to 1.1 cm) exhibit higher stiffness than those beneath. Further testing to include tissue changes over time, stiffness of deeper tissues, effects of demographic variables, differences among amputation causes and types, and variations due to prosthesis type or gait pattern are now possible. These results provide a basis for the development of an improved instrument that should be clinically usable to quantify tissue status and prosthetic fit.

REFERENCES