Biomechanical assessment of below-knee residual limb tissue

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ABSTRACT—In vivo indentation properties of the residual limb tissues of a group of senior subjects with below-knee (BK) amputation were measured and compared with those of nondisabled young adults. It was found that differences attributable to site variations, states of muscular activity, and the differences between the nondisabled young group and the group consisting of the seniors with amputation were all noted to be highly significant statistically. However, paired comparison between the residual limb and the sound contralateral limb of the senior group showed no significant difference. Residual limb properties measured right before the first prosthetic measurements and fittings and those measured at the first outpatient follow-up were found to be slightly different.

Key words: below-knee residual limb, biomaterials, biomechanics, indentation, prosthetic socket design

INTRODUCTION

The term “residual limb tissues” is used to describe the soft tissues around the residual skeletal element of the amputated limb. The exact anatomical characteristics depend on the sites around the residual limb and the particular surgical procedure followed during residual limb configuration (1). The soft tissue layer consists of the epidermis, the dermis, the hypodermal tissues (including possibly the adipose tissue), and the underlying muscle fasciae (2). Given the lack of an adequate long-term method for direct fixation of the prosthesis percutaneously to the skeletal system, current prosthetic technology demands that the entire load transfer between the skeletal component and the prosthesis occur via the residual limb tissues in contact with the prosthetic socket and the other suspension elements. Thus, the comfortable control of the prosthesis by the subject with amputation requires careful attention on the part of the clinical team to this interfacing layer of tissues.

Residual limb evaluation is an important step in the process of prosthesis design and fabrication. In addition to dimensional measurements, the biomechanical properties of the residual limb tissues are important factors in deciding how much volume reduction/addition should be made in a prosthetic socket, and how much internal stress might be generated within the residual limb tissues. Traditionally, in most prosthetics clinics, prosthetists assess the “mechanical integrity” of residual limb tissue by feeling the firmness of the tissue with their fingers by pushing on the skin. Such subjective assessments, which can significantly affect the efficiency of the prosthetic service, require substantial experience acquired through trial and error. The qualitative nature of such expert knowledge has also made the transfer of this expertise slow and imprecise. New breakthroughs and advances in prosthetic technology require a systematic accumulation of professional experiences quantitatively documented to fa-
cilitate intelligible discussions on why certain design features with some particular sets of design parameters would work for some groups of clients with certain dimensional, biomechanical, and functional measurements. With the introduction of computer-aided design and computer-aided manufacturing (CAD/CAM) technology to the delivery of prosthetic sockets, quantitative information about residual limb tissue firmness could be efficiently and meaningfully integrated into the design system and used in the rational design process.

A number of investigators have reported on the biomechanical behaviors of skin tissues on bony substratum (3-15). Oomens et al. (7) performed in vitro indentations on layers of porcine skin and fat bonded to a perspex plate. The creeps in the displacement responses after step loadings were measured for oblong and flat-ended indentors. For 15-mm-thick layers subjected to a flat-ended indentation of 20 × 40 mm² under the action of an 8 N step load, steady-state responses apparently may be reached within 10 minutes.

Schock et al. (11) quoted from Roth et al. (9) some previously unpublished results of unconfined compressive experiments on porcine skin, fat, and muscle tissues. Those results suggested that, in the context of isotropic elasticity, the Poisson’s ratios for these tissues were quite low. Their values were substantially lower than some previous expectations that skin and the subcutaneous tissues are relatively incompressible and might have a Poisson’s ratio close to 0.5 (16). It should be emphasized, however, that because skin and muscle tissue properties are generally anisotropic the above implications cannot be accepted without reservations.

Ziegert and Lewis (15) measured in humans the in vivo indentation properties of the very thin layer of soft tissue covering the anterior-medial tibia. By applying a preload of 22.4 N for 5 minutes using indentors (6 mm or 25 mm in diameter), the subsequent load-displacement relationship was observed to be essentially linearly elastic. Site variations up to 70 percent and individual variations up to 300 percent were noted. The stiffness measured for a given load applied after a short time period was about 20 percent higher than that for the equivalent quasi-static test.

Lanir et al. (5) measured the in vivo indentation properties of human forehead skin by using average pressures of 0-5 kPa. With such low pressures, the stiffness was noted to increase linearly with the applied pressure.

Sacks et al. (10) studied the in vivo indentation property of the soft tissue covering the lateral aspect of human femoral trochanters. The reported results on four subjects suggested that there were no distinct differences between the two nondisabled subjects and the two subjects with paraplegia. Nevertheless, the apparent indentation stiffness seemed to increase with age. It was not clear, however, whether there were any significant differences in the tissue thickness among these subjects.

Reger et al. (8) used magnetic resonance imaging to study in vivo deformations of the tissues covering the ischium of supine human subjects. Corresponding pressures on the epidermal surfaces were measured by interface pressure sensors. The average stiffness of the skin and fat layer was noted to be higher than that of the muscle and also apparently higher for the nondisabled subjects than for the subjects with paraplegia. The thicknesses of the soft tissue layers for the nondisabled subjects were also noted to be consistently greater than the corresponding values for the subjects with paraplegia.

Bader and Bowker (3) studied the in vivo indentation properties of the soft tissues on human forearms and thighs. Age dependence and sex dependence were discussed. There was significant difference between results from the thighs and those from the forearms. Apparently, no significant differences were noted, however, between sexes or between the young and senior female tissues when the other variables were controlled (3).

Vannah and Childress (14) measured the in vivo indentation properties of calf tissue of the legs of nondisabled persons and remarked that most stress relaxation apparently took place within 1 second of the applied indentation and that they did not observe the usual preconditioning phenomena associated with mechanical testing of many other biological tissues. Furthermore, their results did not demonstrate any distinct and consistent stiffening effects caused by muscular activities.

Only recently have there been literature reports on the biomechanical characterization of residual limb tissue by the use of objective quantitative techniques. Steege et al. (12) estimated the biomechanical properties of the below-knee (BK) residual limb tissues at stance by using a combination of indentation tests and finite element analyses.
They reported a Young's modulus of approximately 60 kPa and assumed the Poisson's ratio to be 0.49. Torres-Moreno et al. (13) reported their indentation experiments on three subjects with above-knee (AK) amputation. They suggested that the biomechanical properties of the residual limb tissues were significantly nonlinear, site-dependent, and rate-sensitive, and could be influenced by muscular activities. The residual limbs were tested in situ within the quadrilateral sockets, and the indentations were performed at specific ports through the socket wall. Thus, the material constants that Torres-Moreno extracted from the experimental data with the use of the elastic solution described in Timoshenko and Goodier (17) would reflect not only the material properties of the tissues but would also include the effects of the boundary conditions.

Among the various biomechanical testing protocols, indentation is one of the most popular methods used to assess the material behaviors of the skin and subcutaneous tissues. The experimental set up for indentation is relatively simple and straightforward. Also, the results are easily interpreted by the prosthetists. The test itself very much resembles the prosthetists' intuitive "push and feel" way of residual limb assessment. The load-displacement curve obtained during indentation provides an assessment of the biomechanical properties of the entire tissue layer as an integral part of the constituting nonhomogeneous tissue layers beneath the indentor. Instead of using the surface displacement immediately under the indentor as a measure of deformation, a more direct measurement of the change of overall tissue thickness under loading has also been attempted by using ultrasound reflection (18). Truong (19) and Levinson (20) used ultrasound to measure the \textit{in vitro} viscoelastic and the anisotropic properties of skeletal muscles, respectively. Krouskop and his colleagues were the first to apply Doppler ultrasound techniques to measure the \textit{in vivo} point-to-point biomechanical property of AK residual limb tissues of subjects with amputation (4,6). Agreements with mechanical tests were claimed to be within 7 percent (4). Tests on the forearms and legs of six volunteers suggested that the computed elastic moduli strongly depended on the contraction status of the underlying musculatures. A 16-fold increase in the modulus was reported at 10 percent strain level with maximal muscle contraction.

Malinauskas et al. (6) used the same technique to measure the mechanical properties of the residual limb tissues of nine subjects with AK amputation and reported that the average posterior moduli were significantly higher than those at other areas and that superficial tissues apparently were stiffer than the deeper tissues. They noted differences of up to two- to threefold.

It is apparent from the above literature review that there is indeed a strong need for objective, quantitative information on the biomechanical properties of residual limb tissue. There is an even greater need for data about BK residual limbs. The effects of muscle contraction on such properties are still somewhat unclear, so further systematic investigations must be undertaken.

The objectives of this paper are 1) to measure the biomechanical properties of the soft tissues at the pressure-tolerant sites around the proximal tibia; 2) to examine the site-dependence of these biomechanical properties; 3) to assess the change in these biomechanical responses caused by underlying muscular activities; 4) to compare these biomechanical properties between nondisabled young adults and senior subjects with BK amputation; and 5) to determine the changes in these biomechanical properties of the subjects with amputation at their first clinical follow-up visits within 6 months after hospital discharge with their prostheses.

**MATERIALS AND METHODS**

An indentation apparatus was designed and built to measure the indentation behavior of soft tissue at a number of pressure tolerant areas. A flat-ended cylindrical indentor (4 mm in diameter) in series with a 2-kg load transducer was driven by a stepping motor (Figures 1a and 1b). The whole indentation unit was mounted on two magnetic stands with adjustable joints so that the indentor could be aligned perpendicularly to the skin surface (Figure 1b). The speed and the excursion were controlled by a laptop microcomputer. Both the indentation displacement and the corresponding force were monitored and recorded with the same laptop microcomputer for further data analysis. The speed of indentation was \( \approx 4 \) mm/sec. The fixed indentation was maintained for 2-3 seconds to
Figure 1a.  
Schematic illustration of the indentation apparatus.

Figure 1b.  
The indentation apparatus: a 2-kg load cell connected in series with a stepping motor. The flexible holding jig on both sides allows the manual alignment of the indenter perpendicular to the skin surface. The hinged wooden platform can be positioned to support the limb segment with the knee at 20° flexion.

Figure 2a.  
Sites for indentation around the proximal tibia (X’s).

Figure 2b.  
Indentation sites on the patella tendon and the lateral side of the lower leg between the fibula and tibia of an nondisabled subject (X’s).

2c). Tissue preconditioning was achieved with three consecutive trial tests. The final indentation was ~5 mm for the medial and lateral sites and ~3 mm at the patella tendon area. At each location, the test was carried out first with an instruction for the

observe the subsequent stress relaxation. On the proximal tibia, there are three sites regarded by prosthetists as pressure tolerant areas where socket volume reductions could be introduced. Namely, they are the patella tendon area below the patella, the lateral side between tibia and fibula, and the medial side away from the tibia (Figures 2a, 2b, and
subjects to relax the associated muscles and then repeated with an instruction for the subjects to co-contract their muscles isometrically. Repeatability of the results was checked by performing the same test at least five times at the same site. All tests were done with the limb segment supported on a wooden platform and with the knee at 20° flexion (Figure 3).

Six nondisabled male subjects between the ages of 25 and 35 (mean = 28.3, S.D. = 3.6) were tested. A total of eight senior subjects with BK amputation (2 male, 6 female) between the ages of 57 and 78 (mean = 68.8, S.D. = 7.5) were tested at a rehabilitation ward after (a) their amputation wounds had healed, (b) the initial edema had subsided, and (c) the patients were ready for prosthetic measurement and fittings. The subjects with amputation went through the identical testing protocol as the nondisabled subjects. The same series of tests were again performed on each of the subjects with amputation as they returned for their first follow-up visits, which ranged from 3 to 6 months after they had been discharged from the rehabilitation ward with their BK prostheses.

The biomechanical moduli of the soft tissues measured initially in the ramp period (E_in) and those measured later as the load-displacement curves approached steady-state (E_eq) were obtained from the data by using the mathematical expression developed by Hayes et al. (21) for a rigid, frictionless plane-ended indentor indenting on the top surface of a laterally unconstrained infinite layer with the base bonded to a rigidly fixed foundation:

\[ E = \frac{P(1 - \nu^2)}{2awx(a/h, \nu)} \]  

where \( E \) is the modulus of elasticity; the layer was assumed to be homogeneous, isotropic, and linearly elastic; \( a \) is the radius of the flat-ended indentor tip; \( w \) is the indentation displacement; \( P \) is the corresponding force applied to the indentor; \( \nu \) is the Poisson’s ratio; \( h \) is the thickness of the tissue layer; \( a/h \) is the aspect ratio; and \( k \) is the geometric scaling function, which depends on the aspect ratio and the
Poisson’s ratio. The aspect ratio of the indentor radius to the tissue thickness was noted to be small enough that an infinite half-space solution could be assumed with the function $\kappa$ approaching one in such a limiting case (17). An ultrasound thickness meter was used to estimate the tissue thickness to ensure that the above assumption was correct. To obtain the initial modulus $E_{in}$, a Poisson’s ratio of 0.5 was assumed to simulate the initial apparent incompressibility condition of the tissue as a whole. To estimate the steady-state modulus $E_{eq}$, equation [1] was used with the corresponding Poisson’s ratio taken to be 0.45. The possibility that soft tissues might have a Poisson’s ratio lower than 0.4 has been suggested by some authors (7,22,23). The effects of this assumption will be discussed below.

RESULTS

A typical load transient in response to the ramp-plateau indentation of the residual limb tissue surface is given in Figure 4. A stress overshoot phenomenon indicative of tissue viscoelasticity was observed, and it peaked at the turn from the ramp to the plateau phase. The subsequent stress relaxation was noted to be rather fast. Curve fitting the relaxation data with an empirical exponential decay function suggested that over 90 percent of the relaxation was completed within 2 seconds after the start of the plateau phase. The secant slope of the middle 80 percent of the ramp response was used to determine $E_{in}$ by using equation [1]. The average of the last 50 data samples of the plateau period (~0.1 sec) was used to estimate the steady-state modulus $E_{eq}$ from equation [1]. To determine $E_{in}$ and $E_{eq}$ at each location for each subject, data that were more than one standard deviation from the mean of all the measurements obtained in that particular series of repeated testings on the given subject were discarded. The mean and the standard deviation were then updated. This procedure was performed to screen out significantly variant results caused by possible subject noncompliance, indentor misalignment, or limb positioning.

The initial moduli and the steady-state moduli obtained for the various sites around the proximal tibia for the nondisabled subjects are given in Table 1. Although group-t comparisons did not demonstrate significant difference between $E_{in}$ and $E_{eq}$ at the 0.05 level, pair-t tests did show that $E_{in}$ was significantly higher than $E_{eq}$ at 0.005 level for the sites on the medial and lateral sides, and at 0.01 level for the patella tendon areas. Table 1 also demonstrates the site dependence of the moduli at the initial and steady states. In general, the lateral tissues between the tibia and fibula were stiffer than those on the medial side. The difference was noted to be highly significant at the 0.001 level by pair-t comparisons. With the knee at 20° flexion, the indentation stiffness at the patella tendon areas was lower than that for the tissues on either sides. Such difference was again very significant ($p<0.001$) by pair-t comparisons.

Table 2 shows the influences of the isometric co-contraction of underlying muscles around the

### Table 1.
Mean and standard deviation of the computed elastic moduli for relaxed tissues at various sites for the 6 nondisabled subjects.

<table>
<thead>
<tr>
<th>Sites</th>
<th>Elastic moduli at steady state ($E_{eq}$)</th>
<th>Elastic moduli at initial state ($E_{in}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (kPa)</td>
<td>SD/ Mean</td>
</tr>
<tr>
<td>Medial</td>
<td>99.8</td>
<td>9.2%</td>
</tr>
<tr>
<td>Lateral</td>
<td>130.1</td>
<td>6.1%</td>
</tr>
<tr>
<td>Patella tendon</td>
<td>20.9</td>
<td>8.5%</td>
</tr>
</tbody>
</table>

kPa = 1000 N/m²
SD = standard deviation
Table 2.
Variation of the computed elastic moduli due to muscle contractions at various sites for the 6 nondisabled subjects.

<table>
<thead>
<tr>
<th>Elastic Moduli</th>
<th>Relaxed State</th>
<th>Contracted State</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (kPa)</td>
<td>SD/Mean</td>
<td>Mean (kPa)</td>
</tr>
<tr>
<td>Medial sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$E_{eq}$ (kPa)</td>
<td>99.8 (9.2%)</td>
<td></td>
<td>142.9 (11.7%)</td>
</tr>
<tr>
<td>$E_{in}$ (kPa)</td>
<td>102.6 (8.4%)</td>
<td></td>
<td>147.3 (10.7%)</td>
</tr>
<tr>
<td>Lateral sites between tibia and fibula</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$E_{eq}$ (kPa)</td>
<td>130.1 (6.1%)</td>
<td></td>
<td>188.4 (12.2%)</td>
</tr>
<tr>
<td>$E_{in}$ (kPa)</td>
<td>132.9 (5.4%)</td>
<td></td>
<td>194.3 (12.7%)</td>
</tr>
</tbody>
</table>

kPa = 1000 N/m$^2$
SD = standard deviation

Table 3.
Mean and standard deviation of the computed steady-state elastic moduli of relaxed below-knee residual limb tissue at the three locations around the proximal tibia.

<table>
<thead>
<tr>
<th></th>
<th>Medial Side</th>
<th>Lateral Side between Tibia/Fibula</th>
<th>Patella Tendon Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amputees</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (kPa)</td>
<td>55.9</td>
<td>77.9</td>
<td>29.1</td>
</tr>
<tr>
<td>SD (% Mean)</td>
<td>8.6%</td>
<td>12.8%</td>
<td>17.0%</td>
</tr>
<tr>
<td>Nondisabled Subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (kPa)</td>
<td>99.8</td>
<td>130.1</td>
<td>20.9</td>
</tr>
<tr>
<td>SD (% Mean)</td>
<td>9.2%</td>
<td>6.1%</td>
<td>8.5%</td>
</tr>
</tbody>
</table>

BK = below knee
kPa = 1000 N/m$^2$
SD = standard deviation
Data on nondisabled subjects are included for comparison.

knee joint. It can be seen that muscle contractions could increase the indentation stiffness of the tissues on the medial and the lateral sites by approximately 45 percent. The differences were highly significant ($p<0.005$) by group-t tests.

Figure 4 also shows a typical load transient for the indentation experiment on the senior BK residual limb tissues. For the senior residual limb tissues, the force peak was almost 20 percent higher than the steady-state value, whereas for the nondisabled cases, the corresponding increase was about 10 percent. Explanation of this interesting difference would demand a systematic histological comparison of the senior residual limb tissues with the younger tissues.

Table 3 presents the means and standard deviations of the computed steady-state moduli of relaxed BK residual limb tissues at the test sites around the proximal tibia. It is important to note that while the lateral side was still shown to be stiffer than the medial side and that the patella tendon area was still the most compliant given the knee resting at 20° flexion on the support, the stiffness of the senior residual limb tissues was in general only 55–60 percent than that of the younger tissues. The differences were again highly significant by group-t tests ($p<0.001$).

Table 4 shows the changes in the computed elastic moduli due to co-contractions of the underlying muscles within the senior BK residual limbs. It is important to note that compared with the 45 percent increase in stiffness caused by muscle contractions in younger subjects, residual limb tissues for the senior subjects with BK amputation only stiffened up by approximately 20 percent when the underlying muscles were contracted. The stiffening effects were lower for the lateral residual limb tissues than for the medial sides, whereas for the younger tissues,
Table 4.
Changes in the computed elastic moduli due to muscle contractions of below-knee residual limbs.

<table>
<thead>
<tr>
<th>Elastic Moduli</th>
<th>Relaxed State</th>
<th>Contracted State</th>
<th>% Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medial side</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steady-state E&lt;sub&gt;eq&lt;/sub&gt; (kPa)</td>
<td>55.9</td>
<td>69.4</td>
<td>24%</td>
</tr>
<tr>
<td>Initial E&lt;sub&gt;in&lt;/sub&gt; (kPa)</td>
<td>64.4</td>
<td>80.8</td>
<td>25%</td>
</tr>
<tr>
<td>(SD within 10%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lateral side between Tibia/Fibula</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steady-state E&lt;sub&gt;eq&lt;/sub&gt; (kPa)</td>
<td>77.9</td>
<td>87.6</td>
<td>12%</td>
</tr>
<tr>
<td>Initial E&lt;sub&gt;in&lt;/sub&gt; (kPa)</td>
<td>90.4</td>
<td>101.1</td>
<td>12%</td>
</tr>
<tr>
<td>(SD within 20%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

kPa = 1000 N/m<sup>2</sup>
SD = standard deviation

The percentage increases in the moduli were roughly similar for the medial and lateral tissues. The biological reasons for the differences of such stiffening effects need to be studied further.

Table 5 presents the changes in the computed elastic moduli. Measurements were taken before prosthetic fitting (approximately 3 months post-amputation) and at the first follow-up visit (within 6 months after discharge). Generally speaking, there were some increases in the stiffness with time after amputation both for the initial moduli and the steady-state moduli, and both for the moduli measured with no instructed for muscle contractions and also the ones measured with instructed muscle contractions. These increases were quite small; particularly so for the measurements at the patella tendon. Group-t tests, however, did not demonstrate significance for the above differences. Nevertheless, pair-t comparison between the measurements at these two separate instances did demonstrate significance at the 0.005 level.

**DISCUSSION AND CONCLUSIONS**

The indentation method was proven to be a useful tool for the objective quantitative biomechanical assessments of residual limb tissues. The method for indentor alignment and limb positioning seemed to be reasonably adequate. In general, the results obtained in this study agreed well with other previous reports (4,6,14). Differences caused by site variations, states of muscular activity, nondisabled or subjects with amputation, and time after amputation were all noted to be statistically significant with low p values.

Krouskop et al. (4) reported a range of computed elastic moduli from 6.2 to 109 kPa, depending on the muscular contraction state, for the soft tissues in the forearms or legs of six volunteer subjects. It was not clear whether the tissues tested were all residual limb tissues of subjects with amputation. The average age of the volunteer subjects and the exact test sites also were not given. The initial- and equilibrium-computed elastic moduli obtained in the present study cover a range from 21 to as high as 195 kPa, depending on the test site, the muscular contraction state, and other factors such as age. If the data measured at the patella tendon areas were excluded, the moduli measured on the medial and lateral sides of the lower legs ranged from 56 to 195 kPa. The computed elastic moduli for AK residual limb tissues measured at various sites by Malinauskas et al. (6), showed values from 53 to 141 kPa, a range very close to what was observed in this study.

The site dependence observed by Malinauskas et al. (6) for AK residual limb tissues showed that
Table 5.
Mean and standard deviation of the computed elastic moduli at the three locations around the below-knee residual limbs.

<table>
<thead>
<tr>
<th>Location</th>
<th>Time after Amputation</th>
<th>Soft Tissues at Relaxed state</th>
<th>Soft Tissues at Contracted state</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3 weeks* Mean (SD) kPa</td>
<td>6 months** Mean (SD) kPa</td>
</tr>
<tr>
<td></td>
<td></td>
<td>kPa</td>
<td>kPa</td>
</tr>
<tr>
<td>Medial Side</td>
<td>E_{eq}</td>
<td>55.9 (8.6%)</td>
<td>61.5 (7.7%)</td>
</tr>
<tr>
<td></td>
<td>E_{in}</td>
<td>64.4 (9.9%)</td>
<td>68.1 (10.0%)</td>
</tr>
<tr>
<td>Lateral Side</td>
<td>E_{eq}</td>
<td>77.9 (12.8%)</td>
<td>81.6 (13.1%)</td>
</tr>
<tr>
<td></td>
<td>E_{in}</td>
<td>90.4 (12.4%)</td>
<td>93.5 (12.4%)</td>
</tr>
<tr>
<td>Between Tibia/Fibula</td>
<td>E_{eq}</td>
<td>29.1 (17.0%)</td>
<td>29.8 (16.7%)</td>
</tr>
<tr>
<td></td>
<td>E_{in}</td>
<td>30.6 (14.3%)</td>
<td>31.7 (13.7%)</td>
</tr>
</tbody>
</table>

SD = standard deviation
kPa = 1000 N/m²
*Measured before prosthetic fitting (~3 weeks postamputation)
**Measured at first follow-up (~6 months postamputation)

the posterior modulus was significantly higher than the anterior and lateral values. The difference between the posterior and the lateral moduli was as high as 66 percent. Results from the present study on the lower leg also showed significantly stiffer tissues on the lateral aspect than on the medial side. However, such difference was noted to be approximately 30 percent for nondisabled subjects and approximately 40 percent for the senior subjects with BK amputation.

The residual limb tissues became stiffer when tested at approximately 3 to 6 months after the subject was discharged from the hospital with a temporary prosthesis. It is not clear from this study whether the changes in the biomechanical properties were due to the biomechanical interactions of the residual limb with the prosthesis or simply due to a natural course of further tissue reconfiguration post-amputation regardless of whether the residual limb was loaded. Further investigation along this direction would be necessary to answer this question.

The dependence of the measured moduli on the muscle contraction state reported by Krouskop et al. (4) showed a 17-fold increase in the modulus for muscles under maximal contraction from those measured with the muscle relaxed. The results obtained in the present study showed that muscular activities did increase the computed elastic moduli measured by indentation. However, such an increase was noted to be about 45 percent for the nondisabled young subjects and about 12 to 24 percent for the senior subjects with BK amputation. The level of muscle activities was not quantified in the present study, which may explain the difficulty in comparing the present results with those of Krouskop et al. Another reason for a smaller increase observed in the present study could be that the elastic modulus obtained by indentation represents an effective modulus averaged over the entire tissue thickness, whereas the ultrasound technique developed by Krouskop et al., was designed to assess only a point-wise modulus. The local increase in the muscle modulus due to contraction, when averaged with other noncontractive tissue layers, could lead to a lower effective modulus measured by indentation.

The differences in the biomechanical properties between the nondisabled young subjects and the senior subjects with amputation were noted not only in the values for the moduli but also in the percentage of stiffening effects caused by the contractions of the underlying muscles. It is important to note that there was a distinct age difference between the nondisabled group and the group with amputation. A supplementary follow-up study on the indentation properties of the soft tissues around the proximal tibia of both the sound and the amputated limbs of unilateral subjects with BK amputation with a mean age of 68.8 (S.D. = 7.5) and
using the same apparatus indicated that there were no statistically significant differences between the sound limb and the residual limb by the paired-t test at the 0.05 level. This finding suggested that the differences measured between the nondisabled young subjects and the senior subjects with amputation could very well be primarily attributable to age. A follow-up age-matched study on nonamputees would be useful to confirm such a contention. Other factors, such as gender and body weight, could also be controlled in the future studies.

The tissue biomechanical responses were noted to be viscoelastic in general and nonlinear particularly during the initial load response. These conclusions were supported by the evidence of the stress overshoots and by the slightly concave shape of the load response curves in the ramp phase. Data reductions using the linearly elastic solution of Hayes et al. (21), were done with the expectation that the moduli so obtained would then be time dependent and displacement dependent as reflected by the difference in the moduli measured initially and at equilibrium. A more thorough investigation on such nonlinear viscoelastic analysis, including nonlinear material properties and nonlinear deformation measures, should be pursued in the future.

It should be noted that because equation [1] assumes a homogeneous infinite layer, the elastic modulus obtained in the present study should be interpreted as an effective elastic modulus, incorporating the average effects of various tissue sublayers, namely the epidermis, dermis, and muscle, as well as the possible effects of additional lateral constraints due to the presence of the tibia and fibula. Such an effective modulus would be especially useful clinically, giving an objective and quantitative assessment of the overall biomechanical property of the tissues at that particular site. This information could be useful to the prosthetists in deciding how much socket volume reduction could be introduced at that site.

In the use of Hayes' elastic solution, the Poisson's ratio was taken to be 0.45 to estimate the corresponding steady-state elastic modulus $E_{eq}$. The effect of such an assumption on the results was easier to follow if the aspect ratio $a/h$ was small enough, in which case the geometric correction function $\kappa$ in equation [1] would tend to unity, leaving a simple and explicit dependence of the modulus $E$ on the Poisson's ratio $\nu$ in the form of $(1 - \nu^2)$. If the Poisson's ratio were 0.3 instead of 0.45, the $E_{eq}$ obtained would be 14 percent higher. For the determination of the initial modulus $E_{in}$, the assumption of incompressibility was made (i.e., $\nu$ was taken as 0.5) based on the fact that the tissue together with its large water content would behave overall as an incompressible elastic material because initially the tissue fluid would not have had the time to move within the tissue. This assumption was consistent with the interpretation of the indentation results using the modern biphasic poroelastic theories (7,24). Most other investigators in the residual limb tissue assessments have made similar assumptions of a constant Poisson's ratio. However, the assumption of a constant Poisson's ratio for various sites, states of muscular activity, for both normal and residual limb tissues, and for both young and old tissues was rather a bold one, because it is likely that the Poisson's ratio might also be different in each of the situations listed. Ideally, measuring the Poisson's ratio (or equivalently an additional elastic constant, such as the shear modulus) together with the elastic constant $E$ should best be done in another independent experiment. Although technically possible, it might have made the assessment time for the entire testing protocol too long to be logistically feasible in this preliminary research program. The information on the force-indentation relationships collected in this study, however, has provided an adequate assessment of the "firmness" of the residual limb tissues in a manner that was objective, quantitative, and immediately relevant to current prosthetic practices.

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