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A method of residual limb stiffness distribution measurement

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Abstract — A method of recording a residual limb indentation stiffness map was developed for possible use as an aid in calculating prosthetic socket rectifications. The method was tested to determine the level of repeatability attainable. A hand-held, pencil-like device was used, with an air-driven piston that indented the tissue 10 times per second. The indentor tip contained an electromagnetic digitizer element that sensed position and orientation 120 times per second. The examiner moved the device around the limb; sampling was variable in density, and typically concentrated on critical areas. An interactive visual display of sampled data quality was used to guide sampling. The indentation maps typically contained ~4,000 locations, in a cylindrical coordinate system, with sampling locations spaced every 3.2 mm vertically, and every 0.087 radians tangentially. The behavior of the system was characterized using six test subjects on whom recorded indentations ranged from 1.5 to 21 mm. The largest range of indentations (i.e., worst disagreement) recorded at a single location was 5.4 mm. The average standard deviation on repeated measurement ranged from 7 to 15%, and averaged 0.67 mm in absolute terms. Many of the structurally significant anatomical features of the limbs were visible, including the patella and patellar tendon, fibular head, shin, biceps femoris tendon, semitendinosus, and popliteal area.

Key words: *artificial limbs, computer-aided design, indentor tests, orthosis, prosthesis, soft tissue stiffness.*

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INTRODUCTION

Current methods of computer-aided design (CAD) for prosthetic sockets begin by measuring the shape of the residual limb. A template of standard rectifications (alterations to the socket shape to improve fit) is then retrieved from computer memory and applied to the shape. The prosthetist can accept the rectified shape as is, or further modify it, based on observations about the particular individual. These custom modifications aside, the main input to the CAD process is the shape of the residuum. Numerous investigators have suggested that the results might be improved if data relating to the stiffness of the residual limb were used as an input to the process as well (1-4). This report describes a system for measuring the stiffness distribution of residual limbs.

The stiffnesses of soft tissues under contact loads have often been measured by an indentor test (5-15), in which an instrumented probe is pressed into the tissue, and the indentation force and corresponding depth of indentation are recorded. Softer tissues indent further for a given applied force.

Some investigators have used arrays of indentors (loosely resembling a bed of spring-loaded nails), so that all indentations occur at one point in time (12,14,16). Taking all the data simultaneously minimizes the effect of subject motion. These indentor arrays have most commonly been used in the design of footware and seating, where the shape of the orthosis or seating surface lends itself to this approach. However, note that adjacent indentors may interfere with one another's measurements. For instance, due to the manner in which tissues displace under loading, some indentors may actually travel out rather than in. This is a consideration only if one wants to record a stiffness map with the indentor array. The fact that arrays can be useful in directly calculating custom seating shapes has already been demonstrated (12,14,16).

Indentor arrays have not been used in socket design, perhaps because sockets surround the limb in such a way that a suitable array would be difficult to design. Stiffness measurements of residua have commonly used single indentors employed at various sites around the limb (6,9,10,15,17,18). The number of sites tested has typically been small: six (18), five (15), and four (7). Testing at more locations results in higher resolution of the indentation stiffness map.

Various indentation rates have been used, from quasistatic (11) to oscillations of eight cycles per second (6). During testing, the subject may move relative to the measurement coordinate system, altering the measured indentation: faster indentation rates minimize the effects of this motion.

Ideally, indentation testing should be rapid and sample many locations, in order to produce a repeatable, high-resolution limb stiffness map. A method designed with these objectives in mind was developed and tested with the ultimate aim of using these stiffness maps to calculate socket rectifications in prosthetic socket CAD/CAM systems. The objective of the testing was to determine the level of repeatability attainable with the current system.

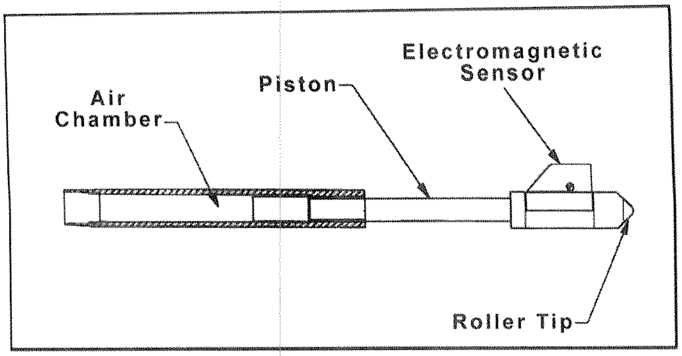

Figure 1.
The air-driven, oscillating indentor used to measure tissue stiffness. The handle acts as an air chamber to the inserted shaft; an oscillating pressure air source connected to the handle by a flexible rubber hose varied the pressure, at 10 Hz, between 0 and 20 psi (1.36 bar). An electromagnetic sensor recorded the position of the tip of the indentor at 120 Hz.

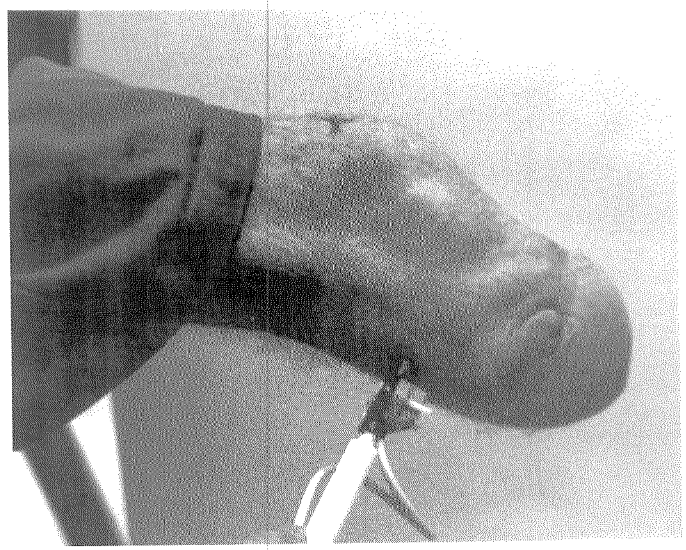

Figure 2.
The hand-held indentor, while oscillating 10 times per s, is slowly moved across the limb. The distal limb restraint device was removed from the photograph for clarity.

METHODS

Equipment

Indentor

An oscillating, air-driven indentor (**Figures 1** and **2**) was used to measure tissue stiffness. This pencil-like device was hand-held, and its electromagnetic sensor (Fastrack; Polhemus, Inc.; Colchester, VT) measured position and orientation 120 times per s. All selectable filtering options of the Fastrack instrument were turned off. The sensor was mounted in a fixed geometric relationship to the 7.94 mm roller ball tip; therefore, the position of the tip could be calculated from the geometry and the measured sensor position and orientation. The static accuracy of the sensor in this application was observed to be 0.13 mm RMS (19). The shaft was inserted into a handle that acted as an air chamber. An oscillating pressure air source was connected to the handle by a flexible rubber hose. The pressure was varied, at 10 Hz, between 0 and 0.68 bar (10 psi), as measured at the inlet to the hose. The indentor was held so that indentation was normal to the surface of the skin. When pressed against the soft tissues, the tip cyclically indented, with the amplitude of indentation varying as a function of tissue stiffness.

Computer Software

The indentor position data were processed using a 75-MHz Pentium-based computer. A cylindrical coordinate system was established by digitizing three points on the limb. The surface area of the residuum was divided into small compartments (in software), each compartment being 3.2-mm high and 0.087 radians (5.0°) in arc. Coarser resolutions risk losing significant features of the limb shape (20).

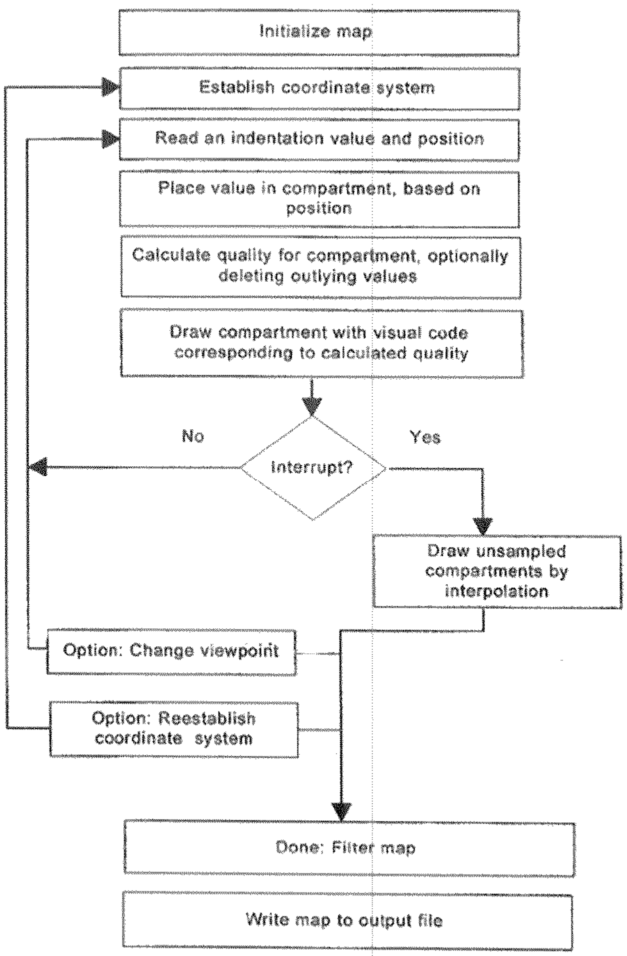

Figure 3.
Control flowchart for software. The method generates a color-coded image of the limb, as it is being digitized, on a computer monitor. The color code indicates the quality of the data existing in each area of the image. This quality is a function of the number of samples in that area, and the SD of those samples. By being aware of the quality of sampling in each area, the operator can sample further in areas of poor quality, or in the more critical areas.

Because the indentor tip cycled at 10 Hz, while its position was read at 120 Hz, 12 data points described the path of each indentation. The indentation amplitude was extracted from these 12 points. The indentor was moved about the limb, sampling in various areas as the operator saw fit. Sampling density was allowed to vary; that is, compartments of the map could contain zero, one, or many valid indentation measurements, depending on how often the operator sampled in that area. The average and standard deviation (SD) of the data (i.e., indentation depths) in each compartment were calculated in real time. As sampling continued, an image of the limb was drawn on an adjacent computer screen, color-coded to represent the quality of the data recorded in each compartment. The quality code was a function of the number of valid indentations recorded for that compartment, the SD of those indentations, and other factors (19). This visual display provided feedback to guide the operator in positioning the digitizer (**Figure 3**). In general, areas of the limb that were more important in terms of fit were sampled until the quality code was uniformly high in that area. Areas of low importance were only sparsely sampled, relying on subsequent filtering to smooth the map, and saving time in the process. Thus, the stated sampling resolution (i.e., 3.2 mm by 0.087 radians) was only achieved in critical areas of the limb, such as the fibular head.

When sampling was complete, the stiffness map was smoothed by an averaging filter. The average stiffness in each compartment was replaced by the average of all the data in the surrounding compartments. The filtering was sampling density-weighted; that is, the amount of smoothing applied at each compartment was an inverse function of the sampling density in that compartment. This filter's performance in smoothing, versus inadvertently removing significant features of the shape, has been reported elsewhere (19,20).

Testing

The objective of the testing was to observe the repeatability attainable with the method. A convenience sample of six subjects was tested; two

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researchers (both whole-limbed, aged 28 and 41), and four persons with transtibial amputation, aged 12, 15, 17, and 20). The study was approved by an institutional review board, and informed consent was obtained from subjects and their parents/ guardians. The lower leg was tested.

The test methods followed the procedures we use in casting limbs clinically. The subject was seated, with the Fastrack transmitter, on which the root coordinate system was based, mounted to the underside of the seat. The knee was positioned at the customary 20° flexion angle, and subjects were

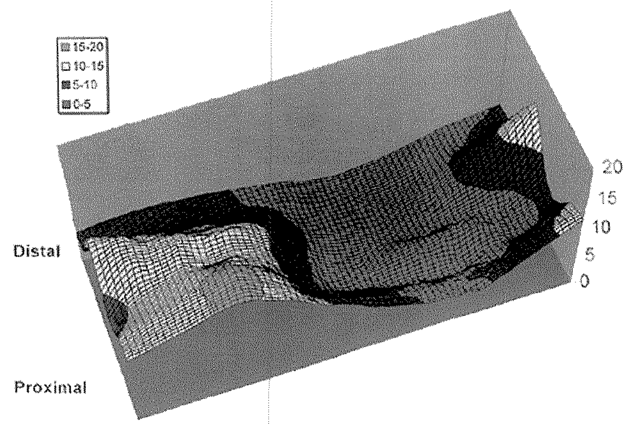

Figure 5.
A topograph for a person with transtibial amputation, similar to **Figure 4** in the anterior aspect, but showing the absence of the muscle belly of the gastrocnemius and a more evident popliteal area. Data are from a single test, rather than averaged; hence the small bumpiness of 'noise.'

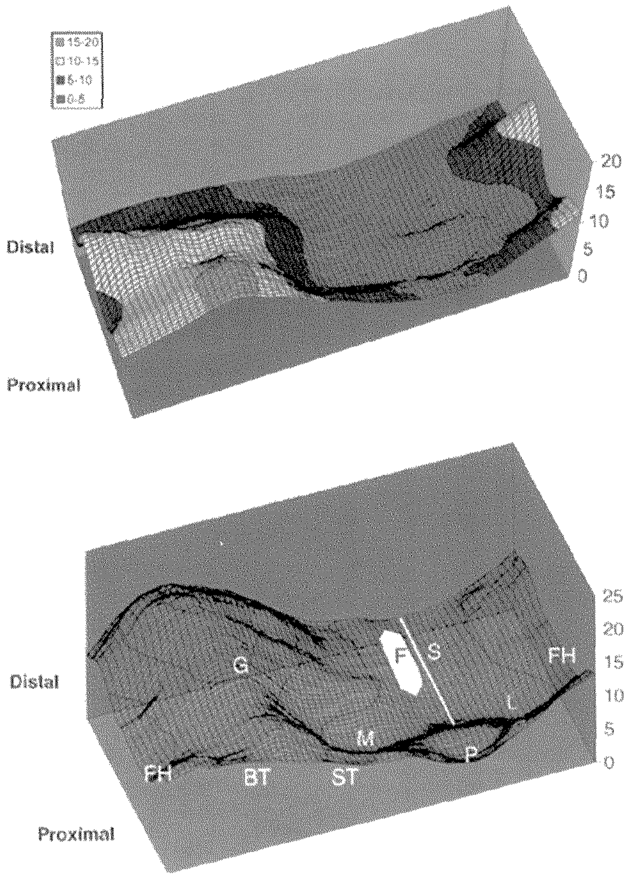

Figure 4.
A topograph for a whole-limbed subject: at top the indentation depths in mm; high areas are large indentations, low areas small ones. Bottom: the same topograph, with various anatomic features labeled. Line S=the vertical axis along the tibial crest or 'shin'; P=the patella; M and L=the medial and lateral aspects of the tibial plateau; F=the thinly padded portion of the tibia, medial to the crest; BT=biceps tendon; ST=semi tendinosus. The fibular head is split by this 2-D map, appearing in the two locations labelled FH. The highest indentations (> 20 mm) are just proximal to the split of the gastrocnemius heads, labeled G. Data from four tests are averaged to reduce noise and improve readability.

requested to relax and minimize motion of the residuum. The level of muscular activity in the residuum was not further controlled. In order to help the subjects remain motionless and to provide proprioceptive feedback as to when limb position was changing, the mid-thigh was restrained with velcro straps, and a rubber tip was adjusted so that it bore lightly on the distal end of the residuum.

The digitizer was first used to record three non-colinear points on the limb, so that successive tests could be oriented to a common coordinate system. The indentation stiffness map was recorded four times, with the sampling time for each map restricted to 10 min. Each subject was tested during a single day; that is, day-to-day variations in the stiffness map were not assessed.

RESULTS

Typical indentation maps are shown in **Figures 4** and **5**. The maps typically contain ~4,000 locations. Note that many anatomic features significant in socket rectification are visible: the patella and patellar tendon, fibular head, shin, medial and lateral aspects of the tibial plateau, the medial flare of the tibia, the biceps femoris tendon and semitendinosus, and the soft popliteal area.

The range of indentations recorded, across all subjects and tests, was from 1.5 to 21 mm. The largest range of indentations (i.e., worst disagreement) recorded at a single location was 5.41 mm; the average amplitude at that location was 8.99 mm. An average SD for the method was calculated as follows: at the completion of recording a map, each location had been assigned an indentation value (whether this value was the average of several data points falling on that location, or an interpolated value assigned from neighbors to those locations on which no data points fell). Each limb was sampled four times, generating four indentation maps. Subsequently, an SD for each compartment was calculated based on the four indentation values for that compartment. The average SD of the indentation observed, across all compartments and subjects, was 0.67 mm. If the SD at a location was expressed as a percentage of the average indentation at that location, the range was from 7-15 percent.

There was a significant amount of variation, or 'noise,' in the indentation maps. The largest differences between the four, both in absolute terms and relative to the average local indentation, were typically in areas of high indentor excursion.

Note that the effects of subject motion are limited because indentation is measured as the difference between the maximum and minimum positions of the indentor. Indentations could be incorrectly assigned to adjacent compartments if the subject changed position, but the indentations themselves were less affected, particularly because each indentation took 0.1 s. If the change in position resulted in new data different from the earlier data in those compartments, the quality of the compartments fell, causing a change in their visual feedback code. Thus, a trail of poorly colored compartments could be observed behind the indentor position, signaling the operator to stop and resample the three orientation points.

DISCUSSION

The method creates a comprehensive stiffness map, rather than sampling at a few locations, allowing a high resolution description of the residuum's stiffness. The stiffness map typically contains ~4,000 locations (although all compartments are actually sampled only in high priority areas of the limb). It has previously been shown that this level of resolution is the point of diminishing returns; that is, beyond it the benefit increment decreases as resolution increases (20). In previous methods, the number of locations tested has been limited to 6 or fewer (7,9,10,15,18). A second advantage to high resolution is that anatomic structures (for instance the fibular head) used to register rectification templates in current CAD systems can be located with precision.

The average SD observed (0.67 mm) is of the same order as the calibration resolution (1.0 mm) of first-generation CAD socket hardware (21,22). Average SDs have been observed in previous residual limb indentor tests, from repeated measures on the same subject at the same site, ranging from 12.7 percent (22) to 15 percent (21). In comparison, the present system has repeatability averaging from 7 to 15 percent. Large erroneous bumps do occur in the map from time to time. The largest range of indentations (i.e., worst disagreement) recorded at a single location in these tests was 5.4 mm. There are several possible sources of these variations. First, the operator's hand may have made unintentional movements (shaking or uneven pressure against the shape). Second, the subject's limb might have moved relative to the orienting transmitter or limb restraint device. Third, random error in the digitizing transducer itself will produce noise. Finally, the noise was significantly more pronounced at higher indentations, and appeared to be an uncontrolled oscillation of the tissue, aggravated by insufficient damping in the indentor mechanism.

The indentation stiffness maps are intended for use in calculating rectification maps (23); the data show that they can be recorded with high resolution and repeatability. Trials of algorithms for calculating a rectification map from the indentation stiffness map are currently underway, and will be described in a future report. One algorithm applies rectification equal to a fixed fraction of the indentation map, then adjusts the rectification map so that there is zero global volume change. In a sense, the algorithm treats the residuum as a bed of one-dimensional, radially directed, linear springs. While this method is simplistic, a very similar approach has been successful in custom seating (12,14,16).

The method presented does not calculate material stiffness. Other reports on tissue mechanics related to prosthetic socket fitting have calculated material stiffnesses, such as are customarily employed in engineering stress analyses (4,6,10,15,18). Examples of these traditional material descriptions are Young's modulus and Poisson's ratio for linear elastic analysis, and strain-energy function constants in nonlinear analysis. The oscillation amplitude may be significantly affected by factors aside from material stiffness. A dynamic, as opposed to static, indentation is imposed; that is, the soft tissues are in motion. Soft tissues are viscoelastic, so the measured stiffness may be partly a function of the speed of indentation. Residual lower limb tissue (15) and bulk muscular tissue (11) of the lower leg exhibit viscoelasticity with a time constant of ~1 s. Thus, a 10 Hz oscillation is within the range where viscoelastic stiffening presumably occurs. Further, a portion of the oscillation may be the well-known dynamic oscillation of a spring-mass system. Previous indentor methods have used various indentation speeds: 8 Hz oscillations (6), quasistatic indentation (18), indentation rates controlled by machine (15,10), and an indentation rate controlled by hand (9), and presumably have been likewise affected. Therefore, we cannot infer that the method allows a stress analysis-based solution where the indentation map provides material properties.

CONCLUSIONS

The method recorded a comprehensive (~4,000 locations) indentation stiffness map. The indentations ranged from 1.5 to 21 mm. The average SD on repeated measurement ranged from 7-15 percent, or 0.67 mm in absolute terms. Many of the structurally significant anatomical features of the limb were visible; including the patella and patellar tendon, the fibular head, the medial and lateral aspects of the tibial plateau, the biceps femoris tendon and semitendinosus, and the popliteal area.

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