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State-of-the-art methods for geometric and biomechanical assessments of residual limbs: A review

YP Zheng, PhD; Arthur FT Mak, PhD; Aaron KL Leung, MPhil
Jockey Club Rehabilitation Engineering Center, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong

Abstract—A review is presented on the state-of-the-art methods for geometric and biomechanical assessments of residual limb tissues. Residual limb assessments are needed throughout different stages of prosthetic management, namely preamputation, residual limb maturation, prosthetic design, prosthetic fitting, and subsequent follow-ups. Geometric assessments include the monitoring of the volumetric change as the residual limb matures after amputation. Geometric and biomechanical assessments of the residual limb are important considerations in prosthetic design.

Quantitative geometric and biomechanical assessments are becoming more important in the development of a computer-aided system for prosthetic socket design. It is noted that, except for the external shape measurements of residual limbs, most of the instruments used in residual limb assessment are not particularly cost-effective for clinical applications in prosthetics. Further developments are needed to facilitate the incorporation of the internal geometric assessments and biomechanical assessments into the current computer-aided design systems for clinical prosthetics.

Key words: *amputees, CT, hand-held digitizer, imaging, indentation, laser, Moiré contourography, MRI, prosthetics, residual limb, silhouetting, socket design, socket fitting, tissue assessment, ultrasound.*

Address all correspondence and requests for reprints to Dr. Yongping Zheng, Assistant Professor, Rehabilitation Engineering Center, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong; email: rczheng@polyu.edu.hk.

INTRODUCTION

Residual limb assessments are needed throughout different stages of prosthetic management, namely preamputation, residual limb maturation, prosthetic design, prosthetic fitting, and subsequent clinical follow-ups. Assessments of surface contour and internal skeletal geometry are important to prosthetic design and fitting to create a functional socket. Biomechanical assessment of residual limb soft tissues is an important consideration during prosthetic design. Quantitative biomechanical and geometric assessments are becoming more important in the development of clinical systems for computer-aided socket design. This review mainly focused on the residual limb assessment at the stages of prosthetic design and fitting.

Current prosthetic technology demands that the entire load transfer between the skeletal components and the prosthesis occurs via the residual limb soft tissues in contact with the prosthetic socket and the other suspension elements. The comfort of the prosthesis and its utility in restoring the amputee's mobility are mainly determined by the fit of the prosthetic socket that is the interface between an amputee and his/her artificial limb. Therefore, the main challenge in lower-limb prosthetic socket design is to obtain an appropriate pressure distribution at the limb/socket interface. Such pressure distribution pattern depends mainly on the geometry, the biomechanical properties, and the stress tolerance levels of the residual limbs.

A systematic and comprehensive evaluation of a residual limb could improve the functional outcome (1). The basic parameters of the traditional clinical assessment of a residual limb include (1) residual limb dimensions, (2) proximal joint mobility, (3) peripheral vascular circulation, (4) neurological condition, (5) residual limb shape, (6) skin condition, (7) scar, (8) soft tissue firmness, (and 9) the condition at the end of the residual limb (1–5). The following are typically included in a conventional residual limb assessment.

The residual limb length and the bone length from a reference anatomical landmark to the distal bone end are measured with a measuring tape. The amount of redundant tissue is noted. Circumference measurements are taken at regular intervals along the long axis of the bone. These measurements can give information about volume changes. The range of movement of the closest proximal joint is measured with a goniometer. The degree of spasticity or joint contracture is noted. Peripheral vascular circulation is examined by sensing the superficial pulse and surface temperature with the examiner's hand and by observing the color of the limb. Sensation of touch with the use of a wisp of cotton, discrimination between hot-and-cold and dull-and-sharp objects, and proprioception are assessed to indicate the neurological condition. Location and degree of pain, if any, in terms of frequency, intensity, and duration are examined. Experience of phantom sensation and of phantom pain is recorded (6,7).

The shape of the residual limb is usually qualitatively described as cylindrical, conical, or with bulbous end. Terminologies such as "dog ears" or "adductor roll" are sometimes used to describe certain abnormalities. The skin of the residual limb is inspected for abrasion, blister, ulcer, or epidermoid cyst (8) that may be caused by abnormal pressure at the residual limb/socket interface. The presence of folliculities, infected ulcer, or eczema, if any, would be noted (9). Suction discoloration, or verrucuous hyperplasia, is taken to indicate that the residual limb could be housed in an undersized suction socket. When a scar is observed, notes are taken on its location and whether it is healed, unhealed, adherent, or in extreme case with bone exposed. Residual limb tissues are manually assessed to judge whether they are firm or flabby. The amount and the firmness of the residual limb tissues are taken into account during cast rectifications. A rounded residual limb end is taken to be better protected with soft tissue than one with a pointed end.

Traditionally, the design of the prosthetic socket very much relies on the above observations and the skills and experiences of individual prosthetists. As a result, conventional socket designs are largely subjective and vary among prosthetists.

EXTERNAL GEOMETRIC ASSESSMENT

Water Immersion and Circumferential Measurements

Before the scanning methods for shape measurements of residual limbs were developed, water immersion devices were often used for volume measurements of residual limbs. An example involved a cylindrical tank supported on an elevator (10). The water-filled tank could be raised on the elevator to fit the residual limb. With the position of the elevator and the depth of the water with the residual limb immerged being measured, the segmental volumes as well as the total volume of the residual limb could be measured. A similar method using an overflow mechanism was also attempted (11). The residual limb volume was measured by a water displacement method including a transparent water tank with a calibrated overflow receiver. The precision for volume measurement with the use of the method of water immersion could apparently be up to 1.1 percent (12).

Krouskop et al. (13) reported a method that used circumferential measurement and a programmable calculator to compute the total and the incremental volumes of residual limbs based on the assumption that two successive cross sections were parallel and essentially similar in geometry. A special area measurement tool was developed and used with a computer socket design system (14). The tool was used to determine the cross-sectional area of the below-knee residuum at various levels. It consisted of a rigid front section that could fit on the bony anterior region of the residual limb and a soft tape that could measure the posterior aspect. Computer software converted the area tool readings to cross-sectional area values. These values were used for socket design together with the anteroposterior and mediolateral dimensions at the knee measured with a caliper (15).

Contacting Methods

We developed various contacting methods to measure the surface contour of a residual limb by digitizing the cast or the residual limb. The scanning of negative casts by a pivoting arm was used most often. During the measurement, the negative cast was rotated about a longitudinal axis as a measuring arm whose tip touched on the inside of the cast moving along this axis (16). The tip of the probe traced a helical path round the inside of the cast, and its displacement from the axis was measured. The contacting methods were used in some CAD/CAM socket design systems (17,18).

A contact method to digitize positive casts horizontally positioned was also developed (19). The device consisted of an electronic digitizer tablet, a guiding probe, and a cast-holding device with a rotatable vertical plate and a guide pointer. The cast was arranged to rotate step by step about its longitudinal axis, and longitudinal traces of the cast shape were collected. The accuracy and resolution of these contacting methods depended on the position measurement of the tracer and the step interval of each movement.

Contact shape scanning directly from the residual limb was also attempted (20–22). One device consisted of a fixed disk and a rotating contact tip, which could measure the contour of a cross section of an amputee's residual limb at any chosen level. The contour was directly drawn on a paper placed on the disk (20). Another device consisted of two probes mounted on a rotatable base (21,22). The probe traveled horizontally toward and away from the limb as it was manually moved vertically. As the probe rotated around the limb, its position was electronically recorded and stored in a computer. This method could suffer from the movements of the residual limb during the measurement due to the long scanning time required. The reliable detection of the contact of the probe with the skin was important to the accuracy of the measurement.

Moiré Contourography

Moiré contourography or fringe topography was an optical method for spatial analysis of an object in a nondestructive and virtually instantaneous manner (23–25). It was used in various engineering and medical applications, such as in the measurement of spinal curvatures (26), head contours (27), facial features (28), limb and body dimensions (29), as well as residual limb geometry (30–35). The underlying theory behind the Moiré fringes was that object shape could be determined by measuring the distortion of a fringe pattern projected onto the surface. An accuracy of about 2 mm (root-mean square) was reported with the use of single plane projection for relatively planar surfaces, such as the chest or back (23).

For applications in residual limb assessments, multiple projections and photographs taken at incremental angles or different directions around the limb were used to reconstruct the limb geometry. Saunders and Vickers (30) scanned the positive casts of feet and residual limbs using a rotational Moiré method. The shadow Moiré fringe pattern was formed on a rotating model and recorded on a moving film. The result was a single contourograph that covered the full surface of the object. The photograph was manually digitized at the intersection of the fringe lines to form a 3D model of the object, which was then used for the purpose of computer-aided manufacture (CAM).

Instead of using a single moving sensor (27,30), Commean et al. (34,35) used a stationary multiple-sensor design in which the sensors covered the surface in multiple segments. This system was initially developed for scanning faces and heads (36,37). Three projectors and four video cameras were used to establish a triangulation baseline for scanning the residual limb surface including the distal end, which was difficult to view with the use of other methods. To achieve a high scanning speed, we projected many fringe patterns simultaneously onto the surface. The method involved the challenge to uniquely identify each of these contours in the sensed image in order to solve for the 3D surface correctly (38,39). It was reported that better than 1-mm resolution, 2.2-percent precision for volume measurement, 2.4-mm accuracy for the surface distance measurement, and a fast scanning time of 0.75 s were achieved (12,34,40). A similar system using 2D coded fringe patterns has also been reported for residual limb scans (32,33).

Laser Video Scanning

Laser video scanning was a special Moiré fringe topographical method. Instead of using a light source for generating a frame of the fringe profile for an entire area, a laser beam was used to generate a laser line along the surface of residual limb that was recorded with a video camera. The residual limb was scanned line by line. The laser line could be generated from a single laser source with a cylindrical prism or an oscillating mirror. The laser projection source and the video camera were generally arranged at an angle to each other, typically 15 to 60 degrees. The recorded curves of the laser trace on the surface of the object were used to represent its shape. The distorted lines were collected into a computer to generate a 3D contour of the residual limb.

Laser video scanning is becoming more common in the commercial CAD/CAM socket design systems. There are mainly three types of laser video scanners developed for residual limb scanning, namely the rotational scan, the vertical scan, and the combined scan.

Fernie et al. (41) developed a rotational scan system for scanning positive casts. The laser line was vertically projected along the rotating cast. The distorted laser line was collected by a video camera at 5-degree intervals and at a rate of approximately one scan per second. Accuracy better than 1 mm was reported. Fernie et al. (42) also developed a vertical scan system for directly scanning residual limbs. To reduce the scanning time, we used nine video cameras to record the distortion of laser lines that were projected along the residual limb by a rotating laser projector. The residual limb was arranged in the central portion of the scanning area. A scanning time as short as 0.6 s was achieved for 5-degrees scanning interval. A similar system was reported by Oberg et al. (43), in which a single video camera was rotated with a laser projection line around the residual limb. The early version of this system had the disadvantage of being very large and slow. A newer version took approximately ten seconds to scan a residual limb (CAPOD system, 44). Engsberg et al. (45) reported another system using rotating scan with a single camera. The reported resolution of this system was 1.5 mm, and the scanning time was about 10 seconds for 256 lines in 360 degrees. The vertical resolution depended on how many points were taken for a laser line. This mainly relied on the resolution of the video camera used, typically about 250 points per line (41,42,45).

Volume measurements with a CAPOD laser scanning system were compared with volumes obtained by the method of water immersion or mathematical calculation using cylinders and amputation residual limb models (46). It was found the random error, represented by the coefficient of variation, was 0.5 percent. Using a similar approach, Johansson and Oberg (47) evaluated the laser scanning devices of a CAPOD system as well as a Seattle ShapeMaker system (MIND Corp., Poulsbo, WA). Similar results as those of Lilja et al. (46) were reported. A systematic error of about 3 percent was reported for those scanning systems.

Instead of using a rotational arrangement, Houston et al. (48) developed a vertical laser scanning system consisting of two scan heads mounted on vertical uprights on the opposite sides of the scan field. Each scan head contained a laser scan generator, two CCD video cameras, and could be vertically elevated under computer control. To scan a residual limb or limb segment, we positioned the subject in the scanner with the limb anatomically aligned and centered in the scan area. As the scan heads traveled along the uprights, horizontal cross sections of the patient's limb were sequentially scanned. The data collected by the video cameras in the two scan heads were combined to generate an entire contour of a cross section. The incremental spacing between two consecutive digitized cross sections determined the speed of the vertical scanning. With an incremental axial spacing of 3.1 mm, a velocity of 9 cm/s was achieved for the vertical scanning, enabling a scan over a 32-cm-long residual limb in approximately 3.5 s. The resolution of this vertical scanning system was approximately 0.5 mm to 3.0 mm.

The third laser scanning type for the residual limb combined rotational scan with vertical scan with the use of a point laser source. It could be used for scanning both the positive and negative casts of the residual limb (BioSculptor system). The image resolution in both rotational and axial directions depended on the step intervals of the scanning.

Silhouetting

Silhouetting was a method that produced a 3D shape from a series of 2D outlines of an object taken in different directions. It could be used to digitize residual limb geometry (49–52). During a measurement, light was projected onto the residual limb and the silhouette images were taken with a video camera. The position of the light source and the video camera were known for each image. Profiles of high contrast between the residual limb silhouette and the background were determined with the use of image-processing software or with the detection of the voltage transitions in the video signals using hardware (50,52). By relating the silhouette profiles to the known camera position, we could reconstruct the edges of the limb to produce a 3D representation.

The silhouetting method could provide the mere outline information of the residual limb, and it could not detect surface concavities. However, the speed of this method could be high enough for scanning residual limb directly, and high resolution was also reported.

The silhouetting system of Duncan et al. (49) grabbed the necessary images in about 1 second. Their preliminary data were utilized in creating plaster molds but no accuracy tests were reported. The system that Smith et al. (50) produced could scan a residual limb at 10-degree increments during manual camera rotation with a scan time of about 2 s. Mackie et al. (51) reported an accuracy of 2.0 mm for a similar system. Schreiner and Sanders (52) reported that a residual limb could be scanned at an interval of 13.5 degrees within a period of 1 s and with a radial resolution of 0.5 mm. This system has been used for the measurement of shape changes of the residual limb over time (53).

Hand-held Digitizer and Scanner

A hand-held scanner used a probe to digitize the contour of the surface it touched where the position of the probe was determined by a certain type of computer-controlled 3D location measurement device. It offered advantages such as an ability to be used on a wide variety of shapes without reprogramming or constructing a new mechanism, and it was less expensive and more portable because a positioning mechanism for the digitizing probe was not required (54). However, the lack of a positioning mechanism made it more difficult to guarantee the data points to be recorded in a geometrically regular manner. Some areas of the shape might be under-sampled. In a system used by Lemaire et al. (55), a button was pressed to collect data when the digitizer was positioned properly. In this manner, sample points could be collected with a relative regular interval. The need to manually enter each point could slow down data acquisition in such a system. Vannah et al. (54) described an alternative method in which a hand-held digitizer operated in a continuously sampling mode. An interactive visual display of sampling quality was provided, allowing the operator to judge whether all areas of the surface were adequately represented (54,56). It was reported that the accuracy of the hand-held digitizer and of the surface reconstruction algorithm was better than 1 mm in clinically relevant cases (54).

Compared with other scanning methods, hand-held digitizing systems had an inherently higher incidence of signal noise associated with them. The signal noise could result from the transducer itself, the shaking of the operator's hand, or the subject's motion during sampling (57,58). Different methods with the use of digital filters were used to smooth out the raw data to keep the overall contour of the residual limb (59). For the influence of the motion of the object being digitized to be reduced, reference points could be marked, the position and orientation of which could be continuously monitored (54). Since the residual limb or the model had to be digitized point by point with the hand-held digitizer moving over the object, the scanning time with the use of such a hand-held scanner could also be a concern. In addition, geometric readings would be affected by the indentation if the probe needs to contact the limb tissues. It is a challenge for the operator to maintain a consistent pressure on the tissue surface during a measurement. A noncontacting hand-held laser scanner would solve some of the problems described above. It incorporates the technologies of the laser video scanning into the contact hand-held scanning, and could provide higher scanning speed. Currently, a number of commercial hand-held scanners are available in the market (e.g., BioSculptor, CAPOD, TracerCAD, VORUM).

INTERNAL GEOMETRIC ASSESSMENT

X-ray and CT

Traditional X-ray technique could be used to view 2D images of residual limbs. With the use of these images, the conditions of the skeletal tissues and the rough dimensions of the surrounding soft tissues could be somewhat monitored (60,61). By using contrast liquid injection, one could monitor the atrophy of the arteries and veins. X-ray image could also be used in a static manner to analyze residual tibial movement within transtibial sockets (62–65) and residual femoral movement within transfemoral sockets (66–68). The contact between the residual limb and prosthetic socket was also studied with the use of X-ray imaging (63,69).

Residual limbs were assessed with the socket under weight-bearing and non-weight-bearing conditions. However, traditional X-ray images did not permit volumetric and other 3D measurements. The residual limb assessment with the use of X-ray was further extended to the use of computer tomography (CT), especially spiral X-ray computed tomography (SXCT).

Using CT, one could reconstruct the 3D shape of the residual limb from a number of 2D slices taken transversely to the limb's long axis (70). The feasibility of incorporating CT data into a CAD prosthetic design system was demonstrated (71,72). The 3D volumetric images obtained by CT were also used to establish the finite element model for the residual limb for the interface analysis with the internal bone identified from soft tissues (73–75). However, CT was quite expensive and was hazardous for repeated measurements due to its use of ionizing radiation.

SXCT could provide improved image quality with less X-ray dose (76). Scanning the extremities and avoiding X-ray exposure of the reproductive organs was considered to be of low risk and relatively noninvasive (77). Using SXCT for the residual limb assessment was extensively investigated (12,34,40,73,77–81). A resolution of better than 1 mm could be achieved with SXCT (34). The socket, residual soft tissues, and bone could be individually extracted from the SXCT images. The changes in the bone orientation, soft tissues dimensions, and surface mark positions could be determined with or without the socket in place. It was reported that 0.88-mm precision and 2.2-mm accuracy for the surface distance measurement could be achieved (34,40).

The advantages offered by SXCT were particularly useful when the prosthesis could be imaged under weight-bearing conditions. Since 20–45 s scanning time was required for scanning a residual limb and scanners were usually constrained to have subjects positioned horizontally, simulation of the physiological load-bearing condition could be a challenge (82). Commean et al. (80) used a harness arrangement in which the force applied to the prosthesis was borne by the shoulders. More recently, a special adjustable chair was designed for this purpose (82). It allowed the subject to sit during the imaging process and the force to be borne more comfortably by the hips and lower back.

Plain X-ray and CT could primarily provide static images of the residual limb and the interfacing socket. Thus, many studies on prosthetic fitting were restricted to static analyses at simulated instances of the gait cycle. A videofluoroscopic technique was introduced to evaluate the dynamic residual limb-socket relationships during gait (83). The X-ray images were collected in real time with the use of this technique.

MRI

Magnetic resonance imaging (MRI) could be used to establish computational models of residual limbs (84–87), to monitor skeletal movement during different maneuvers within the socket (88), and to determine muscle atrophy (88,89). Similar to CT, standard MRI required the subject to lie horizontally. Gravitational forces could distort the distribution of the residual limb soft tissue relative to the skeletal structure. To limit such artifact of tissue distortion, Torres-Moreno et al. (87) imaged the residual limb with a plaster shell fabricated by an experienced prosthetist. Lee et al. (84) and Zhang et al. (88) imaged the residual limb with a prosthetic socket. An automatic segmentation of MRI images for bone and skin surface was introduced for establishing the finite element model for computational analysis (85).

MRI could provide high resolution and clear differentiation between tissues. However, it was expensive and required a long scanning time of up to 8 min to scan the entire residual limb (84). Its application in residual limb assessment is currently limited to mostly research purposes and to static analysis.

Ultrasound

Ultrasound imaging was used for residual limb assessment in many different ways. A number of investigations were targeted at the 3D volumetric imaging of the residual limb (90–96). The systems comprised a tank containing water in which ultrasonic pulse or echoes could be transmitted and detected by a moving array of ultrasonic transducers. The ultrasound transducers could scan the residual limb rotationally and vertically to collect images. The 3D volumetric imaging was then constructed from the scanned images. It was estimated that the achievable resolution and accuracy in limb measurement with the use of ultrasound was approximately 3 mm (93).

For the ultrasound residual limb scanning systems reported in the literature, commercial B-mode ultrasound systems were generally used. Sector mode transducers (93,95,97) and linear mode transducers (94,96) have both been adopted. Both horizontal and vertical scanning modes have been developed for residual limb scanning. In the horizontal mode, the long axis of the ultrasound transducer was arranged horizontally and a series of cross-sectional images of the residual limb were obtained with the transducer rotating around the residual limb. Since the images tended to overlap with each other, the imaging quality could be improved by compounding the images obtained from different angles (92,93,95,97,98). The scanning speed of the horizontal mode was relatively low. For a typical system with a B-scan image acquired every 10 degrees, 3- to 5-mm vertical interval between cross sections, 12-s scanning duration for each level, and the speed of vertical translation of the transducer being 15 mm/s, the total scanning time could be about 12–15 minutes, depending on the exact length of the residual limb (93,97). Morimoto et al. (96) reported a similar result.

For the improvement of the scanning speed, vertical scanning modes were developed (94,96). In vertical modes, the array of ultrasound transducers was arranged vertically with the array long axis along the long axis of the residual limb. For a residual limb 26 cm long, a vertical scan could take about 80 s. The acquired skin surface had a resolution of 2.5 degrees in the transverse direction and a resolution of 28 points/cm in the longitudinal direction (94).

Since ultrasound scanning of the residual limb took relatively longer compared with other methods, the movement of the residual limb during scanning was a concern. He et al. (93) used a pair of thigh clamps and a limb stabilizer to keep the limb still during data acquisition. However, such mechanical constraints could distort the skin surface (96). Any limb motion during scanning will blur the reconstructed image.

Walsh et al. (91) used several ultrasonic transducers located at fixed positions within the tank to provide a baseline indication of the initial limb location. Motion compensation methods based on the image features were reported (96,99). In the horizontal scanning mode, the majority of the image information of two consecutive frames resulted from the same geometrical features within the limb. Any motion of the limb between the acquisitions of two frames could then be detected accordingly (96). Ultrasound technique could be used to monitor the motion of the residual bone within a socket during gait.

The residual femur within a transfemoral socket was investigated with the use of two simultaneously transmitting transducers (100–102). Two linear array ultrasound transducers were proximally and distally positioned through slots in the socket. The ultrasound images were synchronized with the gait by mixing a video recording of the gait to the ultrasound image (101). Preliminary results showed that the procedure was time-consuming due to the manual analysis of the ultrasound images. However, measurement of the motion of the residual femur within the transfemoral socket during gait was achievable. Ranges of flexion/extension and abduction/adduction of the residual femur within the socket during gait could be estimated with a cumulative level of inaccuracy of about 0.5 degree. It was estimated that the accuracy of ultrasound measurement could be up to 1 mm (102). The use of ultrasound to monitor the skeletal motion within the socket during gait was not suggested for extensive clinical evaluations (101), unless the mounting of ultrasound transducers to the socket could be simplified and the method for ultrasound data analysis could be improved.

BIOMECHANICAL PROPERTIES ASSESSMENT

Indentation Measurement

Indentation apparata. Indentation test is the most popular technique for determining the *in-vivo* biomechanical behaviors of limb soft tissues. The test itself very much resembles that of palpation. Investigations with the use of various indentation apparata were reported on the dependence of the biomechanical properties of limb soft tissues on subjects, sites, states of muscular contraction, age, gender, and pathological conditions, etc. (103–112). Testing sites on lower limbs and forearms were usually selected in those investigations. Since late 1980s, a number of apparata for indentation measurement have been developed for biomechanical assessment of residual limb soft tissues (75,86,113–127).

When indentation tests were used to measure the mechanical properties of limb tissues *in vivo*, the following issues had to be considered: (1) how to attach and drive the indentor, (2) how to measure the indentation depth, (3) how to measure the tissue thickness, and (4) how to interpret the indentation result.

Various kinds of mechanical alignment devices were used to attach the indentor (103,104,107–110,121). Those devices provided an anchorage for the indentor to be driven toward the surface of the tissues to be tested. A common attachment method was to install the indentation apparatus to the prosthetic socket or a similar shell, and the indentor was pushed into the soft tissue via specific ports through the socket or shell (86,113,116, 118,126,127). These indentors could be driven manually (113,116,118) or by microprocessor-controlled stepping motors (86,121,126,127). The indentation depth was generally measured by the displacement of the indentor.

In cases where the indentor was driven manually, the displacement of the indentor was often determined with a linear variable differential transformer (LVDT). While, in the case where the indentor was driven by a motor, the displacement could be determined by the movement of the step motor. In the latter case, the indentation speed could be controlled by the movement of the motor. In the earlier indentation apparata, a constant load was applied with the use of a static weight. For the assessment of residual limb tissues, the applied load during the indentation test was generally determined with force sensors. The indentation apparata using mechanical alignment devices were generally designed for the assessment of limb tissues at specific anatomical sites and in specific postures. A portable motor-driven indentation apparatus was recently reported (126,127). However, the apparatus still required attachment to a frame or a shell during the assessment test.

A number of indentation apparata with a hand-held indentor were reported in the literature (111,112,122,123, 125). The indentor was driven manually (111,122,124) or pneumatically (112,125) onto the skin surface. Horikawa et al. (111) used a laser distance sensor to determine the indentation depth. A point on the skin surface some distance away from the indentor was used as a reference for the laser displacement measurement. This reference point could be perturbed by the movement of the indentor if its position was too close and the accuracy of the displacement measurement could subsequently be compromised. Ferguson-Pell et al. (112) described a pneumatic indentation apparatus with the compressive force prescribable using a close-loop control.

Vannah et al. (125) reported a pencil-like indentation probe with a pneumatically driven piston that indented the tissue 10 times per second. The indentor tip contained an electromagnetic digitizing element, and this element sensed the position and orientation of the indentor. The indentation depth and the location of the indentation site could be calculated. The pneumatic pressure was measured at the inlet of the hose connector. The device could be used to scan around the limb to map the indentation behaviors of the limb tissues. Like many other indentation apparata, the thickness of tissues could not be monitored easily. The indentation responses recorded with the use of these devices depended on the tissue thickness as well as on the tissue properties.

Zheng and Mak (122,123,128) developed an ultrasound palpation system including a pen-size hand-held indentation probe. An ultrasound transducer at the tip of the probe served as the indentor. The thickness and deformation of the soft tissue layer were determined from the ultrasound echo signal. A load cell was connected in series with the ultrasound transducer to determine the corresponding force response. The probe was manually pushed onto the surface of the limb tissues during assessment tests. The indentation speed could be calculated from the indentation response. This probe has been used for the assessment of residual limb soft tissues (124), plantar foot tissues (129), and neck fibrotic tissues (130). The probe could also be used to determine the tissue properties of different tissue sublayers (122,131). Indentation apparata with hand-held probes could be readily used to assess tissues at different anatomical sites.

Extraction of biomechanical properties. The following issues related to the extraction of the tissue biomechanical properties were reviewed in this section, namely the nonlinearity and viscoelasticity of the tissue properties, effects of indentation rate, indentor misalignment, muscular contraction, and whether the limb tissues are confined within a socket or not.

In earlier investigations, indentation tests were commonly performed in a loading-creep-unloading sequence, and the tissue responses were characterized empirically (104). Hayes et al. (132) derived a rigorous elasticity solution to the problem of indentation on a thin elastic layer bonded to a rigid foundation. The authors obtained an analytical solution for the case of a rigid, frictionless cylindrical plane-ended indentor. This solution yields an expression for the Young's modulus:

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

Where P is the load and w is the depth of the penetration of the indentor, ν is the Poisson's ratio of the layer medium, a is the radius of the indentor tip, and κ is a scaling factor that is numerically determined by solving an integral equation. The scaling factor provides the theoretical correction for the finite thickness of the elastic layer, and it depends on both the aspect ratio a/h and Poisson's ratio ν. Values of κ for a range of a/h and ν were provided by Hayes et al. (132). A closed form solution of the function κ was proposed by Sakamoto et al. (133), and the results were demonstrated to agree well with those obtained by Hayes et al. (132). When the aspect ratio a/h is small enough, i.e., the tissue thickness is large enough compared with the radius of the indentor, κ tends to be 1. **Equation 1** can then be simplified to the solution for an elastic half space (86,134).

According to Hayes' solution, the thickness of the soft tissue is an important parameter to determine the material properties from the indentation response, especially under the condition of a large aspect ratio a/h. Various methods were used to determine tissue thickness with the use of skinfold calipers (110), CT (113), X-ray (118), and MRI (86), and ultrasound (107,121,122,128). Another parameter that is normally assumed in the process is the Poisson's ratio. The choice of the Poisson's ratio would cause a variation in the determination of the Young's modulus, particularly for an aspect ratio a/h greater than unit (124). In the indentation studies on skin and subcutaneous tissues, most investigators assumed the Poisson's ratio to be a constant ranging from 0.45 to 0.5 to simulate the nearly incompressible behavior of the tissue as a whole (86,111,113,114,117,118,121,124). Although this assumption was consistent with the interpretation of the instantaneous or short-time indentation results using the modern biphasic theories (135,136), 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. Ideally, the Poisson's ratio should be measured together with the Young's modulus *in vivo*. The technique for measuring Poisson's ratio of the limb tissues *in vivo* deserves to be investigated further.

In addition to Hayes' solution, computational methods with the use of finite element (FE) analysis were developed to extract the modulus from the indentation responses of the residual limb (113,114,117,118). Reynolds estimated the Young's modulus E by matching the experimental load-indentation curves with the predictions by FE modeling of an indentation into an assumed infinite tissue layer with idealized material properties. Steege et al. (113) and Silver-Thorn (114) developed another method to extract the material properties of the residual limb tissues from the indentation responses. The estimation of the E was conducted using the limb-socket FE model that was initially established for the study of the interaction between the socket and the residual limb.

The testing sites were identified on the FE model, and a unit-normal compressive load was applied. The soft tissue was assigned an initial E value and an analysis was carried out. It was assumed that the value of E and the displacement of the indentor were inversely proportional in the model. By comparing the FE analysis results with the experimental displacements at the ports, an estimation of Young's modulus was obtained. Silver-Thorn (114) demonstrated that the assumption of the soft tissue thickness would significantly affect the estimated value of E. Vannah and Childress (117) used a strain energy function to represent the tissue properties in a similar FE approach and to extract the corresponding material parameters from the indentation response.

The method to use a general indentation solution to extract material properties of soft tissue is fast and can be used to extract tissue properties in real time measurements if the boundary conditions could be satisfied. In case of more complicated geometry and boundary conditions, the FE method may be a better way to extract the tissue properties from the *in situ* indentation response. The relatively long time required for establishing the FE model could be a drawback of this approach. Both methods face the challenge of how to handle the nonlinearity and viscoelasticity of the tissue properties, which have been demonstrated in the indentation responses reported in the literature.

The nonlinearity of biomechanical responses is rather common for many soft tissues (137). It was reported that the load-indentation responses of limb soft tissues could be well represented by quadratic functions with the tissues unconfined (124,128) or by third-order polynomials with the tissues confined by a prosthetic socket (114,127). The usefulness of the derived polynomial coefficients was limited because these indentation responses not only depended on the biomechanical properties of the soft tissues but also on the tissue thickness and the boundary/interface condition. The extracted material properties also depended on the predeformation or preload and the total deformation or load applied on the tissues during indentation tests. These testing conditions had to be documented during the assessment test.

Torres-Moreno (86) measured the moduli at several different levels of indentation to demonstrate the nonlinear dependence of the soft tissue properties. Zheng and Mak (123,138) used an incremental method to derive an initial modulus and a nonlinear factor. The effective modulus could be calculated in an incremental manner with the use of thickness adjusted in each step. The nonlinear properties of limb soft tissues were also extracted using a quasilinear viscoelastic indentation model (122,123). Vannah and Childress (117) reported an approach to extract their nonlinear material parameters of soft tissues using a strain energy function.

In addition to the material nonlinearity, the large deformation effects of indentation on a soft tissue layer should also be taken into account. Infinitesimal deformation was assumed in the mathematical solution proposed by Hayes et al. (132). This assumption was not always satisfied in the indentation tests on skin and subcutaneous tissues. To correct that, a large-deformation finite element analysis of Hayes' elastic layer problem was reported (139). It was shown that the scaling factor κ in **Equation 1** increased slightly as indentation depth increased. Thus, the nonlinearity of the indentation responses is partially caused by this large-deformation effect. Simply using Hayes' infinitesimal elastic layer solution to calculate Young's modulus for a large indentation depth may produce an error in the result, especially for a large aspect ratio (a/h) (124,139).

Viscoelasticity is another important issue in soft tissue biomechanics (137). The viscoelasticity of limb tissues could be observed in the load-indentation response, such as hysteresis and rate dependence. Most of the investigators selected the loading phase for the extraction of material properties to avoid complications due to hysteresis.

The effect of indentation rate is a common concern during the extraction of the effective Young's modulus from the indentation responses. Some investigators measured the instantaneous and equilibrium modulus just after the ramp indentation phase and after a long enough force-relaxation time (121). That study showed that the instantaneous modulus was slightly larger than the equilibrium modulus for the residual limb tissues. The influences of the indentation rate on the load-indentation response have been reported in the literature (86,118,127). The loading rates were 0.3, 0.8, and 1.3 mm/s for Reynolds' study; 9.9, 14.2, and 19.8 mm/s for Torres-Moreno's study; and 1, 5, and 10 mm/s for Silver-Thorn's study. In these studies, the limb tissues were confined within sockets or other type of shells, and the interaction between the limb tissues and the socket or shell was not analyzed. Hence, it was not known whether all the rate-dependent responses observed in these studies were caused by tissue viscoelasticity or not. It was also demonstrated in these studies that such rate-sensitivities apparently depended also on subjects and sites. Krouskop et al. (140) reported that their extracted modulus of soft tissues was rate insensitive. In their *in-vitro* study on normal and abnormal excised breast and prostate tissues, three rates ranging from approximately 0.2 to 10 mm/s were used. The corresponding variation in stiffness was noted to be within 10 percent. Using *in-vivo* tests on forearms with 5 manually controlled indentation rates ranging from 0.75 to 7.5 mm/s, Zheng et al. (124) have demonstrated that the extracted Young's modulus was roughly rate independent. Silver-Thorn (127) also noted that testing at a higher indentation rate might not result in a larger slope of the load-indentation response. The rate dependence of biological tissues is usually significant over a range of many decades and may not be so significant over just one decade (37). That might be the reason why relatively small rate dependence was observed in some studies.

The issue of viscoelasticity has been studied in other biological tissues. To address the indentation creep behavior of articular cartilage, Coletti et al. (141) modeled the phenomenon using a Kelvin-type standard linear solid model. A similar one-dimensional model was used by Silver-Thorn (127) to extract the viscoelastic parameters of limb soft tissues from the load-indentation response. Parsons and Black (142) extended the Hayes's elastic-layer indentation solution (132) to a generalized Kelvin-type viscoelastic solid. A continuous relaxation spectrum was derived from the experimental data with the use of some approximations. Mak et al. (135) obtained a mathematical solution for the indentation creep and stress-relaxation behavior of articular cartilage using a biphasic model by assuming the tissue as a fluid-filled deformable porous layer (136). Spilker et al. (143) and Suh and Spilker (144) reported further biphasic analysis of the indentation of articular cartilage using finite element analysis. These mixture models have also been introduced to the investigation of skin and subcutaneous soft tissues (139,145–148). Fung (137) proposed a quasi-linear viscoelastic (QLV) theory to describe the load-deformation relationship of biological soft tissues. In this theory, the load response of a tissue to an applied deformation history was expressed in terms of a convolution integral of a reduced relaxation function and a nonlinear elastic function. Zheng and Mak (149) applied this solution form to the indentation solution. The QLV indentation model was used to study the nonlinear and time-dependent behavior of the limb soft tissues. Linear and nonlinear moduli and the associated time constants for the limb soft tissues were extracted from the cyclic load-indentation response via a curve-fitting procedure.

The misalignment of the indentor is another important issue of the indentation test. A numerical study with the use of finite elements demonstrated that the stress distribution in the tissue directly under the indentor during indentation was influenced significantly by the indentor misalignment. However, the total resultant force transient of the indentation response was only slightly affected for misalignment up to eight degrees, under the assumption the Poisson's ratio to be 0.3 to 0.45 (150). An *in-vitro* experiment on a fresh fish tissue layer demonstrated that the effect of indentor misalignment depended on the ratio of tissue thickness over indentor diameter.

Indentation responses could be significantly influenced by the indentor misalignment at sites with soft tissue thickness comparable to or less than the diameter of the indentor (123,124). It was observed with up to 12.5 degrees misalignment of the indentor, the effect on the indentation response decreased as the tissue thickness increased and became almost negligible when the thickness was more than 2 times the indentor diameter. Similar results were observed in an *in-vivo* experiment (124).

Some investigators measured the limb soft tissue properties with the tissues confined in a socket or in other types of structures that confined the tissues (75,86,113–120,126,127). The indentation apparatus was attached to the socket, and the indentation test was performed through a hole on the socket. Other investigators tested the limb tissues with the tissues in a free state (121,123–125,128). When the tissues were confined, the load-indentation response not only depended on the material properties but also the boundary/interface conditions. Torres-Moreno (86) experimentally demonstrated that the interaction between the socket and the residual limb tissue would affect the indentation response when the test was conducted through the port on the socket. The boundary conditions should be properly taken into account in the extraction of the material properties. Otherwise, the extracted parameters would not be real material properties.

Vibration Measurement

The material properties of limb soft tissues have also been measured by vibration methods. Krouskop et al. (151) developed an ultrasound measurement apparatus with a vibration device. During the test, the limb tissue was oscillated at 10 Hz. The vibrational response of the internal tissue was measured with the use of an ultrasound Doppler technique. The Young's moduli of the tissue were then calculated from the tissue density and the tissue motions induced by the oscillations. The method can be used to measure the material properties of tissues in different depths. To ensure that the oscillating head was in good contact with the soft tissues during the test, we required a preload. This preload should be but is not always reported for the test. Due to the nonlinearity of the soft tissue properties, such a preload could affect the measured parameter (152).

Another vibration method in tissue assessment involved the measurement of the tissue acoustic impedance, which was related to the stiffness of the tissue (153). A piezoelectric vibrator working in ultrasound frequency was used to contact the skin surface and the change in resonant frequency was measured and used to calculate the stiffness of the tissues. Since the measured material parameter primarily reflected that of the tissues in the superficial layer, this device was mainly used for the biomechanical assessment of skin (153). If the deeper tissues need to be tested, the testing head should be firmly pushed against the tissues to minimize the effects of the superficial layer. It would be useful to further develop this technique to include the nonlinear and time-dependent behaviors of the tissues.

Measured Material Properties

The effective Young's moduli of lower limb soft tissues were reported to be 60 kPa (113), 53–141 kPa (151,152), 50–145 kPa (119), 27–106 kPa (86), 21–194 kPa (121), 60–175 kPa (128), and 10.4–89.2 kPa (124). Results from these studies demonstrated that the effective Young's modulus of lower-limb soft tissues depended significantly on age, testing site, body posture, muscular contraction, biological condition, and gender. Due to the difficulties of imaging the material parameters of the whole residual limb, in most studies the material properties were only measured at specific sites.

APPLICATIONS OF THE GEOMETRIC AND BIOMECHANICAL ASSESSMENTS

Assessment of Residual Limb Maturation

The residual limb volume is reduced gradually during the early maturation process. After a major amputation, a severe traumatic edema in the residual limb can happen. Volume reduction occurred in a relatively rapid manner corresponding to the reduction of this edema. A slower phase persists in parallel as a result of the atrophy of the soft tissues (60,154). The amount of this atrophy could be correlated to the level of physical activity, postoperative bandaging, and prosthetic fit (8). Renstrom et al. (155) found an atrophy of the quadriceps muscle after transtibial amputation, and the mean muscle fiber area was reduced to 74 percent compared with the nonamputated leg.

It is important to define the suitable time for definitive prosthesis fitting by monitoring the volume change of the residual limb postoperatively. Using a water immersion method, Fernie et al. (10) observed three shrinkage patterns in different subjects postoperatively. It was found that the proper time for definitive prosthesis fitting was about 150 days after amputation. Fernie and Holliday (156) reported similar results. Using both the volume measured by a water immersion method and the circumference measured at different level from the distal limb by tape, Golbranson et al. (11) demonstrated an average reduction of the residual limb volume of 0.011 percent per day. The maturation point of the residual limb was difficult to identify, and there was significant variation in volume change among individuals.

Using a water immersion method (157), which simplified Fernie's design (10), Kegel et al. (158) measured the volume change to study whether the residual limb volume of transtibial amputees could be affected by an isometric muscle training program. From the result, an increase in the cross-sectional area at the gastrocnemius muscle group was observed. It was concluded that isometric training of the residual limb should be prescribed for the transtibial amputee. Using a laser scanner, Lilja and Oberg (154) found that the postoperative residual limb volume could be described with a power function. It was found that the proper time for definitive prosthesis fitting occurred at about 120 days. Sanders et al. (53) measured the changes of residual limb shape over time using a silhouetting system.

It was demonstrated that localized swelling in the residual limb could be observed over a 23-min interval after ambulation. Chahande et al. (159) reported the use of a feature extraction technique in the study of residual limb shape changes over time. Features like volume, slice and quadrant areas, and length of the residual limb were computed from the residual limb image obtained by a laser scanner. The changes caused by edema and atrophy could be differentiated if the dimensions of the muscles and skin could be individually measured. Attempts were made to answer this question with the use of MRI on a small number of subjects (89). Three MRI examinations were performed on each patient in different time periods after amputation. This study documented substantial changes after transtibial amputation in the cross-sectional area of the transtibial residual limb and of the individual muscle groups of the residual limb. Zhang et al. (88) studied three subjects with unilateral above-knee amputation using MRI. Shape differences were found between the amputated limb and the contralateral side, and the muscles in the amputated side had obviously atrophied.

Computer-aided Design of Prosthetic Socket

Most developments in the external geometric assessment methods were targeted for CAD applications (17,18,160). The technology in this area is becoming relatively mature. A number of commercial CAD socket design systems are available. Manually designed prosthetic sockets are difficult to evaluate quantitatively since the hand-sculpting modification process does not retain the initial shape for comparison. A quantitative method for defining and comparing manual socket modifications was developed and integrated into a CAD software package (161). The numerical comparison procedure consisted of (1) digitizing premodification and post-modification models of a prosthetic socket, (2) aligning these two shapes to a common axis, and (3) generating a color-coded 3D image. The between-socket differences were used to outline individual modifications. Modification outlines from a series of patients were averaged to determine a prosthetist's general modification style. This alignment and comparison system should help transfer these hand-sculpting skills to prosthetic CAD/CAM expert systems. Sidles et al. (162) described the use of different colors to represent modifications of a 3D image of a prosthetic socket to indicate the distribution of pressure build-ups and relieves. Borchers et al. (163) described the use of different colors to represent the shape differences between a foot and a shoe last.

Information derived from the external and internal geometric assessments and from the biomechanical assessments can be used to establish the computational model to analyze the interaction between the prosthetic socket and the residual limb (164–167). FE models were used to estimate the interface stresses based on the geometries of the residual limb and socket, their mechanical properties, boundary and interfacial conditions, and the external forces induced during standing or walking. It is expected that FE models can be used to facilitate the design of socket shapes. The use of better geometric and biomechanical assessments has allowed these computational models to become more realistic and sophisticated.

Socket Fitting

The quality of prosthetic socket fitting can be evaluated by the subjective observation of the prosthetists and feedback of the patients, the measurement of interface pressures, gait analysis, and finite element analysis. Prosthetic fitting quality has also been evaluated by SXCT, MRI, and ultrasound imaging modalities with the residual limb confined within a socket during different phases of a gait cycle (77,80,81,83,101).

The volumetric changes of the residual limb soft tissues with and without a prosthetic socket were measured with the use of SXCT (77). It was also used to evaluate the change in the residual limb tissues fitted with a poor- and a good-fitting prosthetic socket (81). A good fitting could be evaluated in a quantitative way in terms of its compression into the soft tissues. The residual limb slippage within the transtibial prosthesis was also studied using a similar method (80). Small lead markers on the residual limb were scanned with the residual limb and socket and were used to measure the movement of the residual limbs at corresponding sites.

Six sites over the proximal and distal tibia were measured. It was found that the surface of the residual limb slipped 2 to 6 mm relative to the prosthesis under two static axial loading conditions (44.5 N and 178 N). The tibial residuum moved 10 mm distally relative to the prosthesis internal wall. Bocobo et al. (83) evaluated dynamic residual limb-socket relationships during gait using a videofluoroscopic technique. Dynamic analysis of the residual limb motion could also be monitored using ultrasound. Convey and Murray (101) analyzed the motion of the residual femur within a transfemoral socket during gait using ultrasound images obtained through slots on the socket. Preliminary result of one subject suggested that during gait the maximum range of flexion, extension, abduction, and adduction of the residual femur relative to the socket wall would be approximately 7, 7, 9, and 3 degrees, respectively.

DISCUSSION

We have reviewed here three categories of residual limb assessments, namely the external geometric assessment, the internal geometric assessment, and the biomechanical properties assessment. These assessments provided useful information at different stages of prosthetic management. Only the external geometric assessment, i.e., surface geometry, has been incorporated into a number of clinical CAD systems for prosthetic socket design. Biomechanical properties assessments and internal geometric assessments can be incorporated into the prosthetic socket design process through the FE analysis. However, FE modeling of the socket/residual limb interface is still in the research stage mostly. The potential benefit to incorporate the internal geometry and biomechanical properties of the residual limb directly into the CAD system to enhance the socket design has been proposed by many investigators (34,35,93,124). Prosthetists in principle can modify socket designs more quantitatively based on the bone location and orientation within the residuum and the thickness and stiffness of the residuum soft tissue. The skills of the prosthetists can be accumulated for an expert system based on the quantitative information they used in the socket design.

However, these have yet to be facilitated in the future prosthetics CAD systems. While FE analysis can estimate the stress distribution within the residual limb and at the socket interface, it cannot tell us whether a stress distribution is good or not. A good interface stress distribution should facilitate effective load transfers during gait and should be well tolerated by the residuum soft tissues. Such tissue tolerance involves tissue damage criteria and tissue adaptation mechanism in response to external loading. How residuum tissues react and adapt to external loading deserve much further investigation (168). Future residual limb assessments should include tissue tolerance assessment as well.

For most studies on residual limb maturation, only geometric maturation was investigated. The results of computational analysis have demonstrated that the loading pattern not only depended on the surface contour but also on the biomechanical properties of the tissues. It would be useful to also monitor the biomechanical properties of the residuum soft tissues as a residual limb matures postoperatively. For the assurance of ready clinical use, user-friendly systems need to be made available for these geometric and biomechanical assessments.

It is noted that, except for the surface contour measurement, most of the instruments for residual limb assessments are not particularly cost-effective for applications in clinical prosthetics. Except for the published information, the impact of these studies on the clinical practice seems limited. Most of the residual limb assessment technologies have not been integrated into clinical prosthetic services. Much effort is still needed to transfer the laboratory technology to clinical instrumentation.

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