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A SPECIAL REPORT

The VA-Cyberware lower limb prosthetics-orthotics optical laser digitizer

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Abstract—Characterization of the residual limbs and limb segments of patients for prosthesis and orthosis design has principally been a subjective process, highly dependent upon the skill, level of training, and experience of the prosthetist/orthotist involved. Even with the application of computer-aided design (CAD) and computer-aided manufacturing (CAM) technologies in prosthetics and orthotics, residual limb/limb segment characterization has remained substantially subjective and dependent upon prosthetist/orthotist skill, training, and experience. To eliminate the variations and errors that frequently occur because of this dependence, and to further quantify the patient measurement process, rehabilitation engineering researchers at the New York Department of Veterans Affairs Medical Center developed an optical laser digitizer for quantitative characterization of patients' residual limbs'/limb segments' spatial geometry and surface topography. The optical digitizer developed is described, and results of laboratory and clinical tests with the digitizer are presented. Examples showing the capability of the digitizer to accurately, rapidly, repeatably, and consistently capture the contours over the entire surfaces of the residual limbs of patients with below-knee (BK) and above-knee (AK) amputation, the lower limbs of orthotics patients, and the feet and ankles of pedorthics patients, are given. In addition, results of a comparative clinical study of optical digitization and standard prosthetics CAD plaster wrap cast electromechanical digitization of the residual limbs of subjects with BK and AK amputation are presented. The enhanced accuracy, repeatability, and consistency afforded by optical digitization are shown. Finally, areas for refinement of the optical digitizer's design, identified in the project's laboratory and clinical tests, are discussed.

Key words: *AFMA, anthropometry, CAD/CAM, computer-aided design, limb (segment) measurement, optical laser digitizer, orthotics, prosthetics, residual limb measurement, three-dimensional spatial digitization.*

INTRODUCTION

Research which began in the early 1980s in prosthetics computer-aided design and computer-aided manufacturing (CAD/CAM) has produced an extensive armamentarium of tools, enabling prosthetists to design and manufacture prosthetic sockets with precisely controlled shapes and dimensions. However, significant portions of the prosthetics CAD/CAM process still remain largely subjective and need to be further quantified and improved. Almost all current prosthetics CAD/CAM systems acquire and input patient residual limb measurement data by (opto-)electromechanical digitization of plaster wrap casts. Either unmodified or modified residual limb plaster wrap casts may be used. When modified plaster wrap casts are used, the casts and measurements for CAD system input are subject to inter- and intraprosthetist variations and errors just as in conventional prosthetics practice. In two separate studies, variations of up to 10 percent in cast circumferential measurements, 21 percent in cast cross-sectional areas, and 33 percent in cast segmental volumes were observed among different prosthetists measuring and casting the same patient employing conventional prosthetics techniques. Similarly, as

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much as 8 percent, 17 percent, and 27 percent variations, respectively, were observed for a single prosthetist measuring and casting the same patient multiple times[1] (1). When unmodified plaster wrap casts were taken, digitized, and used for CAD system input, interprosthetist variations up to 6 percent in circumferential dimensions, 10 percent in cross-sectional area dimensions, and 22 percent in cast segmental volumes were observed. Although less than those observed with modified casts, these variations are still quite significant.

Because nearly all current prosthetics CAD (opto-)electromechanical digitizers record three or fewer reference marks, the CAD prosthetist must estimate the location, orientation, size, and shape of key residual limb anatomical structures, tissue anomalies, stress tolerant and intolerant regions, etc. In conventional prosthetics practice, this information is marked on the surface of the patient's limb, transferred to the plaster cast, and then to the positive plaster model for subsequent use in socket design. Errors can be, and frequently are, introduced when the surface landmarks are displaced with tissue movement during the casting process. Although limited in accuracy, the information the conventional prosthetist has regarding the location, shape, size, and topographies of residual limb anatomical structures, tissue anomalies, and stress tolerant and intolerant regions is, nevertheless, more than the CAD prosthetist has. The CAD prosthetist currently must estimate this information, based on recollections of the examination of the patient, and his or her prosthetics knowledge and experience; or, he or she must depend on the compliance of the patient to the "statistical average values" implemented in CAD system socket design templates, and also upon the accuracy of the CAD system in locating and scaling the respective template modification regions.

During the socket design process, the CAD prosthetist is able to more precisely and accurately control socket model geometries, dimensions, areas, and volumes, than is the conventional prosthetist building up and cutting away regions on a positive plaster model. But the CAD prosthetist currently has less information with which "to build" a computerized socket model than does the conventional prosthetist. This situation is further aggravated by the wide range of variations that exist in the anatomies and residual limb tissue mechanical properties of patients. As found in the Department of Veterans Affairs (VA) Rehabilitation Research and Development (Rehab R&D) Service National Automated Fabrication of Mobility Aids (AFMA) Study, when default template modification regions, appropriately scaled to match residual limb size but otherwise fixed, were used, considerable additional custom modification was usually required before a successful socket design, affording good fit, comfort, and function, was achieved. In the National AFMA Study, 67 percent of the test subjects with below-knee (BK) amputation required additional custom modification in the socket template patellar bar region; 61 percent of the subjects required additional custom modifications in the anterodistal tibial region; 59 percent in the anterolateral tibial region; 52 percent in the anteromedial tibial shaft region; 52 percent in the popliteal depression region; 52 percent in the medial femoral and tibial condyle region; 50 percent in the lateral femoral and tibial condyle region; 49 percent in the fibular head region (especially posteriorly); 46 percent in the fibular end region; 37 percent in the region over the medial tibial condylar flare (especially posteriorly near the insertion of the medial hamstring tendon); 37 percent in the popliteal trim line region near the hamstring tendons; and 34 percent required additional modifications over the fibular shaft (2).

An improvement in CAD system capabilities and performance was made when modification region linking to specific residual limb landmarks (as performed routinely in conventional prosthetics practice) was introduced in the VA-Seattle ShapeMaker CAD System. However, modification region linking to a limited number of landmarks, as the two locations currently implemented in ShapeMaker, has proven to be insufficient in many cases. For the low angular and axial digitizer resolutions and the three or fewer residual limb landmarks currently input for use in standard prosthetics CAD/CAM systems (**Figures 1** and **2**), appreciable deviations in template modification region location, orientation, and size still frequently occur. In a sample of 14 test subjects with BK amputation, variations in modification region location as large as 3.8 cm linearly on the surface and angularly as large as 22° occurred upon application of the ShapeMaker BK PTB socket design template to digitized residual limb measurements with only the three anatomical reference landmarks currently available (**Figure 3a**). Similarly, variations as large as 11 cm linearly on the surface and angularly as large as 183° were found to occur in modification region location with the ShapeMaker AK IC socket design template for 14 test subjects with above-knee (AK) amputation (**Figure 3b**).

[1] *Residual limb geometric characterization: Comparison of prosthetics CAD/CAM optical digitization, electromechanical digitization, and conventional prosthetics casting techniques,* by V.L. Houston, C.P. Mason, K.P. LaBlanc, et al., is in preparation.

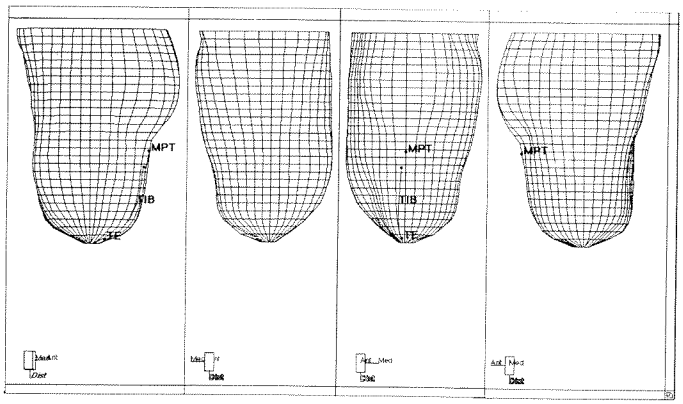

Figure 1.
Lateral, posterior, anterior, and medial views of the electromechanically digitized unmodified plaster wrap cast of the right residual limb of a person with BK amputation are shown input into the VA-Seattle ShapeMaker CAD System. The wire frame residual limb measurement model is shown at the 10° cross-sectional angular increment and 6.35 axial increment resolutions output by most prosthetics CAD/CAM (opto-)electromechanical digitizers. The anatomical landmarks most commonly registered—the mid-patellar tendon (MPT), the tibial shaft (TIB), and the tibial end (TE)—are also shown.

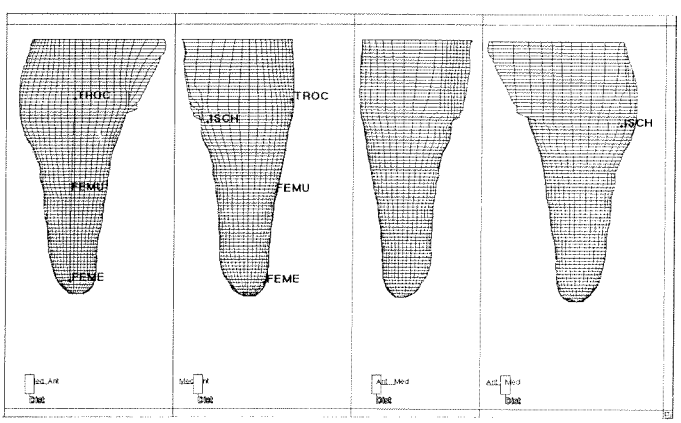

Figure 2.
Lateral, posterior, anterior, and medial views of the electromechanically digitized unmodified plaster wrap cast of the right residual limb of a person with AK amputation are shown input into the VA-Seattle ShapeMaker CAD System. The wire frame residual limb measurement model is shown at the 10° cross-sectional angular increment and 6.35 axial increment resolutions output by most prosthetics CAD/CAM (opto-)electromechanical digitizers. The anatomical landmarks most commonly registered—the greater trochanter (TROC), femoral shaft (FEMU), femoral end (FEME), and ischium (ISCH)—are also shown.

However, if as demonstrated in our investigations, CAD system template modification regions are linked to multiple anatomical residual limb landmarks, identified during patient examination, preserved through residual limb digitization, and registered in the measurement file input into the CAD system, then variations in socket modification region location, orientation, and size become minimal. The principal issue for successful socket design is then the establishment of the magnitudes and topographies of the modification regions. The values for these variables required for achievement of successful socket fit, comfort, and function depend upon the residual limb tissue morphology, geometry, and tissue biomechanical properties of the individual patient. The skilled conventional prosthetist obtains subjective information regarding these variables during the casting process, as he or she molds the residual limb tissues of the patient. Only if the CAD prosthetist makes and uses a modified residual limb cast does he or she have

CAD PTB Socket Design Template Location of Fibular Head Modification. Region Vs. BK Amputee Residual Limb Fibular Head Location.

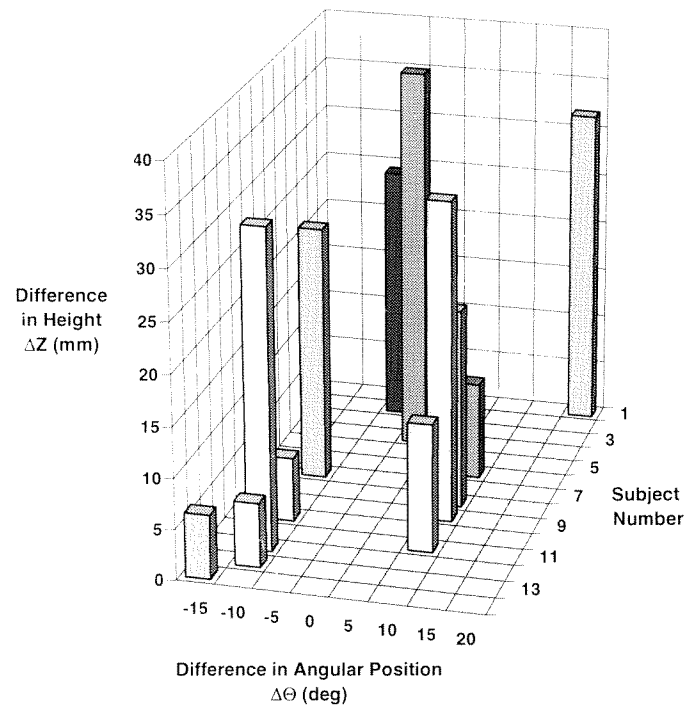

Figure 3a.
Prosthetics CAD system socket design template modification region location errors from insufficient residual limb landmark information. Differences in the optically measured location of the residual limb fibular head apex versus the position of the ShapeMaker PTB socket design template fibular head modification region apex for 14 subjects with BK amputation are shown.

CAD AK IC Socket Design Template Location of Quadriceps Modification. Region Vs. AK Amputee Residual Limb Quadriceps Location.

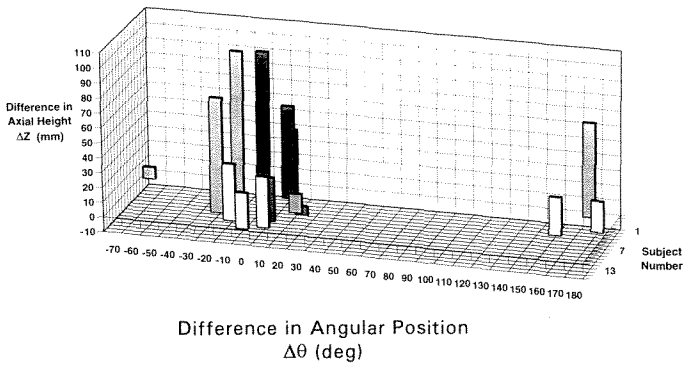

Figure 3b.
Prosthetics CAD system socket design template modification region location errors from insufficient residual limb landmark information. Differences in the spatial location of the residual limb quadriceps (mediolateral) midpoint at ischial level versus the position of the ShapeMaker AK IC socket design template quadriceps depression modification region focus for 14 subjects with AK amputation, are shown as measured (i) optically on the residual limbs of the test subjects, and (ii) in the VA-Seattle ShapeMaker CAD System following application of the respective socket design templates to the subjects' electromechanically digitized undistorted plaster wrap cast measurements.

similar information. Quantitative characterization of these parameters for input into prosthetics CAD systems is needed. This is currently under investigation by NY VAMC Rehab Engineering researchers.

Even with these limitations, as shown in the National AFMA Study (2), CAD/CAM technologies improved the mean quality of, and expedited the delivery of, patient prosthetics care. CAD/CAM technologies, on the average, reduced the time required for residual limb measurement acquisition/socket design model preparation and socket design and manufacture. In conventional prosthetics practice, 1.5 hr or more are required for BK amputee residual limb casting, and subsequent cast pouring, plaster setting, and plaster wrap stripping in preparation of a positive plaster model for socket design. In current prosthetics CAD, there is a savings of approximately 40 minutes for BK amputee residual limb measurement acquisition, (opto-)electromechanical digitization, and CAD system residual limb measurement input. (The time savings in residual limb measurement acquisition, digitization, and CAD model input may be reduced, however, for large patients with AK amputation, if resolutions higher than the current standard prosthetics CAD 10° angular and 6.35 cm longitudinal resolutions are used during (opto-)electromechanical digitization of the plaster wrap cast.) If little or no custom modification is required, CAD socket design can be performed in approximately 2 to 5 min, and CAM of a corresponding positive plaster socket model requires approximately 15 to 20 min. Automated CAM thermoforming of a socket requires approximately 30 min (15 min to heat the plastic preform, 5 min to form the socket, 5 min for the plastic to cool to ambient temperature, and approximately 5 min to remove the positive plaster model). Conventional prosthetics procedures require 30–60 min, at least, for design of a socket through modification of a positive plaster residual limb cast, and a minimum of 1 to 2 hr to laminate a socket over the resulting positive model. Thus, 45 min to 2 hr, or more, in time savings can be achieved in socket design and manufacture through application of CAD/CAM technologies. To ensure that these time savings are realized, and to ensure that the best fitting, most comfortable, functional, and cosmetic prostheses possible are provided to patients, complete and accurate quantitative information characterizing residual limbs of patients for CAD system input is needed.

To more accurately, consistently, and reliably characterize the spatial geometry and surface topography of patients' residual limbs and limb segments—and to significantly reduce measurement acquisition and CAD socket/orthosis design model input times still further—in 1991, we established specifications and a design for a prosthetics-orthotics optical laser digitizer capable of directly scanning the residual limbs and limb segments of patients, and detecting and preserving the locations of multiple landmarks in 5 sec or less (3,4). In 1992, a prototype digitizer was designed and manufactured under VA Rehab R&D sponsorship by Cyberware Laboratory, Inc. of Monterey, CA. In 1993, software was developed for the VA-Cyberware prototype digitizer for control, data acquisition, image generation, image processing, and measurement file format conversion for prosthetics-orthotics-pedorthics CAD/ CAM system input. A series of laboratory and clinical tests were conducted to determine the performance capabilities and limitations of the prototype digitizer. This paper reports the results to date of this work.

METHOD

In its present design, the VA-Cyberware prosthetics-orthotics optical laser digitizer consists of two scan heads

(an anterior master head and a posterior slave head) mounted on vertical uprights on synchronized, stepper motor driven, elevation control assemblies (**Figure 4**). Each scan head contains a 10 mw near-infrared laser, two charge coupled device (CCD) cameras, prisms, mirrors, and associated optics. To digitize a residual limb or limb segment of a patient, the patient is positioned in the digitizer with the limb properly anatomically aligned and centered "as best as possible" in the digitizer's scannable spatial envelope. The scan heads are elevated under computer control to a position slightly above the segment of the limb to be scanned, and then are synchronously driven down the vertical uprights. As the scan heads travel down the uprights, horizontal cross sections of the patient's limb are sequentially digitized. Samples are taken with resolutions of ≤ 1.0 mm radially (from the cameras) in 460 angular increments (from the cameras). The data are then parsed and processed to yield 128 uniformly spaced samples around each cross section of the patient's limb. The incremental spacing between digitized cross sections is determined by the speed at which the scan heads are driven down the vertical uprights. Speeds yielding longitudinal incremental spacings of 1.5–6.35 mm, to an accuracy of < ± 0.1mm, can be selected by the digitizer operator. With selection of an incremental axial spacing of 3.1 mm, a scan head velocity of 9 cm/sec is achieved, enabling 22,250 points over a 15-cm-long residual limb of a subject with BK amputation to be digitized in approximately 2 sec. Similarly, approximately 3.5 sec are required to digitize 47,500 points along a 32-cm-long residual limb of a patient with AK amputation, and approximately 10 sec are required to digitize 141,000 points over the 95 cm length of the lower limb of an orthotics patient, from the crest of his or her pelvic ilium to the plantar aspect of his or her foot.

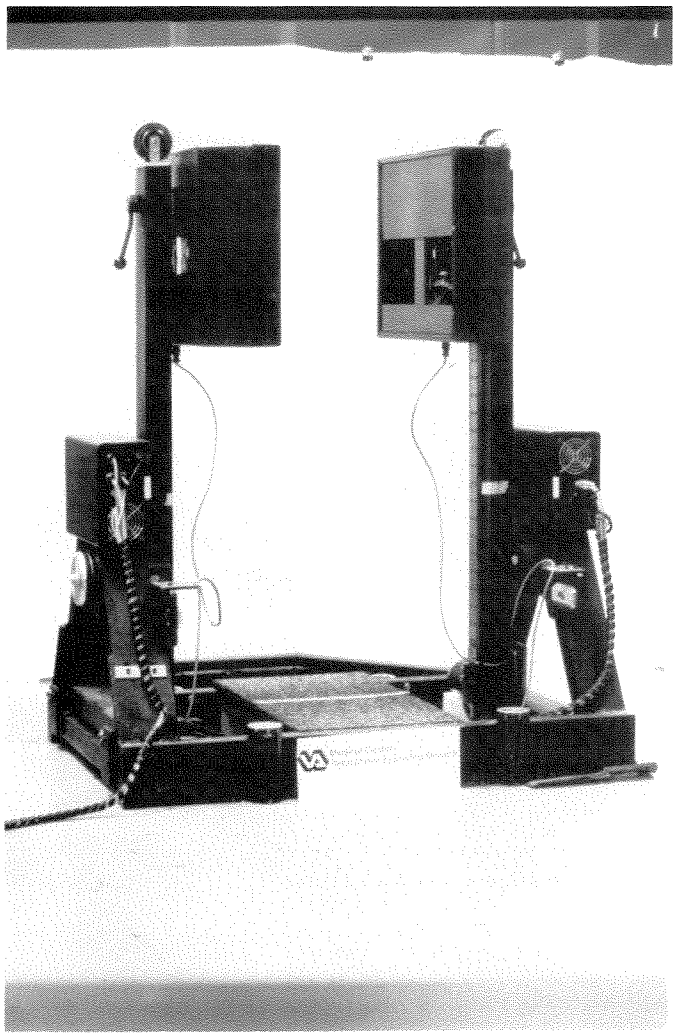

Figure 4.
The VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer. The master and slave scan heads, containing the lasers, optical elements, and charge coupled device (CCD) cameras, are shown at their proximal limits at the top of the digitizer's vertical uprights. The stepper motors actuating scan head movement may be seen at the base of the vertical uprights. The scan head electronic control circuitry is housed in the enclosures in the digitizer frame next to the vertical uprights. For digitization, the patient is positioned between the vertical uprights, centered in the digitizer's scannable envelope. The scan heads are raised proximal to the patient's limb and are synchronously driven down the vertical uprights, incrementally sampling horizontal cross sections over the length of the patient's limb/limb segment.

During digitization, light emitted from the laser diode in each scan head is optically split by mirrors in the scan head and refracted into plane segments of coherent, near-infrared light, transmitted into the right and left sides of each head. The resulting plane segments of light are then redirected with mirrors and projected at ± 41.5°, respectively, from the scan head normal onto the right and left sides of the patient's limb. The right and left plane segments from each scan head overlap in the center of the scannable field, so that together they form a continuous horizontal plane of laser light, incident approximately 200° around the limb of a patient (**Figure 5**). The light from the anterior and posterior scan heads also is designed to overlap by approximately 10° on the medial and lateral sides of a patient's limb, so the limb is completely encircled. The lasers and cameras in the anterior and posterior scan heads are synchronously gated on and off 180° out of temporal phase to avoid interference with each other. As seen in **Figures 5** and **6**, the laser light specularly reflected from the anterior and posterior halves of a patient's limb follows paths similar to that traversed by the laser source light,

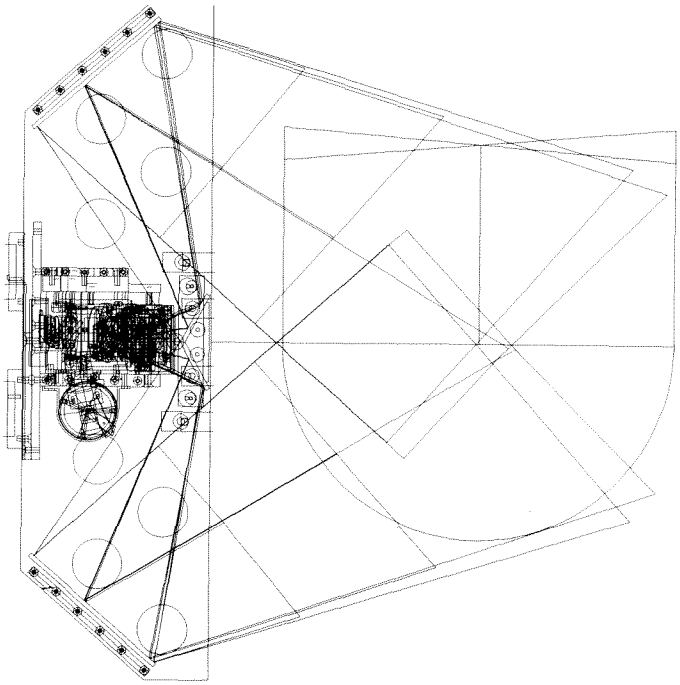

Figure 5.
Schematic diagram of a VA-Cyberware Optical Laser Digitizer scan head. The scan head's field of illumination is shown defined by the boundary of the paths of laser light emitted, split, defracted, and redirected in the right and left sectors of the scan head at ± 41.5° to the normal. The scan head's cameras' fields of view are shown defined by the lines of sight that map into the cameras' outermost pixels. As shown, the scan head's laser's field of illumination is larger and contains the scan head's cameras' fields of view. The "D"-shaped target depicted being scanned, is a cross section of an NY VAMC test phantom.

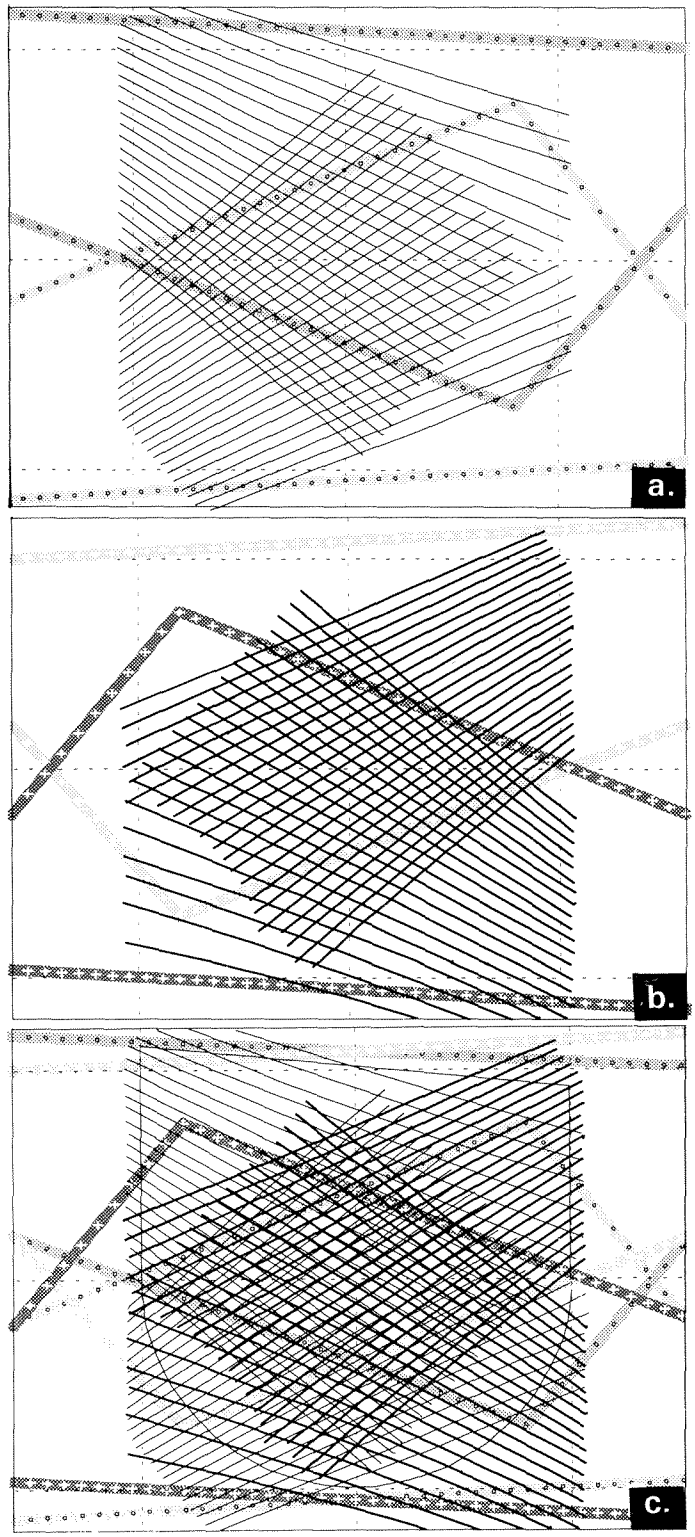

Figure 6.
The empirically measured fields of view of the present prototype VA-Cyberware Optical Laser Digitizer scan heads. The "lines of sight" of the scan heads' cameras' pixels are shown for every fifth pixel for (a) the slave scan head; (b) the master scan head; and (c) the composite fields of view of the master and slave scan heads. The broad, light gray lines define the theoretically predicted boundaries of the scan heads' cameras' fields of view. The nonlinearities, nonsymmetry, and nonuniformity of coverage of the fields of view by the cameras' pixels' lines of sight, together with the differences in these characteristics between the master and slave scan heads, are apparent. The increased inter-pixel line of sight spacing near the medial and lateral borders of the scan heads' cameras' fields of view is also apparent in (c).

except that when it enters the scan head and reaches the vicinity of the laser, the returning reflected light is focused onto the right or left half, respectively, of the given CCD arrays of the scan heads' cameras. The two cameras in each scan head are mounted directly above and directly below the laser, so that they view the reflected cross-sectional

images of the limb from 15° above and from 15° below the plane of laser light incident on the limb. With this design, the optical digitizer is functionally equivalent to a digitizer with four lasers and eight cameras.

The output signals from the upper and lower cameras in each scan head are averaged when both signals are present, or passed through if only one signal is present. This enables contours on a patient's limb hidden from one camera's view, but seen by the other camera, to be captured and preserved. The resultant output signals from the cameras of each scan head are also passed through empirical correction filters to compensate for nonlinearities in the respective scan heads' optics. The resulting corrected output signals, with the relative positional information (CCD array row and column addresses) of the cameras' illuminated pixels, are subsequently mapped into (x,y,z)-coordinates via a triangulation algorithm relating camera pixel equivalent optical origin and height to the corresponding reflecting limb surface's relative spatial coordinates. During postprocessing of the measurements, the pixel image data obtained from the digitizer scan heads' cameras are displayed, and the digitizer operator is permitted to interactively select longitudinal and latitudinal boundaries inside of which the data are saved, and outside of which the data are deemed extraneous and are discarded. This considerably reduces the optical digitizer measurement file size and subsequent data processing time. After the operator has selected the portion of the measurement data to be saved, the data are further filtered to remove high frequency optical and electrical noise and any outliers. Also, where the measurements in the right and left, anterior and posterior quadrants overlap, a moving average least mean square fit of the data is performed to derive a continuous, uniformly angularly spaced, estimate of the respective limb surface cross-sectional contours.

To identify landmarks, surface markers similar to the markers used in computer-aided tomography (CAT) and magnetic resonance imaging (MRI) are pre-positioned at the surface locations of key anatomical features on the patient's limb. The markers are detected during scanning and identified and registered during postprocessing of the measurements. Unlike the CT or MRI reference markers, however, the prosthetics-orthotics optical markers are color encoded (white and black), so they can be detected from measurements of the digitizer cameras' RGB (gray scale) output intensities. The detected markers' centroids are calculated and mapped via optical triangulation to their corresponding scan field spatial coordinates. The measurements are then compiled in a file, together with the anatomical landmark information, in a format selected by the digitizer operator. The resulting measurement file is then stored in the given patient's subdirectory on the digitizer computer, and subsequently transmitted to a designated CAD system for prosthesis, orthosis, or pedorthosis design.

RESULTS

Laboratory Tests

Laboratory tests have shown the VA-Cyberware Optical Laser Digitizer prototype to be capable of accurately digitizing the surface contours of three-dimensional objects lying inside a 28-cm-deep × 30-cm-wide × 95-cm-high spatial envelope. Tests, using calibrated "phantoms" similar to those employed in testing and calibration of radiological CAT and MRI scanners, have shown the digitizer to be capable of resolving contours on the surface of a scanned object to $< \pm 0.5$ mm mediolaterally along the y-axis near the center of the horizontal scan field and to ± 1.5 mm mediolaterally near the scan field periphery; to $< \pm 1.0$ mm anteroposteriorly along the x-axis near the center of the horizontal scan field and to ± 3.0 mm anteroposteriorly near its periphery; and, operating at its minimal vertical scanning speed, to $< \pm 0.5$ mm in height along the z-axis. Laboratory tests have further shown that the digitizer has a repeatability from scan-to-scan of $< \pm 0.5$ mm relative to a fixed spatial reference frame. Over a 6-mo period, the digitizer has also been shown to have a consistency from day-to-day between scans of $< \pm 0.5$ mm (provided the digitizer's optics are kept clean, the digitizer is not moved, and the scan heads are not pivoted so that the alignment of the optical elements is not altered—which necessitates recalibration and calculation of new compensation coefficients. It should be noted that cleaning the digitizer's optical elements, unlike inadvertant displacement, restores the digitizer's sensitivity without the need for recalibration.)

Clinical Tests

Clinical tests have shown the optical digitizer to be an effective, accurate, consistent, and expeditious tool for quantitative characterization of the spatial geometry and surface topography of the residual limbs of persons with amputation, and the limb segments of orthotics and pedorthics patients. **Figure 7** shows the residual limb of a test subject with BK amputation being scanned. **Figure 8** shows the distal view of the composite pixel images acquired from the digitizer scan heads' cameras. The pixel

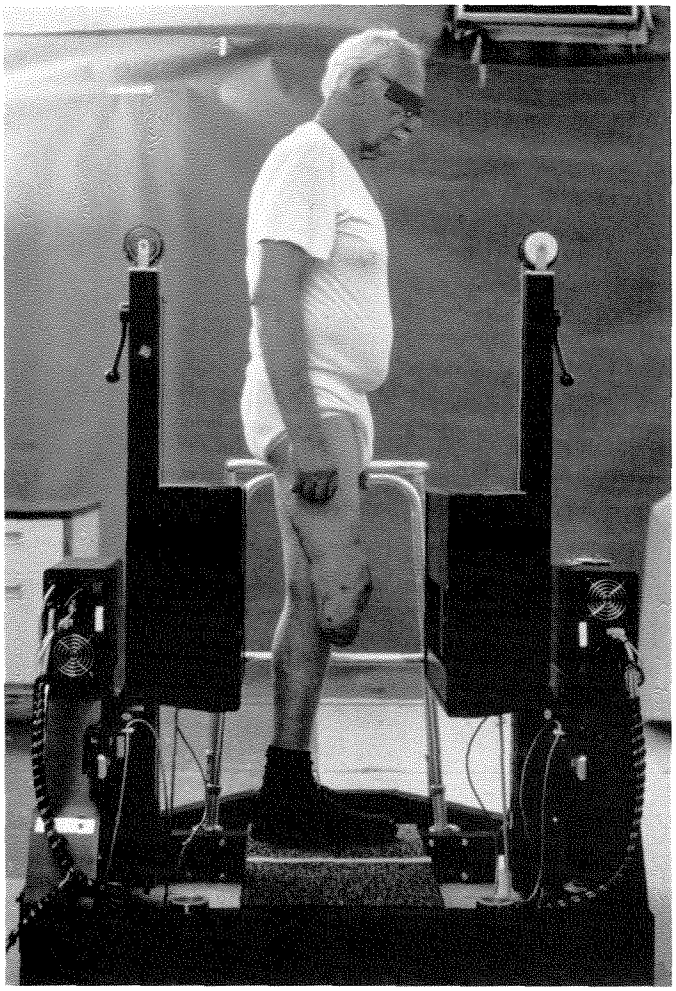

Figure 7.
Clinical testing of the VA-Cyberware Optical Laser Digitizer in measurement of the spatial geometry and surface topography of the residual limb of a test subject with right BK amputation.

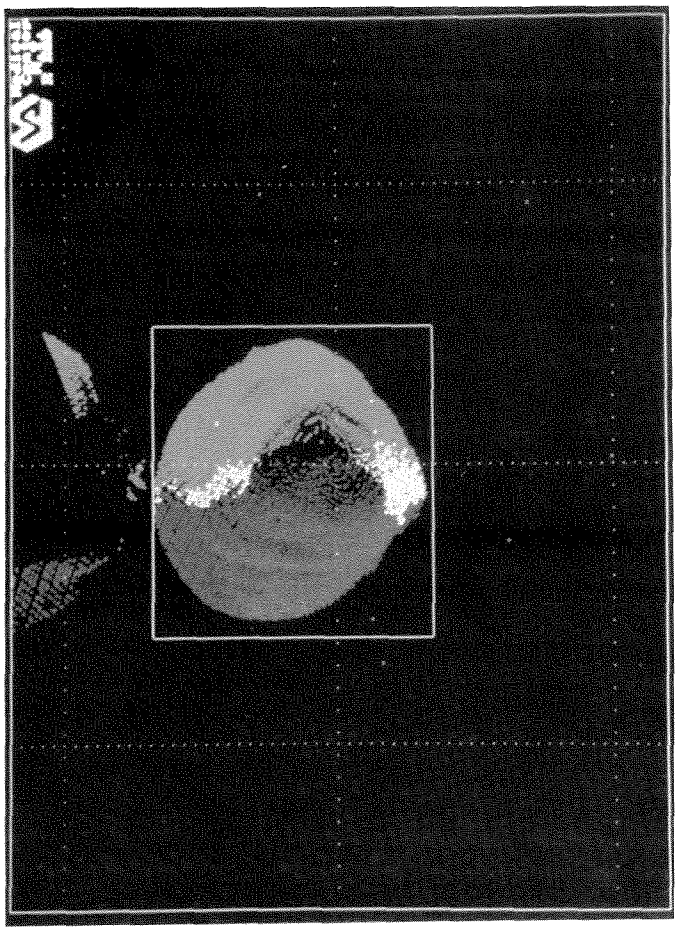

Figure 8.
Distal view (from the floor up) of the optical digitizer's master and slave scan heads' composite pixel measurements of the residual limb of the test subject with right BK amputation shown in Figure 7. The scan heads' cameras' pixel measurement data are shown mapped into their corresponding scan field (x,y,z)-spatial coordinates, but otherwise unprocessed. On the medial and lateral aspects of the residual limb, where the illuminated pixel densities are higher, is where the measurement data from the master and the slave scan heads' cameras overlap. The white lines boxed around the subject's residual limb are the scan postprocessing "data extraction windows," interactively defined by the digitizer operator, for selection of the pertinent scan data to be saved and the extraneous scan data to be discarded.

image data are shown mapped to their relative spatial coordinates via the optical triangulation transformation, but otherwise unprocessed. Data sorting boundaries for extraction of pertinent residual limb data may be seen in **Figure 8.** The light gray dots in this figure are the data acquired by the anterior scan head cameras, and the darker dots are the data acquired by the posterior scan head cameras. The data from the anterior and posterior scan heads' cameras overlap where the illuminated pixel densities are greater on the medial and lateral sides of the residual limb. **Figure 9** shows the lateral, posterior, anterior, and medial views of the residual limb measurement data, after they have been processed, formatted, and input into the ShapeMaker CAD System for prosthetic socket design.

Figure 10 shows digitization of the residual limb of a test subject with AK amputation. Anterior and distal views of the resulting composite pixel images from the digitizer's scan heads' cameras are shown in **Figure 11.** The ability of the digitizer "to see" between patients' legs, completely capturing residual limb cross-sectional contours, is illustrated in **Figure 11b.** The regions with increased pixel density on the medial and lateral aspects of

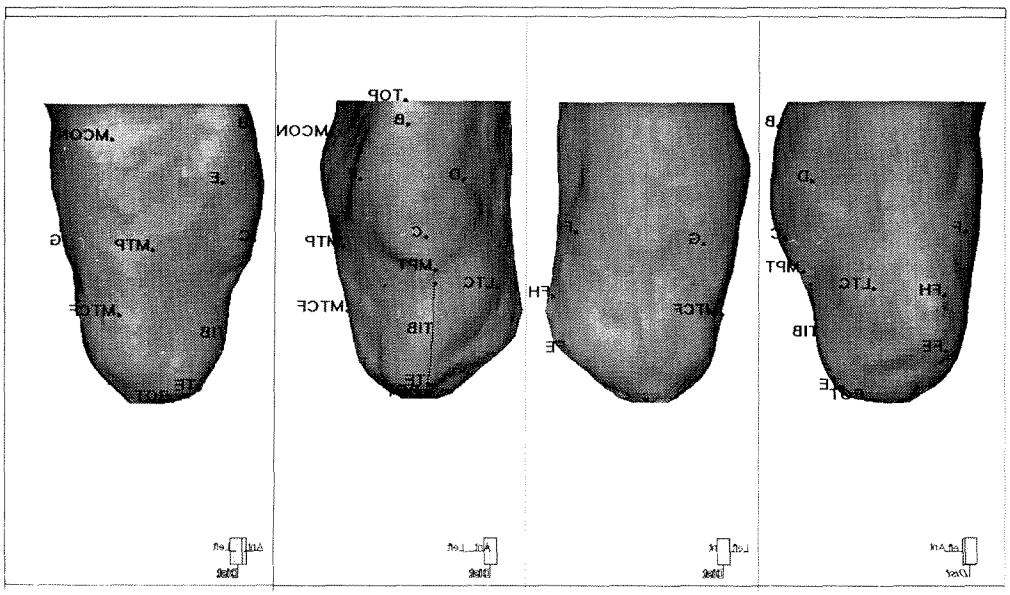

Figure 9.
Lateral, posterior, anterior, and medial views of the residual limb measurement data from the optical scan of the test subject with right BK amputation in Figure 8 are shown input into the VA-Seattle ShapeMaker CAD System for prosthetic socket design.

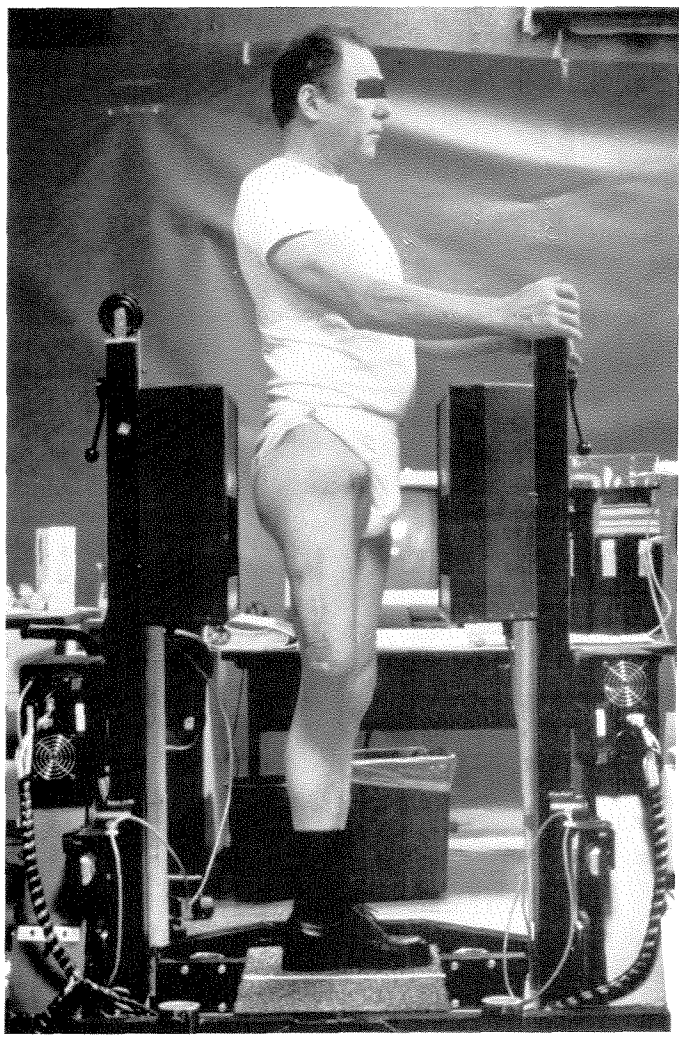

Figure 10.
Clinical application of the VA-Cyberware Optical Laser Digitizer in measurement of the spatial geometry and surface topography of the residual limb of a test subject with right AK amputation.

the limb are where data from the anterior and posterior scan heads' cameras overlap. **Figure 12** shows lateral, posterior, anterior, and medial views of the resulting residual limb measurement data after they have been processed, formatted, and input into the ShapeMaker CAD System for socket design.

Figure 13 shows digitization of the lower limb of a neuromuscularly impaired orthotics patient. Posterior and distal views of the resulting composite pixel images from the digitizer scan heads' cameras are shown in **Figure 14.** The ability of the digitizer to characterize the spatial geometry and surface topography of the lower limbs of orthotics patients, from the crests of their ilia to the plantar aspect of their feet, is demonstrated in **Figure 14a.** The digitizer's ability to see between the legs of orthotics patients capturing femoral and tibial limb segment contours is evident in the distal view shown in **Figure 14b. Figure 15** shows lateral, posterior, anterior, and medial views of the digitizer measurement data, after the data have been processed, formatted, and input into the ShapeMaker CAD System for knee-ankle-foot orthosis (KAFO) design. During scanning, if a patient's limb is malaligned (e.g., in excessive recurvatum, varus, or valgus), then either 1) the orthotist or physician can properly align the respective limb segments, holding them in position during digitization, and

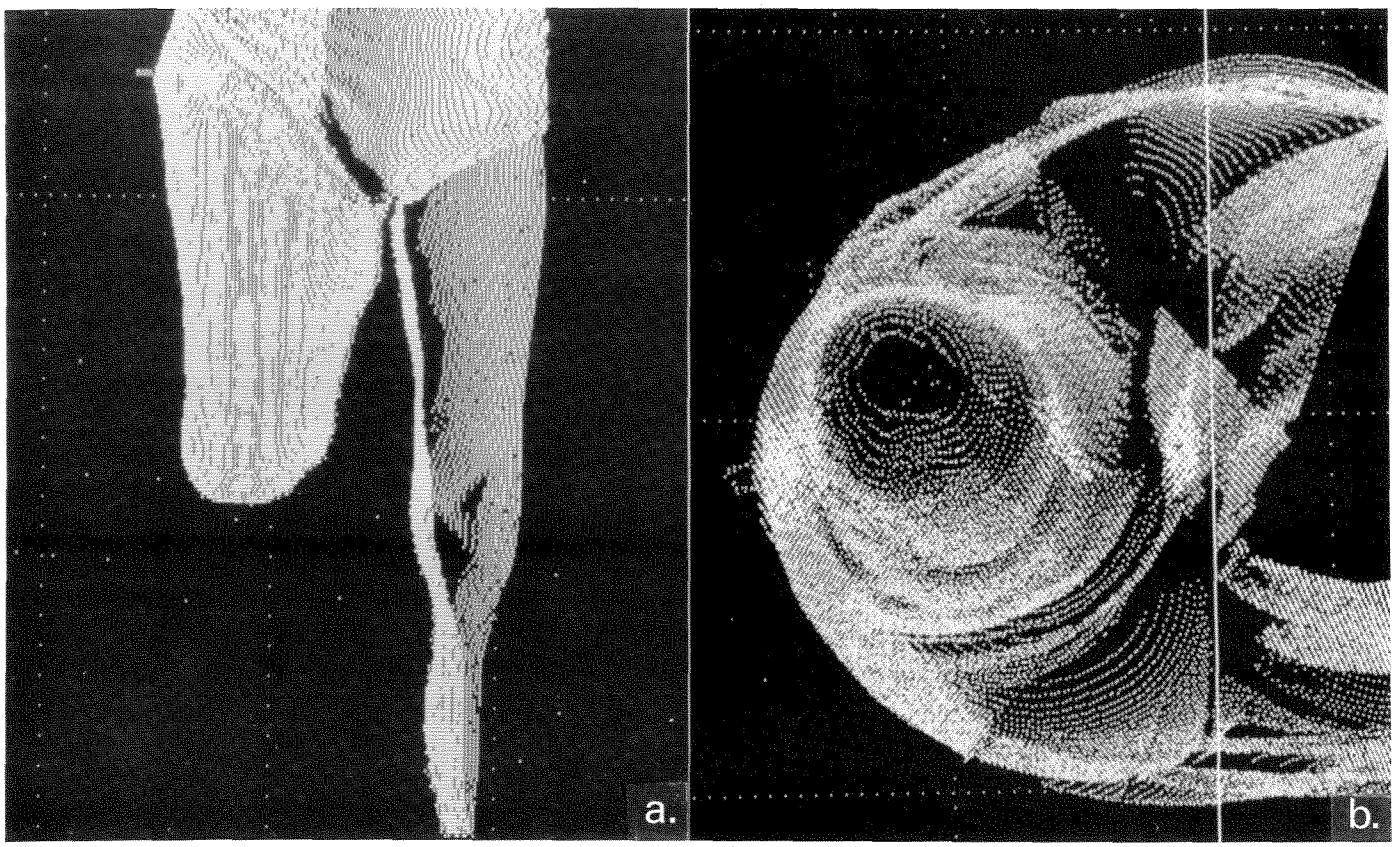

Figure 11.
The optical digitizer cameras' pixel measurement data from the scan of the test subject with right AK amputation in Figure 10 are shown. (a) The slave scan head's pixel measurement data of the anterior surface of the subject's residual limb; and (b) the distal view (from the floor up) of the master and slave scan heads' composite pixel measurement data are shown. The pixel measurement data have been mapped into their corresponding scan field (x,y,z)-spatial coordinates, but are otherwise unprocessed. Where the illuminated pixel densities are greater, on the medial and lateral aspects of the subject's residual limb in the distal view (b), is where the measurement data from the master and the slave scan heads' cameras overlap. The digitizer's ability to capture contours over the entire surface of the subject's residual limb, including over the perineal and lateral aspects of the limb, is clearly shown.

subsequently editing out any artifacts that ensue (e.g., an orthotist's fingers encroaching in the measurements); or 2) the orthotist can select common reference frame coordinates, apply appropriate optical reference markers on each limb segment, scan each limb segment separately, and then mutually align and "zipper" the resulting limb segment measurement sets together using specialized digitizer application software. The former method is less complex and usually found to be easier.

Figure 16 shows digitization of the foot and ankle of a pedorthics patient: the horizontal plane of laser light incident on a cross section of the foot of the subject during digitization is evident. As in orthotics applications, pedorthics patients' feet/ankles that are malaligned can be corrected (to the extent possible) during the digitization process, and any resulting artifacts edited out when the data are imported into the CAD system for subsequent pedorthosis design.

Detection and identification of residual limb (limb segment) landmarks are illustrated in **Figure 17.** High contrast red, white, and black optical markers were pre-positioned at the femoral adductor tubercle, medial femoral epicondyle, lateral femoral epicondyle, mid-patellar tendon, medial tibial condylar flare, fibular head, fibular end, and mid-tibial shaft crest of a test subject with BK amputation. The subject's residual limb was then scanned. The resulting output intensities from the digitizer's cameras were measured and filtered. Bandpass filtering the digitizer camera output intensities at the marker intensity variation frequencies attenuates the "background" portion of the data produced by light reflected from the surface of the residual limb, and "passes," unchanged, the portion of the

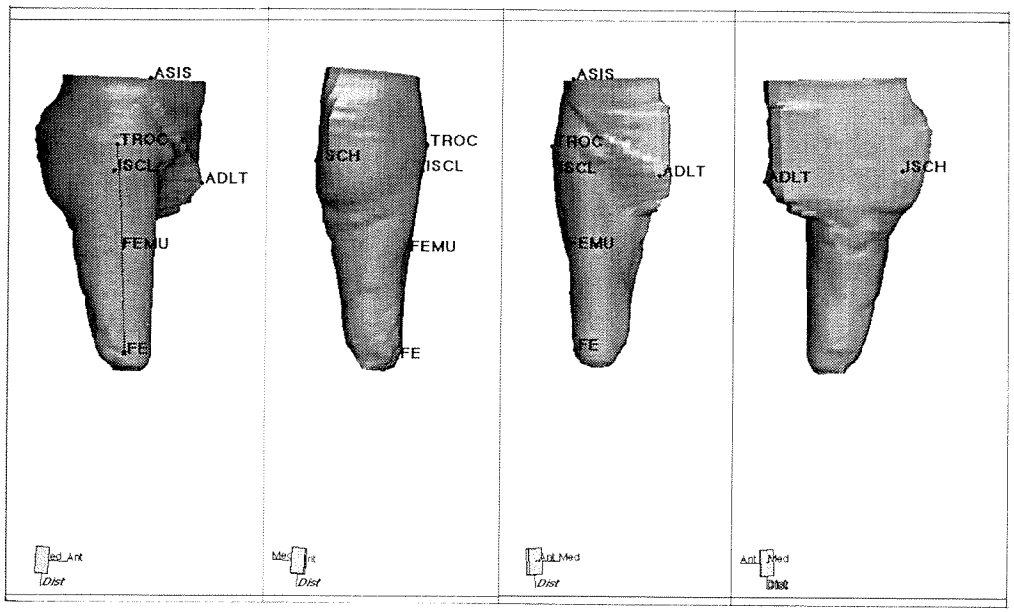

Figure 12.
Lateral, posterior, anterior, and medial views of the residual limb measurement data from the optical scan of the test subject with right AK amputation in Figure 10 are shown input into the VA-Seattle ShapeMaker CAD System for prosthetic socket design.

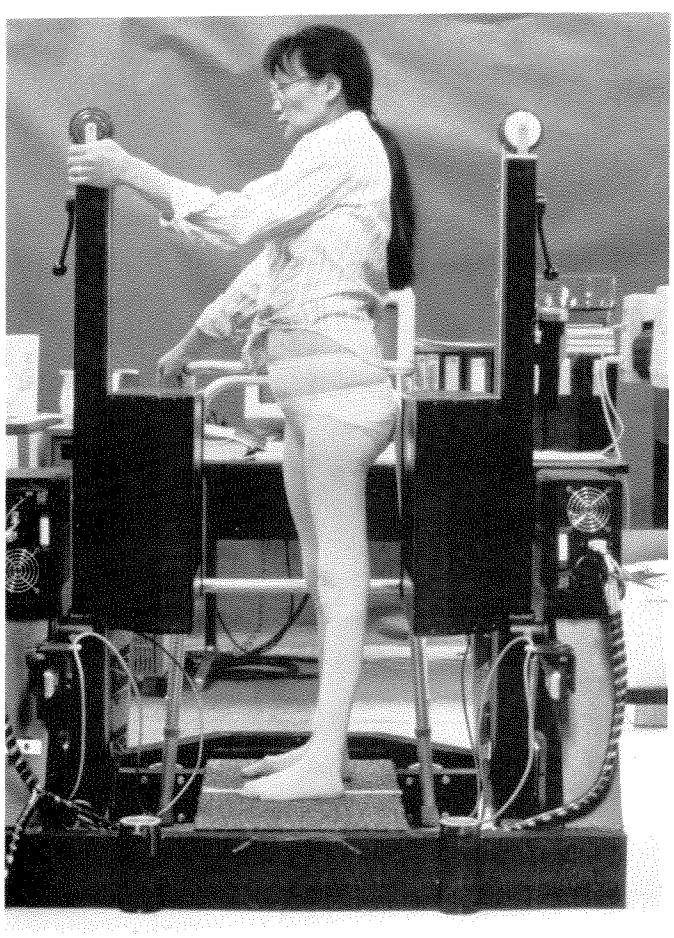

Figure 13.
Clinical application of the VA-Cyberware Optical Laser Digitizer in measurement of the spatial geometry and surface topography of the lower limb of a neuromuscularly impaired orthotics patient.

measurements due to light specularly reflected from the markers. The locations of the markers in the data thus become more prominent. Identification of which residual limb anatomical features correspond to which of the detected markers is not readily apparent, however, in the camera output intensity data obtained from the digitizer as a function of pixel number and cross-sectional scan number. A further transformation of the data through optical triangulation, to the equivalent function relating camera output intensity to the scan field (x, y, z)—spatial positions "viewed" by each of the camera pixels at the respective cross-sectional scan heights—is necessary to facilitate identification of which residual limb anatomical feature(s) correspond to the respective detected optical markers. Detection of residual limb or limb segment landmarks is further enhanced by quantization of the transformed output intensity data into discrete levels, with subsequent mapping of the resulting levels into distinct, contrasting, coded colors. As shown in **Figure 17,** such contrast enhancement of the camera output intensity measurements causes the optical markers to appear as small, circular regions superimposed on the lighter, shaded image of the residual limb. In addition, transformation and enhancement of the digitizer cameras' output intensity measurements facilitates application of a pattern recognition scheme for automated landmark identification and registration, such as the "blackboard" scheme (5) currently under development by NY VAMC and Wright Patterson Air Force Base CARD Laboratory researchers.

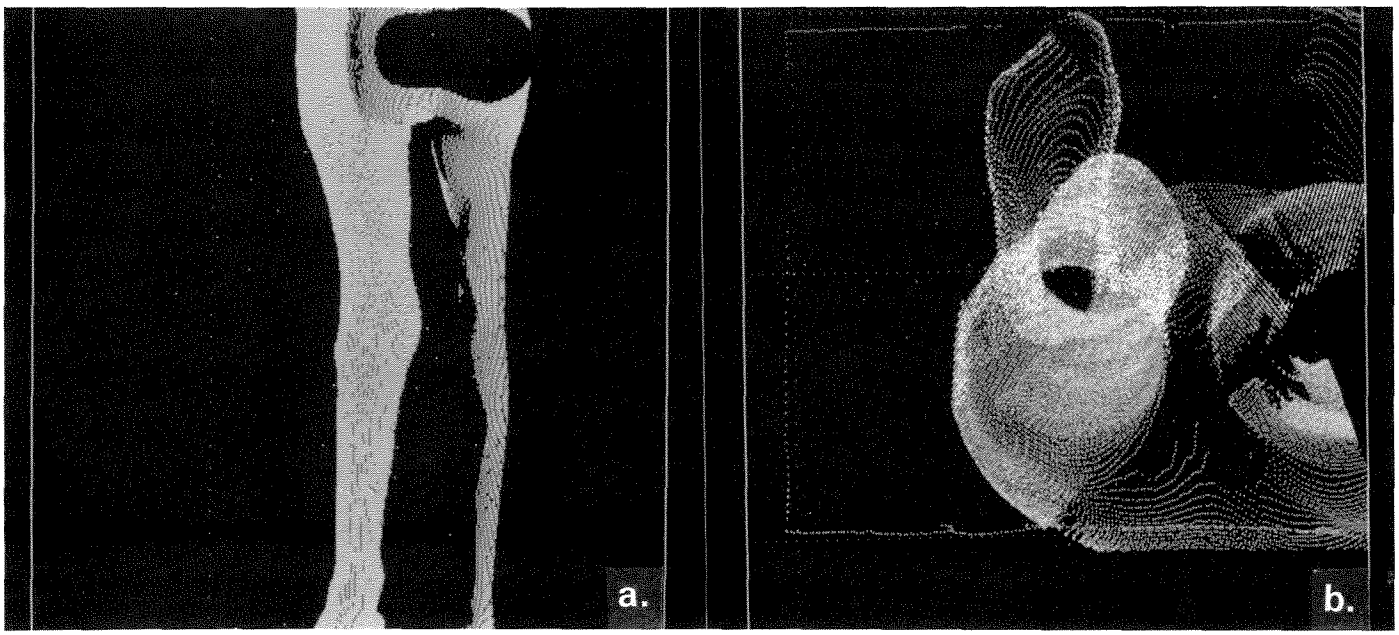

Figure 14.
The optical digitizer cameras' pixel measurement data from the scan of the left lower limb of the orthotics patient shown in Figure 13. The slave scan head's pixel measurement data of the posterior surface of the subject's pelvis and left leg are shown in (a). The distal view (from the floor up) of the master and slave scan heads' composite pixel measurement data is shown in (b). The pixel measurement data have been mapped into their corresponding scan field (x,y,z)-spatial coordinates, but are otherwise unprocessed. The digitizer's ability to completely capture the surface contours of the subject's limb, from the crest of her ilium to the plantar aspect of her foot, is evident.

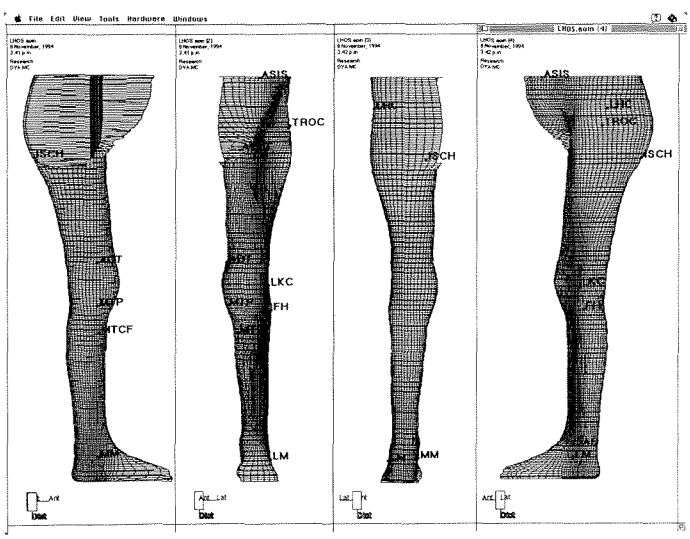

Figure 15.
Lateral, posterior, anterior, and medial views of the measurement data from the optical scan of the left lower limb of the orthotics patient in Figure 13 are shown input into the VA-Seattle Shape-Maker CAD System for knee-ankle-foot orthosis (KAFO) design.

Figure 16.
Pedorthic application of the VA-Cyberware Optical Laser Digitizer for measurement of the spatial geometry and surface topography of patients' feet and ankles. The horizontal plane of light from the digitizer scan heads' lasers can be seen incident on a transverse cross section of the patient's foot during the scanning process.

As part of the investigations with the VA-Cyberware Optical Laser Digitizer prototype, comparative clinical studies were performed in which test subjects with BK and AK amputation were optically scanned, and the relative positions of designated residual limb reference frame landmarks recorded. The subjects' residual limbs were also cast with plaster bandage, the resulting casts were then digitized

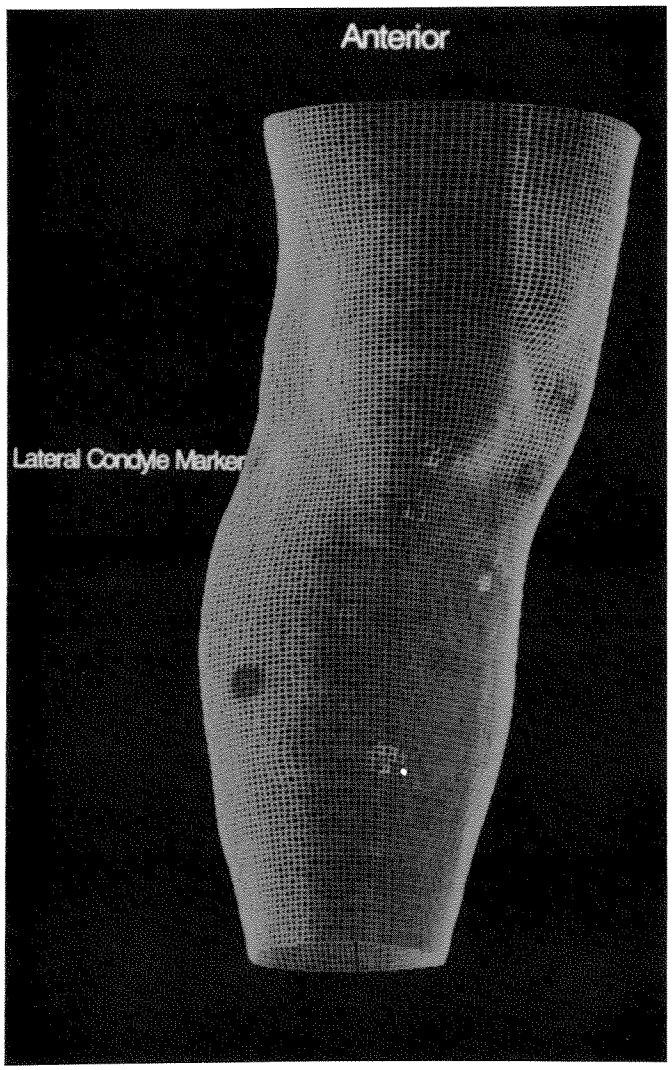

Figure 17.
Detection and identification of residual limb landmarks from the optical digitizer's cameras' output intensity measurements. Color encoded markers were placed on a right BK amputee test subjects' residual limb femoral adductor tubercle, medial femoral epicondyle, lateral femoral epicondyle, mid-patellar tendon, medial tibial condylar flare, fibular head, fibular end, and mid-tibial shaft crest prior to optical digitization. The digitizer scan heads' cameras' output intensity measurements from the resulting scan of the subject's residual limb are shown mapped via optical triangulation into their corresponding (x,y,z)-spatial coordinates, bandpass filtered at the optical marker intensity variation frequencies, and contrast enhanced to improve the detectability and identifiability of the landmarks.

using the NY VAMC Prosthetics CAD/CAM electromechanical digitizer, preserving the spatial locations of the given reference frame landmarks. The sets of optically digitized measurements and electromechanically digitized plaster wrap cast measurements for each subject were then mutually aligned and analyzed.

Considerable care was taken in the clinical studies to control experimental variables. A single engineer and single prosthetist performed all of the optical scans. They meticulously identified and marked the reference landmarks on the residual limbs of each of the subjects, and carefully, and as consistently as possible, aligned the residual limb of each subject for scanning and casting. Similarly—to maintain consistency in experimental technique, and minimize measurement variability and error—all test subjects were cast by the same prosthetist. During casting, the project prosthetist expended considerable effort to avoid displacing or distorting the subjects' residual limb tissues (the same type of plaster bandage was used for each subject, applied proximally to distally in a medial-to-lateral direction, without modification or molding of the residual limb tissues, and with application of only enough tension to prevent wrinkling of the plaster bandage). In addition, to minimize the potential for edematous swelling, the subjects were asked to remain in their prostheses until the time of scanning and casting, and to re-don their prostheses and walk about in the interval between scanning and casting. Half of the subjects were optically scanned first, and half were cast with plaster bandage first. As an additional control, multiple scans and multiple casts of four of the test subjects were taken and analyzed.

For the multiply scanned BK and AK subjects, maximum volumetric deviations of 1.2 percent and 3.0 percent were observed, respectively. However, most of the optical scans for these subjects evidenced volumetric variations of 1.0 percent or less. Volumetric variations of 7.6 percent and 12.3 percent were found in the undistorted plaster wrap casts for the multiply cast BK and AK test subjects, respectively. No correlation between scanning or casting order and the magnitude of the variations observed in the resulting scans or casts was found upon analysis of the data. Edematous swelling of the subjects' residual limb tissues was therefore discounted as a causative factor for the residual limb scan and cast measurement variations that were observed. A strong correlation was found, however, between the contractile state of the test subjects' residual limb musculature and the residual limb segmental volumes optically measured. Specifically, it was discovered that some subjects, when told to "hold perfectly still" during the scanning operation, inadvertently isometrically contracted their muscles, thereby changing the shape and increasing the volume of their residual limbs. Precautions were thence taken to instruct the test subjects not to tighten

their muscles during the scanning procedure. The 20-min time period involved in the residual limb casting procedure, however, is felt to preclude muscular contraction as a causative factor in the electromechanically digitized plaster wrap cast variations that were observed. The magnitudes of the intra- and intersubject cast measurement variations that occurred indicate that substantial differences existed in the subjects' cast/residual limb tissue interface stresses. Such interface stress variations are believed to almost certainly be attributable to deviations in plaster bandage application tensions, and differences in the subjects' residual limb tissue viscoelastic responses to radial and tangential loading. To the extent possible, these factors were controlled by the investigators. They still inherently led to greater variations in the electromechanically digitized plaster wrap cast measurements than the factors correspondingly adversely affecting the optical scan measurements. This demonstrates the enhanced consistency and repeatability afforded by optical digitization in characterizing residual limb and limb segment spatial geometry and surface topography. It also demonstrates the increases in cast/limb tissue interface stresses—potentially adversely impacting localized tissue circulation and metabolism, especially in chronic diabetic and atherosclerotic patients (6)—that can arise as a result of the residual limb or limb segment casting process. These stresses are inherently carried through into the prosthetic socket/ orthotic cuff designed and manufactured from the casts.

Typical examples of the *results* obtained in the *clinical tests* are shown in **Figures 1, 2, 9,** and **12.** The additional geometric and topographic information contained in the optically digitized residual limb measurements is clearly evident in **Figures 9** and **12,** compared with the electromechanically digitized plaster wrap cast measurements for the same subjects shown in **Figures 1** and **2,** respectively. Quantitative analysis of the data obtained from the two measurement techniques shows that, although the optically digitized and electromechanically digitized plaster wrap cast measurements were similar for each subject, they were not geometrically identical. Computation of cross-sectional circumferences, areas, and segmental volumes of the test subjects' residual limb measurements reveals the optically digitized measurements, on the average, to be larger than the corresponding electromechanically digitized plaster wrap cast measurements. In addition, the optically digitized measurements were found to be slightly axially longer, on the average, than the corresponding electromechanically digitized plaster wrap cast measurements. However, as seen in **Figure 18,** this was not true for all of the subjects tested. For some subjects, the cross-sectional circumferences, areas, and segmental volumes of their electromechanically digitized plaster wrap cast measurements were larger than their corresponding optically digitized residual limb measurements.

The magnitudes of the intersubject variations in the residual limb measurement differences shown in **Figure 18** are too large to be attributable to intrasubject optical scan and electromechanically digitized plaster wrap cast measurement deviations, as established from the multiply scanned and cast test subjects. Other factors must have produced the large variations observed. The data in **Figure 18** are presented in order of increasing residual limb length. Calculation of the sample correlation coefficient for the data indicates there is no appreciable correlation between residual limb length and optical scan—electromechanically digitized plaster wrap cast measurement deviation. Further analysis of the measurement variance reveals mild correlation between residual limb measurement deviation and the qualitatively assessed residual limb tissue stiffness of the subjects. The study sample sizes in the "very soft" and "firm" tissue stiffness categories, however, were too small to accurately predict trends. Additional inspection of the measurements in **Figure 18** reveals residual limb tissue parametric variations common to all of the test subjects. Specifically for the subjects with BK amputation who were tested, the differences in residual limb cross-sectional circumferences, areas, and segmental volumes measured at the femoral epicondyle (FC), mid-patellar tendon (MPT), and medial tibial condylar flare (MTCF) levels were found to all either shift up or down, indicating a proximal and/or distal flow of the subjects' soft tissues during plaster wrap casting of their residual limbs (**Figure 18a**). The more limited data in **Figure 18b** indicate similar factors and conditions occurred for the AK test subjects as well.

Despite the great care taken to avoid residual limb tissue distortion and displacement during the casting process, cross-sectional rounding and distortion were observed in the electromechanically digitized plaster wrap cast measurements of all of the subjects. In comparison, the subjects' optically digitized residual limb measurements were found to be more "normal" and anatomical in shape. This was especially true for the tested subjects with AK amputation. The reduced internal mechanical structural (skeletal) support, and the greater volume of soft tissues, increased the susceptibility of the residual limb tissues of the AK amputees to displacement and distortion, when subjected to external stresses (such as the surface tensions and radial compressions inherent in circumferentially

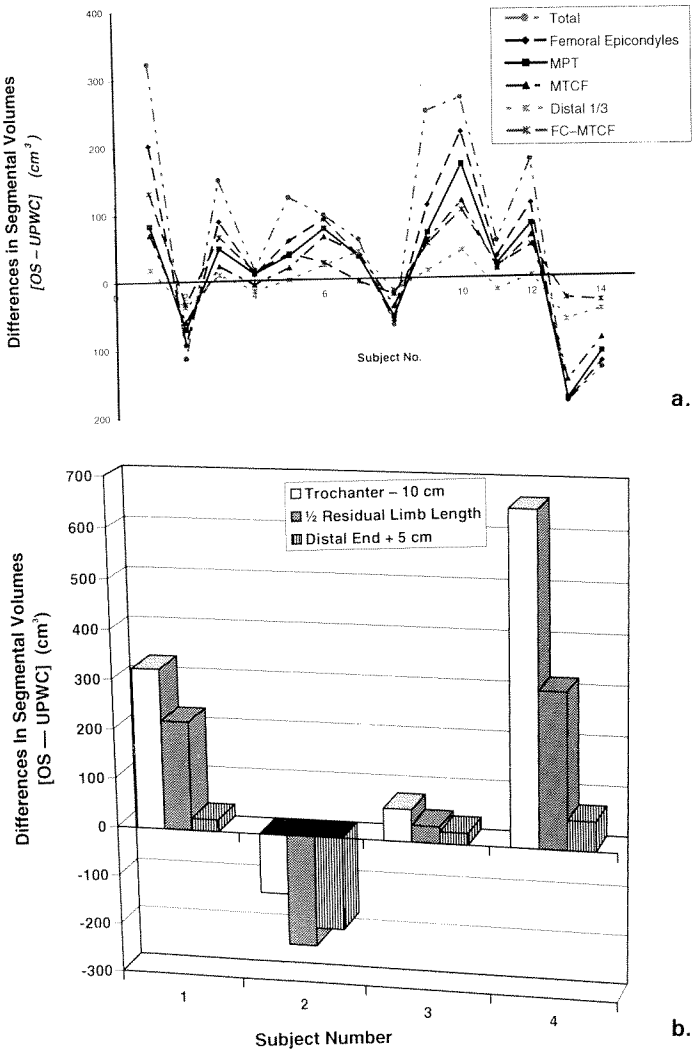

Figure 18.
Differences in residual limb segmental volumes observed between optically digitized measurements and corresponding standard prosthetics CAD electromechanically digitized unmodified plaster wrap cast measurements for (a) 14 test subjects with BK amputation and (b) four test subjects with AK amputation. The differences (optical scan values minus electromechanically digitized unmodified plaster wrap cast values) are shown in order of subject increasing residual limb length.

wrapped plaster bandage). This resulted in the significant differences in geometric shape observed between the subjects' optically digitized and electromechanically digitized plaster wrap cast measurements. This is evident in the comparative anterodistal views of an AK test subject's optically digitized and corresponding electromechanically digitized plaster wrap cast measurements shown in **Figure 19.** Marked cross-sectional rounding, as well as considerable proximal displacement, of the residual limb tissues of the subject is evident in the electromechanically digitized plaster wrap cast measurements in **Figure 19.**

The regional differences that occurred between the test subjects' optically digitized and corresponding electromechanically digitized plaster wrap cast measurements were further illustrated through calculation of radial comparative AFMap plots for the test subjects. In the VA-Seattle Shapemaker AFMap plots, optically digitized residual limb measurements were mutually aligned with, and superimposed on, the corresponding electromechanically digitized plaster wrap cast measurements. The radial difference between the optically digitized and the plaster wrap cast electromechanically digitized measurements over each nodal region of the subject's residual limb were then displayed as a color-encoded value (7). Significant differences between the optical scan and electromechanically digitized plaster wrap cast measurements over the BK test subjects' medial femoral condyles, patellar tendons, medial tibial condyles, fibular shafts, and the distal ends of the residual limbs of the subjects were observed. Differences over the subjects' popliteal gastrocnemius regions were usually less significant. Marked differences were observed for the subjects with AK amputation in the measurements obtained from the two techniques. Major differences occurred over the subjects' Scarpa's triangles, the proximal anterolateral and anterolateral-to-mid-lateral aspects of their residual limbs, and the distal ends of their residual limbs. Significant differences were also frequently found over the subjects' posteromedial gluteal and proximal perineal regions. All these regions are crucial in prosthetic socket design. They require accurate modification to within close tolerances of the patient's musculoskeletal dimensions to achieve successful socket fit, comfort, and function. This is a requirement that is difficult to attain through application of "generalized" prosthetics CAD modification templates, or through application of fixed conventional prosthetics socket modification paradigms, if the relative amounts, locations, and shapes of the residual limb or limb segment tissues vary appreciably and seemingly unpredictably from cast-to-cast and from patient-to-patient.

DISCUSSION

The broad applicability, high level of performance, and enhanced repeatability and consistency achievable with the VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer have been established in

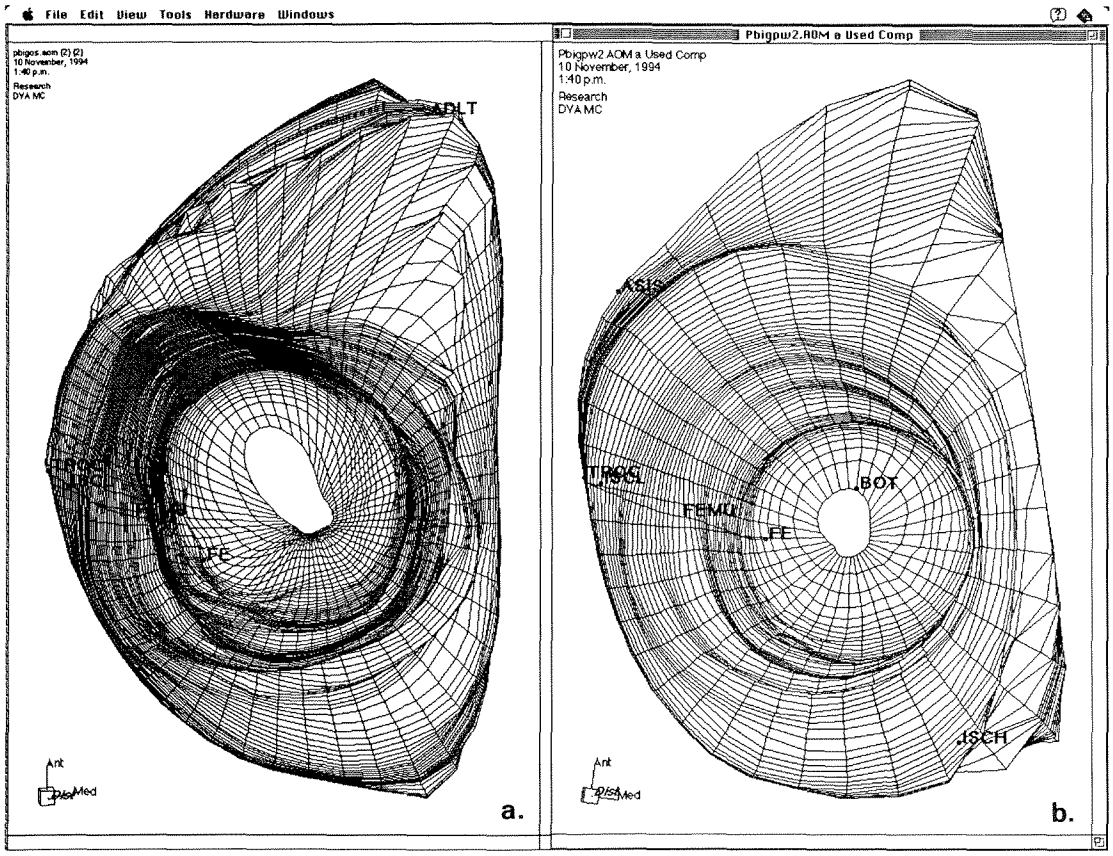

Figure 19.
Anterodistal views of the (a) optically digitized and (b) corresponding electromechanically digitized unmodified plaster wrap cast measurements, of the residual limb of a test subject with right AK amputation. The more "natural" shape of the optically digitized residual limb measurements is apparent, compared with the rounded and proximally displaced tissue geometry inherent in the electromechanically digitized unmodified plaster wrap cast measurements.

the tests we have performed. The laboratory and clinical tests have also identified several areas where the current digitizer prototype requires further refinement. In particular, the 28-cm-deep × 30-cm-wide × 95-cm-high scannable spatial envelope of the current prototype has been shown to be insufficient. Patients with amputation and orthotics patients whose anteroposterior and/or mediolateral dimensions exceed these values, or who have long residual limbs or limb segments with hip and/or knee joint flexion contractures exceeding 20°, causing their (residual) limbs to protrude outside of the scannable envelope, cannot be completely "seen" by the digitizers scan heads' cameras.

Three other subtler factors affecting the digitizer's performance identified in our laboratory tests are 1) nonuniformities in the intensities and dispersions of the prototype digitizer scan heads' lasers; 2) lack of matching in the optical characteristics of the prototype digitizer scan heads' optical components; and 3) nonuniformities in the output responses of the prototype digitizer scan heads' cameras. As seen in **Figure 6,** these factors adversely impact the digitizer scan heads' cameras' fields of view, depths of field, and output responses. The severity of these effects was found to differ significantly between the digitizer prototype's master and the slave scan heads, causing nonuniformity of the data obtained from the heads. This further complicated estimation of residual limb and limb segment contours using the composite data from the two scan heads.

In the outer regions of the scan heads' fields of view, as shown in **Figure 6,** the CCD cameras' optical lines of sight bend and separate from each other more than at the centers of the cameras' fields of view. The effects of these nonuniformities and nonlinearities on the outputs of the scan heads' cameras' pixel and intensity output responses, from which the (x,y)-coordinates of the digitized objects' surface contours are estimated, can, and have, to the extent

possible, been compensated for through incorporation of empirically established optical compensation algorithms in the digitizer image generation and processing software. However, it is impossible to correct for the loss of resolution precipitated by these effects. The increase in spacing between the scan heads' cameras' adjacent optical lines of sight at the periphery of the fields of view, results in an increase in the portions of the digitizer's scannable envelope that are mapped into individual pixels on the scan heads' CCD cameras. As a consequence, the maximum resolution achievable over the outer portion of the digitizer's scannable envelope is only ± 3.0 mm anteroposteriorly and ± 1.5 mm mediolaterally. Whereas, at the center of the scan heads' cameras' fields of view, the optical lines of sight are more uniformly and closely packed, so that resolutions of < ± 0.5 mm are achieved. In scanning the residual limbs of subjects with AK and BK amputation, and the lower limb segments of orthotics patients, accurate characterization of the contours of the limb, and precise determination of the locations of key anatomical structures on the lateral aspects of the limb (e.g., the trochanter, distal end of the femur, fibular head, fibular end, malleoli, etc.) are essential. For patients of medium-to-large stature, these structures inevitably lie in the peripheral regions of the digitizer's fields of view, and are thus less accurately detected, or may be lost altogether. In addition, for accurate detection of lateral contours, brighter lasers with more uniform fields of illumination, matched between each of the scan heads, are needed. Brighter lasers with more uniform illumination are also essential for improvement of landmark detectability. When the color encoded markers used for anatomical landmark detection lie in the center of the digitizer scan heads' cameras' fields of view, they are readily detectable via bandpass filtering and contrast enhancement of the camera output intensity measurements (**Figure 17**). However, because of the nonuniform, dispersive illumination produced by the prototype digitizer's lasers, when the markers fall near the periphery of the scannable envelope, the intensity of the light (the signal) reflected from the markers is weak, so the markers begin to become indistinguishable from the ambient and background light reflected from the surface of the patient's residual limb or limb segment (background noise). This is apparent in the diminished detectability of the BK test subject's lateral femoral epicondyle and fibular head markers in **Figure 17.**

Clinical testing of the digitizer with pedorthics patients revealed two additional problems. The digitizer prototype was designed so the uprights could be unlocked and pivoted 90° into a horizontal position. A chair could then be placed within the frame of the digitizer, and a pedorthics/orthotics patient seated with his or her foot placed in partial weightbearing on the glass plate of a support fixture inserted between the horizontally rotated uprights. The scan heads could then be driven horizontally along the uprights' translation rails, scanning transverse cross sections over the medial, lateral, dorsal, and plantar surfaces of the patient's foot and ankle (**Figure 20**). *Clinical pedorthic testing* of the digitizer showed the digitizer functioned properly mechanically. However, differences in the indices of refraction between pedal soft tissues, glass, and air, together with the acute angle of incidence of the scan heads' laser light, were found to produce up to five planes of laser light incident on patients' feet, resulting from

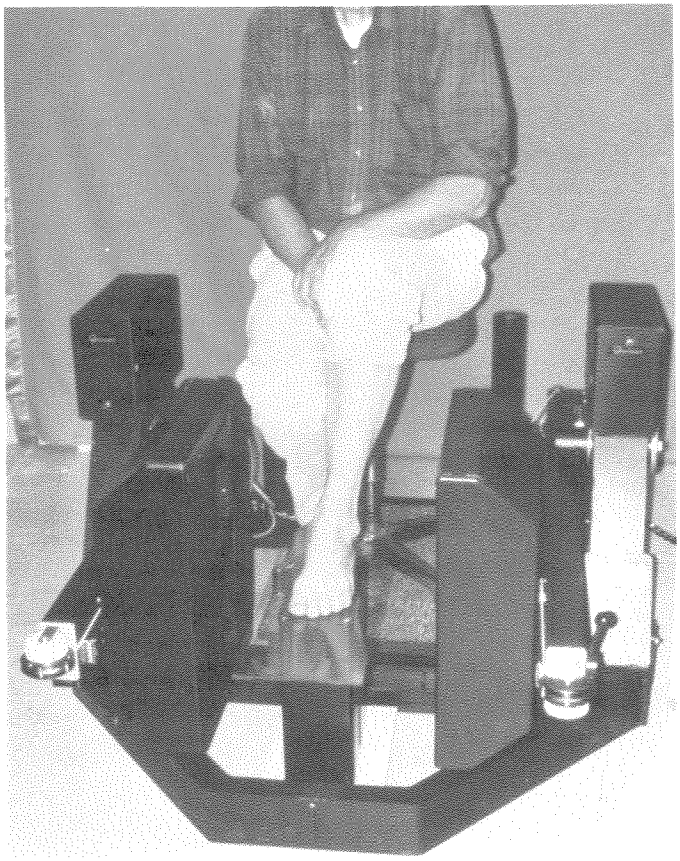

Figure 20.
Pedorthic scan mode of the VA-Cyberware Optical Laser Digitizer prototype as originally designed. The patient is seated on a chair in the base of the digitizer; the uprights, scan heads, and translation assemblies are rotated 90°; and the patient's foot/ankle is positioned and aligned in partial weightbearing on a pedal support fixture located between the horizontally rotated uprights and scan heads.

multiple reflections in the support fixture glass plate (**Figure 21**). The spurious signals from these multiple reflections irrevocably corrupts the digitizer camera output data, making it impossible to estimate cross-sectional contours where the multiply reflected light is of appreciable intensity. In addition, it was discovered that upon derotation of the digitizer uprights back to their vertical positions, the scan heads did not precisely return to their original positions. This necessitated laborious recalibration of the digitizer, and computation of new correction coefficients to compensate for the nonlinearities in the scan heads' optics. Thereafter, the horizontal scanning mode for pedorthic applications was abandoned.

A new, enhanced digitizer prototype is currently being constructed with 1) brighter and more uniformly illuminating lasers; 2) matched linear optics; 3) CCD cameras with approximately four times the resolution of those in the current prototype; and 4) an expanded scannable envelope at least 35-cm-deep × 40-cm-wide × 130-cm-high, with scan head "standoff" distances of at least 10 cm. These refinements should remedy the problems encountered in testing the first optical digitizer prototype, with the exception of those associated with horizontal pedorthic scanning, which, for now, has been replaced with the vertical scanning procedure shown in **Figure 16.**

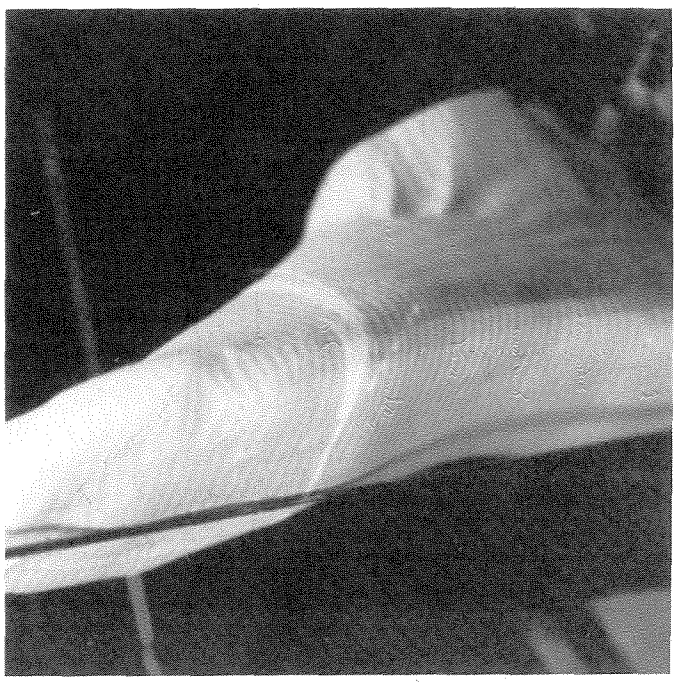

Figure 21.
Laboratory simulation demonstrating the problems inherent in the prototype optical digitizer's original pedorthic scan mode design. Five planes of laser light can be seen incident at the lateroplantar-dorsal edge of the cast of a pedorthics patient's foot/ankle. The multiple, incident planes of laser light result from reflections in the glass plate of the digitizer's pedal support fixture, because of differences in the indices of refraction between the patient's pedal tissues (simulated by the plaster cast), the pedal support fixture's glass plate, and air (the coupling medium between the scan heads' lasers and the glass plate of the pedal support fixture).

CONCLUSION

The VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer has been shown to be a powerful tool, capable of effectively and rapidly generating accurate, repeatable, and consistent quantitative measurements characterizing the spatial geometry and surface topography of the residual limbs of persons with amputation and the limb segments of orthotics and pedorthics patients. When the deficits identified in the original digitizer prototype design are corrected, and the new, enhanced prototype under construction is tested, the optical digitizer will be ready for widespread field-testing and general clinical use. The digitizer can then begin to be utilized by prosthetists, orthotists, physicians, and therapists in clinical practice, and in expanded studies and applications 1) for quantitative database compilation of residual limb and limb segment measurements for development of improved prosthesis/orthosis/pedorthosis CAD designs; 2) for compilation of quantitative patient records and histories for assessment of residual limb "state" and rate of "maturity" following amputation; 3) for tracking and assessment of the efficacy of various rehabilitative and/or pharmacological treatment regimens in regulating and controlling tissue edema/volume/mass; 4) for tracking the relative spatial locations and trajectories of adjoining limb segments as a function of their biomechanical functional state; and 5) as an instructional aid to facilitate visualization and understanding of prosthesis-orthosis-pedorthosis design, fit, and function. In all of these areas, the VA-Cyberware Lower Limb Prosthetics-Orthotics Optical Laser Digitizer offers potential for improving and enhancing the quality of prosthetic, orthotic, and pedorthic rehabilitative care for U.S. veteran (and nonveteran) patients.

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