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3D Ultrasound Imaging for Prosthesis Fabrication and Diagnostic Imaging

Alan K. Morimoto, Wallace J. Bow, D. Scott Strong, Fred M. Dickey, John C. Krumm, David D. Vick, David M. Kozlowski, Savannah Partridge, Nicolas Walsh, Virgil Faulkner, Bill Rogers

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3D Ultrasound Imaging for Prosthesis Fabrication and Diagnostic Imaging

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Abstract follows.

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Abstract

The fabrication of a prosthetic socket for a below-the-knee amputee requires knowledge of the underlying bone structure in order to provide pressure relief for sensitive areas and support for load bearing areas. The goal is to enable the residual limb to bear pressure with greater ease and utility. Conventional methods of prosthesis fabrication are based on limited knowledge about the patient's underlying bone structure.

A 3D (three dimensional) ultrasound imaging system was developed at Sandia National Laboratories in collaboration with The University of Texas Health Science Center at San Antonio. The imaging system provides information about the location of the bones in the residual limb along with the shape of the skin surface. Computer assisted design (CAD) software can use this data to design prosthetic sockets for amputees. Ultrasound was selected as the imaging modality based on comparative low-cost, safety, portability, and speed. Prior to hardware fabrication, a computer model was developed to analyze the effect of the various scanning parameters and to assist in the design of the overall system.

The 3D ultrasound imaging system combines off-the-shelf technology for image capturing, custom hardware, and control and image processing software to generate two types of image data -- volumetric and planar. Both volumetric and planar images reveal definition of skin and bone geometry with planar images providing details on muscle fascial planes, muscle/fat interfaces, and blood vessel definition. The 3D ultrasound imaging system was tested on 9 unilateral below-the-knee amputees at the Health Science Center in San Antonio. Image data was acquired from both the sound limb and the residual limb. The imaging system was operated in both volumetric and planar formats. An x-ray CT (Computed Tomography) scan was performed on each amputee for comparison.

Qualitative and quantitative studies were performed to compare CT and ultrasound data sets. Results of the test indicate beneficial use of ultrasound to generate databases for fabrication of prostheses at a lower cost and with better initial fit as compared to manually fabricated prostheses. In addition, qualitative results indicate that planar images represent substantial improvements over standard ultrasound images and that they could serve as improved diagnostic images.

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INTRODUCTION

This report outlines the work that occurred during fiscal years 1991 through 1994 to develop a 3D ultrasound imaging system for prosthesis fabrication. The work was funded by the Laboratory Directed Research and Development (LDRD) program at Sandia National Laboratories and research was performed in collaboration with the Department of Rehabilitation Medicine at The University of Texas Health Science Center at San Antonio (UTHSCSA). The Sandia team focused on the development of the 3D ultrasound imaging system while the UTHSCSA team developed the CAD software that generates the model of the prosthesis based on biomechanical adjustments of the ultrasound images. Prosthesis fabrication can then be performed based on the CAD model of the prosthesis.

The 3D ultrasound imaging system provides a database of skin and bone surfaces that represents an accurate model of the remaining (residual) portion of the amputee's limb. Ultrasound was selected as the imaging modality for this purpose because of its low-cost, non-ionizing radiation, portability, and speed as compared to other imaging modalities such as x-ray computed tomography (CT) and magnetic resonance imaging (MRI). The two latter modalities are orders of magnitude higher in cost to operate and far less portable. Furthermore, in the case of CT, ionizing radiation from the x-ray has been known to have harmful effects (Kreel & Meire, ND).

In order to define issues and requirements associated with 3D ultrasound imaging of human limbs successfully, it became essential to gather data on human subjects that could be used to refine the design. Our initial plans included using an ultrasound phantom, rather than scanning human limbs, because it was thought that a phantom would adequately mimic the ultrasonic properties of the human limb. Unfortunately, after obtaining a phantom and acquiring data, it became apparent to all involved that phantom data alone could not be used to define human leg geometry adequately for prosthesis fabrication. The inability of the phantom to model the complex geometry and tissue characteristics of the human limb combined with the overriding belief that a tremendous amount of effort and cost would be needed to provide an adequate phantom (a topic of research in and of itself) resulted in the decision that human scanning was necessary for the success of the project.

Coincidentally, Sandia decided to create a Human Studies Board (HSB) whose charter was to approve experiments that involved humans. The Sandia team obtained HSB approval for ultrasound scanning of a select small number of participants in order to improve system parameters and refine image processing software. However, the time between HSB conception and initial approvals was several months. This time lag significantly impacted the team's ability to complete the originally proposed milestones. Results from the first human studies were completed during the last few months of the second and final year of the approved work. A third and final year of funding was proposed and approved in order to move the work to a useful conclusion. During this final year, additional experiments were performed on a number of subjects to bring the platform to a level that would allow us to perform clinical trials at UTHSCSA. Approval was requested and obtained for a clinical trial to compare the images gathered from ultrasound and CT on patients at UTHSCSA. The results of the human experiments and the clinical trials are described below.

STATEMENT OF PROBLEM

Approximately 60,000 lower extremity amputations are performed each year in the U.S. for a variety of medical reasons. Ninety-seven percent of these patients are candidates for ambulation (AOPO Almanac, ND). These people can be fitted with a prosthesis that consists of an artificial foot, shaft, and hand-crafted socket into which the residual limb is inserted. The resultant device allows the patient to stand, walk, run and climb by providing a mechanical extension to the residual limb. To accommodate individual differences, current practice is to custom make each prosthesis. See Figures one through seven for a visualization of the manual fabrication process. This process is time consuming, costly and requires a highly skilled prosthetist (Stokosa, 1984). The number of amputees grows annually, and yet, the number of prosthetists within the field is shrinking (Schurr, 1990). Although prostheses have been improved in quality over the years based on improvements in the manual techniques and in the use of new materials, the basic techniques remain largely the same as in previous generations.

Inadequacies of Manually Fabricated Prostheses

Currently, the cost of a prosthesis averages \$4,000 with the range of prices from \$3,000 to \$15,000. The most important aspect of the prosthesis is the socket design (Williams, 1986) because it is the interface between the human leg and the mechanical support system. Ultimately, the design and fit of the socket determines patient acceptance, comfort, suspension and energy expenditure. These factors determine the real utility and acceptance of the product.

As patients walk and age, their residual limbs change shape in a manner that is not yet quantified. This change in shape occurs, in part, because of atrophy of the soft tissue, as well as callusing, edema, scar tissue development, aging, and other complex processes. These changes alter the limb/socket interface and can result in pain or skin breakdown. The average amputee will need three to five new prostheses within the first five years after amputation because of changes in the residual limb that result in "socket failure" (Lasson, 1985). For each replacement or new prosthesis, the patient must undergo the entire measuring and fitting process, and the prosthetist must begin anew the design and fabrication processes.

This situation is complicated by the fact that current design and fabrication procedures are more an artisan's craft than a science. Construction of the patellar-tendon-bearing (PTB) type device, which is best suited to ambulation of below-the-knee (BK) amputees, involves techniques that are labor intensive and result in inconsistent products. Acquiring data about the shape of the limb and identifying weight-bearing and potentially sensitive areas are critical early steps in ensuring an effective fit. It is important to note that the weight-bearing and sensitive areas are in close proximity to the underlying bone structure. It is necessary to modify the socket shape to provide pressure relief directly over bony prominences because pressure in these areas will cause immediate skin breakdown. Additionally, it is necessary to modify the socket shape to support the patient in areas that can bear weight. These weight bearing areas are identified by their proximity to the underlying bone structure. The prosthetist uses his/her experience and knowledge of anatomy to *approximate* the location of the bone structure.

Manual Socket Fabrication Process

Accuracy in the manual fabrication process as it has been conducted in the past has been a function of craft and intuition, rather than being a scientifically reliable and repeatable process. Currently, a prosthesis is fabricated using the steps displayed in Figures one through seven.

Figure 1 Marking the sock on the leg to indicate where the bony regions are closest to the skin.

Figure 2 Forming the plaster impression of the leg to generate a negative mold.

Figure 3 Generating the plaster positive pattern - Step 1.

Figure 4 Removing the negative impression to complete the fabrication of the positive mold - Step 2.

Figure 5 Making biomechanical adjustments to the positive mold of the leg to relieve pressure in front of the bony regions of the leg and to add support in other regions. Patellar tendon bearing support is being added to the positive mold in this image.

Figure 6 Vacuum thermoplastic forming of the socket.

Figure 7 Complete prosthesis: socket, pylon and foot. The cosmetic cover will be added after patient trials.

There are several disadvantages to this method. First, because the process is manual, the final fit depends entirely on the precision modeling of the leg. That leg model is generated in a step-by-step method that introduces errors at each step. Second, the original model of the leg is not preserved during this process. Therefore, if at the end of fabrication, the prosthesis does not fit and cannot be adjusted, the entire process must be repeated. Finally, because the process is labor intensive and takes several days, the product is expensive.

COMPUTER-AIDED DESIGN OF SOCKET BASED ON LEG MODEL

As an alternative method to manual socket fabrication, computer-aided design and manufacturing techniques are now being applied to the problem of designing prosthetic sockets. The data required at the initial stage of socket design involves converting measures of residual limb shape into computer-readable formats. Researchers have discussed methods of gathering shape data including the following:

- use of silhouettes (Smith, Crew, & Hankin, 1986),
- digitizers (Vikers, Foort, & Saunders, 1981),
- shadow moire contourography (Duncan, Dean, & Pate, 1980) (Ferne, 1985),
- light streak shape sensing (Proceedings - RESNA, 1989) (Faulkner, Walsh, & Gall, 1987),
- Computer Assisted Tomography (CT) (Faulkner & Walsh, 1987),
- ultrasound (Childress, 1986),
- Magnetic Resource Imaging (MRI) (Oshima & Saito, 1985), and
- linear potentiometers (Faulkner & Walsh, 1989).

Most of the work in this area has focused on utilizing surface shape data.

The most commonly used alternative system of acquiring shape data employs a mechanical digitizer that measures the inside of a plaster mold of the patient's residual limb. It provides relatively low resolution because of its indirect nature and is not effective in digitizing the distal end of the residual limb. Non-contact laser imagers can also provide shape information. Scanning is completed in just a few seconds and relatively high resolution data can be acquired. Mechanical digitizers and laser imagers only generate surface topology data.

Complete images, including skin and bone have been obtained using either CT or MRI, but these methods have multiple disadvantages. Both of these procedures are costly and slow. Typical CT and MRI machines will cost several million dollars for initial purchase and can cost hundreds of thousands of dollars more for specialized facilities that provide shielding of patients and personnel. Furthermore, CT uses ionizing radiation that has been determined to be harmful to humans (Kreel & Meire, ND) (Oshima & Saito, 1985). Most computer workstations for this technology are based on proprietary technology and are limited in their ability to interface with other data processing systems. Because of these problems neither CT nor MRI systems are practical for regular use (Oshima & Saito, 1985).

Continuing the computer oriented process, once the leg geometry is gathered from the various methods and stored in a digital format, prosthetic computer-aided design (CAD) programs are used to modify interactively the digitized shape of the residual limb to that of a biomechanically correct socket. The shape of the residual limb can be viewed and manipulated on the computer screen. However, the prosthetist, who is familiar with modifying a plaster model with hand tools, now has to work with a computer screen that eliminates direct touch and depth perception. The elimination of the three dimensional nature of the model increases the problem of knowing where the bone structure resides.

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SOLUTION TO HAND-CRAFTED PROSTHESES

With automation, prostheses can be fabricated based on a CAD model of the residual limb. Models created by this method must be based on some form of imaging modality, and the most likely technologies are CT, MRI, laser scanning, and ultrasound. As described above, CT and MRI are the most expensive. Laser scanning can define skin surface geometry. However, in prosthesis fabrication, knowledge of bone geometry is essential to proper fabrication, and laser scanning does not provide bone information because of its surface mapping limitations.

3D Ultrasound Used for Leg Model Generation

Ultrasound can be argued to be the logical choice as an imaging modality because it provides surface and subsurface information about the leg. In addition, ultrasound is a non-ionizing form of radiation and, currently, there are no known harmful affects from FDA approved ultrasound machines designed for medical diagnostic imaging. Ultrasound machines are relatively low in cost (less than one hundred thousand dollars) as compared to CT or MRI. The machine that was purchased for the research work was an ATL Mark 9, Diagnostic Ultrasound Machine with 3.5 DFT Linear Transducer. It is produced by Advanced Technology Laboratories (ATL).

This machine was purchased, rather than developed, because diagnostic ultrasound machines are available that use technology that cannot be surpassed for the price of research and development. The ATL machine provides resolution of images within a range that is acceptable for prosthesis fabrication. For example, the resolution in depth is 1.0 mm and the lateral resolution is 2.0 mm. Relative accuracies of each modality are comparable at 1.0 mm (Melson, Biello, & Lee, 1983). Image frame rates vary depending on the number of focal zones and the depth of penetration from 30 frames per second (fps) to 7 fps. The slower frame rates reduce the speed of image acquisition. Even at 7 fps, however, a complete leg image set of 400 images can be acquired within 72 seconds.

ULTRASOUND IMAGE MODEL

A first order model, or simulation, of the ultrasonic imaging system was developed for the following reasons:

- to provide insight into the ultrasound imaging process,
- to evaluate the effects of refraction and scan geometry, and
- to aid the system design process (Curry, Dowdy, & Murry, 1990).

The model was first developed in two dimensions and later extended to three dimensions. Geometrical optics were used to determine the image geometry. The acoustic beam is modeled as a Gaussian beam (Saleh & Teich, 1991) and the transducer is treated as a point receiving transducer. The limb being imaged is modeled as being composed of two materials, homogeneous flesh and homogenous bone.

Despite its apparent simplicity, the 2D model provides useful simulated images that illustrate some of the problems encountered in developing an ultrasonic imaging system. Because reflection and refraction are inherently planar calculations, the following text describes elements of the computer model developed in terms of the 2D model (Temkin, 1981). The calculations are carried out in the plane of incidence. Three dimensional aspects of the problem will be addressed when they are appropriate.

The 2D model provides a useful estimate of image distortion and image brightness because it displays the following characteristics:

- Refraction
- Acoustic impedance
- Attenuation
- Acoustic velocity
- Object geometry
- Scan geometry

Ultrasonic Sensor Geometry

The ultrasonic sensor geometry modeled in computer software is shown in Figure 8. The ultrasonic transducer is located at point *A* in the figure with its beam direction aimed at the line *AF*. Point *B* is located on the surface of the skin, and point *C* is located on the surface of the fibula in the model. There are two types of scanning that are appropriate to model:

- **Circular Scan:** The simplest and most common type scan is a circular scan. This type of scan is determined by picking a center point *F* in the limb data coordinates. The transducer is then located at radius *AF* with the beam oriented along the line *AF*. The transducer is then rotated through 360 degrees about point *F* to generate the image. Scan increments are determined by the resolution and image definition requirements. The point *F* is a variable in the program.
- **Programmable Scan:** The programmable scan is an option that allows the transducer position and orientation to be programmed to follow an arbitrary path. One scan geometry of interest is a linear scan where the transducer is moved along a line with the angle held constant. More general scans can be made up from linear scans by summing linear scans with a discrete variation in the angle variable (parameter). Another scan geometry of interest is one in which the transducer is scanned over a range of angles at each position along a prescribed curve.

Figure 8 Ultrasonic Sensor Geometry

Ultrasonic Computation

In order to model an ultrasound image obtained from the leg model, a single ray is traced through its full path from initial transmission to return at the sensor. Intensities and angles are calculated at each interface encountered by the ultrasound beam in order to calculate the final returns. The beam typically passes through the skin surface (such as point *B*), reflects off bone (such as point *C*), and must again pass through the skin interface (point *B*) before returning to the transducer.

The angles of reflection and transmission are calculated using Temkin's equations (1981)

$$\text{(Reflection)} \quad \Theta_i = \Theta_r \quad (1)$$

$$\text{(Transmission)} \quad \frac{\sin \Theta_i}{\sin \Theta_t} = \frac{c_i}{c_t} \quad (2)$$

where the subscripts refer to the incident (i), reflected (r), and transmitted (t) rays while c_i and c_t are the acoustic velocities in the corresponding medium. Distances such as AB (transducer to skin surface) and BC (skin surface to bone surface) are calculated using an algorithm for computing the intersection of rays with the limb, data skin, and bone surfaces. The coefficients of reflection (α_r) and transmission (α_t) which characterize the percentage of incident energy reflected or transmitted at an interface are calculated using the equations

$$\alpha_r = \left[\frac{\rho_2 c_2 - \rho_1 \sqrt{c_1^2 - c_2^2 \sin^2 \theta_1}}{\rho_2 c_2 + \rho_1 \sqrt{c_1^2 - c_2^2 \sin^2 \theta_1}} \right]^2 \quad (3)$$

$$\alpha_t = \frac{4\rho_1 c_1 \rho_2 c_2 \cos \theta_1 \sqrt{1 - (c_2/c_1)^2 \sin^2 \theta_1}}{\left[\rho_2 c_2 \cos \theta_1 + \rho_1 \sqrt{1 - (c_2/c_1)^2 \sin^2 \theta_1} \right]^2} \quad (4)$$

and

$$\alpha_r + \alpha_t = 1 \quad (5)$$

In these equations, the numerical subscripts are ordered in the direction of the acoustic wave, or ray, being considered where 1 refers to the medium the wave travels in before reaching the interface, and 2 refers to the medium on the other side of the interface. The ρ 's are the corresponding material densities.

The intensity (I) of the acoustic beam is represented as a function of the angle from the beam's center axis (designated by φ), with the beam represented as a Gaussian beam. The relative intensity (β) of the beam with respect to the maximum intensity along its center axis ($\varphi = 0$) is given by (Saleh, & Teich, 1991)

$$\beta(\varphi) = \frac{I(\varphi)}{I(0)} = \exp \left[-2(\sin \varphi / \sin \varphi_0)^2 \right] \quad (6)$$

where

$$-\frac{\pi}{2} < \varphi < \frac{\pi}{2}$$

and the beam divergence angle φ_0 (where intensity equals $\frac{1}{e^2}$) is given by

$$\sin \varphi_0 = \frac{2}{\pi} \cdot \frac{\lambda}{d_0} \quad (7)$$

In equation 7, λ is the acoustic wavelength and d_0 is the beam width at the beam waist, the smallest beam width. The beam width is usually taken to be the effective width of the transducer. However, the beam divergence angle can be empirically adjusted to account for scattering or receiver aperture width.

Generally, acoustic beams decrease in intensity as they propagate due to absorption and scattering. In the model beam, attenuation is incorporated as an exponential decrease by the equation (Kuttruff, 1991)

$$I(x) = I(0) \exp[-\eta x] \quad (8)$$

where η is the effective absorption coefficient. In its present form, the model does not include a decrease in intensity due to the divergence of the beam.

Image Generation

The relative image brightness is determined by tracking the acoustic rays as they bounce off the various surfaces taking into account the loss of intensity due to reflection, transmission, and attenuation as appropriate. The computation is illustrated for a few points in Figure 8 by the following.

The relative image brightness of point B which is located on the skin surface of the model and which is relative to the incident intensity displayed in Figure 8 is given by

$$\frac{I_r(B)}{I_i} = \alpha_r \beta(2\theta_1) \quad (9)$$

The factor of 2 in the argument of β occurs because the angle between the reflected ray and the ray returned to the transducer is twice the incident angle. However, when calculating the image brightness of the return from the bone (point C), the reflection coefficient (α_r) is assumed to be 1, meaning that the beam is fully reflected, and no transmission occurs through the bone.

The relative brightness of the return from point C is given by

$$\frac{I_r(C)}{I_i} = \alpha_i \alpha'_i \beta(2\theta_B) \quad (10)$$

where the prime denotes the transmission in the opposite direction after reflection off of the bone. One then continues in this manner, beginning with different initial trajectories (such as along line EF) and keeping track of the rays as they intersect the various surfaces. The number of

intersections (or surfaces) the ray encounters during a scan affects the resulting image by increasing the amount of time it takes to return to the detector. The increased time is interpreted as increased distance from the transducer to a point on the leg. Attenuation is accounted for using equation 8 and the computed distance between consecutive reflection points.

Errors can occur in the computed distances due to discrepancies between the reference acoustic wave velocity assumed in computations (V_R) and the actual velocity in the medium (V_{AB}). The image of point B is located a distance

$$AB' = \frac{V_R}{V_{AB}} \cdot AB \quad (11)$$

from point A along line AF . AB' is the computed distance, and AB is the actual distance. Similarly, the image point location of point C is given by the distance

$$AC' = \frac{V_R}{V_{AB}} \cdot AB + \frac{V_R}{V_{AB}} \cdot BC \quad (12)$$

again, along line AF .

Two Dimensional Computer Model

A principal goal of this work was to determine the optimum scanning method. The two dimensional ultrasound simulation package was a C/C++ program that applied ultrasonic computation and image generation mathematics to mock ultrasound beams and pre-determined tank and leg geometries. The calculations are applicable to a plane containing both the incident and scattered beam and to a two dimensional leg model.

Attempts were made to model the acoustic properties of both the ultrasound beam and the materials it traveled through. The goal for the 2D simulation was to optimize the mechanical design of the system and the scanning methods so as to achieve the highest quality images that would provide the most possible information. Varying parameters between the simulations illustrate the effects generated by the different scanning setups. The basic equations used in the simulation have been given above.

Menu

Figure 9 (page 16) is the menu for the two dimensional simulator. Details for each of the fields, or buttons, are listed below.

Definitions of each field, or button, follow reading from top to bottom in screen order.

- *Coordinates of the center of the leg:* This field allows the user to specify the X,Y coordinates of the center of the object being scanned. The coordinate parameters allow the object to be placed at various locations in the tank during the simulated scan.
- *Nominal speed of sound (cm/sec):* This field allows the user to declare the nominal speed of sound in water.
- *Frequency in Hz:* This field allows the user to specify the frequency of the simulated ultrasound beam.
- *Lower limit of return signal:* This field sets the lower limit of signal strength for return beams to be detectable.
- *Initial transmitted power:* This field sets the power of the initial beam transmission.
- *Focus beam radius (cm):* This field sets the radius of the beam width at the beam waist.
- *Max time for return signals:* This field sets the maximum duration of time allowable for return signals to be detected.
- *Number of sensors in scan:* This field sets the number of discrete locations (or stops) from which scans are done. They are concentrically located around the "tub".

This menu is used to create the scan path file.

Enter desired options – defaults are shown

Coordinates of center of leg: X: 0.0 Y: 0.0

Nominal speed of sound (cm/sec) : 154000

Frequency in Hz : 3500000

Lower limit of return signal : 0.0001

Initial transmitted power : 100

Focus beam radius (cm) : 0.025

Max time for return signals (sec) : 0.01

Number of sensors in scan : 50

Create Scan Path

Display Plot

Data type: Simulated Data CT Data 3D View

Model type: Leg Circles

Quit

Number of Sweep Scans: 1 1 |
20

Sweep Angle: 0 0 |
45

Figure 9 Menu Panel, Two Dimensional Simulator

- *Create scan path:* This field initiates the creation and execution of the simulation using the specified parameters, generating a file containing the output results.
- *Display plot:* This field causes one of two types of display to appear. If simulated data, or CT data, have been chosen on “Data type,” a Gnuplot window displays the results of the simulation run. If “three dimensional view” is selected, it causes a three dimensional grid display of the stored CT geometry but without scan data.

- *Data type:*
 - *Simulated data* - selects simulated data for the scan - either a leg model or circles.
 - *CT data* - selects leg geometries obtained from actual CT scans for the simulation.
The user may choose any of the available CT cuts.
 - *Three Dimensional View* - allows display of a three dimensional view of the CT data.
- *Model type:* When "Simulated data" is selected under "Data type," "Model type" allows you to select either a leg model or circles for the scanned object.
- *Number of sweep scans:* This field selects the number of actual angular scans taken at each of the stops in the scan (at each of the discrete locations of the scanner).
- *Sweep angle:* The angle over which the "Number of sweep scans" is uniformly distributed at each of the discrete scan locations.

Data Input

The algorithm requires input of leg and scan tank geometries along with the ultrasound beam parameters

- where the scans originate from,
- the direction they travel, and
- the strength of the beam.

It also requires the acoustic properties of the materials being scanned in each region, for instance, water, muscle, fat, or bone.

Comments on Code

This code is a collection of C and C++ programs with a Devguide (an X-View based GUI development tool) based user interface. The output displays use Gnuplot windows. Beams are traced using recursive calls on reflected and transmitted components of rays as they intersect surfaces in the simulation. The return is always assumed to occur along the incident beam path. Therefore, the resulting data points consist only of specular returns, where the ultrasound beam incidence is normal to the surface. Each point in the illustration derives from a rotating scan.

Examples

Figures 10 - 14 are examples of the simulation. Figure 10 is an example using CT data of a leg cross-section with 50 sensors, 1 scan per sensor using simulated leg geometries. The points on the surfaces of the skin and bones are the data returned to the transducer during the simulation. Portions of the bones do not return data to the sensor because the signal is reflected away from the incident beam path.

Figure 10 50 Sensors, 1 scan per sensor, CT Data

In Figure 11 concentric circles are used to model the skin and bones, again with 50 sensors and 1 scan per sensor. This figure shows the optimum performance of the system where all the points are at normal incidence to the ultrasound beam, and no returns are lost.

Figure 11 50 Sensors, 1 scan per sensor

Figure 12 has the same settings as Figure 11 except the center of the circle has been offset. This displacement shows that by varying the position of the model away from the center, results are altered significantly. All points are no longer at normal incidence, and data is lost. Notice the sides of the small circle.

Figure 12 Offset Center

The use of simulated leg data is illustrated in Figure 13 (again with the same settings). In this simulation, effects of multiple reflections are illustrated more clearly. Several stray or extraneous data points can be seen inside the tibia (larger bone), near the top. They are caused by multiple reflections during the scan simulation, causing the beam to “bounce” around between skin and bone several times before returning to the transducer. The distance calculations incorporate this time delay as a longer distance, incorrectly placing the points deeper in the leg than they should be.

Figure 13 Simulated Leg Data

Figure 14 demonstrates the use of five simulated scans at each of 30 sensors for redundant data collection. In the simulation each sensor sweeps across an angle and takes 5 scans at varying angles. Although this method collects more data on the skin, there was not a significant increase in the amount of information collected from the edges of the bones (compare with Figures 10 and 13).

Figure 14 Multiple Simulated Scans for 30 Sensors

Three Dimensional Computer Model

The three dimensional computer model uses logic similar to the two dimensional model. The 3D model includes scan beams that have X, Y, Z components to both their origin and their direction. Points of intersection occur between three dimensional vectors and planes, as opposed to lines contained in the $Z = 0$ plane, and, therefore, may have components in the Z direction. Finding the points of intersection is much more involved, and, consequently, the run time is much greater. Because of time constraints, this algorithm has only been implemented in batch mode with precalculated fixed scan parameters.

Data Input

This file is created by a separate algorithm containing the parameters of the scan beams which consist of the origin and direction (in 3D space) as well as the beam strength. Separate files are created for tub and leg geometries which define the three dimensional surfaces of the objects.

Comments on Code

The three dimensional simulation is a batch mode C program which uses three dimensional vector geometry to trace the beams with recursive calls on the reflected and transmitted components of rays that result from intersections with object surfaces. Rays are terminated when their power has dropped below a predetermined threshold, or are absorbed by the tank wall. Return signals are calculated at each intersection;. Again, assume a return along the incident beam path. Output is a file of three dimensional points.

Menu

None is required. The file runs in batch mode.

Examples

Figure 15 is an example of the output points displayed as small black cubes with the 3D rendering of the skin and bone surfaces used in the scan.

Figure 15 Three Dimensional Leg

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IMAGE CAPTURING SUBSYSTEM

Mechanical Scanner

Because the ultrasound machine provides a planar image that represents a cross-sectional view of the object, an additional spatial dimension must be sent to the transducer to generate a 3D, volumetric image. The mechanical scanner (Figure 16) provides the additional scanning motion necessary to develop the third dimension of the image. This scanner was designed based on the results of a computer model that indicated that a circular scan around a Below-the-Knee (BK), residual, limb would be sufficient to provide skin and partial bone surface information. (Goodgold, 1974)

Figure 16 The Mechanical Scanner with ATL Ultrasound Machine

The mechanical scanning system consists of the transducer holder, scanning tub, servo motor, and motor controller. The transducer holder is a bracket (See Figure 17) that holds the transducer in a rigid fashion and maintains the position and orientation of the transducer in the scanning tank window. The window (Figure 18) is a flexible membrane that keeps water in the tub and allows ultrasound to penetrate without attenuation. The scanning tank is filled with water that transmits ultrasound signals in non-contact scanning operations of variable size legs. Scanning without contact is essential for the definition of “unloaded” soft tissue surfaces.

Figure 17 Transducer Holder

Figure 18 Scanning Tank Window

The tank diameter (11.5 inches) was selected to accommodate the leg size of the largest amputee while optimizing the penetration range of the ultrasound. For the frequency of ultrasound selected (3.5 MHz), the depth of penetration was limited to 22 centimeters, or 8.7 inches. At this frequency, data can be scanned beyond the center of the tank. Thus, any object within the tank can be imaged without strict constraints on its location. The servo motor (Figure 19) is controlled by position and velocity so that the proper number of frames can be captured around the BK limb.

Figure 19 Servo Motor Mounted on Tank

With position and velocity control, the servo-controlled scanner can be varied during image capturing. Thus, leg regions that are of more interest can be scanned with finer resolution of spacing. The position of the frame capture is recorded along with the image. This information allows the image processing package to reconstruct the images based on the raw data.

Vertical vs. Horizontal Image Acquisition

The current configuration of the three dimensional ultrasound scanning system allows for variations in the orientation of the ultrasound transducer. The two orientations that have been explored are vertical, where the linear array is oriented parallel to the long axis of the leg, and horizontal where the linear array is oriented transverse to the long axis of the leg.

When performing the vertical orientation, scanning the transducer in a circular pattern around the leg generates a volumetric data set. The resolution of image spacing is measured in degrees. When variable scan rates are used, the bony regions of the leg are scanned with finer resolution than the soft tissue regions. Regardless of the resolution of the image captured, there remains a space between captured data sets that is unaccounted for. Interpolation is used to provide smooth transitions between images.

When the transducer is oriented horizontally, circular scanning generates a planar image of the transverse cross-section. The data set is redundant, causing each point in the leg to be imaged multiple times at the different angles. The advantages provided by this method of scanning are many. Because each anatomical location within the leg is imaged multiple times, image processing algorithms can be used to optimize the image based on the data.

Consequently, the image with the most detail can be generated where each pixel within that image has been optimized for brightness and clarity. The resulting images from this technique can be used for diagnostic imaging that is comparable to the resolution of x-ray computed tomography. In fact, because ultrasound is better suited for soft tissue definition than x-ray, ultrasound images demonstrate clearer tissue interfaces. Volumetric image sets can be generated from horizontal scans by swiping the transducer vertically.

Patient Motion

Even with the scan time on the order of minutes, patient motion during the scan is undesirable and introduces errors in acquired leg geometry. In order to reduce or prevent patient motion, several mechanical devices were designed and implemented to help stabilize the patient while the leg is being scanned. During this part of the procedure patients can rest either limb on a support that attaches to a support bearing mounted on the bottom of the tank (Figure 20). Either support allows the patient to stabilize the lower portion of his/her leg in the scanning tank at the same time that it isolates him/her from the movement of the rotating tank.

Figure 20 The Support Bearing.

Two types of supports are attached to the bearing. The first (Figure 21) is a ramped fixture that lifts the heel while providing support, which is necessary to accommodate normal limbs and to keep the toes away from the sides of the tank. The tank was not designed to accommodate normal, footed limbs without a heel lift support. The other support shown in Figure 22 is designed for stabilization of the residual limb of an amputee.

Figure 21 Heel Lift Support

Figure 22 Residual Limb Support

The residual limb support is meant to act as an indicator of position by providing a tactile point of origin. Such a point should allow the patient to sense whether his/her leg is moving, but during the clinical trials at UTHSCSA, it was determined that many amputees lack tactile sensation at the distal end of the residual limb. This lack of sensation may be due to a loss of nerve function.

It is clear that future modifications of the support would benefit from better lateral stability. It may also be necessary to provide a cup at the tip of the support to assist in lateral stabilization because, in some cases, the patient's limb exhibited tremor associated with nerve damage. The cup size should be optimized to reduce the amount of leg surface area that is obscured during scanning.

Image Acquisition Subsystem

The ultrasound image acquisition system consists of a Motorola 68030 based CPU, video frame grabber, motor controller, and an additional memory board, all housed in a VME bus based enclosure. A Sun-based GUI is used for command and control of the entire system.

Utilizing the GUI, the operator can perform a number of actions:

- Select the number of images to acquire from the ultrasound machine,
- Choose the start and stop position of the scanner,
- Choose several other variables for correct operation of the system, and
- Select images at constant or variable spaced intervals about the subject's leg.

The VME central processing unit performs the following functions:

- Reads the command from the operator and calculates the correct rotation rate for the scanner,
- Commands the scanner to start rotating,
- Monitors continuously the position of the scanner to decide when to grab the next ultrasound image,
- Grabs images and stores them in memory, and
- Transfers all images (on command from the operator) by Ethernet to a host computer to signal that the operation is complete and ready for post processing and image reconstruction.

Because the ultrasound machine outputs standard video images, a major portion of the image acquisition is performed by that machine. Although it would be advantageous to obtain the data at the digital level prior to image processing and output of the video image, the data that is provided at the video level is adequate for an initial study¹. Image capturing and scan speed are synchronized to a seven Hertz image frame rate. Recently, ATL provided a feedback signal that can be used to indicate frame transition timing and can be incorporated into the system if desired. The heavy line in Figure 23 encapsulates the VME functions.

¹ATL has agreed to work with Sandia on future work that will be funded by the Advanced Research Projects Agency (ARPA).

Figure 23 Flow Chart of Image Capturing Control

Incident Angle Tests

Ultrasound is most accurate when the incident beam is normal to the surface of the subject. As the angle between the transducer and surface normal increases, image quality rapidly drops because of reduced pixel intensity and inaccurate representation of distance. Because human legs are curved and have very few flat areas, it is necessary to determine the accuracy of the data returned when the ultrasound is directed at different angles.

A mechanical fixture was designed and fabricated to hold the ultrasound transducer in a large rectangular testing tank. Figure 24 displays the fixture and Figure 25 shows it in use within a testing tank.

The fixture allows the orientation of the transducer to be adjusted between plus and minus 45 degrees from normal while the subject is positioned at a constant distance from the transducer. Under these conditions the distance and intensity of the subjects could be compared using images taken at different angles. Consequently, this process can determine the level of accuracy at an increased incident angle. The testing consisted of the following steps.

Figure 24 Transducer Fixture

Figure 25 Transducer Fixture in Place

- Scan the subject with the ultrasound transducer,
- Vary the angles of incidence between ± 45 degrees from normal,
- Use software to measure the distance to the surface of the subject, and
- Use software to set the peak pixel intensity of the subject in each image.

Note that a strip of aluminum was placed next to the subject during scanning to indicate the true position at normal incidence.

Distances to the subject were measured at several points across the image, and the results were averaged. Also, in order to determine the position of the actual surface of the subject in the image, distances were measured to the first return above threshold and to the position of peak pixel intensity at the surface of the subject. The true distance between the subject and the scanner was determined by finding the distance to the aluminum strip image, which gave an accurate return at normal incidence. The tests were performed on several materials including a human arm, to show results from skin, and a human skeleton femur, to show results from bone.

From these results, it was observed that the image quality of the leg is best when the incident angle is between ± 10 degrees. The intensity values in the bone and skin images drop noticeably at larger angles. Image pixel intensities can range anywhere from 0 (black) to 255 (white). The pixel intensities in both the skin and bone test images peak at incident angles near zero degrees and at values between 220 and 230. Between angles of ± 10 degrees, the intensity values for skin drop to the 175 range and the intensity values for bone drop to the 80 range. At incident angles greater than 10 degrees, these values decrease further to minimums of below 100 for skin and approximately 35 for bone.

The distances represented on the images of both the skin and bone varied inconsistently with the true distance and were not dependent on angles between ± 45 degrees. However, there was a

slight trend away from the true distance when the incident angle exceeded ± 20 degrees, indicating that the results were most accurate between ± 20 degrees. In this range, the average percentage error of the distances in the image with respect to the true distances was -0.135% for bone and -0.508% for skin. The worst case in this range occurred when the image distance was 3.8 pixels short for skin and 2.2 pixels short for bone, with respect to the true distances. At larger incident angles, the average percent error increased to -0.92% for bone and -2.94% for skin. At incident angles larger than 20 degrees, the worst case discrepancies between image distance and true distance increased to 9.6 pixels for skin and 7 pixels for bone.

These observations led to the conclusion that image quality is best when ultrasound incident angles are between ± 10 degrees, and that inaccuracies in distance representations in the images occur with incident angles greater than ± 20 degrees. Using a computer model of our image acquisition process, the incident angles involved in scanning a human leg were predicted. The results showed that most of the predicted incident angles should be within ± 10 degrees so that the returns achieved in the process would be of maximum integrity.

Ultrasound System Characterization

The ATL Ultramark 9 has several modes of operation:

- 2D,
- M-mode, and
- Doppler.

M-mode provides a motion representation of the echoes and the Doppler mode extracts Doppler information from the echoes. The imaging capabilities of the 2D mode provide a 2D sector image format and a 2D linear display image format. The 2D linear format provides images by electronically scanning a linear transducer in one dimension and by converting time to distance by using velocity in the other dimension, a process called range or time gating.

Beam Profile

A beam profile is one characteristic of ultrasound that influences resolution. Beam profile refers to the shape of the ultrasound transmitted beam. The beam from the transducer is designed to focus at some distance from the transducer to a narrowed region called the waist. Depending on the plane of orientation, the waist is generally located at different distances from the transducer. Within the plane of the transducer array, the waist can be changed in depth and in location throughout the field of view. Perpendicular to this plane, there is another waist which is fixed at mid range.

In the transducer plane, focus can be switched electronically as many as four times during the generation of an image. The resulting image is a contiguous mosaic of four high resolution images in range which is defined as the distance from the transducer.

Lateral resolution, which is defined as transverse to the beam direction, is determined by the beam profile and is a function of the direction from the transducer. Lateral resolution will be different when measured in the transducer plane or in a perpendicular plane. Typical lateral resolutions at three trial distances from the transducer are displayed in the following table.

Trial Zone Distance	- 6dB Resolution	- 20dB Resolution
5.0 cm	1.6 mm	4.2 mm
10.0 cm	1.5 mm	3.7 mm
15.0 cm	1.2 mm	3.7 mm

Figure 26. Table of Trial Zone Resolutions

In general, it is best to measure the beam profile, or lateral resolution, directly. This measurement can be taken using a phantom designed for that purpose, or by using a general test tank and a string or wire suspended in the water. A test tank shown in Figure 25 was designed for general ultrasound measurements using water as the wave propagation medium. A phantom was also obtained for system measurements.

Plumb Bob Experiments

In order to help center the scanning circle on the center of the water tank, a plumb bob was hung in the center of the tank to establish the center coordinate of the tank. Horizontal scans were then taken around it. These images provided data on both the center point and the point spread function of the scanner. See Figure 27.

Center Point

The plumb bob scans were taken at approximately one-degree intervals. The plumb bob string appears as a small spot in the images. The exact location of the spot in each image was computed from the centroid of this spot.

Point Spread Function

The plumb bob string is thin, consequently its image serves as an approximation of the system's point spread function. A point spread function was computed by registration through translating and rotating the plumb bob images and averaging them. The resulting point spread function is shown in Figure 27. The "cross rangers" width is larger than the "down range" width, and it shows a lobe in the direction of the sound source.

Figure 27. Point Spread Function from Plumb Bob String

ULTRASONIC IMAGE PROCESSING

Introduction

The scanning system developed at Sandia National Labs was designed to acquire ultrasonic images in two modes: horizontal and vertical. In the horizontal scanning mode, individual frames are acquired at a predetermined angular increment about the limb, as depicted in Figure 28. A cross-sectional reconstruction process is then applied which involves angular rotations, motion compensation, and the filtering of rank values, resulting in a highly defined planar cross section of the limb.

Figure 28 Horizontal Reconstruction

In the vertical scanning mode, the transducer is oriented parallel to the vertical axis of the tank. Individual scans are acquired at a predetermined angular increment about the limb, as seen in Figure 29.

Figure 29 Vertical Reconstruction

A reconstruction process is then applied which uses angular rotations and polar interpolation resulting in a volumetric reconstruction. The software developed to process ultrasonic images has been integrated into the Khoros system, which is an environment that explores algorithmic development and image processing. It uses industry standard routines for basic image conversion, processing, and display. Application-specific routines can also be integrated into the system. These routines may contain calls to standard Khoros library functions, or user written library functions that add variations to the system. See Appendix B for a list and description of Khoros routines.

System Description of Horizontal Processing Coordinates

In the horizontal scanning mode, the linear transducer is oriented parallel to the bottom of the tank and transverse to the leg. In this mode, the x axis corresponds to the coordinate axis along the face of the transducer (or cross range), the y axis corresponds to the depth of penetration, or the direction along which sound travels into the tank (or range), and Θ corresponds to the clockwise angle of the acquired frame with respect to the top, or front, of the limb. See Figure 28.

In this mode, a mechanical scanning system rotates the ultrasonic transducer about the limb. During the scanning process, individual ultrasonic frames are digitized along with the angle (Θ) of the acquired frame. The reconstruction process involves rotating the individual frames about the center of the trunk. In this reconstruction process individually captured images are rotated with respect to the initial coordinate frame, and all frames are co-registered and combined to generate a composite image. It can be seen from the scanning geometry in Figure 28 that an individual limb will be scanned by the transducer repeatedly over a range that may extend to 180° .

For prosthesis fitting, the points of interest are the surfaces of the tibia, fibula, and skin. Both bone and skin in ultrasound data show up as relatively strong signal echoes. Exploiting the redundancy in the data, the maximum signal echo was chosen from all those signal echoes corresponding to any given point within the limb. The resultant cross section reconstruction seen in Figure 30 emphasizes the strong signal echoes of the skin and bone, but at the cost of also emphasizing any noise in the system, such as the tank noise about the limb.

In analyzing a number of cross section reconstructions similar to the one shown in Figure 30, an initial hypothesis was made that the noise was spatially incoherent, meaning that from frame to frame the noise does not show up in the same spatial location after rotation. A technique typically applied to improve signal to noise ratio averages the signal echoes over the number of frames in the redundancy depth. This technique assumes that the signal echo equals signal plus noise and results in an increase in the signal to noise ratio (S/N) of the square of N , where N is the number of frames of the redundancy depth.

Figure 30 Horizontal Reconstruction Based on Maximum Signal Echo

Figure 31 Horizontal Rank Value Filtering Reconstruction

After further analysis, it was determined that the noise signal echoes made up from tank reflections, bubbles, etc. are not coherent additions to the signal. Instead, the ultrasonic limb signal echoes replace the noise signal echoes. A better technique of filtering under these circumstances chooses a rank value filter that employs a percentage ranking of the frames, instead of the average value over N frames. This choice preserves the desirable signal echoes of the limb while it reduces the undesirable signal echoes from the tank noise. Using this technique, Figure 30 represents the maximum signal echo and displays 100% ranking. When this technique was applied to the data set corresponding to that in Figure 30 and the 90% ranking was chosen, it produced the reconstruction shown in Figure 31.

Further, the use of the non-zero values in the reconstruction in Figure 31 as a mask to the reconstruction shown in Figure 28 produced the masked reconstruction shown in Figure 32. This combination simplifies the task of recognizing the skin and bone signal echoes from within the reconstructed images because it maximizes the signal strength of the skin and bone surfaces while reducing noise. The images produced from this technique can be segmented more easily because of the high contrast displayed between different surfaces in the leg.

Figure 32 Horizontal Masked Reconstruction

Motion Compensation

A horizontal scan that is generated between 40 and 180 frames will typically require 10 - 30 seconds to complete. Even during this short period of time, patient motion can cause discontinuities in the reconstructed image. Any mechanical method to constrain the motion of the limb will distort the unloaded skin surface. Further, a small amount of motion during the scan should be expected. Such motion will manifest itself as a blur in the reconstructed image, and adversely affect the overall image.

Depending on the angular increment of successive frames of the acquisition, which is typically 4 degrees, the majority of the information results from the same geometry within the limb. Because of the redundant information from frame to frame the data are highly correlated. Any motion of the limb between the times the two frames are imaged will result in a shift of the correlation peak between the two frames. This shift will correspond to the amount of the relative motion. Compensation for such motion is shown in Figure 33.

Figure 33 Before and After Motion-Compensated Images

Notice the top of the image, which corresponds to the motion-compensated reconstruction, where the error has been reduced, but not eliminated. This improvement is a result of the integrated residual error over the entire scan. Also notice in the motion-compensated reconstruction, that more high spatial frequency information of the structure of the internals of the limb is present. Consequently, by incorporating motion compensation a more accurate image can be obtained because it allows for easier segmentation of features.

Angular Dependency

Of the first order of importance, the ultrasonic signal echoes of a limb typically exhibit either reflective (specular) or volumetric scattering characteristics. Any given tissue type such as bone, skin, or muscle layers is usually dominated by one of the characteristic types. Specular signal echoes usually fall off quickly with changes in angles of incidence when compared to scattering signal echoes. During the imaging process the following sequence can be observed.

- A two dimensional angle of incidence, as compared to a signal echo value, can be generated for each point within the reconstructed image.
- The angular dependency of a given point within the limb can be determined.
- A classifier can be designed to recognize the differences in tissue type based on their angular dependency.

Figure 34 Angular Dependency of Skin, Bone, and Muscle Layers

From within the reconstructed image in Figure 34, three points were selected which correspond to skin signal echo, bone signal echo, and a muscle layer signal echo. The plots exhibit the angular dependencies of these three tissue types. Notice the specular nature of both the muscle and bone, while the skin is much more scattering in nature. This angular dependent characteristic may be useful in providing segmentation of skin, bone, and muscle, which then can be used for 3D reconstruction and fabrication of prostheses.

System Description of Vertical Processing Coordinates

In the vertical scanning mode, the transducer is oriented parallel to the vertical axis of the tank. In this mode

- the z axis corresponds to the individual ultrasonic transducer number, or height. It increases as it goes up the limb,
- the r axis corresponds to the radius from the center, or plumb line, of the tank, and
- Θ corresponds to the clockwise angle of the acquired frame as observed from above.

See Figure 35.

Figure 35 Vertical Scanning Mode Concept

A mechanical scanning system rotates the ultrasonic transducer about the limb. During this process, individual ultrasonic frames are digitized along with the angle (Θ) of the acquired frame. The reconstruction process involves rotating the individual frames about the center of the tank. The resultant series of frames represents the ultrasonic signal echoes of the limb produced as the transducer is rotated about the limb. By contrast to the horizontally oriented transducer, where redundant information exists from frame to frame, individual points within the limb are observed only once during the scan, and some parts will not ever be visible to the transducer because of the shadowing effect behind the bones and because of incident angles. See Figure 36.

A bilinear interpolation scheme is employed to produce a volumetric reconstruction of the limb. The bilinear interpolation is carried out for a given z (height) value, which corresponds to a cross-sectional plane of the reconstructed limb. The acquired data are presented in polar coordinates, but it is desirable to perform the reconstruction in Cartesian coordinates. Consequently, a polar to Cartesian transformation is performed on the acquired data. For each point in the reconstructed plane, the four "surrounding" points from the acquired data are determined. A bilinear interpolation is performed to determine the value of the reconstructed point. The result is a "stack" of reconstructed cross sections of the limb, one corresponding to each z (height) value. See Figure 36.

Figure 36 Vertical Reconstruction - 1 Slice

An individual frame from a vertical acquisition is shown by the raw image in Figure 37. This image corresponds to a vertical slice through the limb. The skin was recognized by correlating a set of gabor filters used in the Khoros system (See Appendix B). These filters were oriented at -30° , 0° , and $+30^\circ$ degrees for each frame to determine the maximum response from a set of filters. See Figure 37. The size of the gabor kernels was determined by a practical examination of the ultrasonic skin signal echoes. The leading edge of the skin response was then determined by the brightest pixel observed for any XY location. Rank values were determined by reduction of signal noise and scattering.

Figure 37 Skin Recognition Process

The skin locations are recorded in the forms r , z , Θ . Combining these sets of points creates an overall 3D description of the skin surface of the limb. This 3D description can be entered into a CAD package for potential fabrication of a prosthesis, or any 3D rendering package. See Figure 38.

Figure 38 A 3D CAD Mesh and Visual Rendering

Image processing operations were performed within Khoros. See Appendix B for a list and description of Khoros functions. A Visual Programming Environment (VPE) was also provided that allowed Khoros operators to direct inputs through a series of these library functions and display the results. With Khoros, a new algorithm can be rapidly prototyped and handed off to image analysts for review. The VPE can also be used by the image analyst for production work. Nine ultrasound specific application routines have been developed and integrated into the Khoros system to date.

HUMAN ASSISTED SEGMENTATION OF SKIN AND BONE SURFACES FROM VERTICAL VOLUMETRIC IMAGES

Application of Edging Algorithms to Clinical Trial Data

The ultrasound platform was taken to The University of Texas Health Science Center in San Antonio to test the process on a group of nine amputee patients. The volunteers were imaged with both the ultrasound system and a CT machine. The intent was to compare the quality and accuracy of the images created by the ultrasound platform to the CT images. See Appendix D, Human Studies Background and Data, for a review of initial parameters of the study.

Algorithms were developed to "edge" accurately the two dimensional ultrasound cross-sections extracted from volumetric ultrasound images and the two dimensional CT cross sections. These edges are then used to make up the surface data for volumetric representation of the leg. See Figures 39 and 40 for examples of the ultrasound and CT images respectively.

The edges obtained from the ultrasound process can be used to produce three dimensional models of the leg. The process follows these steps.

- Bring the images to a threshold to eliminate noise in and around the leg cross section.
- Start the edging algorithm from a "first" valid point, usually chosen by the operator.
- From that point, use the algorithm to search for the next point on the edge within a bounding box of specified size.
- Assign a value of 180 to the initial point perpendicular to the surface at that point.
- Define vectors from the first point to each point in the bounding box.
- Choose the next valid point on the edge as the one with the smallest vector angle with respect to the perpendicular.
- Continue around the leg, computing angles to the points contained in the bounding box with respect to a perpendicular to the edge created by the last two valid points.
- Choose the point with the smallest angle as the next point on the edge.
- Continue the process around the leg until the first point on the edge is contained within the bounding box, indicating the completion of the edge.

See Figure 41 for an example of a resulting edge from a CT scan. This edging algorithm is used for edging the CT scans, including skin, tibia, and fibula, all of which must be measured separately. The algorithm is also used for edging the ultrasound skin image, but it cannot be used for the bones in the ultrasound images. Ultrasound images are somewhat coarse. The bones appear "incomplete" on the inside of the leg where the ultrasound has been reflected and attenuated by the bone, shading the back portion. Therefore, the only valid bone data on the ultrasound scans is that near the surface, or skin, of the leg. Instead of using the automated edging algorithm, the bone images must be edged by "placing and re-sizing" templates of the bones on each cross-section.

Markers made from polyvinyl chloride (PVC) triangles were affixed to the skin. They can be seen at the upper right edge of the image in Figure 39. These markers had been previously tested

to ensure that they showed up in both ultrasound and CT images, and they were used to aid in registration of the 3D models produced from the ultrasound and CT data sets.

Figure 39 Ultrasound Cross-Section

Figure 40 CT Cross-Section

Figure 41 CT Edge

Human Assisted Initial Segmentation

Skin and bone surface segmentation was performed from vertical scans with a flexible, interactive program that displays transverse sections extracted from the volumetric reconstruction. The program works on one cut at a time. The operator begins the segmentation by providing an initial approximation on one cut. An automated segmentation program then takes over to refine the initial approximation. The final result is a file of three dimensional points made up of all the cuts. An example of a segmented image with the operator interface is shown in Figure 42.

Figure 42 Operator Interface

Refined Edging

The operator provides initial approximations of discrete contour points that give a rough outline of the skin and two bones. Our GUI displays the image data and gives mouse-driven controls for making these measurements. To approximate the outline of the skin, the operator sets a gray-level threshold that distinguishes the darker image background from the brighter pixels on the skin. A radial line is traced from the outer edge of the image toward the center. The first skin

point is taken at the place where this line first crosses the threshold. Starting from this point, the program traces the remainder of the skin looking for nearby above-threshold values. The two bone contours come from pre-stored, approximate outlines of typical bones consisting of about 20 points each. The operator drags these contours to the approximately correct location on the image. The program allows the operator to rotate and scale all the contours and to move individual points of the contours.

These initial approximations serve as the starting point for our automatic segmentation program. This program refines the discrete contour points to make them fall precisely on the bright ridges in the image. The automatic segmentation program uses active contours called "snakes" (Kass, Witkin, & Terzopoulos, 1988). Snakes work by solving an energy minimization problem for each contour. The "energy" is a sum of the (negative) pixel brightness along the contour and the bending energy of the contour. The bending energy is proportional to a weighted sum of the first and second derivatives along the contour. The positions of the contour points are iteratively moved to minimize the total energy. The brightness term tends to move the points toward image maxima, while the bending terms tend to keep the contour smooth. Together, these terms make the contour track bright ridges in the image while remaining smooth through gaps and noise.

Two Dimensional Display and Comparison

A GUI was designed which allows the operator to compare qualitatively images obtained with the ultrasound platform to the CT images obtained at the UT Health Science Center. The interface was written for use on a Silicon Graphics (SGI) machine, using "Forms" (SGI software for creating windows, buttons and other operator interfaces), Graphics Language, and C programming.

With the GUI, the operator can load a series of images for a particular patient including ultrasound, CT and edge points created by the edging routine. See Figure 42 for an example of an image viewed using the GUI. The operator may "browse" through the series of ultrasound or CT cross-sections image by image. In order to make a comparison, the operator may, for instance, display an ultrasound image at a particular position on the leg. Next, the operator can display the CT edge image, generated from the corresponding CT scan taken at approximately the same position on the patient's leg, overlaid in red on top of the ultrasound image. Features such as "click and drag", rotation, mirror, and scale are incorporated in the edge image display in order to properly line it up with the corresponding ultrasound image. Once the image has been positioned for the "best fit," a visual comparison of the proportions and positions of the features in the leg can be made.

Three Dimensional Display and Volumetric Comparison

Differences in leg orientation during CT scanning (where the patient is prone) and Ultrasound scanning (where the patient is standing) resulted in differences in soft tissue location in comparative images. Consequently, comparisons between the ultrasound and CT scans were difficult. Two dimensional comparisons are greatly affected by any deformation because

displaced tissue can make cross-sections taken at the same position on the leg look very different. It was decided that three dimensional volumetric comparison methods would give more accurate results than two dimensional scan-by-scan comparisons. The theory behind this idea was that if any deformation occurred at a point on the leg, the tissue would be displaced a small distance away from its usual position. By examining the entire volume of the leg model, any individual tissue displacements should not affect the overall volume calculation.

Figure 43 Side View - Ultrasound and CT
(Left - Ultrasound Right - CT)

Figure 44 Top View - Ultrasound and CT
(Left - Ultrasound Right - CT)

Another GUI was created which displays three dimensional wire frame and solid polygon models generated from both ultrasound and CT images. See Figures 43 and 44 for examples of ultrasound and CT three dimensional solid models. Edge points from the ultrasound and CT images for the specified patient are loaded by the application. The operator can rotate and translate the models in order to facilitate viewing, or to align the models for comparisons. The application contains a routine developed to orient iteratively the corresponding CT and ultrasound volumetric models by rotating and translating for the best geometric fit.

Three dimensional point sets from the ultrasound data were registered with corresponding three dimensional point sets from CT scans. The two models can be registered by their entire volumes, or only their intersecting length portions. If the ultrasound and CT models are separated initially, they should be registered based on their entire volumes because there is no intersection. If, however, the models have been approximately registered by the operator beforehand, using the registration based on their intersection will refine the pose of the ultrasound point sets to find the best registration. See Figures 45 and 46 for examples of the ultrasound and CT models after registration.

Figure 45 Registered Ultrasound and CT Volumes - Side View

Figure 46 Registered Ultrasound and CT Volumes -Top View

The point sets are registered based on Besl and McKay's "iterative closest point" (ICP) algorithm (Besl & McKay, 1992). This algorithm searches for the minimum mean-squared distance between the two point sets. For each point in the moveable point set (ultrasound in this case), the algorithm finds the closest point in the stationary point set (in that case, CT). The ICP then computes a transformation matrix to minimize the distances between the matched points. The moveable points are moved according to this computed transform. This process of matching and moving is repeated until the mean-squared distance cannot be reduced any further.

Once the models are properly registered, a quantitative volumetric comparison can be made. In order to accurately compare the volumes of the ultrasound and CT three dimensional models, only the intersecting length portions of the two volumes are considered. This process is necessary because the CT volumes often represent a much longer portion of the leg than the ultrasound data. The volumes of the two models are then calculated, and a percent difference value is given.

RESULTS OF CLINICAL TRIALS - VOLUME CALCULATIONS

Comparative Analysis of Clinical Trial Data

From the nine volunteer subjects imaged at UTHSCSA, nine functional data sets were obtained. Markers were attached to the imaged area of each patient's leg prior to scanning to aid in registration of the 3D models produced from the ultrasound and CT data sets. Some ultrasound and CT data gathered from the nine volunteers was disregarded because of miscellaneous discrepancies such as missing markers which made vertical registration of the resulting volumes impossible, motion of the subject during ultrasound imaging, and data acquired only at knee with no tibia or fibula information. Imaging of the amputated legs presented more challenges because of the difficulty of properly locating the stump in the tank to prevent motion during scanning. See Figure 47 for descriptions of the conditions of each image set.

Volume Comparisons

Because of the differences in subject leg orientation during ultrasound and CT imaging, it was decided that volume comparisons would be more informative than comparisons of two-dimensional scans. An assumption was made that even though tissue location could not be compared, tissue volumes of equivalent leg intersections could be compared since tissue displacement along the axis of the leg was thought to be minimal. Volume comparisons were performed in a two step process. The first step involved registration of reconstructed CT and ultrasound volumes to properly align them for comparison purposes. Registration of the volume data was performed by manually aligning the segmented ultrasound skin and bone surface geometry with the CT model using the markers described above, and then applying the registration algorithm to minimize distances between corresponding bone or skin geometry. Once registered, percent volume difference calculations were performed.

Calibration

In order to calibrate scale values for the CT and ultrasound data, a set of three PVC pipes of varying diameters and lengths were imaged with CT and ultrasound to determine the length per pixel values. Based on the scans, CT provided 1.0 mm/pixel and ultrasound provided 0.52 mm/pixel along the vertical axis and 0.50 mm/pixel in the cross-sectional plane. These values were used to scale the ultrasound and CT images prior to performing either the volume or distance comparisons. See Figure 47 for percent volume error. The results show approximately a one to three percent volume error for ultrasound as compared to CT for the pipes. This small error was attributable to inaccuracies in image reconstruction and segmentation processes. By imaging inanimate, rigid pipes, inaccuracies caused by subject motion and deformations between imaging modalities were eliminated.

Results of Clinical Trial Data

Figure 47 shows results from the clinical trial volume comparisons, providing volume percent differences of the ultrasound data with respect to the CT data. For the most part, the values fall

in the target range of one to three percent. In the case of the left legs of subjects 6, 8, and 9, errors were greater than three percent due to factors such as data acquisition errors that included patient motion during ultrasound scanning and inaccuracies in segmentation of the images due to noise in the images.

Unlike typical engineering experiments, clinical trials are highly patient dependent. This dependency leads to uncontrollable factors that affect the results of the process including the following:

- the patient's strength to support his/her own weight,
- the amount of uncontrollable tremor in the person's musculo-skeletal physiology, and
- the flexibility of the patient.

These factors as well as others resulted in leg data that is limited to healthy legs alone. Future work will lead to increased stabilization for amputees. The chart below displays the resulting data that was used in our investigation of volume comparisons between ultrasound and CT.

<i>Name</i>	<i>Leg</i>	<i>% Error by Volume</i>	<i>Comments</i>
Pipe 1		3.11	Medium diameter
Pipe 2		1.73	Large diameter
Subject 1	Right		CT & US markers do not correspond (Imaged at different times preventing registration)
Subject 2	Right	-1.23	Good. Markers visible
Subject 3	Right	-----	No CT images taken. Comparison impossible.
	Left	-8.27	
Subject 4	Left	2.79	Good. Markers visible.
Subject 5	Left	3.63	US good. CT images had extraneous data which had to be removed.
Subject 6	Right	2.08	Good. Markers visible.
Subject 7	Right	-2.78	No markers - Vertical registration very questionable.
Subject 8	Left	4.46	Good - markers visible.
Subject 9	Right	2.97	Good - markers visible.

Figure 47 Table of Ultrasound and CT Comparison

Prosthetic Computer Aided Design for Use with Ultrasound

Prosthetists use currently available prosthetic CAD programs to adjust interactively the digitized surface shape of the residual limb to that of a biomechanically correct socket. The regions of modification are located relative to the underlying bone structure, and the locations of bony prominences are read into the system using manual procedures which rely upon the skill of practitioner. These anatomical markers prove to be inadequate for showing extended regions where bones are near the skin surface.

Custom software is required for the design of prosthetic sockets from shape data. General purpose mechanical CAD/CAM programs such as Autocad and Cadkey are not suitable for designing sockets because they are complicated to use and are unsuited for dealing with freeform shapes.

The University of Texas Health Science Center has developed its own CAD software for the production of prosthetic limbs. This program, called SOCKETS, allows the interactive manipulation of freeform shapes. It outputs data used to produce socket patterns using NC milling machines. Even though the program was originally written for use with surface data, it has been modified in order to accommodate bone data as well. It was tested using data acquired from CT scans, and it also accepts the three dimensional surface data acquired by ultrasound during clinical tests.

SOCKETS was written using Ithaca Software's Hoops graphics subroutine libraries. The Hoops routines are available for a wide variety of personal computers and workstations. It was decided at the beginning of the design process that the software would have to run well on reasonably priced personal computers in order to be accepted by the prosthetics community. The bulk of the development work has taken place on Sun and Silicon Graphics workstations. The source code is then recompiled on IBM/MSDOS and Apple Macintosh computers and linked with the Hoops libraries for those platforms.

The skin surface and each of the bones are treated as individual objects. All share a common coordinate system. Each object can be rendered as a wire frame or a shaded image. When the skin is shown as a wire frame, the bones can be seen in relationship to the skin in Figure 48. Only the skin surface object can be modified. The three dimensional shape of the bones can be shown at the same time as the skin surface.

When the skin surface is displayed as a wire frame, the bones can be seen underneath the skin surface. See Figure 48.

Figure 48. Three Dimensional Bone Shape

Cross sectional views can be shown at any location along the limb as in Figure 49. After selecting the cross-section function, the operator uses the mouse to select a point on the limb shape. The cross-section at that point is displayed in another window. The selected cross-section includes the bone locations and the perimeters of the original and modified shapes.

Figure 49 Cross Section Picture

A variety of measurements are available to the practitioner. Distance measurements allow point to point measurements as well as measurements along the surface. Cross sectional perimeters and areas are calculated. The difference in volumes between original and modified shapes can be calculated.

The modification methods mimic the conventional tools that the prosthetist uses in fabricating a socket by hand. These software tools are used to make indentations in the socket and to press on areas that can bear weight. They also provide pockets in the socket to keep sensitive areas from rubbing. A modification consists of an area of interest and an operation on that area. Each modification is linked to the underlying bone structure relative to bony prominences. A list of the modifications is stored along with the original shape data.

An individual modification can be edited at a later time and reapplied to the socket shape. This modification then allows fine tuning of the socket design in order to obtain the optimum fit. For example, the Patch modification consists of an area of interest and a control line within the area. The pseudo-color display makes it easy to locate the fibula head which is a sensitive area requiring pressure relief.

Figure 50 Modifications to Residual Limb

The operator outlines the region around the fibular head to create the area of interest. A control line is drawn inside that area. See Figure 50. Sliders are used to select the distance to displace the control line from the surface and to set the rate of blending from the control line to the edge of the area measured. The rate of blending is determined by an exponential function. The location of the Patch modification is linked to one or more bony landmarks. See Figure 51

The modifications to the residual limb shape are stored as a list of operations. The operator determines an area to be modified and selects an operation to be performed on the points in that area. See Figure 51.

Figure 51 CT Modification Screen

Another method of visualization that aids in modification uses shades of color to indicate the depth of the bone beneath the skin surface. In Figure 51 the colors are displayed as shades of gray. This method allows the practitioner to readily identify the areas of the limb where the bone is near the surface. These areas generally require pressure relief. The load bearing areas are identified by their location relative to the underlying bone structure.

Each modification is linked to the underlying bone structure in a method that is independent of shape. These operations can be applied to other shapes that have the same bony landmarks. The menu in Figure 51 creates a template for a socket design. In the future, these templates will be further refined by an artificial intelligence system to provide the best fit. This system will take into account the patient's age, weight, activity level, and other factors.

Other modifications include spline based surface modifications, volume changes, length changes, and provision for attachment fittings. A list of the modifications necessary to create a biomechanically correct socket can be stored as a template which can be placed in memory and

then applied to other shapes. In the future, these templates will be further refined by an artificial intelligence system to provide the best fit. This system will take in the patient's demographic data as well as the shape of the residual limb.

CONCLUSIONS

The ultrasound system developed under the funding provided by LDRD has demonstrated at a proof-of-concept level that surface skin and bone geometry can be obtained with relatively low-cost for the purposes of prosthesis fabrication. A side benefit of this work has been the demonstration of high resolution ultrasound slice images that rival any ultrasound images which are available to date. This conclusion has been confirmed by medical personnel at various hospitals, at meetings such as Medicine Meets Virtual Reality (1995), and in meetings with ultrasound manufacturers and researchers at a joint Advanced Research Projects Agency/Office of Naval Research (ARPA/ONR) meeting on ultrasound medical imaging in February 1995. As a result of the image quality provided as a side benefit of this work, ARPA has provided funding for work on improvements to our system for 3D high resolution ultrasound imaging for battlefield applications.

The results for prosthesis fabrication indicate that there is still work to be done to improve on the system to provide a platform that would repeatedly provide data accurate enough for prosthesis fabrication, but that the amount of work necessary is minimal. Our goal from the beginning was to demonstrate a prototype system that would provide proof-of-concept, which our work has done. In addition, the work has added benefits to the image processing technologies that were gleaned from the synthetic aperture radar work and automatic target recognition work at Sandia National Laboratories. These benefits include improvements in correlation, understanding, application, and advances in identification of objects based on angular dependency.

3D ultrasound is currently being investigated across the country and there is a ground swell of enthusiasm surrounding the results that this work has accomplished and the future applications of this work in the following areas:

- database generation for fabrication of custom body worn appliances,
- diagnostic imaging comparable to CT or MRI, and
- the potential for real-time 3D ultrasound imaging.

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REFERENCES

- Allardice, J.T., Jacomb-Hood, J., Cookson, J., Dykes, E., Holman, J., Abulafi, A.M., Williams, N.S., 1993, "Accurate Measurement of Surface Areas of Anatomical Structures by Computer-Assisted Triangulation of Computed Tomography Images," British Journal of Radiology 66:426-434.
- , "For Amputees - Walking to a Healthier Life," AOPA Almanac, 37(1):22.
- Besl, P. & McKay, N.D., 1992, "A Method for Registration of 3-D Shapes," IEEE Transactions on Pattern Analysis and Machine Intelligence, v. 14, no. 2, pp. 239-256.
- Childress, D.S., PhD, 1986, Telephone Conversation, Prosthetics Research Laboratory, Northwestern University, Chicago, IL.
- Curry, T.S., III; Dowdy, J.E., & Murry, R.C. Jr., 1990, Christensen's Physics of Diagnostic Radiology, Lea and Febiger, pp 323-371.
- Duncan, J.P., Dean, D.P., & Pate, G.C., 1980, "Moire Contourography and Computer Aided Replication of Human Anatomy," I Mech Eng 9.
- Faulkner, V.W. & Walsh, N.E., 1989, "Computer Designed Prosthetic Socket Form Analysis of Computed Tomography Data," Journal of Prosthetics and Orthotics 1(3):154-164.
- Faulkner, V. W. & Walsh, N.E., 1987, "An Ultrasound Shape Sensing Mechanism," Presented at 13th Annual Meeting of the American Academy of Orthotists and Prosthetists, Tampa, FL.
- Faulkner, V.W., Walsh, N.E., & Gall, N.G., 1987, "Computerized Tomography as an Aid to Prosthetic Socket Design," Rehabilitation Research & Design Progress Report 1:7-8.
- Fernie, G.R., et al., 1985, "Shape Sensing for Computer-Aided Below-Knee Prosthetic Design," Prosthetics Orthotics International, 9:12-16.
- Goodgold, J., 1974, Anatomical Correlates of Clinical Electromyography, The Williams and Wilkins Company.
- Kass, Michael, Witkin, A., & Terzopoulos, D., 1988, "Snakes: Active Contour Models," International Journal of Computer Vision, pp. 321-331.
- Kreel, L. & Meire, H.B., NO DATE "Computed Tomography and Ultrasound - A Comparison," Computed Tomography V Chapter 35, Section 8.
- Kuttruff, H., 1991, Ultrasonics Fundamentals and Applications, Elsevier Applied Science.

- Melson, G. Leland, Biello, D.R., & Lee, J.K.T., 1983, "Comparative Imagery," in Computed Body Tomography ed. J. Leg, S. Sagel, and R. Stanley, pp. 523-546.
- Oshima, T. & Saito, Y., 1985, "CAD/CAM System Applied to the Foot Shape for Prosthetic Device," Proceedings RESNA 8th Annual Conference, pp. 222-224.
- Presperin, J.J., ed., 1989, Proceedings of the '89 RESNA Annual Conference, New Orleans, LA, June.
- Radcliffe, D.F., 1986, "Computer-Aided Rehabilitation Engineering-Care," Journal of Medical Engineering Technology, 10: 1-5, .
- Saleh, B. E. A. & Teich, M. C., 1991, Fundamentals of Photonics, John Wiley and Sons, New York, NY, Chapter 3.
- Schurr, D.G., 1990, Prosthetics and Orthotics, T.M. Cook, pp. 1-15.
- Seeds, J. & Cefalo, R.C., 1986, Practical Obstetrical Ultrasound, Aspen System Corp., Rockville, MD.
- Smith, D.M., Crew, A., & Hankin, A., 1986, "Silhouette Shape Sensor" in Bioengineering Centre Report, ed. M.R. Davies, pp. 41-42, University College, London.
- Stokosa, J., 1984, "Prosthetics for Lower Limb Amputees," in H. Haimovicci, Vascular Surgery Appelton-Century-Croft, pp. 1143-1162, Norwalk, CT.
- Temkin, S., 1981, Elements of Acoustics, John Wiley and Sons, New York, NY., Chapter 3.
- Vikers, G.W., Foort, J., & Saunders, C.J., 1981 "Shoe Last Replication by Moire Contourography," Proceedings of the 4th Rehabilitation Engineering Conference, Washington D.C.
- Williams, T.W., 1986, "The Boston Elbow," SOMA - Engineering for the Human Body, 1:29-33.

APPENDIX A

Glossary of Technical Terms and References:

ARPA - Advanced Research Projects Agency.

ATL - Advanced Technology Laboratories, Inc.

Amputation - A process where part of a limb is severed from the body.

BK Limb - Below the Knee Limb

CAD - Computer Aided Design.

CT - X-ray Computed Tomography.

Devguide - An X-View based GUI development tool.

Forms - SGI software used to create windows, buttons and other user interfaces.

GUI - Graphical User Interface.

HSB - Human Studies Board.

ICP - iterative closest point algorithm (Besl & McKay, 1992).

Khoros - a software integration and development environment that processes image suites. It was originally developed by Sandia National Laboratories and the University of New Mexico.

LDRD - Laboratory Directed Research and Development.

MRI - Magnetic Resonance Imaging.

Phantom - A model of human anatomy that mimics the acoustic properties of the actual tissue.

Prosthesis - An artificial device used to replace a missing body part.

SGI - Silicon Graphics

SOCKETS - The University of Texas Health Science Center CAD software

2D - Two dimensional.

3D - Three dimensional.

UTHSCSA - The University of Texas Health Science Center at San Antonio, Department of Rehabilitation Medicine.

VME - Versa Module Eurocard.

V_x Works - Software by Wind River Systems, Inc.

APPENDIX B

Khoros

Khoros is a Sandia/University of New Mexico software system that provides an environment for image processing algorithm exploration with industry standard routines for basic image conversion, processing, and display. Application-specific routines can be integrated into the Khoros system. They may contain calls to standard Khoros library functions, or user-written library functions, that add new functionality to the system. The VPE routines include the following Khoros Terms.

- *gabor* - a routine used to generate a kernel containing a *gabor* function. The kernel can be arbitrary in orientation and size. The *gabor* program can generate both even and odd *gabor* functions.
- *ncorr* - will calculate the normalized correlation of a kernel with an input image. The resulting image will be the extent of the input image. Normalized correlation is only calculated for those positions in which the kernel fits entirely within the input image. Edge effects are not handled.
- *us2viff* - "Ultrasound to Visualization Image File Format (VIFF)" conversion - *us2viff* takes the raw individual ultrasound frames in conjunction with the acquisition header information (sensor orientation, acquisition angle, date, time, subject, machine characteristics) and produces a multiband VIFF image file. The individual frames are stored as bands in the multiband image.
- *ush2dxs* - "Ultrasound horizontal two dimensional cross section generation" - *ush2dxs* rotates the individual frames about the plumb line to the angle which corresponds to the actual acquisition, compensates motion between the individual frames, and determines the maximum response throughout the frames on a pixel by pixel basis to produce a composite cross sectional ultrasonic image.
- *ushmocomp* - is used to compensate the individual horizontal ultrasound frames for motion of the limbs between successive frames. It exploits the highly correlated nature of successive frames and determines the amount of motion by the shift in the correlation peak.
- *ushplumb* - is a calibration verification tool which will recognize the signal echo of a plumbob within the ultrasound imagery to verify the proper orientation of the sensor with respect to the center of the tank. Statistics are generated for both leading edge and maximum point signal echoes of the plumbob.

- *ushrank* - "Ultrasound horizontal rank value cross sections generation" - rotates the individual frames about the plumb line to the angle which corresponds to the actual acquisition, motion compensates motion, and ranks, across all frames, the individual pixel values to produce a set of ranked cross sections. These cross sections can be chosen to filter out incoherent noise, or other undesirable signal echoes.
- *usv3dxs* - "Ultrasound vertical three dimensional volumetric reconstruction" - rotates (about the plumb line) the individual frames to the angle which corresponds to the actual acquisition, performs polar to Cartesian coordinate system transformation, and then executes a bilinear interpolation scheme to produce a series of two dimensional cross sections. The resulting "stack" of two dimensional cross sections is then assembled to produce an overall volumetric reconstruction of the limb.
- *usvskin* - uses the individual vertically scanned frames to create a 3D description of the skin surface. The skin is recognized by applying a set of gabor filters to the individual frames and determining the maximum response to the set of filters. The skin location or leading edge of the skin response is saved in the form r, z, Θ . These sets of points give rise to an overall 3D description of the skin surface of the limb.

APPENDIX C

Ultrasound Procedure Checklist

Setup: (before subject arrives)

- _____ 1. Place **heel locator and bearing** in tank.
- _____ 2. Place **thigh locator** on tank.
- _____ 3. Place **coupling gel** on transducer and mount to tank (cable to right for horizontal or down for vertical). Smooth gel from inside tank to remove bubbles.
- _____ 4. **Fill tank** with water (allow time for bubbles to settle).
- _____ 5. Make sure ultrasound **video input cable** is connected properly.
- _____ 6. Turn on **motor, vme, SUN, and ultrasound machine**. (Make sure motor is actually on and E-stop is not depressed by trying to manually turn the tank.)
- _____ 7. Set **parameters** correctly on ultrasound machine.
- _____ 8. Bring up **usi2** and hit **find home** to prepare for scanning.
- _____ 9. **Calibrate** transducer fixture using plumbob, viewing at 0, 90, and 270 degrees. (only if transducer orientation has been changed from previous scans)

Procedure: (with subject present)

- _____ 10. Measure **temperature** of water.
- _____ 11. Complete **log** (subject's name, parameters, file, temp, etc.).
- _____ 12. Complete **usi2** information. (filename, number of scans, scan set #, subject's name, horiz/vert, variable scan information - in vfc and message fields)
- _____ 13. Have subject wear **nylon**, if necessary.
- _____ 14. Place subject's leg in tank, and **adjust heel and thigh locators** to center leg (or stuff a towel between leg and top of tank to steady leg during scan).
- _____ 15. **Adjust gain** setting so can see inside leg without saturating image. (Record in log.)
- _____ 15. **Center leg:** view leg at 0, 90, 180, and 270 degrees on ATL monitor and adjust leg until approximately centered.
- _____ 16. Hit **"GO"** on usi2 to run scans.
- _____ 17. **Save** scans to files. (Adjust scan set number for each save.)
- _____ 18. Check **scan quality**. (Make sure there are no motion errors and proper gain setting.)
- _____ 19. If images bad, **re-run scans** (repeat from 10, discard files containing scans).

Clean-Up: (after subject leaves)

- _____ 20. Send **Email** to Wallace and Scott to let them know where scans are saved.
- _____ 21. Turn off ultrasound machine, VME, and motor.
- _____ 22. Drain tank (place diffuser on end of hose in sink).
- _____ 23. Remove heel locator and rotator.
- _____ 24. Use sponge to remove excess water from bottom of tank.
- _____ 25. Dry bearing completely, inside and out. (Remove ball-bearings.)
- _____ 26. Remove transducer from tank.
- _____ 27. Clean coupling gel off window and transducer.

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APPENDIX D

HUMAN STUDIES BACKGROUND AND DATA

Risk Assessment

In general there are no reported risks related to the use of diagnostic ultrasound on humans (Seeds & Cefalo, 1986). Furthermore, the National Institute of Health Consensus Development Conference on Obstetrical Ultrasound concluded that documented evidence indicated no substantial evidence of ultrasonic damage or genetic damage to human fetuses.

In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee which reviewed available data on possible effects of ultrasound exposure. The U.S. Food and Drug Administration (FDA) also addressed bioeffects by establishing Acoustic Power and Intensity (AP&I) limits for exposure for different clinical uses. Bioeffects are limited to two known causes: thermal and cavitation.

- Thermal bioeffect is the rise in temperature of tissue when it is exposed to acoustic energy. The temperature rise depends primarily on the amount of energy, the area of exposure, and the thermal characteristics of the tissue. Tissue perfusion is not accounted for in the AIUM model.
- Cavitation refers to gases that come out of solution due to the pressure changes that are caused by high power ultrasound. The AIUM reports that cavitation is deleterious to human tissue. However, cavitation does not occur at normal ultrasound power levels.

The AIUM report also includes the following conclusions. Other mechanisms for bioeffects are not known. No known adverse effects have arisen from exposure to diagnostic ultrasound in over 25 years of widespread clinical use. And, there are no independently confirmed significant in-vivo bioeffects with focused spatial peak, time average energy density below 1000 m W/cm^2 for less than 50 seconds, or when a product of energy and time is less than 50 joules/cm^2 .

The FDA has established maximum *in situ* limits for different clinical uses regardless of the modes of operation. These limits are not based on bioeffects but rather on output levels of devices manufactured prior to 1976 Amendments of FDA legislation.

The following table summarizing the limits set by the FDA and AIUM demonstrates that the current machine in use, the Ultramark 9 (UM-9) ultrasound machine made by Advanced Technology Laboratories (ATL), has values of "spatial peak, pulse average intensity" (ISPPA) and "spatial peak, time average intensity" (ISPTA) well below the desired limits. Also according to ISPPA standards, the product of energy and time for a scan should not exceed the allowable energy level of 1000 m W/cm^2 . These levels are much higher than can be produced by the UM-9. Consequently, the UM-9 complies to all of these limits and will not impose any health risks based on the above described evidence. See Figure 52.

Energy density	FDA limits	AIUM bioeffect limits	UM-9 levels
ISPPA (m W/cm ²)	190	none	55
ISPTA (W/cm ²)	94	1000	2

Figure 52 Table of Energy Densities

Because commercially available diagnostic ultrasound machines must comply with FDA regulations, other commercially available ultrasound machines that we considered using in the human trials (such as the Aloka 500 described in the original LDRD), were acceptable machines for use in human studies. Because of limits in time and budget, however, we used the ATL UM-9, an approved machine.

Procedures

In general, the human subjects placed their legs within the water bath while holding onto the support railing. Protection from electrical shock was provided and is described in the Risk Assessment for the 3D Ultrasound Imaging Project. (See also ES&H Activity Specific Standard Operating Procedure 3D Ultrasound Imaging Project, SP 472426, and Preliminary Hazard Assessment, PHA471038.) The ultrasound gains were set for optimum image quality. Images were stored on the computer and can be retrieved for later manipulation. Consent forms approved by the appropriate human studies board, or internal review board, were provided for each patient for review and signature prior to scanning. Only adults who were capable of understanding and signing the consent form were allowed to participate.

Human Studies

During FY94, ten subjects volunteered for human studies through the approved process outlined above. These subjects were five women and five men and they comprised the database to establish the repeatability and quality of the ultrasound scanning system. Each subject was scanned using the vertical and horizontal oriented transducer. Each subject's leg was scanned to double the effective data set, and the system was fine-tuned based on the results of the scans.

After each data set was obtained, the images were processed through the visualization software used to generate a composite image. For the men in the study, leg hair posed a problem for image acquisition. Leg hair tends to trap air bubbles and tends to blur the definition of the skin surface. The volunteers opted to wear women's leg hosiery to keep the leg hair close to the skin rather than shaving the leg. Movement, high reflection at the surface of the sock, and poor centering were corrected. Modifications in the scan procedure were made based on the "lessons learned" during the scans as well as improvements to the visualization software. The result of this exercise was an improved image acquisition procedure and improved visualization software. The ultrasound procedure checklist is found in Appendix A.

Clinical Trials - UTHSCSA

In order to define the qualitative and quantitative value of the 3D ultrasound system, a clinical trial was performed to compare the ultrasound images to x-ray computed tomographic images of the same anatomical structures. The accuracy of x-ray CT has been documented in several articles. Surface areas of the composite volumetrically rendered skin and bone images have been known to be within 2.5% of actual CT triangulation (Allardice, Jacomb-Hood, Cookson, Dykes, Holman, Abulafi, & Williams, 1993). The clinical trial was planned for 12 individuals of varying age and gender. Nine of the twelve people participated in the actual clinical trial, which occurred during a one week period. Each of the participants in the trial was selected from a patient population at UTHSCSA. These individuals were selected for their cooperative nature and for their representation of the general patient population.

Specific Aims of Study

The objective of this study was to determine the clinical accuracy of a new ultrasound imager for measuring residual limbs of amputees. This imager measured the shape of the skin surface and location of the underlying bone structure. Volunteer subjects were imaged using the ultrasound imager and the x-ray computed tomography system. The results of the two methods were compared to evaluate the accuracy of the ultrasound unit.

Significance

The results of this study will have an important impact on the prosthetics field in both direct clinical application and long term clinical research.

The first direct clinical application of this research was to interface ultrasound data to existing prosthetic CAD programs for the design of below-the-knee prostheses. The ultrasound imager developed by Sandia is capable of rapidly inputting the shape of residual limbs. The incorporation of bone data in the prosthetic CAD software will aid the prosthetist in identifying sensitive bony prominences and potential load bearing regions. This research also provided input for an artificial intelligence assisted prosthetic CAD program now under development at the Department of Rehabilitation Medicine.

Long term clinical research will benefit from being able to track the atrophy of residual limbs over time. There has been no method of accurately measuring this phenomenon because suitable data has not been acquired. Soft tissue atrophies with time, but the bone structure remains much the same. Locating the bone structure is necessary to track where the relative changes occur in the soft tissue. If the location of the bone structure can be determined using a non-contact ultrasound imager, then it will be possible to track patients over time using a low cost non-invasive procedure.

Plan of Trial Work

Select Research Subjects from the University of Texas Health Center at San Antonio (UTHSCSA)

Nine of 12 selected patients from the University Clinic and BCHD participated. The subjects were below-the-knee amputees with medium length stumps. Weight, measured with the prosthesis, was within normal limits of an ideal body weight based on height. Height was also within normal range. All subjects were amputees with mature residual limbs who had worn a definitive prosthesis for at least six months. Subjects were excluded for histories of co-existing orthopedic, musculoskeletal or neurologic conditions which might alter the surface to bone geometry.

Population

The nine subjects for the study were recruited by word-of-mouth. Rehabilitation Medicine faculty members did the recruitment. Consent forms were completed by one of the researchers (N. Walsh, B. Rogers or V. Faulkner) and were witnessed on the day of the study. The consent forms are stored in room 628L (Dr. Walsh's office) at UTHSCSA. Subjects were identified only by an eight character alphanumeric code in order to assure confidentiality.

Risks

Risks included radiation from one computed tomogram of the amputee's stump, giving a total body effective dose equivalent HE of 111 mRem. Since there is no other radiation risk this exposure placed this study in Category I, which is close to naturally occurring background radiation, and is less than, or equal to, radiation from most routine radiological and nuclear medicine procedures.

Other risks were minimal, such as that of falling out of a chair while sitting to have the amputee stump measured. The Sandia ultrasound imager used an FDA approved ultrasound unit. This ultrasound imager used an ATL UM 9 ultrasound machine which is already FDA approved. Since the greatest risk is from having a CT scan of the amputee stump, no additional specific risk minimization is needed. A researcher remained with the subject during the entire study to assure safety. Only amputees who could safely don and doff their own prosthesis were accepted into the study. If injured, the subject was provided emergency medical care. We were not be able to give the subject money if they were injured.

All subjects signed consent forms approved by the Institutional Review Board . Each subject received \$100 compensation for his/her time. It was anticipated that the CT scan and ultrasound imaging would take place on the same day. If a subject decided to drop out of the study before the end, then the incentive was pro-rated. The subject received \$50 if only the CT scan was completed or \$50 if only the ultrasound scans were completed.

Tasks

Acquire Measurement Data

- 1) Acquire ultrasound image data from residual limbs using the Sandia ultrasound imager.
- 2) Acquire CT image data from residual limbs using the Phillips X-ray CT unit in the Medical Center Hospital. The patients were scanned from the bottom of the residual limb to 5 cm above the top of the patella. The data was written to a tape for transfer to the Biomedical Image Analysis Division of the Research Imaging Center.

Convert Data from the Three Imaging Modalities to a Common Format

- 1) The data from the ultrasound imager was transferred to the Silicon Graphics workstation in Rehabilitation Medicine for data conversion.
- 2) The CT data was loaded onto a Sun Workstation in the Research Imaging Center. The MR Console software package segmented out the skin and bone images. The point lists for the surface of the skin and for each bone was written to separate data files. The files were transferred to the Silicon Graphics workstation in Rehabilitation Medicine by the University Ethernet network. The data was then converted to a format readable by the prosthetic CAD program.

Data Analysis

The purpose of the study was to determine the accuracy of the Sandia Ultrasound Imager in a clinical setting. Data acquired by the ultrasound imager was compared to the data acquired by CT.

The distance accuracy of the Sandia Ultrasound Imager was tested by ultrasound data compared to CT data. In test subjects, three anatomical points were located: the tubercle of the tibia, the head of the fibula, and the distal end of the crest of the tibia. The locations of these bony prominences are critical to socket design and are easy to identify. These locations were manually marked on the three dimensional images reconstructed from the CT and ultrasound data using software under development in Rehabilitation Medicine. The distances between anatomical points was calculated for the CT and ultrasound for each of the nine subjects. The ultrasound distance was subtracted from the CT distance for each pair of locations for each subject. This measurement produced nine difference measurements for each pair of anatomical locations. The mean and standard deviation was reported for each pair of anatomical locations. The 95% confidence intervals were calculated for each pair of locations.

It is difficult to compare soft tissue measurements because soft tissue is easily deformed. Volumes of defined regions were compared by setting proximal and distal bounding points that were defined by bony landmarks. The volume measurements were reported using data from the ultrasound imager and the CT.

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