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Conference Paper *in* IEEE International Conference on Rehabilitation Robotics : [proceedings] · July 2017

DOI: 10.1109/ICORR.2017.8009416

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Capturing Prosthetic Socket Fitment: Preliminary Results Using an Ultrasound-based Device

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***Abstract*—The acceptance of advanced prosthetic systems by users requires overcoming unique challenges of fitting prostheses to unique user anatomies to achieve systematic performance across a user base. Variations among individuals introduce complexities in fitting the sockets. Due to the difficulty of measuring socket interface characteristics, there is a lack of quantifiable diagnostic fitment information available. As a result, the process of fitting sockets is currently a labor-intensive, manual approach, and can often result in sockets that are uncomfortable, unstable, or impede full range of motion. Additionally, results can be difficult to reproduce reliably. A diagnostic tool has been developed to quantify the relative movement between the socket and the residual bone during the fitting process. The approach leverages low cost and high precision ultrasound transceivers and intuitive visualization software to provide quantifiable socket fitment data. The goal is to enable a systematic socket-fitting strategy that yields reliable and reproducible results. Human subject testing and results are presented that show movement tracking relative to a cuff with an ultrasound transducer with an RMSD of 0.36 mm.**

I. Introduction

The quality of fit of a prosthetic socket is a significant role in prosthetic outcomes during use. Poorly fit sockets can lead to discomfort, further damage to local tissue, and can overstress other parts of the body that are forced to adapt and compensate. This can ultimately decrease the functionality a user can get from their prosthesis. Fitting an individual with a prosthetic socket is a labor-intensive, manual process; variations among prosthetists and a lack of quantifiable information about the socket-limb interface characteristics make assessing and reporting socket fit measures impossible. As a result, the process can often result in sockets that are uncomfortable, unstable, impede full range of motion and methods of fabrication that are difficult to reproduce across patients. This paper describes a new diagnostic tool being developed to measure the relative movement between the residuum bone and prosthetic socket while the user dynamical interacts with the prosthesis as shown in Fig. 1. The ability to observe bone motion during the fitment process will provide more information on socket-limb mechanics and quantify socket fitments to allow for reproducible methods and results across users.

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The current practice of socket fabrication begins with the residual limb being either cast in plaster or digitally scanned to create a mold. The mold is then modified by the prosthetist (physically or digitally) to distribute forces based on industry best practices and their own personal skill. To assess the initial fit, a 'check' socket is then molded from thermoplastic and worn by the patient. Based on verbal feedback and visual assessment of the patient using the 'check' socket with their prosthesis during routine exercise, manual corrections are made to the socket in order to balance the trade-off of functionality and comfort. Once the prosthetist and patient are satisfied, a final socket is fabricated.

Subjective patient feedback is the primary method used to evaluate socket fit and performance. A quality socket fit is essential to optimize the performance of the prosthesis, affecting patient acceptance and use of the device. Currently, there are few tools or sensors that can directly assist or assess socket fitment. Existing diagnostic tools focus on quantifying interface pressures, or generalized forces. These tools do not provide the kinematic information to describe the soft tissue motion occurring at the interface that can be detrimental to overall socket performance. The additional information of bone movement within the socket during the fitment process would give insight into the efficiency of limb loading and bone controllability.

There has been a number of attempts to measure the bone motion inside prosthetic sockets. Researchers have used a Roentgenological technique to look inside the socket in static

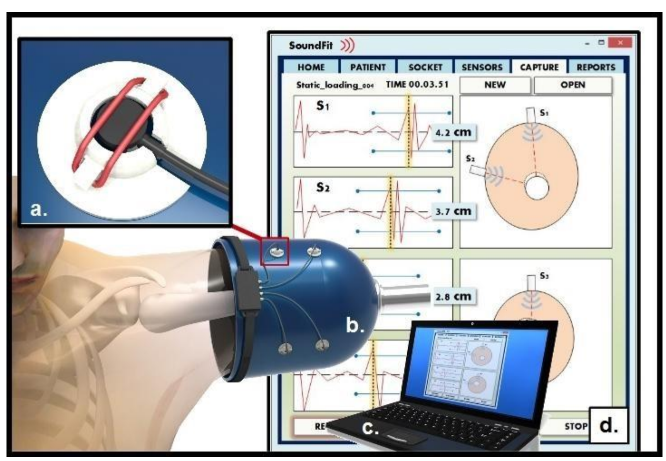


Fig. 1. The device concept is shown with (a) ultrasound transducer attachment clips, (b) a wireless four-channel sensor module configured for a check socket during socket fitting, (c) wireless laptop for data recording, and (d) custom application software.

positions [1][2]; other authors used Dynamic Roentgen Stereogrammetry [3], CT scanner [4], and X-ray technology [5][6][7]. Convey and Murray had used a B-mode ultrasound method to get the motion of a residual femur within a transfemoral socket by observing planar images of the residuum [8]. The main disadvantages of these methods are that they are difficult to setup and are too expensive to be a realistic diagnostics option for most of the rehabilitation and prosthetic facilities and many researchers as well. Also, radiation exposure is hazardous to the health of the patients/subjects.

A-mode (amplitude mode) ultrasound has been widely used and is safe in the medical field below prescribed power levels [9]. In this method, single or dual crystal ultrasound transducers are used to send and receive high-frequency sound waves through soft tissue, recording the time difference between the initial pulse and echoes off of subdermal acoustic impedance discontinuities. A one-dimensional distance is obtained based on time of flight calculations. One such application of A-mode ultrasound is non-invasive diagnosis and registration in surgery [10][11]. Amstutz et al. used A-mode ultrasound for non-invasive registration of the head in computer-aided surgery of the skull. Results on the 12 A-mode ultrasound matchings in the patient study had an error of 0.49 ± 0.20 mm [10]. Moustris el al. chose an A-mode ultrasound transducer to register phantom-sawbones of the tibia, femur, and cadaveric specimens for robotic orthopaedic knee surgery. The results showed root mean square errors less than 0.5 mm for calibration, less than 1.0 mm for phantom-sawbones, and less than 2.0 mm for cadaveric specimens [11].

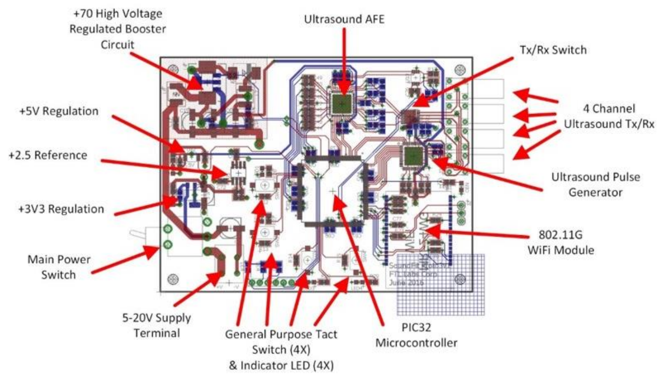
The concept presented in this paper utilizes four A-mode ultrasound transducers attached to the prosthetic socket at orthogonal locations. With multiple sensors monitoring ultrasound echoes, generalized movements of the residual bone within the socket can be calculated. It is intended that this distance information can be used to reconstruct bone motion during the fitment process. It allows one to monitor directly the effects of socket adjustments on bone control. In the remainder of this paper, we present an overview of the hardware design, a preliminary evaluation, and results of a single channel system.

II. Materials and Methods

The device hardware, called SoundFit, consists of a four-channel A-mode ultrasound system, used to measure up to four distances between the bone and prosthesis socket. When sensors are placed at orthogonal locations at the distal and proximal ends of the socket, bone motion relative to the socket can be calculated. In this study, a single-channel of the system is demonstrated in a cross-platform validation on a healthy subject with intact limbs. The single channel distance calculation is compared to a distance obtained from a commercial motion capture system for comparison.

A. Electronics Hardware

A custom four-layer printed circuit board (PCB) was designed to act as a fully embedded, wireless solution. The major components of the board consist of power regulation and distribution, logic control, four ultrasound Tx/Rx channels, and user interface components (Fig. 2).



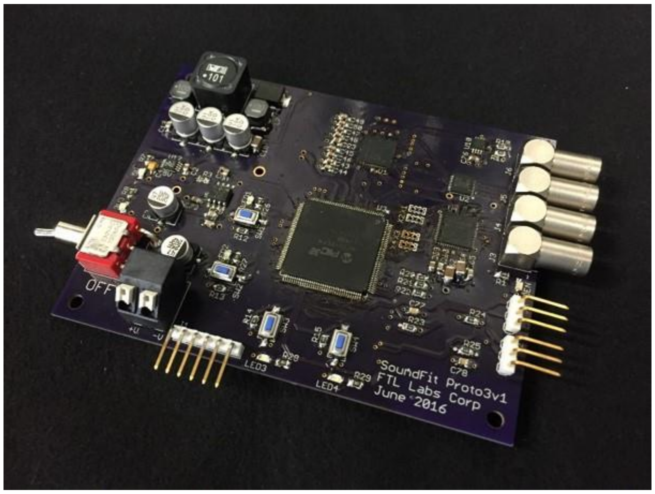


Fig. 2. Custom PCB architecture (top) and shown assembled (bottom).

The power regulation/distribution portion of the PCB is capable of running on a 5-20 V DC power supply. A benchtop power supply was used for testing purposes. However, the design allows for two 3.7 V lithium-ion batteries in series to be used. The supply is distributed to other board components regulated at 3.3 and 5.0 V with linear regulators and supplies a 2.5 V reference signal. The input voltage supplies a high voltage, low noise boost circuit which powers the ultrasound driver. The high voltage boost circuit is regulated with a closed loop controller. It uses the the onboard microprocessor to regulate to a software specified reference voltage between the input supply and 100 V DC.

Most ultrasound systems use field programmable gate arrays (FPGAs) for pulse generation and signal acquisition and conditioning in combination with a microprocessor for high-level logic. With increased performance of recent microcontrollers however, it was possible to eliminate FPGAs for this application, reducing the overall cost and complexity of the design. A microprocessor was used (PIC32MZ, Microchip Technology, Chandler, AZ) that implements a 32-bit architecture, runs at 200 MHz, implements four 6-bit analog to digital converters (ADCs) at

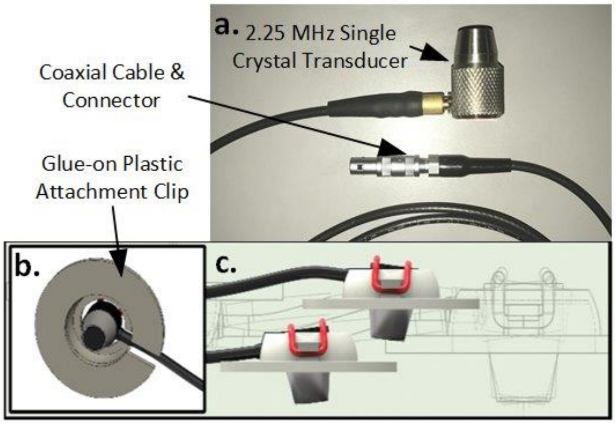


Fig. 3. (a) Ultrasound transducer; (b) Glue-on plastic attachment clip; (c) Transducer installation

9 MSPS simultaneous multichannel conversion/storage rate for this project, has 2048 kB flash memory and 512 kB RAM. The microprocessor is responsible for regulating the high voltage boost circuit, generating precision pulse timing, controlling all other integrated chips and voltage regulators, acquisition of ultrasound echoes and performing all logic and digital signal processing necessary.

The ultrasound circuit consists of three integrated chips. The ultrasound pulser (HV7350, Supertex Inc.) is an 8-channel, high speed, high voltage MOSFET driver, capable of sinking or sourcing ±60 V and ±1 A at frequencies up to 20 MHz. The system can be expanded to utilize all eight channels, but the current design only uses four. The driver outputs are directed to the ultrasound transducers as well as a high voltage protection Tx/Rx switch (MD0105, Microchip Technology), which separates the analog front end (AFE) from being damaged from high voltage spikes during the initial excitation Tx pulses. The Tx/Rx switch turns on and off maximally in 20 ns when a voltage of ±2.0 V is exceeded. The AFE (MAX2077, Maxim) is an 8-channel integrated chip that conditions the analog echo before being converted to digital. This IC acts as a low noise amplifier (LNA), a variable gain amplifier (VGA), an anti-aliasing filter (AAF), and is reprogrammable during operation.

To interface with the hardware, four programmable general-purpose buttons are used to select between operation modes, control gain, control pulse voltage, and connect to a wireless network. There are three LEDs indicating 3.3 V power, 5 V power, and if the driver is active. Four other general purpose LEDs are available for various indications, and a USART serial port is used for PC terminal communication. Wireless communication is achieved using a WiFi module (MRF24WG, Microchip Technology), with the Microchip TCP/IP software stack installed on the PIC32 microprocessor. A PC GUI is currently in development using the Unity gaming engine (Unity Technologies, San Francisco, CA) for more advanced interaction with the hardware.

B. *Ultrasound Transducer*

Ultrasound diagnostic tools used in medical imaging applications use piezoelectric transducers that have a resonance frequency of 1-20 MHz, with a more specific value depending on hardware signal sampling capability and desired resolution. Since maximum multichannel sample rate is 9 MSPS, commercial 2.25 MHz transducers were chosen (Dakota Ultrasonics, Scott Valley, CA) in order to guarantee that the waveform would be captured after the ADC process (Fig. 3a). A transducer is connected to each channel on the PCB via a coaxial cable and RF connectors having a total impedance of $50\,\Omega$. The transducers are attached to the test socket with attachment clips (Fig. 3b) 3D printed with using a FORMIGA P110 (EOS). The transducers protrude through a 12.7 mm hole in the test socket, allowing direct contact between the transducer and patient dermis. The attachment clips are designed to provide an easy way for the prosthetist to add the ultrasound sensor to the socket and steer the field of view of the sensor towards the bone to achieve a strong return echo, and then lock the transducer into the frame of the socket (Fig. 3c). This ensures that measured bone-socket motion does not include any uncertainty or creep in the mounting system. It should be noted that optimizing the angle of transducers results in a stronger signal and larger echo amplitude, but does not change the accuracy of the distance calculation.

C. *System Operation*

During normal operation, a finite state controller sequentially pulses and listens to each channel individually in 1 ms intervals, in order to avoid echo crosstalk. The pulses have 50 V amplitudes and 440 ns wavelengths, corresponding to the transducer resonant frequency of 2.25 MHz. After three precision timed pulses on a single channel, the Microcontroller samples the return echo, which has been conditioned and amplified by the AFE, over a 100 µs window. As each sample is available, it is stored in a data buffer with direct memory access (DMA). After the 100 us window, there are approximately 900 µs to process the data before the next channel pulse/listen sequence is triggered. During this time, the data array is swept with a moving average difference filter, where the local average is subtracted from single data point in order to remove ring-

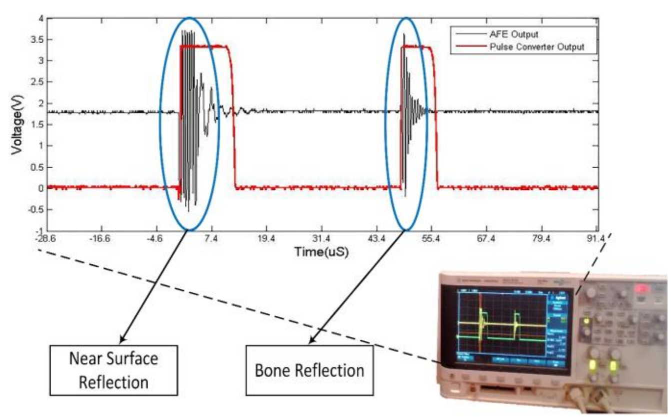


Fig. 4: Reflection signal and output signal from pulse converter.

down drift and offset from the data. A search algorithm then finds the maximum echo magnitude signifying the largest acoustic impedance mismatch (soft tissue to bone) and marks the corresponding data point (Fig. 4). The algorithm then saves the total number of data points taken in the 100 μs window to a variable. The actual sampling frequency is then calculated. Using the recorded sample number of the data point having peak magnitude, and calculated sample frequency, the propagation delay *t* is calculated. The distance *x* is then calculated as

$$x = \frac{1}{2} vt \tag{1}$$

where *x* is distance, and *v* is the propagation speed of the sound. The average propagation speed of sound in soft tissue is 1540 m/s [12]. The sequential pulse/listen pattern across all transducers is repeated at 60 Hz.

D. Experimental Protocol

In this experiment, the distance measurement accuracy of a single channel is evaluated by comparison to a commercial 11 camera Qualisys Oqus 3-Series optical motion capture system (Qualisys Inc., Göteborg, Sweden) on an intact upper limb with a pseudo-socket cuff representing the test socket. Human subject testing approval was received through the University of Massachusetts Amherst Institutional Review Board. The test subject is a 27 year-old male, 58 kg mass, 1.67 m height, and testing took place in the Biomechanics Laboratory in the Kinesiology Department at the University of Massachusetts Amherst.

The arm cuff is placed on the subject's right upper arm segment, and a single transducer is attached with mounting clips in the center of the cuff to measure the linear relative motion of the humerus and cuff (Fig. 5). The angle of the transducer is adjusted while watching the return echo on an oscilloscope to maximize the echo signal. Reflective markers were placed on anatomical landmarks of the shoulder and elbow and also placed on the cuff. During data recording, the cuff was loaded manually to produce relative movement between the cuff and the bone, simulating the movement of residual limb inside of a test socket. Three trials were performed. Linear distances were recorded with the ultrasound-based system through a custom MATLAB interface (Mathworks), and marker coordinates were recorded at 240Hz. During post processing, the distance data was smoothed with a moving average filter, and the relative linear motion of the humerus and cuff was calculated with inverse kinematics methods using OpenSim [13].

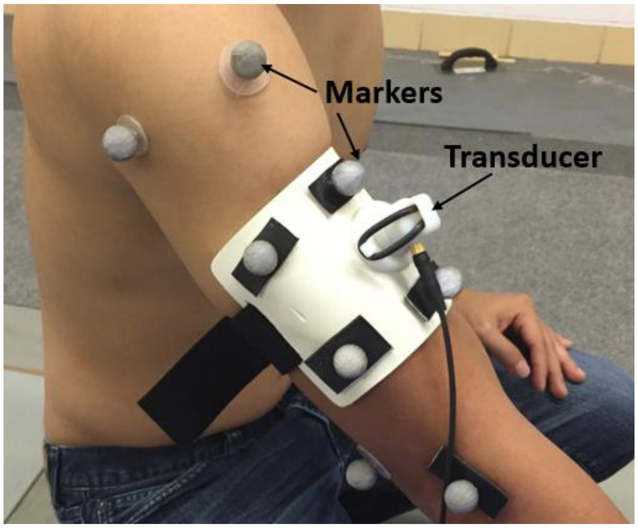


Fig. 5. Experimental setup for motion capture. Markers are placed on the cuff and subject's arm to get displacement between the cuff and the humerus.

III. Results and Discussion

A. Results

Fig. 6 shows displacements of the cuff relative to the bone for three trials. The results of ultrasound system data and motion capture data were shifted in the time axis by a constant for data synchronizing. Raw data obtained via ultrasound (Fig. 6 – "SoundFit Raw") contained small noise; therefore was smoothed with a moving average filter (Fig. 6 – "SoundFit Filtered") before comparing with data from motion capture (Fig. 6 – "MoCap IK"). When no load applied to the cuff, the displacement was zero. When the cuff was loaded, the cuff moved closer to the bone, which resulted in a displacement of up to 6 mm. The device distances were plotted against the motion capture data in Fig. 7. The results show the accuracy for three trials with a root mean square deviation (RMSD) of 0.36 mm.

B. Discussion

The test results show the accuracy for all three trials with the RMSD of 0.36 mm (Fig. 7). This error is compatible with other works using ultrasound based systems for measuring the distance to the bone through tissue [10][11]. During the experiment, the cuff was loaded manually, and ultrasound system was able to obtain consistent data across all three trials. The deviations are also consistent over the displacement (Fig. 7). The motion capture approach has been used for measuring residual limb - socket movements in the literature [14][15]. Different from these works, in our testing, markers can be placed at both above and below of the pseudo-socket cuff on the intact limb. As a result, the movement of bone relative to the cuff is obtained by the motion capture system in a wearable system with high accuracy. However, motion artifacts are still present. It is reasonable to assume that with a more direct validation of true bone motion, a higher degree of accuracy may be measured.

In this experiment, a single channel was used to obtain the distance to the bone in one axis. In the next phase, four transducers will be used as shown in Fig. 8 to capture the movement of the bone relative to the socket. The position of bone (e.g. rotation angle, translation) in three-dimensions can be obtained. This is done by considering the difference of the distances from the proximal and distal sensors to

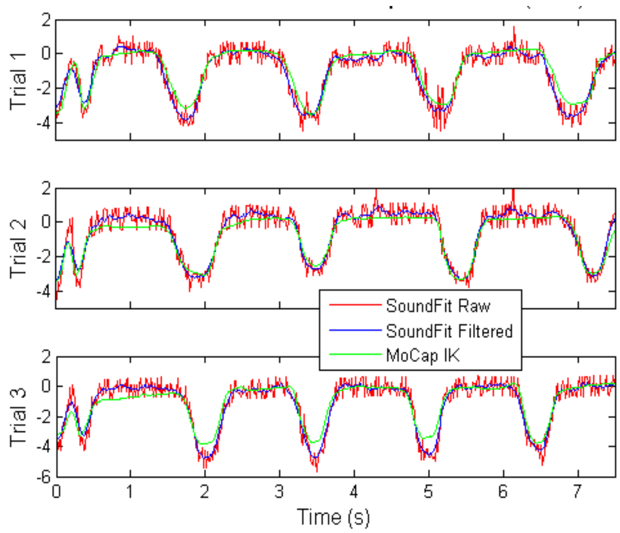


Fig. 6. Cuff displacement results obtained from ultrasound device (SoundFit Raw, SoundFit Filtered) and motion capture system. (MoCap IK).

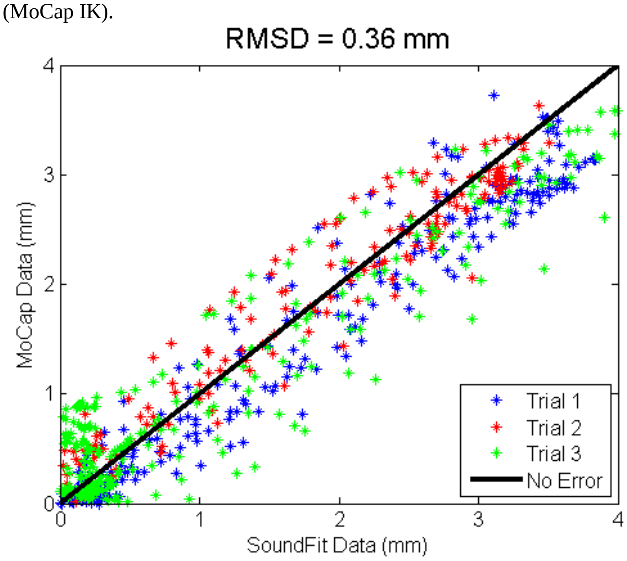


Fig. 7. Recorded distances are plotted against motion capture data to visualize accuracy. The calculated root mean square deviation is 0.36 mm.

calculate the angle of the bone relative to the axis perpendicular to the plane of the second sensor.

New socket designs are regularly being developed, but objectively comparing these designs to standard approaches is difficult. Additionally, many prosthetists prefer different socket styles and liner thicknesses for different patient populations. Aggressive socket styles such as the compression-release stabilization sockets are reported to provide a superior fit [16], but are more difficult for a prosthetist to fit. Therefore, a tool for systematically quantifiable socket fit would assist in both the fitting process and socket type evaluation. The described ultrasound based system with the ability to measure the bone movement within socket can be applied to both fitting process and socket type evaluation. Furthermore, using ultrasound has advantages over other methods with the ease of setup and use and low cost. The system could have broad potential uses for other application areas such as orthotic and exoskeleton interface design, and biomechanics research.

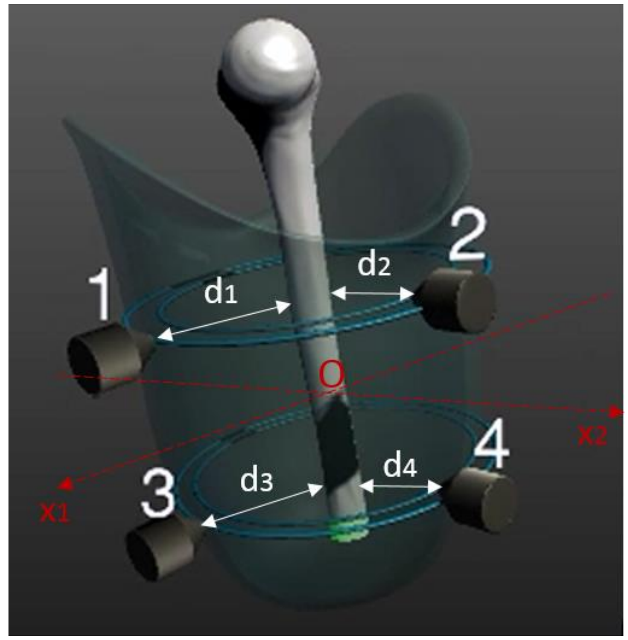


Fig. 8. Calculation of bone position inside sockets. Distances d_1 and d_3 give the translation relative to sensors 1 and 3, and the rotational angle of the bone about Ox_2 axis. Similar holds with d_2 and d_4.

IV. Conclusion

In this study, an ultrasound based system for monitoring bone movements within a prosthetic socket was developed. An experiment with a subject for testing and validating the system was conducted. The results showed high accuracy of the system with a measured RMSD of 0.36 mm. This approach is a promising option for measuring intra-socket bone movements that can be used in the socket fitting process.

Acknowledgment

This project is supported by the Defense Advanced Research Projects Agency (D16PC0092) and National Institute on Disabilities, Independent Living and Rehabilitation Research (90BI0033-01-00).

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