Rationale

Pressure ulcers continue to be a common complication and costly clinical problem. Interface pressure distributions between the buttocks and seat support surfaces are used clinically to evaluate the efficacy of seat cushions relative to the risk of pressure ulcer development. Soft tissue deformation, resulting in internal strain, is potentially a superior indicator of pressure ulcer risk, however, limitations of current clinical assessment technology render tissue deformation measurements inaccessible in the clinic. As an alternative, interface pressure, a parameter that is clinically accessible, is used as an indicator for potentially harmful internal stresses and strains. This task was designed to provide additional support to a research effort (Paralyzed Veterans of America, Spinal Cord Research Foundation, PVA #1503) to develop an ultrasound system that may be used to study in vivo soft tissue response to external loading on the weight-bearing human buttocks during seating, and, therefore, a means to determine how external loading contributes to the risk of pressure ulcer development. Results from the work will also produce valuable information concerning the efficacy of using external pressure as an indicator for harmful internal strain in soft tissues—muscle, skin and fat.

Goals

1. Design, develop and evaluate an ultrasonic transducer that will be compatible with the computer controlled seating system (CASS) and useful in evaluating soft tissue response to external loading in vivo
2. Design and evaluate a compound sensor containing pressure, force, and ultrasonic transducers
3. Develop and evaluate of a multi-channel ultrasound system to allow for data collection from and control of the ultrasonic transducers
4. Integrate ultrasound system and force measurement system into the CASS
5. Develop and evaluate software tools necessary for control of new system
6. Perform pilot and clinical evaluations to test system performance and efficacy

Outcome Summary

A unique ultrasound-seating system for soft tissue characterization has been developed at the University of Pittsburgh based on the CASS system developed by Brienza et al. [Brienza et al., 1996]. Ultrasonic detection has been combined with the closed-loop, dynamically controlled shape and pressure sensing system. This allows quantification of the complex relationships between shape, tissue deformation and interface pressure under controlled loading conditions. This system contains an 11 by 12 array of sensors for which the height can be computer adjusted to vary loading conditions and surface shape in 3-dimensions. Ultrasonic and force transducers have been integrated into 9 of the support element heads to form a 3 by 3 array so that we can also investigate soft tissue deformation around the ischial tuberosities.

Sensor Configuration

Specifications for the sensor to be developed required that external loading and tissue deformation information be measured simultaneously. However, the sensor also had to meet the limitations due to the geometrical structure of the CASS, especially the ultrasonic transducers. One of the first steps of the project was to determine the configuration of the sensor. Initially, two sensor configurations were
One design allowed the measuring point of the pressure transducer to coincide with that of the ultrasonic transducers. An alternate configuration was chosen and is shown in Figure 32. The chosen configuration consists of a pressure sensor centrally located in the swiveling head of an actuator element, surrounded by four planar ultrasound transducers. This design was chosen over others using custom ultrasonic transducer configurations because of the need to design a less expensive sensor using an established technology with well-defined parameters. The overall size of the sensor is 33.7 mm in diameter by 7.2 mm high. Each ultrasonic transducer has as 5 mm diameter and a height of 7.2 mm. The pressure transducer had previously been evaluated [Brienza et al., 1996]. The sensor can detect pressure from 0 to 10 psi with 0.15% linearity and an ultrasonic echo from 5 to 50 mm depth with an axial resolution exceeding 0.5 mm.

An analysis of the preliminary data and a review of the literature led us to a tissue model for use in characterizing the buttocks soft tissue. Our’s and other’s data suggests that it is necessary to model buttock soft tissue as a viscoelastic material. The model we chose to use is the quasi-linear viscoelastic (QLV) model defined by Fung [Fung, 1981]. This model required force-deformation data to characterize the tissue. Rather than using the pressure data to approximate the normal force applied to the tissue, we chose to measure it directly. Thus, we expanded the capability of the 9 support elements with the compound sensors to also measure force and tilt angle. Force is measured through bonded strain gages mounted on a load-bearing cantilever beam located in the actuator body. Vertical force applied to the sensor head is transmitted by a piston with a conical end that contacts the cantilever beam through a concentrated load at the tip. The head of the sensor is free to tilt and rotate on all support elements on the CASS to allow the sensor head to be normal to the tissue surface at all times. In order to determine normal force, a linear potentiometer was added to calculate the angle of tilt of the head. Figure 33 shows the compound sensor with force and angle sensing capabilities added.

Ultrasonic Transducer Specifications

The next step was the specification of an appropriate ultrasonic transducer for the sensor. Geometric constraints dictated that the diameter of the ultrasonic transducer had to be less than 5 mm, have a long cable to connect to the existing seating system, and have good acoustic and electric characteristics. For example, the transducer had to provide an acoustic impedance match between the transducer and soft tissue, and an electric impedance match between transducer and emitting/receiving amplifier. The transducer also needed to have high sensitivity, a broad frequency bandwidth, narrow pulse width, good axial resolution and low noise. Among these are two tradeoffs, that between the small size and high sensitivity, and the tradeoff...
between high emitting frequency with a long cable and low noise.

Etalon, Inc manufactured two prototype PZT ultrasonic transducers to our specifications. The pertinent performance measures of the transducers were quantified and the data indicated that the transducers would meet the basic use requirements. However, some parameters did not meet the design requirements; sensitivity, ring down, bandwidth and electrical impedance. These parameters affect the resolution and sensitivity of the system. Since these prototypes did not meet all our specifications, we contacted a second manufacturer, Furuno Diagnostics America, Inc. Furuno had recently commercialized a novel composite ultrasonic transducer using a 1-3 ceramic-polymer structure. We requested that they construct one of these composite transducers to meet our needs. Specifications determined for the ultrasonic transducer included a central frequency of 7.5 MHz, a frequency bandwidth more than 60%, pulse width less than 0.2 µs and sensitivity more than -22 dB. In addition, the coupling materials needed between the sensor and body soft tissue must be compatible with the pressure transducer. The composite transducer was compared with the two conventional PZT transducers. Table 1 summarizes the performance results of the transducers.

### Table 1. Sensor performance results

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Composite</th>
<th>PZT 1</th>
<th>PZT 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (dB)</td>
<td>-22</td>
<td>-31</td>
<td>-35</td>
</tr>
<tr>
<td>Bandwidth (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(-3 dB)</td>
<td>81.7</td>
<td>42.7</td>
<td>34.04</td>
</tr>
<tr>
<td>(-6 dB)</td>
<td>98.7</td>
<td>53.3</td>
<td>43.9</td>
</tr>
<tr>
<td>Central Frequency (MHz)</td>
<td>7.506</td>
<td>7.157</td>
<td>8.136</td>
</tr>
<tr>
<td>Pulse width ( )</td>
<td>0.165</td>
<td>0.23</td>
<td>0.295</td>
</tr>
<tr>
<td>Axial Resolution (mm)</td>
<td>0.3</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Cable Length (m)</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

The composite ultrasonic transducer, using 1-3 piezocomposite material was shown to have several advantages. Its sensitivity is 9-13 dB higher than the homogeneous PZT ceramic transducers. The bandwidth is wider by 39-47.7% and pulse width is reduced by more than 0.065 ms. The expanded bandwidth improves the near-zone ultrasound properties of the transducer. Thus, it improves the ability to identify soft tissues just beneath the subcutaneous skin layer, for example, connective and adipose tissue. In addition, the axial resolution was improved to 0.3 mm. Although the cable of the composite transducer was 3 m, its performance was much better than that of the conventional PZT transducers with a 2 m cable. The composite transducer has higher sensitivity, signal-to-noise ratio and resolution than the conventional PZT ultrasonic transducers.

### Multi-channel Data Acquisition and Control System Development

A 36-channel ultrasound system was integrated into CASS. The main computer, a Gateway 2000-64G Pentium Pro PC, sends control instructions using a serial port to a slave computer that controls the positions of the 11 by 12 sensor array using 8 axis step motor controller. The pressure signals from the sensor array are scanned into the main computer with 12 bit resolution by a data acquisition processor (Oregon micro systems, Model-DAP1200E). At the same time, the system triggers the ultrasound transducer to emit an ultrasound wave. The system also receives the ultrasonic echo from the soft tissue interface and sends it to the main computer. A 100 MHz high-speed data acquisition card (CompuScope 250) was used for digitizing the ultrasound echo signals with 8-bit resolution. Two CYDIO-96 digit I/O units are used to select the channel measured or controlled in the motor, pressure, and ultrasonic arrays. The software for motor control was developed using Turbo Pascal 7.0 for Windows 3.1 and other components are implemented in LabView 4.0 for Windows 95. The ultrasound system consists of a synchronizing signal generator, 36 ultrasound transducers, 36 emitting/receiving channels, Multiple analog complexer and pre-amplifier, dynamic compression amplifier, TGC control, a Compuscope 250-2M high speed data acquisition board, and the Gateway 2000-64G Pentium Pro PC.

The ultrasound system specifications included the following:

- Central frequency: 7.5 MHz
• Detecting range: 5 – 75 mm
• Emitting repeat frequency: 10 KHz
• Field scan repeat frequency: 278 Hz
• Bandwidth: > 75%
• Axial resolution: 0.3 mm
• Signal Noise Ratio (SNR): > 45 dB
• TGC compensation: 40 dB/80 dB (Option)
• Dynamic compression: 60 dB
• Digit sampling frequency: 25 / 50 / 100 MHz with 8 Bits resolution (option)
• Tracking precision: 0.030 / 0.0150 / 0.0075 mm (option)

System Software

The main program and all data collection software were implemented in LabView 4.0 for Windows 95. The motor control is resident on the slave computer and was developed using Turbo Pascal 7.0 for DOS. The thickness of each layer is obtained by tracking the ultrasound echo signal peaks reflected from the interfaces between different layers. Depending on the echoes that need to be monitored, several tracking windows can be used to measure the thickness of these soft tissue layers during loading/unloading. In the program, two echoes, from the fat-muscle and muscle-bone interfaces, are tracked simultaneously during loading.

In Vitro Testing

The composite ultrasonic transducer was used to scan a pelvis in vitro. The system used is shown in Figure 34. A cadaveric pelvis was submerged in a water tank with the composite transducer mounted onto a computer-controlled, 3-axis positioning mechanism. The transducer scanned the pelvis at 6.35 mm increments. The ultrasound echoes were sent to another computer, which then displayed a two-dimensional projection of the three-dimensional contour. The computer sampled the echoes with a 50 MHz sample frequency. Typical results are shown in Figure 35(a). The points in the figure are from the ultrasound scan. The ischial tuberosities were clearly identified. Figure 35(b) shows a typical echo from the pelvis. The effect from the trigger pulse is less than 1.5 mm.
Additional in vitro testing was performed on porcine tissue using a compound sensor integrated into the CASS. This testing was performed for the development and fine tuning of the signal analysis software and control algorithm. Figure 36 shows the experimental set up used for this in vitro testing. This software development continued through this evaluation and experimentation phase of the project. Interface pressure and tissue thickness data were successfully collected and repeatability was demonstrated. After some fine-tuning, the system was for in vivo data collection.

**Figure 36 - CASS system with integrated ultrasound system—In vitro test setup**

**In Vivo Testing**

In vivo tests began using able-bodied human subjects to finalize the development of the software and to begin to evaluate the in vivo performance of the sensor. The testing was performed with individuals seated on the CASS support surface. In the initial tests, the compound sensor determined by initial ultrasound scans to be directly beneath the ischial tuberosity (IT) was moved sequentially through three phases: indentation, recovery and hold. A typical result is shown in Figure 37. The subject was a 135 lb. female. Interface pressure and ultrasound echoes were scanned into the computer as the sensor moved. The total indentation was 6 mm. Thickness 1 of Figure 37 includes the combination of skin and subcutaneous fatty tissue. Thickness 2 is the deeper muscle layer. The total thickness is the distance from skin surface to bone.

The results in Figure 37 demonstrated that the system is capable of performing multiple parameter measurements simultaneously. The system also demonstrated good tracking capability, allowing measurement of the changes in tissue thickness as the tissue was compressed or during recovery. It also demonstrated the ability to measure multiple tissue layers simultaneously. In this data, we observed that the muscle tissue had a larger percent deformation than the first layer of tissue (first layer decreased 3.3%, the muscle layer decreased 19.2%). This indicates that the muscle layer over the IT deforms more than the skin and fat under uniaxial loading.

**Figure 37 - Results from initial in vivo testing**

After the integration of the force and tilt angle measurement capabilities, additional in vivo testing occurred, as well as data analysis. A 140 lb male subject was positioned on the CASS seating support surface, with special care taken to locate the ischial tuberosity (IT) directly above the 3 x 3 array of sensor probes equipped with ultrasound capabilities. The sensing probe directly beneath the IT was lowered away from the tissue until a zero pressure state was obtained. To conduct the stress-relaxation experiment, the probe was raised at a constant indentation rate (0.25 mm/sec), loading the tissue, to a maximum upward probe travel of 10 mm. The probe was held at its maximum indentation position for 50 sec, then lowered away at the same constant rate to the initial
starting position. During the entire load hold-recovery cycle, continuous force and bulk tissue thickness measures were collected. Time of flight of the ultrasound wave was used to determine tissue deformation-time history.

Force time history data was used to characterize soft tissue relaxation response according to the reduced relaxation function, $G(t)$, of the QLV model [Fung, 1981]. Relaxation parameters were approximated through curve fitting to experimental data. The force-time history data (Figure 38(a) from the load-indentation experiment was used to approximate relaxation parameters. A comparison of the $G(t)$ calculated from the QLV model vs. experimentally derived $G(t)$ is shown in Figure 38(b). The QLV reduced relaxation function appears to adequately model experimental results.

Examples of data from additional pilot testing are presented in Figures 39 and 40. Figure 39 shows the force-time and deformation-time history and Figure 40 shows a force-deformation curve for a second male subject. These results demonstrate that our system can be used to measure the biomechanical properties of buttock soft tissue in vivo and in situ.
The in vivo pilot testing also showed that acquiring and maintaining the ultrasound echoes was challenging and took time and proper positioning of the subject. The challenge was maintaining the ultrasound echoes during the dynamic load cycle. There are several variables affecting this, such as subject posture, loading range, test site on the buttocks, tissue deformation and the change in angle of the sensor head. We found that we needed to learn more from pilot tests before going forward with clinical trials.

In addition to the tissue thickness data, additional data on the mechanical response of tissue to external loading can be obtained using this system. This information can be used to investigate the biomechanical properties of the tissue and allow more accurate tissue characterization using existing tissue models.

**Recommended Future Research**

Given the development and refinement of the new above technology, clinical trials with various populations should follow. These studies should investigate the biomechanical properties of the buttock soft tissue and allow more accurate tissue characterization using existing tissue models. A project has been funded by the Department of Education to continue with the work begun by this project. The project will determine the relationships between the deformation of soft tissue and externally applied load to determine differentiating intrinsic soft tissue characteristics for spinal cord injured subjects with and without past pressure ulcer pathology. If successful at identifying differentiating characteristics, the project will result in the development of a tissue characterization based risk assessment tool for individuals with spinal cord injuries. An understanding of soft tissue biomechanics for stratified patient populations will also lead to improved clinical practice guidelines for the prevention of pressure ulcers through improved support surface design criteria.

**Publications**

Bertocci GE, Brienza DM, Karg PE, Wang J. In vivo test protocol to determine soft buttock tissue relaxation properties Accepted for publication *ASME 1999 Summer Bioengineering Conference Proceedings*, Big Sky, Montana, June 16-20, 1999


**References**