BME Design

Mid-semester Report

TI Project: Acoustoelastic Evaluation of Tissue Damage using DSP

By:

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Introduction

Ultrasound has become a widespread imaging technique since its invention. Indeed, there are a number of reasons for this – the technique is non-invasive and can be used to find many abnormalities so that proper treatment may be administered at a proper time. Currently, there is no evidence that ultrasound imaging has side effects (Radiological Society of North America website). There is an important issue in ultrasound imaging that limits its usefulness, however. It is that ultrasound only provides qualitative data in the form of images, but no numerical data. Thus, interpretations of current ultrasound images are based purely on the individual physician's judgment. This makes the diagnosis less reliable. Only materials with significantly different stiffness, or pathologies that cause stiffness to change significantly, can be diagnosed.

Research has been done and a possible solution to both of these limitations has been proposed by Dr. Vanderby and Dr. Kobayashi. They have created an algorithm that analyzes the changes in tissue stiffness as it is stretched. The algorithm provides increased contrast compared to traditional analyses that use only a single measure of stiffness. Thus, the reliability of diagnoses and the range of diagnosable pathologies are increased.

Currently, the algorithm is run on a computer and only stored images can be analyzed. Also, the analysis takes a significant amount of time to run. We propose using a Digital Signal Processing (DSP) chip to enable data processing in real or near real time. This addition would not only increase speed but add new capabilities. It will be possible to take data in a clinical setting, verify its quality, and allow the user of the device to have immediate feedback on the gathered data. Indeed, this step is necessary for the device to be used in diagnosis.

Background and Motivation

Ultrasound and Acoustoelasticity

Ultrasound imaging operates by sending out a pulse of sound and then "listening" for the echo. Tissues in the body absorb and reflect these sound waves, which the ultrasound then interprets by recording properties of the returning sound wave such as amplitude, frequency, and time delay. Such a device provides excellent qualitative data; for instance, the picture that is produced can be used to look at a developing fetus, look for a tumor, etc. However, since this is qualitative data, the actual usefulness of the obtained information is mostly determined by the skill of the physician operating the ultrasound machine. Indeed, even this is limited as an ultrasound picture can only reveal basic structure. Studies done on ultrasound technology show that it is possible to obtain quantitative as well as qualitative data (Research of Dr. Vanderby and Dr. Kobayashi).

To obtain quantitative data, a property called acoustoelasticity will be used (Research of Dr. Vanderby and Dr. Kobayashi). This property is based on the idea that as a material is stretched, it becomes stiffer. As it becomes stiffer, the pitch at which it vibrates becomes higher. Indeed, this is not such a surprising idea as this is observed regularly with stringed instruments. As the strings are pulled tighter, the pitch that they will vibrate at becomes higher. When

applying this principle to the idea of an ultrasound, think of the initial pulse of sound waves as the "plucking" of the string. The stiffer the string, the higher the pitch of the returning echo.

Using this property, one can create useful quantitative data with an ultrasound machine. We will gather and compare the stiffness of a particular tissue with the strain (deformation normalized by original length) of that tissue. This relationship is not linear for all tissues, thus different relationship curves can differentiate different types and states of tissues. The calculated data can be compared against previously gathered "normal" data, and any large deviation from the previously defined normal is most likely the sign of a serious problem.

Client Setup

Currently, ultrasound machines gather enough data for this to be done, and our clients are able to carry out the necessary tasks to gather this stiffness vs. strain data through a rather lengthy process. This current procedure is as follows:

1. The client collects the necessary ultrasound data in a clinical or laboratory setting and stores this data on a computer's hard drive.

2. A two-part algorithm is run on the set of ultrasound images to collect the necessary stiffness vs. strain data. The first part places a border around a user-selected area of interest, and the second part creates the stress vs. strain overlay for this area (see Figure 1 and Figure 2). Unfortunately, these algorithms need to be executed separately and once for every image that must be analyzed.
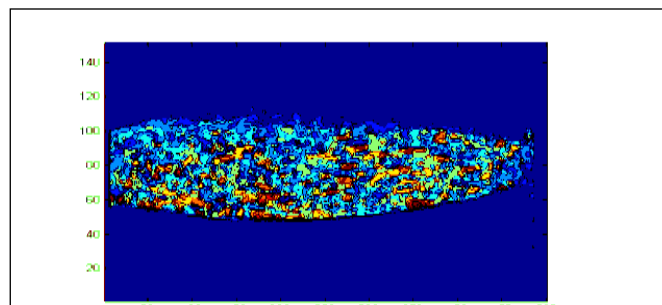

Figure 1. Clipping algorithm output.

Figure 2. Stiffness vs. Strain algorithm output.

One can easily see that this process could become quite lengthy for large amounts of data. Another disadvantage is that the actual data processing must be done away from the laboratory or clinical setting; thus, if the necessary data was not gathered correctly, our client must now go through the inconvenient process of going back to the laboratory and completely redoing the experiment.

To solve this problem, we will produce a device that can act as a "middle-man" between the ultrasound and computer in order to process data in real-time. This stream of data would then be stored and displayed on a computer. This device will not only speed up the process of creating

the stiffness vs. strain overlay but will allow the user to have feedback during the course of the experiment or examination.

Goals

The ultimate goal of this project is to create a surgical or diagnostic device that measures and displays the distribution of stiffness vs. strain in the body in real time. This will be done in two stages. First, we will create a device capable of measuring stiffness vs. strain from ultrasound images. The focus at this stage is accuracy in previously recorded images. The second stage involves optimizing the device for real time use in clinical, laboratory, and surgical settings.

In the first stage, stored ultrasound video will be analyzed from a hard disk and then returned to the computer. The algorithm will be optimized for speed and implementation on a real time processor. In the second stage the device will interface directly with the ultrasound device, outputting the distribution of stiffness vs. strain (Figure 3).
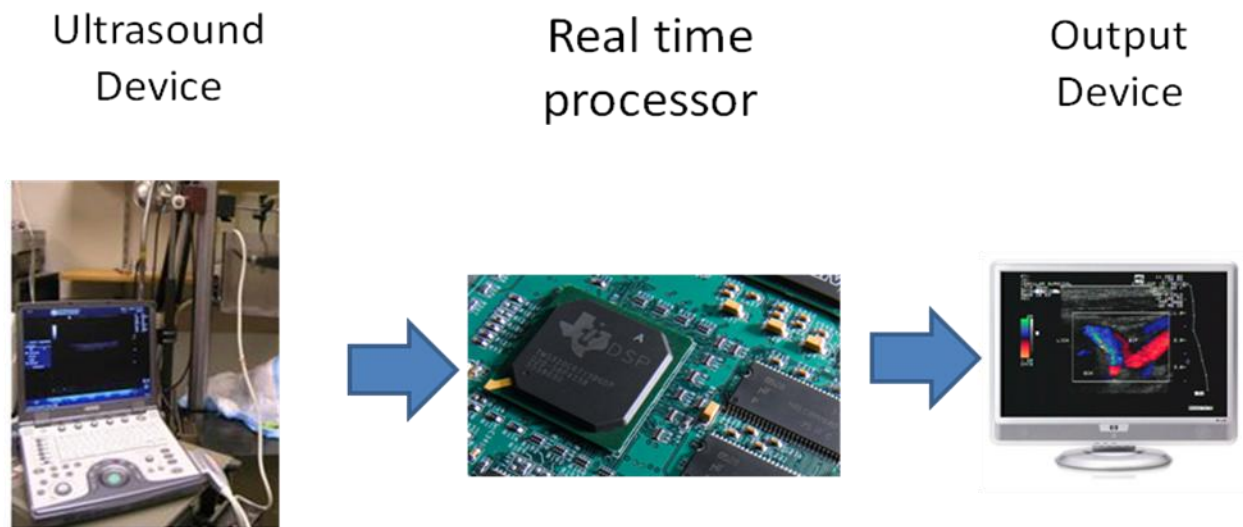

Figure 3. Schematic of device implementation. The ultrasound device sends out a video stream that is manipulated by the real-time processor, whose output is then stored and displayed.

For just this semester, we plan on completing the aforementioned first stage (perfecting and combining the algorithms into one, smooth-running program). The chief aspect of this stage would be implementing the algorithms on a real time processor. They will analyze stored data consisting of .avi files (a type of video file) and will be judged based on the speed and accuracy of the stiffness vs. strain calculation.

Why DSP?

Electronically, an image consists of a series of pixels, which are stored as numbers representing either the pixel's shade of grey or its mix of red, blue, and green. Image processing involves performing a series of relatively simple mathematical operations on each of those numbers. Thus, the speed of image processing relies not so much on its ability to perform complex operations as on its ability to quickly perform many iterations of relatively simple calculations.

Personal computers are not optimal for image processing because they are usually designed to manage data rather than perform simple mathematical calculations (Smith, ch. 28). The difference between data management and mathematical calculation is illustrated in the following figure:

Figure 4. Explanation of data manipulation and mathematical calculation; both of which are capabilities expected of typical processors.

An alternative to personal computer processors is a digital signal processor (DSP). DSPs are designed to perform relatively simple calculations quickly (Smith, ch. 28). They are optimized for speed, usually utilizing large amounts of parallel processing. To minimize their memory management requirements, they are often hardwired with separate memory components for their programs and data, and are designed to allow different units of the processor to access the processor's memory independently of the central processing unit (a feature called "direct memory access"). Unlike computers, DSPs do not include a memory management unit, and are, therefore, incapable of virtual memory (splicing fragmented pieces of physical memory together for a program to use). Thus, DSP chips spend less processing power on data management and are able to dedicate more to simple mathematical processing.

Unfortunately, though image processing involves relatively simple data manipulation, it can involve large amounts of reading and writing to memory, as images generally need to be stored in memory before they can be manipulated. Because DSPs are optimized for fast computing, memory reading and writing are more likely to slow down computations than slow processing power. Thus, to minimize delays, we decided to select the DSP with the highest available memory.

The highest available memory we could locate in a DSP was in the Texas Instruments' C6000™ High Performance DSP, which has 2112 KB of memory and a 1200 MHz processing power

(Texas Instruments, Inc. website). Fortunately, this was also the highest processing power we could find, so we did not have to trade processing power for memory.

Although the C6000 has an impressive memory compared with other DSPs, it is unlikely that its memory will be sufficient for the total range of image sizes it will need to process. Thus, we need to incorporate additional memory into the device. We still need to research available types of memory, so we have not selected which type we will use. The memory type will be selected based on the speed with which it can be written to and read and its compatibility with the DSP chip.

Software

As mentioned previously, a regular ultrasound image displays the distribution of stiffness within the imaging area. One tissue can be distinguished from another because their stiffness differs significantly. Also, the stiffness of a tissue is not an absolute quantity – it will increase if the tissue is stretched. In a given tissue, loads are not distributed in a perfectly even manner. However, the pattern of distribution may be a strong indicator of a pathology. If this difference from normal distribution is large enough, regular ultrasound can be used to diagnose the pathology. Osteoarthritis, for example, can be detected by multiple stiff (bony) insertions in the ligament. Unfortunately, for many pathologies the difference is small – for example a ligament that contains some torn fibers, which causes pain and may be prone to tearing further, would not be distinguishable from a normal ligament in a traditional ultrasound image.

Dr. Vanderby's and Dr. Kobayashi's algorithm uses another important property of organic materials. Ligaments, for example, unlike metals, do not have a linear increase in stiffness as they are stretched. Ligaments consist of folded fibers that unfold when stress is applied. Thus, their stiffness increases more slowly before the fibers are completely unfolded. Due to mechanisms such as this, every tissue has a unique pattern of stiffness change with strain. This means that tissues can be distinguished more easily using this algorithm than conventional ultrasound images alone. Likewise, when a pathology is present the tissue's pattern of stiffness change, with respect to strain, changes much more drastically than stiffness at one strain level alone.

For better speed, the stiffness versus strain algorithm will only be used on a region of interest in the images. First, a clipping algorithm will detect the edges of a tissue in the images and pass them to the stiffness versus strain algorithm. Then, the ultrasound image will be used as a stiffness map. Strain will be determined, and an image of stiffness divided by strain will then be produced. In these images, areas of the tissue that behave abnormally will be clearly visible.

Both, the clipping and the stiffness versus strain algorithms are being provided by the client. Details about how each operation is performed, especially the strain analysis, still need to be examined. A possible problem in the analysis is that the ligament changes in size and moves while a force is applied. To deal with more complex and realistic images, a motion tracking algorithm may need to be implemented in the future. The stiffness versus strain algorithm also raises a data storage question. While on chip memory will be enough to analyze a small number of images at a time, the data produced by the analysis will need to be stored. A possible solution

to this is the utilization of RAM memory, which is significantly faster than any conventional hard disk, for temporary data storage.

Conclusion

In a clinical setting, ultrasound imaging currently provides only qualitative anatomical data, but it has the potential to provide quantitative data, such as the response of tissues to stress. For this to be useful in a clinical setting, it ought to be done in real-time to allow the ultrasound operator to immediately see the tissue's response to different forces.

This semester, we plan to create a device to determine and display the stiffness vs. strain distribution of tendons and ligaments in a research setting using stored images. We plan to do this with a digital signal processor and a two-stage algorithm which isolates a user-selected area of interest and analyzes its stiffness vs. strain distribution, thus increasing the capabilities of ultrasound imaging. In the future, this device can be expanded for clinical applications to analyze images directly from an ultrasound machine in real-time.

Appendix A: Product Design Specifications

Date: September 17, 2008

Clients: Dr. Ray Vanderby, Dr. Hirohito Kobayashi, and Texas Instruments

Advisors: Dr. Tom Yen and Dr. Walter Block

Function: Texas Instruments (TI) is interested in finding applications in the medical field for their Digital Signal Processing Chips (DSP's). DSP's are able to collect information and process it in real-time, unlike other micro-processors. The guidelines for this project are that a TI DSP chip be used and that the final product solves a meaningful medical instrumentation or medical imaging design problem.

We have chosen to apply the DSP chip in the field of medical imaging, where it would function as a part of a portable ultrasound medical imaging system that would identify and analyze stress and injury in tissues on-the-fly. Though significant work can be done on such a project, we have decided on three goals that we would like our device to satisfy by the end of the semester:

1. Implement an algorithm that processes stiffness vs. strain in tissues using stored data
2. Optimize this algorithm for real-time or near-real-time processing

In the future, this device could be used for surgical or clinical diagnostic purposes. However, currently our client just requires a device that can quickly process this data for research purposes.

Client Requirements:

➢ **Device that processes data quickly:** We plan to provide this capability with a TI DSP Chip. Though the client does not explicitly require real-time processing, we feel that real-time or near-real-time processing should be used so that this device can have useful future applications. A TI C6000 High Performance DSP Chip will be used.

➢ **Appropriate programming language:** MATLAB will be the programming language that will be used. The reason for this is threefold:

1. The matrix manipulation capabilities of MATLAB will be very useful for the image processing that must be done.
2. The previous work done on the necessary algorithms by the client is already in MATLAB.
3. The design team and the clients are proficient in MATLAB.

➢ **Interface**

The interface should be relatively easy to use, as the clients have described themselves as very "low-tech guys." Currently, the interface is very straightforward as user input is limited to selecting the area of interest and specifying whether it is darker or lighter than the surrounding tissues.

Design Requirements: As this device will primarily be used by the client to process ultrasound data being used in research, the device design has only a few constraints. It must be able to effectively identify tissues and analyze their properties in real time, and it must have an effective interface that an expert in this field can easily use. The size of the device should be convenient and weigh less than 10 lb. In the future, it is possible that the device may be used for clinical diagnosis or as a surgical tool, so the detector end should not be damage by sterilization.

Physical and Operational Characteristics

a. Performance requirements: The ultimate goal of this device is to continuously process data in real-time and send the processed data to an output and storage device. It should be able to consistently identify tissues and analyze their strain. The device will initially be used for research purposes, perhaps once a day. The system needs to be portable - including a weight of less than 10 lb, a size smaller than 1 cubic foot, and should run, or have the capability to run, on battery power. Because the device may eventually be used in surgery or clinical diagnosis, the probe must not be damaged by sterilization.

b. Safety: Ultrasound imaging has no known negative effects. If the device is used in surgical settings, the probe must be sterilized between uses.

c. Accuracy and Reliability: The device must be able to identify tissues in ultrasound video images accurately and in real-time. It should be able to provide information about loading and damage of tissues. The techniques for the latter purpose are in the research stage, so final accuracy of the device is difficult to predict at this time.

d. Life in Service: Due to the nature of its use, the device does not experience much stress. Its lifetime, thus, should be fairly extensive, on the order of several years or more. It will most likely become obsolete before it wears out.

e. Shelf Life: To prevent damage, the device should be stored without batteries, at room temperature and at low humidity. Under these conditions, it should remain operational for over a decade.

f. Operating Environment: The device contains circuitry and plastics. It should not be exposed to very high or low temperatures, high humidity, strong magnetic fields, corrosive materials, or shock.

g. Ergonomics: Ultimate goal is to package DSP chip and ultrasound device into one working machine to be used by a physician.   Although the entire device will not be built this semester, it is beneficial to keep future packaging in mind in order to make it work well with the physician.

h. Size: Initially size is not a concern. Being compact is necessary as the final design stages are implemented.

i. Weight: Initially weight is not a concern. Being light is necessary as the final design stages are implemented and ready to use with the physician.

j. Materials: A DSP chip from Texas instruments, the appropriate ultrasound data, and a device for the DSP Chip to display and store the edited data on.

k. Aesthetics, Appearance, and Finish: This is not a concern for this semester, but eventually the device will be fitted into some type of case or box.

2. Production Characteristics

a. Quantity: Only one is currently needed for our clients. In the future, if the device is useful for research, clinical, or surgical applications, the quantity that will need to be produced is unknown.

b. Target Product Cost: This is not a concern as TI will be funding the project.

Miscellaneous Requirements

A. FDA Approval:
If the device is to be used for more than just research purposes, then FDA approval will be necessary. The FDA defines a medical device as "an instrument... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals" (FDA, 2002). The device will be classified as an Ultrasonic pulsed echo imaging system, as described below (FDA, 2008):

> PART 892 -- RADIOLOGY DEVICES
> Subpart B--Diagnostic Devices
> Sec. 892.1560 Ultrasonic pulsed echo imaging system.
>
> (a)Identification. An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
>
> (b)Classification. Class II.

The device will not need full FDA approval while it is being clinically tested. It will, however, be subject to the Clinical Trials & Investigational Device Exemption, which requires the following (Quoted from FDA, 2003):

- An IDE approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA.
- Informed consent from all patients,
- Labeling for investigational use only,

- Monitoring of the study, and
- Required records and reports.

B. Customer:

We have two clients, whose expectations are as follows:

- Texas Instruments has agreed to donate "all resources necessary to develop new applications including hardware and software development tools," including a DSP developer's kit, supporting hardware, and consultation with their engineers. In exchange, they expect that their resources will be used to solve "a meaningful medical instrumentation or medical imaging design problem" (BME, 2008)
- Dr. Vanderby and Dr. Kobayahsi are overseeing this ultrasound project. They expect a device that can work in conjunction with a computer to quickly process stored ultrasound data to be developed by the end of the semester. In the future, they expect this device to be able to process the ultrasound data in real-time and to interface with a computer only for data storage and display purposes.

C. Research and Patient-related Concerns:

Sterility
The device will need to be sterilized between uses if used for anything beyond medical research. Due to the sensitivity of the device's electronics to heat, it will probably be sterilized by chemical means.

Privacy
Clinical testing of the device will involve storage of patent data. This data will need to be stored securely, to protect the privacy of research participants.

D. Competition

To our knowledge and to the knowledge of our client, no device which measures and displays the stiffness vs. strain distribution in a tissues in real-time exists.

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Figures 1 and 2
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Figure 3
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