

Cavitation Studies of Lumbar Zygapophysial Joints using Vibration Measurements

by

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Abstract

The purpose of this research project was to locate the level of cavitation in zygapophysial (Z) joints in the lumbar spine (L1/L2-L5/S1) and the sacroiliac joints (SIJs) during side-posture positioning and spinal manipulative therapy (SMT).

Forty healthy subjects were sought to complete this study, in which seven 1cm³ accelerometers were placed on the L1-L5 spinous processes (SPs) and the S1 and S2 sacral tubercles. Two more accelerometers were placed lateral to the midline, one 3 cm to the left and the other 3cm to the right mid-distance between the L4 and L5 accelerometers. Subjects were randomized into one of the two groups: Group 1, SMT Group (n=30) or Group 2, Side Posture Positioning Group (n=10). Data from the accelerometers was collected from both groups.

Two types of reliability studies were performed: one, comparing the results of two observers (blinded to the results of one another) in identifying vertebral level of cavitations and the other, comparing presence of a cavitation found by clinician, subjects and accelerometers.

Artifacts (noise signals other than cavitation) were identified, described and categorized as Flexible Spine (or loose superficial fascia), Hyper-Muscular Subjects, Resisting or Not Relaxed Subjects, Unstable Hand Contact (UHC) and Miscellaneous, depending on notes taken during data acquisition, assessment, and the unique pattern of waveform signals.

Vertebral levels of cavitations were identified and results were compared between: Group 1 vs. Group 2, targeted (L3/L4, L4/L5, and L5/S1) vs. non-targeted Z joints, left-side (up-side during side-posture positioning and SMT) vs. right-side.

Fifty-six (56) cavitations were recorded from 40 subjects. A reliability study comparing the results of two observers (blinded to the results of one another) to identify cavitations from the accelerometers recordings showed “almost perfect agreement” between the two observers ($Kappa = 0.841$, $Std E = 0.151$). The reliability study comparing presence of a cavitation found accelerometers recordings of cavitations were in “almost perfect agreement” with the subjects and clinician. The clinician and subjects were also in “almost perfect agreement”.

Subjects randomized into Group 1 cavitated more often (96.67% of Group 1 subjects) than those who were just held in side-posture positioning (30% of Group 2 subjects). Most cavitations were recorded on the left side (up-side 94.63%) and at the targeted Z joints (73.20%). Multiple cavitations were recorded from the same joint. Double cavitations were recorded in seven joints and, interestingly, four cavitations in one joint. A maximum of six cavitations were recorded from a subject randomized in Group 1, with four cavitations at the same joint (Left L3/L4) and two cavitations at another joint (Left L2/L3).

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1. INTRODUCTION

Therapeutic value of cavitation and gapping is discussed in this chapter along with the future scope of diagnostic methods. The review of literature in each section is arranged in chronological order.

1.1 Review of Literature

Zygapophysial (Z) Joint Gapping

Z joint gapping is explained as separation of the surfaces of a Z joint and has therapeutic value in the clinical studies. Janse (1976) explains that the chiropractic adjustment is an effective way of restoring motion to hypomobile vertebral and pelvic segments: *“If, to a segment held in partial articular fixation [Z joints], a quick deft thrust is applied, not sufficient in force to produce trauma but sufficient to break the fixation, there will result a definite tendency for the articular surfaces to find the normal relationship in full freedom of motion”*. Our research study was part of a larger study to determine the relationship between cavitation and Z joint gapping and its potential therapeutic benefits as discussed here. If a relationship is found between cavitation and gapping, then cavitation can be used to locate the specific Z joint gapped.

McFadden and Taylor (1990) performed a study on the effect of axially rotating the lumbar spine and gapping Z joints. Lumbosacral spines (L3-S2) were removed, along with all muscles and tissues, from 12 unfixed cadavers ranging in age from 14 to 75

years. They fixed one end of each spine while a weight and pulley system applied torque/twist to the opposite end. They concluded that lumbar motion segments are too stiff to undergo pure axial rotation in healthy spines, producing gapping only in the Z joints of spines showing significant pathology with degenerative changes. Healthy subjects were sought for our research study as they can be helpful to see if Z joint gapping takes place when followed by spinal manipulative therapy (SMT).

Cramer et al., (2000; 2002) performed two studies to test if lumbar side-posture SMT produces gapping in Z joints. Volunteers were randomized into 4 different groups: Group 1, (neutral position, followed by side-posture positioning); Group 2 (neutral position, followed by side posture spinal adjusting on left side, followed by neutral position); Group 3 (neutral position, followed by side posture spinal adjusting on the left side, followed by side posture positioning) and Group 4 (neutral position followed by neutral position). First, a magnetic resonance imaging (MRI) scan was taken in neutral position, followed by a second scan either in neutral or side posture position, depending in which group the patient was randomized. MRI scans were taken of the L3-S1 region. Patients with side-posture adjusting produced more gapping than the control group or the side-posture positioning without spinal adjusting group. The left side, in particular produced the most gapping, as the patients underwent SMT of the left side. Similar methods were used in our study by first taking an MRI scan in neutral position followed by side-posture positioning to determine cavitation in Z joints followed by SMT or side-posture positioning.

Cavitation

Unsworth et al., (1971) conducted a study of cavitation in the metacarpophalangeal (MCP) joint. A machine was designed and built to apply loading on the MCP joint in 17 males. X-rays were taken during the loading before cavitation of the joint and simultaneously when cavitation was heard, the amount of load applied was recorded. A crescent shaped area of high contrast was seen in the space between the articular surfaces on X-rays for patients who produced cavitation and was absent from the X-rays of patients who did not produce cavitation. They concluded that low pressures develop in the synovial fluid during the separation of joints and caused gas to liberate and vaporize from the fluid. When these vapor-filled bubbles move into the higher pressure areas, instant collapse takes place with a very high energy release called cavitation. Theory behind cavitation and its effect on the MCP joint is discussed in this study and a similar theory could be applied to Z joint cavitation and gapping.

Meal and Scott (1986) performed a study to see if cavitation had therapeutic value, to see when the joint went into the paraphysiological space (the expanded range of motion following cavitation) and to understand when the sound is produced in relation to separation of the joint surfaces. They used a method of simultaneously recording the sound produced by the joint while measuring the tension across the MCP joint. A cubicle was used to isolate extraneous sounds from the actual MCP joint sound. An ultraviolet recorder was used instead of a pen recorder for greater accuracy, wider choice and broader range of speed. A tension transducer was positioned directly on the joint using adhesive tape. The experiments showed that the cavitation played an important role as an indicator that the MCP joint had separated and moved into the paraphysiological space.

Joint cavitation was seen on oscilloscope recordings as a double sound wave, with the majority of joint surface separation occurring between the two sound waves. Sound recordings have been used to observe cavitation following gapping in the MCP joint and can be used to determine cavitation in Z joints and SIJs.

Brodeur (1995) reviewed the literature on cavitation associated with SMT. While previous studies had concluded that cavitation occurred during SMT as joints separated suddenly, the mechanisms behind this separation remained unclear. Brodeur's review led him to propose that cavitation occurs by elastic recoil of the synovial capsule. This recoil in Z joints initiates beneficial neurological reflex actions (decreased pain and muscle relaxation). Therefore, if cavitation was required for the recoil of the synovial capsule that led to its reflex actions, cavitation would be essential to the therapeutic benefit of joint manipulation. Consequently, studying cavitation in Z joints and SIJ is important in understanding the therapeutic value of gapping.

Reggars and Pollard (1995) conducted a study to record cavitation using microphones in the cervical region. They placed a microphone on the left and right side of the neck immediately in front of (anterior) the transverse process of C2. Interestingly, in 94% of the subjects, the cavitation was recorded on the same side as head and neck rotation (i.e., head and neck rotated to the right was associated with cavitation on the right). They were unable to identify the segmental (vertebral) level of cavitation, since only two microphones were used. Our study could determine if higher percentages of cavitations occur in the same side in which force is applied during SMT or side-posture positioning. Reggars and Pollard's research is discussed further as microphones were an important part of recording cavitation.

Beffa and Mathews (2004) conducted a study to locate cavitation sounds during “L5 spinous hook” and lower SIJ SMT. Eight microphones were taped to the subject’s back at respective Z joints using adhesive tape, and their locations were confirmed by taking a radiographic image. After SMT Fast Fourier Transformation (FFT) analysis was done, the maximum amplitude of each microphone was identified to determine the location of cavitation. No correlation was found to exist between the anatomical location of cavitation sounds and the respective technique used for SMT. New accelerometry techniques used in our study could be used for locating level of cavitation to help develop methods to improve SMT techniques. Beffa and Mathews’ research is included in the microphone section of this chapter because microphones were important part of their study.

Ross et al., (2004) used accelerometers to determine if cavitation occurs at the targeted joints following SMT. They used three accelerometers (same as used in our study) positioned at the twelfth thoracic (T12), third lumbar (L3), and first sacral segments (S1). While the patient was lying in the side-posture position, they measured the distance between the accelerometers. Since they found that the velocity of vibration waves from cavitations traveled through the body at 1400m/sec, to get distance discrimination of 0.5cm the sampling rate was set to 320,000Hz. A grease pencil marked the targeted area where a cavitation was supposed to occur. Therefore, the location of each cavitation was determined from the distances above or below each accelerometer based on the time of the accelerometers’ response. The side where cavitations occurred (left or right) could not be determined, however this study helped us in determining the sampling rate of data acquisition from accelerometers and deciding additional

accelerometers on the left and right side of the spine to determine on which side the cavitation occurred. Our study will help in finding cavitation at specific lumbar Z joints or SIJs and also side (left or right) of cavitation. Ross's study is also included in the accelerometers section of this chapter, because accelerometers were an important part of this study.

Flynn et al., (2006) conducted a study to determine the relationship between cavitation associated with spinal manipulation and improvement in pain and functions of patients suffering from low back pain. For this study, 70 patients were randomly assigned to get physical therapy for a total of 5 sessions. Therapists recorded if they heard cavitations during high velocity thrust manipulation and outcomes were measured on an 11-point rating scale called the Oswestry Disability Questionnaire. They concluded that cavitation was heard in 84% of the patients and no difference was recorded in pain during baseline visits or any of the follow-up therapies related with the cavitation. Results also showed that cavitation may not relate to possible outcomes from spinal manipulation in terms of the improvement for patients with low back pain. This study used a specific technique for manipulation of SIJ that is very rarely used by clinicians.

Teodorczyk-Injeyan et al., (2006) performed a study to examine the effect of SMT on the in vitro production of proinflammatory cytokines (chemicals involved in producing inflammation) in relation to the systematic levels of neurotransmitter substance P. Sixty-four subjects were sought to complete this study. It was found that subjects who cavitated after SMT had reduced production of inflammatory cytokines as compared to the subjects in which no cavitation occurred after SMT. Cavitation has been associated

with positive outcomes and our study can be used to locate level of cavitation at lumbar Z joints and SIJs.

Teodorczyk-Injeyan et al., (2008) performed a study to determine changes in the production of the immunoregulatory cytokine interleukin 2 (IL-2) followed by SMT and determined changes that might differ with or without cavitation. Seventy-six asymptomatic subjects were sought to complete the study. It was concluded that in the presence or absence of cavitation followed by SMT there was increase in the presence of IL-2 synthesis compared with controls and hence it is important to study localization of cavitation.

Cramer et al., (2008) conducted a study to find out if the method proposed in this study was feasible or not. First, an MRI scan of the subject was taken in the neutral position to find out if there was any pathology in the subject and also to determine the accuracy with which high signal markers (filled with mineral oil) could be taped on the T12, L3 and S1 locations. This was used for accurate placement of the accelerometers as the high signal markers were easily identified on MRI. The markers also left a slight indentation on the subject's back. After this, the subject was held in the side-posture position with accelerometers placed at the desired location; the distance between each of the accelerometers was measured, and the subject was given SMT with the left side up. This system was capable of finding the location of cavitation but not the side of cavitation, because there were no accelerometers taped on the left and right side of the spine. Methods used in our study were similar to the methods discussed above, except the number of accelerometers used in our study was greater, which determined cavitations at targeted and non-targeted area. This study is also discussed in the "accelerometers"

section of this chapter, because of the importance of using accelerometers in locating cavitation in Z joints.

Accelerometers:

Nokes et al., (1984) recorded vibration response of bone from a skin mounted accelerometer; preloading of the accelerometers was done to overcome the damping effect from the interposed soft tissue. Measurements were taken on left legs of randomly chosen cadavers ranging in age from 68-75 years. Two accelerometers weighing 15g were used. One accelerometer was positioned on the skin, perpendicular to its surface, while the second was mounted adjacent to the first, directly on the bone by means of a pin that was screwed to its base and put through the skin of the left leg tibia. An impulse was applied by a 28g steel ball dropped from a constant height down a vertical Perspex tube. They concluded that excessive preload in accelerometers caused distortion of the recorded signal by a high frequency component. The required preload is proportional to the soft tissue thickness, but for any given soft tissue thickness, the range of allowable preload was fairly wide. Strong adhesive tape was used in our study to apply sufficient preload on accelerometers and help in keeping accelerometers in firm contact with skin.

Ross et al., (2004) performed a study as discussed earlier using three accelerometers to find location of cavitation followed by SMT. Accelerometers were an important part of the study and helped in locating cavitation some distance away from the accelerometers.

Cramer et al., (2008) conducted a feasibility study using three accelerometers to find out if the accelerometry methods proposed in our study was feasible or not. This

study was also discussed in the previous section because of its importance in locating cavitation, but not the side (left or right) of cavitation.

Microphone:

Heffez and Blaustein (1986) used modern sonographic techniques for recording and interpreting joint sounds from the temporomandibular joints (TMJ). They discussed modern sonographic techniques and presented preliminary observations on the wave patterns and power spectral analysis of TMJ sounds. They used a digital DSP-200 stethoscope and specially designed external auditory canal listening device for the purpose of auscultation and recording of the TMJ sounds, in a soundproof room. They found that TMJ sounds are a composite of sinusoidal waves. This method can be used to find unique pattern of waveform signals of cavitation as compared to noise signals in our study.

Gay et al., (1987) performed a study to record and analyze sound emitted from the left and right TMJs during simple motions for diagnosing disorder of the joint from a total of 79 patients. Sound was detected from each joint simultaneously using two separate vibration transducers (small conventional condenser microphones). They found three different categories of TMJ disorders: internal derangement, degenerative disease and extra capsular disorders depending on acoustic waveform pattern. They also found that amplitude (or changes in sound amplitude) might have a relation to the severity of the disease. However it was not possible to quantify this parameter because amplitude or changes in sound amplitude was affected by the impedance of the intervening tissue, the distance between the transducer and the joint, and the acoustical fit of the transducer at

the placement site. But one important thing was shown: that although the amplitude of the signal is conditioned by transmission line factors, the duration and the shape of the signal are not. Considering these factors, it will be difficult to estimate gapping depending on the amplitude of cavitation signals in other study not reported here.

As discussed earlier, Reggars and Pollard (1995) determined the side of cavitation in the cervical region, but not the vertebral level of cavitation by using two microphones. Reggars and Pollard's research is included in this section because microphones were important part of their study.

Siffert and Kaufman (1996) conducted a study to determine the capabilities and limitations of auscultatory percussion (the act of striking a body part with short, sharp blows as an aid in diagnosing the condition of the underlying parts by the sounds obtained) technique for assessing the healing of bone fractures. A portable vibration analysis device was used and experiments were conducted to objectively evaluate the capabilities of auscultatory percussion techniques. Technique was based on observations of the ability of bone to conduct sound, which required simply tapping a bony prominence distal to the suspected or known fracture and listening over the opposite end of that bone. They found that decrease in volume and pitch of vibration energy wave indicates discontinuity at a fracture site or an established nonunion. They concluded that vibration assessment is, however, subject to systematic and random errors, and thus cannot always discriminate between the stages of healing in a fractured bone. In addition; various artifacts can lead to significant uncertainty in diagnosis, and more sophisticated methods could be used in the future to improve accuracy of vibration techniques, as well as placement of transducers. Accelerometers were placed on spinous processes (SPs) in

our study because bone is discussed as a good conductor for transmitting vibration waves and an accurate placement of transducer on bone is necessary to overcome dampening effects.

As discussed earlier, Beffa and Mathews (2004) conducted a study to locate the cavitation sounds using microphones, during an “L5 spinous hook” and lower SIJ SMT. Microphones were an important part of this study in locating cavitation hence, included in this section.

Diagnosis

Accelerometers and microphones can be used in future studies to develop new techniques to deepen the understanding of the mechanics of the spine.

Chu et al., (1976) performed a study to analyze the sound emitted by normal and pathological knee joints during active movements. Two identical microphones were attached to the knee by means of a holding assembly. One microphone was directed towards the knee and other was rotated 180 degrees opposite to the first microphone (i.e., away from the knee) to hear the surrounding noise and implement the noise cancellation method. They concluded that the recordings covering normal, rheumatoid, arthritic, and degenerative knees showed respective waveforms, spectral patterns and statistical property. Also, auto correlation appeared to be unique and therefore may well prove to be a promising non-invasive tool for early detection of the type and extent of knee joint damage. This noise cancellation method can be used in future studies to eliminate unwanted surrounding noise by using a differential amplifier for microphones and develop new methods in detecting degenerative disease in spine.

Gallo et al., (1993) attempted to record the sounds emitted by healthy TMJs with and without mandibular movements for determination of baseline spectra. TMJ sounds were recorded bilaterally from 40 subjects with healthy joints by means of a self developed recording system using miniature capacitor microphones inserted into the earpieces of a medical stethoscope. The recordings were performed with no mandibular movements and during three consecutive opening and closing movements. Acoustic recordings conducted for patients without mandibular movements were below 800Hz and were significantly less than frequencies with mandibular movements. The baseline frequency spectrum could be developed in future studies to differentiate healthy subjects and subjects with different pathologies.

Widmalm et al., (1992) attempted to better understand the cause of different sounds from the TMJ joint in 27 fresh autopsy specimens. They displayed the time frequency distribution of sound as a three dimensional graph and correlated the sound character to morphologic observations at subsequent dissection. It was also shown that all joints with sounds had different degrees of intra-articular changes and the reciprocal clicking occurred both in joints with disc displacement with and without reduction, as well as in joints with arthrotic changes. Crepitation occurred only in joints with arthrosis and perforation. A high-frequency sound appeared to be associated with arthrosis of the articular surfaces. It was concluded that joint sounds indicate abnormality, but the absence of joint sound does not exclude intraarticular pathology. New methods can be developed in the future to record the sound of crepitus in the spine, which can help in early detection of degenerative disease using non-invasive tools.

Reddy et al., (2001) developed the accelerometry technique to characterize various types of arthritis and spondyloarthropathy in knee joint. An ultra-miniature accelerometer was placed on the patella, and the subject was asked to rhythmically rotate the knee from 90 degree flexion to full extension. They concluded that mean power of acceleration signal in the range of 100–500 Hz is significantly different for spondyloarthropathy patients when compared to rheumatoid arthritis patients. Degenerative disease in the spine could be detected and diagnosed using new methods depending on the unique waveform patterns.

Brown (1997) used a clinical heart sounds stethoscope and an electronic stethoscope to identify difference in sound frequency of muscles between healthy patients and patients with untreated Parkinson's disease. Sound signals were analyzed spectrographically on a computer. Measurement of muscle discharge was made 6-18 hours after withdrawal of antiparkinsonian medication and again 1-2 hours after treatment was restarted on the same day. Microphone signals from the forearm of untreated parkinsonian patients maximally extending the wrist showed discrete bursts of sound at a frequency of about 10 Hz, while increase in frequency was seen for healthy patients at around 40 Hz.

Jaskolska and Madeleine (2007) conducted a study to compare mechanomyogram (MMG) recording using a condenser microphone (MIC) and an accelerometer (ACC), during submaximal isometric, concentric and eccentric contractions in 14 males. The reason for using ACC and MIC together was for the reason that each of the devices respond differently and can be used together in diagnosis in the future. The maximal voluntary force (MVC) of the biceps brachii was measured, and they concluded that

during isometric, concentric and eccentric contractions of increased intensity, the results found from accelerometer, microphone, and MMG signals were different despite of the similar trends.

1.2 Main Objective:

The main objective of this research project is to locate the level of zygapophysial (Z) joints in the lumbar spine (L1/L2-L5/S1) and the sacroiliac joints (SIJs) that cavitate during side-posture positioning and spinal manipulative therapy (SMT).

The specific goals that will contribute to achieve the objective are:

1. To refine previously designed accelerometry techniques used to evaluate cavitations following SMT.
2. To conduct recordings in a clinical investigation using the refined accelerometry methods.
3. To report the results of accelerometry recordings during SMT (Group 1) and side-posture positioning alone (Group 2) and make comparisons of cavitations between: Group 1 vs. Group 2; left side (up-side during SMT) vs. right side (down-side during SMT); and “target” Z joints (L3/L4, L4/L5, and L5/S1) vs. “non-target” Z joints (L1/L2, L2/L3, and SIJs).
4. To assess the accelerometry methods used in the clinical study to determine the strengths and challenges (weaknesses) of the methods.
5. To propose ideas to further refine the accelerometry methods and to add acoustics methods for future studies.

Each specific goal is discussed in the future chapters to achieve main objective of this research project.

2. ANATOMY AND PHYSIOLOGY OF LUMBAR SPINE

This chapter describes the basic anatomy of the spine. A basic knowledge of spinal anatomy is needed to understand the research described in future chapters. The spine is a very important part of the body, as it helps to give the body its structure and support. The spine is also designed to protect the spinal cord and the nerves that carry information from the body to the brain and from the brain to the body.

2.1 Spinal Column

The adult spine is composed of the vertebral column and the muscles, ligaments and other connective tissues that attach to the vertebral column. The vertebral column is made up of 24 small bones called vertebrae that are stacked on each other (Figure 2.1) (Taiwanspinecenter, no date). In addition, the sacrum and the coccyx (found below the sacrum) are part of the vertebral column (Cramer and Darby, 2005).

The spine is made up of 5 regions (Rodts, 2008):

- Cervical / (C1- C7)
- Thoracic / (T1- T12)
- Lumbar / (L1-L5)
- Sacrum
- Coccyx

The cervical region is the upper part of the spine and is made up of seven vertebrae. The thoracic region is the middle portion of the spine and is made of 12 vertebrae. The lumbar region is the lower portion of the spine and is made of 5 vertebrae, but some people can have 6 lumbar vertebrae. These 3 areas are the main regions of the spine. The sacral region (sacrum) is situated below the lumbar spine and is also made of specialized vertebrae that help to connect the vertebral column with the pelvis. The coccyx is the lowest part of spinal column and is made of approximately 4 fused, undeveloped vertebrae (Cramer and Darby, 2005). The normal spine has an 'S' like curve when seen from side. This 'S' shape curve helps the spine to withstand all kinds of stresses.

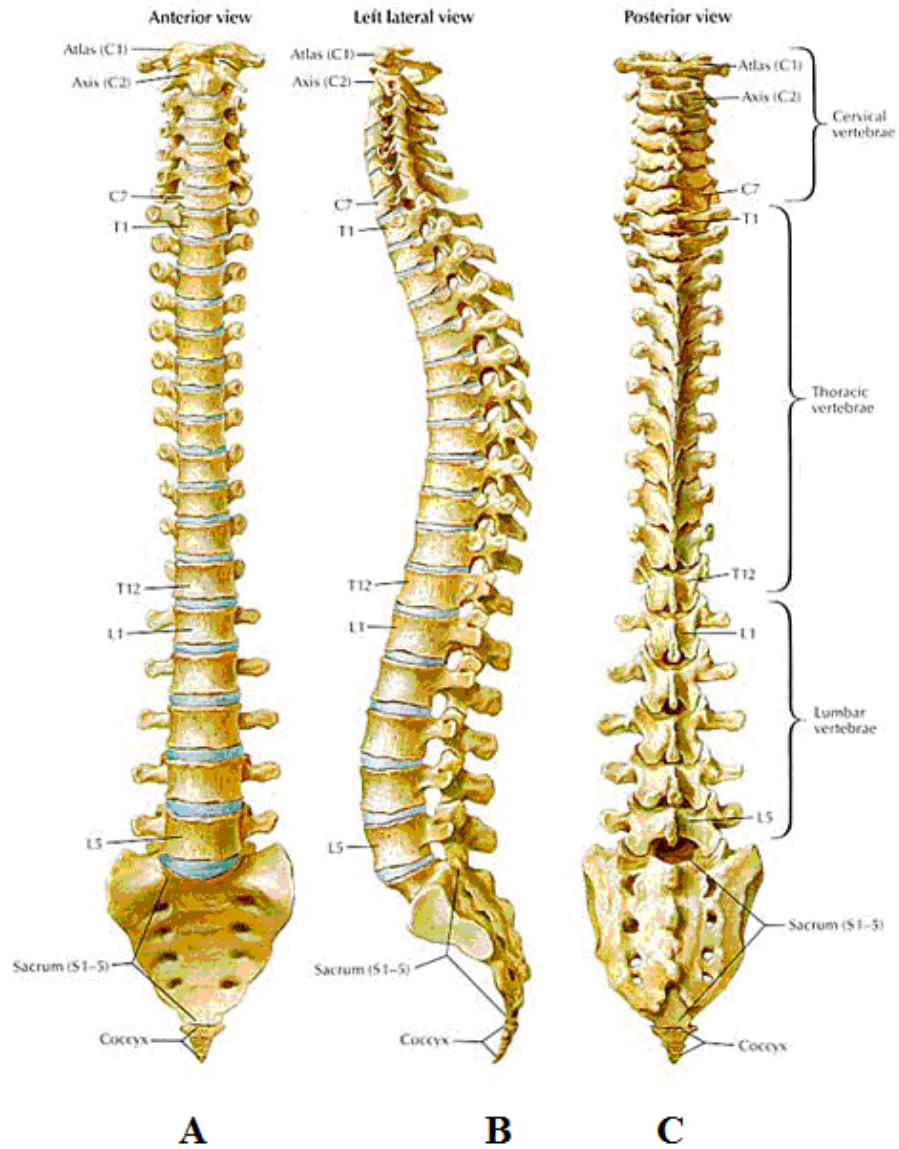


Figure 2.1: Three views of the vertebral column showing:

- A) Anterior view
- B) Lateral view
- C) Posterior view showing cervical, thoracic, lumbar, sacral, and coccyx regions

Between each vertebra there is a gel-like cushion called the intervertebral disc (Figure 2.3) (University of Maryland Spine Center, 2007). The intervertebral discs allow

motion to occur between vertebral segments and absorb various forces placed on the vertebrae.

2.2 Vertebrae

The individual bones of the spine are called the vertebrae (Cramer and Darby, 2005). These are the building blocks of the vertebral column. A vertebra supports and protects the spinal cord and also bears the majority of the weight added on the spine. A vertebra is made up of the following parts: (Figure 2.2) (University of Maryland Spine Center, 2007). The **body** of each vertebra is the large front portion of the vertebra. The body is attached to a bony ring (posterior arch). The vertebral foramen is a hole found between the body and the posterior arch of each vertebra. When vertebrae are stacked on each other, the vertebral foramina creates a hollow tube through which the spinal cord passes. The posterior arch consists of several parts. The left and right pedicles and **laminae** (Figure 2.2) extend from the body to cover the vertebral foramen on each side and behind the **spinous process (SP)** is the bony portion opposite the body of the vertebra. One can feel the SPs as projections in the midline of the back. Several large processes extend from the junction of the pedicles and laminae. Two (left and right) **transverse processes** project to each side. Finally, **superior articular process** (top side) and **inferior articular process** (bottom side) project from the junction of the pedicle and lamina on the left and right side. The articular processes help to form the zygapophysial (Z) joints.

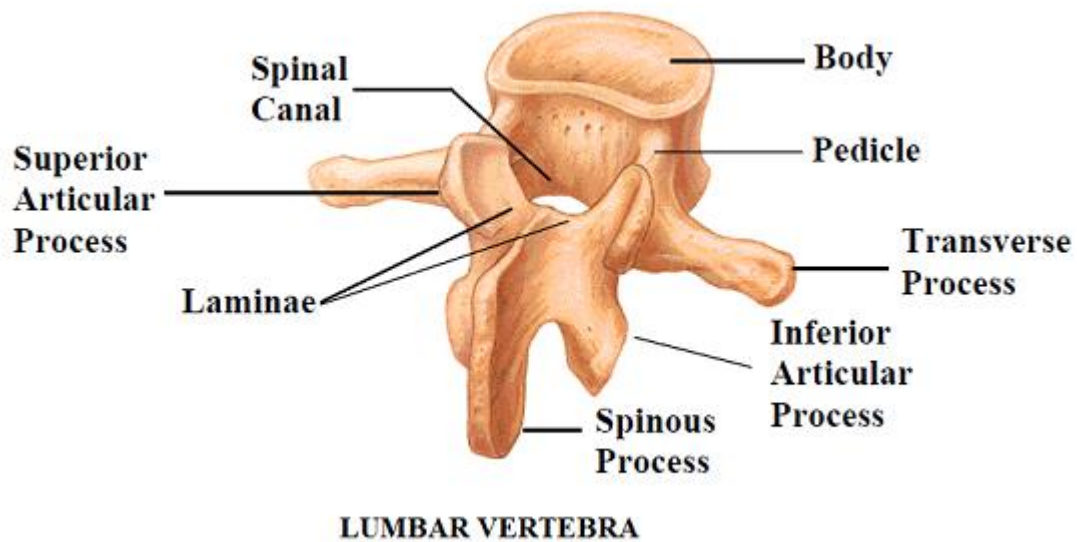


Figure 2.2: Parts of lumbar vertebrae

2.3 Zygapophysial (Z) Joints

Zygapophysial joints are also called as facet joints. The facets are the smooth articulating surfaces of the superior and inferior articular processes. The facets of adjacent superior and inferior articular processes meet to form the zygapophysial joints (Figure 2.3) (University of Maryland Spine Center, 2007). The left and right Z joints (along with the intervertebral disc) join to adjacent vertebrae together. Without the Z joints, there would not be motion in the vertebral column.

The Z joints are a type of synovial joint. The synovial joints, such as those found in the knees or elbows, are joints that allows movement between two bones. In a synovial joint, the ends of the bones are covered with a material called articular cartilage. This is a spongy material that allows the bones to glide against each other without much friction. Synovial fluid is found in the synovial joints and is important for reducing friction.

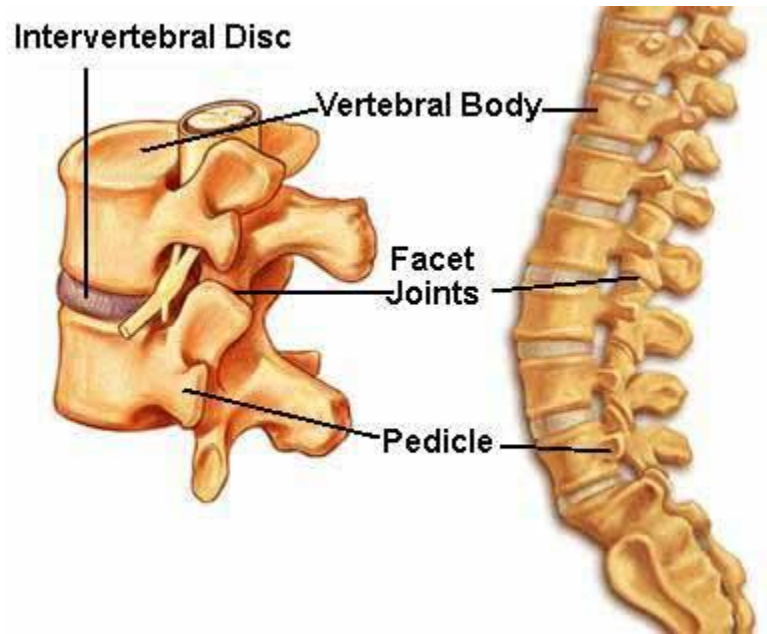


Figure 2.3: Lumbar zygapophysial joint

In addition, the Z joints help to carry loads placed on the spine, particularly during extension and rotation.

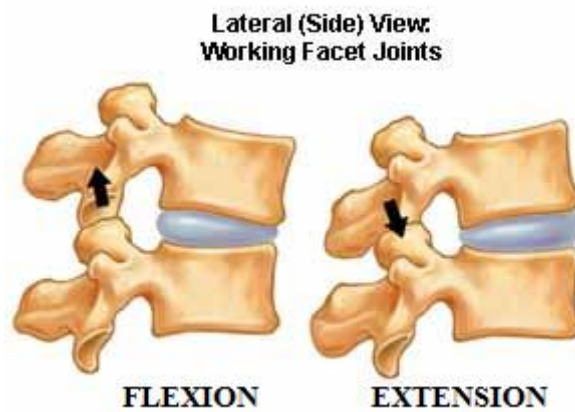


Figure 2.4: Showing motion in Z joints during flexion and extension

Two vertebrae, and the tissues that connect them, comprise the smallest working unit of the spine. This unit is referred to as the “spinal motion unit”. This motion unit (Figure 2.4) (All About Back and Neck Pain , 2009) allows for normal flexion, extension, lateral bending (lateral flexion), and rotation to occur between adjacent vertebrae.

3. ACCELEROMETERS AND MICROPHONES

Accelerometers are an important part of the research described in the following chapters. Microphones are being considered for future studies. Both are described in this chapter.

3.1 Accelerometers

An accelerometer is an electromechanical device that measures acceleration forces (Brueel & Kjaer, 2010). These forces may be static, like the constant force of gravity pulling at your feet, or they could be dynamic, caused by moving or vibrating the accelerometer.

3.2 Types of Accelerometers

1. Piezoelectric accelerometers
2. Piezoresistive accelerometers
3. Capacitive accelerometers

3.2.1 Piezoelectric Accelerometers

Piezoelectricity is the ability of some materials (notably crystals and certain ceramics) to generate an electric field or electric potential in response to an applied mechanical strain (ratio of change in volume to original volume) (Gautschi, 2002). The effect is closely related to a change of polarization density within the material's volume. If the material is not short-circuited, the applied stress/strain induces a voltage across the material (Figure 3.1) (Wikipedia, no date). However, if the circuit is closed, the energy will be quickly released. So, in order to run an electric load (such as a light bulb) on a piezoelectric device, the applied mechanical stress must oscillate back and forth. The root “piezo” is derived from the Greek *piezo* or *piezein*, which means to squeeze or press (Avallone and Baumeister, 1996). The piezoelectric effect is reversible. Materials exhibiting the *direct piezoelectric effect* (the production of an electric potential when stress is applied) also exhibit the *reverse piezoelectric effect* (the production of stress and/or strain when an electric field is applied).

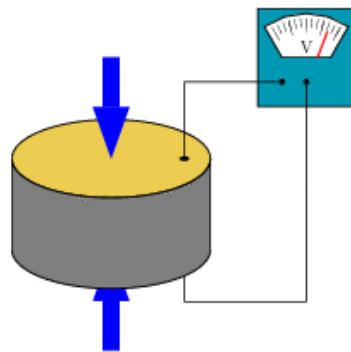
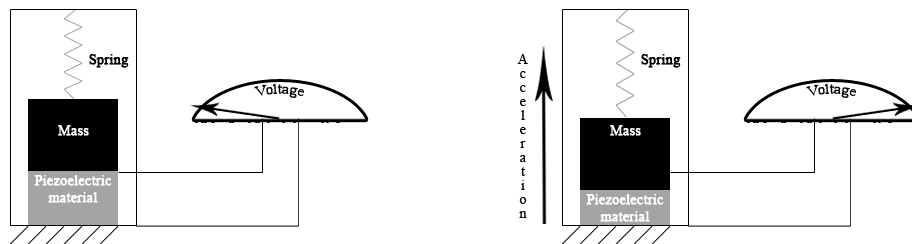


Figure 3.1: A piezoelectric disk generates voltage when deformed

A piezoelectric accelerometer (such as those used in this study) utilizes the piezoelectric effect of certain materials to measure dynamic changes in mechanical variables (E.g. acceleration, vibration, and mechanical shock).

Piezoelectric accelerometers convert one form of energy into another and provide an electrical signal in response to a quantity, property, or condition that is being measured (Figure 3.2) (Wikipedia, no date). In this instance, acceleration acts upon a seismic mass that is restrained by a spring or suspended on a cantilever beam, and converts a physical force into an electrical signal (Dimension Engineering, no date). Before the acceleration can be converted into an electrical quantity, it must first be converted into either a force or displacement.

Piezoelectric accelerometers rely on piezoceramics (e.g. lead zirconate, titanate, etc) or single crystals (e.g. quartz, tourmaline, etc). They are unmatched in terms of their upper frequency range, low packaged weight and high temperature range. They are frequently used in aerospace, ballistics, engine testing and other applications (Aszkler, 2005).



A) Before acceleration.

B) After acceleration.

Figure 3.2: Piezoelectric accelerometer showing no voltage when acceleration is not applied and voltage generated with acceleration

3.2.2 Piezoresistive Accelerometers

The piezoresistive effect describes the changing electrical resistance of a material under applied mechanical stress (Avallone and Baumeister, 1996). In contrast to the piezoelectric effect, the piezoresistive effect only causes a change in resistance and does not produce an electric potential.

The sensitivity of piezoresistive devices is characterized by the gauge factor (Avallone and Baumeister, 1996):

$$K = (dR/R)/\epsilon_L$$

Where dR is the change in resistance due to deformation, R is the undeformed resistance and ϵ_L is the strain

Piezoresistive accelerometers may be fabricated from metal strain gauges, piezoresistive silicon, or as a MEMS (Micro Electro Mechanical Systems) device. In such designs, a resistive material is typically bonded to a cantilever beam that bends under the influence of acceleration. This bending causes deformation of the resistor, leading to a change in its resistance (Figure 3.3) (PCB Piezotronics, 2009). The resistors are normally configured into a Wheatstone bridge circuit which provides a change in output voltage proportional to acceleration. Piezoresistive accelerometers are capable of measuring constant, transient, and periodic acceleration. Piezoresistive accelerometers are preferred in high shock applications.

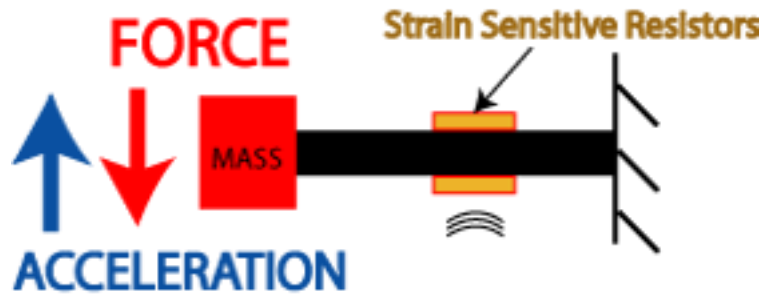


Figure 3.3: Piezoresistive accelerometer

3.2.3 Capacitive Accelerometers

Capacitive accelerometers utilize the properties of an opposed plate capacitor for which the distance between the plates vary proportionally to applied acceleration, thus altering capacitance (Figure 3.4) (PCB Piezotronics, 2009). This variable is used in a circuit to deliver a voltage signal that is proportional to acceleration. Capacitive accelerometers are capable of measuring constant as well as slow transient and periodic acceleration. These accelerometers are suited for measuring low frequency vibration, motion, and steady-state acceleration.

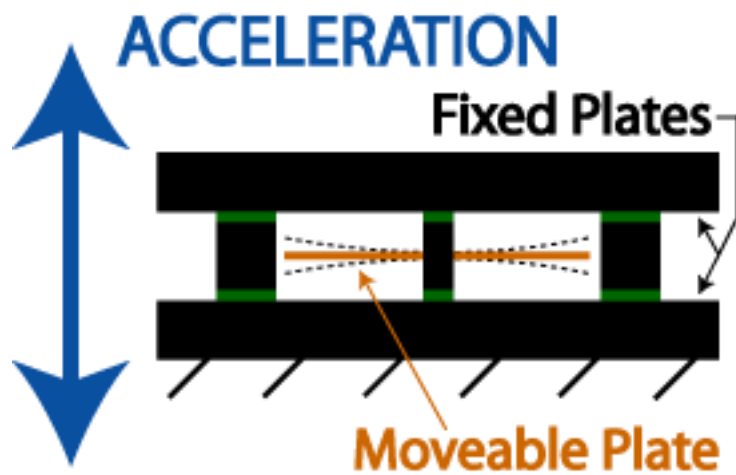


Figure 3.4: Capacitive accelerometer

Capacitive accelerometers typically use a silicon micro-machined sensing element. Their performance is superior in the low frequency range, and they can be operated in servo mode to achieve high stability and linearity.

3.3 Applications

3.3.1 Medical Applications

Within the last several years, Nike, Polar and other companies have produced and marketed sports watches for runners that include foot pods that contain different kinds of accelerometers that determine the speed and distance for the runner wearing the unit.

3.3.2 Transport

One of the most common uses for MEMS accelerometers is in airbag deployment systems for modern automobiles. In this case, the accelerometers are used to detect the rapid negative acceleration of the vehicle to determine when a collision has occurred and the severity of the collision (Bruel & Kjaer, 2010). Piezoresistive accelerometers are also commonly used in detecting crashes. Another common automotive use is in electronic stability control systems, which uses a lateral accelerometer to measure cornering forces. The widespread use of accelerometers in the automotive industry has pushed their cost down dramatically. Another automotive application is the monitoring of noise, vibration and harshness (NVH), conditions that cause discomfort for drivers and passengers and may also be indicators of mechanical faults.

3.3.3 Consumer Electronics

Accelerometers are increasingly being incorporated into personal electronic devices such as smart phones, audio players, video game consoles, camcorders etc.

Motion Input

Some smart phones, digital audio players and personal digital assistants contain accelerometers for user interface control; often the MEMS accelerometer is used to present landscape or portrait views of the device's screen, based on the way the device is being held.

Nintendo's Wii video game console uses a controller called a Wii Remote that contains a three-axis MEMS accelerometer (Analog Devices, 2010) and was designed primarily for motion input. Users also have the option of buying an additional motion-sensitive attachment, the Nunchuk, so that motion input could be recorded from both of the user's hands independently.

The Nokia 5500 sport features a 3D accelerometer that can be accessed from software. It is used for step recognition (counting) in a sport application, and for tap gesture recognition in the user interface. Tap gestures can be used for controlling the music player and the sport application, for example to change to next song by tapping through clothing when the device is in a pocket (Nokia, 2010).

Orientation Sensing

A number of modern notebook computers use 3 axis MEMS accelerometers to automatically align the screen depending on the direction the device is held, i.e. switching between portrait and landscape modes. For example, Apple uses an LIS302DL accelerometer in the iPhone, iPod Touch and the 4th&5th generation iPod Nano allowing the device to know when it is tilted on its side (Stmicroelectronics, 2010).

Image Stabilization

Camcorders use accelerometers for image stabilization. Still cameras use accelerometers for anti-blur capturing. The camera holds off snapping the CCD "shutter" when the camera is moving. When the camera is still (if only for a millisecond, as could be the case for vibration), the CCD is "snapped".

3.4 Microphones

A microphone (mic) is an acoustic-to-electric transducer or sensor that converts sound into an electrical signal (PCB Piezotronics, 2009). In 1876, Emile Berliner invented the first microphone used as a telephone voice transmitter.

The sensitive transducer element of a microphone is called the *element* or *capsule*. A complete microphone also includes a housing, which brings the signal from the element to other equipment.

3.5 Types of Microphones

1. Condenser Microphones
2. Dynamic Microphones
3. Piezoelectric Microphones
4. Fiber Optic Microphones

3.5.1 Condenser Microphones

Condenser microphone is also called a capacitor microphone or electrostatic microphone. A capacitor is an electronic component which stores energy in the form of an electrostatic field.

A capacitor has two plates with a voltage between them. In the condenser microphone, one of these plates is made of very light material and acts as the diaphragm (Figure 3.5) (Media College, no date). The diaphragm vibrates when struck by sound waves; changing the distance between the two plates and therefore changing the capacitance (Sessler and West, 1962). When the plates are closer together, capacitance increases and a charge current occurs. When the plates are further apart, capacitance decreases and a discharge current occurs. Nearly all cell-phone, computer, PDA and headset microphones are condenser microphones.

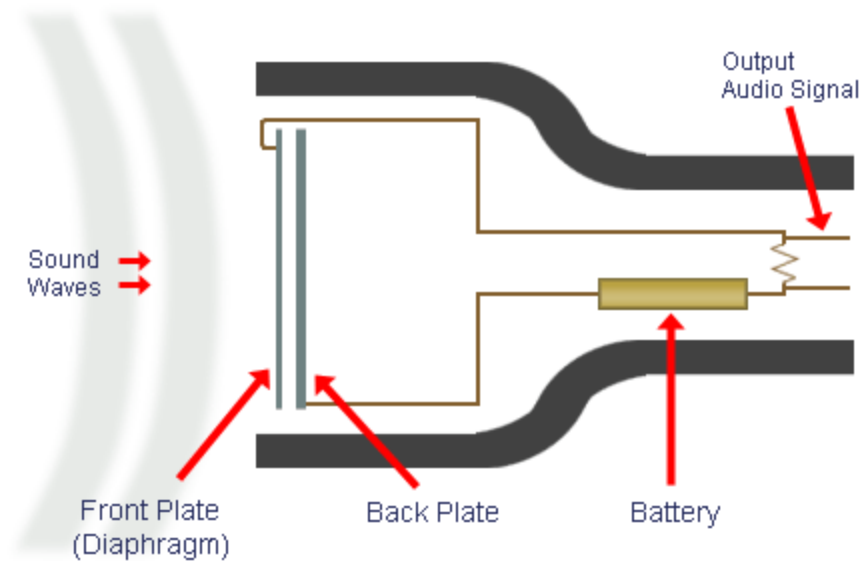


Figure 3.5: Cross section of condenser microphone

3.5.2 Dynamic Microphones

Dynamic microphones are versatile and ideal for general usage. They use a simple design with few moving parts. They are relatively sturdy and resilient to rough handling. They are also better suited for handling high volume levels, such as those from certain musical instruments or amplifiers. They have no internal amplifier and do not require batteries or external power.

When a magnet is moved near a coil of wire, an electrical current is generated in the wire. Using this electromagnet principle, the dynamic microphone uses a wire coil and magnet to create the audio signal (Figure 3.6) (PCB Piezotronics, 2009). The diaphragm is attached to the coil. When the diaphragm vibrates in response to incoming sound waves, the coil moves backwards and forwards past the magnet. This creates a current in the coil which is channeled from the microphone by wires.

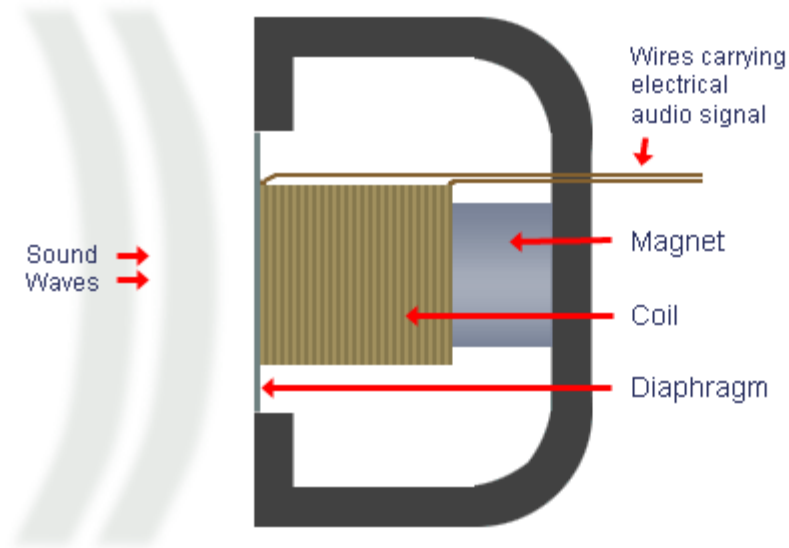


Figure 3.6: Cross section of Dynamic Microphone

3.5.3 Piezoelectric Microphones

Piezoelectric microphones work on the principle of the piezoelectric effect as described earlier in piezoelectric accelerometers (Section 3.2.1). Piezoelectric microphones use ceramic or quartz crystals (or other piezoelectric materials) linked to a diaphragm or directly exposed to acoustic waves (Figure 3.7) (PCB Piezotronics, 2009). Stresses in the crystals, resulting from a sound field, generate an output proportional to the acoustic pressure. Many designs incorporate a built-in preamplifier next to the crystal. This arrangement reduces the electrical noise and output impedance. Piezoelectric microphones are commonly used in medical and aero acoustic applications because of their high sensitivity (Horowitz et al., 2006).

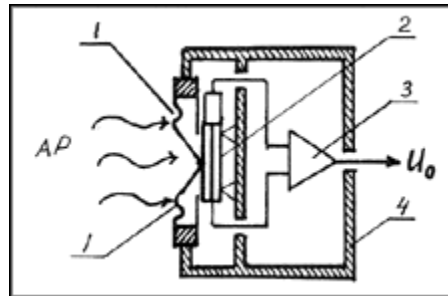


Figure 3.7: Cross section of Piezoelectric Microphone

Where:

AP: Acoustic pressure.

U_o : Output voltage.

- 1) Diaphragm.
- 2) Piezoelectric material.
- 3) Built in preamplifier.
- 4) Case.

3.5.4 Fiber Optic Microphones

A fiber optic microphone converts acoustic waves into electrical signals by responding to changes in light intensity, rather than changes in capacitance or magnetic field (Paritsky and Kots, 1997).

Fiber optic microphones use light from a laser source travelling through an optical fiber to illuminate the surface of a tiny, sound-sensitive reflective diaphragm. Sound causes the diaphragm to vibrate, thereby minutely changing the intensity of the light it reflects. The modulated light is then transmitted over a second optical fiber to a photo detector which transforms the intensity-modulated light into analog or digital audio for transmission or recording.

Fiber optic microphones do not react with any electrical, magnetic, electrostatic or radioactive fields. The fiber optic microphone design, therefore, is ideal for use in areas where conventional microphones are ineffective or dangerous, such as inside industrial turbines or in magnetic resonance imaging (MRI) equipment environments.

3.6 Applications of Microphones in Research and Industry

3.6.1 Research and Product Design

Since excessive sound pressure can cause damage to products or human hearing, microphones are used to measure the pressure level exerted on a surface. Sound measurement is used in a variety of applications including the study of door slams, clutch engagements, starter impact and sunroof noise. Engine noise in a cabin or car interior and sound exhibited from consumer appliances is tested and analyzed to extend the lifespan of the product and minimize external noise (Briel & Kjaer, 2010).

Increased sound levels or changes in frequency can indicate that a product is not working to its capacity. Motors, gears, bearings, blades, and other industrial components can all experience changes in decibel level or frequency shift when not working properly. High precision microphones can be utilized to confirm that a product is experiencing a problem, or can be used to predict failure of a component (PCB Piezotronics, 2009).

3.6.2 Compliance

Microphone tests can be performed and recorded for verification of pressure levels on products, and can be utilized in legal situations. Companies can use high precision microphone tests for proof of sound pressure levels during design. Microphones are used on sound level meters to ensure compliance with national standards for shop noise (Extech Instruments, 2010).

3.6.3 Environmental Noise Analysis

There are certain sound pressure levels that the human ear can only be subjected to for specific amounts of time before ear damage occurs, such as industrial shop, airport, and automotive highway noise. Acoustic testing is performed to better understand the sound levels that are experienced in these surroundings and make adjustments to provide greater personal protection (Extech Instruments, 2010).

4. INSTRUMENTATION AND METHODOLOGY

This chapter describes the instrumentation for accelerometry equipment used in this study and our methodology. The methods begin with a description of the process used to refine previous methods, followed by descriptions of the clinical study for Group 1 and Group 2.

4.1 Instrumentation

Nine accelerometers (Bruel & Kjaer Delta Tron4507, Naerum, Denmark) (Figure 4.11) were used to pick up vibration data created by cavitations during side-posture positioning and SMT. Direction of acceleration (Figure A.1., Appendix section A.1) was also considered for all the accelerometers during clinical study. These piezoelectric accelerometers were used because cavitations stimulated them at their natural frequency of 21 KHz. Three signal conditioning amplifiers (Bruel & Kjaer 2693, Naerum, Denmark) (Figure A.2, Appendix section A.2) (Bruel & Kjaer, 2010) were used to amplify the signal from accelerometers. Each amplifier was capable of handling data from 4 different channels/accelerometers (Figure 4.1). The analog signal was converted into digital information at a maximum rate of 10MHz (10 million samples per second) by two NI PXIe 6356 (National Instruments, Austin, Texas, USA) (Figure A.3, Appendix section A.3) (National Instruments, 2010) data acquisition (DAQ) devices. The velocity

of vibration waves from cavitations travelling through the body is at 1400m/sec (Ross et al., 2004). To get distance discrimination of 0.5cm the sampling rate was set to 320,000Hz. Given that Z joints between adjacent vertebrae and on the left to right sides are separated by a distance of 3 to 4.5 cm, there was no reason to sample at a rate any greater than this, even though the equipment had the potential to do so. Since the study required nine analog channels, we used two data acquisition devices, each capable of handling data from eight simultaneous channels. Each device was capable of handling a maximum sampling rate of 1.25 MS/s/channel (million samples per second per channel). These devices included multithreaded NI-DAQmx (National Instruments, Austin, Texas) driver software, which was compatible with the following versions (or later) of NI application software: LabVIEW 8.2, Lab WindowsTM/CVI 7.x, or Measurement Studio 7.x; LabVIEW Signal Express 1.x; and LabVIEW with the LabVIEW Real-Time Module 8.2.

LabVIEW 9.0 was used in this study to write different programs for data acquisition and storage and data analysis.

Two NI BNC 2090 connector blocks (Figure A.4, Appendix section A.4) (National Instruments, 2010) were used to connect data from the amplifier to DAQ devices (Figure 4.1). A NI PXIe 1073 (Figure A.5, Appendix section A.5) (National Instruments, 2010) chassis was used to house both high speed DAQ devices. This chassis was capable of accepting PXI Express modules in two slots and supporting standard PXI hybrid-compatible modules in up to three slots. This chassis was also used to supply

power for the system. A NI PXIe-Express Card 8360 (Figure A.6, Appendix section A.6) (National Instruments, 2010) was used to connect to a Dell Precision M6400 laptop via an Express Card MXI cable connected to slot 1 of the chassis. All equipments were placed on a portable cart (Figure 4.2). This configuration provided the portability to relocate the entire system and the flexibility to unplug the components. This way, for example, the computer could be used in a different location for data analysis, etc.

The system was powered up and powered off in the following sequential manner:

Powering up

1. Amplifiers
2. PXIe chassis
3. Laptop

Powering off

1. Laptop
2. PXIe chassis
3. Amplifiers

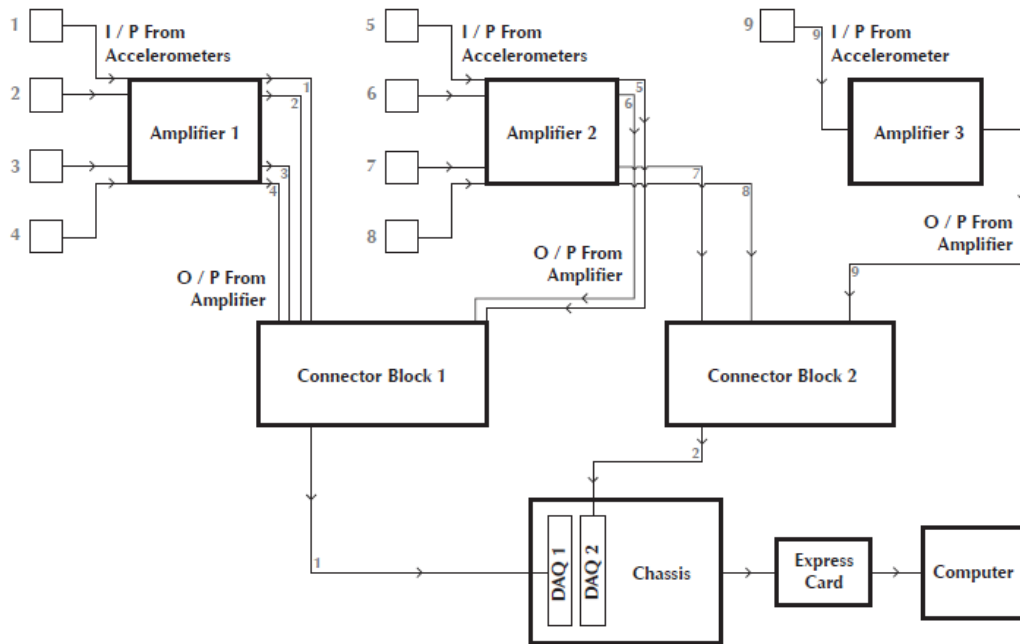


Figure 4.1: Block diagram of the system

Where:

Connector Block 1, 2: NI BNC 2090

DAQ 1, 2: NI PXIe 6356

Chassis: NI PXIe 1073

Express Card: NI PXIe- Express Card 8360



Figure 4.2: Instrument located on a portable cart/trolley

4.2 Refining Previously Designed Accelerometry Techniques Used to Evaluate Cavitations Following Side-Posture Positioning and SMT

4.2.1 Previously Designed Accelerometry Methods

Accelerometers were previously used to identify cavitations originating from the left and right L3/L4, L4/L5, and L5/S1 Z joints during side-posture positioning and SMT. The original plan for the current study was to tape seven accelerometers to the subject's skin. Three accelerometers would be placed over the spinous processes (SPs) of the third (L3), fourth (L4), and fifth (L5) lumbar segments (Figure 4.3). Another would be placed 3 cm to the left and another 3 cm to the right mid-distance between the SP L3 and SP L4 midline accelerometers. Finally, one more would be placed 3 cm to the left and another 3 cm to the right mid-distance between the SP L4 and SP L5 midline accelerometers (Figure 4.3).

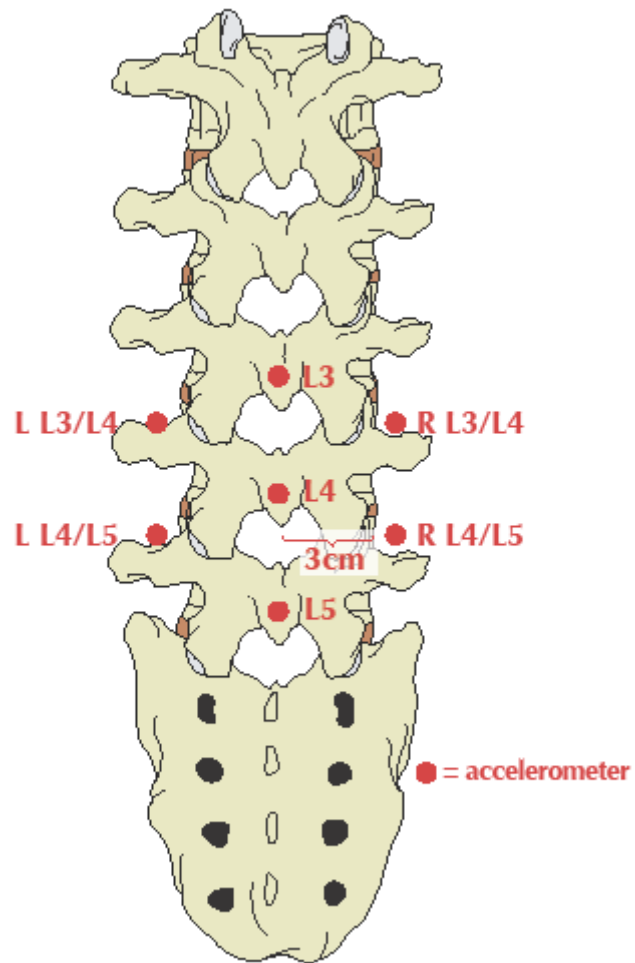


Figure 4.3: Position of accelerometers as per the original (previous) design

4.2.2 Re-Design of the Accelerometry Methods

Several problems were identified during initial testing. Differentiating cavitations originating in segments immediately above the SP L3 accelerometers or SIJ cavitations below the SP L5 accelerometer from L3/L4 or L5/S1 cavitations was very difficult. A specific configuration of nine accelerometers resolved these challenges. Seven accelerometers were placed over the spinal column of a subject's back at the levels of the SPs of the first (L1), second (L2), third (L3), fourth (L4), fifth (L5) lumbar segments, and the S1 and S2 (sacral tubercles) (Figure 4.4). Another was placed 3 cm to the left and another 3 cm to the right mid-distance between the SP L4 and SP L5 midline accelerometers. This configuration was designed to identify the specific Z joints from which cavitations originated by identifying the order in which the recordings of individual accelerometers deviated from the baseline.

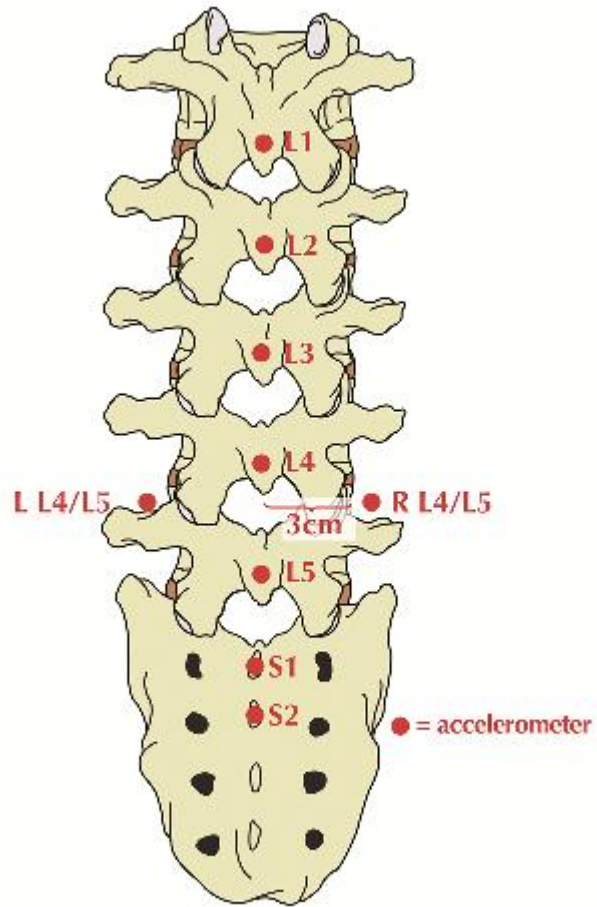


Figure4.4: Position of accelerometers in the re-designed method

4.3 Testing the System

4.3.1 Re-Designed Method

Accelerometers were taped on top of a table in the same configuration as if they were to be taped on the spine at SPs L1, L2, L3, L4, L5, S1 and S2. These accelerometers were separated by 3cm. Two accelerometers were also placed lateral to the midline accelerometers, one 3 cm to the left and one 3 cm to the right of the mid-distance between the SPs L4 and L5 midline accelerometers (Figure 4.5).

A target area was marked and a steel ball was dropped in between accelerometers at SPs L4, L5, and Left L4L5 and the data was collected and analyzed. In this experiment, the accelerometer at SP L4 or SP L5 would respond first, then Left L4L5, Right L4L5 and then accelerometers sitting above and below SPs L4 and L5 (i.e., SP L3 and S1) would respond. The order of the response would be based upon how the vibration wave reached the individual accelerometers. The experiment was repeated several times at different locations.

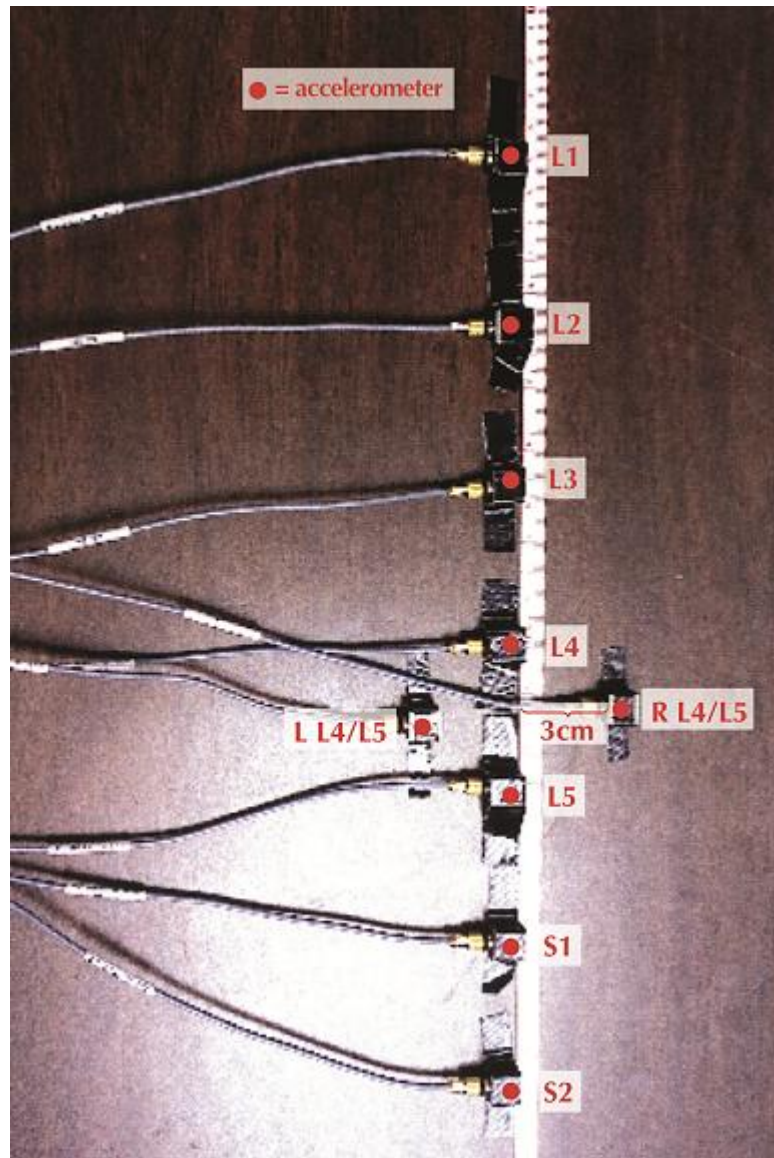


Figure 4.5: Accelerometers taped on the table according to the re-designed system. Each accelerometer was separated by a distance of 3cm

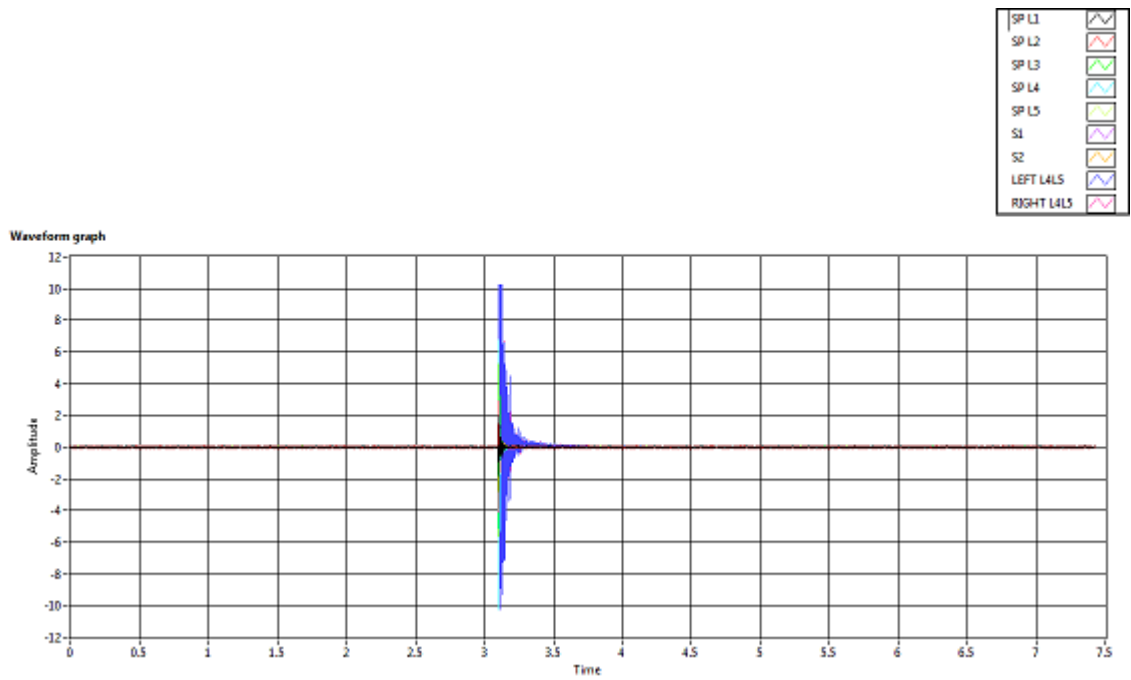


Figure 4.6: The complete time scale of the collected data during dropping of the ball at the Left L4L5 location for redesigned system. The legend above the graph shows the different colors assigned to each accelerometer

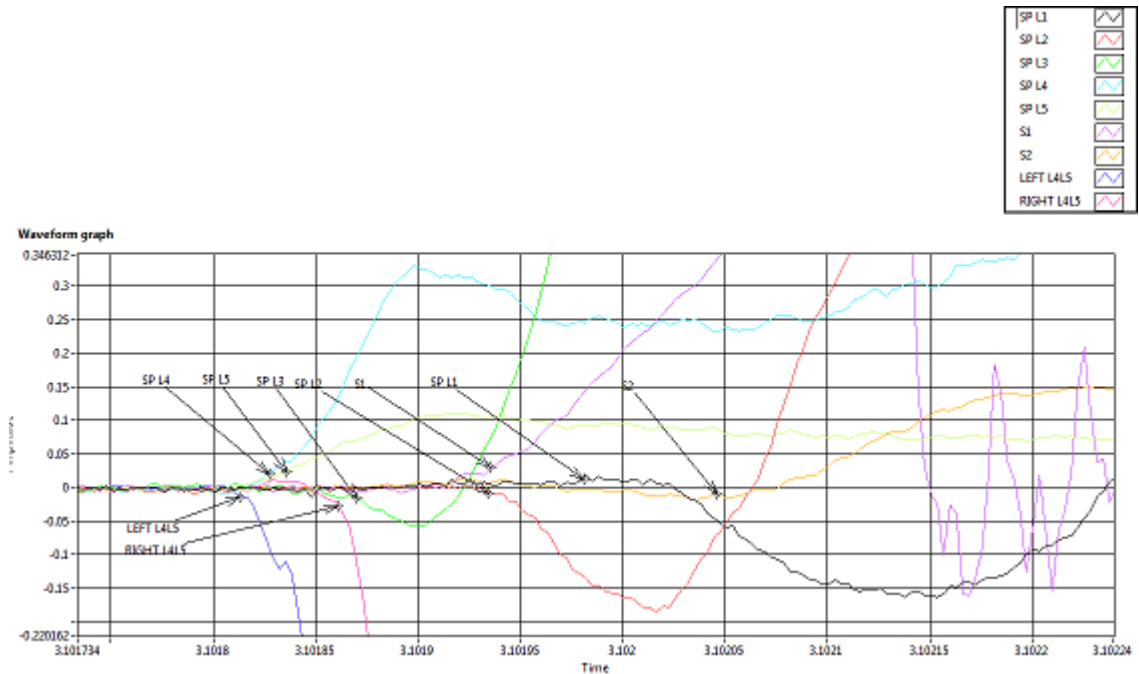


Figure 4.7: The timeline and amplitude (X-axis and Y-axis) of Figure 4.6 have been expanded (zoomed in during the time period of 3.101734 to 3.10224 sec) showing the sequence in which each of the accelerometer responded for redesigned system

Accelerometers responded in the following order: Left L4L5, SP L4, SP L5, Right L4L5, SP L3, SP L2, S1, SP L1 and S2 (Figure 4.7). As Figure 4.7 shows, the experiment successfully determined that the ball was dropped in between Left L4L5, SP L4, and SP L5 accelerometers. The experiments reported at other locations were equally successful.

4.3.2 Comparison with Previously (Originally) Designed Method

Accelerometers were taped on top of a table in the same configuration as if they were to be taped on the spine at SPs L3, L4, and L5 (Figure 4.8). One accelerometer was taped 3 cm to the left and another 3 cm to the right mid-distance between the SP L3 and SP L4 midline accelerometers. Finally, one more accelerometer was taped 3 cm to the left and another 3 cm to the right mid-distance between the SP L4 and SP L5 midline accelerometers (Figure 4.8).

A target area was marked and a steel ball was dropped in between accelerometers at SPs L4, L5, and Left L4L5 and the data was collected and analyzed. According to the hypotheses, if cavitation occurred, or a ball was dropped as in our example, in the designated area then the accelerometer at SP L4 or SP L5 should respond first (or both would respond approximately at the same time), followed by the Left L4L5 and then other accelerometers. Figures 4.8-4.10 show the methods and results of this experiment. Several trials at different locations were also performed.

Y axis for all the collected cavitation data shows the change of voltage generated in the piezoelectric accelerometers used.

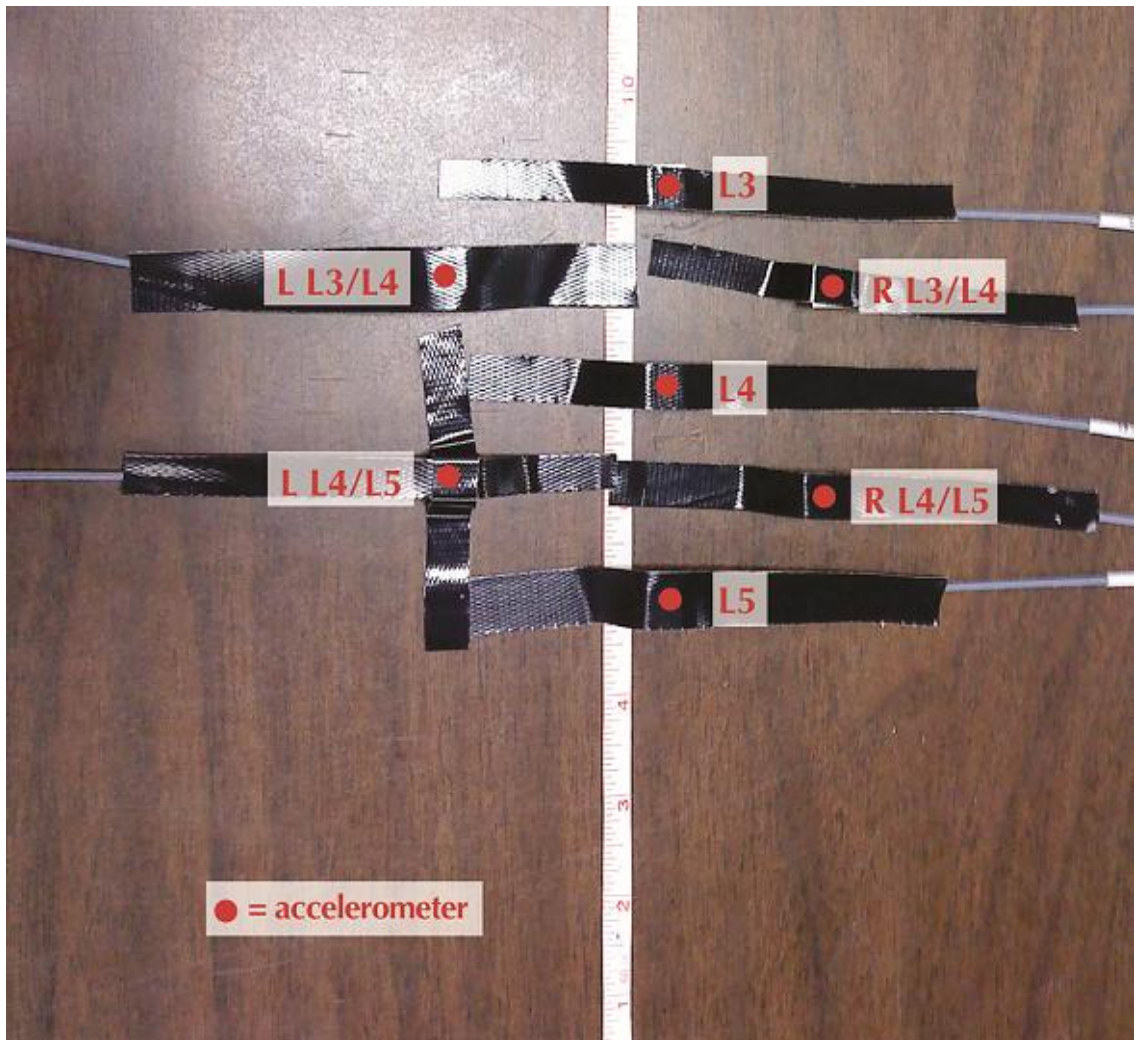


Figure 4.8: Accelerometers taped on the table according to the previously designed method. SPs L3, L4 and L5 accelerometers were separated by a distance of 3cm

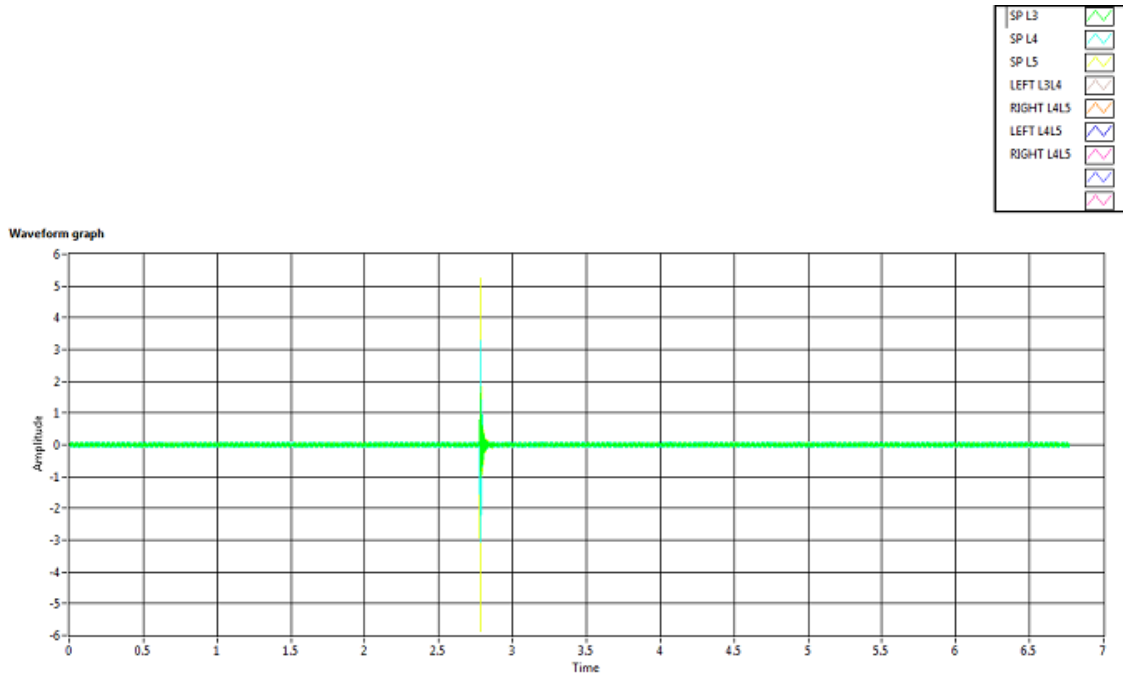


Figure 4.9: The complete time scale of the collected data during dropping of the ball at the Left L4L5 location for the previous (original) designed system. The legend above the graph shows the different colors assigned to each accelerometer.

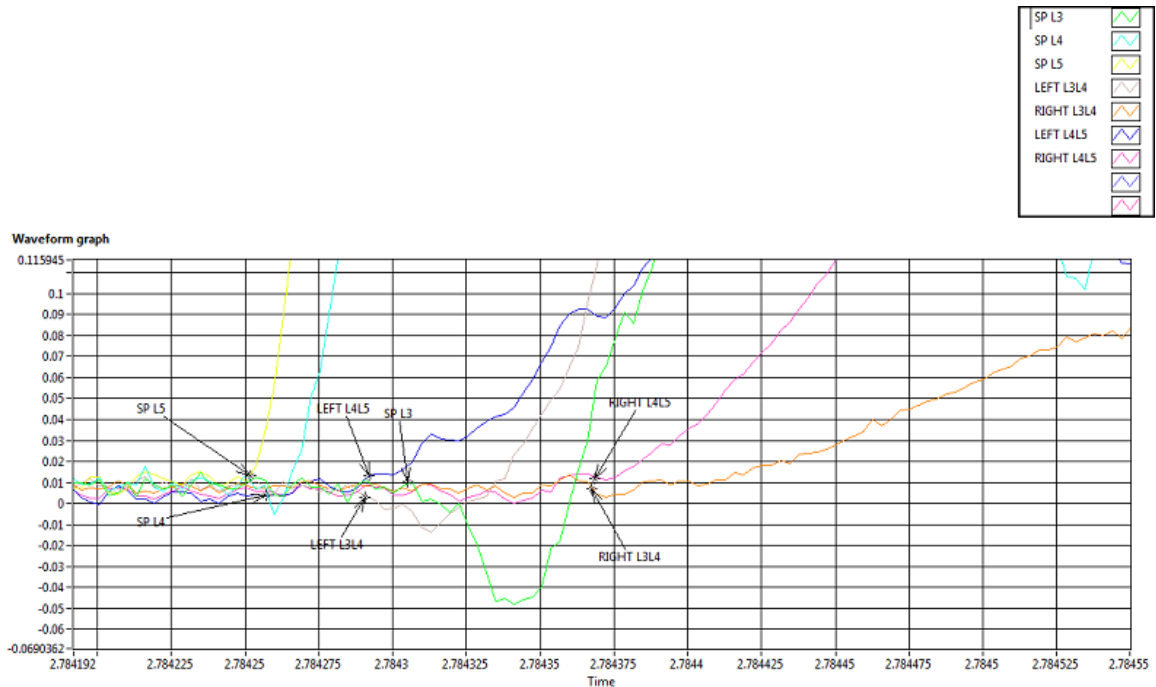


Figure 4.10: The timeline and amplitude (X-axis and Y-axis) of Figure 4.9 have been expanded (zoomed in during the time period of 2.784192 to 2.78455 sec), showing the sequence in which each of the accelerometer responded for previous (original) design

Accelerometers responded in the following order: SP L5, SP L4, Left L4L5 and Left L3L4 (both at same time), SP L3, and then Right L4L5 and Right L3L4 (both at same time) (Figure 4.10). It was difficult to determine where the ball was dropped based on the graph. The graphs of other trials were equally difficult to interpret.

Consequently, the new re-designed nine accelerometers method was used in the clinical study. The new method also allowed identification of cavitations at targeted (L3/L4, L4/L5, L5/S1) and non-targeted Z joints. The targeted Z joints were used in another clinical study (not reported here) in which MRI scans were taken of L3/L4, L4/L5 and L5/S1 Z joints. Therefore, being able to identify cavitations from targeted and

non-targeted Z and SIJ joints was important. The new design was capable of detecting cavitations at Left L1/L2, Right L1/L2, Left L2/L3, Right L2/L3, Left L3/L4, Right L3/L4, Left L4/L5, Right L4/L5, Left L5/S1, Right L5/S1, Left SI joint and Right SI joints.

4.4 Clinical Study

The new methods were used in the clinical study. A total 40 subjects were included in the IRB approved study and randomized into one of the two groups. These groups were:

Group 1, SMT Group (total of 30 subjects were randomized into this group) who received SMT; and

Group 2, Control Group (total of 10 subjects were randomized into this group) who were just held in side-posture position but didn't receive SMT. Data was collected from accelerometers with subjects in Group 2, because it was assumed and found that some Z joints cavitate when subjects are held in the side-posture position.

Specific programs written using LabVIEW were used for collecting and analyzing data. Frank Balester from NUHS wrote these programs with the aid of technical support from National Instruments. Writing separate programs added flexibility to the process of collecting and storing data into the computer RAM in the approximate format and analyze it at anytime.

The procedures used in the clinical trial were as follows:

1. After initial screening (phone screening), consenting subjects were scheduled for examination. Examination was performed against the inclusion and exclusion criteria for this research project. Eligible subjects were scheduled for an MRI appointment.

2. Location of SP L4 was marked using grease pencil before the first MRI scan and high signal marker was taped to the subject's skin, at marked location by trained

clinician, while the subject was lying on their stomach. Targeted area of the MRI scan was L3/L4, L4/L5 and L5/S1 area.

3. The subject was asked to lay on his or her back and first MRI scan was taken in neutral position. During the first MRI scan, location of SP L4 was identified by the high signal marker (distinct bright white appearance) on MRI. This procedure was used to verify the SP L4. The SP L4 was used as the primary landmark from which all of the accelerometers were placed at their designated locations.

4. A radiologist checked first MRI scan of the subject for any pathology (required for other study not discussed here) against the inclusion, exclusion criteria. Accelerometry and second MRI scan was proceeded only for eligible subjects and those who were ineligible were excluded from the study.

5. After the first MRI scan, the eligible subject was pulled out of the MRI unit (subject remained on the MRI gantry table) and asked to lay on his/her stomach again. A trained research assistant (tenth trimester chiropractic intern) then used a grease pencil to mark the remaining levels of the SPs, SIJs and the left and right locations (mid-distance between SPs L4 and L5) where accelerometers were to be placed.

6. The Auburn University Graduate Student Preetam Bora (PB), who was running the accelerometry equipment, helped the research assistant tape accelerometers to the subject's back starting with the levels of the first (L1), second (L2), third (L3), fourth (L4), fifth (L5) SPs of the lumbar segments, and S1 and S2 (sacral tubercles). Another was placed 3 cm to the left and lastly another one 3 cm to the right mid-distance between the SPs L4 and L5 midline accelerometers (Figures 4.11-4.15).

7. Each accelerometer was specifically identified (i.e., the same

accelerometer was always used for the SP L1, the left accelerometer between SPs L4 and L5, etc.). For this, each accelerometer was specified with a unique number to make sure it was placed correctly at the desired location (Figure 4.11).

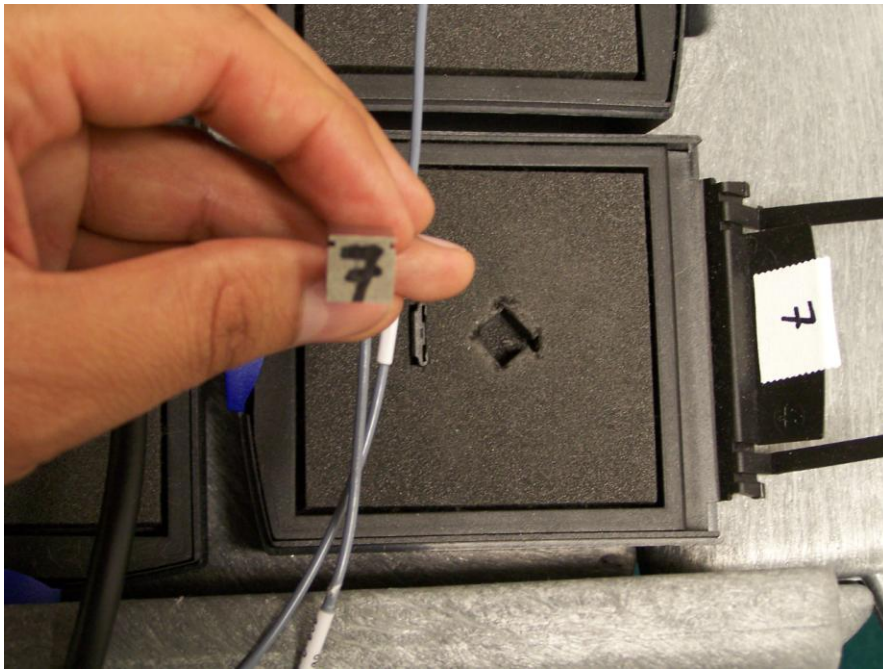


Figure 4.11: Unique number of the accelerometer marked and the same accelerometer placed in its box (notice corresponding label) for error-resistant methodology

Hooks were placed behind the cart to roll wires for each accelerometer and labeled according to their number (Figure 4.12). This reduced the amount of time required to tape the accelerometers to the subject's back and lessened the chance of a mistake. The same number was marked on the box of each accelerometer, ensuring the correct accelerometer was used for each location on the subject's back. This correct labeling also ensured the accelerometers were placed back in the correct box after data

collection (Figure 4.11, 4.13). The same number was also marked on the amplifier's input and output ports (Figure 4.14).

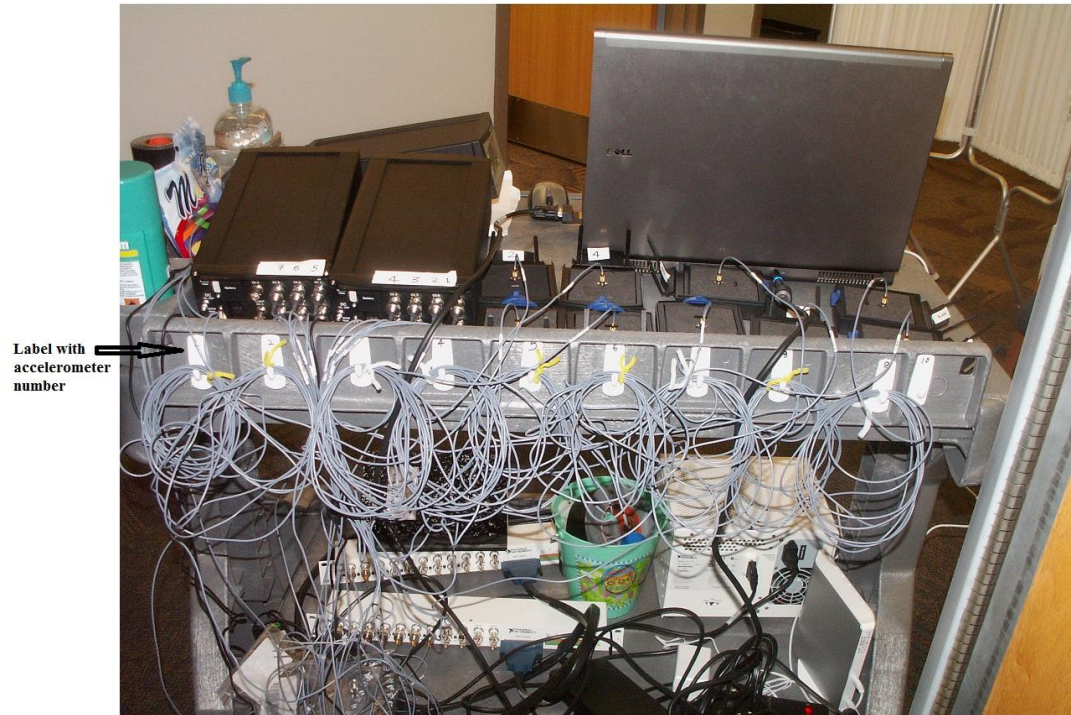


Figure 4.12: Hooks with respective accelerometer number marked on each, with properly rolled up wires attaching to corresponding accelerometers



Figure 4.13: Accelerometers placed in marked boxes

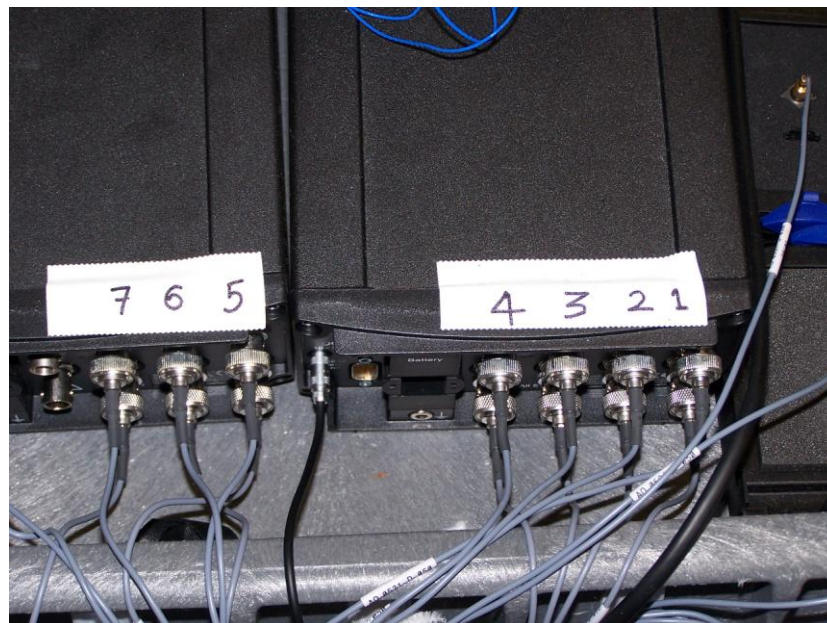


Figure 4.14: Amplifiers marked with respective accelerometer number attached to input (I/P) and output (O/P) ports

Table 4.1 was prepared and posted in the MRI room where the study was conducted. The table included the assigned number for each accelerometer and the designated location where it should be placed on the subject. This sequence was followed while taping accelerometers on the subject's back for error-proof methodology throughout the study. The table also shows the color assigned to each accelerometer on the LabVIEW program.

Table 4.1: Assigned number for each accelerometer and the designated placement location on the subject

| ACCELEROMETER | POSITION | COLOR |
|----------------------|-----------------|---------------|
| 1 | SP L1 | WHITE |
| 2 | SP L2 | RED |
| 3 | SP L3 | GREEN |
| 4 | SP L4 | LIGHT BLUE |
| 5 | SP L5 | YELLOW |
| 6 | S1 | PURPLE |
| 7 | S2 | ORANGE |
| 8 | LEFT L4L5 | DARK BLUE |
| 9 | RIGHT L4L5 | PINK |

8. After all the accelerometers were taped on the subject's back (Figure 4.15), he/she was asked to slowly lay on his/her right side slowly without cavating their back (it was assumed and found that cavitation occurs when subjects are held in side-posture positioning). At the same time, the subject was randomized into either Group 1 (subject was placed on right side and received SMT on left side) or Group 2 (subject was placed on right side and held in side-position without receiving SMT).

A unique Subject ID number was given to each subject, and data was collected and stored into computer RAM using this ID number as file name.

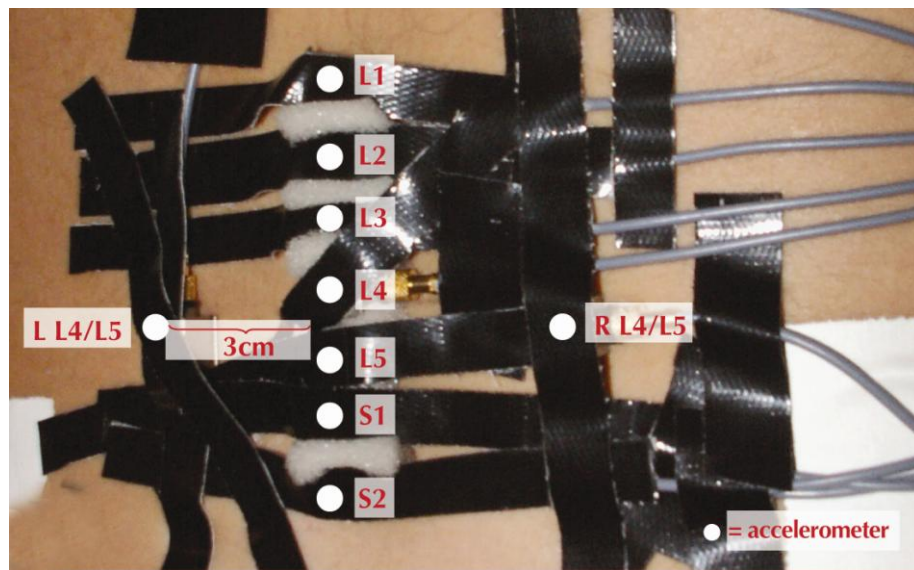


Figure 4.15: All nine accelerometers taped in the assigned position on a subject's back

9. Data was collected and stored in computer memory for analysis at a later time.

During methods testing procedures on mock subjects, we found that collecting data at the high sampling rate (320,000 Hz) from the nine accelerometers created a buffer issue in the computer, leading to a 5 sec limit on data collection. Collecting data in this time window required a great amount of understanding between the clinician (Dr. Scott Selby); PB and the trained research assistant (Adam Habeck), who was responsible for recording the time of first thrust using a stop watch.

Two different procedures were practiced and used, depending into which group the subject was randomized (see next section).

4.5 Data Acquisition for Subjects Randomized into Group 1

- Unique Subject ID number was used as file name for data collected from each subject.
- When the clinician was ready to give side-posture SMT to the subject, he would say “ready” loudly.
- PB would click on the “run” button (Shown as 1 in figure 4.16) and then click the “collect” button (Shown as 2 in figure 4.16) and say “go” simultaneously. The run button was used to see if the system was running perfectly and the actual collection of data started after clicking on the “collect” button.
- The clinician would apply two rapid thrusts using a common SMT procedure (hypothenar ilium) and then say “stop” when he was done with the SMT. PB would then click the “stop” button to stop collecting data (Shown as 3 in figure 4.16). Two thrusts were applied to increase the likelihood of producing a cavitation.

- During the procedure, the research assistant (AH) recorded time using a stop watch, beginning when PB said “go” and stopping when he saw the clinician starting to apply the first thrust on the subject’s body. This time was recorded to get the time of initiation of the first thrust of the SMT.

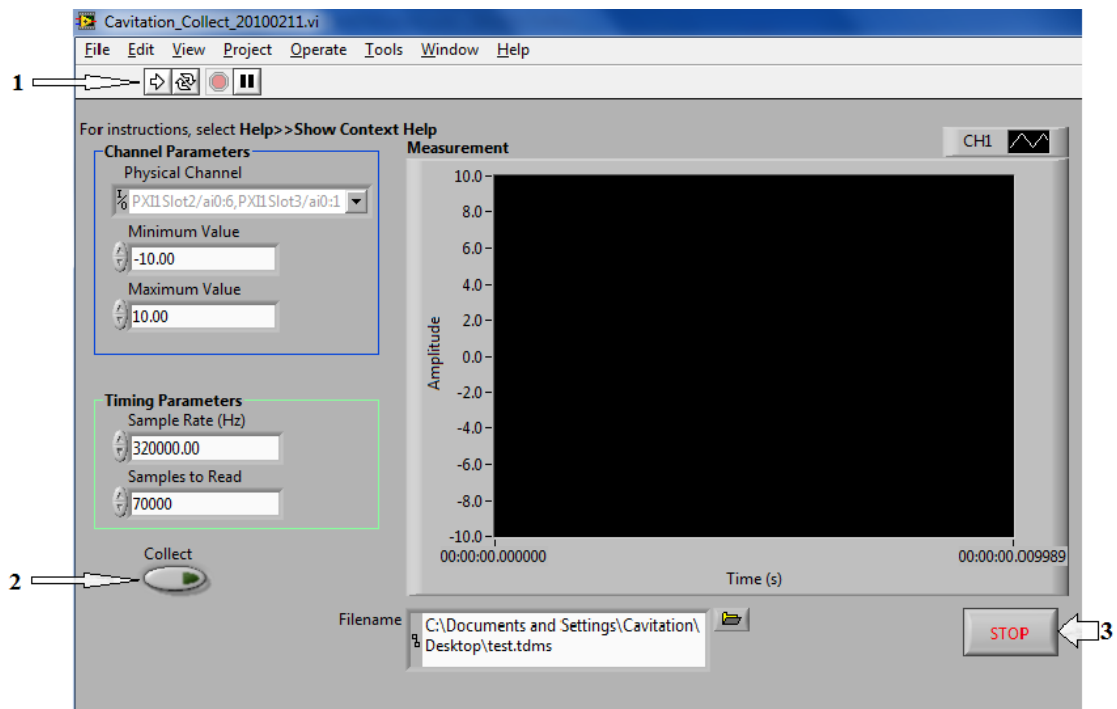


Figure 4.16: LabVIEW data acquisition window



Figure 4.17: Spinal manipulative therapy (SMT) performed while recording from accelerometers

4.6 Data Acquisition for Subjects Randomized into Group 2

Procedure was slightly modified to accommodate for the unique attributes of Group 2.

- Unique Subject ID number was used as file name for data collected from each subject.
- When the clinician was ready to hold the subject in side-posture position, he would say “ready” loudly.
- PB would click on the “run” button (Shown as 1 in figure 4.16) and then click the “collect” button (Shown as 2 in figure 4.16) and say “go” simultaneously. The

run button was used to see if the system was running perfectly and the actual collection of data started after clicking on the “collect” button.

- *The research assistant recorded time using a stop watch, beginning when PB said “go” and stopping when he saw the time of three seconds on the stop watch. He would say “stop” loudly and then PB would click on the stop button (Shown as 3 in figure 4.16) to stop collecting data.*

These procedures ensured that data collection did not exceed 5 seconds for any subject (i.e., the recording time was approximately the same for all subjects in both groups).

- When the collection of data was completed for subjects either in Group 1 or Group 2, accelerometers were removed from the subject. The research assistant asked the subject and clinician whether each heard a cavitation during side-posture positioning, first thrust, and second thrust, and their responses (blinded to each others) were recorded. The second MRI scan was taken in side-posture position with the left side up (the second MRI scan was part of the other study).

To save the subject’s time, all the accelerometers were taken outside the MRI room after they were removed from the subject’s back, so the second MRI scan could start immediately. Alcohol wipes were used to clean the accelerometers, the wires were rolled, and the accelerometers were arranged on the cart for the next subject.

4.7 Information Collected for Subject Data Base during the Accelerometry Procedures

The following points were noted in each subject's file for later references (after data analysis was completed).

- Randomization in Group 1 or Group 2
- Time
- Time of first thrust for subjects randomized into Group 1

OR

Total time of side posture positioning for subjects randomized into Group 2.
Responses to questions asked by research assistant to the subject and clinician regarding whether or not each heard a cavitation during side-posture positioning, first thrust, and second thrust.

5. DATA ANALYSIS

The accelerometry data was analyzed with a program written by Frank Balester in LabVIEW 2009 using technical support from National Instruments (Figure 5.1). This program provided the flexibility of analyzing collected data (stored in computer memory) at any time.

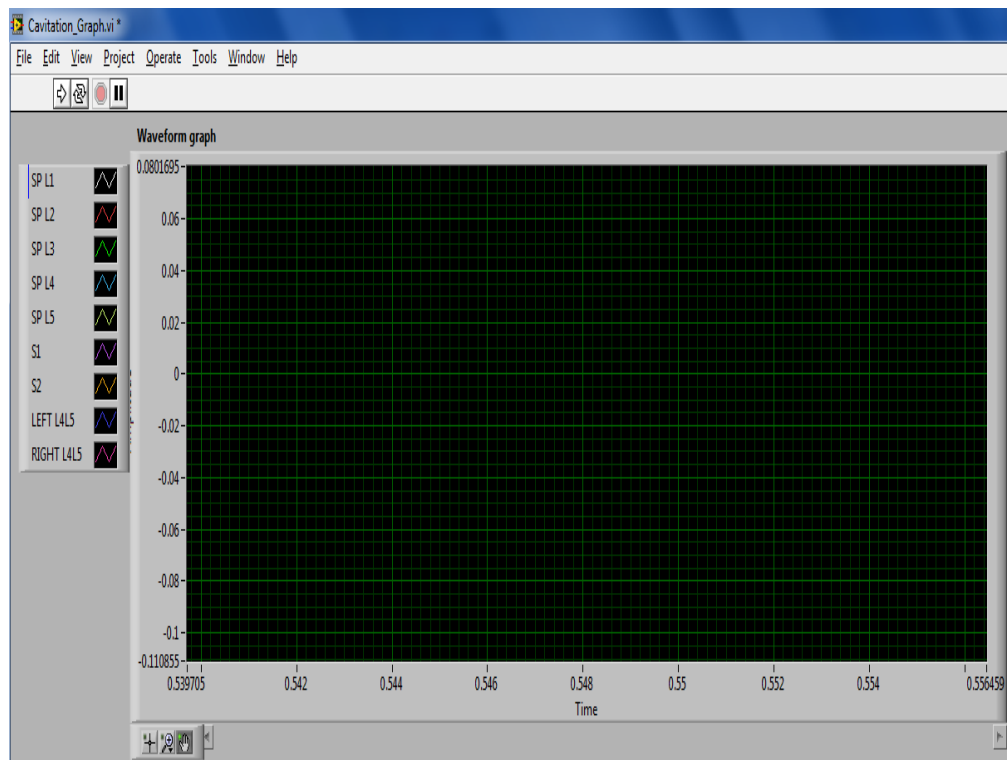


Figure 5.1: LabVIEW data analyzing window before accelerometry data was loaded

Data was stored in the computer using Subject ID numbers and opened in the data analysis program. Data was acquired from the computer RAM, and displayed for all the nine accelerometers simultaneously, but the recording of each accelerometer was identified by a unique color. The colors assigned to each of the accelerometers were shown on the color pallet to the left of the waveform graph window (Figure 5.1). This color pallet also showed the relative position of the accelerometer's placement on the subject's spine.

5.1 Training in Data Analysis

Dr. Kim Ross (an expert in accelerometry as it applies to SMT) (Ross et al., 2004) trained the Auburn University Graduate Student (PB) to detect cavitations from noise or artifacts during several visits to NUHS. Data was also collected from mock subjects (test subjects) during this time, and we analyzed the collected data together to identify cavitations.

Cavitations were recognized by their unique “non-continuous” (Macquarie University, 2008) waveform pattern (Figure 5.3B) that differentiated them from noise or artifacts created by different sources which will be discussed later in this chapter. Accelerometers responded sequentially to cavitations depending on the location of its origin (Figure 5.3C). For example, if the cavitation occurred at the Left L1/L2 Z joint (Figure 5.2); accelerometers responded or “fired” in following sequence:

- SP L1 or SP L2
- SP L2 or SP L1
- SP L3

- SP L4
- SP L5
- SP S1
- SP S2
- Left L4/L5 and Right L4/L5 accelerometer may respond or “fire” at any

instance between the accelerometers placed on SP L1 to S2. But if the cavitation occurred at the left Z joint then the Left L4/L5 accelerometer responded first, followed by the Right L4/L5 accelerometer.

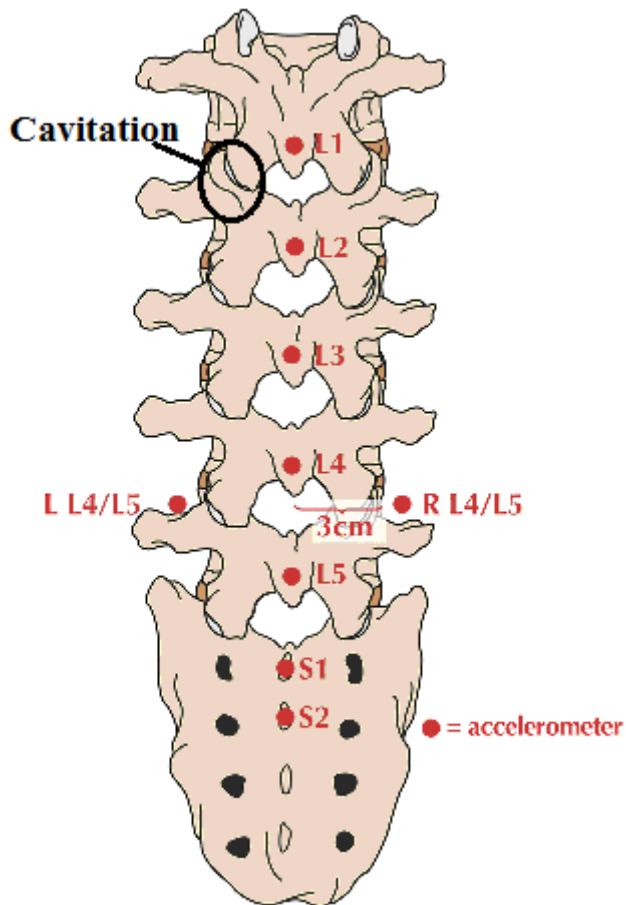
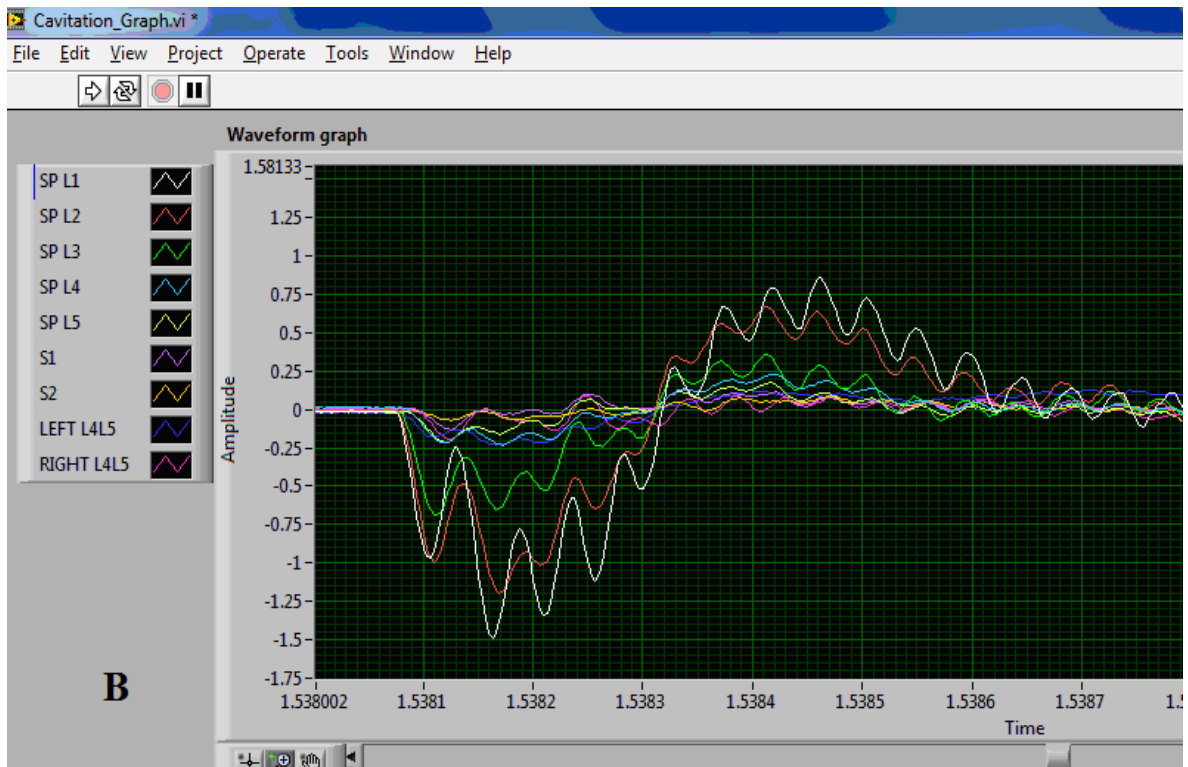
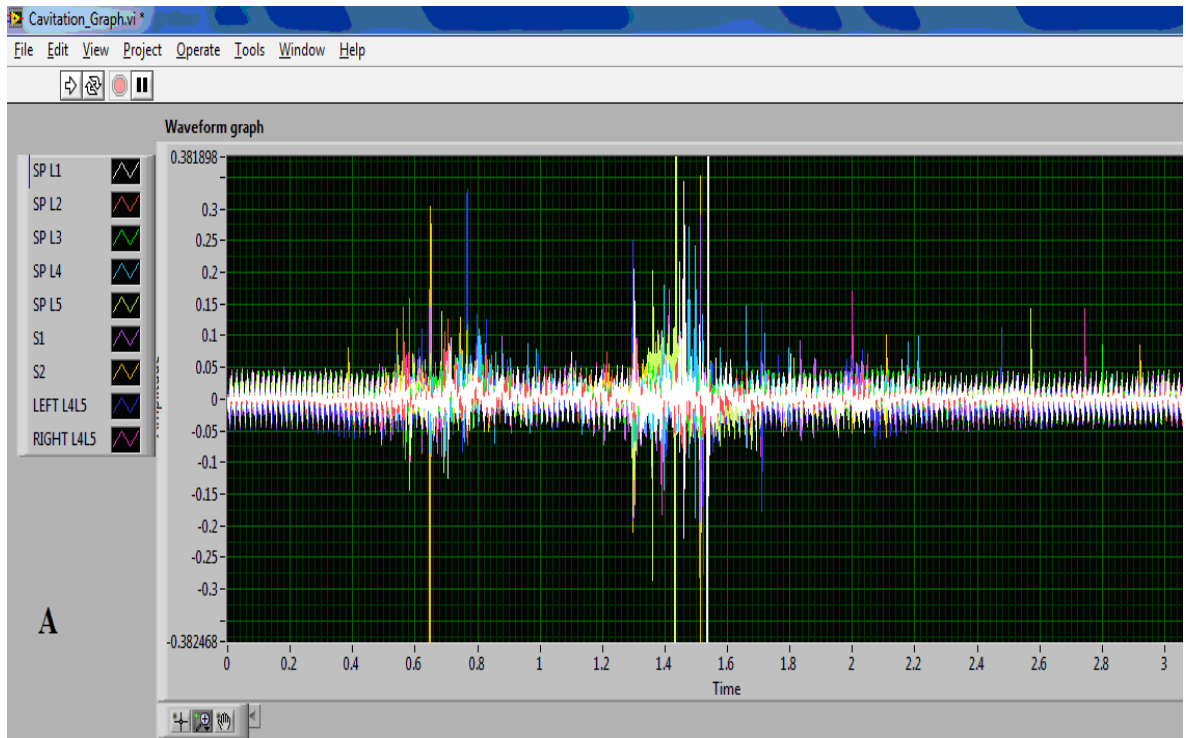


Figure 5.2: Cavitation at Left L1/L2 Z joint as demonstrated in the recordings of Figure 5.3



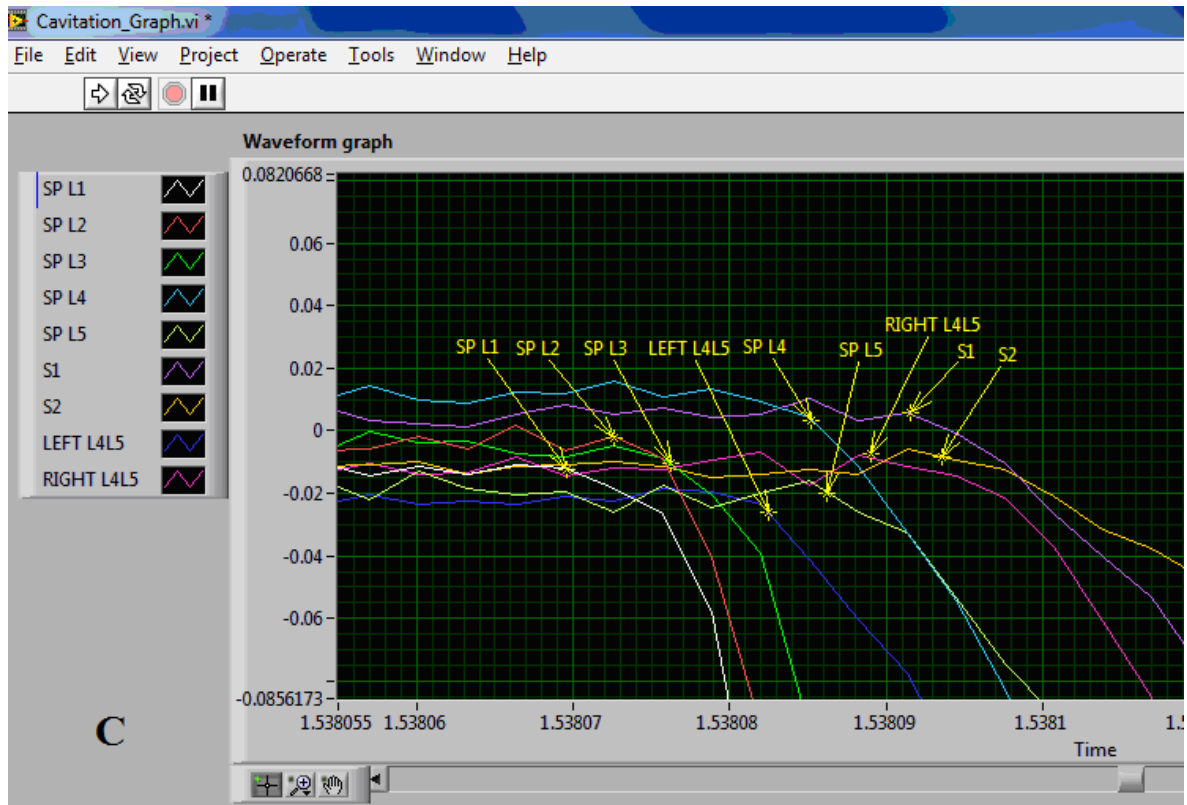


Figure 5.3: Figure A shows the complete time scale of data collected during side-posture positioning and SMT with the subject laying on their ride side. Figure B is an expanded timeline of Figure A (zoomed in during the time period of 1.5380 to 1.5387 sec), showing the unique waveform pattern of a cavitation. Figure C shows a timeline that is further expanded from Figure B (zoomed in during the time period of 1.538055 to 1.5381 sec) with accelerometers responding in the following sequence: SP L1, SP L2, SP L3, LEFT L4L5, SP L4, SP L5, RIGHT L4L5, S1 and S2. As there is only one accelerometer placed on left and right side of the SP, the sequence of responses from the accelerometers indicates that the cavitation occurred at the Left L1/L2 Z joint

Analyzing the data for the presence of cavitations (Figure 5.3B) required evaluating the entire time line from start to end (Figure 5.3A). Once a cavitation was identified, the sequential response or “firing” of the accelerometers was determined (Figure 5.3C).

5.2 Data Analysis by Two Observers

PB analyzed the data of each subject and made notes on cavitations. These notes included the time of occurrence of each cavitation, the sequential response or “firing” of accelerometers and PB’s hypothesis of the Z joint where the cavitation occurred.

Microsoft Windows Live Meeting software was used to discuss the analyzed data with Dr. Kim Ross, who was in Toronto, Canada. This software had the capability of sharing data from each other’s desktop. The program also had audio and video capability and could add as many attendees or presenters as needed (Figure 5.4).

Windows Live Meeting helped in analyzing and discussing the data with Dr. Ross, who was able to see the same screen and data PB was viewing even though they were separated by several hundred miles.

Data analyzed by PB was discussed with Dr. Ross using Microsoft Windows Live Meeting in the following way:

- Live Meeting was scheduled with Dr. Ross.
- A subject’s data was opened (using the Subject ID number) from the LabVIEW program and shared using Windows Live Meeting (Figure 5.5 B and C). Dr.

Ross was able to see the shared data from LabVIEW on his screen even though he didn't have LabVIEW installed on his computer.

- Control was handed to Dr. Ross using a tool in Windows Live Meeting, so he and PB both had full control of the shared content. This allowed Dr. Ross to zoom in, zoom out etc., and both observers were able to see each other's cursor moving and the changes (e.g. Zooming) taking place on each other's screen.
- PB would zoom in on the area where a cavitation occurred and compare opinions with Dr. Ross. Together they would decide whether or not the recordings indicated a cavitation, and if so, Z joint where the cavitation occurred.

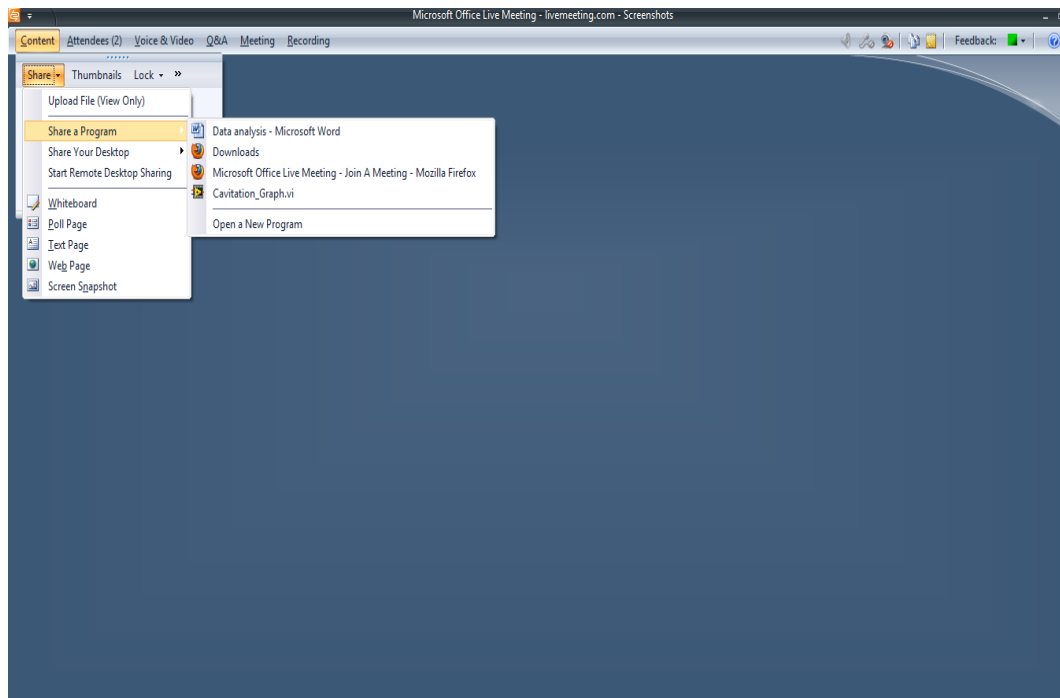


Figure 5.4: Microsoft Windows Live Meeting, showing number of persons in the meeting (2) and the content to be shared in the meeting

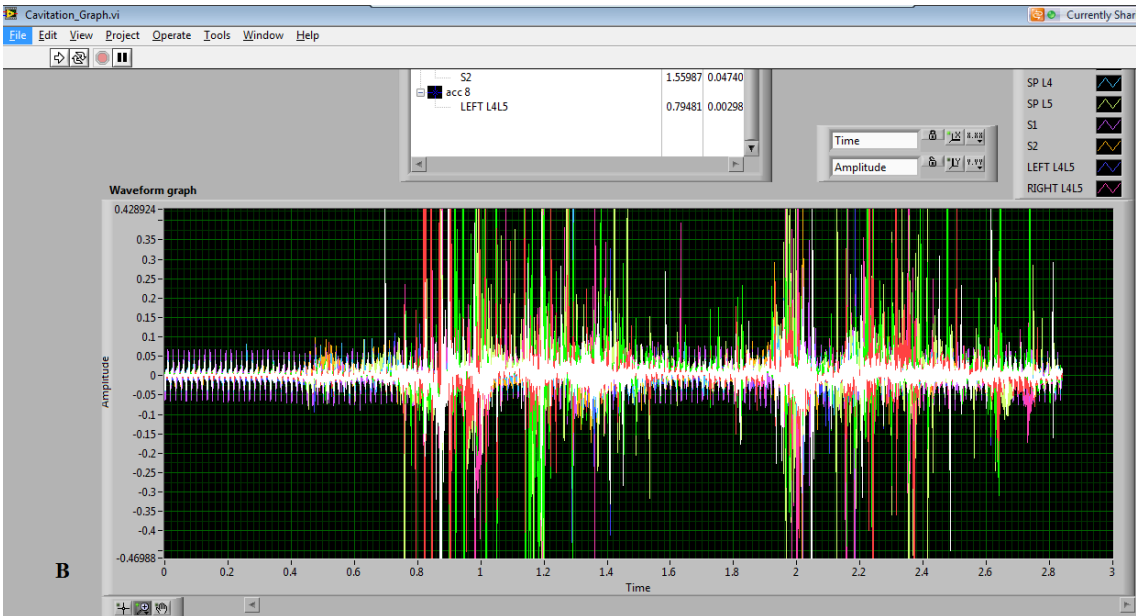
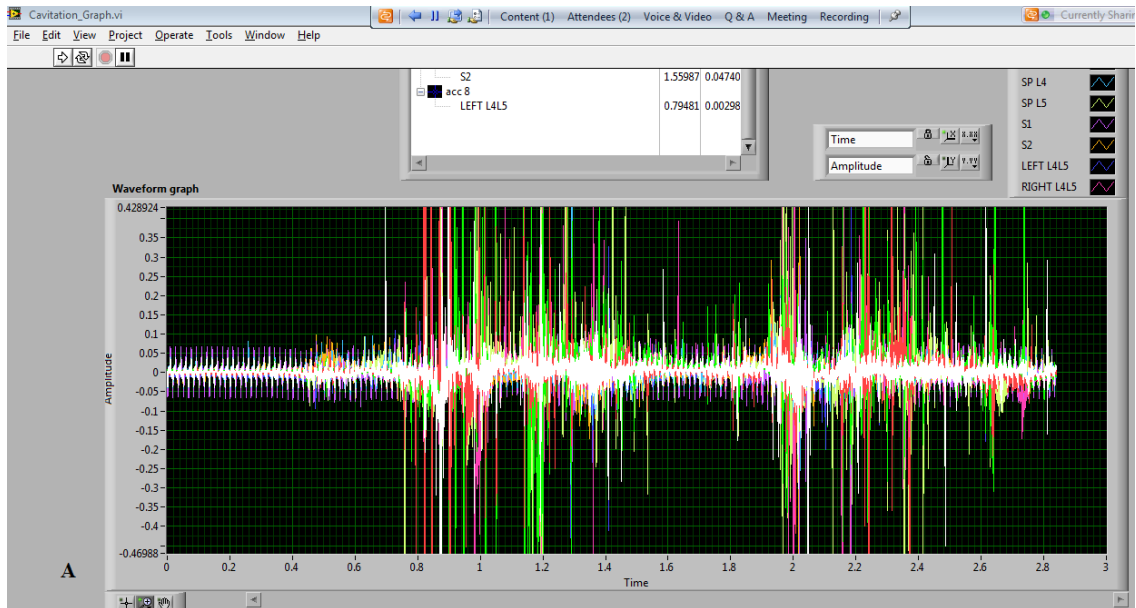


Figure 5.5: A and B shows LabVIEW data being shared using Windows Live Meeting. A show shared data viewed by PB and B shows shared data viewed by Dr. Ross in Canada.

5.3 Amplitude of Cavitation Waves

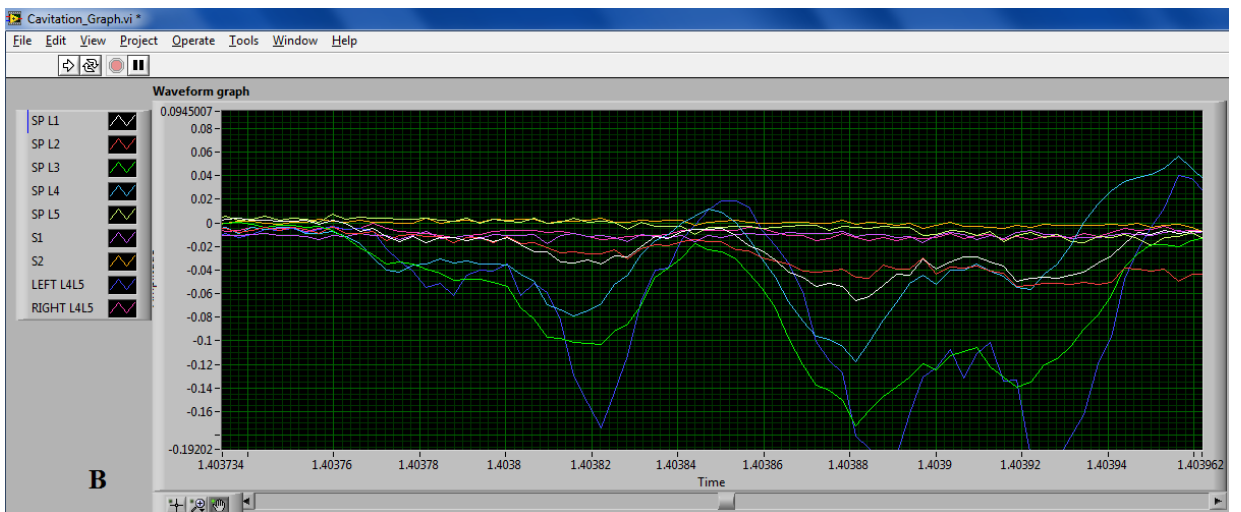
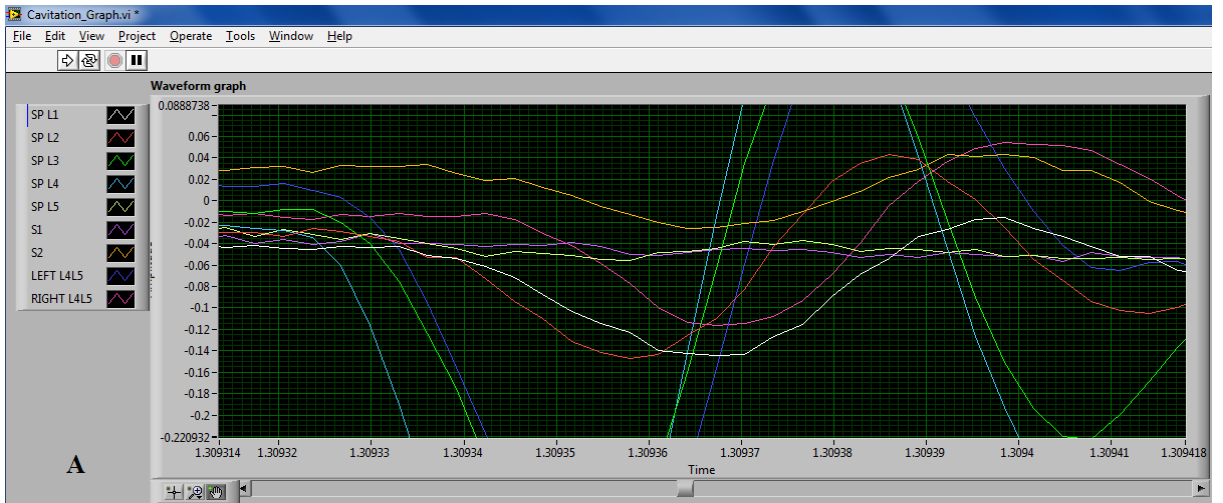
Each analyzed cavitation was categorized under one of the following amplitude levels.

1. High
2. Medium
3. Low

Confidence level of cavitation was based on the amplitude of its recorded waves. If the intensity of cavitation itself was high, then the cavitation was assumed to have created stronger vibration waves. Accelerometers responding to these stronger vibration waves created signals of larger amplitude and responded sequentially and clearly. Amplitude of the signals decreased for cavitations categorized as medium or low.

Quantifying the amplitudes of the nine accelerometers to assign an overall amplitude level was not considered feasible because of the normal variation of amplitudes in a typical recording. Consequently, the high, medium, and low amplitude levels subsequent decision made by consensus of Dr. Ross and PB. The decisions were relatively easy because the cavitations naturally divided into three general levels of amplitude as discussed below.

Figure 5.6 A, B, C shows three different Left L3L4 Z joint cavitations with high, medium, and low amplitudes, respectively (Y axis shows the signal amplitude).



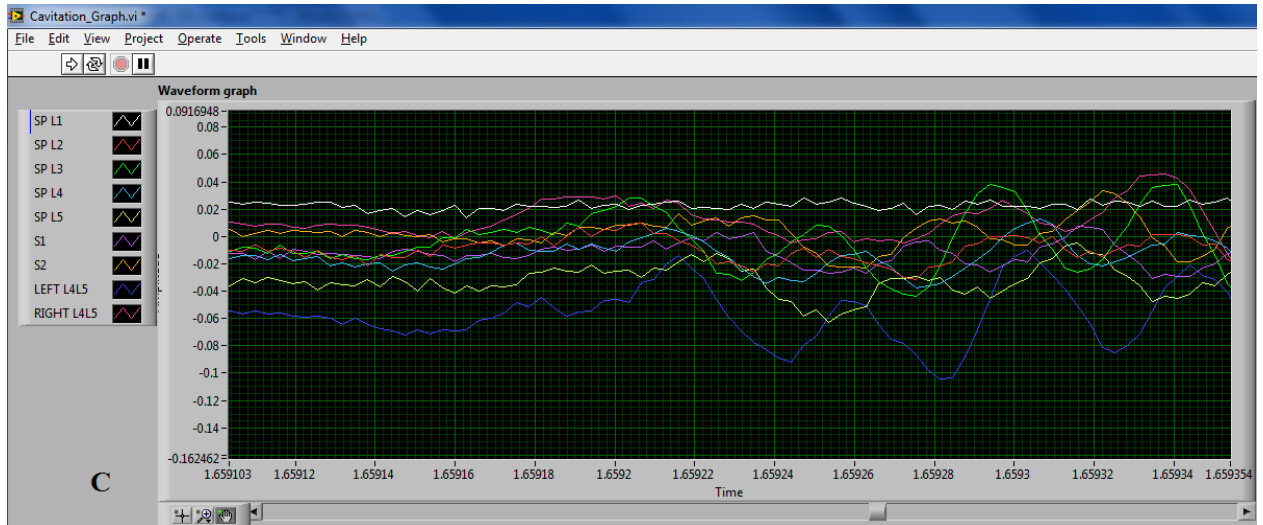


Figure 5.6: A, B and C show cavitations occurring at the Left L3/L4 Z joint from three different subjects with high, medium, and low levels of cavitation amplitude, respectively. All the graphs are shown with the same scale (Y axis, which shows amplitude of signal in voltage). Figure A shows the accelerometers responding sequentially and very clearly. But in order to get the same visualization of response from accelerometers, the scale of Figure B would have to be expanded more than Figure A and Figure C expanded more than Figure B. The program easily allowed for such expansion

5.4 Artifacts

The identification and categorization of artifacts was important to the overall success of the project. However, clearly identifying artifacts allowed for efficient analysis of cavitations, which were the primary focus of this project. Some accelerometer signals that were not caused by cavitation were known as artifacts or noise. The wave forms for artifacts were irregular with larger spikes and did not fit the smooth “non-continuous” wave form pattern found in cavitations. In addition, accelerometers responded dramatically out of sequence when recording artifacts, whereas the accelerometers responded in a very predictable pattern when recording cavitations. If only one accelerometer responded, (Figure 5.7) or if two-three responded or “fired” but in non-sequential order, (Figure 5.8) this was considered an artifact, generally caused by a clinician accidentally touching the tape or the accelerometers. Other causes of artifacts were movement in wires, excessive movement in skin and muscles, movement of the subject’s body while applying force to cavitate the joints, and the subject excessively resisting movement.

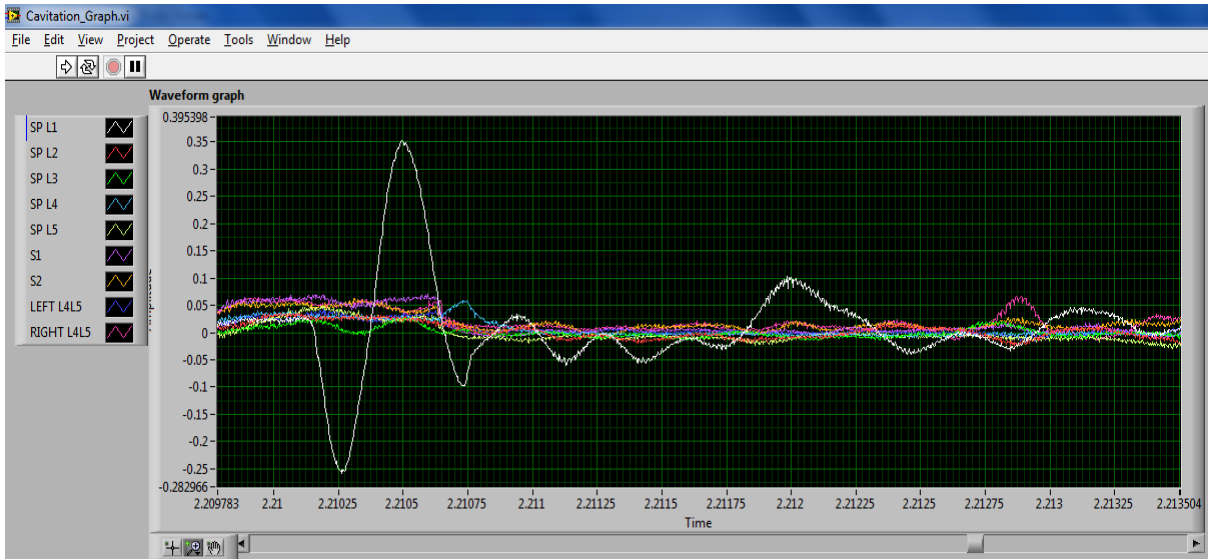


Figure 5.7: Accelerometer placed at SP L1 responding alone. This was one type of artifact identified during the study

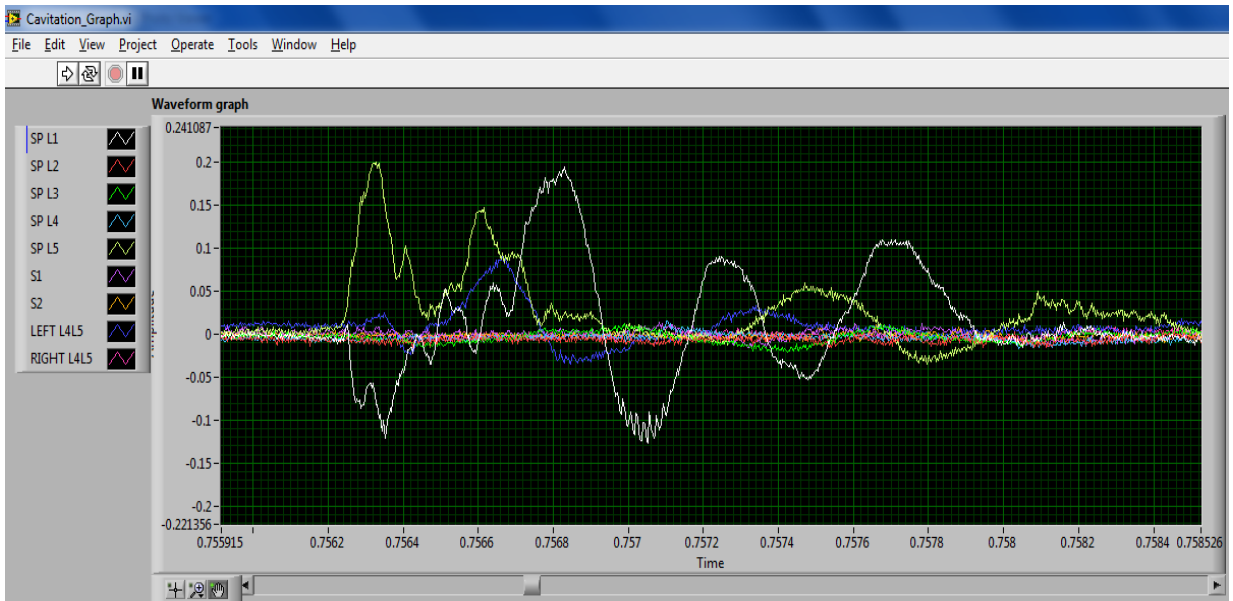


Figure 5.8: Accelerometers placed at SP L1 and SP L5 responding at the same time, with no other accelerometers responding, indicating that this was an artifact rather than a cavitation

5.5 Types of Artifacts

Based on notes taken during data acquisition and assessment for all the subjects several times, combined with the unique pattern and nature of recorded waveform signals, artifacts were identified and categorized into the following groups:

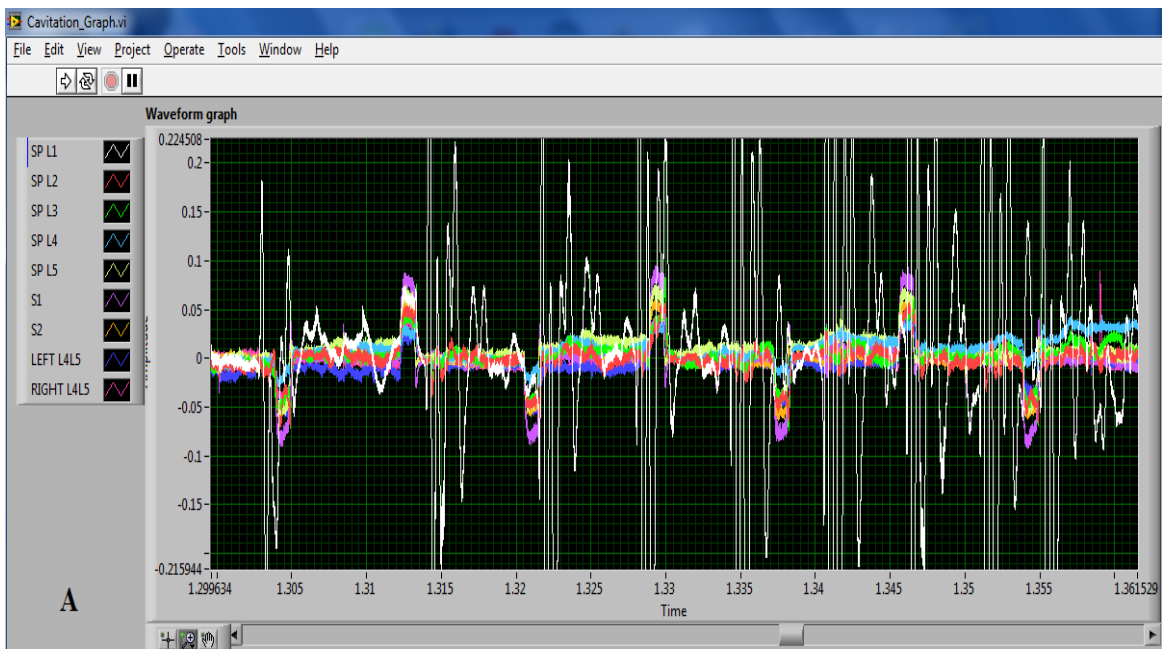
1. Flexible Spine (or loose superficial fascia) subjects
2. Hyper-muscular subjects (e.g., body builders)
3. Resisting or Not Relaxed Subjects
4. Unstable hand contact (UHC) (i.e., clinician's hand contact)
5. Miscellaneous

The following subsections discuss each type of artifact.

5.5.1 Flexible Spine (or Loose Superficial Fascia) Subjects

The spine of some subjects was very flexible and the large amount of loose adipose tissues in other subjects made their superficial tissues (superficial fascia) very flexible. Similar artifacts were found in both types of subjects. The artifacts were spikes from the superior most and inferior most accelerometers. These artifacts can be explained with an analogy of the spine as a rope. Consider a flexible rope, and suppose someone tried to twist it by holding it at both ends. Then imagine that accelerometers were taped along the rope. The accelerometers taped nearest to the ends (superior most and inferior most) (SP L1 and S2 in our case) will tend to pop off (i.e., the rope will not hold) because of the greater amount of rotation at their locations. Likewise, the accelerometers taped to SP L1 and S1, and S2 tend to partially pop off with these subjects. This tendency was enhanced by the accelerometer being placed in the spinal gutter (the grooved area created

by the muscles surrounding the SPs). This resulted in artifacts in which large spikes (Figure 5.9A) were seen throughout the time the thrust was applied. The accelerometer placed on S2 also tried to pop off, but the spikes were smaller (Figure 5.9B) than those from the SP L1 accelerometer, because there was usually more fat from the sacral area underneath, and supporting the accelerometer. Also, the majority of response was seen from these accelerometers compared with the other types of artifact (Figure 5.9C). To minimize this artifact, more tape was used to apply the accelerometers on the subject's back in side-posture position during clinical study.



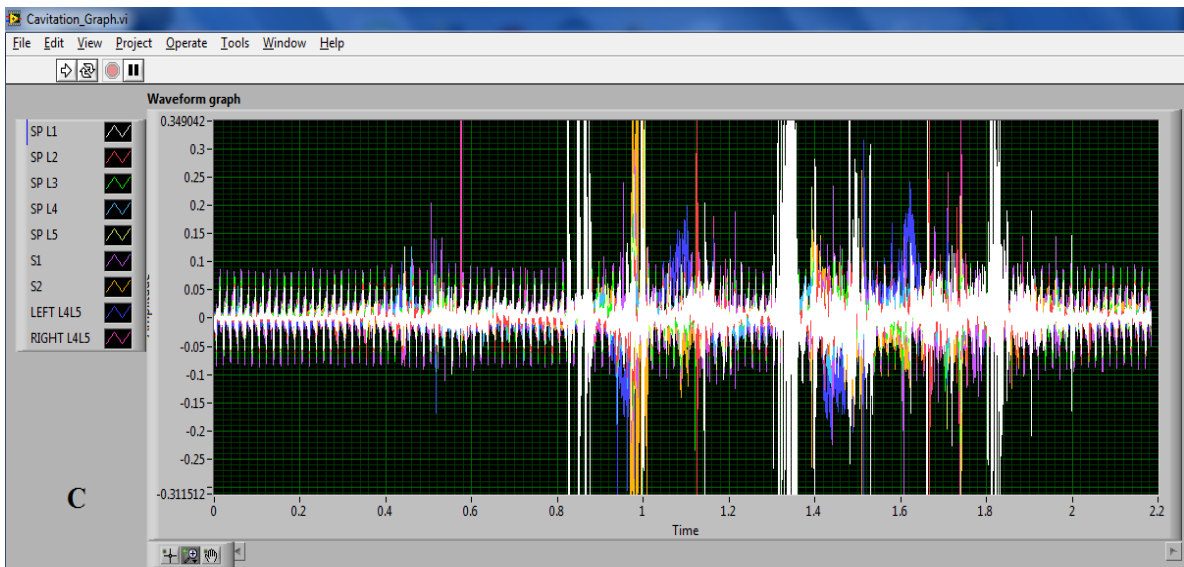
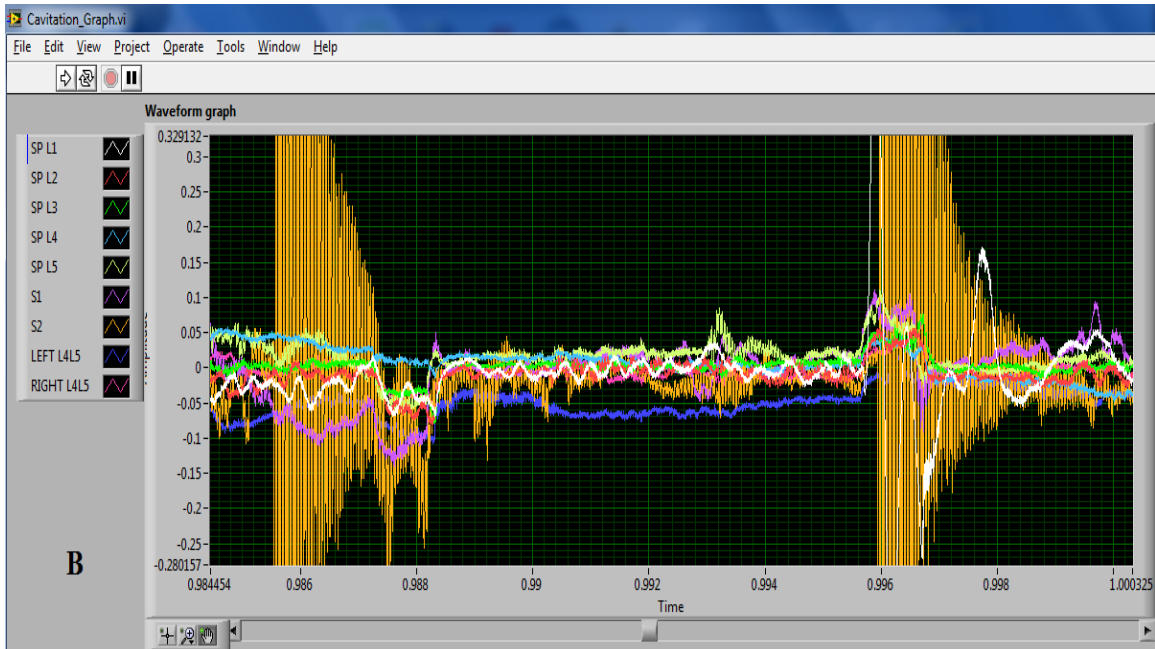


Figure 5.9: The flexible spine (or loose superficial fascia) subject artifact, A shows large spikes from the accelerometer placed at SP L1. B shows spikes from the accelerometer placed at S2 (zoomed in during the time period of 0.984454 to 0.998 sec). Note the pattern of waveform for both the accelerometers. C shows the complete time of collected data from all the accelerometers

5.5.2 Hyper-Muscular Subjects (e.g., Body Builders)

Subjects in this category were much more muscular than other subjects in the study. So the tape for all the accelerometers were placed on the larger curved area created by the paraspinal muscles. Also all the seven midline accelerometers were placed in the deeper groove area (spinal groove or gutter) created by the hypertrophic paraspinal muscles. Contrast this with subjects with a flexible spine where only accelerometers placed near to the top and bottom end (SP L1 and S2) were positioned in a deep groove area (as discussed earlier, Section 5.5.1). When a thrust or force was applied to the muscular subject's body during SMT, almost all the accelerometers responded (Figure 5.10A) because they were placed deeper in the groove area, which caused additional movement of the tape used for their application to the subject's skin. So compared to the subjects with flexible spine (or loose superficial fascia) subjects in which only accelerometers placed at SP L1 and S2 responded, in muscular subjects most of the accelerometers responded with large spikes. Cavitations could be easily distinguished from this type of artifact.

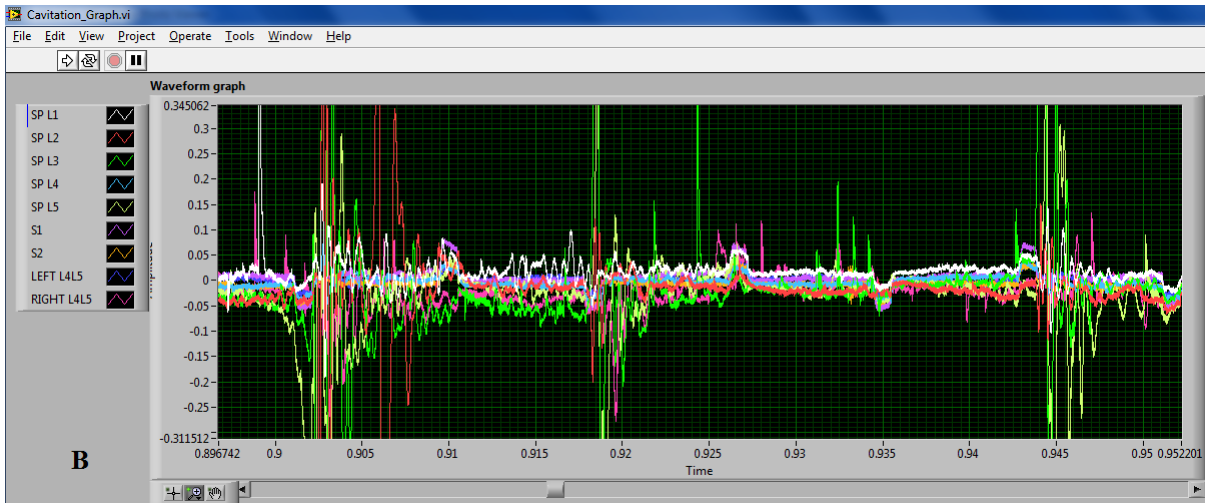
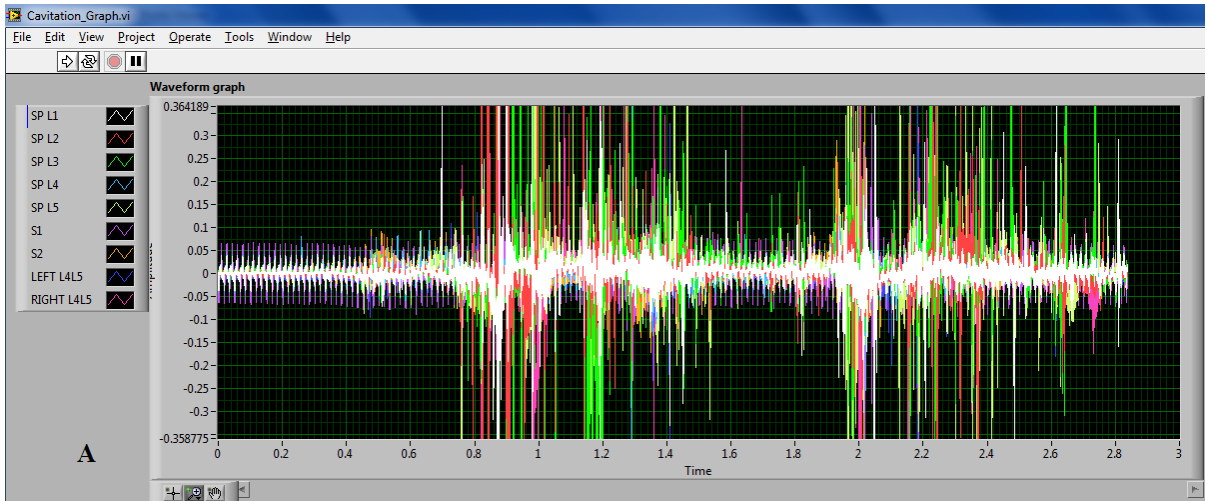


Figure 5.10: The hyper-muscular subject artifact. A shows complete time of collected data. Figure B shows most of the accelerometers responded

5.5.3 Resisting or Not Relaxed Subjects

Subjects in this category were not completely relaxed (subjects were “jittery”), causing the muscles under the treatment area, or the area where the accelerometers were placed, to be excessively stiff or contract irregularly. For example, often the clinician will ask the subject to relax. If a subject is relaxed, the clinician should be able to lift and release the subject’s arm and have it fall down freely. By contrast, if the subject tries to control the arm and prevent it from falling down, the muscles in that area will be stiff. Similarly, if the subject tries to resist the clinician at the time when data was collected during side-posture positioning and/or side-posture SMT, a force (applied by clinician) and a reaction (resisting force by the subject) will occur. This makes almost all the accelerometers placed on the subject’s skin respond because of the reacting force and stiffness or resisting contraction occurring in the subject’s muscles (Figure 5.11). This type of artifact was not compatible with assessing cavitations, and subjects with this type of artifact were not included in the study. To overcome resisting, or not-relaxed subject artifacts for the remaining part of the study, subjects were asked to relax and not to resist the study clinician.

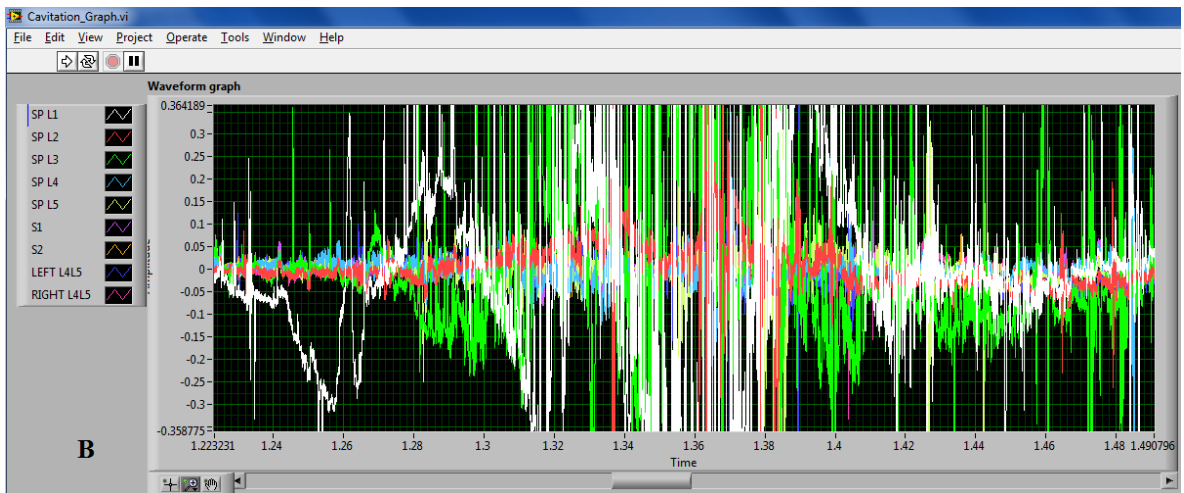
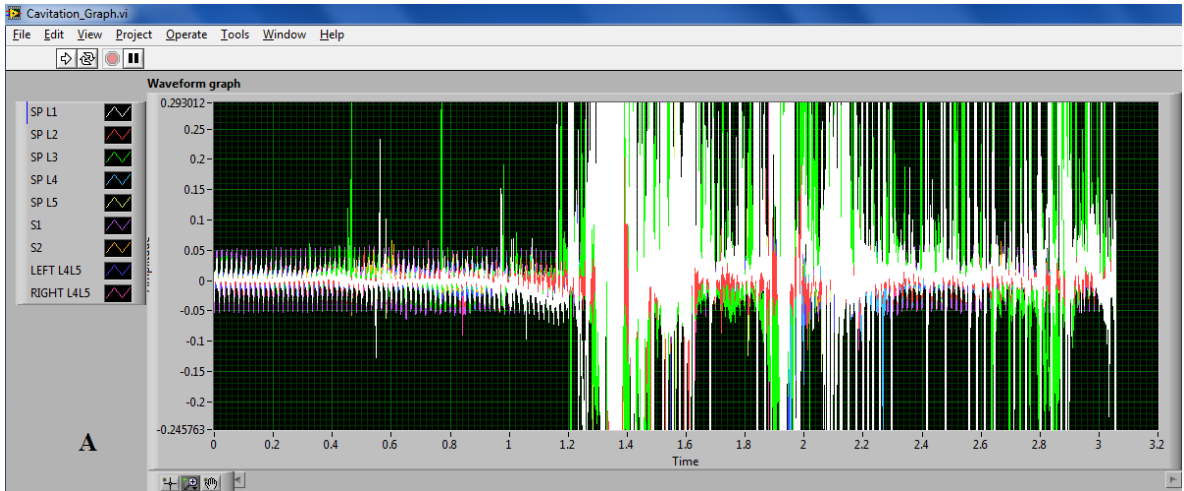


Figure 5.11: Resisting or not relaxed subject's artifact. Figure A shows complete time of collected data. Figure B shows most of the accelerometers responded and went off from the baseline because of stiffness and resistance of the not-relaxed subject (zoomed in during the time period of 1.223231 to 1.490796 sec of Figure B)

5.5.4 Unstable Hand Contact (UHC) (i.e., Clinician's Hand Contact)

Subjects in this category were wearing shorts made of a slippery type of fabric (basketball shorts made of slippery nylon or a similar fabric, for example). This could prevent the clinician from getting a firm contact on the subject's body, making it slip during application of the thrust during SMT. This could cause jiggling of the muscles and/or skin, causing most of the accelerometers to respond (Figure 5.12). This type of artifact was sometimes compatible with assessing cavitations, but other times caused too much "noise" to adequately assess the data for cavitations. This artifact was identified relatively early in the project. As a result, cotton surgical scrub pants were purchased in several sizes and all subjects were required to wear the scrubs during the experiments.

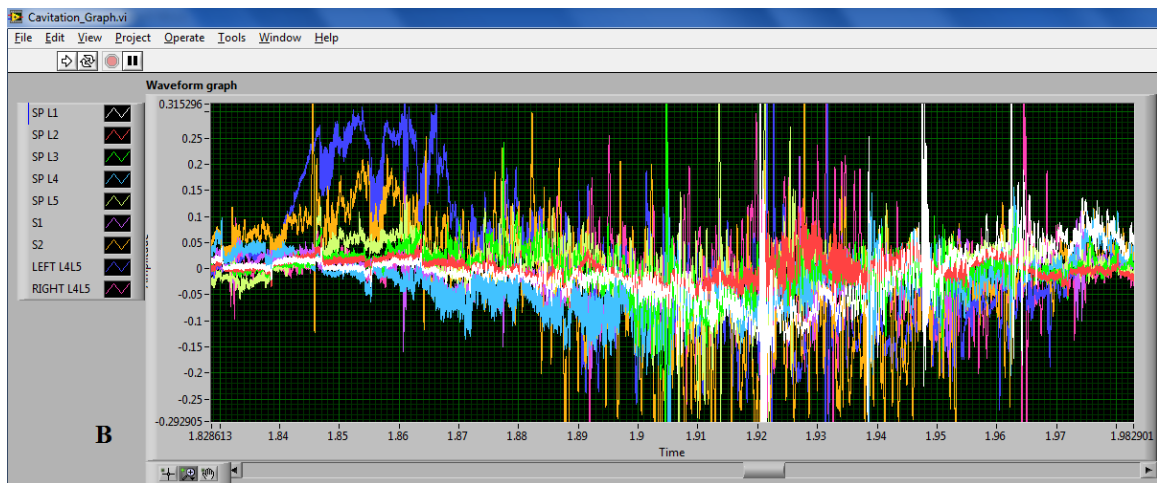
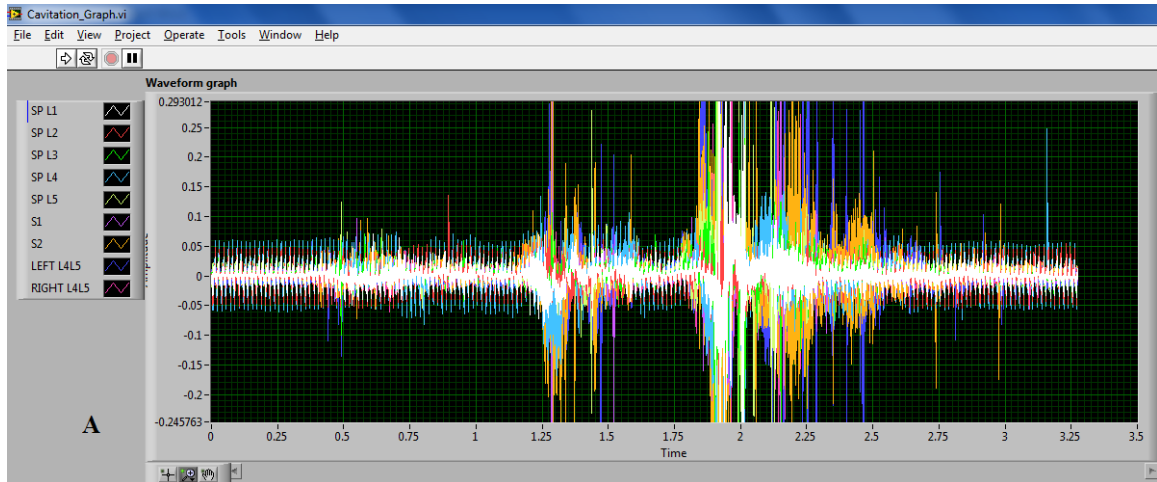


Figure 5.12: Unstable Hand Contact (UHC) (i.e., clinician’s hand contact) artifact. Figure A shows the complete time of the collected data. Figure B shows that most of the accelerometers responded simultaneously because of the jiggling of tissues due to the clinician’s unstable hand contact caused by “slippery shorts” (zoomed in during the time period of 1.828613 to 1.982901 sec of Figure A)

5.5.5 Miscellaneous

Some artifacts were generated because of reasons other than flexible spine (or loose superficial fascia) subjects, hyper-muscular subjects (e.g., body builders), resisting or not relaxed subjects, and UHC (i.e., clinician’s hand contact). These subjects were

included in the miscellaneous category. The number of artifacts in this category was less than the others. In general, these artifacts were caused by an irregular movement of the subject's body while applying SMT. Frequently; these artifacts were localized and did not interfere with the assessment of cavitations. Figure 5.13 shows an example of this type of artifact.

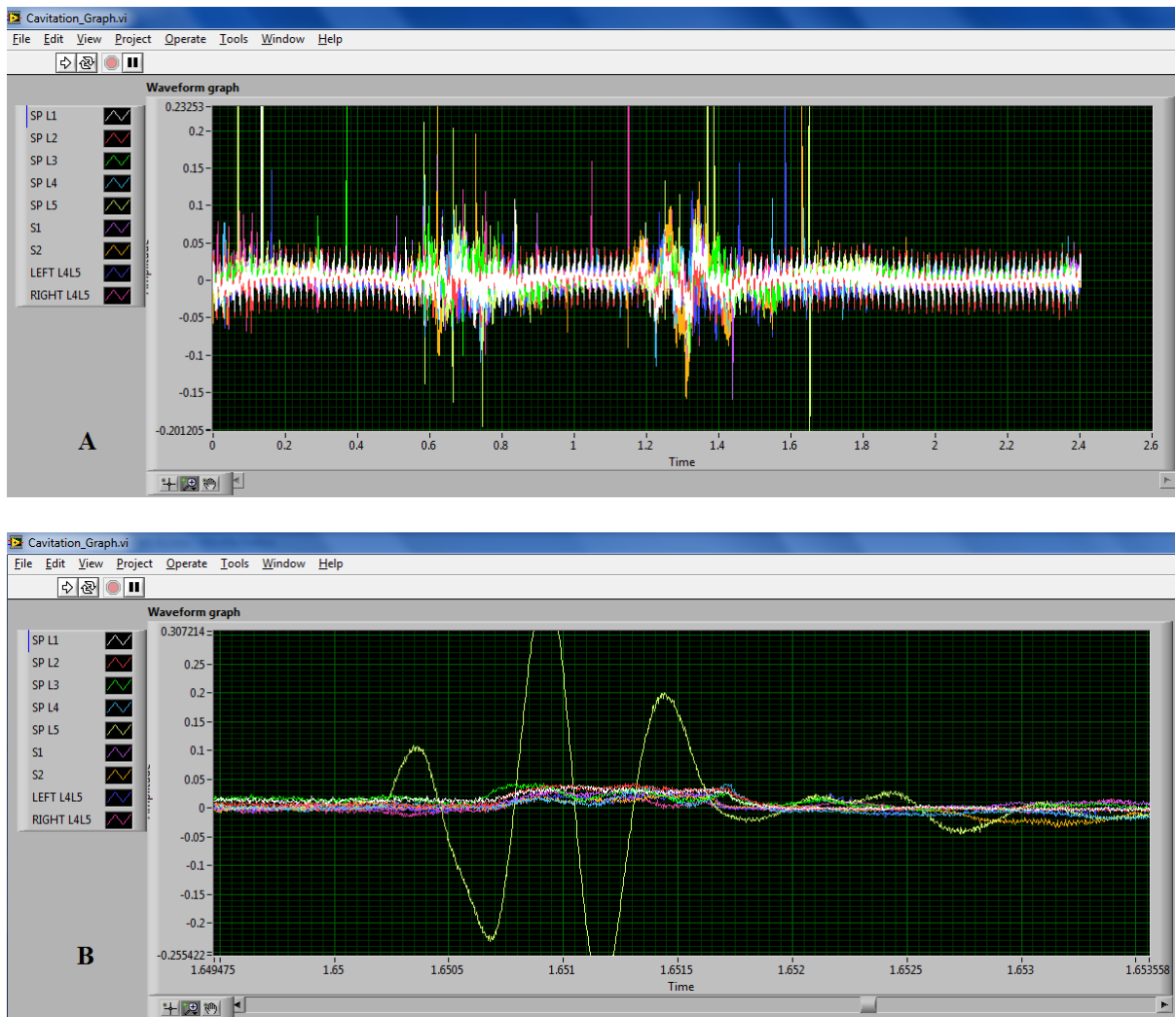


Figure 5.13: Miscellaneous artifacts. Figure A shows the complete time of the collected data. Figure B shows the accelerometer placed at SP L5 was the only one that responded during this brief time period

5.6 Data Sheets

Data sheets were made specifically for this project and were completed for all the subjects that finished the project (n=40).

Data sheets (with no personal identifiers) were prepared, burned on compact disc (CD) and printed to keep electronic and hard copy records of all the subjects included in the study. This also helped the “clinical studies office” to efficiently enter the analyzed data into their system. Two separate binders of printed data sheets were made, one for keeping record of all the subjects with the Principal Investigator (Dr. Gregory Cramer) and the other for Clinical Studies Office. Dr. Cramer also kept the CDs in a locked fireproof safe in his office.

The following information was noted for inclusion on the data sheet for each subject (identified by ID number during the accelerometry appointment):

- Subject ID number
- Date
- Time
- Time of first thrust for subjects randomized into Group 1

OR

Time of side-posture positioning for subjects randomized into Group 2.

- Questions asked by research assistant to the subject and clinician about report of cavitation heard and/or felt during side-posture positioning, first thrust, and second thrust were recorded in the subject’s research file and entered into the master data base.

The following information was noted on the data sheet for each subject during data analysis:

Assessment of accelerometer data: Artifacts

- Sequential number (by time) for each artifact.
- Time of occurrence of each artifact.
- Comments/ notes on each artifact.

Assessment of accelerometer data: Cavitations

- Sequential number (by time) for each cavitation.
- Time of occurrence of each cavitation.
- Comments/notes on each cavitation.

Amplitude of cavitations

- Sequential number for each cavitation.
- Order of response of accelerometers placed on SP.
- Order of response of accelerometers placed Left and Right of L4/L5 interspinous space.

interspinous space.

- Level (grade: high, medium, low) of amplitude for each cavitation.

Comments/ notes for each subject.

Printouts were made of the oscilloscope recordings for each artifact, cavitation, and any other finding of interest were attached in sequential order as entered into the data

sheet and were a part of the electronic and hard copy record for each subject. These supporting documents for each subject ID number were printed on a white background using the “Export Simplified Image” option in LabVIEW. This procedure produced a clear image.

Examples of data sheets and supporting documents (printouts of artifacts and cavitations) for representative subject from Group 1 and Group 2 are included in the following pages.

DATA SHEET (from subject in Group 1 with many artifacts)

SUBJECT ID: 0035

DATE: 03/11/2010

**TIME OF FIRST
THRUST (SEC)**

TIME OF MRI: 8:45am

**Or
POSITIONING TIME: 1.19**

**Table 5.1: ASSESSMENT OF GROUP 1 ACCELEROMETER DATA--
ARTIFACTS**

| ARTIFACTS | TIME (SEC) | COMMENTS/ NOTES |
|------------------|-----------------------|--|
| 1) | 0.7936 | Only L2 responded, which shows no sign of cavitation (Miscellaneous). |
| 2) | 0.9 | L5, L3 and then L2 responded but L4 hasn't responded after L5, hence it's not a cavitation (Hyper-muscular subject). |
| 3) | 0.9436 | L3, L2 and then L5 responded but L4 haven't responded before L5, hence it's not a cavitation (Hyper-muscular subject). |
| 4) | 1.0148 | L3, L2 and then L5 responded but L4 hasn't responded before L5, hence it's not a cavitation (Hyper-muscular subject). |
| 5) | 1.1395 | L3, L2 and then L5 responded but L4 hasn't responded before L5, hence it's not a cavitation (Hyper-muscular subject). |
| 6) | 1.408356 | Only L1 and Left L4L5 responded, which shows no sign of cavitation (Miscellaneous). |
| 7) | 1.8262 | L5 and then L3 responded but L4 haven't responded after L5, hence it's not a cavitation (Miscellaneous). |
| 8) | 2.0478 | Only L1 and Left L4L5 responded, which shows no sign of cavitation (Miscellaneous). |

**Table 5.2: ASSESSMENT OF GROUP 1 ACCELEROMETER DATA—
CAVITATIONS**

| CAVITATIONS | TIME | NOTES |
|-------------|---------|-----------|
| 1) | 1.2923 | Left L4L3 |
| 2) | 1.35686 | Left L4L3 |

Table 5.3: AMPLITUDE OF CAVITATIONS GROUP 1

| CAVITATION NO | ORDER OF SP FIRING | ORDER (LEFT OR RIGHT) | LEVEL OF CONFIDENCE |
|---------------|--|-------------------------|---------------------|
| 1) | L4 L3 L5 L2 S1 S2 L1 | Left L4L5 Right L4L5 | High |
| 2) | L3 L4 L2 L5 L1 | Left L4L5 Right L4L5 | High |

COMMENTS/NOTES:

This subject was in group one (adjustment) and interestingly two cavitations were recorded at the same joint.

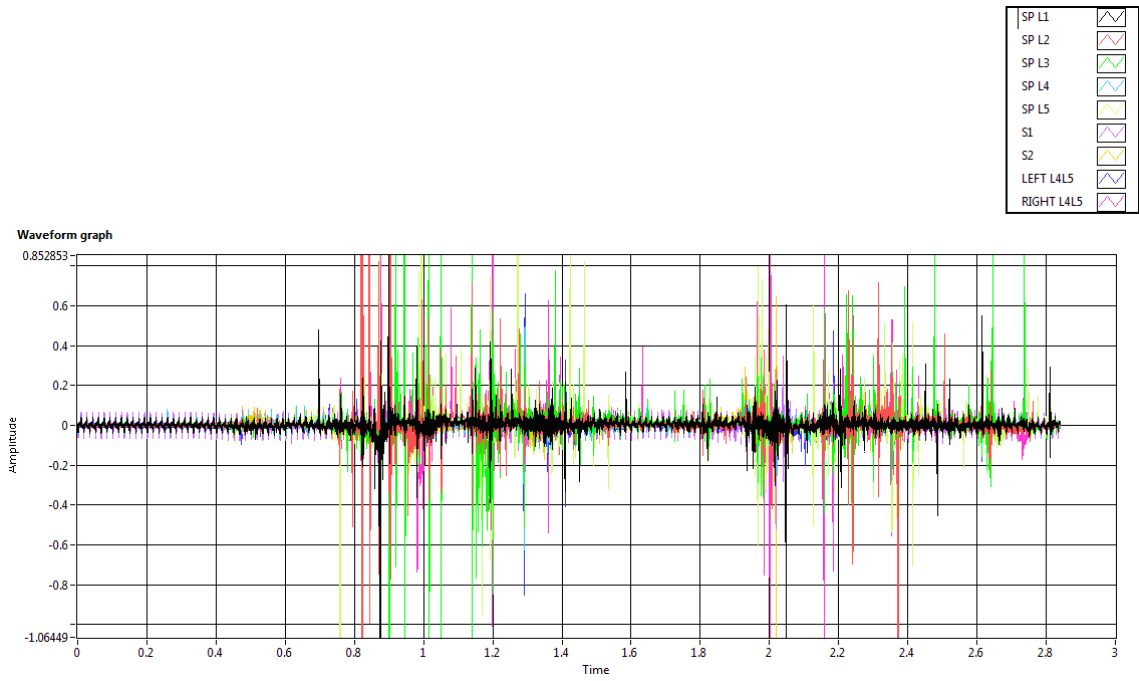


Figure: 5.14: Complete time cycle for subject ID 0035

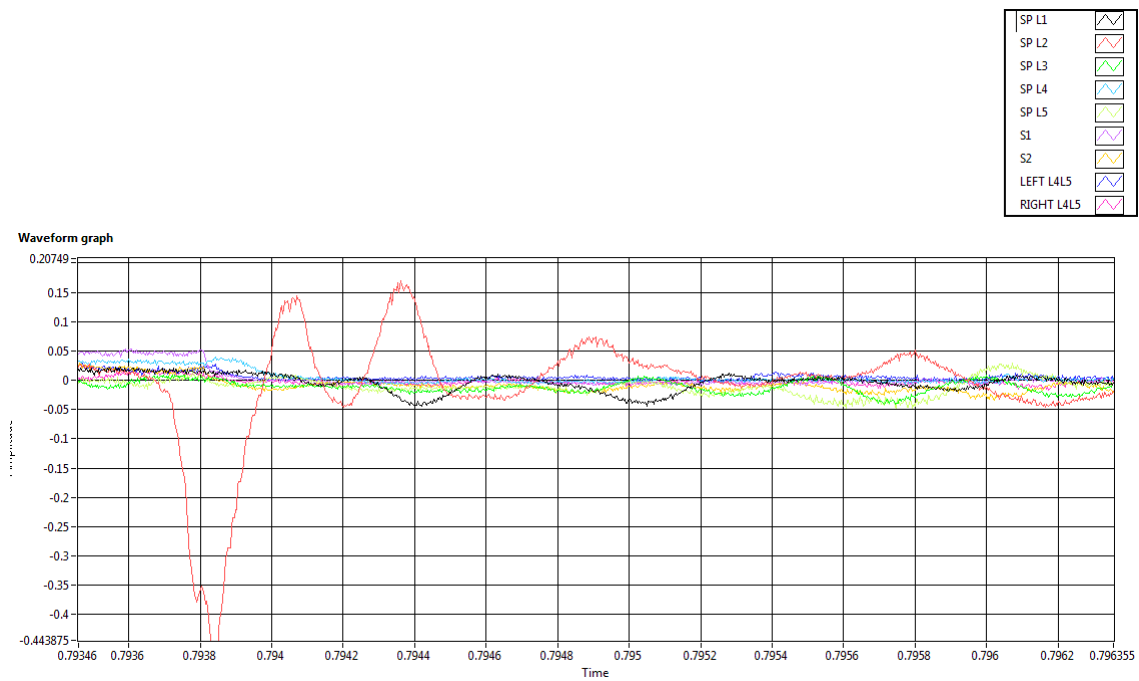


Figure 5.15: Artifact 1 for subject ID 0035

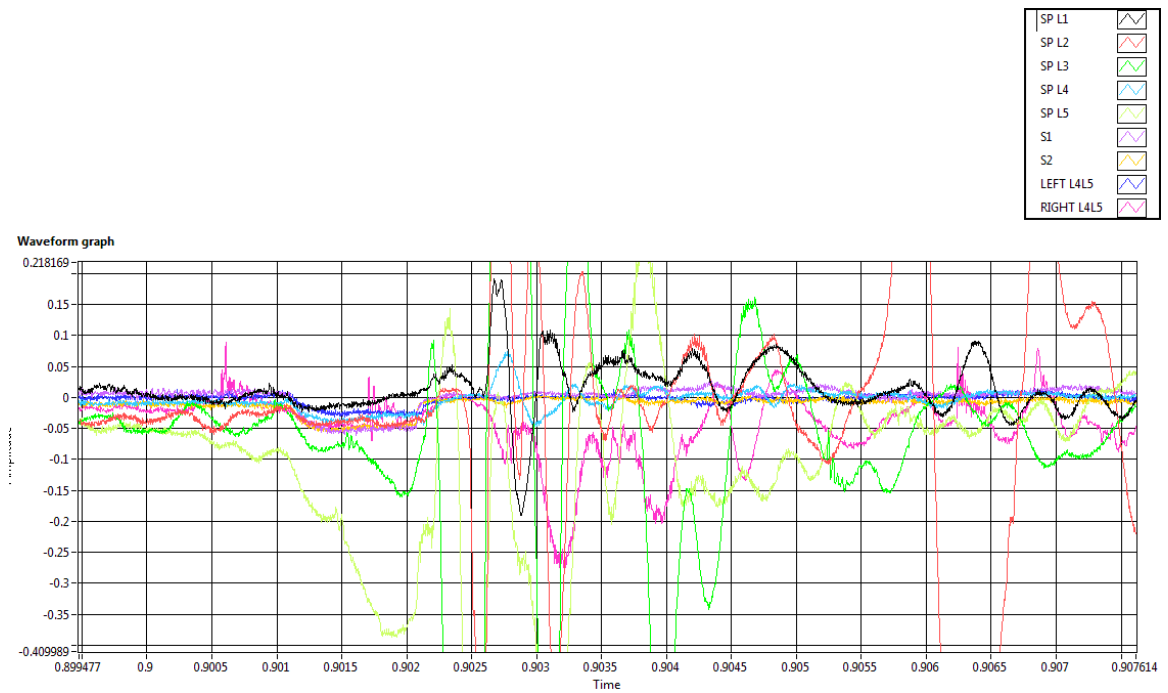


Figure 5.16: Artifact 2 for subject ID 0035

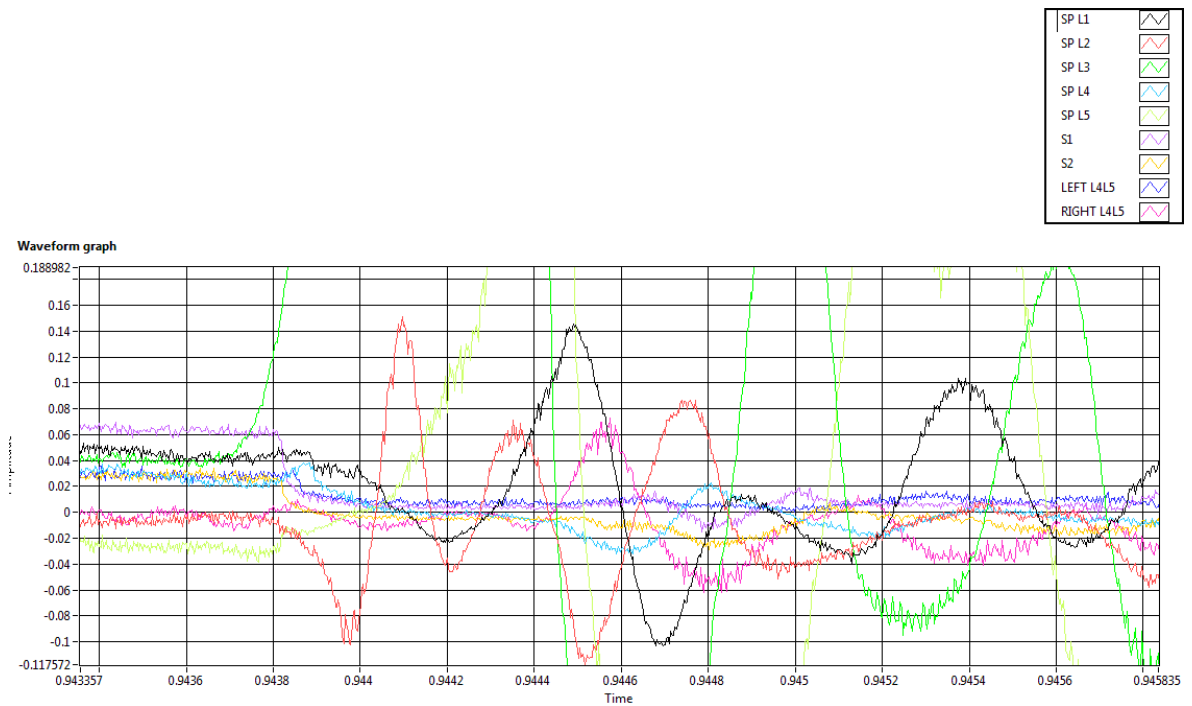


Figure 5.17: Artifact 3 for subject ID 0035

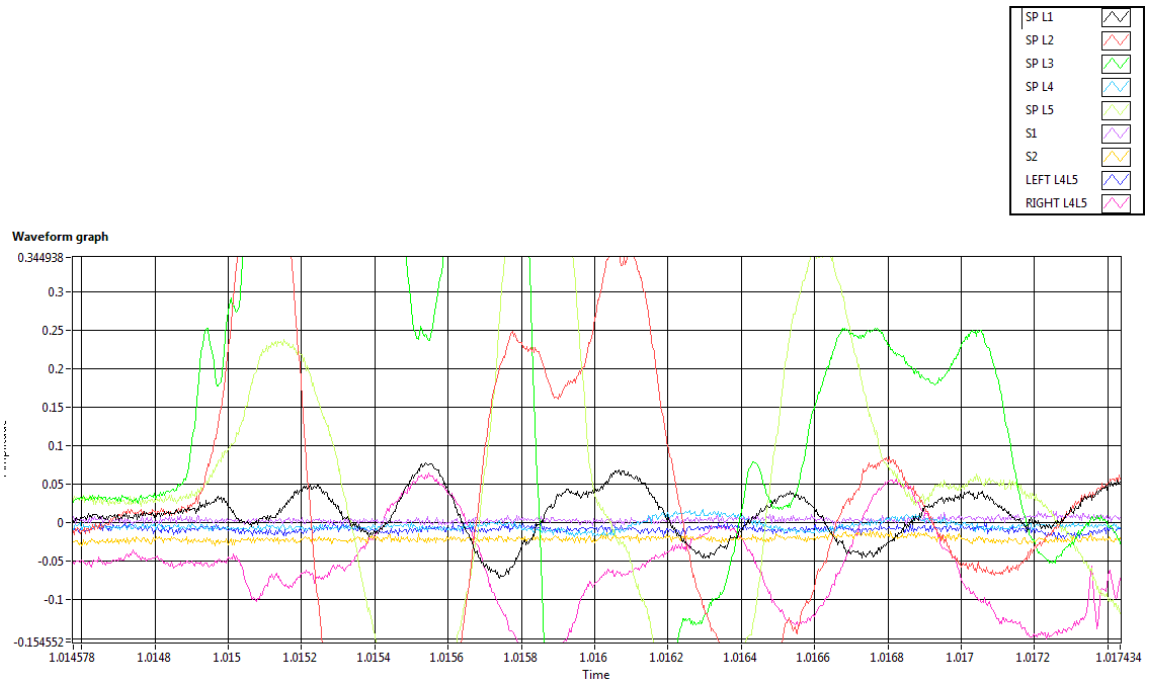


Figure 5.18: Artifact 4 for subject ID 0035

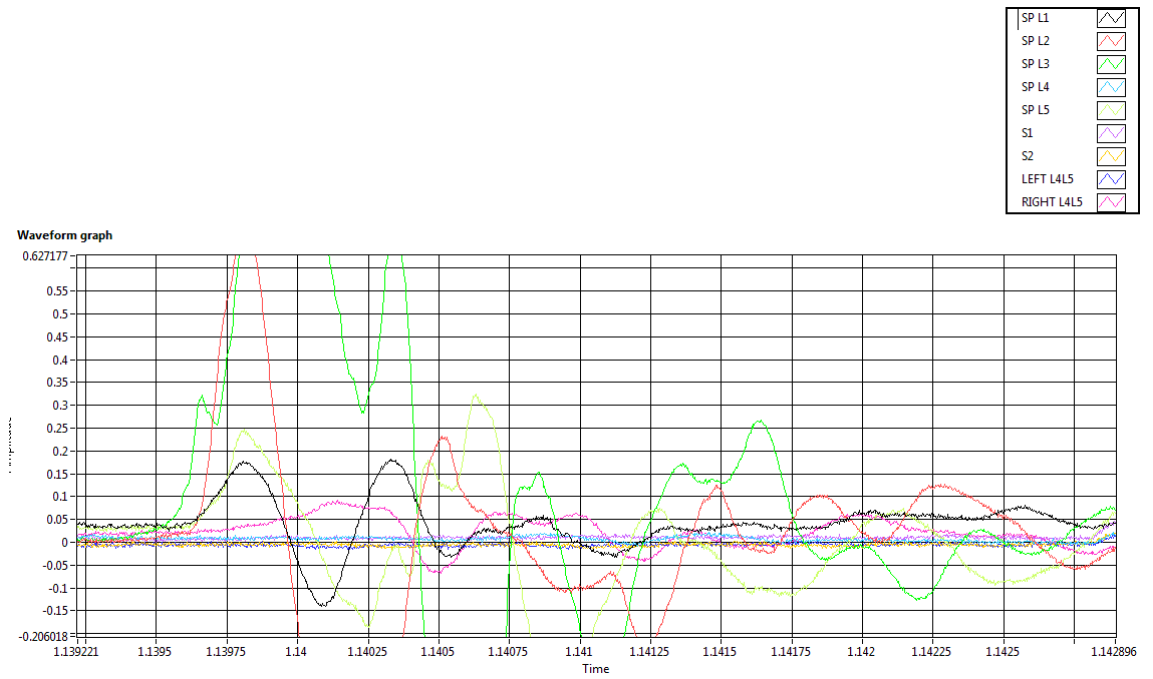


Figure 5.19: Artifact 5 for subject ID 0035

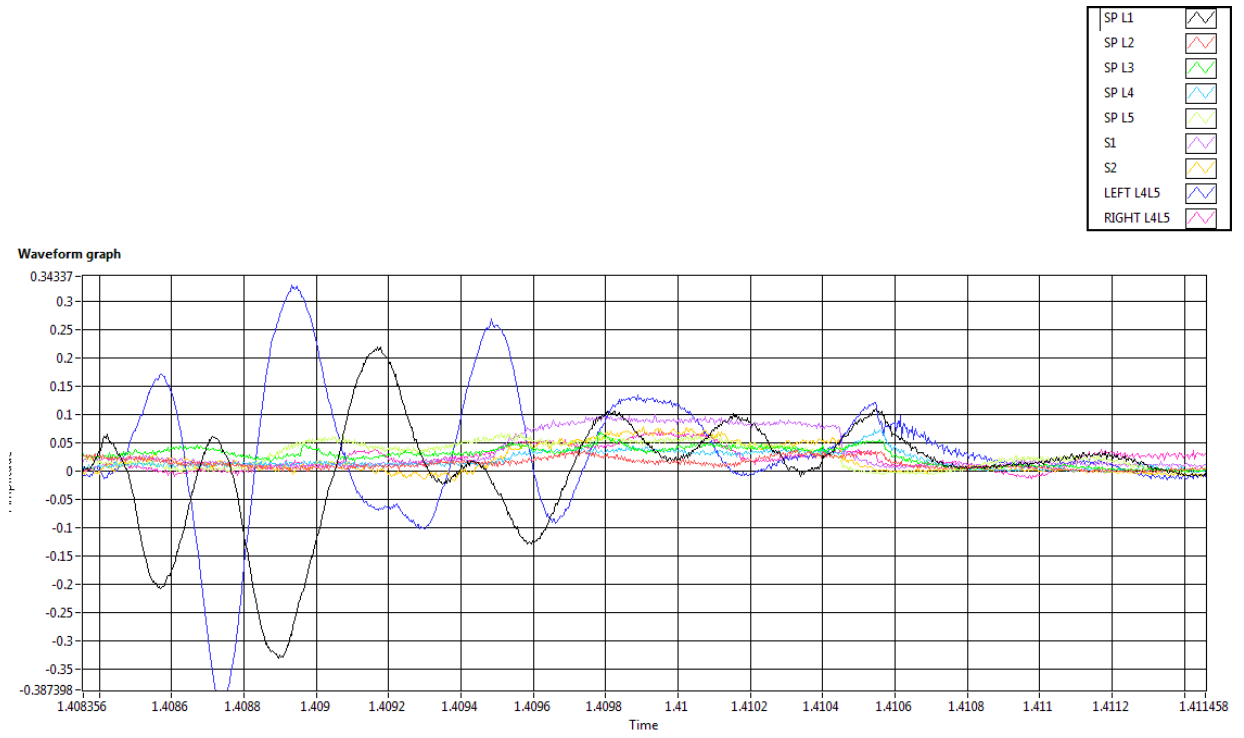


Figure 5.20: Artifact 6 for subject ID 0035

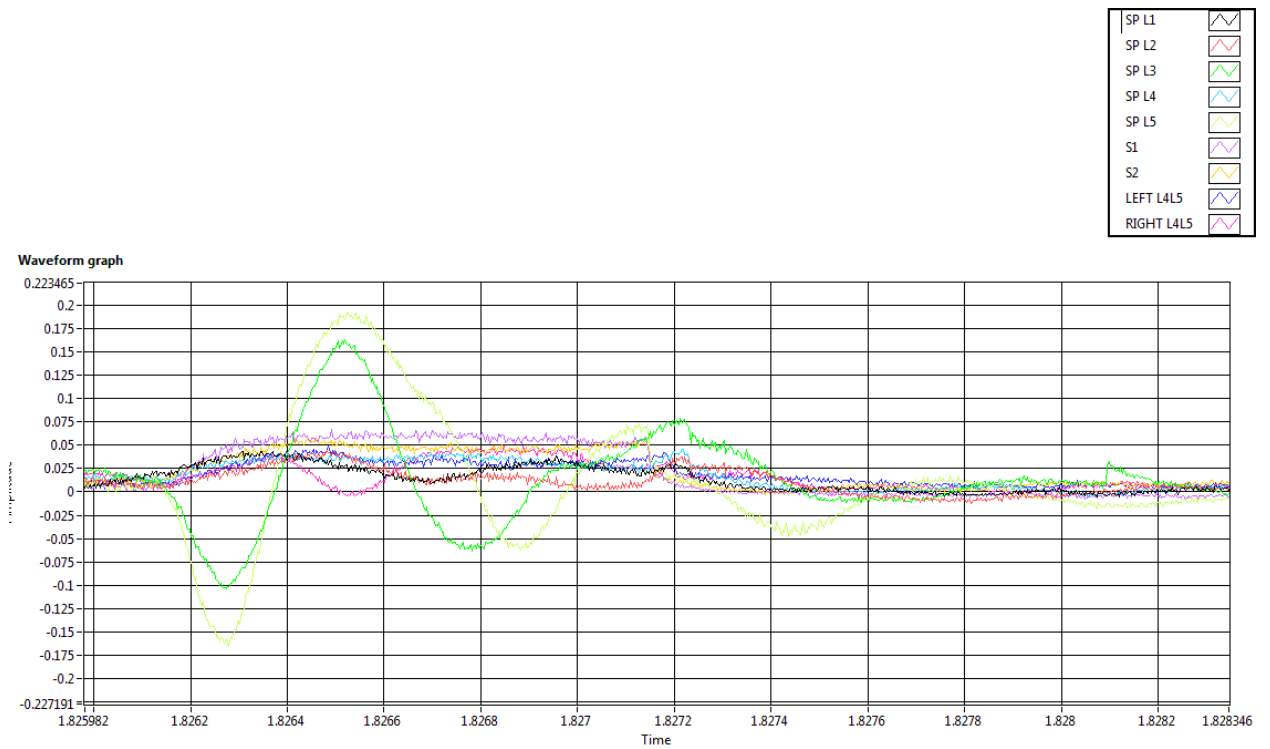


Figure 5.21: Artifact 7 for subject ID 0035

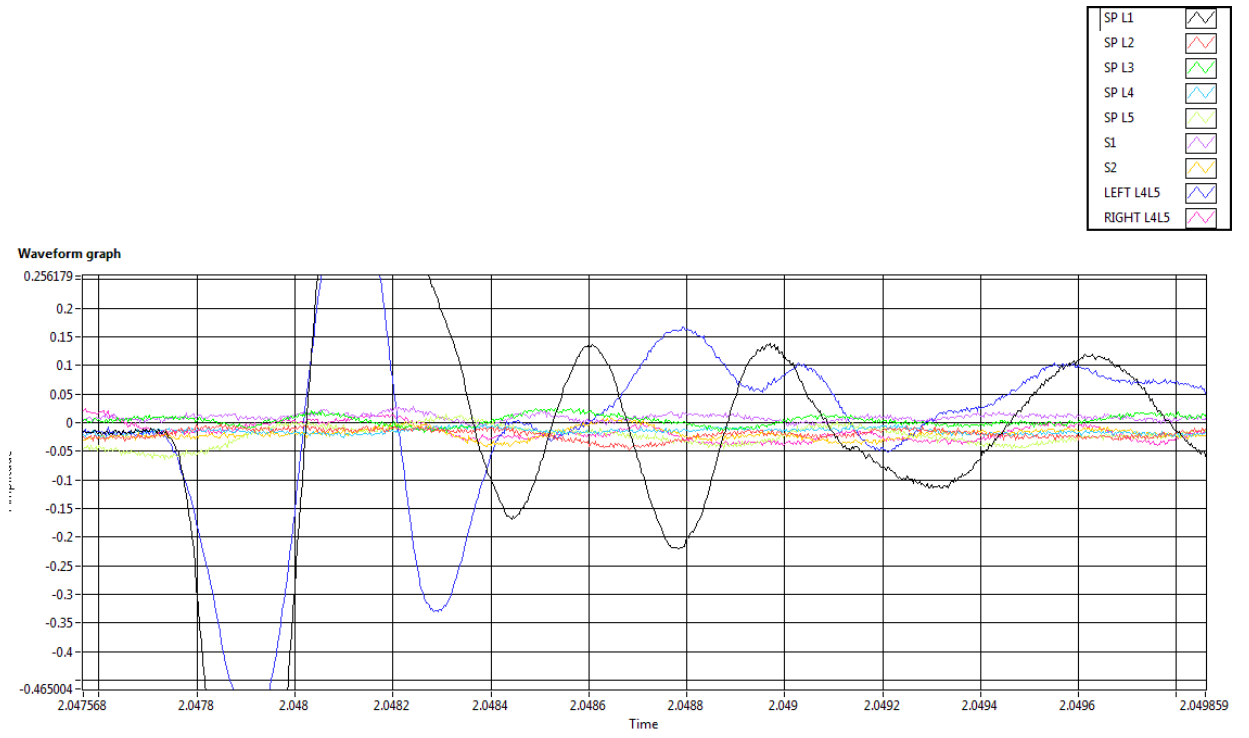


Figure 5.22: Artifact 8 for subject ID 0035

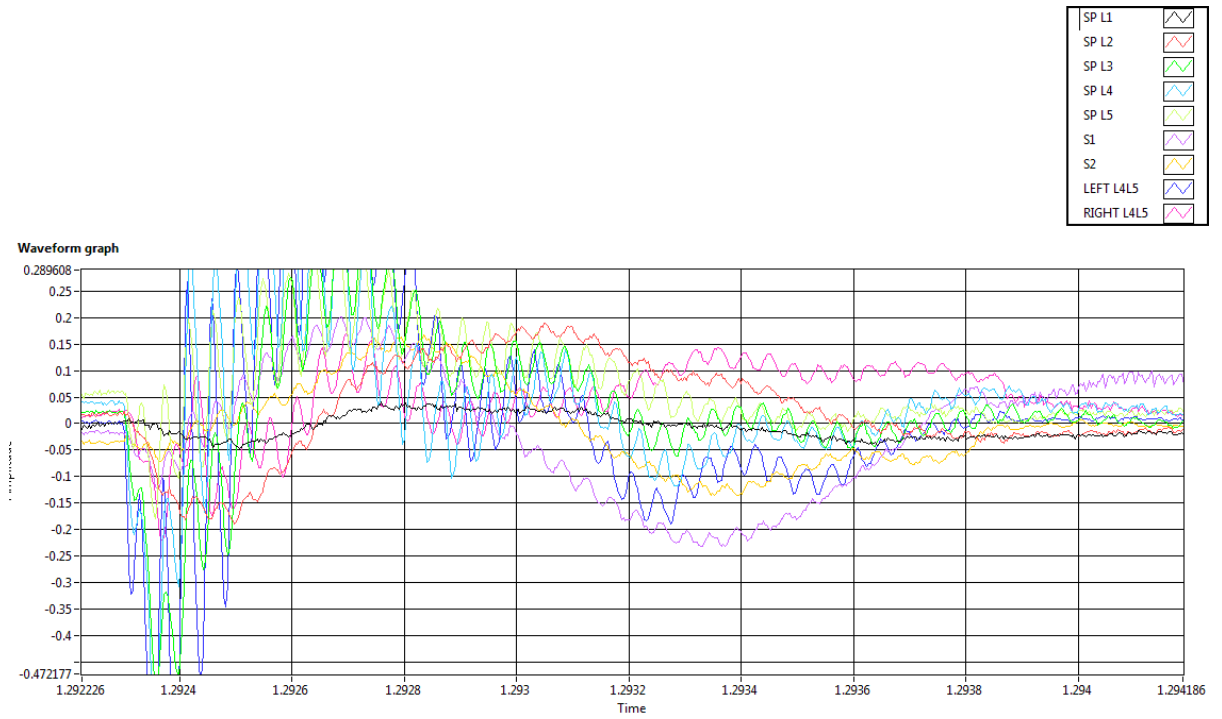


Figure 5.23: Cavitation 1 full view for subject ID 0035

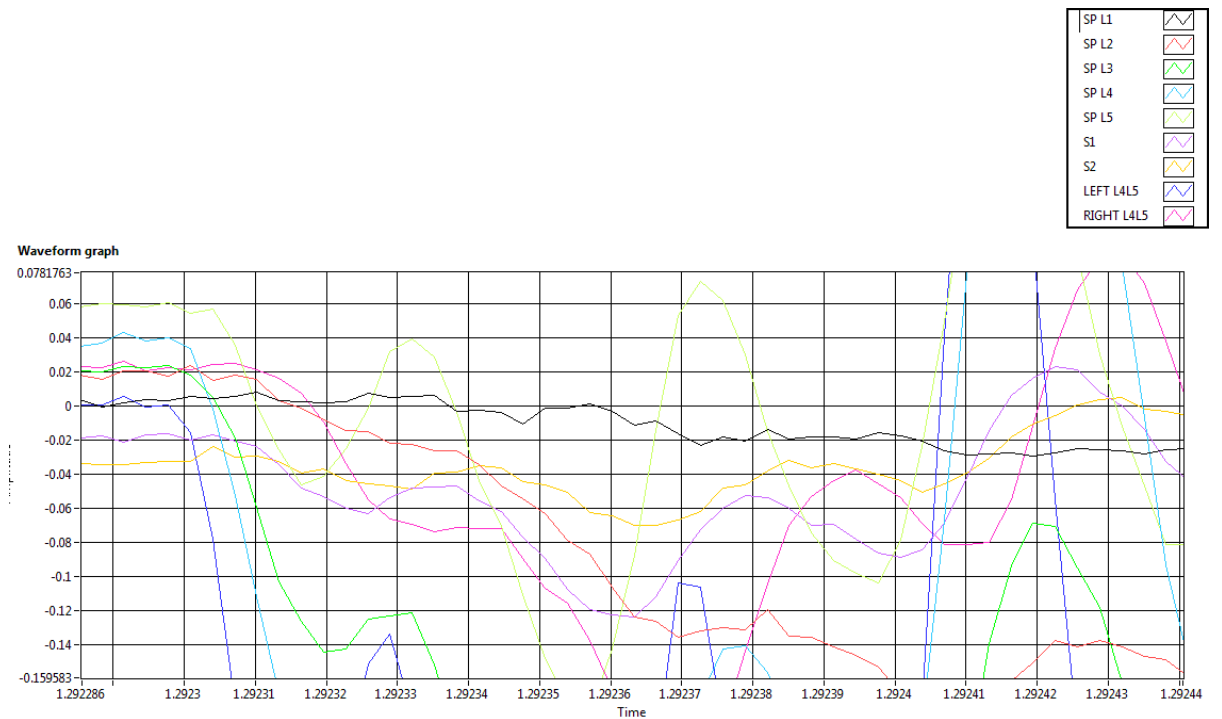


Figure 5.24: Expanded (zoomed), view of figure 5.23 (1.292286 to 1.29244 sec)

showing sequential response of accelerometers

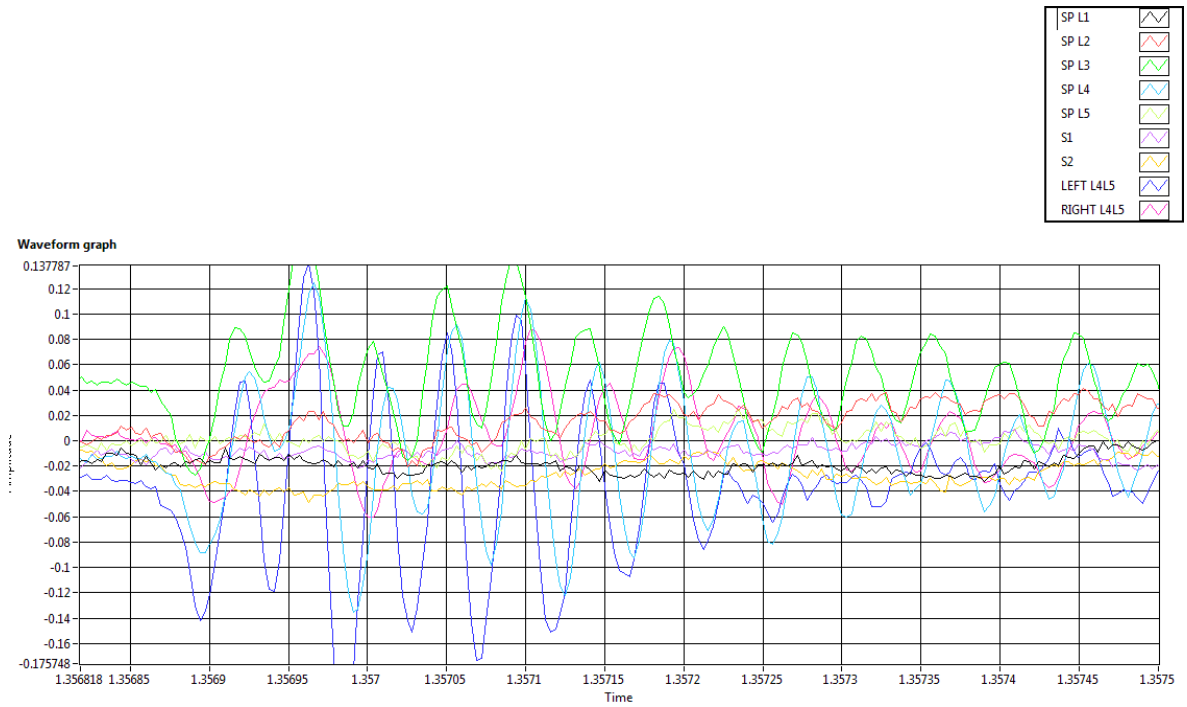


Figure 5.25: Cavitation 2 full view for subject ID 0035

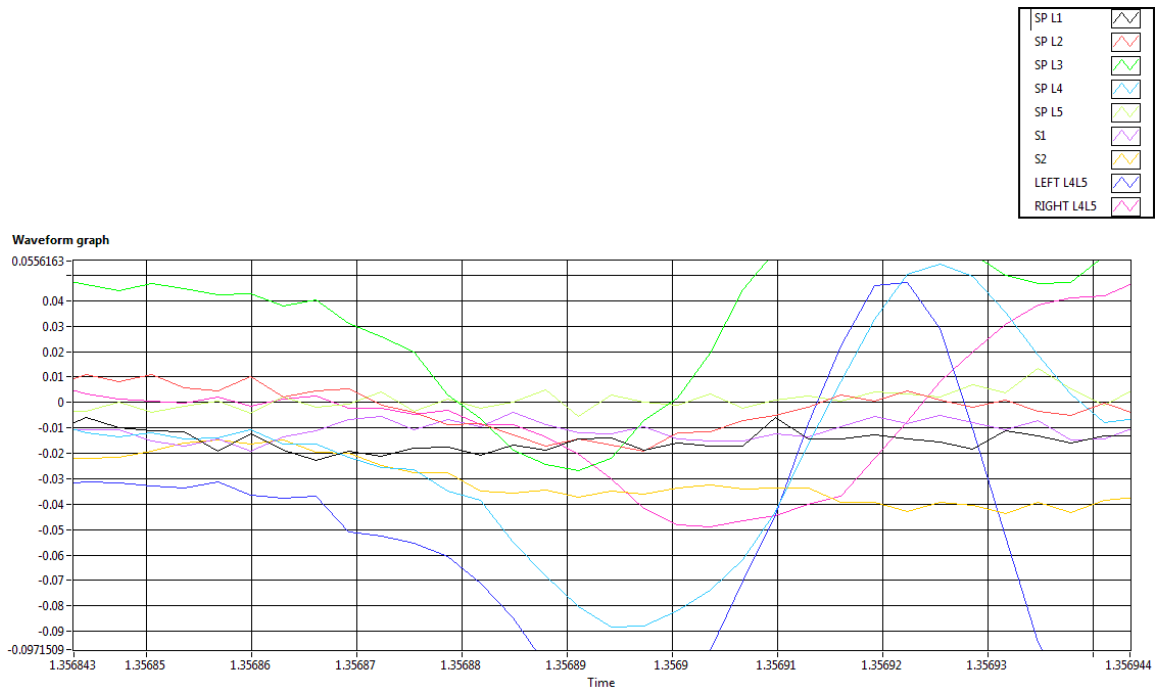


Figure 5.26: Expanded (zoomed), view of figure 5.25 (1.356843 to 1.356944 sec)
showing sequential response of accelerometers

DATA SHEET (for subject in Group 2)

SUBJECT ID: 0046

DATE: 03/12/2010

TIME OF FIRST THRUST

TIME OF MRI: 11:00am

or

**POSITIONING TIME: 2.84
(SEC)**

**Table 5.4: ASSESSMENT OF GROUP 2 ACCELEROMETER DATA--
ARTIFACTS**

| ARTIFACTS | TIME (SEC) | COMMENTS/ NOTES |
|------------------|-----------------------|--|
| 1) | 0.50585 | L5 and then L1 responded, which shows no sign of cavitation (Miscellaneous). |
| 2) | 0.546 | S1 and then L1 responded, which shows no sign of cavitation (Miscellaneous). |
| 3) | 0.9159 | Only S2 responded, which shows no sign of cavitation (Miscellaneous). |
| 4) | 1.3382 | Only L4 responded, which shows no sign of cavitation (Miscellaneous). |
| 5) | 1.5966 | Only S2 responded, which shows no sign of cavitation (Miscellaneous). |

**Table 5.5: ASSESSMENT OF GROUP 2 ACCELEROMETER DATA—
CAVITATIONS**

| CAVITATIONS | TIME | NOTES |
|--------------------|-------------|--------------|
| None | | |

Table 5.6: AMPLITUDE OF CAVITATIONS GROUP 2

| CAVITATION NO | ORDER OF SP FIRING | ORDER (LEFT OR RIGHT) | LEVEL OF CONFIDENCE |
|----------------------|-------------------------------|----------------------------------|--------------------------------|
| None | | | |

COMMENTS/NOTES:

This subject was in Group two (side-posture positioning) and no cavitation was recorded.

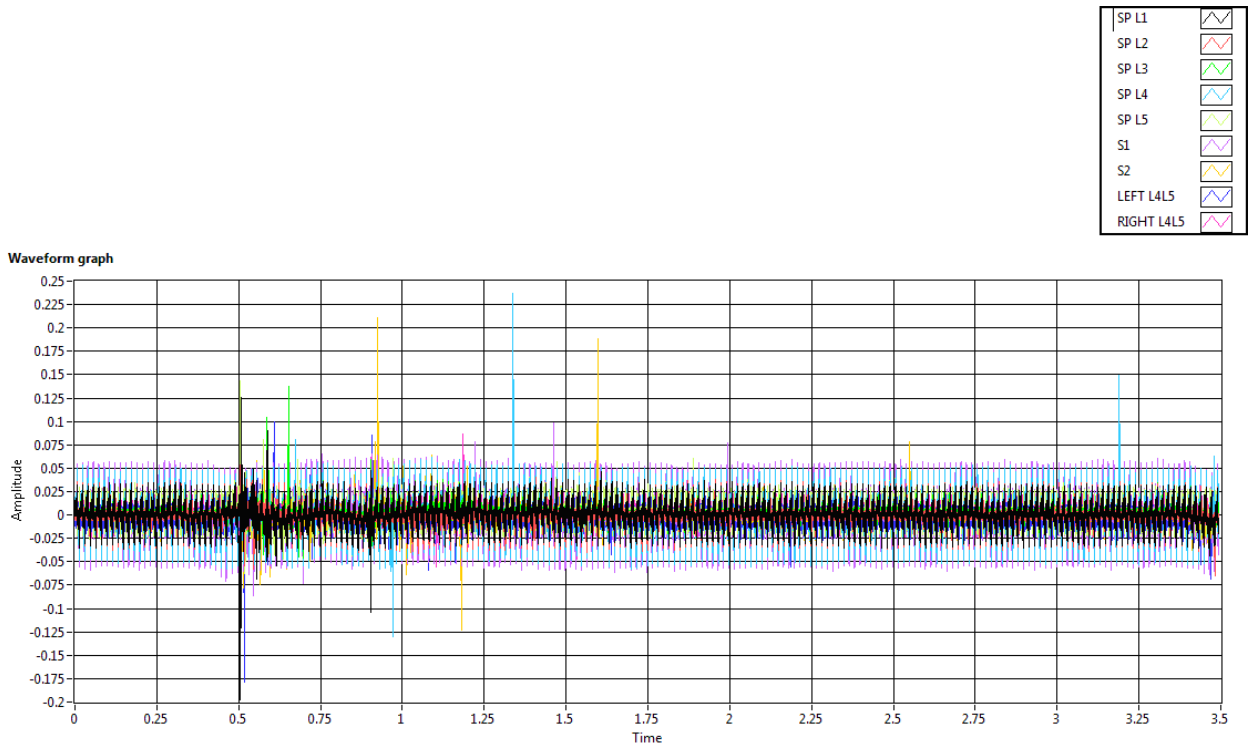


Figure 5.27: Complete time scale for subject ID 0046

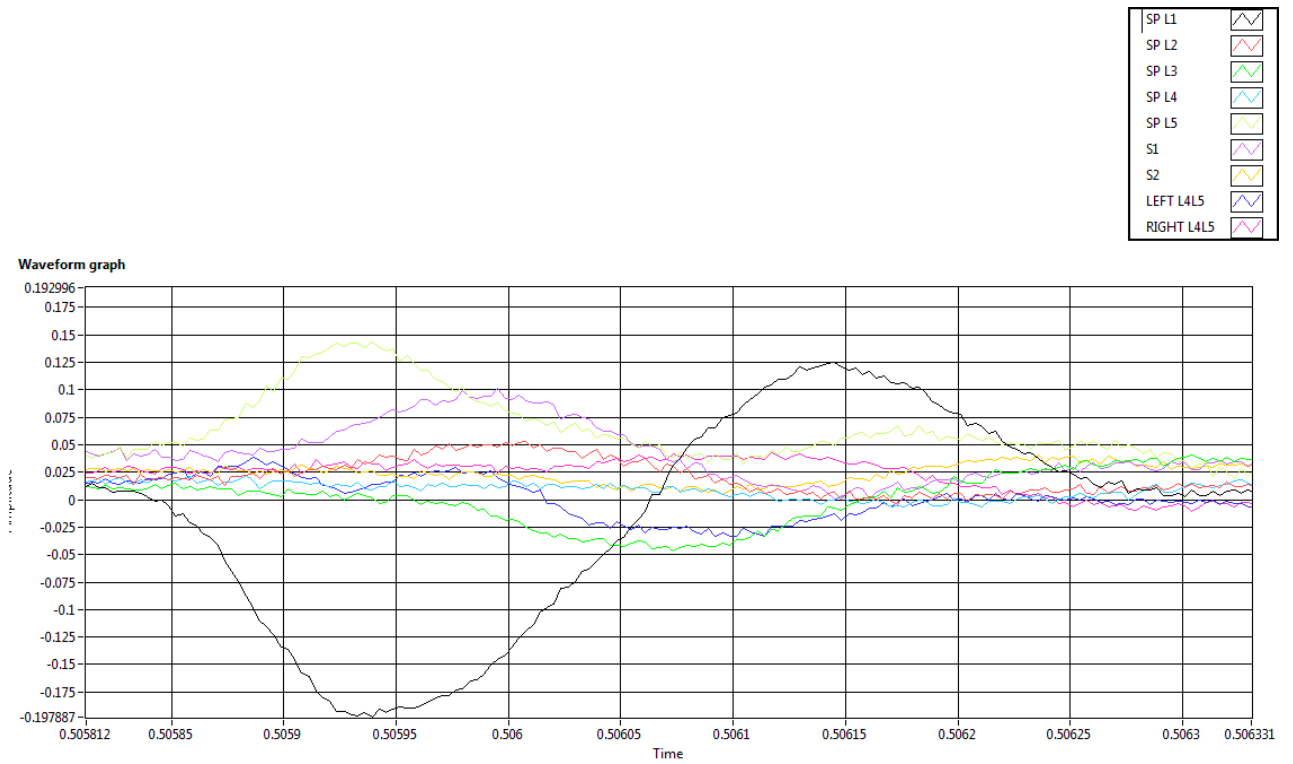


Figure 5.28: Artifact 1 for subject ID 0046

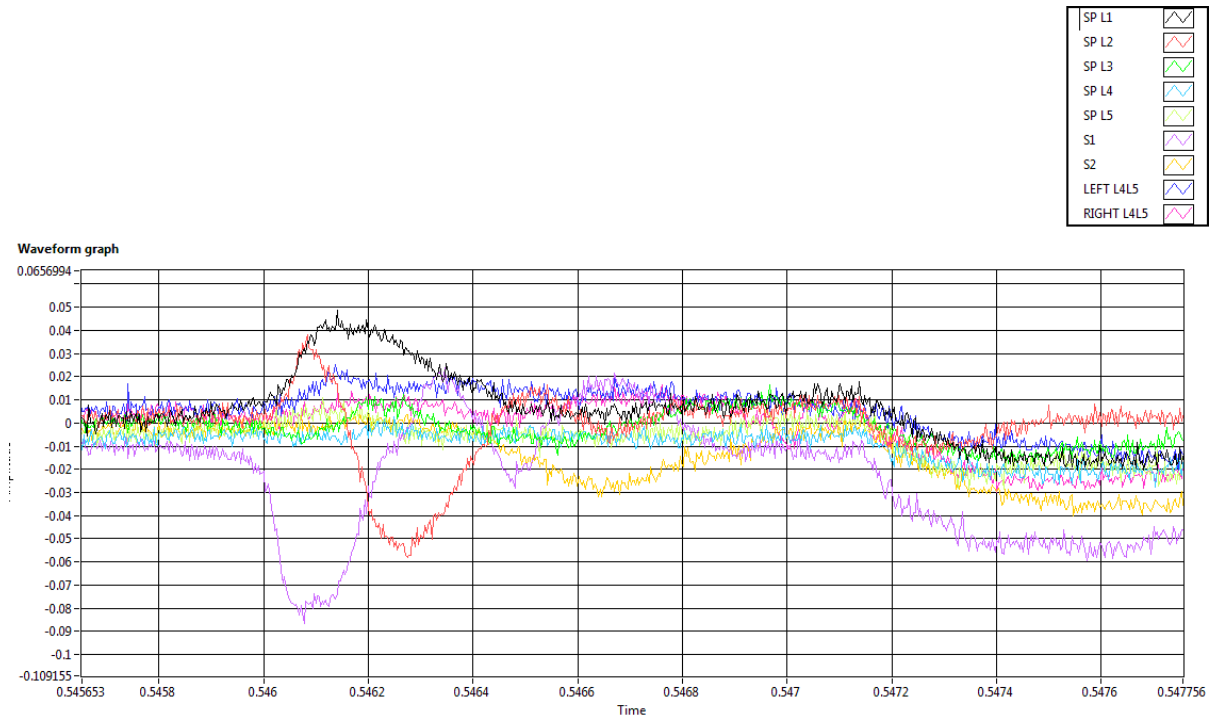


Figure 5.29: Artifact 2 for subject ID 0046

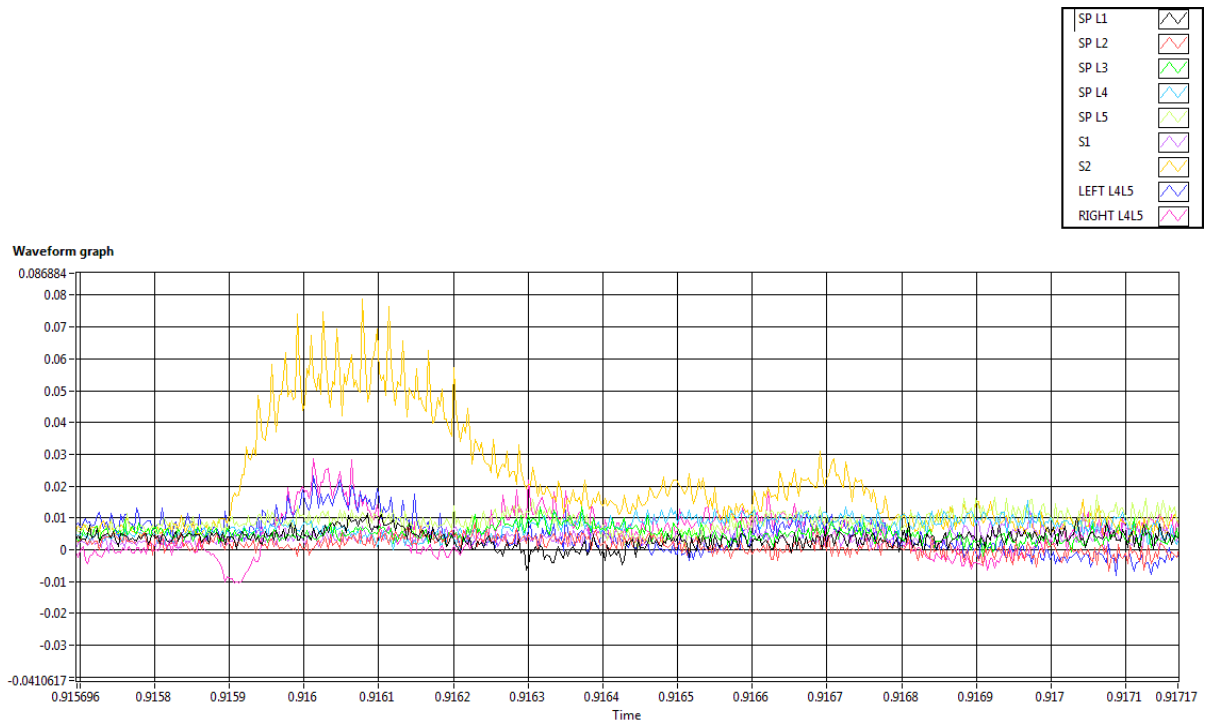


Figure 5.30: Artifact 3 for subject ID 0046

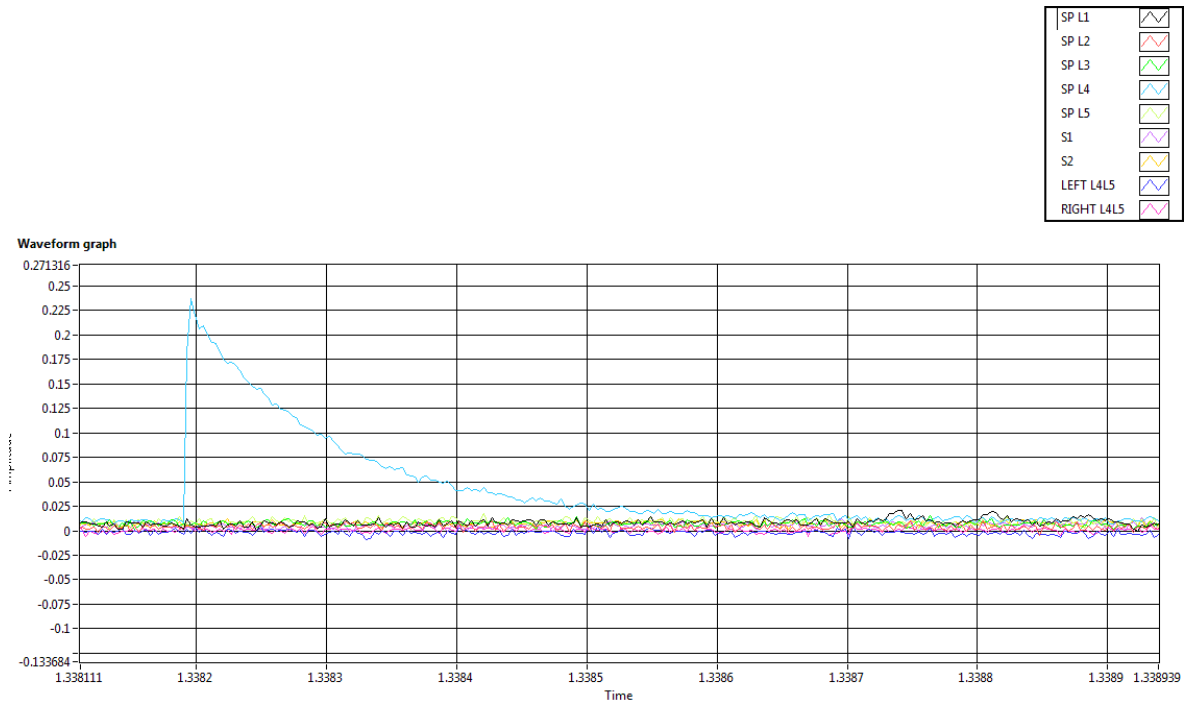


Figure 5.31: Artifact 4 for subject ID 0046

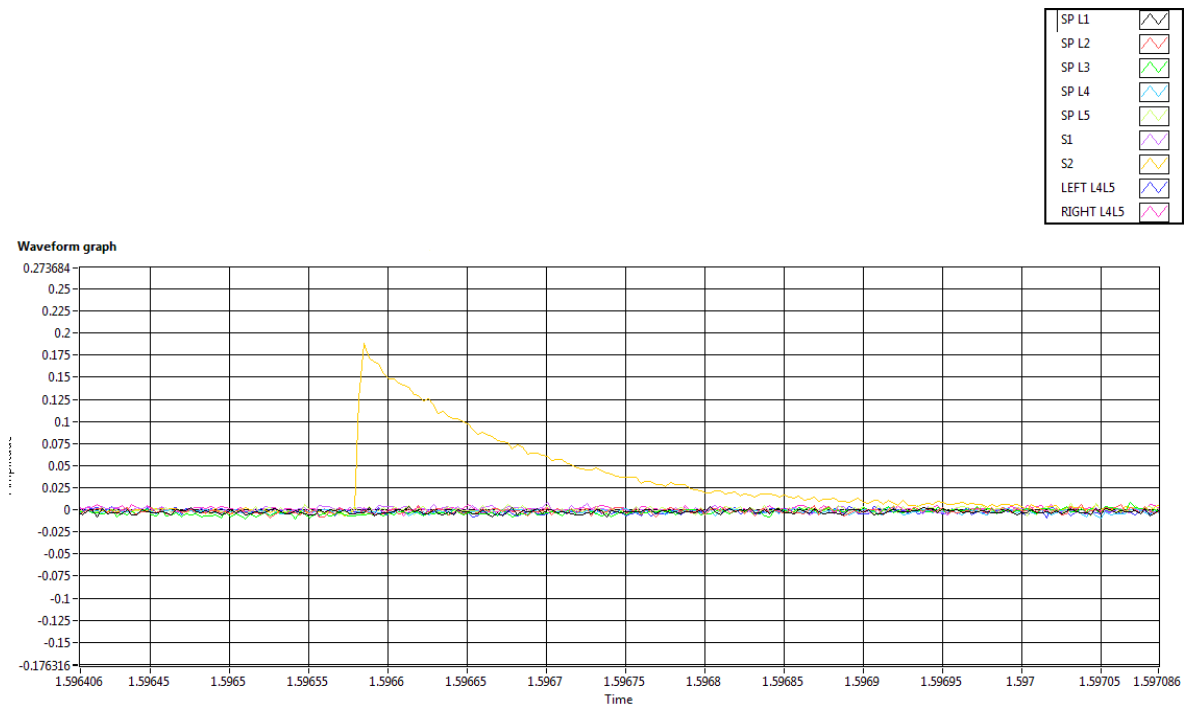


Figure 5.32: Artifact 5 for subject ID 0046

5.7 Reliability Studies

Two types of reliability studies were conducted in this research project.

5.7.1 Inter-Rater Agreement between Computer (Accelerometers), Clinician, and Subject

In this reliability study, agreement between the computer (accelerometers), clinician, and subject report in determining any cavitation during side-posture positioning or SMT was determined. As discussed earlier in the “clinical study” section, a trained research assistant noted the responses of a clinician and subject (both blinded to each other) and whether or not they heard or felt cavitation during SMT or side posture-positioning. Inter-rater agreements (Kappa) were calculated using Medcalc. Agreement is quantified by the Kappa (K) statistic:

- K is 1 when there is perfect agreement between the observers using the classification system (when they agreed on the presence of a cavitation, in our case).
- K is 0 when there is no agreement better than chance.
- K is negative when agreement is worse than chance.

Table 5.7: Presence of cavitations as identified by the accelerometers, clinician, and the subject

| *SUBJECT ID | ACCELEROMETERS | CLINICIAN | SUBJECT |
|-------------|----------------|-----------|---------|
| 6 | 1 | 1 | 1 |
| 9 | 0 | 0 | 0 |
| 10 | 0 | 0 | 0 |
| 11 | 1 | 1 | 1 |
| 12 | 1 | 1 | 1 |
| 13 | 1 | 1 | 1 |
| 14 | 1 | 1 | 1 |
| 16 | 0 | 1 | 1 |
| 18 | 1 | 1 | 1 |
| 21 | 1 | 1 | 1 |
| 24 | 1 | 1 | 1 |
| 30 | 1 | 1 | 1 |
| 32 | 1 | 1 | 1 |
| 34 | 1 | 1 | 1 |
| 35 | 1 | 1 | 1 |
| 37 | 1 | 1 | 1 |
| 40 | 1 | 1 | 1 |
| 41 | 0 | 0 | 0 |
| 45 | 1 | 1 | 1 |

| | | | |
|----|---|---|---|
| 46 | 0 | 0 | 0 |
| 47 | 1 | 1 | 1 |
| 58 | 1 | 1 | 1 |
| 59 | 1 | 1 | 1 |
| 61 | 1 | 1 | 1 |
| 65 | 1 | 1 | 1 |
| 69 | 1 | 1 | 1 |
| 71 | 1 | 1 | 1 |
| 72 | 1 | 1 | 1 |
| 74 | 1 | 1 | 1 |
| 75 | 1 | 1 | 1 |
| 80 | 0 | 0 | 0 |
| 82 | 1 | 1 | 1 |
| 84 | 0 | 1 | 0 |
| 85 | 1 | 1 | 1 |
| 86 | 1 | 1 | 1 |
| 87 | 0 | 0 | 0 |
| 90 | 1 | 1 | 1 |
| 92 | 1 | 1 | 1 |
| 93 | 1 | 1 | 1 |
| 97 | 1 | 1 | 1 |

* Subjects are listed in ascending order by their Subject ID number (each was assigned a random Subject ID number 1-100).

5.7.2 Reliability Study for Agreement Assessing Accelerometry Data

This study was conducted between two observers, (PB and Dr. Kim Ross DC, PhD), each blinded to the other's results, to identify the vertebral level of cavitations

For this study, initial cavitations for ten subjects were chosen using a "Random Number Generator" program. PB assessed the cavitations, recorded his results and gave them to Dr. Cramer. A Windows Live Meeting was then scheduled with Dr. Ross, and each cavitation was shared with him one at a time. Control was given to Dr. Ross, so that he could scroll through the accelerometer recording time and magnify the scales in any manner he chose. Dr. Ross recorded his results and sent them to Dr. Cramer via email. PB and Dr. Ross were blinded to each others results.

Inter-rater agreement (Kappa) was calculated using Medcalc software. The Z joints identified as having cavitated were individually and sequentially entered into the database for each observer (PB and Dr. Ross). Since there were 12 joints included in the study in total, (Left L1L2, Right L1L2, Left L2L3, Right L2L3, Left L3L4, Right L3L4, Left L4L5, Right L4L5, Left L5S1, Right L5S1, Left SIJ and Right SIJ) a number was assigned to each of them sequentially from 1 to 12. For example, 1 was assigned to the Left L1L2 Z joint, 2 was assigned to the Right L1L2 Z joint, etc. So, if PB and Dr. Ross concluded cavitation occurred at the same Z joint for a particular joint, the same number would be entered for each of them in the data entry table of Medcalc. The weighted Kappa statistic was used to analyze the data.

Table 5.8: Assignment of numeric values to Z joints for reliability study data entry

| DATA ENTRY | JOINTS |
|-------------------|---------------|
| 1 | LEFT L1L2 |
| 2 | RIGHT L1L2 |
| 3 | LEFT L2L3 |
| 4 | RIGHT L2L3 |
| 5 | LEFT L3L4 |
| 6 | RIGHT L3L4 |
| 7 | LEFT L4L5 |
| 8 | RIGHT L4L5 |
| 9 | LEFT L5S1 |
| 10 | RIGHT L5S1 |
| 11 | LEFT SIJ |
| 12 | RIGHT SIJ |

5.8 Summary of Cavitation Assessment

Data analysis in this research project included the identification of the vertebral level where cavitation occurred (i.e., identification of cavitation at specific Z joints from L1-L5 SPs and SIJs). Inferential methods were used to compare cavitations in the following manner: Group 1 (SMT group) vs. Group 2 (side-posture positioning group), targeted area (L3/L4, L4/L5, L5/S1) vs. non-targeted area (L1/L2, L2/L3, SIJ), left side vs. right side.

5.9 Statistical Analysis

Statistical analysis was conducted between Group 1 and Group 2 using the chi-square method because of the independent location of cavitations in two groups. McNemar's test was done for statistical analysis for cavitations in left side vs. right side and targeted vs. non-targeted areas. McNemar's test was done because two related measurements on the same sample group were considered (Snedecor and Cochran, 1967).

6. RESULTS

Forty-nine subjects were randomized into Group 1 or Group 2. Nine of these were excluded from the study immediately after side-posture positioning or SMT because of many artifacts incorporated during accelerometry data collection (Three subjects were excluded because of UHC (i.e., clinician's hand contact) artifact. Five subjects were excluded because of resisting or not relaxed subjects artifact. One subject was excluded from the study because of incomplete data collection). Consequently, a total of 40 subjects (20 males and 20 females) completed the study. As planned, 30 subjects were randomized into Group 1, and 10 subjects were randomized into Group 2. Group 1 was the SMT group (a total of 30 subjects were randomized into this group) and Group 2 was the Control Group (a total of 10 subjects were randomized into this group). These subjects were held in side-posture position, but didn't receive side-posture SMT. Data was collected from accelerometers with subjects in Group 2 to test the hypothesis, that cavitation can occur when subjects are held in side-posture position.

6.1 Reliability Studies

As discussed earlier, two types of reliability studies were conducted. One study attempted to find agreement between the computer (accelerometers), clinician report and subject report in determining any cavitation during side-posture positioning or SMT. The other attempted to identify the vertebral level of cavitations by two observers (PB and Dr. Kim Ross DC, PhD) blinded to each others results. Results of reliability studies were calculated using Medcalc.

6.1.1 Agreement between Accelerometers and Subjects

There was agreement between the accelerometer recordings and subjects for 39 of the 40 instances, and they both disagreed for one instance as seen in Tables 5.8, 6.1 and in Figure 6.1. When no cavitation was identified from accelerometer recordings (n=8) then also, subject said “no” (0 on Table 5.8) 7 times (agreement) and “yes” 1 time (disagreement) (Tables 5.8, 6.1 and in Figure 6.1). When the accelerometers identified a cavitation (n=32) the subjects said yes (1 on Table 5.8) all 32 times (complete agreement) (Tables 5.8, 6.1 and in Figure 6.1).

Accelerometer recordings of cavitations were in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003) with the subjects ($K=0.918$, 95% CI= 0.759 to 1.077) (Table 6.1).

Table 6.1: Inter-rater agreement (Kappa) between accelerometers and subjects

| Inter-rater agreement (kappa) | | | |
|-------------------------------|----------------|---------------|------------|
| Observer A | Accelerometers | | |
| Observer B | Subjects | | |
| Observer B | Observer A | | |
| | 0 | 1 | |
| 0 | 7 | 0 | 7 (17.5%) |
| 1 | 1 | 32 | 33 (82.5%) |
| | 8 (20.0%) | 32 (80.0%) | 40 |
| Kappa | 0.918 | | |
| Standard error | 0.0809 | | |
| 95% CI | 0.759 to 1.077 | | |

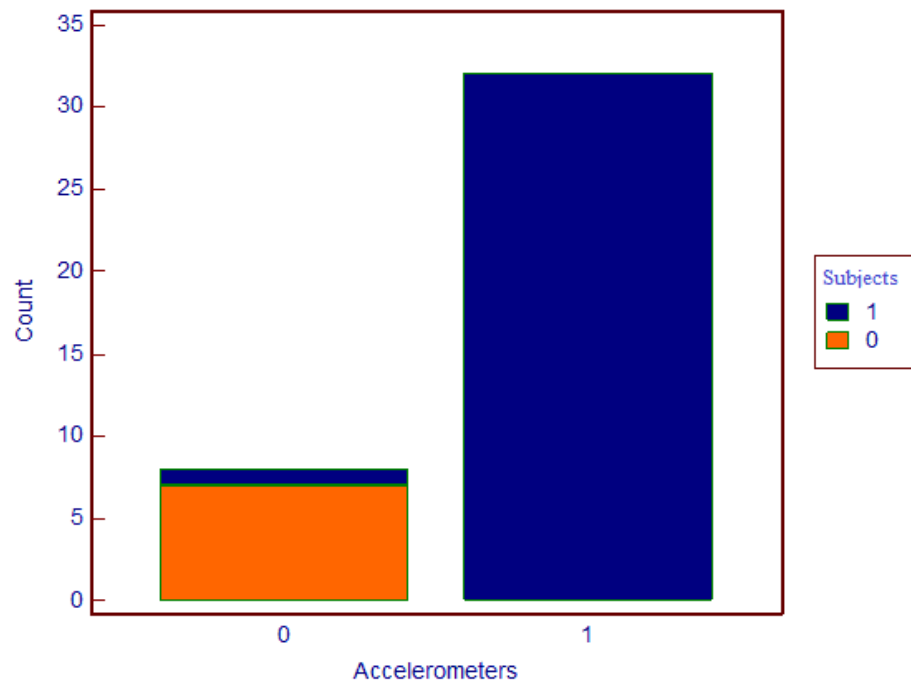


Figure 6.1: Frequency chart for Inter-rater agreement (Kappa) between accelerometers and subjects

6.1.2 Agreement between Clinician and Subjects

Of 40 subjects, there was agreement between clinician and subjects for 39 instances and they disagreed in one instance as seen in Tables 5.8, 6.2 and Figure 6.2. When the clinician reported “no cavitation” (0 on Table 5.8, n=6), the subjects reported “no” all 6 times (complete agreement) (Table 6.2). When the clinician reported “yes, there was a cavitation” (1 on Table 5.8, n=34) the subjects reported “no” 1 time (agreement in all but 1 instance) (Tables 5.8, 6.2 and Figure 6.2).

Clinician report of cavitations were in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003) with the subjects (K=0.918, 95% CI= 0.731 to 1.086) (Table 6.2).

Table 6.2: Inter-rater agreement (Kappa) between clinician and subjects

| Inter-rater agreement (kappa) | | | |
|--------------------------------------|----------------|---------------|------------|
| Observer A | Clinician | | |
| Observer B | Subjects | | |
| | Observer A | | |
| Observer B | 0 | 1 | |
| 0 | 6 | 1 | 7 (17.5%) |
| 1 | 0 | 33 | 33 (82.5%) |
| | 6 (15.0%) | 34 (85.0%) | 40 |
| Kappa | 0.908 | | |
| Standard error | 0.0906 | | |
| 95% CI | 0.731 to 1.086 | | |

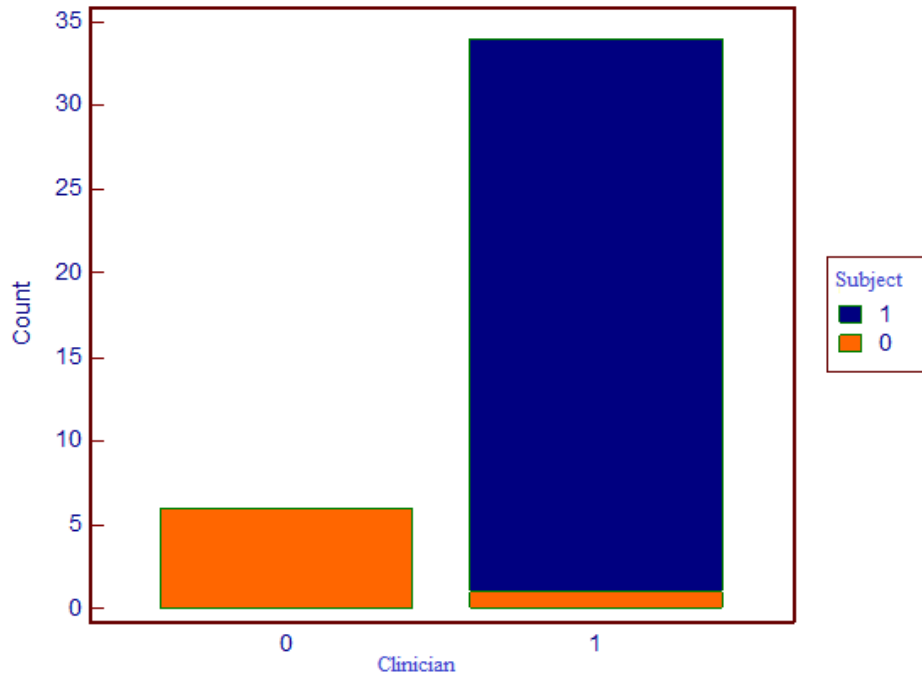


Figure 6.2: Frequency chart for Inter-rater agreement (Kappa) between clinician and subjects

6.1.3 Agreement between Accelerometers and Clinician

Of 40 subjects, there was agreement between accelerometers and the clinician for 38 instances and disagreement for two instances as seen in Tables 5.8, 6.3 and Figure 6.3. When the accelerometers did not identify a cavitation (0 in Table 5.8, n=8) the clinician reported no 6 times and yes 2 (1 in Table 5.8) times (Table 6.3). When accelerometers identified a cavitation, (1 in Table 5.8, n=32) the clinician reported yes all 32 times (complete agreement).

Accelerometer recordings of cavitations were in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003) with the clinician ($K=0.828$, 95% CI= 0.595 to 1.060) (Table 6.3).

Table 6.3: Inter-rater agreement (Kappa) between accelerometers and clinician

Inter-rater agreement (kappa)

| Observer A | Accelerometers | | Clinician |
|----------------|----------------|---------------|----------------|
| Observer B | Observer A | | |
| | 0 | 1 | |
| 0 | 6 | 0 | 6 (15.0%) |
| 1 | 2 | 32 | 34 (85.0%) |
| | 8 (20.0%) | 32 (80.0%) | 40 |
| Kappa | | | 0.828 |
| Standard error | | | 0.119 |
| 95% CI | | | 0.595 to 1.060 |

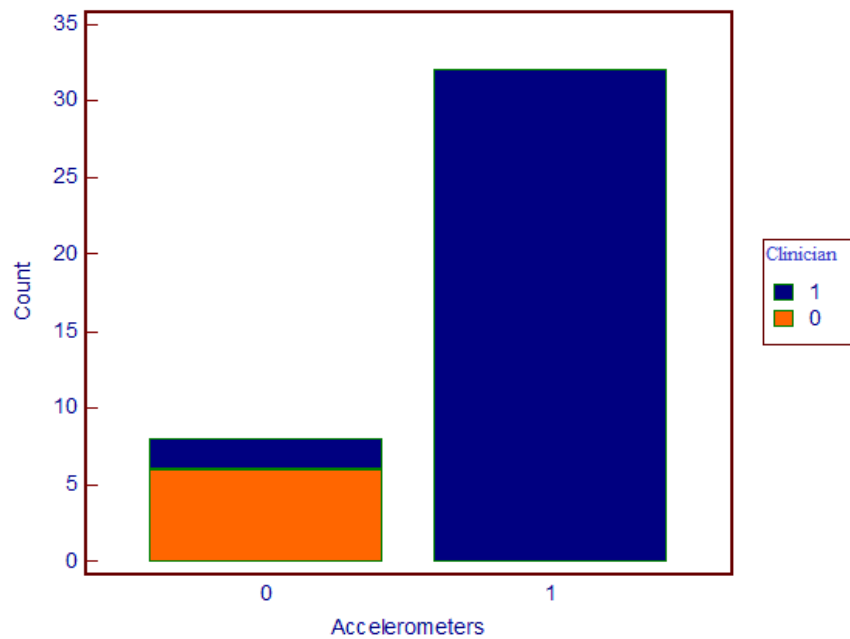


Figure 6.3: Frequency chart for Inter-rater agreement (Kappa) between accelerometers and clinician

6.1.4 Agreement Assessing Accelerometry Data

This reliability study was conducted between two observers (PB and Dr. Kim Ross DC, PhD), blinded to each others results, to identify the vertebral level of cavitations. Initial cavitations for ten subjects were chosen using a “Random Number Generator” program and the level of cavitations was identified by each observer using a previously discussed method.

Of ten cavitations, there was agreement between PB and Dr. Ross in nine instances identifying the level of cavitation (Cavitation number 1-9 Table 6.4) (complete agreement) and disagreement in one instance (cavitation number 10 Table 6.4). PB and Dr. Ross identified level of cavitation at Left L1/L2 Z joint in 2 instances (1 in Table 6.5 and Figure 6.4), Left L2/L3 Z joint in one instance (3 in Table 6.5 and Figure 6.4), Left L3/L4 Z joint in 5 instances (5 in Table 6.5 and Figure 6.4), and Left SIJ in one instance (11 in Table 6.5 and Figure 6.4). Only in one instance PB identified level of cavitation at the Left L3/L4 Z joint and Dr. Ross identified the same cavitation as the Left L2/L3 Z joint (Tables 6.4, 6.5 and Figure 6.4). PB and Dr. Ross agreed on all but one Z joint and were only off by 1 level in that instance, i.e., they agreed in 9 of 10 instances (Table 6.4).

The reliability study in assessing accelerometry data between PB and Dr. Ross was in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003) ($K=0.841$, 95% CI = 0.546 to 1.136).

Table 6.4: Interpretation of cavitations by PB and Dr. Ross

| CAVITATION NUMBER | PB RESULTS | DR. ROSS RESULTS |
|--------------------------|-------------------|-------------------------|
| 1 | LEFT L3L4 | LEFT L3L4 |
| 2 | LEFT L3L4 | LEFT L3L4 |
| 3 | LEFT L1L2 | LEFT L1L2 |
| 4 | LEFT S1S2 | LEFT S1S2 |
| 5 | LEFT L3L4 | LEFT L3L4 |
| 6 | LEFT L2L3 | LEFT L2L3 |
| 7 | LEFT L1L2 | LEFT L1L2 |
| 8 | LEFT L3L4 | LEFT L3L4 |
| 9 | LEFT L3L4 | LEFT L3L4 |
| 10 | *LEFT L3L4 | *LEFT L2L3 |

* Single disagreement between observers.

Table 6.5: Inter-rater agreement (Kappa) for analysis of accelerometry recordings
between two observers

| Inter-rater agreement (kappa) | | | | | |
|-------------------------------|----------------|--------------|--------------|--------------|-----------|
| Observer A | | PB | | | |
| Observer B | | Dr. Ross | | | |
| Observer B | Observer A | | | | |
| | 1 | 3 | 5 | 11 | |
| 1 | 2 | 0 | 0 | 0 | 2 (20.0%) |
| 3 | 0 | 1 | 1 | 0 | 2 (20.0%) |
| 5 | 0 | 0 | 5 | 0 | 5 (50.0%) |
| 11 | 0 | 0 | 0 | 1 | 1 (10.0%) |
| | 2 (20.0%) | 1 (10.0%) | 6 (60.0%) | 1 (10.0%) | 10 |
| Kappa | 0.841 | | | | |
| Standard error | 0.151 | | | | |
| 95% CI | 0.546 to 1.136 | | | | |

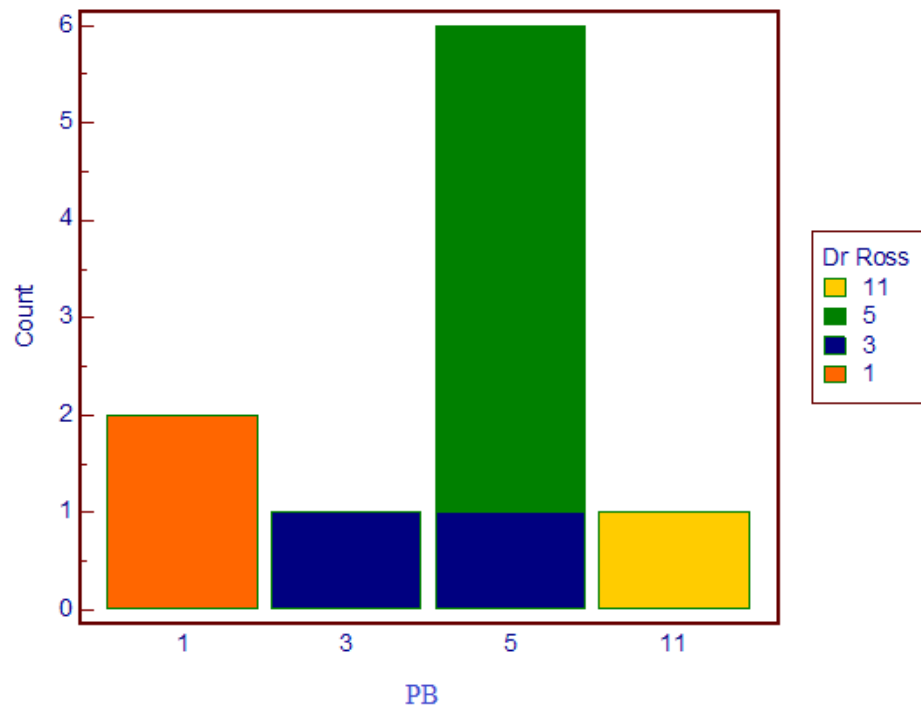


Figure 6.4: Frequency chart for reliability study of analysis of accelerometry recordings

6.1.5 Summary of Reliability Studies

Kappa findings of both reliability studies are summarized in this section.

6.1.5.1 Agreement between Accelerometers, Clinician, and Subjects

- For 38 (No=6; Yes=32) of 40 subjects, all three sources (accelerometers, clinician and subjects) agreed.
- For the remaining 2 subjects, accelerometers detected nothing.
 - The doctor reported cavitation in both instances.
 - The subject reported cavitation in one of these instances.
- Inter-rater agreement (Kappa) between accelerometers and subjects was 0.918 (almost perfect) (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003).
- Inter-rater agreement (Kappa) between clinician and subjects was 0.908 (almost perfect) (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003).
- Inter-rater agreement (Kappa) between accelerometers and clinician was 0.828 (almost perfect) (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003).

6.1.5.2 Agreement between Two Observers in Assessing Accelerometry Data

Both observers, PB and Dr. Ross agreed on all but one Z joint and were only off by 1 level in that instance, i.e., they agreed in 9 of 10 instances. Inter-rater agreement (Kappa) between two observers was 0.841 (almost perfect) (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003).

6.2 Number and Percentage of Cavitations (CAV) Detected By the Accelerometers at Each Joint

The main focus of this research project was to find cavitations at SP L1-SIJ and, for this reason; each cavitation recorded by accelerometers is reported in this project. A total of 56 cavitations were recorded from 40 subjects. 53 cavitations were recorded from subjects randomized into Group 1 and 3 from subjects randomized into Group 2 (Table 6.6). The maximum number of cavitations was recorded at Left L3/L4 Z joint (Table 6.6, Figure 6.5). No cavitations were recorded at the Right L1/L2, L2/L3, and L3/L4 Z joints (Table 6.6).

Table 6.6: Number and percentage of cavitations recorded at each joint

| JOINT | GROUP 1 | GROUP 2 | PERCENTAGE CAV/ JOINT |
|-------------------|----------------|----------------|----------------------------------|
| LEFT L1L2 | 7 | 0 | 12.50 |
| RIGHT L1L2 | 0 | 0 | 0 |
| LEFT L2L3 | 6 | 0 | 10.71 |
| RIGHT L2L3 | 0 | 0 | 0 |
| LEFT L3L4 | 24 | 2 | 46.43 |
| RIGHT L3L4 | 0 | 0 | 0 |
| LEFT L4L5 | 8 | 0 | 14.28 |
| RIGHT L4L5 | 1 | 0 | 1.78 |
| LEFT L5S1 | 4 | 1 | 8.93 |
| RIGHT L5S1 | 1 | 0 | 1.78 |
| LEFT SIJ | 1 | 0 | 1.78 |
| RIGHT SIJ | 1 | 0 | 1.78 |
| TOTAL | 53 | 3 | 100 |

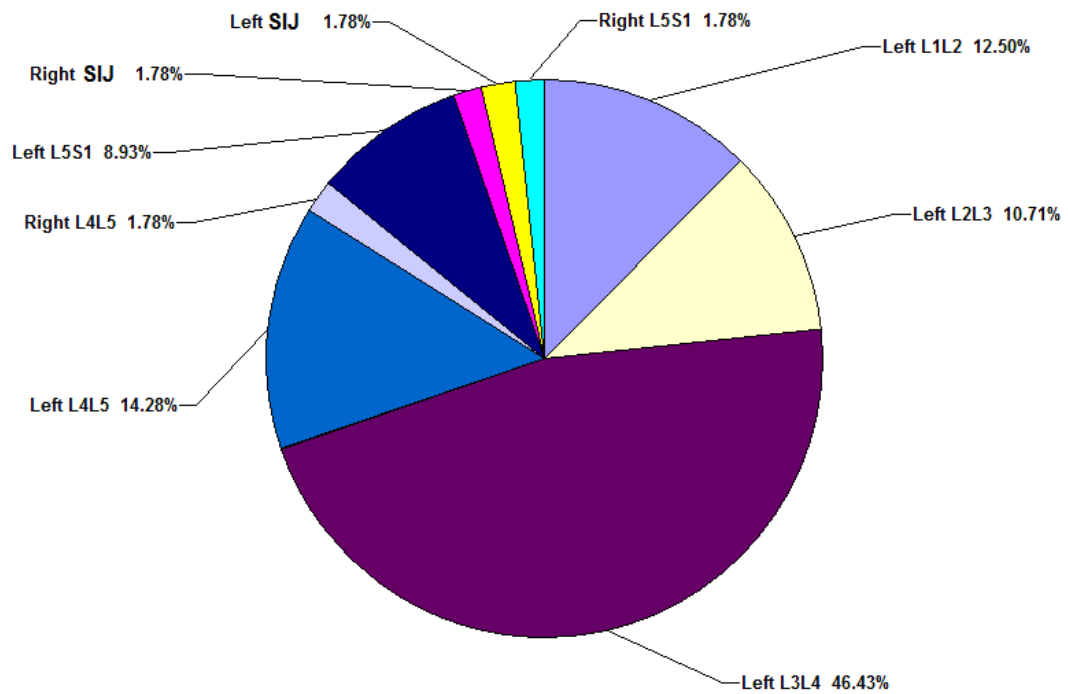


Figure 6.5: Percentage of cavitations recorded at each joint.

Notice the maximum number of cavitations was recorded at Left L3/L4 Z joint and that Right L1/L2, L2/L3, and L3/L4 did not cavitate at all

6.3 Cavitations in Group 1 and Group 2

Comparisons of cavitations between Group 1 and Group 2 can be summarized as follows:

- 53 cavitations ($53/56 = 94.64\%$) were recorded from subjects randomized into Group 1 (n=30 subjects) (Table 6.6, and Figures 6.6, 6.9). 38 of 53 cavitations were recorded at the targeted area (L3/L4, L4/L5, and L5/S1) and 15 of 53 cavitations were recorded at the non-targeted area (L1/L2, L2/L3, and SIJ) from subjects randomized into Group 1 (Figure 6.9).

- 3 ($3/56 = 5.36\%$) cavitations were recorded from subjects randomized into Group 2 (n=10 subjects) (Table 6.6, and Figures 6.6, 6.10). None of the cavitations were recorded on right side for the subjects randomized into Group 2 (Figure 6.10).

- 29 out of 30 subjects cavitated in Group 1 ($29/30 = 97\%$), which was significantly more vs. 3 out of 10 subjects that cavitated in Group 2 ($3/10 = 30\%$) (2 sided test, $p < 0.0001$, $95\%CI=34\%-86\%$) (Refer chi-square test).

- Average cavitations / subject in Group 1 was 1.77 (53 / 30).
- Average cavitations / subject in Group 2 was 0.3 (3 / 10).

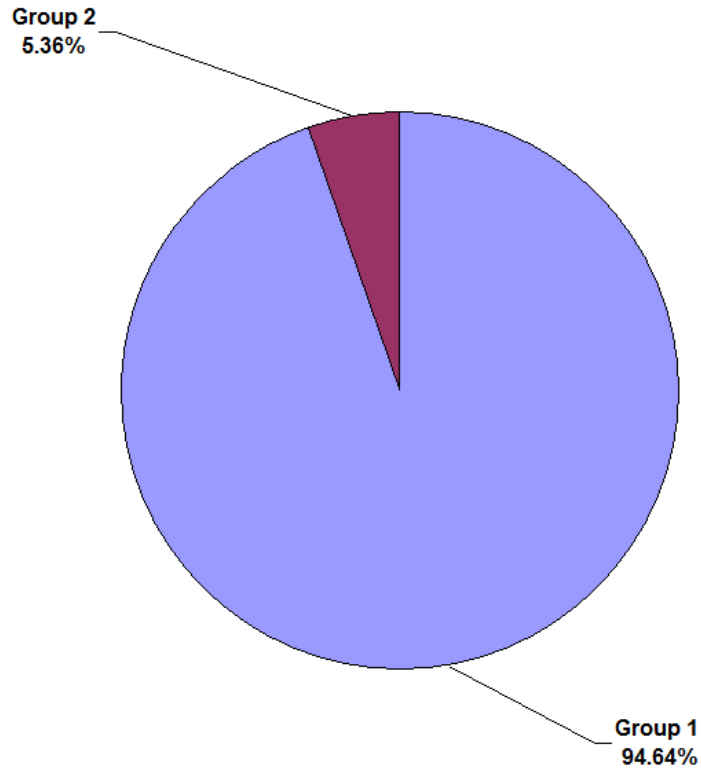


Figure 6.6: Percentage of cavitation in Group 1 and Group 2

6.4 Cavitations at Targeted and Non-targeted Area

Forty-one cavitations ($41/56 = 73.21\%$) (Figures 6.9, 6.10) were recorded at the targeted Z joints (Left L3/L4, Right L3/L4, Left L4/L5, Right L4/L5, Left L5/S1, and Right L5/S1). Of these 41 cavitations, 39 were recorded on the left side, and only 2 were recorded on the right side (Figures 6.9, 6.10). Fifteen cavitations ($15/56 = 26.80\%$) (Figures 6.9, 6.10) were recorded at non-targeted Z joints (Left L1/L2, Right L1/L2, Left L2/L3, Right L2/L3, Left SIJ and Right SIJ). Of the 15 cavitations, 14 were recorded from

left side non-targeted Z joints, and only 1 cavitation was recorded on the right side of non-targeted Z joints (Figures 6.9, 6.10).

Thirty-eight of 53 cavitations were recorded at the targeted area, and 15 of 53 cavitations were recorded at the non-targeted area for the subjects randomized into Group 1 (Figure 6.9). All 3 cavitations were recorded at the target area and, interestingly, on the left side for subjects randomized into Group 2 (Figure 6.10).

Cavitation occurred significantly more frequently at the targeted Z joints vs. non-targeted Z joints ($p < 0.001$).

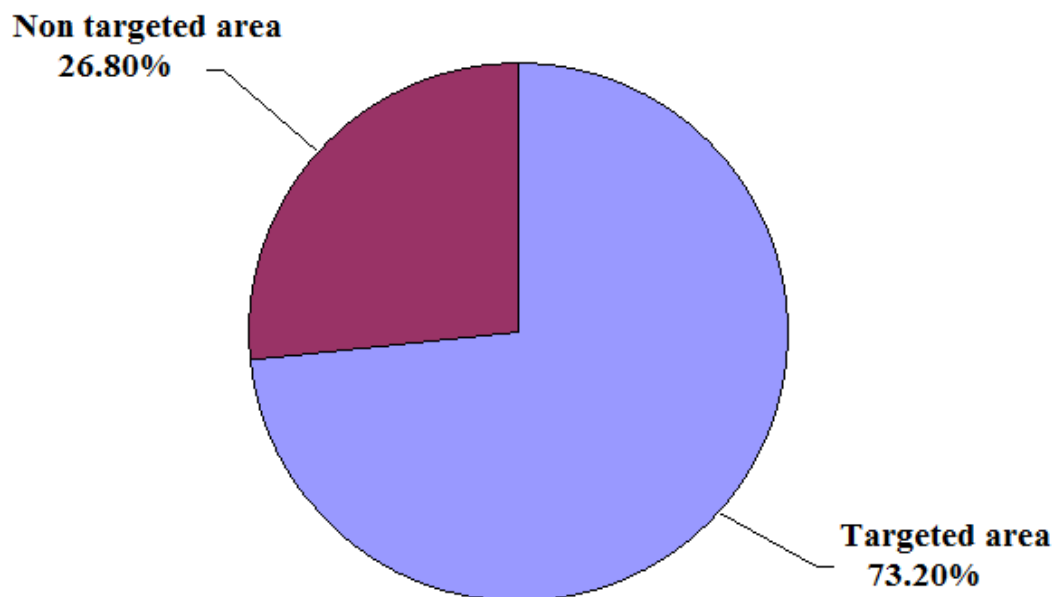


Figure 6.7: Percentage of cavitations at targeted and non targeted Z joints

6.5 Cavitations at Left Side and Right Side

Fifty-three cavitations ($53/56 = 94.63\%$) (Figure 6.8) were recorded from joints located on the left side, 39 of which were recorded at targeted Z joints and 14 at non-targeted Z joints (Figures 6.9, 6.10). Three cavitations ($3/56 = 5.43\%$) (Figure 6.8) were recorded from joints located on the right side, 2 of which were recorded at targeted Z joints and 1 at non-targeted Z joints (Figures 6.9, 6.10). Cavitation occurred significantly more frequently at left-side vs. right-side ($p < 0.001$).

Fifty of 53 cavitations (Figure 6.9) were recorded at the left side and 3 of 53 cavitations (Figure 6.9) were recorded at the right side from subjects randomized into Group 1. All 3 cavitations were recorded at the left side from subjects randomized into Group 2 (Figure 6.10).

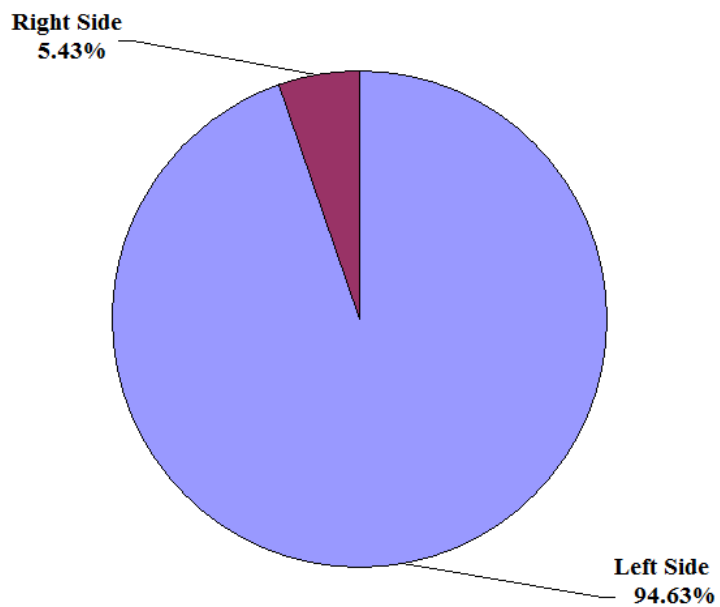


Figure 6.8: Percentage of cavitations recorded on left side and right side

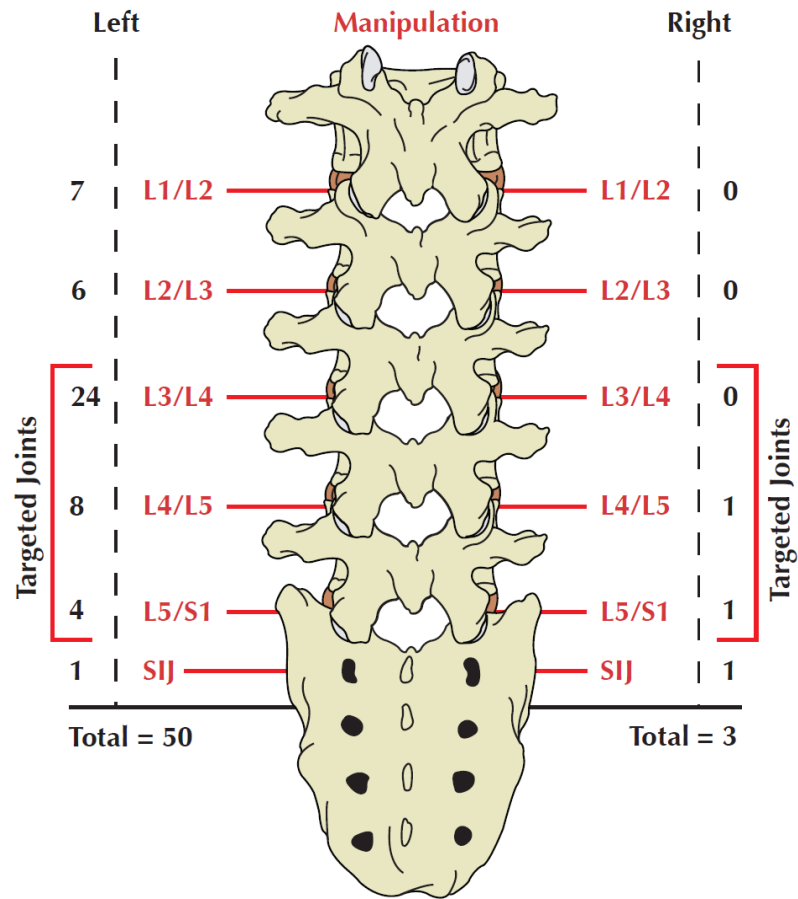


Figure 6.9: Posterior view of the spine with the number of cavitations recorded at each joint on the left and right side for Group 1 (SMT group). Red line shows the targeted Z joints (L3/L4, L4/L5, and L5/S1). Significantly more cavitations were recorded on left side as compared to right side ($p < 0.001$). Interestingly, more cavitations were recorded at targeted Z joints than non-targeted Z joints ($p < 0.001$)

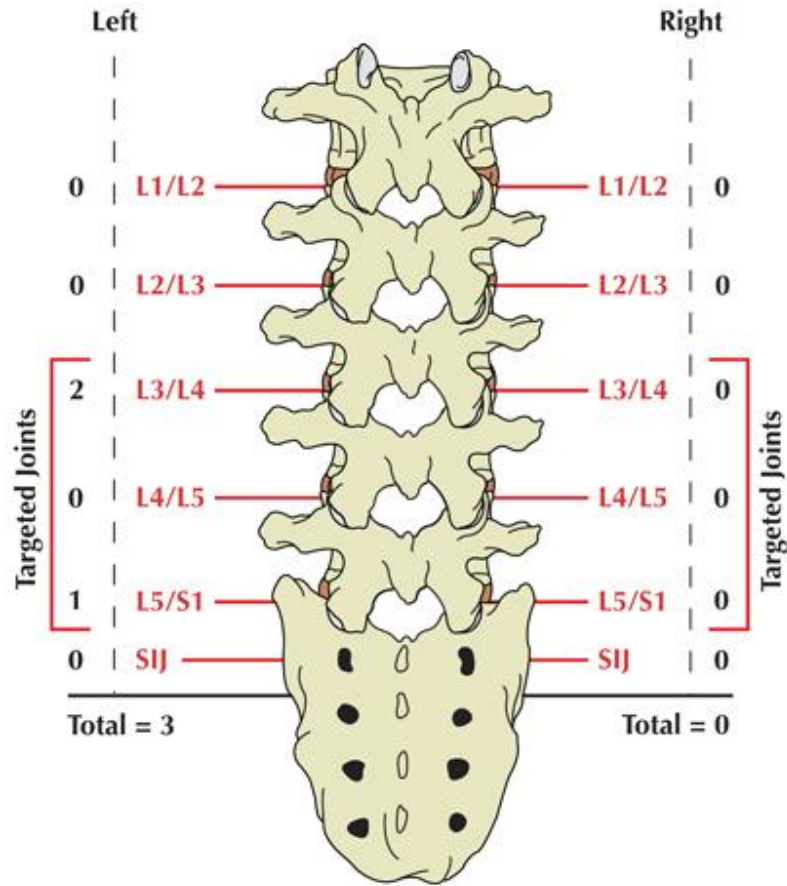


Figure 6.10: Posterior view of the spine with the number of cavitations recorded at each joint on the left and right side for Group 2 (non-SMT group). Red line shows the targeted Z joints (L3/L4, L4/L5 and L5/S1). Interestingly, all the cavitations in this group were recorded on the left side and in the targeted area

6.6 Multiple Cavitations

The accelerometry methods used in this study showed the capability of recording multiple cavitations from different joints during a single SMT. Also interestingly; multiple cavitations from the same joint were recorded.

Fifty-six cavitations were recorded from a total of 40 subjects randomized into Group 1 or Group 2 (Table 6.6). Out of these 56, single cavitations were recorded in 38 joints (Table 6.7) (35 in Group 1 and 3 in Group 2), double cavitations in 7 joints and 4 cavitations in 1 joint (Table 6.7). Multiple cavitations from the same joint were detected only on the left side in Group 1; none were detected on the right side or in Group 2 (Table 6.7).

The range of cavitations for subjects included in Group 1 was 0-6 and was 0-1 for subjects in Group 2.

The maximum of six cavitations were recorded from a subject randomized in Group 1, interestingly with 4 cavitations at the same joint (Left L3/L4) and 2 cavitations at another joint (Left L2/L3). This unique subject's data was collected in the late evening, the only evening recording in the study.

Table 6.7: Distribution of cavitations detected by accelerometers

| Joints | Number of Cavitations Reported for a Single Joint | | | |
|------------|---|----|---|---|
| | 0 | 1 | 2 | 4 |
| LEFT L1L2 | 49 | 5 | 1 | 0 |
| RIGHT L1L2 | 0 | 0 | 0 | 0 |
| LEFT L2L3 | 50 | 4 | 1 | 0 |
| RIGHT L2L3 | 0 | 0 | 0 | 0 |
| LEFT L3L4 | 30 | 14 | 4 | 1 |
| RIGHT L3L4 | 0 | 0 | 0 | 0 |
| LEFT L4L5 | 48 | 8 | 0 | 0 |
| RIGHT L4L5 | 55 | 1 | 0 | 0 |
| LEFT L5S1 | 51 | 3 | 1 | 0 |
| RIGHT L5S1 | 55 | 1 | 0 | 0 |
| LEFT SIJ | 55 | 1 | 0 | 0 |
| RIGHT SIJ | 55 | 1 | 0 | 0 |

6.7 Amplitude of Cavitations

Table 6.8 shows the amplitude grade for each cavitation. This data will be used in an ongoing study (not reported here) to see if there is any relation between amplitude of cavitation signals (high, medium, and low) and the amount of gapping in the respective Z joints.

Table 6.8: Amplitude of cavitation signals

| SUBJECT ID NUMBER | LEVEL OF CAVITATION | AMPLITUDE OF CAVITATION |
|--------------------------|----------------------------|--------------------------------|
| 6 | LEFT L3L4 | MEDIUM |
| 9 | NONE | NONE |
| 10 | NONE | NONE |
| 11 | RIGHT L5S1 | HIGH |
| | RIGHT L4L5 | HIGH |
| 12 | LEFT L3L4 | MODERATE |
| | LEFT L4L5 | HIGH |
| 13 | LEFT L3L4 | HIGH |
| | RIGHT SIJ | HIGH |
| 14 | LEFT L4L5 | MEDIUM |
| | LEFT L2L3 | HIGH |
| 16 | NONE | NONE |
| 18 | LEFT L4L5 | HIGH |
| | LEFT L2L3 | HIGH |
| 21 | LEFT L3L4 | HIGH |
| 24 | LEFT L3L4 | LOW |
| | LEFT L4L5 | MEDIUM |
| 30 | LEFT L3L4 | HIGH |
| 32 | LEFT L3L4 | HIGH |
| | LEFT L3L4 | HIGH |
| 34 | LEFT L5S1 | HIGH |
| | LEFT L5S1 | MODERATE |

| | | |
|----|-----------|--------|
| | LEFT L4L5 | HIGH |
| 35 | LEFT L3L4 | HIGH |
| | LEFT L3L4 | HIGH |
| 37 | LEFT L3L4 | MEDIUM |
| | LEFT L4L5 | LOW |
| 40 | LEFT L3L4 | HIGH |
| | LEFT L3L4 | HIGH |
| 41 | NONE | NONE |
| 45 | LEFT L5S1 | HIGH |
| 46 | NONE | NONE |
| 47 | LEFT L3L4 | HIGH |
| | LEFT L3L4 | HIGH |
| 58 | LEFT L4L5 | HIGH |
| | LEFT L5S1 | HIGH |
| 59 | LEFT L1L2 | MEDIUM |
| 61 | LEFT L4L5 | LOW |
| 65 | LEFT L3L4 | HIGH |
| 69 | LEFT L3L4 | HIGH |
| 71 | LEFT L1L2 | HIGH |
| | LEFT SIJ | HIGH |
| | LEFT L1L2 | HIGH |
| 72 | LEFT L3L4 | LOW |
| 74 | LEFT L5S1 | LOW |
| 75 | LEFT L2L3 | HIGH |
| | LEFT L1L2 | HIGH |
| 80 | NONE | NONE |
| 82 | LEFT L1L2 | HIGH |
| 84 | NONE | NONE |
| 85 | LEFT L3L4 | HIGH |
| 86 | LEFT L3L4 | HIGH |
| 87 | NONE | NONE |
| 90 | LEFT L1L2 | HIGH |
| 92 | LEFT L3L4 | HIGH |
| | LEFT L2L3 | HIGH |
| 93 | LEFT L3L4 | HIGH |

| | | |
|----|-----------|--------|
| | LEFT L1L2 | HIGH |
| 97 | LEFT L3L4 | HIGH |
| | LEFT L3L4 | HIGH |
| | LEFT L3L4 | HIGH |
| | LEFT L2L3 | HIGH |
| | LEFT L3L4 | MEDIUM |
| | LEFT L2L3 | HIGH |

* Subjects are listed in ascending order by their Subject ID number (each was assigned a random Subject ID number 1-100)

7. DISCUSSION

The main objective of this research project was to locate the level of Z joints in the lumbar spine that cavitated following SMT and side-posture positioning. Specific goals were set to refine previous methods (Goal 1 of Section 1.2), conduct recordings using the re-designed methods (Goal 2 of Section 1.2), and report the results of accelerometry recordings (Goal 3 of Section 1.2). The re-designed instrumentation and methodology were successful in accomplishing the main objective. Cavitations were recognized by their unique waveform pattern (“non-continuous” or “damped” waveform pattern) (Macquarie University, 2008) and by the sequential response of accelerometers (Ross et al., 2004).

The reliability study comparing the results of two observers (blinded to the results of one another) in identifying cavitations from the accelerometer recordings showed “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003). Accelerometer recordings of cavitations were also in “almost perfect agreement” with verbal reporting by the subjects and clinician. The clinician and subject were also in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003).

Assessing the relationship between amplitude of cavitations and Z joint gapping in the ongoing study may be challenging, because the amplitude was affected by the impedance of the intervening tissue and the distance between the transducer and the joint.

This is similar to the difficulty other authors have had in interpreting the severity of degenerative disease by waveform amplitude (Gay et al., 1987).

Fifty-six cavitations were recorded from 40 subjects. Fifty-three cavitations were recorded from subjects randomized in Group 1 (SMT group) and 3 cavitations were recorded from subjects randomized in Group 2 (Control group in which subjects were only held in the side-posture position but did not received SMT). The range of cavitations for subjects included in Group 1 was 0-6 and in Group 2 was 0-1. Therefore, the hypothesis that subjects can cavitate during side-posture positioning was confirmed. Group 1 subjects (SMT) cavitated more than Group 2 subjects (side-posture position), putatively because of the additional force received by the Z joints and SIJs during SMT.

Fifty-three cavitations ($53/56 = 94.63\%$) were recorded from joints located on the left side and 3 cavitations ($3/56 = 5.43\%$) were recorded from the joints located on the right side. Reggars and Pollard (1995) conducted a study to determine the side of audible release in the cervical region using two microphones. Interestingly, they found that in 94% of the subjects, audible release was on the same side as head and neck rotation (i.e., head and neck rotated to the right associated with cavitation on right side). Our findings agree with Reggars and Pollard, as the rotation in the lumbar spine during side-posture positioning and SMT in this study was the same as theirs in the cervical region (Reggars and Pollard, 1995). Subjects in our study were held in side-posture position, and SMT was applied on left side as subjects were laying on their right side. That is to say, a higher percentage of cavitations were recorded on the same side in which force was applied.

A robust cavitation response was found in the targeted Z joints. Forty-one cavitations ($41/56 = 73.21\%$) were recorded at targeted Z joints (Left L3/L4, Right

L3/L4, Left L4/L5, Right L4/L5, Left L5/S1, and Right L5/S1) and 26.80% cavitations were recorded at non-targeted Z joints (Left L1/L2, Right L1/L2, Left L2/L3, Right L2/L3, Left SIJ and Right SIJ). Interestingly, a maximum of 46.43% cavitations were recorded at Left L3/L4 Z joint. These results indicate that although SMT is not precise (Ross et al., 2004) at producing cavitation at a specific single segment, it was precise up to 3 segments in our study.

Multiple cavitations were recorded from the same joint. Double cavitations were recorded in 7 joints, and interestingly, 4 cavitations in 1 joint. There might be several reasons behind this. First, methods used in this study always included two thrusts, increasing the chances of getting multiple cavitations. Second, the resistance within the Z joint to the force of SMT may have been unique in these joints. Third, the specific mechanism of gapping in these joints may have been unique. That is, some joints may gap evenly along the joint surfaces while others may gap in stages, first at the medial or lateral border and then at the opposite side of the joint. Fourth, the shape of the Z joints associated with multiple cavitations might differ from the shape of the Z joints that cavitated once or did not cavitate. A future study is planned that will assess this last potential mechanism associated with multiple cavitations. In the study, the shape of the Z joints that cavitate multiple times will be compared with the shape of Z joints cavitating once, as well as those that did not cavitate at same segmental level and in the subjects of same gender.

A maximum of 6 cavitations were recorded from a single subject randomized in Group 1, with 4 cavitations at one joint and 2 cavitations at another joint. As mentioned previously, this interesting case was the only subject on which data was collected in the

late evening. There might be several reasons for getting multiple cavitations at this time. First, the disc is less hydrated in the evening as compared to the morning, increasing motion of the Z joints (Paajanen et al., 1994). Also, because of various activities performed by the subject throughout the day, the Z joints might be more lubricated in the evening, providing increased freedom of motion. Further study of relative lubrication (synovial fluid volume) in the morning vs. evening is needed to determine if this hypothesis is biologically plausible.

Some accelerometer signals that were not caused by cavitation, known as artifacts or noise, provided a challenge to this study. The waveforms for artifacts were irregular with larger spikes and did not fit the smooth “non-continuous” or “damped” waveform pattern found in cavitations. In addition, accelerometers responded dramatically out of sequence when recording artifacts, whereas the accelerometers responded in a very predictable pattern when recording cavitations. Artifacts were generated by the clinician accidentally touching the tape or accelerometers, movement in wires, movement in skin and muscles, movement of the subject’s body while applying force to cavitate joints, a subject not relaxing or opposing the clinician, and other yet undetermined (miscellaneous) reasons. Based on notes taken during data acquisition and assessment, combined with the unique pattern and nature of recorded waveform signals, artifacts were categorized into the following groups: flexible spine (or loose superficial fascia) subjects, hyper-muscular subjects (e.g., body builders), resisting or not relaxed subjects, unstable hand contact (UHC) (i.e., clinician’s hand contact), and miscellaneous. It was not possible to assess cavitations from data that included resisting or not relaxed subjects or UHC artifacts. Consequently, subjects with these artifacts were excluded from data

analysis for cavitations. To reduce the artifacts due to flexible spine (or loose superficial fascia) subjects, additional tape was applied to the accelerometers on all subjects' backs in side-posture position during the clinical study. In order to prevent resisting or not relaxed subject artifacts, subjects were asked to relax and not resist the study clinician. UHC artifacts were prevented by requiring subjects to wear cotton surgical scrub pants (rather than "slippery shorts") during the clinical study.

Goal 4 of this study (discussed in Section 1.2) was: "To assess the accelerometry methods used in the clinical study to determine the strengths and challenges (weaknesses) of the re-designed methods." Several strengths and challenges of the re-designed methods used in this study were identified and are listed immediately below.

Primary Strengths – The new methods were able to:

1. Differentiate cavitations from artifacts.
2. Identify cavitations reliably (two reliability studies).
3. Capture cavitations at the targeted Z joints and non-targeted Z joints during side-posture positioning and SMT.
4. Record, archive cavitations, and artifacts using screenshots of the complete time scale.

The primary challenge of the re-designed methods was the presence of artifacts. The challenge of differentiating between cavitations and artifacts was overcome by assessing the accelerometry data. Cavitations had a smooth, non-continuous (damped) waveform pattern and responded sequentially, whereas artifacts had a waveform pattern characterized by many large irregular spikes and the accelerometers responded in a

chaotic sequence. Artifacts were able to be categorized based on the notes taken during data acquisition and the unique pattern and nature of waveform signals.

Goal 5 (discussed in Section 1.2) was set to propose ideas for future studies that would further refine accelerometry methods and add acoustics methods. Future spine research combining microphones with accelerometers should use a surface microphone in addition to accelerometers. Recordings should be made during full ranges of motions (full flexion, extension, left and right lateral flexion, and left and right rotation), side-posture positioning and SMT. This would allow for the recording of additional joint sounds known as “crepitus”. Data should be collected from accelerometers and the microphone simultaneously, because each captures unique and complementary information (Jaskolska and Madeleine, 2007). Subjects in younger and older age groups should be sought to find unique information related to changes in joints with age. Lumbar x-rays of the subjects should be taken, and the amount of spinal degeneration should be graded from the x-rays (Cramer et al., 2008). Fast Fourier Transformation (FFT) should be performed to determine the unique characteristics of the sound waves recorded during the ranges of motions and SMT. Such frequency analysis of sound waves has been used to assess sounds associated with temporomandibular joint dysfunction (Heffez and Blaustein, 1986; Widmalm et al., 1992; Gallo et al., 1993). The amount of degeneration graded from the x-rays in the proposed study should be used to explore the possibility of unique waveform patterns associated with different amounts of degeneration. A relationship between degeneration or other joint pathology and analysis of sound waves has been successfully investigated in the knee (Chu et al., 1976). The processing capacity of the computer can be increased for longer-duration sampling at a higher sampling rate

to prevent the computer from overloading the buffer during simultaneous data collection from 10 channels (9 accelerometers and 1 surface microphone). Kinesio tape (Kinesio tape, 2010) could be used to place accelerometers and the microphone on the subject's body to prevent the tape from "popping off" during data collection of the subject's full ranges of motion. Kinesio tape allows for increased flexibility during ranges of motions compared with the strong adhesion and non-flexible tape used in this study. Ultrasound gel should be applied to the location where the microphone is placed, and the microphone could be placed on top of rubber pads. These procedures could minimize frictional noise between the skin and the microphone (Chu et al., 1976). The results of such a study could potentially initiate a line of investigation deepening the understanding of the mechanics of the spine and SMT by assessing differences found during various motions, SMT, and in spines with varying degrees of degeneration.

8. CONCLUSIONS

The accelerometry methods used in this research project effectively identified the segmental level of cavitation, which was the main objective of this research project.

The reliability study showed “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003) between the results of two observers (blinded to the results of one another) in identifying cavitations in the accelerometer recordings.

Accelerometer recordings of cavitations were in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003) with the subject and clinician. The clinician and subjects were also in “almost perfect agreement” (Cohen, 1960; Landis and Koch, 1977; Gottman, 1995; Fleiss et al., 2003).

Cavitations were recognized by their unique “non-continuous” or “damped” waveform pattern combined with the sequential response of accelerometers. Subjects randomized into Group 1 who received SMT cavitated significantly more often (96.67% of Group 1 subjects) than those who were just held in side-posture-positioning (30% of Group 2 subjects) ($p < 0.0001$). Most cavitations were recorded on the left-side (up-side, 94.63%) and at targeted Z joints (73.20%). Instruments used in this study showed the capability of recording multiple cavitations from different joints and also (interestingly) multiple cavitations from the same joint. The range of cavitations for subjects in Group 1

was 0-6 and Group 2 was 0-1. A maximum of 6 cavitations were recorded from a single Group 1 subject, with 4 cavitations at one Z joint and 2 cavitations at another Z joint.

Artifacts had waveform patterns distinctly different from cavitations. The waveforms for artifacts were irregular with larger spikes and did not fit the smooth “non-continuous” or “damped” waveform pattern found in cavitations. In addition, accelerometers responded dramatically out of sequence when recording artifacts, whereas the accelerometers responded in a very predictable pattern when recording cavitations. Based on notes taken during data acquisition and assessment, combined with the unique pattern and nature of recorded waveform signals, artifacts were categorized into the following groups: flexible spine (or loose superficial fascia) subjects, hyper-muscular subjects (e.g., body builders), resisting or not relaxed subjects, unstable hand contact (UHC) of clinician (i.e., clinician’s hand contact) and miscellaneous.

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APPENDICES

A. Technical Specifications

1) Bruel & Kjaer Delta Tron4507 Accelerometer

Bruel & Kjaer Delta Tron4507 accelerometer was used in our research project as shown in figures 4.11, A.1 (Bruel & Kjaer, 2010) because of its size and high sensitivity.

Reference Sensitivity: 9.766mV/ms^{-2}

Frequency Range: 0.3Hz to 6 kHz

Mounted Resonance Frequency: 18 kHz

Electrical

Bias Voltage: At full temperature and current range: +12V +-1V

Power Supply requirements: Constant Current: +2 to +20mA

Unloaded Supply Voltage: +24V to +30 V

Output Impedance: Less than 2 ohms

Recommended cables: AO 1382

AO 0531

AO 0463

Environmental

Temperature Range: -54 to +121°C

Temperature Coefficient of Sensitivity: +0.09 %/°C

Magnetic Sensitivity: $3\text{ms}^{-2}/\text{T}$

Maximum Non-destructive Shock: 50 kms^{-2} peak (5000 g peak)

Humidity: 90% RH non-condensing

Mechanical

Case Material: Titanium ASTM Grade 2

Sensing Element: Piezoelectric, Type PZ 23

Construction: Theta Shear

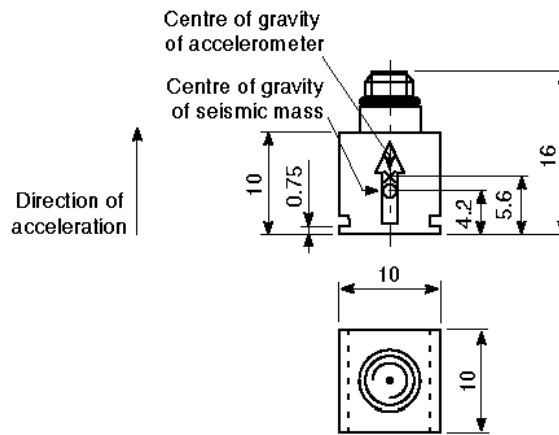
Sealing: Welded

Weight: 4.8 gram

Electrical Connector: 10-32 UNF-2A

Mounting Surface Flatness: $< 3\mu\text{m}$

Geometric Dimensioning:



All dimensions in millimetres

Figure A.1: Geometric dimensioning of Bruel & Kjaer Delta Tron4507 accelerometer

Polarity of the electrical signal is positive for acceleration in the direction of the arrow on the drawing.

2) **Bruel & Kjaer 2693 NEXUS Signal Conditioning Amplifier**

Connector: TNC

Grounding: Single-ended or floating

Differential Charge: 10 nC (peak);

Common Mode Voltage: 4.2V (peak)

Amplifier gain: 0.1mV/pC to 10 V/pC (.20 to +80 dB gain with 1 nF transducer capacity);

Transducer sensitivity range: 10.19 to 10.6 C/MU

(MU = mechanical units: m/s²; g, N, lb., Pa)

Frequency range: Acceleration: 0.1Hz to 100 kHz (transducer cable length <10m)

Magnetic Field: <0.2 fC/ (A/m)

Electromagnetic Field: <20 fC/ (V/m) or <4 fC/V

Vibration (10 to 500Hz): <30 fC/ (m/s²)

DeltaTron® Input

Connector: BNT

Grounding: Single-ended or floating

Input impedance: 1M Ω || 100 pF (AC coupled)

Differential Voltage: \leq 31.6V (peak)

Common Mode Voltage: 4.2V (peak)

Amplifier gain: .20 to +60 dB gain (80 dB with reduced specs.)

Transducer sensitivity range: 10.12V/MU to 103V/MU

General Specifications:

Power Supply: Internal battery

Each amplifier is capable of supporting four transducers as shown in figure A.2 (Briel & Kjaer, 2010), displayed on the first column. Amplifier uses Nickel-Metal Hydride rechargeable battery supporting SMBus and on-battery charge level meter. It provides typically 15 hours of continuous use with a single channel and 4 hours with four channels without backlighting and without optional filters. With backlighting on, and with optional filters, battery provides typically 3 hours of continuous use.

External dc power input: Complies with ISO 7637.1 (12 V) and 7637.2 (24V)

Input Range: 10 to 33VDC

Mains supply: Supported via supplied Mains Adaptor ZG-0426 (included), 90 .264VAC, 40.65Hz

Display Interface

Display: 64 × 128 pixel graphical display with back-lighting on/off

Overload detection: On both common-mode and differential signals applied before filters. LED overload indication at the front panel and overload indication via RS.232 control interface.

Dynamic range: .30 to +10 dB V (peak)

Resolution: 1 dB



Figure A.2: Brüel & Kjaer 2693 NEXUS signal conditioning amplifier (an accelerometer is shown to the right of the microphones, microphones were not used in this study)

3) NI PXIe-6356 Simultaneous X Series Data Acquisition Card

- 8 simultaneous analog inputs at 1.25 MS/s/channel with 16-bit resolution (National Instruments, 2010).
- Two analog outputs, 3.33 MS/s, 16-bit resolution, ± 10 V.
- 24 digital I/O lines (8 hardware-timed up to 10 MHz).
- Four 32-bit counter/timers for PWM, encoder, frequency, event counting, and more.
- Analog and digital triggering and advanced timing with NI-STC3 technology.
- Support for Windows 7/Vista/XP/2000.

Overview

NI X Series multifunction data acquisition (DAQ) devices provide a high-throughput PCI Express bus, excellent NI-STC3 timing and synchronization technology, and multicore-optimized driver and application software.

High-Throughput PCI Express Bus

PCI express offers dedicated bandwidth of up to 250 MB/s in each direction to each device, and X series devices feature a native PCI express interface with optimizations for high throughput and low latency.

NI-STC3 Technology

NI-STC3 timing and synchronization provides advanced timing functionality, including independent analog and digital timing engines, retriggerable measurement tasks, and four counter/timers with more functionality than previous technologies.

Technical Specifications

PXI Bus Type: PXI express, PXI hybrid compatible

Operating System/Target: Real-Time, windows

LabVIEW RT Support: Yes

DAQ Product Family: X Series

Measurement Type: Digital, frequency, quadrature encoder, voltage

RoHS Compliant: Yes

Analog Input

Channels: 0, 8

Single-Ended Channels: 0

Differential Channels: 8

Resolution: 16 bits

Sample Rate: 1.25MS/s

Throughput: 10 MS/s

Max Voltage: 10 V

Maximum Voltage Range: -10 V, 10 V

Maximum Voltage Range Accuracy: 2.566 mV

Minimum Voltage Range: -1 V, 1 V

Minimum Voltage Range Accuracy: 307 μ V

Number of Ranges: 4

Simultaneous Sampling: Yes

Analog Output

Channels: 2

Resolution: 16 bits

Max Voltage: 10 V

Maximum Voltage Range: -10 V, 10 V

Maximum Voltage Range Accuracy: 3.066 mV

Minimum Voltage Range: -5 V, 5 V

Minimum Voltage Range Accuracy: 1.526 mV

Digital I/O

Bidirectional Channels: 24

Input-Only Channels: 0

Output-Only Channels: 0

Number of Channels: 24, 0, 0

Timing: Software, hardware

Clocked Lines: 8

Max Clock Rate: Sinking, sourcing

Logic Levels: TTL

Input Current Flow: Sinking, sourcing

Output Current Flow: 10 MHz

Programmable Input Filters: Yes

Current Drive Single: 24 mA

Current Drive All: 576 mA

Watchdog Timer: Yes

Maximum Input Range: 0 V, 5 V

Maximum Output Range: 0 V, 5 V

Counter/Timers

Counters: 4

Number of DMA Channels: 8

Buffered Operations: Yes

GPS Synchronization: No

Maximum Range: 0 V, 5 V

Max Source Frequency: 100 MHz

Minimum Input Pulse Width: 10 ns

Pulse Generation: Yes

Resolution: 32 bits

Time base Stability: 50 ppm

Logic Levels: TTL



Figure A.3: NI PXIe-6356 Simultaneous X Series Data Acquisition Card

4) NI BNC-2090 Rack-Mounted BNC Terminal Block



Figure A.4: NI BNC-2090 rack-mounted BNC terminal block

The National Instruments BNC-2090 as shown in figure A.4 (National Instruments, 2010) is a shielded rack-mountable connector block having 22 signal-labeled BNC connectors and 28 spring terminal blocks to simplify connections to I/O signals from NI

data acquisition devices. It connects to any 68-pin M series, S series, E series, or B series DAQ device. The NI BNC-2090 also includes component locations for passive signal conditioning.

- Shielded, rack-mountable BNC adapter chassis
- 22 BNC connectors for analog, digital, and timing signals
- 28 spring terminals for digital/timing signals

5) NI PXIe-1073 CHASSIS

- 3 hybrid slots and 2 PXI express slots - every slot accepts PXI express modules
- 150 W total power available from 0 to 50 °C
- Integrated MXI-express controller included
- Up to 250 MB/s per-slot dedicated bandwidth and 250 MB/s system bandwidth
- Compatibility with PXI, PXI express, compact PCI, and compact PCI express modules



Figure A.5: NI PXIe-1073 chassis

The NI PXIe-1073 chassis with integrated controller is designed for variety of applications. It accepts PXI express modules in every slot and supports standard PXI hybrid-compatible modules in up to three slots. The chassis features compact, rugged

packaging as well as acoustically quiet operation, which makes it ideal for both portable and desktop systems. The sturdy design of the chassis enables it to operate in environments from 0 to 50 °C. The chassis also incorporates all of the latest PXI specification features including PXI and PXI express module support and built-in timing and synchronization.

Specifications

General

Form Factor: PXI platform

PXI Bus Type: PXI express, PXI hybrid compatible

Operating System/Target: Any

LabVIEW RT Support: Yes

Chassis

Power Supply: AC

Number of Slots: 5

Number of PXI Express Peripheral Slots: 2

Number of Hybrid Peripheral Slots: 3

Maximum System Bandwidth: 250

Accepts both 3U PXI and Compact PCI Modules: Yes

Integrated Controller: Yes

Remote Power Inhibit Control and Voltage Monitoring: No

Total Available Power: 150

Input Voltage Range: 100 V, 240 V
Input Frequency Range: 47 Hz, 63 Hz
Field-replaceable Power Supply: No
Auto Fan Sound Pressure Level: 43.3
Auto Fan Sound Power: 51.3
High Fan Sound Pressure Level: 58.3
High Fan Sound Power: 64.6
Auto/High Fan Selector: Yes
Number of Fans: 1

6) NI PXIe-Express Card 8360



Figure A.6: NI PXIe-express card 8360

- Sustained throughput up to 214 MB/s
- Software-transparent link that requires no programming
- Cabling up to 7 m with rugged screw-in connectors
- Ability to use the same PXI express module (NI PXIe-8360) and cable as MXI-express for PXI express

- Ideal for mobile applications such as field tests, in-vehicle data logging, NVH, NDT, and RF testing (and movable accelerometry cart used in this study figure 4.2)
- Direct laptop control of PXI Express/Compact PCI Express

Specifications

General

Form Factor: PXI platform

PXI Bus Type: PXI express

Operating System/Target: Windows, real-time

LabVIEW RT Support: Yes

Controller

Controller Type: Remote

Communication Technology: PCI express

Sustained Performance: 214 MB/s

Cable Material: Copper

Maximum Cable Length: 7 m

Maximum Links per Host Card: 1

Slot Requirement: 1

B. Auburn University Institutional Review Board (IRB) Approval



AUBURN
UNIVERSITY

Office of Research Compliance
307 Sanford Hall
Auburn University, AL 36849

Telephone: 334-844-5966
Fax: 334-844-4391
hsubj@auburn.edu

February 23, 2010

MEMORANDUM TO: Dr. P.K. Raju
Department of Mechanical Engineering

PROTOCOL TITLE: "Relationship of Cavitation to Gapping Following Spinal Manipulation"

IRB FILE NO.: 09-294 EP 1001

APPROVAL DATE: January 6, 2010
EXPIRATION DATE: January 5, 2011

The referenced protocol was approved as "Expedited" by the IRB under 45 CFR 46.110 (5):

"(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)."

You must retain this letter in your files, along with a copy of the approved protocol and other pertinent information concerning your study. If you should anticipate a change in any of the procedures authorized in this protocol, you must request and receive IRB approval prior to implementation of any revision. Please reference the above IRB file number in any correspondence regarding this project.

If you will be unable to file a Final Report on your project before January 5, 2011, you must submit a request for an extension of approval to the IRB no later than December 1, 2010. If your IRB authorization expires and/or you have not received written notice that a request for an extension has been approved prior to January 5, 2011 you must suspend the project immediately and contact the Office of Research Compliance for assistance.

A Final Report will be required to close your IRB project file.

If you have any questions concerning this Board action, please contact the Office of Research Compliance.

Sincerely,

Kathy Jo Ellison, RN, DSN, CIP
Chair of the Institutional Review Board
for the Use of Human Subjects in Research

cc: Dr. Jeffrey Suhling

AUBURN UNIVERSITY INSTITUTIONAL REVIEW BOARD for RESEARCH INVOLVING HUMAN SUBJECTS
RESEARCH PROTOCOL REVIEW **APPROVED**

For Information or help contact THE OFFICE OF HUMAN SUBJECTS RESEARCH, 307 Samford Hall, Auburn University
 Phone: 334-844-5966 e-mail: hsubjec@auburn.edu Web Address: <http://www.auburn.edu/research/vpr/ohs/>

Complete this form using Adobe Acrobat Writer (versions 5.0 and greater). Hand written copies not accepted.

1. PROPOSED START DATE OF STUDY: October 30, 2009
- PROPOSED REVIEW CATEGORY (Check one): FULL BOARD EXPEDITED EXEMPT
2. PROJECT TITLE: Relationship of Cavitation to Gapping Following Spinal Manipulation, PI: Gregory D. Cramer, D.C., Ph.D.
Co-PI (at Auburn) P.K. Raju, Ph.D.
3. P.K. Raju, Ph.D. (Auburn) Professor Mech. Eng. 334-844-3301 rajupol@auburn.edu
 PRINCIPAL INVESTIGATOR TITLE DEPT PHONE AU E-MAIL
 270 Ross Hall, Auburn University, AL 36849
 MAILING ADDRESS FAX ALTERNATE E-MAIL
4. SOURCE OF FUNDING SUPPORT: Not Applicable Internal External Agency, NUHS/NIH/NCCAM Pending Received
5. LIST ANY CONTRACTORS, SUB-CONTRACTORS, OTHER ENTITIES OR IRBs ASSOCIATED WITH THIS PROJECT:
National University of Health Sciences
6. GENERAL RESEARCH PROJECT CHARACTERISTICS

| 6A. Mandatory CITI Training | 6B. Research Methodology |
|---|---|
| Names of key personnel who have completed CITI: <u>P.K. Raju</u> <u>Preetam Bora</u> _____ _____ CITI group completed for this study: <input type="checkbox"/> Social/Behavioral <input checked="" type="checkbox"/> Biomedical Protocol-Specific modules completed: <input type="checkbox"/> Genetic <input type="checkbox"/> Vet's Administration <input type="checkbox"/> International <input type="checkbox"/> Prisoner Research <input type="checkbox"/> Public School Students <input type="checkbox"/> Pregnant Women/Fetuses Other _____ _____ _____ | Please check all descriptors that best apply to the research methodology. Data Source(s): <input checked="" type="checkbox"/> New Data <input type="checkbox"/> Existing Data Will data be recorded so that participants can be directly or indirectly identified? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Data collection will involve the use of: <input type="checkbox"/> Educational Tests (cognitive diagnostic, aptitude, etc.) <input checked="" type="checkbox"/> Interview / Observation <input checked="" type="checkbox"/> Surveys / Questionnaires <input checked="" type="checkbox"/> Physical / Physiological Measures or Specimens (see Section 0E.) <input type="checkbox"/> Internet / electronic <input type="checkbox"/> Private records or files <input checked="" type="checkbox"/> Audio / Video / Photos |
| 6C. Participant Information | 6D. Risks to Participants |
| Please check all descriptors that apply to the participant population. <input checked="" type="checkbox"/> Males <input checked="" type="checkbox"/> Females <input type="checkbox"/> AU students Vulnerable Populations <input type="checkbox"/> Pregnant Women/Fetuses <input type="checkbox"/> Children and/or Adolescents (under age 19 in AL) <input type="checkbox"/> Prisoners Persons with: <input type="checkbox"/> Economic Disadvantages <input type="checkbox"/> Physical Disabilities <input type="checkbox"/> Educational Disadvantages <input type="checkbox"/> Intellectual Disabilities Do you plan to compensate your participants? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | Please identify all risks that participants might encounter in this research. <input type="checkbox"/> Breach of Confidentiality* <input type="checkbox"/> Coercion <input type="checkbox"/> Deception <input type="checkbox"/> Physical <input type="checkbox"/> Psychological <input type="checkbox"/> Social <input checked="" type="checkbox"/> None <input type="checkbox"/> Other <u>None</u> *Note that if the investigator is using or accessing confidential or identifiable data, breach of confidentiality is always a risk. |
| 6E. Institutional Biosafety Approval | |
| Do you need IBC Approval for this study? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes - BUA # _____ Expiration date _____ | |

The Auburn University Institutional Review Board has approved this document for use from 10/31/09 to 10/31/10. Protocol # 09-294-EP 100.

| FOR OHSR OFFICE USE ONLY | | | |
|--|---|--|--|
| DATE RECEIVED IN OHSR: <u>12/15/09</u> by <u>SRA</u> | PROTOCOL # <u>09-294 EP 100</u> | | |
| DATE OF IRB REVIEW: <u>1/6/10</u> by <u>ZPSG</u> | APPROVAL CATEGORY: <u>45 CFR 46.110 (#5)</u> | | |
| DATE OF IRB APPROVAL: <u>1/6/10</u> by <u>S</u> | INTERVAL FOR CONTINUING REVIEW: <u>1 year</u> | | |
| COMMENTS: <u>original received 10/22/09</u> <u>IRB reviewed 10/31/09 (not approved)</u> | | | |

7. PROJECT ASSURANCES

PROJECT TITLE: Relationship of Cavitation to Gapping Following Spinal Manipulation, PI: Gregory D. Cramer, D.C., Ph.D.
Co-PI (at Auburn) P.K. Raju, Ph.D.

A. PRINCIPAL INVESTIGATOR'S ASSURANCES

1. I certify that all information provided in this application is complete and correct.
2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the Auburn University IRB.
3. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with Auburn University policies regarding the collection and analysis of the research data.
4. I agree to comply with all Auburn policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
 - a. Conducting the project by qualified personnel according to the approved protocol
 - b. Implementing no changes in the approved protocol or consent form without prior approval from the Office of Human Subjects Research
 - c. Obtaining the legally effective informed consent from each participant or their legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form
 - d. Promptly reporting significant adverse events and/or effects to the Office of Human Subjects Research in writing within 5 working days of the occurrence.
5. If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise OHSR, by letter, in advance of such arrangements.
6. I agree to conduct this study only during the period approved by the Auburn University IRB.
7. I will prepare and submit a renewal request and supply all supporting documents to the Office of Human Subjects Research before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the Auburn University IRB.
8. I will prepare and submit a final report upon completion of this research project.

My signature indicates that I have read, understand and agree to conduct this research project in accordance with the assurances listed above.

Dr. P. K. Raju

Printed name of Principal Investigator

[Signature]

Principal Investigator's Signature

12/15/09

Date

B. FACULTY ADVISOR/SPONSOR'S ASSURANCES

1. By my signature as faculty advisor/sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.
2. I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
3. I agree to meet with the investigator on a regular basis to monitor study progress.
4. Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
5. I assure that the investigator will promptly report significant adverse events and/or effects to the OHSR in writing within 5 working days of the occurrence.
6. If I will be unavailable, I will arrange for an alternate faculty sponsor to assume responsibility during my absence, and I will advise the OHSR by letter of such arrangements. If the investigator is unable to fulfill requirements for submission of renewals, modifications or the final report, I will assume that responsibility.
7. I have read the protocol submitted for this project for content, clarity, and methodology.

P.K. Raju

Printed name of Faculty Advisor / Sponsor

[Signature]

Signature

12/15/09

Date

C. DEPARTMENT HEAD'S ASSURANCE

By my signature as department head, I certify that I will cooperate with the administration in the application and enforcement of all Auburn University policies and procedures, as well as all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants by researchers in my department.

Jeffrey C. Suhling

Printed name of Department Head

[Signature]

Signature

12/15/2009

Date

8. PROJECT OVERVIEW: Prepare an abstract that includes:

(400 word maximum, in language understandable to someone who is not familiar with your area of study):

- I.) A summary of relevant research findings leading to this research proposal. (Cite sources: include a "Reference List" as Appendix A.)
- II.) A brief description of the methodology.
- III.) Expected and/or possible outcomes, and,
- IV.) A statement regarding the potential significance of this research project.

I.) Previous studies on healthy subjects at the National University of Health Sciences, Chicago, demonstrated gapping of the Z joints following spinal manipulation. The purpose of this study is to evaluate healthy subjects to determine the relationship between cavitation (the audible release or "pop" heard during a spinal adjustment) and the simultaneous gapping (separation) of the zygapophysial joint (Z joint) spaces in the L3-S1 region (joints L3/L4, L4/L5, and L5/S1) that occur as a result of lumbar side posture spinal adjusting. (The left and right Z joints [also known as "facet joints"] are the small joints between adjacent vertebrae.) Please see Appendix A for a list of references.

II.) Gapping will be measured from MRI scans and cavitation from accelerometers. Forty healthy volunteers will be recruited from the NUHS student population. An MRI will be taken with the subjects in neutral (supine) position and then accelerometers will be applied to the subject's back. Subjects will be randomized to either the adjustment group or a control group. The latter group will undergo side posture positioning without side posture adjusting. After the accelerometers are removed, the subjects will remain in side posture for a second MRI scan.

III.) This study is designed to lead to a mechanistic outcome that verifies, by cavitation, whether Z joint gapping has occurred following a lumbar adjustment. Such verification of gapping would be used to provide a quantified standard for manipulations administered in future clinical trials evaluating the effects of spinal manipulation in a variety of conditions.

IV.) Following further investigation, such verification may also be found to be useful in verifying Z joint gapping in clinical practice.

9. PURPOSE.

- a. Clearly state all of the objectives, goals, or aims of this project.

The specific aim of this study is to: Correlate cavitation (audible release) that occurs during spinal manipulation with gapping of the Z joints of 40 healthy subjects.

Hypothesis 1 (primary hypothesis): Following spinal manipulation, joints that cavitate will exhibit more gapping than those that do not.

Hypothesis 2: Joints that cavitate following spinal manipulation will gap more than those that cavitate following side-posture adjusting.

This project will depend the research of the parent grant by further investigating one of the mechanisms of action of spinal manipulative therapy (SMT, or spinal adjusting), that is, the relationship between cavitation (audible release) and gapping (separation) of the zygapophysial joint (Z joint) spaces following SMT. Although cavitation and gapping are thought to be related by many clinicians and researchers, there has been no evidence to support this hypothesis. Consequently, if a positive relationship is found, cavitation could be used to identify patients who would respond optimally to high velocity low amplitude adjustment, whereas no or a negative relationship would provide evidence that cavitation is not a suitable indicator of joint movement during spinal adjusting.

- b. How will the results of this project be used? (e.g., Presentation? Publication? Thesis? Dissertation?)

The project results will be incorporated into graduate student Preetam Bora's Master's thesis, and publications and presentations.

10a. KEY PERSONNEL. Describe responsibilities. Include information on research training or certifications related to this project. CITI is required. Be as specific as possible. (Attach extra page if needed.) *All non AU-affiliated key personnel must attach CITI certificates of completion.*
P.K. Raju, Ph.D
rajupol@auburn.edu

Principle Investigator _____ Title: _____ E-mail address _____
Dept / Affiliation: Mechanical Engineering, Auburn University _____

Roles / Responsibilities:

Dr. P.K. Raju provides the expertise necessary to include additional arrays of accelerometers and interpret the data produced by the additional arrays. This data permits us to identify not only the vertebral segment that cavitates, but also the specific joint (left or right) from which the cavitation originates. Identification of the specific Z joint that cavitates allows us to definitively determine the (see next page)

Individual: Preetam Bora _____ Title: graduate student _____ E-mail address pnb0001@auburn.edu
Dept / Affiliation: Mechanical Engineering, Auburn University _____

Roles / Responsibilities:

Preetam Bora will be responsible for applying the accelerometers to the subjects in the primary and preliminary studies, analyzing the accelerometer data from those studies, and will also work with Drs. Raju, Ross and Cramer to develop new methods of characterizing the various types and subcomponents of sounds emitted from the Z joint positioning and adjusting. The project results will be incorporated into Preetam Bora's Master's thesis and publications and presentations.

Individual: Gregory D. Cramer _____ Title: _____ E-mail address gcramer@nuhs.edu
Dept / Affiliation: National University of Health Sciences _____

Roles / Responsibilities:

Principal Investigator: The Principal Investigator (PI) will oversee all phases of the project and the Key Personnel. Weekly meetings will be held to coordinate the project. Those in attendance will include the following: all coinvestigators, key staff, the graduate student, mentored faculty, and others as needed. Skype will be used for those off campus. Dr. Cramer will interface with the Director of the Clinical Studies Office and the Clinical Coordinator as they complete the Manual of Operating Procedures (MOOP) for the study. (See next page)

Individual: J. Kim Ross, D.C., Ph.D _____ Title: _____ E-mail address kross@cmcc.ca
Dept / Affiliation: Canadian Memorial Chiropractic College _____

Roles / Responsibilities:

Dr. Ross provides the experience and expertise necessary to implement the methods needed to identify which segmental level cavitates during a spinal adjustment. He developed the original acoustic methods that will be used in the project. Dr. Ross will train the graduate student in these methods and will provide input to the graduate student to develop additional acoustic methods. Dr. Ross will make four trips to NUHS during the 11 months (October, November, March/April, and June/July) (See next page)

Individual: Jerrilyn Cambron, D.C., Ph.D _____ Title: _____ E-mail address jcambron@nuhs.edu
Dept / Affiliation: National University of Health Sciences _____

Roles / Responsibilities:

Dr. Cambron will be responsible for supervising the Clinical Studies Office for this project and will work with the Clinical Coordinator to write the MOOP for the study. Dr. Cambron will also be responsible for subject recruitment; Dr. Cambron has published on the topic of recruitment of subjects for clinical trials and is considered an expert in this field. Dr. Cambron will also be involved in reviewing the analyzed data and will be involved in the writing of abstracts, reports, and manuscripts.

Individual: _____ Title: _____ E-mail address _____
Dept / Affiliation: _____

Roles / Responsibilities:

11. LOCATION OF RESEARCH. List all locations where data collection will take place. (School systems, organizations, businesses, buildings and room numbers, servers for web surveys, etc.) Be as specific as possible. Attach permission letters in Appendix E.
(See sample letters at <http://www.auburn.edu/research/vpr/ohs/sample.htm>)

National University of Health Sciences, Lombard, Illinois

Dr. Raju responsibilities, continued: relationship between cavitation and gapping of a Z joint. On this project, Dr. Raju will work with Dr. Cramer, the other co-investigators, and Preetam Bora (Auburn University graduate student) to analyze the data from the accelerometers and also to explore new methods to assess the accelerometer data (part of Preetam Bora's project). This group will also work to design and implement the new methods for acquiring additional acoustic data. Dr. Raju will be the primary advisor of Preetam Bora, with Drs. Cramer and Ross also serving as advisors. Dr. Raju will be the direct supervisor of the graduate student once he returns to Auburn. Dr. Raju will not be involved in any clinical tests in Chicago. All clinical tests will be done at the National University of Health Sciences in Chicago.

Dr. Cramer responsibilities, continued: The PI will also regularly interact with the Research Clinician, Research Assistants, Radiology Technician, Reading Radiologist, Morphometry Radiologist, Morphometry Technologist, and Morphometry Student Assistants. Dr. Cramer will maintain frequent contact with the Clinical Coordinator, Ms. Dexheimer, and will meet often with the Director of the Office of Clinical Studies, Dr. Cambron.

The PI will help ensure the MRI quality control procedures are in place, the equipment is purchased at the beginning of the project, and will observe (and help where needed) as the acoustic methods are implemented. In addition, he will work with Drs. McKinnis and Huang to oversee the execution of the data management plan. During the time that the MRI measurements are being taken, Dr. Cramer will maintain close contact with the Morphometry Radiologist (Dr. Cantu) and will always be available to the MRI observers should any problems arise with equipment or logistical issues. Dr. Cramer will ensure the timely delivery of the raw data to Dr. Huang for statistical analysis, and will work with Dr. Huang and the other co-investigators to interpret the data for writing reports to the funding agency, abstracts for conferences, and manuscripts.

Dr. Cramer will make one trip to Auburn University during the last four months of the project to continue to help advise and mentor the graduate student, Preetam Bora, in his thesis project (Preetam Bora and Drs. Ross, Raju, and Cramer will maintain regular contact via email throughout the last four months and until Preetam Bora completes his program—Dr. Raju will be the primary advisor).

Dr. Ross responsibilities, continued: ...and will be involved in the weekly meetings (via Skype) and regular telephone and e-mail conversations with Dr. Cramer, Dr. Raju, and Preetam Bora. Dr. Ross will also help with the writing of abstracts, manuscripts, and a grant application.

12. PARTICIPANTS.

a. Describe the participant population you have chosen for this project.

(If data are existing, check here and describe the population from whom data were collected.)

Eighteen to 30 years of age (recruitment will include students in NUHS degree and certificate programs; young age for inclusion to decrease the likelihood of osseous and ligamentous degeneration of the lumbar region of the spine)

One hundred eighty-five pounds or less for males and 145 pounds or less for females (to ensure maximum image quality)

No previous history of LBP lasting for more than two weeks, or no more than three episodes of back pain of brief duration (one to two weeks) in any given year (to recruit healthy subjects with no history, or a minimal history, of LBP)

b. Describe why is this participant population is appropriate for inclusion in this research project. (Include criteria for selection.)

The current research proposes to study the relationship between cavitation and gapping during a single MRI appointment in 40 healthy subjects. Because healthy subjects can tolerate the side posture positioning during the study's specialized MRI procedures for a longer time than LBP subjects, we are also able to assess two additional Z joints than the parent grant (left and right L3-L4). Further work will be done to assess the intensity and unique acoustic characteristics of cavitations and other Z joint sounds of healthy subjects. Assessing the low risk variables of cavitation and gapping in a mechanistic study using healthy subjects is appropriate before pursuing the question in a clinical population. The 18- 30 years of age inclusion decreases the likelihood of osseous and ligamentous degeneration of the lumbar region of the spine.

c. Describe, step-by-step, all procedures you will use to recruit participants. Include in Appendix B a copy of all e-mails, flyers, advertisements, recruiting scripts, invitations, etc., that will be used to invite people to participate. (See sample documents at <http://www.auburn.edu/research/vpr/ohs/sample.htm>.)

Healthy male (n=15) and female (n=15) subjects will be evaluated in Group 1 (n=30, adjustment group) and 5 subjects of each sex will be evaluated in Group 2 (n=10, control group). As in a previous study assessing healthy subjects (IRB #H-0709), the subjects will be students and employees from the National University of Health Sciences (NUHS).

Recruitment for the project will consist of displaying posters in many prominent locations throughout the campus. The poster (see attached) will briefly describe the project, list the inclusion criteria, and several of the exclusion criteria. Flyers similar in nature to the posters will also be distributed on campus. This same flyer will be e-mailed to all students, faculty, and staff. In addition, a request for subjects will be placed in the NUHS student newspaper, The Synapse. The telephone number of the clinical trial screening phones in the Office of Clinical Studies will appear on these recruitment instruments. The PI and other study personnel may also speak to individual classes to recruit subjects for the project. If extreme difficulty is obtained in recruiting 40 subjects from the student population (this is not anticipated based upon previous studies) advertising in local newspapers will be conducted to obtain subjects from the general population.

What is the minimum number of participants you need to validate the study? ⁴⁰ _____

Is there a limit on the number of participants you will recruit? No Yes – the number is _____

Is there a limit on the number of participants you will include in the study? No Yes – the number is _____

d. Describe the type, amount and method of compensation and/or incentives for participants.

(If no compensation will be given, check here .)

Select the type of compensation: Monetary Incentives
 Raffle or Drawing incentive (Include the chances of winning.)
 Extra Credit (State the value)
 Other

Description:

Those subjects who are excluded at the initial examination will receive an honorarium of \$25 for their time and participation. Participants who complete the study will receive \$75 for their participation. Checks will be mailed to them within approximately 2 weeks after completing their participation.

13. PROJECT DESIGN & METHODS.

a. Describe, step-by-step, all procedures and methods that will be used to consent participants.

(Check here if this is "not applicable"; you are using existing data.)
Informed consent will be administered by trained Clinical Studies personnel during the appointment for screening and explanation of the project. Informed consent will be administered in both oral and written forms. Clinical Studies personnel will first thoroughly describe the project with the use aid of the Project Flowchart (attached). The subject will then be asked to view a DVD describing the project and read the informed consent document. After the subject has read the document, (s)he will be asked if there are any questions and the Clinical Studies personnel or if necessary, the Research Clinician, will answer questions. The subject will be asked to repeat the basics of the project, its risks and benefits, and the ability to withdraw before being asked to sign the informed consent document.

Research Assistants or the Clinical Coordinator (Jennifer Dexheimer) will administer the Informed consent. These individuals will be thoroughly trained with this specific project (will have read this document and attachments, related papers and Informed Consent Document) and will have discussed the project and related documents with the PI. In addition, these individuals will have completed the training for Protection of Human Subjects as required by this IRB.

b. Describe the procedures you will use in order to address your purpose. Provide a step-by-step description of how you will carry out this research project. Include specific information about the participants' time and effort commitment. (NOTE: Use language that would be understandable to someone who is not familiar with your area of study. Without a complete description of all procedures, the Auburn University IRB will not be able to review this protocol. If additional space is needed for this section, save the information as a .PDF file and insert after page 6 of this form.)

Subject Recruitment:

Healthy male (n=15) and female (n=15) subjects will be evaluated in Group 1 (n=30, adjustment group) and 5 subjects of each sex will be evaluated in Group 2 (n=10, control group). As in a previous study assessing healthy subjects (IRB #H-0709), the subjects will be students and employees from the National University of Health Sciences (NUHS).

Recruitment for the project will consist of displaying posters in many prominent locations throughout the campus. The poster (see attached) will briefly describe the project, list the inclusion criteria, and several of the exclusion criteria. Flyers similar in nature to the posters will also be distributed on campus. This same flyer will be e-mailed to all students, faculty, and staff. In addition, a request for subjects will be placed in the NUHS student newspaper, The Synapse. The telephone number of the clinical trial screening phones in the Office of Clinical Studies will appear on these recruitment instruments. The PI and other study personnel may also speak to individual classes to recruit subjects for the project. If extreme difficulty is obtained in recruiting 40 subjects from the student population (this is not anticipated based upon previous studies) advertising in local newspapers will be conducted to obtain subjects from the general population.

Preliminary Screening of Subjects:

Subjects responding to the posters, flyers, or advertisements, will contact the Clinical Studies Office either by telephone or in person. At that time each subject will be briefly screened to determine his/her general eligibility for the project according to the following inclusion criteria:

- Eighteen to 30 years of age (recruitment will include students in NUHS degree and certificate programs; young age for inclusion to decrease the likelihood of osseous and ligamentous degeneration of the lumbar region of the spine)
- One hundred and eighty-five pounds or less for males and one hundred forty-five pounds or less for females (to ensure maximum image quality)
- No previous history of LBP lasting for more than two weeks, or no more than three episodes of back pain of brief duration (one to two weeks) in any given year to recruit healthy subjects with no history, or a minimal history, of LBP)

Description of Project to Subject and Administration of Informed Consent:

Those subjects who remain eligible after the initial telephone screen will be asked to make an appointment to see the Clinical Coordinator or her designee at their earliest convenience. Those who come in person for the initial screen will be asked if they would like to continue with the next stage of screening or prefer making another appointment to do this. During this "next" appointment with the Clinical Studies Office, demographic information will be taken, and the Informed Consent procedure will be completed. This process will include watching a DVD thoroughly describing the project. If the informed consent form is signed, the subject will be scheduled for a physical examination specifically designed to determine if the subject is eligible to participate in the study.

Physical Examination:

The physical examination, to determine eligibility, will be performed at the NUHS Lombard Clinic under the supervision of one of the two Research Clinicians. As in previous studies, fourth year student interns under the direction of a clinician may perform portions of the exams. The examining physician will again check to make sure that the volunteer meets the inclusion criteria (listed previously) and has none of the following exclusion criteria:

- Under 18 or over 30 years of age
- Weighs over 185 pounds for males and 145 pounds for females (subject will be weighed at this time – see reasons for weight in Inclusion Criteria)

(See next page for continuation)

Continued from page 6

- History of an episode of LBP lasting for more than two weeks, or more than three episodes of back pain of brief duration (one to two weeks) in any given year (see reasons for no LBP in Inclusion Criteria)
- Presence of disc degeneration, significant osteoarthritis, scoliosis of greater than 5 degrees (Cobb's angle), or other significant pathology seen on first trimester x-rays or on x-rays requested for this study (see below for reasons for x-ray, this study is assessing healthy spines, scoliosis decreases ability to adequately image the Z joints for measurement).
- Positive findings on any of the orthopedic or neurological tests listed on exam form; because we are assessing healthy individuals, indication of somatic pathology or neurological deficit are exclusionary criteria)
- Pregnancy (due to unknown risk and potential to require x-rays during the physical examination)
- Presently breast-feeding an infant (unknown risk of MRI, also potential of need for x-ray during examination)
- Inability of clinician to obtain cavitation [articular release(s)] during lumbar side posture adjustment given at the conclusion of the examination (the study is assessing the relationship between cavitation and gapping, consequently the ability to obtain a cavitation is important, one individual was excluded for this reason in the previous study on 64 healthy subjects)
- Intolerance to MRI procedures (including claustrophobia and inability to lie on one's side for 30 minutes).
- Significant pathology discovered on MRI scans. This criterion will be evaluated during the first MRI visit, immediately after the first MRI scan is taken. (Such pathologies constitute contraindications to chiropractic adjusting.)

Note: These inclusion and exclusion criteria were used in the previous study on healthy subjects. Cavitations were obtained in all of the subjects of the study who received a spinal adjustment during the MRI appointment and excellent MRI image quality was obtained using the subjects and the MRI procedures.

Other information taken during this screening examination will include a history of the volunteer's experience with back pain and several orthopedic and neurological tests. Any subject in which manipulative treatment is contraindicated will be excluded from the study. The entire examination will take no longer than one hour. The exam will conclude with a side posture lumbar spinal adjustment. The manipulative procedure will be administered by one of the treating doctors of the study (not Preetam Bora or Dr. P.K. Raju). The adjustment is given to determine if the volunteer can be successfully manipulated. The risks from the types of manipulative therapy proposed in this study are minimal when performed by a trained and experienced chiropractor.

Lumbar Side Posture Adjustment:

Treatment with lumbar side-posture adjustments will be administered with the subject lying on his/her left side on a treatment table in a side-lying posture with the bottom leg in contact with the table. The opposite (up-side) lower extremity will be positioned with the knee and hip flexed. This posture ensures that the manipulation results in the exertion of an unopposed force to the lumbar Z joints. The patient's down-side arm will be crossed over the chest with the hand positioned to rest on the opposite shoulder and the opposite hand will be placed on the lateral aspect of the rib cage. The doctor will be in the fence stance angled approximately 45 degrees to the patient. The patient's pelvis will be supported by contacting the lateral thigh with the doctor's inferior and lateral thigh of the caudally positioned lower extremity. A forearm contact with the caudal upper extremity will be used, contacting the region of the up-side posterior superior iliac spine. The indifferent hand will contact the patient's up shoulder and/or chest area. The manipulation will consist of a high-velocity, short lever, low-amplitude thrust to the L4/L5-L5/S1 region. The force will be generated by the body drop and the shoulder thrust. This is a standard manipulation for the lumbar region [hypothernar Ilium]. The treatment (adjustment) side is the up-side (left side). In some instances more than one thrust may be necessary to gap the L3/L4, L4/L5, and/or L5/S1 articulations. A cavitation (audible release) will be sought for each subject receiving an adjustment. Only one subject was eliminated for this reason in the initial clinical trial using healthy subjects and none were disqualified for this reason in the preliminary study on LBP patients. If an audible release is not obtained during either MRI appointment the subject will no longer be eligible to continue in the project.

MRI Scans:

Those subjects who remain eligible after the initial screening procedures and physical examination will be scheduled for the MRI scanning session. They will also be instructed not to undergo spinal manipulation of the lumbar and sacroiliac regions the day before the MRI appointment. Upon arrival at the MRI facility the subject will be given the "Previous Spinal Adjusting Questionnaire." If the questionnaire indicates that the subject did not comply, the subject will be rescheduled for the next available designated scanning day. Those who remain in compliance will be screened for MRI procedures in similar fashion to patient's being screened for standard MRI diagnostic purposes. Screening will be done for all MRI examinations. The prospective subjects will be interviewed concerning issues related to the following topics: pacemakers, metallic objects, surgical clips, joint replacement prostheses, rods, metallic sutures, implants, hearing aids, surgery, metallic fragments in the eyes, claustrophobia and pregnancy. In those instances where a history of metallic eye fragments is obtained or where protective glasses have not been used in the context of a history of activities involving the grinding, drilling or shaping of metal (occupationally or avocationally), orbit radiograph(s) will be taken. This will usually consist of one 8x10 inch view, however, occasionally two views will be taken if suspicion of metal is found on the first radiograph. Based on previous experience, between 25-30% of the subjects will require this view(s). The view(s) will be done at no cost to the subject. Further, questions relative to the timing of the menstrual cycle for female subjects also are considered mandatory and are included in the MRI screening form. Subjects falling outside the "ten day rule" will be re-scheduled if they are unable to attest that they are not pregnant. Pregnancy testing will be available (at no charge to the subject) for those subjects who can not attest and sign to the effect that they are not pregnant.

Those subjects who remain eligible following the administration of the "Previous Spinal Adjusting Questionnaire" and the screening for MRI scanning will be prepared for the MRI scan (i.e., removal of all jewelry, watches, etc.; and issued a gown) and then positioned in the MRI unit. The subject will first lie prone on the MRI gantry table as the Research Clinician tapes a 2-1/2 inch long (0.25 inch wide) high signal marker (flexible laboratory tubing filled with mineral oil) across the spinous process of L3, L4, and L5. A lumbar spine MRI protocol, specifically designed for low back study (details in Section VIII, Question 4 of this document) will be performed. The MRI scan time is 14 minutes, 24 seconds, however, with time spent positioning the subject in the unit and setting the parameters on the MRI unit, the participant will be in the gantry 20 to 30 minutes. Aside from the risk concerns and screening procedures outlined above, there are no known health risks for magnetic resonance imaging. Nonetheless, the instructions given to the subject and the monitoring of his or her comfort will be no different from those afforded to standard NUHS MRI patients.

The MRI scans will be done from the subject's superior to inferior in an axial plane that passes through the inferior aspect of the intervertebral disc/superior vertebral body margin junction. This will be done at 3 levels (L3/L4, L4/L5, L5/S1). For the initial scan the patient will be in neutral (supine) position with knees elevated for comfort purposes. Scout views will also be used to ensure proper patient positioning for this project. Following the scan, the radiologist (board certified) will interpret the scan for any significant pathology. If pathology is present, the subject will be notified and proper treatment or referral will be arranged. The subject will no longer be eligible for inclusion in the study. For the second scan, the subject will be placed in a side posture body position: The subject will be positioned with his/her pelvis turned to the subject's right so that it is approximately 90° to the gantry table while both the subject's shoulders remain as close to the table as possible. The lumbar coil acts to help standardize positioning for the side posture position. After the subject is centered in the coil, the subject's left (top side) knee is moved superiorly until it comes in contact with the lumbar coil. Finally, several scout views (sagittal, coronal, and axial) are taken to ensure that the subject is positioned properly in the gantry.

Accoustical Methods

~~After the initial scan, the table will be pulled out of the gantry and the subject will immediately be placed in a left side up, side posture position (right and left shoulder in the vertical plane and both knees bent for stabilization). The reading radiologist will evaluate the initial films for signs of pathology. If the images are read as being normal, the reading radiologist will then assess the sagittal scout and final axial images to determine if the high signal markers were accurately placed. The high signal markers leave an indentation on the skin after the initial MRI scan, therefore the Research Clinician has an external mark to place the accelerometers or adjust the placement based on the information provided by the reading radiologist. The Research Clinician tapes 3 midline~~

accelerometers at L3, L4, and L5. An additional 4 accelerometers will be lateral to the midline accelerometer: one accelerometer will be placed 3 cm to the left and one 3 cm to the right of the mid-distance between the L3 and L4 midline accelerometers; one accelerometer will be placed 3 cm to the left and one will be placed 3 cm to the right of the mid-distance between the L4 and L5 midline accelerometers. The distance from the L5 midline accelerometer to the left and right sacroiliac (SI) joints will be measured to exclude SI cavitations from analysis. As the accelerometers are being applied, the subject will be randomized into one of the two groups: Group 1—the left lumbar region will be adjusted, recording from the accelerometers lasting 15 seconds (during final positioning and adjusting), and the accelerometers will then be removed; Group 2 will be positioned in side posture, recording from the accelerometers lasting 15 seconds (during final positioning), and the accelerometers will then be removed. All subjects will remain in this side posture position, the gantry will be moved back into the MRI magnet, and the second axial scan will be taken.

After the first MRI scan, information from the reading radiologist will be used to either place the midline accelerometers in the same location as the high signal marker or to place the accelerometer over the correct spinous process based on the information provided by the reading radiologist. This will be the responsibility of Preetam Bora. He will tape seven accelerometers to the skin. Calculations will be done to determine the side of cavitation, except that recordings from the accelerometers to the side of the midline will be included in the computer calculations that will determine the order in which each accelerometer receives the vibrations produced by the cavitation (i.e. a left sided Z joint cavitation will excite the left sided accelerometers before those on the right side). The data analysis will allow for a comparison of joints that cavitate from only side posture positioning and those that do not. Preetam Bora will also be responsible for analyzing the accelerometer data from these studies.

Immediately following the MRI session, the subject will be told that they have completed their role in the study and sincerely thanked for their participation. They will also be told at this time that within approximately two weeks a \$75.00 check will be mailed to them.

13c. List all data collection instruments used in this project, in the order they appear in Appendix C.

(e.g., surveys and questionnaires in the format that will be presented to participants, educational tests, data collection sheets, interview questions, audio/video taping methods etc.)

Telephone Screen
Research Assistant (RA) Screen
PreMRI

d. Data analysis: Explain how the data will be analyzed.

There are two types of data to be analysed: 1) CAVITATION and 2) GAPPING DIFFERENCE.

Cavitation data will be analysed using accelerometers and gapping difference will be analysed using the two MRI scans (One taken before spinal adjustment and second taken after spinal adjustment). Preetam Bora will be responsible for analysing data from accelerometers and morphometry radiologist (Mirad) and MRI research assistant will help in analysing gapping difference using MRI scans.

14. RISKS & DISCOMFORTS: List and describe all of the risks that participants might encounter in this research. If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use in Appendix D. (Examples of possible risks are in section #6D on page 7.)

The risks in this study are quite minimal. There are no known health risks associated with magnetic resonance imaging. A small percentage of the population experiences claustrophobia during an MRI exam. If at any time during the MRI, a subject becomes uncomfortable, the procedure will be stopped.

The most severe, yet extremely rare, risk to lumbar side-posture adjusting is cauda equine syndrome, which is estimated to occur in one case in 100 million patient visits. An individual is 20,000-30,000 times more likely to die of a lightning strike than develop cauda equine syndrome from the adjustive procedures used in this study.

Unpleasant reactions from spinal manipulative therapy are not uncommon and have been described in numerous studies. In general, the reaction is mild to moderate discomfort, localized to the area of treatment, has little or no effect on normal daily activities, and lasts less than 48 hours. Less common reactions, including fatigue, headache, and nausea, have also been reported.

15. **PRECAUTIONS.** Identify and describe all precautions you have taken to eliminate or reduce risks as listed in #14. If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals. Provide a copy of any emergency plans/procedures and medical referral lists in Appendix D.

The phone screening, initial screening, physical examination, MRI screen, and first MRI scan are all designed to eliminate any person with contraindication to chiropractic spinal manipulation. Since these protective measures are at different stages of subject involvement and administered by different study personnel, we believe these measures will be very effective in identifying exclusion criteria in subjects. We have successfully used these protocols in the past and are currently using very similar in the parent project, H-0107, and to date there have been no unanticipated adverse events. Should any problem arise as a result of the procedures employed in this study, the Research Clinician will re-examine the subject at no charge, and if appropriate, provide treatment for the problem at no charge, or refer the subject to an appropriate specialist. Although the risks to subjects in this study are minimal, the Principal Investigator will provide continuous and close monitoring of the project and prompt reporting of any unanticipated adverse events will be made to the Independent Medical Monitor (IMM) and the NUHS IRB. An IMM will be appointed by the NUHS IRB. His/her duties will include reviewing the research protocol and plans for data and safety monitoring and evaluating the progress of the project, including periodic assessments of data quality and timeliness. In addition, he/she will evaluate participant recruitment procedures, accrual, and retention rates, participant risk versus benefits, and other factors that can affect the study outcome. External factors that will be considered by the IMM when interpreting the data include any recent scientific or therapeutic developments that may have impact on the safety of the volunteers or the ethics of the study. If concerns in any of these areas arise, he will make recommendations to the appropriate NCCAM program officer, the NUHS IRB, and the investigators concerning continuation or conclusion of the study. The IMM will at all times protect the confidentiality of the trial data and the results of the monitoring.

If using the Internet to collect data, what confidentiality or security precautions are in place to protect (or not collect) identifiable data? Include protections used during both the collection and transfer of data.

(These are likely listed on the server's website.)

16. **BENEFITS.**

- a. List all realistic direct benefits participants can expect by participating in this specific study.
(Do not include "compensation" listed in #12e.) Check here if there are no direct benefits to participants.

- b. List all realistic benefits for the general population that may be generated from this study.

Since this study is designed to lead to a mechanistic outcome, the student subjects may indirectly benefit because of their relationship to chiropractics. Although their benefit in this regard would be no greater than those who did not volunteer for the study, their heightened awareness may make them more apt to use the information derived from the study when designing treatment plans for their patients or discussing these procedures with faculty or peers inside or outside the NUHS community.

17. PROTECTION OF DATA.

- a. Will data be collected as anonymous? Yes No *If "YES", skip to part "g".*
("Anonymous" means that you will not collect any identifiable data.)
- b. Will data be collected as confidential? Yes No
("Confidential" means that you will collect and protect identifiable data.)
- c. If data are collected as confidential, will the participants' data be coded or linked to identifying information?
 Yes (If so, describe how linked.) No

Data will be sent as Coded. Subjects are given a Research ID which is used in place of identifiers on all forms utilized in the research study. The assigned identification number will be the only information annotated onto each of the subjects data. Therefore anyone making the measurements or analyzing the data will not have access to any subject's name, age, sex, height, weight, or subject group.

- d. Justify your need to code participants' data or link the data with identifying information.

Subjects' names and addresses are required for the honorarium check to be prepared and mailed.

- e. Where will code lists be stored? (Building, room number?)

All subject files are kept in locked files at NUHS. See 17g for more information.

- f. Will data collected as "confidential" be recorded and analyzed as "anonymous"? Yes No
(If you will maintain identifiable data, protections should have been described in #15.)

- g. Describe how and where the data will be stored (e.g., hard copy, audio cassette, electronic data, etc.), and how the location where data is stored will be secured in your absence. For electronic data, describe security. If applicable, state specifically where any IRB-approved and participant-signed consent documents will be kept on campus for 3 years after the study ends.

All files are kept in a locked file in the Office of Clinical Studies until the last subject has completed the study. At that time, they will be delivered to the PI, who will keep them in a locked file until the final manuscript is complete. Upon completion of the final manuscript, the files will be transferred to a secure storage facility, where they will be stored for approximately 8 years. Both MRI scans are assigned random numbers using a computer generated random number list. This list is locked in a file cabinet in the MRI suite and will be the only identifier on the scan. The subjects' names do not appear on any scans in any way. The form linking the scan to the subject's identity will be secured in the locked file cabinet in the MRI suite.

- h. Who will have access to participants' data?
(The faculty advisor should have full access and be able to produce the data in the case of a federal or institutional audit.)

Dr. Cramer will have access to the participants' data.

- i. When is the latest date that confidential data will be retained? (Check here if only anonymous data will be retained.)

Eight years from data collection.

- j. How will the confidential data be destroyed? (NOTE: Data recorded and analyzed as 'anonymous' may be retained indefinitely.)

NUHS employs Secure EcoShred shredding services to destroy confidential patient and research subject information.