Patient Cushion Interface Pressure during Scoliosis Surgery

by

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Abstract

Scoliosis is the deformation of the spine and, in some cases, surgery is suggested in order to correct the curvature and prevent progression. During scoliosis surgery, the patient is positioned on the surgical frame face down in such a way that the hips and chest are placed over cushions. Lateral femoral cutaneous nerve (LFCN) compression is a complication which is seen after surgery in some cases. Tingling, numbness and pain are the symptoms some patients have as a result of LFCN injury and it is hypothesized that high intraoperative patient cushion interface pressure may cause LFCN compression. The main objective of this work is to quantify the pressure at the patient cushion interface during surgery.

To measure the pressure during scoliosis surgery, a Force Sensing Array (FSA) pressure mapping system including a set of four pressure mats is used in the operating room. Previous research on FSA pressure mats show a number of errors, so the mats were examined in the lab to see if this error affects the data measurements in the operating room. Data from a total of twenty-three patients was collected in the operating room. The patients were positioned on the operating table with the pressure mats on the cushions. In addition to pressure measurement, the patient's body mass index (BMI) and the duration of the surgery were recorded. LFCN injury was determined after surgery by physical examination using light touch sensation tests and asking the patient if they feel any numbness, tingling or pain.

Results from pressure measurements indicate that the average pressure for patients with LFCN injuries is 32 mmHg and 29.5 mmHg for the left and right hips, respectively. By comparison, those who did not have LFCN problems experienced pressures of 27 mmHg and 26 mmHg for the left and right hip, respectively. There was a significant difference between the duration of the surgery for patients with (350 minutes) and without (264 minutes) LFCN injury. BMI was also evaluated as a risk factor for LFCN injury but there were no significant findings. Somatosensory evoked potentials (SSEPs) recorded during the surgery were analyzed to see if they show any abnormal signals in patients with LFCN injury. A detailed analysis of the SSEPs is reserved for future work. It is concluded that the duration of the surgery was the only significant factor in determining LFCN injury during scoliosis surgery.

Preface

"This thesis is an original work by Negar Behzadi Fard. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, project Name "Understanding the Implications of Pressure at the Patient Cushion Interface during Posterior Spine Surgery", Pro00012134, 26/06/2013 renewed until 06/07/2016."

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List of abbreviations

Symbol	Description
AIS	Adolescent Idiopathic Scoliosis
ASIS	Anterior Superior Iliac Spine
BMI	Body Mass Index
CNS	Central Nervous System
FSA	Force Sensing Array
LFCN	Lateral Femoral Cutaneous Nerve
MP	Meralgia Paresthetica
OR	Operating room
PNS	Peripheral Nervous System
SSEP	Somatosensory Evoked Potentials

Chapter 1 Background

The objective of this thesis was to investigate whether there is a relation between intra-operative pressure and Lateral Femoral Cutaneous Nerve (LFCN) compression. LFCN compression occurs in some patients after scoliosis surgery, and it sometimes results in tingling and lack of sensation on the upper front portion of the thigh. It can be hypothesized that high intraoperative pressure at the patient cushion interface may cause this compression. This thesis begins with a general description of scoliosis with details on treatment, surgery and patient positioning. This is followed by a description of the human nervous system anatomy, continued by explaining lateral femoral cutaneous nerve (LFCN) injury, pressure monitoring and a brief description of sensors.

1.1 Scoliosis

This section gives a general description of scoliosis followed by an explanation of different types of scoliosis. Scoliosis treatment is mentioned since surgery is an important aspect of this research. Positioning during scoliosis surgery is also described.

1.1.1 Scoliosis description

Scoliosis is defined as a three-dimensional deformation of the spine in which the lateral curvature of the spine is more than 10˚and it occurs in 2.5% of the population (Altaf et al. 2013, Asher and Burton, 2006). A sample of a scoliosis curve is shown in figure 1.1. Idiopathic scoliosis is caused as a result of mechanical, metabolic, hormonal, neuromuscular, growth, or genetic abnormalities (Altaf et al. 2013). Scoliosis can further be categorized based on the age of the patients, which is summarized in Table (1.1) (Altaf et al. 2013):

Table (1.1): different types of idiopathic scoliosis based on age

Types	Age (years)
Infantile idiopathic scoliosis	0-3
Juvenile idiopathic scoliosis	4-10
Adolescent idiopathic scoliosis (AIS)	>10

Altaf et al. (2013) reported that the prevalence of scoliosis is between 1-3% in children, and this mostly in those between the ages of 10 and 16 years. Although adolescent idiopathic scoliosis is a serious problem, in most cases it does not cause mortality (Asher and Burton, 2006).

The lateral curve angle is commonly measured on X-rays using the Cobb technique to diagnose the severity of curvature in patients (Altaf et al. 2013, Cobb 1948). In this technique, shown in figure (1.1), the superior and inferior end of vertebrae should be

identified in the X-ray. The next step is to draw a line from the top superior vertebrae, the vertebrae at the upper limit of the curve, parallel to the end plate and the same approach is used for the inferior vertebrae, vertebrae at the lower limit of the curve, where the curve ends, with the line parallel to the lower end plate. As a result, the angle at the intersection of these lines is called Cobb angle (Altaf et al. 2013, Cobb 1948).

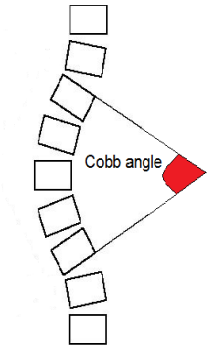


Figure (1.1): Scoliosis curve and Cobb angle measurement

1.1.2 Treatment

Curve progression is more probable in younger patients during their growth spurt (Lonstein 1994). In the case of scoliosis treatment, the severity of the curvature, the patient's age and the growth spurt are key components (Altaf et al. 2013, Nachemson and Peterson, 1996). In order to prevent progression, bracing and surgery are two methods which are commonly used (Asher and Burton, 2006). Braces used for scoliosis patients, as shown in figure (1.2), are most effective in children with Cobb angles between 30 to 40 degrees who are growing swiftly as in, for example, girls before menarche (Lonstein, 1994). Surgery is another way to prevent curve progression especially when the bracing is not successful.

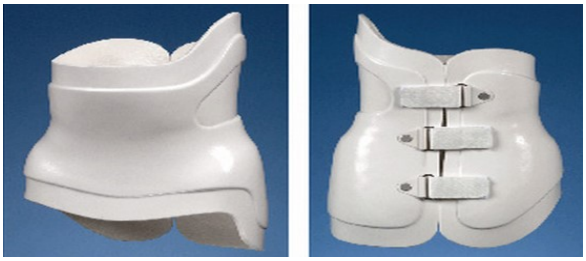


Figure (1.2): A brace used to avoid scoliosis progress (http://sandiegoscoliosiscenter.com/)

1.1.3 Surgery

Scoliosis surgery is usually suggested for patients who have curves greater than 45 degrees (Lonstein, 1994). Depending on the degree, type of the curve and age of the patient, surgical options vary in Adolescent idiopathic scoliosis (AIS) treatment (Hedequist, 2007). There are 3 curve types in scoliosis: thoracic, lumbar and thoracolumbar scoliosis. Depending on the curve type, location and preference of the surgeon, the surgery can be either anterior or posterior. Posterior spine surgery starts with the patient lying face down on the operating table in the prone position. This prone position is further explained in section 1.1.4. During initial incision, the muscles around the spine are retracted for the surgeon to better see the spine deformity. Instrumentation of the spine begins with insertion of screws and hooks. First a small hole is drilled in the vertebra and an awl is used to make the initial screw hole. Screws are then inserted in multiple vertebrae. The number of screws and length of the instrumented area will depend on the severity and curve type. Near the top of the spine where the vertebra is smaller, hooks are used. A template is then used to determine the shape of the rod needed to help straighten the spine. A rod is cut and pre-bent and loosely attached to the screws. The rod is then rotated and fastened

securely on the side of the spine. A second rod is then inserted on the other side of the spine. Distraction and compression is then applied to various sections of the spine depending on the curve the surgeon wants to achieve. Small cross-links are then inserted between the two rods to stabilise the construct and prevent torsion. During surgery, many X-rays are also taken, first, to help the surgeon locate the vertebral level for the first instrumentation, then, some are taken to help with surgical guidance systems for screw insertion, and a final X-ray is taken to verify correct screw placement and to see the correction. Also, during surgery, neuro-monitoring takes place as described in section 1.4.

1.1.4 Positioning

The first, and an important step in scoliosis surgery, is the patient positioning, and prone positioning is what is commonly used for this purpose. Proper positioning is important in spinal surgery in many aspects as it assists and simplifies exposure, reduces bleeding and prevents injury to any involved organs (Schonauer et al. 2004). Posterior operation requires the patient to be prone positioned in order to decrease pressure to the abdomen to reduce bleeding risk. The other advantage of prone positioning during the posterior spine surgery is that it improves exposure to the spine for the surgeon. Relton and Hall (1967) were the first to suggest the type of frame still used today in scoliosis operations. This frame has the benefit of reducing pressure on the abdomen and vena cava by keeping the abdomen in a pendulous, hanging down position (Relton and Hall, 1967). A chest roll and hip cushions are used in the Relton and Hall frame, which makes the frame more comfortable to be used for long spine surgeries like scoliosis surgery.

There are other positioning systems for spinal surgery which have used the same principles as the Relton and Hall frame. Schonauer et al. (2004) provided a review of various scoliosis positioning frames with a focus on blood loss. Type of frame and cushions are believed to be important to avoid skin redness and pressure ulcers during spinal surgeries. The Jackson Table, shown in figure (1.3), is currently used at the Stollery Children's Hospital in Edmonton. This frame was used during data collection in the OR in this thesis, and the cushions on this table are adjustable as the surgeon adjusts the positioning. The Jackson table is designed very similarly to the Relton and Hall frame with more advantages like capability of rotating 360 degrees, which is beneficial especially when positioning the patient on and off the frame (Schonauer et al. 2004). Despite the advantages, there are some problems that occur to the patient's nerves while prone positioned during spinal surgery such as lateral femoral cutaneous nerve compression.

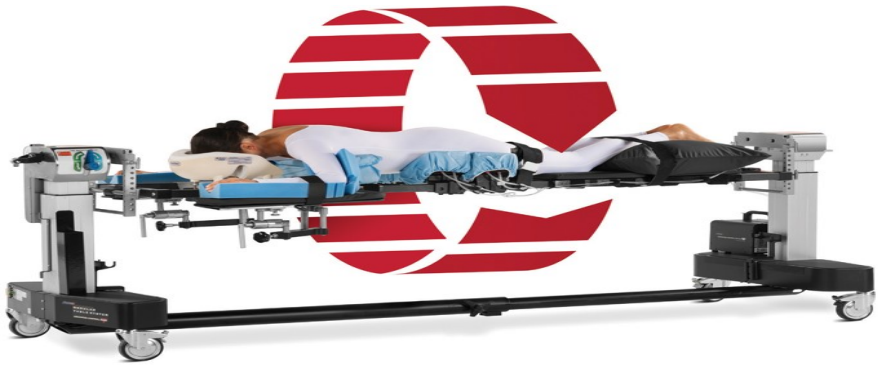


Figure (1.3): Jackson table used in spine surgery with the ability to rotate 360 degrees. This figure shows the prone positioning over the table during surgery

(http://www.outpatientsurgery.net/did-you-see-this/2013/11/mizuho-osi-sts-spinal-table-system)

1.2 Anatomy

This section provides a brief explanation of the anatomy of the central and peripheral nervous systems and talks about the details of a sensory nerve called Lateral Femoral Cutaneous Nerve.

1.2.1 Central and peripheral nervous systems

The brain and the spinal cord together make the central nervous system (CNS) of the human body, and the other nervous tissues belong to the Peripheral Nervous System (PNS) of the human body (Farley et al. 2014). PNS basically connects the CNS to the limbs and other parts of the body. The human nervous system is made of different types of neurons like afferent (sensory) and efferent (motor) neurons. Afferent or sensory neurons transfer the external signals from environmental stimuli to the brain while efferent or motor neurons control muscle functions and also transfer signals from the CNS to the muscles and glands. Monitoring the function of the nervous system during spinal surgery was done for the purpose of detecting whether there are any problems with either PNS or CNS in order to take immediate actions. Sensory receptors in the peripheral nervous system also send signals taken from external stimuli to the somatosensory system during somatosensory evoked potential monitoring.

1.3 LFCN compression (Meralgia Paresthetica)

The lateral femoral cutaneous nerve (LFCN) is a sensory nerve which originates from the second and third lumbar vertebra and appears from the lateral edge of the psoas major muscle and passes the anterior superior iliac spine (ASIS) (Yang et al. 2005, Azsmann et al. 1997). The nerve then divides into anterior and posterior parts in front of the Sartorius muscle. The anterior nerve passes the lateral thigh anterior to the ASIS enclosed within the inguinal ligament (Sürücü et al. 1997). Aszmann et al. (1997) reported that the individual course of LFCN varies in different people, and categorized it into five different types. Investigations show that three types of LFCN are more likely to be compressed and subsequently injured. The compression mostly occurs when the LFCN is placed posterior to ASIS (figure 1.4a) or if it is anterior to the ASIS surrounded by the inguinal ligament (figure 1.4b), or medial to the ASIS surrounded by the Sartorius muscle (figure 1.4c). When the lateral femoral cutaneous nerve is compressed behind the inguinal ligament, the injury to this nerve is shown by burning, tingling and numbness in the hip, leading to the condition called Meralgia Paresthetica (MP) (Tejwani et al. 2006). This complication can be compared to a severe case of your leg falling asleep. Yang et al. (2005) reported that MP occurs in 23.8% of the patients having AIS surgery, while Mirovski and Neuwirth (2000) found it to be 20% (Yang et al. 2005, Mirovski and Neuwirth, 2000). It is hypothesized that, during AIS surgery, the intraoperative pressure on prone positioned patients can be one of the reasons for MP since the patient's weight is burdened on the chest and pelvis due to the form of the Jackson table design (Yang et al. 2005, Brienza et al. 2001). LFCN

compression is most probable in this case when the nerve is trapped between the inguinal ligament and iliac crest (Grossman et al. 2001)

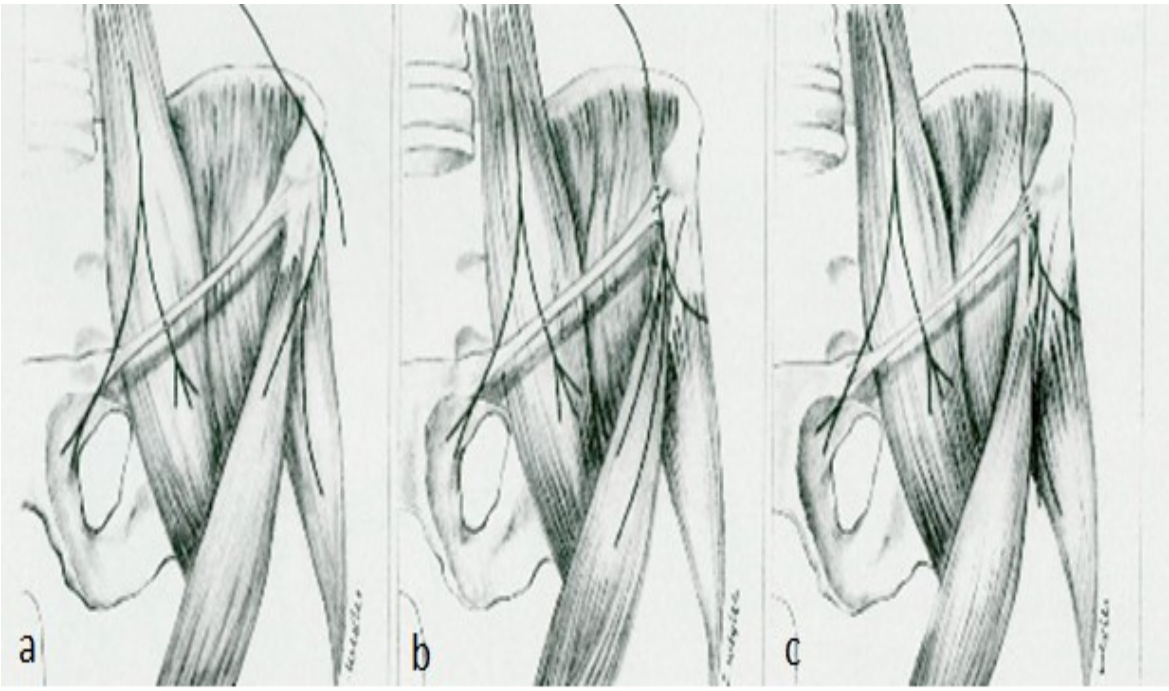


Figure (1.4): Three most capable types of LFCN to be compressed and injured. (a)Posterior course of LFCN close to ASIS (b) Anterior LFCN surrounded by inguinal ligament (c) LFCN through sartorius muscle (Azsman et al. 1996)

1.4 Somatosensory Evoked Potentials (SSEP)

Monitoring neuro-system function during different operations is important to track any abnormality and injury which may occur to the nerves. Somatosensory evoked potentials (SSEP) are known as a reliable method for neuro-monitoring in spine surgeries. The somatosensory system contains body sensation nerves including touch, temperature and pain. Somatosensory Evoked Potentials are the electrical response from the somatosensory system to an external stimulus (Nida et al. 2013). In somatosensory analysis any abnormal wave can give beneficial information (Chiappa and Hill, 1997). SSEPs have small amplitudes (0.2-20 micro-volts) and therefore they cannot be easily seen in the EEG (electroencephalogram) signal. Additionally, there is signal instability on the order of 20 to hundreds of micro-volts mixed with SSEP signals which makes it more difficult to see them (Chiappa and Hill, 1997). Due to this, SSEP signals must be separated from the noise and this occurs by averaging them (Chiappa and Hill, 1997). SSEP responses are categorized into two groups based on their latencies. If the SSEP wave occurs within 25 milliseconds after stimulation in upper side nerves, 40 milliseconds in peroneal nerve and 50 milliseconds in tibial nerve, it is called the short latency waveform. However, if the wave occurs in more than 100 milliseconds after stimulation it is called long latency (Chawla et al. 2014). The stimulation electrodes are most commonly attached to “the median nerve at the wrist, the common peroneal nerve at the knee, and the posterior tibial nerve”, with this configuration the output SSEP signal is delivered to the central nervous system and

recorded at the scalp after 2 milliseconds (Chawla et al. 2014). Measurement of the LFCN SSEP signals is not commonly done but will be investigated in this work.

1.5 Pressure monitoring during AIS surgery

The idea of measuring intraoperative pressure to see if it relates LFCN injury comes from the pressure measurements in wheelchair patients. Wheelchair patients' weight is distributed over the seating cushion and this causes high interface pressure (Crawford et al. 2005). In wheelchair patients, the pressure is a factor used to compare the performance of different surfaces (Brienza et al. 2001). Brienza et al. (2001) investigated the relationship between buttock ulcers and the wheelchair seat cushion interface pressure. They examined thirty-two patients aged 65 or older who were using wheelchairs for six hours or more a day. Their results show that the average and maximum pressure is higher for the patients who had pressure ulcer incidents in comparison with the patients who did not. Based on this article, it would be useful to monitor pressure for patients that are prone positioned and their body weight distributed for long periods of time on spinal surgery table cushions. It is believed that similar to how wheelchair patients with higher pressures develop ulcers, higher pressure may compress the nerve leading to LFCN damage. After surgery patients who suffer from LFCN injury can be identified to see if intraoperative pressure affects this complication. Intraoperative pressure monitoring during scoliosis surgery can help to better understand the pressure effects on LFCN compression after operation. Pressure on the chest and hips is considerable in scoliosis surgery as the body weight is loaded in these areas in Relton and Hall or Jackson table (Orthopaedic Systems,

Inc. Union City, CA) (Yang et al. 2005). Pressure monitoring during surgery is possible using systems like the ones previously used in wheelchair patients to determine increased risk for buttock ulcers. The idea is to place pressure mats under the chest and hips and monitor the amount of pressure during the critical phases of surgery, like rod insertions, where the surgeon pushes on the back and see if there is any relationship with MP. Data should be collected continuously to compare the amount of pressure on the chest and thighs during different stages of the operation.

1.5.1 Force Sensing Array (FSA) pressure mapping system

Although creep and hysteresis were reported for the Force Sensing Array (FSA, Vista Medical, Winnipeg) pressure mapping system, it is still a user friendly and reliable pressure monitoring system used for pressure measurement (Stinson et al. 2003). The FSA pressure mapping system package includes a pressure mat, interface module, FSA software and a series of cables for system assembly. Pressure mats measure 16” by 16” (40.6 by 40.6 cm) and are each made of 256 piezo-resistive semi-conductive polymer sensors located between two thin layers of nylon fabric (Vista Medical). The total area for each pressure mat is 1849 cm^2 and for any individual sensor the area is 7.22cm^2. The FSA pressure mats consisted of two different parts during this study. The first, the SoftFlex mat, was placed on chest, while the second, standard mat, was placed on the hips. The reason to choose different mats for different regions is that the pressure was expected to be greater on the

hips than the chest. The standard mat measures up to 517 mmHg and the SoftFlex mat measures up to 310 mmHg. FSA software provides pressure data for each cell but also the average, maximum, minimum, standard deviation, coefficient of variation, variance and sensing area using various units (psi, mmHg and KPa). The pressure unit used in clinical data for this experiment is mmHg as a standard universal unit. FSA software is also capable to exclude minimum amounts (mostly zeroes).

1.6 Piezo-resistive sensors

Sensors are devices used to convert quantities like force to an electrical quantity like voltage. Piezo-resistive sensors belong to the group of micro-electrical and micro-mechanical devices and, similar to other piezo sensors, they convert the applied pressure to an output signal. Piezo-resistive sensors work as a result of resistance change under mechanical stress (Carter et al.). A piezo-resistive sensor is made of a pressure sensitive diaphragm, a semiconductor material with piezo-electric nature and an electrical circuit, generally a Wheatstone bridge. A Wheatstone bridge is made of two parallel divided voltage circuits and different forms of a Wheatstone bridge can be used in this mechanism in different conditions (Kon et al. 2007). A Wheatstone bridge is mostly used, instead of a voltage divider, for the reason that there is always an error in voltage divider circuits that is problematic to measure accurate data. In piezo-resistive sensors, the change in resistance alters the voltage on the electrical circuit (Kon et al. 2007). This change in

voltage is later compared to the base voltage and the result is used in calculating the strain and the change in resistance (Kon et al. 2007). Figure (1.4) shows a piezo-resistive sensor mechanism.

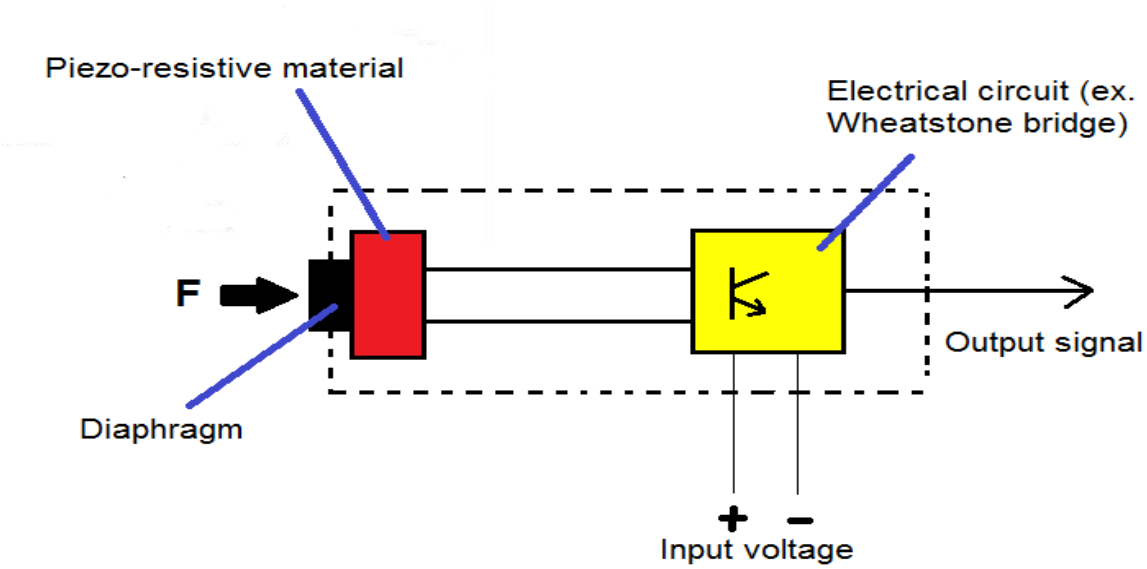


Figure (1.5): Simple schematic of Piezo-resistive sensor

1.7 Load cells

Load cells are a type of sensors which converts the applied load, or force, to an electrical signal like voltage or current depending on the kind of load cell used. The load cell used in the experiments of this thesis is a resistive load cell. A resistive load cell is used in an Instron loading machine during the experiments. The resistance of strain gauges used in the resistive load cells change with applied force. This change in resistance is later converted

to electrical voltage using the Wheatstone bridge. Then the difference between primary voltage and the output voltage after applying load is converted into the applied load. The other type of load cell works based on the change in capacitance of the capacitor and they are called capacitive load cells which have simpler structure than the resistive ones.

Chapter 2 Literature review

This chapter reviews the background of previous research on spine surgery and post-operative LFCN compression. The literature review is primarily concentrated on the clinical aspects of the research. The first part includes the information of relevant research on the compression of the LFCN during scoliosis surgery. The next section reviews the use of pressure mapping systems. The next section discusses the materials and methods used in previous research to measure SSEPs. Finally, the main goal of this study will be discussed in this chapter.

2.1 LFCN compression during scoliosis surgery (Meralgia Paresthetica)

Scoliosis is explained as a deformity of the spine which can be corrected by surgery using instrumentation and fusion (Relton and Hall, 1967). The lateral femoral cutaneous nerve (LFCN), located on the thigh, is a sensory nerve which is compressed during spinal surgery in approximately 20% of the patients. LFCN injury has symptoms like tingling, numbness and loss of sensation in the front upper thigh after surgery (Mirovski and Neuwirth, 2000). Mirovski and Neuwirth (2000) evaluated 105 patients who had spine surgery and examined the LFCN function before and after surgery to find the ones with LFCN compression symptoms such as pain, numbness or tingling. They found 21 patients had the symptoms

of LFCN compression (Meralgia Paresthetica) after operation. They have found that 6 out of 21 patients had bilateral LFCN injury with discomfort and hypothesised that the main cause of LFCN compression after surgery was external compression around the anterior superior iliac spine when positioning on the Relton and Hall or Jackson table. However, they have not considered the external compression to LFCN during different phases of surgery and there were no direct pressure measurements found within their results.

Investigation of the factors which may cause injury to the LFCN during the posterior surgery could help the surgeons and the operating room team to reduce the risk. Yang et al. (2005) examined 252 patients who had posterior spine surgery and followed up with the ones with LFCN problems after the operation. They have reported that 23.8% of the patients had LFCN problems and then concluded that the body mass index and surgery duration were the risk factors caused LFCN compression.

In another study, Tejwani et al. (2006) evaluated the risk factors which may cause Meralgia Paresthetica. They examined 56 patients with posterior spine surgery who did not have LFCN problems preoperatively. During this study, patients were positioned prone on the Jackson table (Orthopaedic Systems, Inc. Union City, CA) which is a type of spinal operating table. Data collected during Tejwani et al. (2006) research was used to determine if the patient's body mass, the surgeon and the duration of surgery are related to LFCN compression. They have found that 10 out of 56 patients (18%) had numbness in the thigh. Results from Tejwani et al.'s (2006) research show that there is no relation between

patients age and sex, surgeon and BMI with MP incidence. However, they have concluded that the shorter surgery time may decrease the probability of MP incidence.

Gupta et al. (2004) studied LFCN injury after lumbosacral spine surgery in 110 patients. Their result shows that 13 patients or 12% of the patients had LFCN injury. It was reported that nine were feeling tingling on their thigh and 4 had numbness. 12% of the patients who had LFCN injury in Gupta et al.'s (2004) research were compared to the results from Mirovski and Neuwirth (2000) research which showed 20% patients with LFCN injury. Gupta et al. (2004) concluded that the decrease in percentage of patients with LFCN injury is as a result of using standard pads over the surgical frame, 66.04 cm long and 13 33.02 cm in circumference. Moreover, they concluded that using standard cushions reduces the pressure points during the surgery.

Yang et al. (2005) and Tejwani et al. (2006) both agreed that time may be an important factor in causing Meralgia Paresthetica. They have concluded that shorter surgery time may avoid the LFCN incident during spine surgery.

2.2 FSA pressure mapping system

Crawford et al. (2005) examined the pressure interface of wheelchair patients in an 8 minutes' period using FSA pressure mats. They have found that the max and average pressure rises even in a short time (zero to two minutes). Defining the time for the pressure mats to stabilise before taking measures is necessary and will be discussed in section 3.2 for this work. The occurrence and location of pressure sores in wheelchair patients has

been found to coincide with peak pressures averaging 115 ± 45 mmHg measured on an FSA (Brienza et al. 2001).

Pressure mapping systems are used in different projects based on their accuracy, convenience of use and output data (Stinson et al. 2003). Measuring intraoperative pressure during scoliosis surgery is sensitive work since it takes place in the operating room. On the other hand, precision and accuracy of data is an important factor to better understand the relationship between LFCN injury and pressure. In this case, choosing a reliable method of pressure measurement is an asset (Ferguson-Pell and Cardi, 1993).

Stinson et al. (2003) examined the pressure measurement system called Force Sensing Array (FSA, Vista Medical, Winnipeg) mats in an armchair and they determined that FSA pressure mats are a reliable system to be used in clinical experiments (Stinson et al. 2003).

Ferguson-Pell and Cardi (1993) compared three different pressure monitoring systems in terms of linearity, hysteresis and stability. They have used four methodologies to test each pressure measurement system. The first experiment tested the accuracy, linearity and reproducibility, hysteresis, and stability by applying planar loads (Ferguson-Pell and Cardi, 1993). In this test, they found the errors for each system and compared them. Results from Ferguson-Pell and Cardi (1993) research show that the FSA pressure mapping system is a reliable and comfortable system to use in clinical studies. Although there are 19% hysteresis and 4% creep reported for this FSA, it is known as a user friendly system with less limitations like speed or data presentation in comparison to others (Ferguson-Pell and Cardi, 1993).

Dey et al. (2013) have focused on the calibration period for pressure mats to figure out the accuracy change before and after regular calibration. They calibrated FSA pressure mats in three different ways including manual, automated and using newer software (Dey et al. 2013). They concluded that frequent calibration can affect the accuracy of the FSA pressure mats and it is best to calibrate pressure mats every two months to obtain precise data (Dey et al. 2013).

Saturation of the sensors is also a concern of pressure measurement systems. In wheel chair seated patients Wininger and Crane (2015) noticed that 13.7% of FSA pressure mats cells were saturated in 4.7% of the time. Duke et al. (2009) also noticed that the maximum of 300 mmHg was sometimes reached. The amount of error in cells for Wininger and Crane (2015) study is greater than what company claims which is 10% but due to the limitations of their study, such as sample size, further experiments are needed to find the error for cells.

Based on the literature review, FSA pressure mats are user friendly to implement in the operating room and they provide accurate data and are used in this thesis work to measure intraoperative pressure in scoliosis surgery.

2.3 Somatosensory Evoked Potentials

The Central Nervous System (CNS) in the human body is the combination of the spinal cord and brain. The spinal cord is a bundle of nervous tissue starting from the brainstem and ending on the first or second lumbar vertebrae. The peripheral nervous system (PNS) contains the nerves placed out of the brain and spinal cord including the femoral nerve

and the LFCN. The electrical response from the central nervous system in the body as a result of external stimuli is called evoked potentials and among different EPs, somatosensory evoked potentials (SSEPs) are a neurophysiological technique used to monitor the PNS function during spinal surgeries.

The nervous system is at risk of injury during spinal operations and this risk is higher in surgeries needing instrumentation such as scoliosis (Cowan, 1998). In this case, monitoring the integrity of nervous system, in order to reduce the risk of injury, is important to be done during spinal surgery (Cowan, 1998).

During the instrumentation in scoliosis surgery, it is important to monitor the spinal cord to prevent any damage or injury. One of the different ways used to assess spinal cord function during surgery was the Stagnara Wake-up method, which was used before somatosensory evoked potentials techniques (Cowan, 1998). In this technique, the patient is awakened during the high risk period of surgery to see if he or she can move his/her limbs (Cowan, 1998). This method can be dangerous for the patient since an embolism may occur as a result of endotracheal displacement (Cowan, 1998).

SSEPs were first introduced in 1992 as a useful intraoperative technique to prevent spinal cord injury by Scoliosis Research Society in North America (Cowan, 1998). In this method, either transcutaneous or transdermal electrodes are set on the scalp, arms and leg (PNS) to record the neural signals (Cowan, 1998). An SSEP machine operator (neurophysiologist) must be familiar with the AIS anesthesia and surgical procedure as well as the instrumentation steps so that he/she can confidently warn the surgical team when the

patient is at risk (Linden et al. 1997). Many factors affect the intraoperative SSEPs such as “electro-cautery” and “blood warmers” (Cowan, 1998). Any change in amplitude and latency of SSEP is a warning to the surgery team and the problem should immediately be diagnosed. SSEPs are monitored by stimulating the median nerve in the wrist and the posterior tibial nerve and the output signals are recorded from the scalp (Misuli et al. 1994, Legatt, 2012). Signal averaging is a typical method to analyse SSEP data since during the surgery many signals may be recorded by electrodes which make the LFCN signals visibility and raw data analysis difficult (Legatt, 2012). Since the evoked potentials are sensitive to anaesthesia, SSEP baseline signal measurement should start immediately after anaesthesia (Bithal, 2014). The normal LFCN SSEP wave form without anaesthesia is shown in figure (2.1). An almost similar signal was expected to be observed as a base line for the surgery.

SSEP monitoring during the spine surgery is accepted and used worldwide in spine deformity surgeries in order to prevent any possible nerve injury and is a tolerable technique especially for children having spine deformity surgery (Levy, 1997, Schwartz et al. 2000).

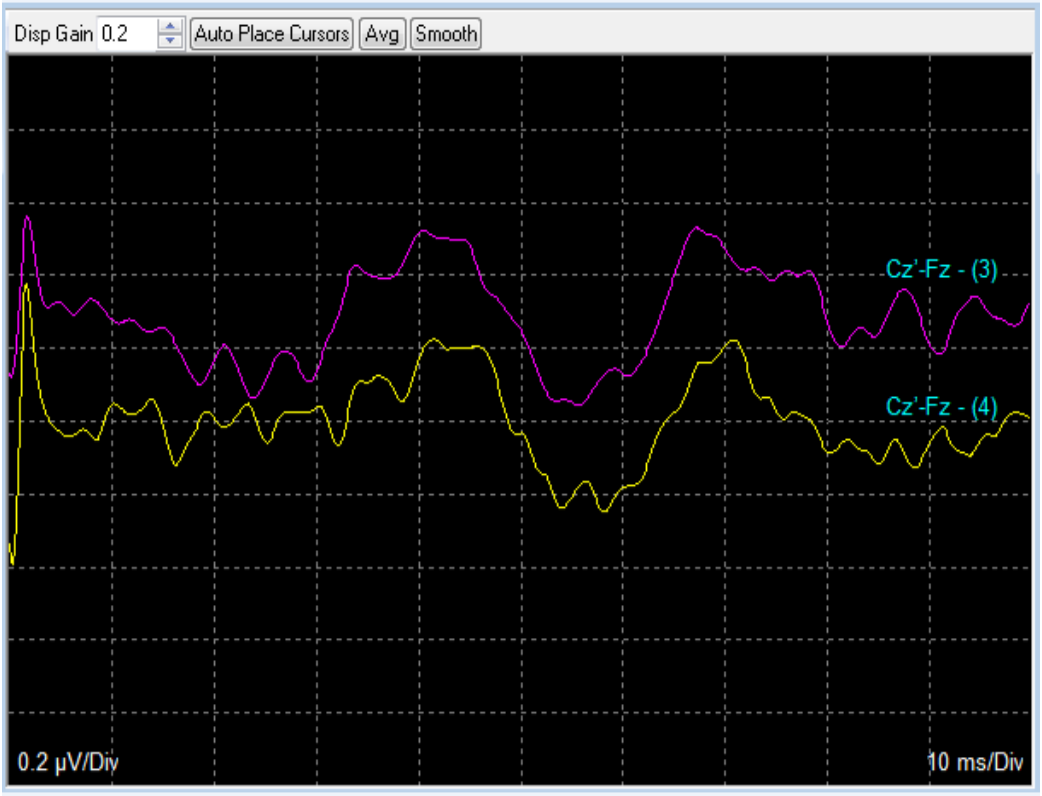


Figure (2.1): Expected normal SSEP waveform. The yellow line shows the baseline measure and the pink line shows a second reproducible measure.

2.4 Literature summary and objectives of this work

FSA pressure mats have been used in numerous applications. In order to validate the feasibility of using them in the operating room various tests will be performed and described in Chapter 3.

This study aims to find the accuracy of the FSA pressure mapping system over a small area, roughly the same size as the OR cushions, before and after calibration. The results then will be compared with the company's claim that says "the actual reading of each sensor at every validation pressure level should be within 10% of the final calibration pressure, with

respect to the pressure level. In this case the final calibration pressure is 200mmHg and 10% of this is 20 mmHg. If reading is at a pressure level of 100 mmHg, the range the pressures should fall between 100mmHg ±20 mmHg, i.e. 80–120 mmHg (Dey et al. 2013)."

Another goal of the study in chapter 3 is to determine the accuracy of the mats under various loading scenarios and over a small area similar to the cushions used in the operating room. Moreover, this study aims to determine the creep in the cushions over time and the repeatability of the measures. Evaluating the creep observed with our set of mats and determining how much time they need to warm-up in the operating room before taking measures is another objective which is discussed in chapter 3.

Previous work has shown that 12% to 24% of patients who have scoliosis surgery report problems such as tingling, numbness and redness on the hip after the surgery (Yang et al. 2005, Mirovski and Neuwirth, 2000, Gupta et al. 2004, Tejwani et al. 2006). It is assumed that the intraoperative pressure can affect the LFCN injury during AIS surgery but this has never been directly measured. The objective in chapter 4 is to measure the intraoperative pressure during the AIS surgery using Force Sensing Array (FSA) pressure mapping system. Since LFCN injury is a relatively common complication of scoliosis surgery, the fourth chapter of this work attempts to determine the effect of BMI and duration of surgery on the LFCN compression.

Overall, chapter 4 aims to measure the pressure at the patient-cushion interface and determine if there is any relationship between LFCN injury and increased pressure.

Chapter 3

Precision and Accuracy of FSA pressure mats

3.1. Evaluation of the Force Sensing Application (FSA) pressure mapping system using Instron loading machine

A Force Sensing Array (FSA) pressure mapping system (Vista medical, Winnipeg) is used as a practical and simple tool in various researches to demonstrate the amount of pressure in a specific sensing area (Crawford et al. 2005, Stinson et al. 2003, Ferguson-Pell and Cardi, 1993). The company claims that the Coefficient of Variation should be less than 10% and frequent calibration has also been recommended at every 2 months (Dey et al. 2013). The system consists of pressure mats made of a matrix of piezo-resistive cells and an interface module connecting the mats to the computer to analyze pressure data via FSA software. A common usage of pressure mats is to investigate the relation between seating ulcers and pressure distribution in different positions for wheelchair patients (Crawford et al. 2005).

Although FSA pressure mats are user friendly and suitable to use for clinical research, there are still concerns about their stability and precision. Dey et al. (2013) reported that under a constant pressure, all regions in FSA pressure mats should show the same amount of pressure but there is no stability in the mats and pressure is not constant in all areas. In order to get more accurate data, frequent calibration is suggested by the company (Vista medical) in order to have accurate results. Moreover, precision and accuracy of the pressure have already been tested and reports show that un-calibrated pressure mats have inaccurate results. Figure (3.1) shows Vista Medical Winnipeg FSA pressure mats.

Figure (3.1): FSA pressure mat

This section evaluates the FSA pressure mats function using an Instron loading machine. The goal of this section is to determine the error of the FSA pressure mats as a pressure

measurement system as well as validate the mats over a smaller area similar to the operating room cushions. Moreover, the final objective of this section is to determine the difference in FSA pressure mats function before and after calibration to see if the periodic calibration is necessary.

3.1.1. Methodology

Within this study a set of four FSA pressure mats, which were later used in operating rooms to measure intraoperative pressure during scoliosis surgery, were tested. Two of the pressure mats were SoftFlex, later used to measure pressure on chest, measuring maximum pressure of 6 psi (310 mmHg), and the other two were standard ones later used to measure pressure on hips, measuring maximum pressure of 10 psi (517 mmHg). FSA pressure mats were calibrated with an air bladder according to the manufacturer's specification four months prior to this study.

Pressure mats were sandwiched between two pairs of foam and wood in the Instron loading machine during each test. The use of foam and wood was used to spread the load on the mats and prevent any damage. The limitation of using foam in this experiment is that the shear stress could not be measured during the pressure and force measurement by Instron. The Instron loading machine was calibrated manually before each test and is also controlled by an operator. The output from the Instron machine is in the form of voltage measured using a voltmeter. The voltage from the Instron machine was converted to force. The force was calculated from the relation between input and output of the

Instron load cell which showed the full scale of 10 volts equal to 1000 pounds. Later the pressure from the Instron loading machine was calculated with the force divided by the contact area of foam and wood. The amount of pressure calculated from the Instron loading machine was then compared to the pressure measured by FSA pressure mats. The maximum load applied to the loading machine during each test was no more than the equivalent of the mats' maximum 6psi and 10 psi for the SoftFlex and standard mats, respectively. Tests were done in three steps: 1. increase the load from 0 to 6 and 0 to 10 psi for SoftFlex and standard mats, respectively; 2. Decrease the load from max to zero; 3. Pick a series of random loading within the range. The tests were repeated after the mat calibrations with an air bladder according to the manufacture's recommendation. Figure (3.2) shows the pressure mats set on the Instron loading machine in the lab.

Figure (3.2): FSA pressure mat (SoftFlex) sandwiched between wood and foam on the Instron loading machine

The wood and foam used in this test had 225.8 cm^2 (17.78cm × 12.7cm) areas. This particular area was selected to represent the size of the Jackson Table cushion as this area would be active during the surgery. The percent error was calculated from the average of absolute difference between the FSA pressure and the Instron applied pressure.

3.1.2. Results

The pressure distribution from the Instron loading as displayed in the FSA software is shown in figure (3.3).

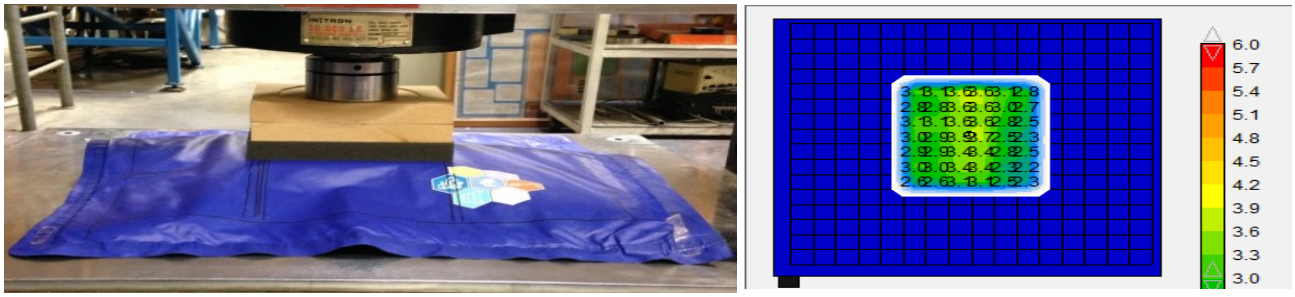


Figure (3.3): FSA software showing the pressure distribution from the Instron loading

The average percent error for the mat before calibration was 18.4% for the mat calibrated four months before this test. This improves slightly to 18.1% after the calibration. This amount of error is high for the device which later will be used in OR. It was observed that the FSA system shows pressure, less than 5mmHg, for the pressure mat cells around the perimeter of the foam and wood when those regions were not even under the load cell. Because of this, the pressure amounts less than 5mmHg on those regions were removed while averaging data and finding the error. Recalculating the error, it reduced to 11.8% and 11.3% before and after calibration respectively. Looking at the absolute difference in measures the average in the mid-point calculation was 0.56 psi and 0.45 psi before and after calibration respectively. This method of removing cells less than 5mmHg was later used when analyzing the clinical data.

. Looking at the absolute difference in measures the average in the mid-point calculation was 0.56 psi and 0.45 psi before and after calibration respectively. A visual comparison of the increasing, decreasing and random pressure before and after calibration is shown in figure (3.4) and figure (3.5) respectively. The average pressure in the active area is presented. The error measured was larger at the ends of the mats pressure range.

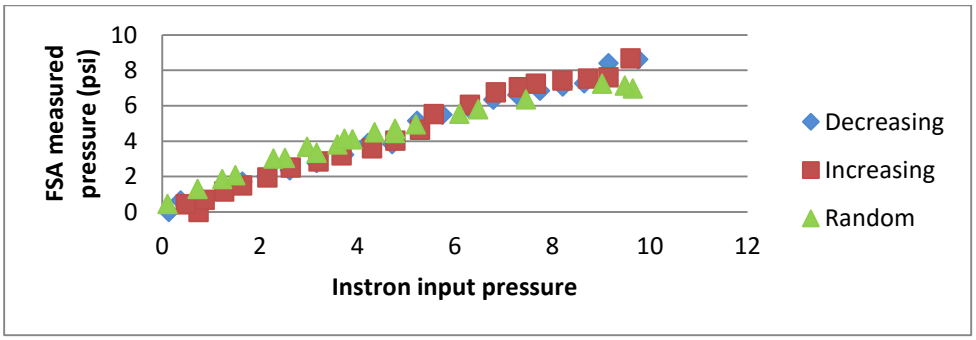


Figure (3.4): Expected and measured pressure results before air bladder calibration for three steps for the standard FSA pressure mat

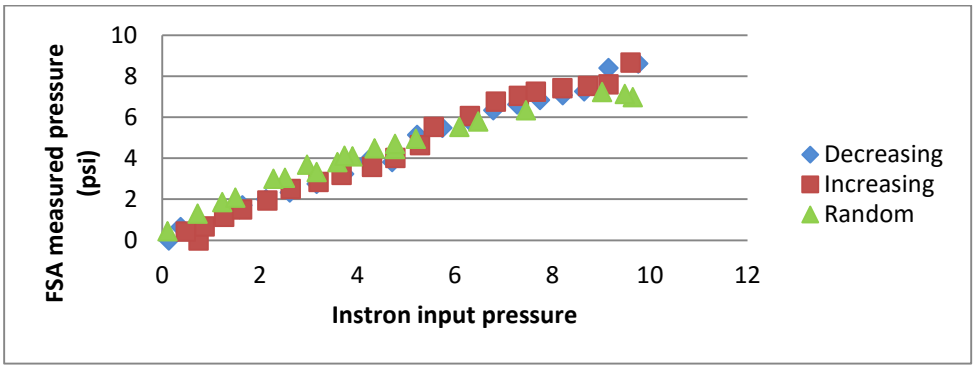


Figure (3.5): Expected and measured pressure (over time) results after air bladder calibration for three steps for the standard FSA pressure mat

3.1.3. Discussion

FSA pressure mats calibration using an air bladder is suggested by the manufacturer and Dey et al. (2013) to reduce errors. Tests show that pressure mats are performing only slightly better after recent calibration. However, regular calibration is still recommended. As the pressure measured was regularly lower for the FSA mats than the pressure applied the reason for error may be the inactive neighboring cells. Moreover, we cannot ignore the Instron load cell error. However, the results show there is not a significant change in pressure measurements before and after calibration in a small area and as a result calibration can help to have more accurate data and less error. During this test, only a specific area in the middle of the pressure mats is used and the outer parts are not activated. There is a probability that if the cells on the perimeter of the testing region are included in the average pressure, this will decrease the FSA average pressure. This is because the cells on the edge may only be partially covered as shown in figure (3.6) and therefore they report a lower pressure. Although the percentage error decreases slightly after calibration, it is still recommended to calibrate pressure mats frequently. An 18% error is a concerning limitation on the pressure mats. However, in the region we have used in this work the error is around 11%. More investigations are needed to see the repeatability of the mats and how they perform over time.

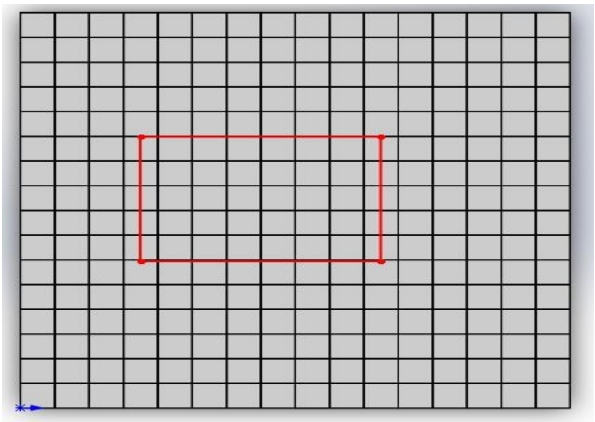


Figure (3.6): Partly covered cells. Depending on how the cushion is lined up over the FSA mat cells, the perimeter cells may only be partially covered

3.2. Creep in FSA pressure mats

In this research the FSA pressure mapping system is used to measure pressure during scoliosis surgery. Monitoring intraoperative pressure is a long procedure as the length of surgery is more than 2 hours. Since accurate data is needed to find the relationship between intraoperative pressure and LFCN problem, it is necessary to be sure there are minimum errors such as creep with pressure mats. There are two types of error that are common in electrical measurements: noise and drift. An example that shows noise and drift is shown in figure (3.7). Noise is a short term fluctuation in the signals often caused by external electrical interference. Drift is a gradual, longer change often related to the system heating up. When discussing piezo-resistive sensors the terms drift and creep are often used interchangeably. Dey et al. (2013) have done the most work on evaluating creep of pressure mats so the term creep, not drift, is used in this current work. Creep is one of

the important issues with FSA pressure mats and is defined as the sense of the pressure mat to increase pressure over time while having a constant load (Dey et al. 2013). This occurs as a result of the pressure mats structure, the FSA software, type of cushions or patient motion (Dey et al. 2013). Precision and accuracy of pressure mats reduces with creep and data will be inaccurate. Ferguson-Pell and Cardi (1993) reported that creep for FSA pressure mats is 3.3% after 2 minutes and 4.6% after 10 minutes. In this study, experiments are done for longer time close to the minimum length of scoliosis surgery (2 hours) to measure the creep.

Since the scoliosis surgery is a long operation, the objective of this experiment is to see how the creep in FSA pressure mats may affect the pressure measurement data over time.

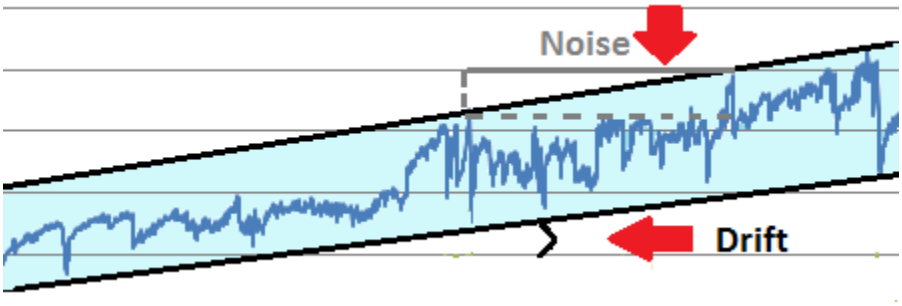


Figure (3.7): Noise and drift in a measured pressure signal

3.2.1. Materials and methods

The tests were done to measure the precision and accuracy of FSA pressure mats over a long period of time. For precision it is important to do and redo the same subject and for accuracy the test must take place with a known load. The previous Instron tests focused on the mat accuracy while this section focuses on precision. The Jackson Table and cushions used in the operating room were simulated with foam cushions placed on a board as seen in figure (3.8).

The experiments simulated the operating room where three volunteers laid on the simulated Jackson table for various times. Three different volunteers, two women and a man did the experiment age ranged from 25-37 and weight from 70-90 kg. Overall data was collected for three test steps. The first experiment included four trials where the pressure was monitored continuously for 15 minutes and repeated after a 5 minutes' rest. The next experiment started an hour later, after the pressure mats were well warmed-up, and three trials where done in the same manner as the first experiment. The last test was ten trials each for two minutes with thirty seconds rest after each trial. After the data collection, average pressure and standard deviation for each time segment were calculated for the active regions of the mat.

Figure (3.8): Simulated surgery table with and without pressure mats installed

3.2.2. Results

Figure (3.9) includes the first four sets of on and off each for 15 minutes. The average for chest, left and right hips for the first data set is summarized in table (3.1). Standard deviation and average pressure given in table (3.1) are higher for the chest than the hips for all data sets. Note that the initial reading was around 35 mmHg for the chest mat and it increased to 70 mmHg during the first experiment trials. Figure (3.10) shows the results

for the second experiment which started after the system warmed up for 20 minutes and the same method, 15 minutes lying on the table followed by a 5 minutes' rest, used in this test. Three trials were done in the second set of data collection. Table (3.2) shows that the average pressure and standard deviation in the second set of data is still higher. Due to the results from chapter 3 experiments, the mats should be left to warm up for 20 minutes, if possible, to reduce the effect of creep in the chest than the hips.

The next test was ten times on and off each for 1.5 minutes to see the creep in short times. Results for the ten times on and off the pressure mats are summarized in table (3.3). Figure (3.11) shows the results from ten times on and off. Maximum amounts in this test are as a result of the volunteer's movements during positioning on and off the table.

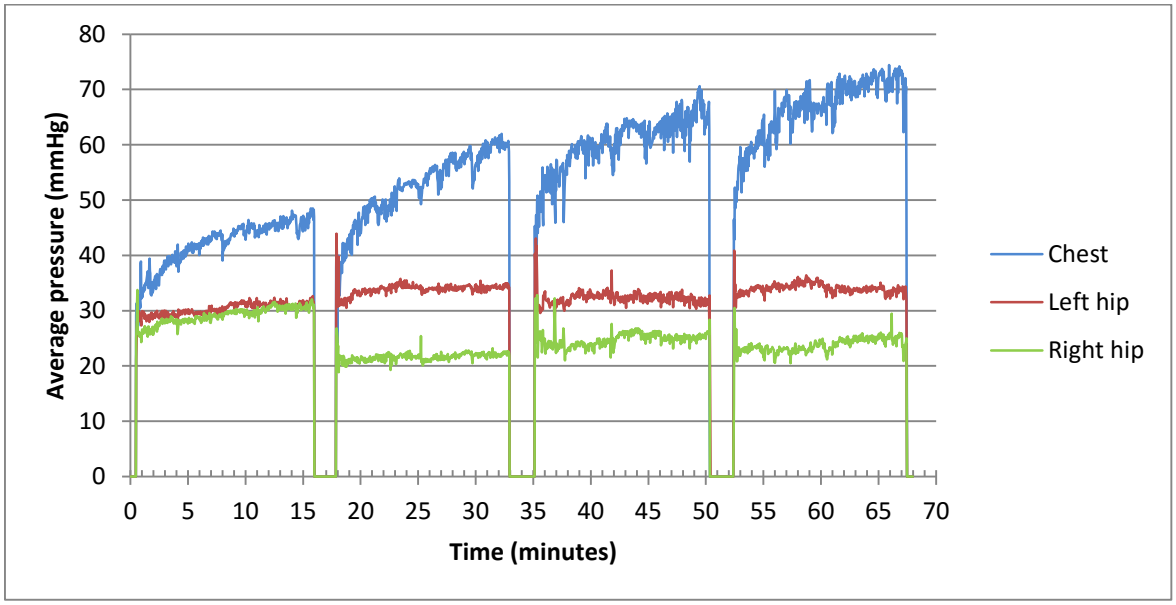


Figure (3.9): First set on the table for 15 minutes and rest for 5 minutes' experiments with the same weight

Table (3.1): Average pressure and standard deviation in first four trials for the chest, left and right hip cushions.

	Average pressure (mmHg)	SD	Average pressure (mmHg)	SD	Average pressure (mmHg)	SD	Average pressure (mmHg)	SD
Chest	50	8.2	52	6.2	60	5.2	67	6
Left hip	29	5.2	34	1.05	32	1.3	34	0.9
Right hip	28	5.1	22	0.74	25	1.3	24	1.2

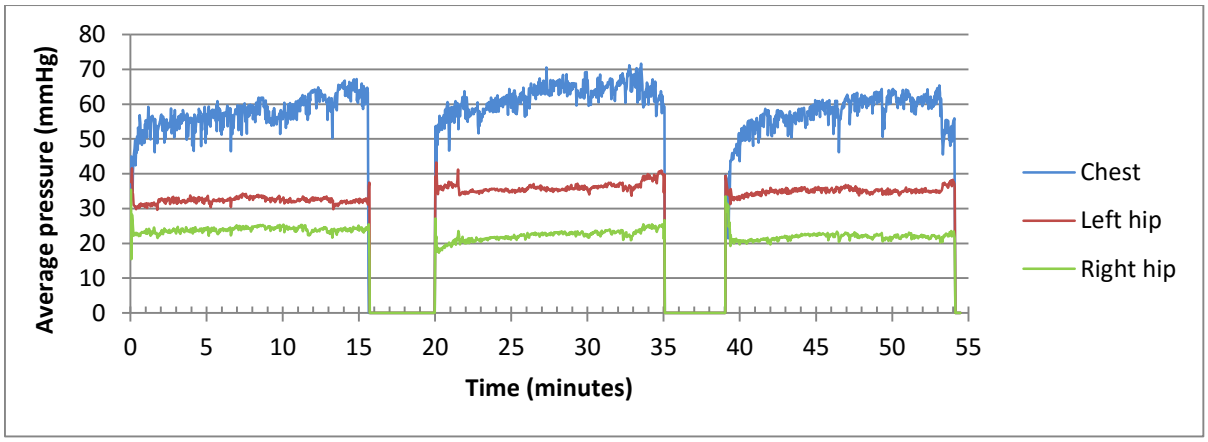


Figure (3.10): Second set of data after system warmed up for twenty minutes then pressure measurement began for 15 minutes followed by 5 minutes rest

Table (3.2): Average pressure and standard deviation in the second trials

	Average pressure (mmHg)	SD	Average pressure (mmHg)	SD	Average pressure (mmHg)	SD
Chest	58	4.7	62	4.3	57	5.7
Left hip	32	0.9	36	1.7	35	2
Right hip	24	1.01	22	1.5	22	1.3

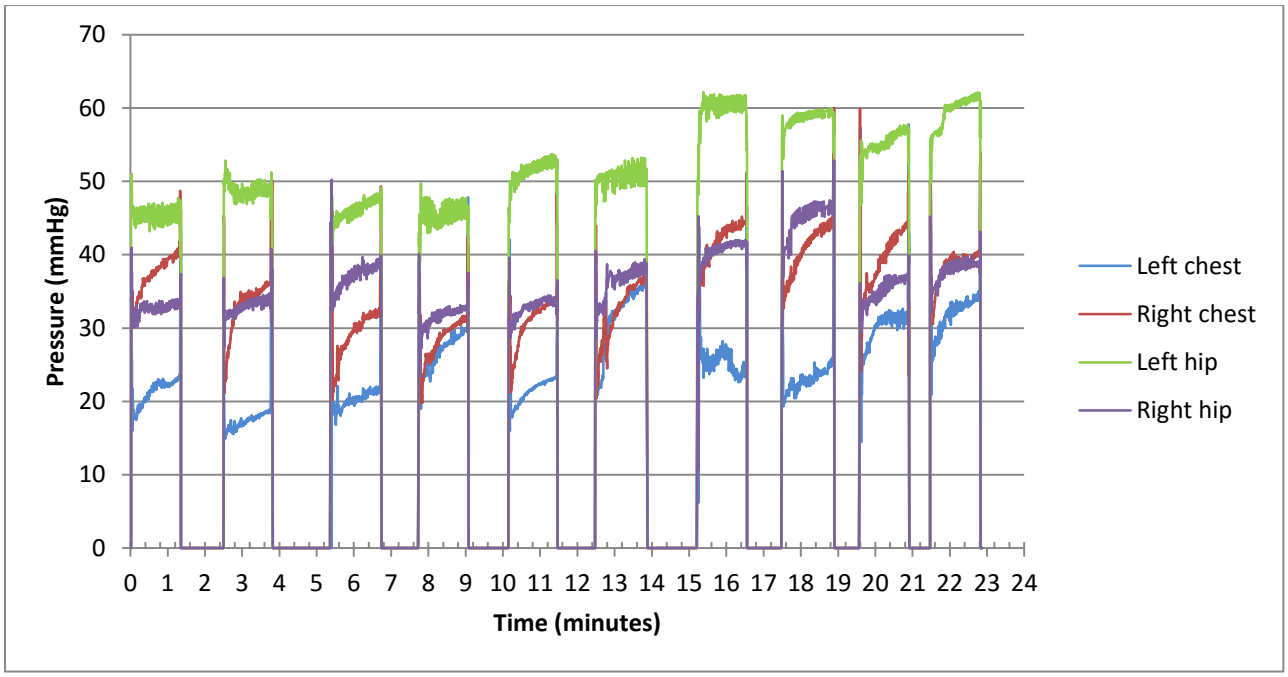


Figure (3.11): Mats creep in short time experiment. Each trial is one minutes and 30 seconds on the table followed by 30 seconds rest.

Table (3.3): Average pressure and standard deviation in ten times on and off

	Trial 1		Trial 2		Trial 3		Trial 4		Trial 5		Trial 6		Trial 7		Trial 8		Trial 9		Trial 10	
	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD	Pressure (mmHg)	SD
Left chest	21.4	3.8	17.6	2.8	20.9	4.1	27.6	4.9	21.6	2.7	31.8	4.8	25.7	3.8	23.4	3.5	30.4	3.9	32.1	3.8
Right chest	37.5	5.8	33.6	5.5	29.5	4.8	28.8	3.7	30.9	4.7	32.7	4.8	42.4	5.6	41	5	39.7	5.2	39.1	6.1
Left hip	45.1	4	49.1	2.2	46.2	1.4	45.8	2.3	51.5	1.6	50.7	1.4	60.5	3.1	58.7	1.2	55.2	1.7	59.6	2.3
Right hip	32.7	1.2	33	2.3	37.3	2.1	31.7	1.8	32.8	1.3	36.5	2.3	40.5	2.4	45	2.5	35.1	1.7	37.9	1.6

3.2.3. Discussion

Looking at the results for the experiments in this chapter, creep occurs in FSA pressure mats in each individual data set. However, creep does not happen at all times. It mostly occurs at the beginning of the data measurement just after the volunteer's positioning. When the mats were not warmed up we observed a lot of creep. The pressure increase from 35 mmHg to 70 mmHg during the first experiment could partially be a result of positioning but is likely mainly due to the mats not warmed up. Standard deviation for each data set shows that the SoftFlex mat used for the chest is less precise than standard mats used for the hips. This occurs even in the recently calibrated pressure mats. This difference could be as a result of the different materials or technology used in producing standard and SoftFlex mats.

Despite the existence of the creep on pressure mats during data collection, it is fortunate that the creep reduces after the mats warmed up. This is also good when using the FSA pressure mats for a long time in operating room. At the beginning of the surgery, FSA data seems to be unstable as a result of movements to place patient over the table and adjust cushions. It is recommended to take a baseline pressure measurement about 20 minutes after the patient is lying on the mats. Moreover, intraoperative pressure data (presented in next chapter) does not show any substantial increase in pressure amount over time which should happen if there is creep over time.

3.4 Preliminary test summary

A general evaluation of FSA pressure mats was done in this chapter. Since the FSA pressure mats calibration is one the important things needing to be done periodically, the average pressure before and after calibration was tested in a small area. The tests showed that the FSA pressure mats do a bit better after calibration. There was not a big difference in the percentage error of pressure mats before and after calibration (0.3 differences in error percentage). The error for FSA pressure mats in this study (11%) is smaller than what already have been found in literature (19% Ferguson Pell and Cardi 1993). The FSA system error was smaller in comparison to the other pressure mapping system errors and also FSA system is easy to use and calibrate in comparison with the other systems. With regard to the experiment on the small area and previous experiments the frequent calibration is still recommended (Ferguson-Pell and Cardi, 1993, Dey et al. 2013).

The investigation of creep on FSA pressure mats was summarized in this chapter. Creep on pressure mats in the experiments in this chapter show that at the beginning of data measurement there is a creep on mats and it returns to normal after some minutes. Using the information in this section, the pressure mats must be installed as early as possible before data measurement in the operating room so that the effect of creep decreases after 20 minutes of warming up.

Chapter 4 Clinical Study

4.1 The objective of this article

The main goal of this thesis work is described in this section. The objective of this work is to quantify pressure at the patient-cushion interface during surgery. The ultimate goal is to study the effect of different factors like intraoperative pressure, BMI and time. Each of these factors may affect the LFCN compression during scoliosis surgery.

This chapter aims to determine the relationship between intraoperative pressure and LFCN compression during scoliosis surgery.

4.2 Article 1: Monitoring LFCN Compression and Injury during Adolescent Idiopathic Scoliosis Surgery

Abstract

Scoliosis is a deformity of spine which occurs in 1-3% of the population. Adolescent idiopathic scoliosis (AIS) occurs in teenagers for an unknown reason. Treatment is performed through the use of bracing or through surgery depending on the age of the patient and the Cobb angle of the spine. During surgery, patients are placed prone on a special operating table with relatively small cushions. Tingling, numbness and pain of the lateral femoral cutaneous nerve (LFCN) occurs in 20% of the patients who have scoliosis surgery. It is assumed that the intraoperative pressure can cause LFCN compression during AIS surgery. In order to measure the pressure continuously during the surgery, a set of four Force Sensing Array (FSA) pressure mats were placed under the hips and chest. Pressure for a total of 23 patients was recorded. Based on clinical observation, about half of the patients (48%) had redness and numbness on their hip after surgery which disappeared in less than a month. Four patients had tingling and signs of lateral femoral nerve damage in the days post-surgery. Results show that intraoperative pressure is not the only cause of LFCN problems after surgery for AIS patients. Other factors like BMI and the duration of surgery have been shown to be important. In this research BMI did not have a significant effect while duration of surgery was significant as the p-value is 0.74 and 0.0064, respectively. Therefore, duration of the surgery is an important factor in LFCN injury.

4.3 Introduction

Adolescent Idiopathic Scoliosis (AIS) is the lateral curvature of the spine that can happen in teenagers. It is reported that 1-3% of the population have AIS in which the Cobb angle in more than 10° (Li et al. 2014). In the case of treatment, when the Cobb angle is more than 45°, surgery is usually suggested (Delorme et al. 2000). During scoliosis surgery, the patient is prone positioned on a table similar to a Jackson Table (Mizuho Orthopedic Systems Incorporated, Union City, CA). The patient is prone positioned on small cushions in order to reduce the extra pressure on the abdomen and vena cava and, as a result, the pressure increases on the chest and hips (Yang et al. 2005). Yang et al. (2005) followed 252 patients after spine surgery. Postoperative LFCN nerve injury was reported in 60 patients. They found that degenerative spinal disorders, overweight and longer surgical time were factors related to LFCN injury It is reported that about 20% of the patients suffer from numbness or feelings of tingling in their upper thigh where the lateral femoral cutaneous nerve (LFCN) passes the pelvic bone (Mirovski and Neuwirth, 2000, Tejwani et al. 2006). LFCN is a sensory nerve which originates from lumbar second and third in the lumbar plexus and appears from lateral edge of psoas major muscle and elapses anterior superior iliac spine (ASIS) (Mirovski and Neuwirth, 2000). The area of sensation for this nerve is around the anterior iliac crest and the upper lateral part of the thigh. Figure (4.1) shows the redness in the iliac crest region after AIS surgery.

Brienza et al. (2001) had a similar study on wheelchair patients using pressure mapping systems. They concluded that the pressure is higher on wheelchair patients with buttock

ulcers than the patients without. Boney parts of the body are more likely to have ulcers since the pressure over those parts is high (Berlowitz and Brienza, 2007) and as a result, pressure might be higher on the hips of thin patients.

In another study, Yang et al. (2005) showed that intraoperative pressure during spinal surgery can vary in people with different BMI and they concluded that patients with higher BMI experienced higher incidence of LFCN injury than the others.

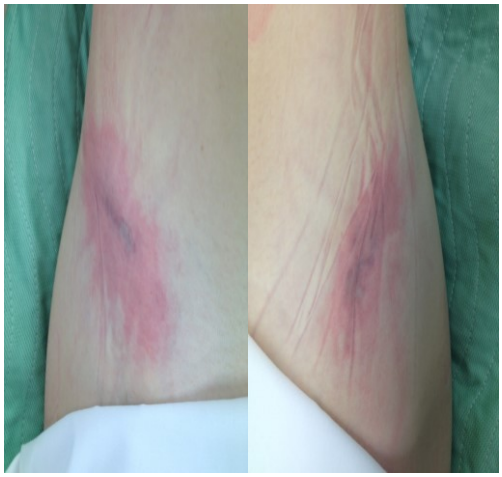


Figure (4.1): Redness on the iliac crests after spinal surgery

4.3.1 FSA pressure mats

There are several pressure measurement systems used mainly for wheelchair patients. In a study, Ferguson-Pell and Cardi (1993) show the errors relating to different pressure mapping systems. They determined that the Force Sensing Array (FSA) (VISTAMED, Winnipeg, Canada) pressure mats with 19% hysteresis errors and 4% creeps are a proper system to be used in a clinical study. The amount of pressure increase over time as a result of load is called creep (Dey et al. 2013). These sensing mats are made of piezo-resistive

sensors covered with polyurethane coated rip stop Nylon (Vista Medical, Winnipeg) and are easy to work with in the operating room.

4.3.2 Objectives

Pressure has been suspected as a cause for LFCN injury during surgery (Yang et al. 2005). However, no work has quantified pressure and related it to LFCN injury. The objective of this work is to quantify the pressure at the patient cushion interface during surgery. We will determine if there is a difference in pressure observed in the normal patients and those who suffer from LFCN injury. Additionally, the length of surgery and the BMI of the patients will be recorded.

4.4 Materials and Methods

A set of four FSA pressure mats (Vista Medical, Winnipeg), made of thin and flexible material are used to measure intraoperative pressure during spine surgery. This pressure mats set is similar to the ones used on wheelchair patient's seat for ulcers evaluation. FSA pressure mats each contain a 16×16 sensor array over 1849 cm^2 sensing area. Somatosensory evoked potentials technique is also used in the OR to monitor the impairment of the spinal cord during fixation of the spinal cord in scoliosis surgery (Nuwer et al. 1995). The internal mechanism of FSA pressure mats is based on the piezo-resistive effect of piezo-resistive sensors.

4.4.1 Pressure mats calibration

Dey et al. (2013) suggest that in order to have more precise and accurate data, a regular 2-month calibration for FSA pressure mats is necessary due to creep and hysteresis errors present in FSA pressure mapping systems (Ferguson-Pell and Cardi, 1993, Dey et al. 2013). Calibration is necessary to have precise and accurate output after the tests. Pressure mats are calibrated as per the instructions from the company. Pressure mats calibration can be done in two ways: auto and manual calibration. The manual method of calibrating the mats uses the calibration pack which comes with the pressure mats. Figure (4.2) shows the wooden jig and inflatable bag used for manual calibration of pressure mats.

Figure (4.2): FSA pressure mats manual calibration set

With this method, a pressurized inflator bag is placed over the pressure mat and this pack is place on the wooden jig. An air pump is used to inflate the bag and there is a pressure gauge placed on the output of the inflator bag to show the pressures, which are limited to 0-6 psi (0-310 mmHg) for SoftFlex mats and 0-10 psi (0-520 mmHg) for standard mats. Instructions on how to do the procedure are provided in FSA software. The mats can be calibrated for different pressure ranges by decreasing the applied pressure from the max amount in 40 mmHg increments and then repeating the procedure and increasing the pressure. Calibration can be done using the auto calibrator, however there is a limitation

on the maximum pressure that the auto-calibrator can measure which is 3.87 psi (200 mmHg). The max amounts for the mats used in this study are 6 psi (310 mmHg) and 10 psi (520) mmHg for SoftFlex and standard mats, respectively, so for this reason, manual calibration was performed on all the mats.

4.4.2 Testing procedure

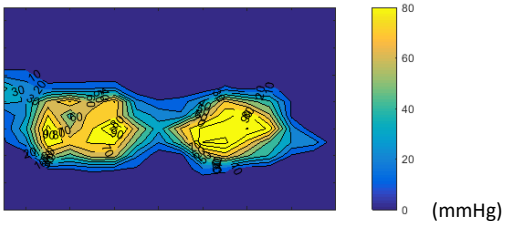
In this study, 23 patients with adolescent idiopathic scoliosis, 2 males and 21 females, age range 9-18 years, lied on pressure mats and the pressure was measured continuously during the surgery in the University of Alberta Stollery children's hospital. The procedure was explained completely to every single patient and they signed the consent form to use pressure mats during their surgery and collect non identifying information. The information form for the ethics consent can be found in Appendix A. Pressure mats were tested in the lab before being used in operating room to avoid any signal impairment and errors. Plugging the pressure mats into the wall showed 50 Hz noise on the SSEP signal. During the operation, the pressure mats are in contact with the patient's body and the 50 Hz noise may cause signal conflict with the electrical devices used in the operation. In order to eliminate this noise in the OR, the box was connected to a battery pack including 6 D-cell batteries which reduced the noise. Figure (4.3) shows the battery pack set used as a power source for FSA pressure mats. The internal hospital biomedical department insisted that the laptop also not be plugged into the wall during the surgery even though it is grounded. Plugging the laptop into the wall also caused noise for the neuro-monitoring so it was left to run off of its battery during the surgery.

The pressure mats must be covered during the surgery in order to prevent contact with blood or other liquids. To avoid this, the pressure mats are covered with plastic bags and then a white cotton sheet. After pressure measurements were taken for some cases, the surgeons forbid the use of the cotton sheets to avoid sliding of the patient and to prevent the extra wrinkles in the patient's chest caused by thick sheets. To solve this problem, disposable and impermeable material was used as a cover for the pressure mats during surgery. After the patient lied on the pressure mats, data was collected continuously for all steps. The first data collection step starts at the beginning of the surgery before the cauterizing. During the cautery, there will be no data collection since the pressure mats do not record any data.

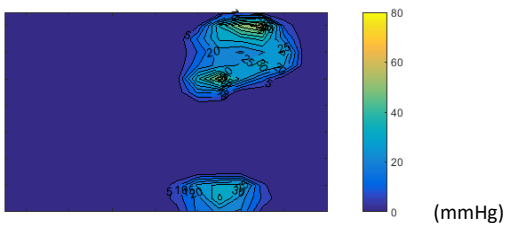
Figure (4.3): 6 D-cell battery pack used in the study. The goal of this pack as a power for FSA mats was to reduce the noise on SSEP signals

Data collection continued during the screw placement and rod insertions and until closure and removal of the patient from the table.

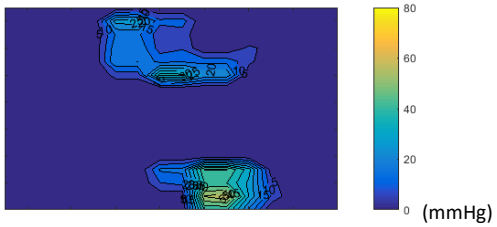
Data from the OR was analysed with the help of Matlab. Figure (4.4) shows the Matlab simulation of FSA results. The Matlab program used to simulate the FSA is shown in appendix B.



Pressure distribution on chest



Pressure distribution on left hip



Pressure distribution on right hip

Figure (4.4): Matlab display of chest, right and left hips. A high pressure is shown on the chest and iliac crests. The regions show pressure distribution in mmHg and the color shows the severity of pressure in different regions. Anterior superior iliac spine (ASIS) is located in the gap between the regions in right and left hips. X and Y axis represent the 16 by 16 inches FSA pressure mats.

A limitation of using FSA software in data analysis is that average and max pressure on FSA are shown frame by frame and there is not a continuous data set to see the change in pressure throughout different steps of surgery. This means that max and average pressure must be plotted over time to conclude the time or step which mostly affects the pressure amount. A second Matlab function was created to plot the average pressure in the active sensing region, as well as the peek (maximum) pressure over time.

Determining the pressure over time is difficult with the FSA pressure mat software as only one frame is shown at one time. The software itself is capable of converting data to an excel sheet so this can be easy to analyze or plot data. Data collected from all patients was converted to an excel spreadsheet and the default unit for pressure was set to mmHg. Looking at raw FSA data, as seen in figure (4.5), there are dark blue cells showing a pressure reading of zero but these are out of the cushion area. To determine the pressure directly between the patient and the cushion, the data below 5mmHg is eliminated. Average pressure is calculated for the active cells area, which is called the overall pressure and is plotted over time. Moreover, the average for the total operation is calculated to compare the results between patients with and without LFCN problem after the surgery.

A problem encountered with FSA pressure monitoring during AIS surgery was slipping of the mats over the cushions on the table while positioning the patient at the beginning of the surgery. As a result, some parts of the thigh or chest were located out of the mats and data was missed for those regions. Figure (4.6) shows a poor body position over the pressure mats and missed data is marked with red circles. To solve this problem, small Velcro attachments were added to the pressure mats, on both sides of the covers and the cushions to fasten them together during positioning.

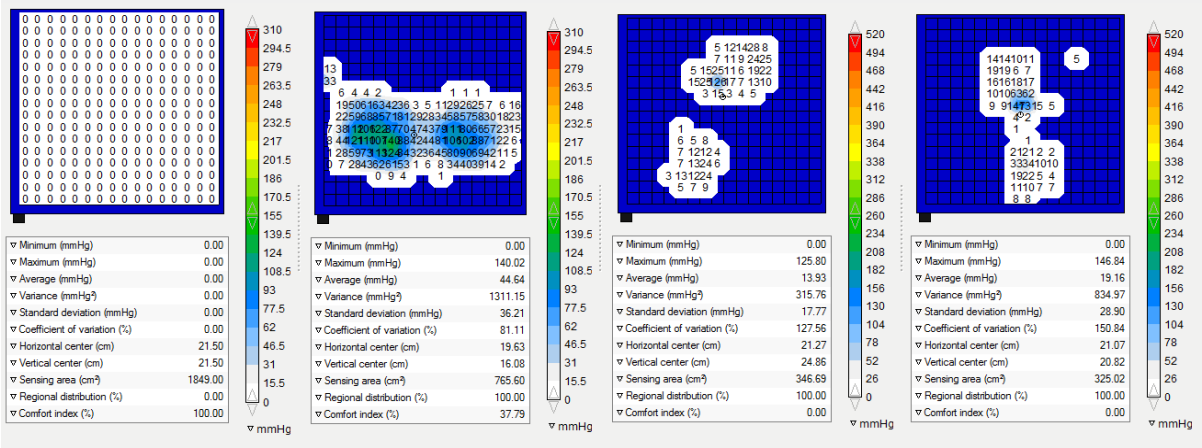


Figure (4.5): Pressure shown for chest bar, left and right hips. The standard calculation done in FSA are also shown

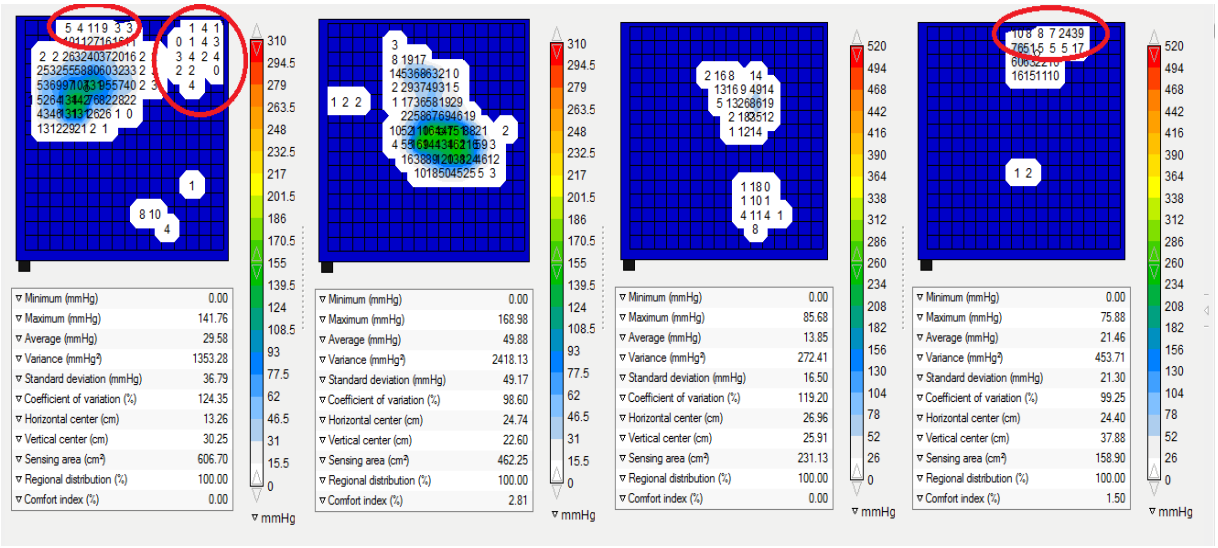


Figure (4.6): Data loss during positioning

A post-operation follow-up form including age, gender, BMI, weight and height of the patient is filled out. This form can be found in appendix C. This follow up form is then used by a nurse to gather information about any numbness or tingling during the time the patient spends in hospital after the operation. At the end of the surgery, pictures were

taken of both hips to document the redness between patients with and without LFCN injury.

During the scoliosis surgery, LFCN SSEPs were recorded intermittently. The electrodes were placed on the patient's body and the baseline waveform was taken immediately after anaesthesia. LFCN SSEPs are monitored during scoliosis surgery to see if they can help to identify the LFCN injury during the surgery. However, LFCN SSEP analysis is out of the scope of this research

4.4.3 Statistical Analysis

Statistical analysis of the data was done to determine if there was any difference in the groups with LFCN injury or redness. Patients with redness on the hip were compared with patients without redness using one tailed t-test. Pressure data for both right and left leg was averaged for each patient and the normality of data was tested using histogram graph shown in figure (4.7). The bell shape graph of data shows that average pressure for 23 patients is normally distributed. One tailed t-test was used since the pressure for patients with LFCN redness or injury, as a factor causing LFCN injury, was hypothesized to be more than the normal patients. The same test was done for the group of patients who had numbness on the hip. Statistical analysis for the effect of BMI on LFCN compression was done using Mann-Witney U test. Mann-Whitney U test was used because of the small sample size, 4 patients in one group, for LFCN injury and BMI same as LFCN injury and duration of surgery

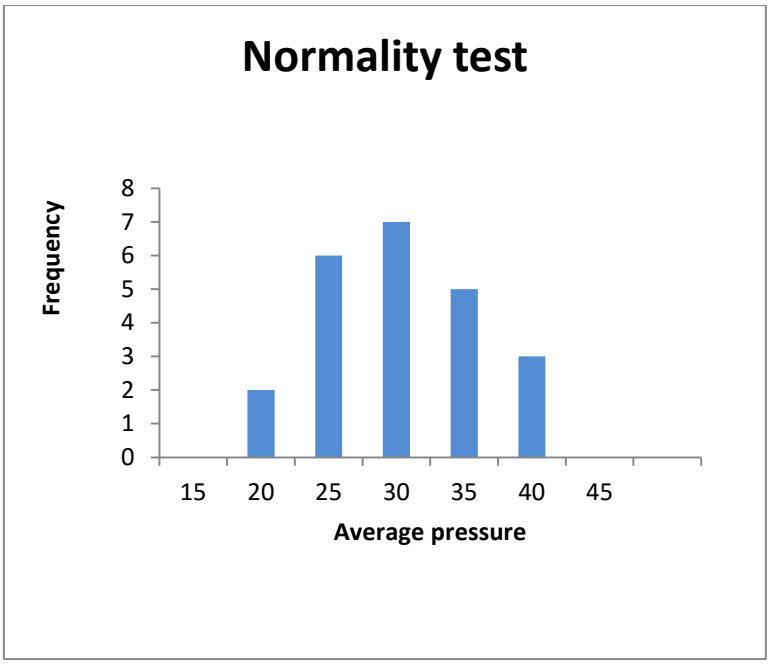


Figure (4.7): Normality test on average pressure data (mmHg) using hysteresis graph. The bell shape graph fo data indicates the normal distribution.

4.5 Results

The results for average overall pressure over time and maximum peak pressure during the surgery are seen in Table (4.1). Overall, 11 patients of the 23 (48%) had problems such as redness and tingling on their hip after the surgery. The patients who had redness on their hip after surgery are highlighted with red and the four patients who had LFCN injury symptoms such tingling or numbness are highlighted with blue.

Table (4.1): Pressure measurement results for 23 AIS patients. The hips that had redness in the days following surgery are shown in red. The hips with LFCN injury are shown in blue.

			Chest		Left Hip		Right Hip		
BMI	Traction	Case #	Overall (mmHg)	Max(mmHg)	Overall(mmHg)	Max(mmHg)	Overall (mmHg)	Max(mmHg)	Duration(/h)
20.7	No	1	52	310	26	402	25	175	5h
26.7	No	2	49	310	36	304	40	372	6h
20	No	3	75	310	36	313	35	199	5h 30m
19.8	No	4	53	149	26	517	31	222	5h 30m
22.3	No	5	71	310	34	330	23	238	5h 30m
20	No	6	29	146	21	286	22	282	3h 30m
23	No	7	24	310	32	100	38	136	5h
23.2	No	8	52	310	45	319	29	163	2h
22.5	Yes	9	92	310	37	517	30	187	8h
22.8	Yes	10	34	185	22	198	23	148	6h 30m
16.9	No	11	85	310	23	225	27	194	5h 45m
19.9	No	12	102	310	28	312	35	273	5h
20.4	Yes	13	27	188	24	272	27	197	5h
23.6	Yes	14	74,45	310,310	25	198	21	85	6h 30m
20.5	No	15	34	248	17	259	23	283	6h
19.6	No	16	83	310	19	276	17	87	3h
19.8	No	17	31	300	24	276	46	517	4h 15m
21	No	18	30	310	23	203	18	122	4
34.5	No	19	72	300	29	133	23	84	4
24	No	20	34	280	24	481	19	119	5h 30m
21.7	No	21	31,41	300,226	25	218	27	152	5h 30m
18.1	Yes	22	38	300	28	425	31	274	6h 30m
16.8	No	23	27	81	38	250	25	59	3h 30m

All patients with LFCN injury also had redness on the post-operative days. 2 patients (9%) had redness only on their left hip, while three (13%) had redness only on their right hip after surgery. 6 patients (26%) had redness on both sides, and 3 of them experienced tingling and numbness on both sides. The average intraoperative pressure for those with redness on their hip is 28 mmHg for both the left and right side and the maximum pressure

for those cases varies between 133-517 mmHg and 87-517 mmHg for the left and right hip, respectively. One of the patients (Case# 9) left the hospital with numbness on the hip and the 4 weeks post operation visit shows everything returned to normal. Another patient had numbness and severe pain leaving the hospital (Case# 21). A summary of the overall and average pressures for the groups that suffered from redness and LFCN numbness can be seen in tables (4.2) and (4.3). The average overall pressure was 29.4 mmHg and 26.7 mmHg for the redness and normal groups, respectively. Again, higher average max pressure of 264.4 mmHg was seen in the redness group compared to the normal group with max pressure of 236.5 mmHg. Comparing the group that had numbness and LFCN injury, the overall average pressure was 30.6 mmHg compared to 27.3 mmHg for the normal. Similarly, their maximum pressures were also higher at 254 mmHg versus 246 mmHg. An expected trend was seen in all groups as the values for pressures were always higher for the LFCN injury and redness groups compared to normal, however, none of the differences were statically significant.

One of the patients with LFCN problems on the hip had traction during the surgery. Traction during the surgery does not affect the intraoperative pressure as the intraoperative pressure on patients with traction looks the same as other patients and their LFCN problem is not worse than others and this lack of difference is shown in figure (4.8) and figure (4.9).

Table (4.2): Measured pressure statistical analysis (one tailed t-test): Patients with redness and numbness on hip vs. patients with normal hips. In this analysis "n" indicates the number of legs that had redness.

	Redness (n=18)		Normal (n=28)		
Pressure (mmHg)	average	stdev	average	stdev	p-value
overall	29.4	5.5	26.7	7.8	0.11
max	264.4	111.1	236.5	122	0.21

Table (4.3): Measured pressure statistical analysis (one tailed t-test): Patients with numbness in addition to redness in hip vs. patients with normal hips. In this analysis "n" indicates the number of legs which were affected by LFCN injury.

	LFCN numbness (n= 7)		No numbness (n= 39)		
Pressure (mmHg)	average	stdev	average	stdev	p-value
overall	30.6	5.9	27.3	7.22	0.13
max	254	132.5	246.2	116.4	0.44

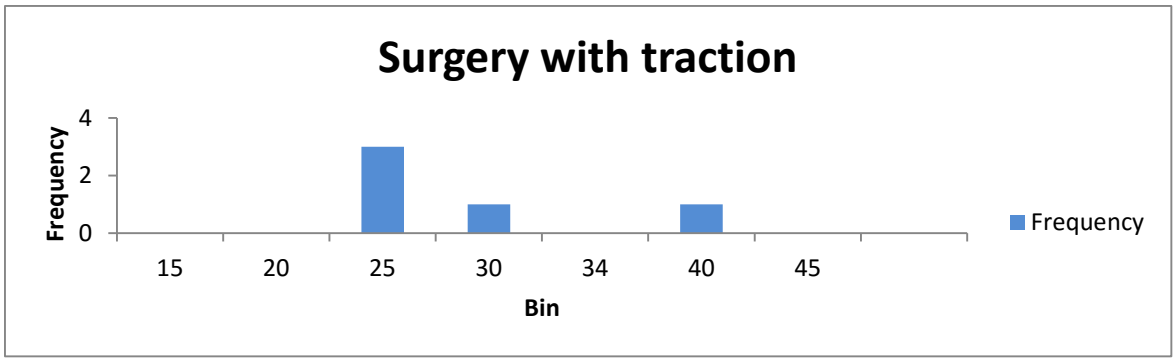


Figure (4.8): Histogram graph, average pressure with traction: This graph shows the distribution of samples in different average pressures during the surgery which traction is used

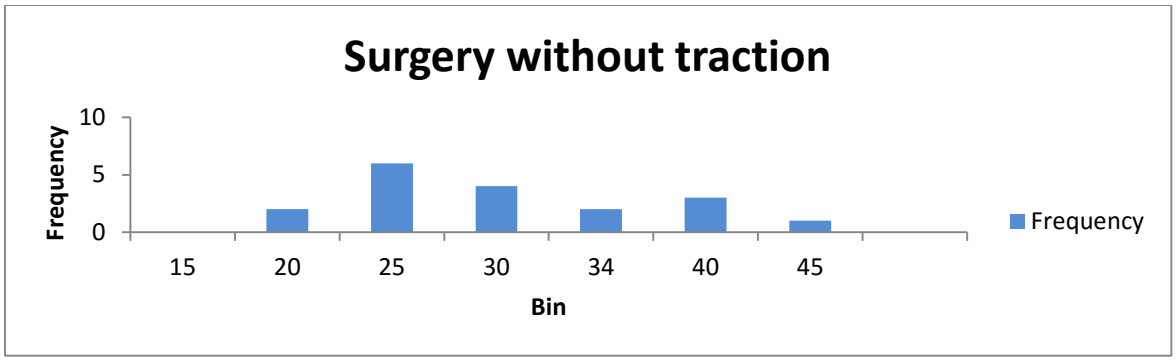


Figure (4.9): Histogram graph, average pressure without traction: This graph shows the distribution of samples in different average pressures during the surgery which traction is not used. There is not a significant difference in average pressure between surgery with and without traction

Results show that most of the patients who had redness after surgery lied on the Jackson table for more than 5 hours. Plotting data over time shows the change in pressure of different procedures. At the beginning of the surgery the data is unstable for almost all patients and this occurs are as a result of adjusting the patient on the Jackson table. After adjustment, the pressure rate is related to patient breathing and contains the lowest instability. Figure (4.10) shows the average pressure over time for the beginning of surgery when the patient is breathing.

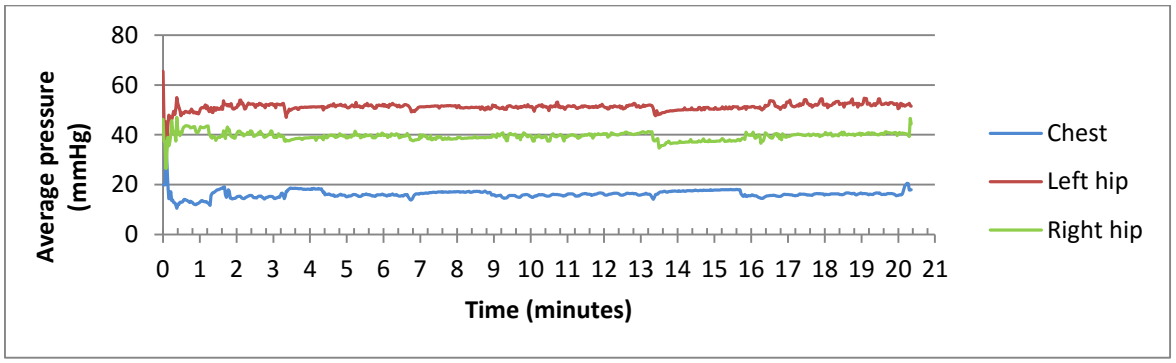


Figure (4.10): Average pressure over time for a breathing cycle. The beginning of the curve shows positioning of the patient and then breathing can be seen

Figure (4.11) shows the pressure over time plot for one patient. As soon as the screws and rods insertion begins, at around 186 minutes after data collection started, pressure becomes more variable and increases. This continues during the instrumentation process and rod insertion. Some additional patient data is shown in appendix D.

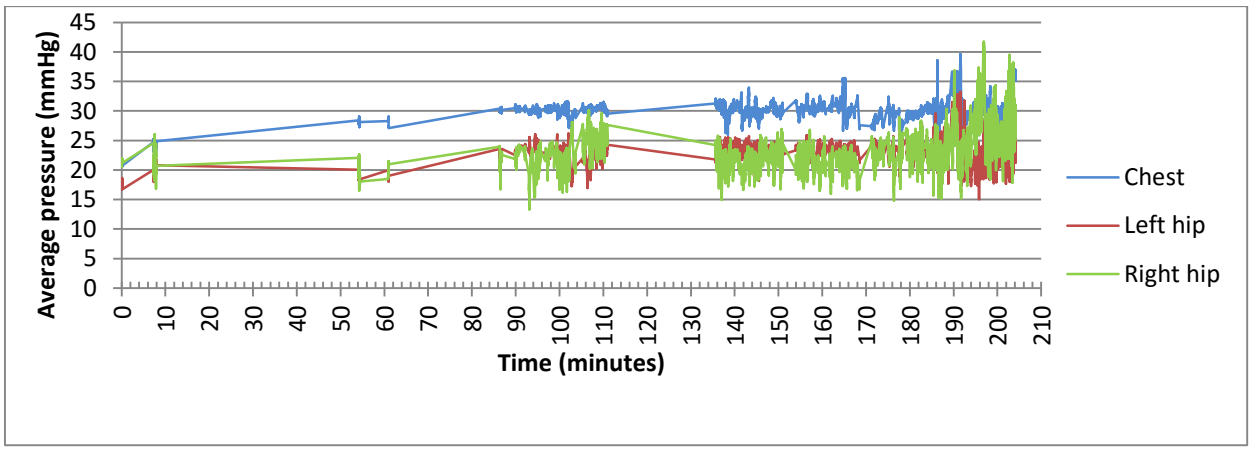


Figure (4.11): Average pressure (mmHg) over time for all regions (Chest, left hip and right hip)

One of the other factors considered important in LFCN injury is the BMI of the patients. The average BMI for patients participated in this study is 22 kg/m^2. Statistical analysis for the effect of BMI on LFCN compression was done using Mann-Witney U test. The U-value is 63.5 and the critical value of U at p≤ 0.05 is 33. Therefore, the result is not significant at p≤ 0.05.

BMI	16.8	16.9	18.1	19.6	19.8	19.8	19.9	20	20	20.4	20.5	20.7	21	21.7	22.3	22.5	22.8	23	23.2	23.6	24	26.7	34.5

Figure (4.12): All patient's BMI. Red highlights show the BMI for patients who had redness in hip after surgery; the patients highlighted in blue also had redness and additionally LFCN injury, finally, the BMI for patients with normal hip is shown with white.

Statistical analysis of the BMI showed that there was no significant difference between patients with and without redness. A hypothesis within our research team is that the patients with a low BMI will have problems because they are boney and the patients with a high BMI will have problems because they are heavy. We did not see evidence of this and, in fact, all four of the patients with LFCN issues had a normal BMI. The average BMI was 23.8 kg/m^2 (± 2.7) for the LFCN injury group and 22 kg/m^2 (± 4.4) for the others. A ranking of BMI for the patients can be seen in figure (4.12) where patients with redness are shown in red, those with LFCN injury in blue and the normal patients in white.

As the scoliosis surgery is a long surgery, it is important to investigate the effect of surgery duration. Statistics show that the effect of time is considerable in LFCN injury. The p-value is 0.0064 for this analysis which shows that length of the surgery is a significant factor causing LFCN injury. The average time for patients with LFCN injury was 350 (± 54) minutes compared to 264 (± 79) minutes for the normal group. The U-value is 27. The critical value of U at $p \leq 0.05$ is 33. Therefore, the result is significant at $p \leq 0.05$.

4.6 Discussion

Redness on either the left or the right hip after surgery did not seem to be a serious problem as it disappeared during the time the patients spent in the hospital. Based on the results from FSA pressure mats, the pressure increases during the surgery but the post-surgery follow up for some patients shows that although they have more pressure on their hips in comparison with others, they do not have any symptoms like numbness or tingling.

One of the important problems mentioned in post-surgery follow up data sheets was the numbness or tingling in the thigh which continued after the patient left the hospital. This redness of the thigh can also be seen in the pictures after surgery. The average AIS surgery in this study takes 5 hours from the moment patient lies down until the operation finishes. Duration of surgery can have an effect on LFCN compression. Results show that for most patient's redness on the thigh only disappeared during post operation days in the hospital. In some cases, patients with a considerable amount of pressure on both sides did not experience any LFCN problems or redness after the surgery. This means that intraoperative pressure during AIS surgery may be one of the significant factors causing LFCN compression but is not the only one. Considering the pressure distribution in FSA software, it seems that the lipids act as a natural cushion and avoid the compression to LFCN since the pressure is higher in boney areas of the iliac crest and in skinny patients. The magnitude of the average pressure in this study using the Jackson table in the operating room differs with the previous researches on the Relton and Hall frame. Duke et al. (2009) have measured the average pressure of 92.4 mmHg and 96.4 mmHg for left and right hip respectively using FSA pressure mats compared to 28 mmHg for both sides of the hips in this research (Duke et al. 2009). This can be as a result of three differences, positioning, anesthesia and cushion size. Different positioning techniques may be in the operating room since this study occurred in the OR on anesthetised patients and the previous research was in the lab with 12 patients who were awake. Additionally, the frames used were different and cushions with a smaller surface area were used in the original Duke

study. In a small feasibility study by Duke (2005) in the OR with 3 patients average pressure ranged between 24-44 mmHg which is more consistent with this work.

4.7 Conclusion

The magnitude of pressure in the results of this study was not found to be conclusive in predicting LFCN injury. Higher pressures did show a trend for LFCN injury and redness but this was not statistically significant. It is likely that pressure is not the only factor which can affect the LFCN compression. This work showed that intra-operative time was the only factor that had a significant effect on LFCN compression. Due to the limitations with this study, further investigations is needed to determine the most significant factor causing LFCN compression and to say the exact threshold for pressure that helps the LFCN injury during AIS surgery.

Chapter 5

5.1 Discussion, conclusion and future work chapter 3

5.1.1 Discussion and conclusion Chapter 3

The FSA pressure mapping system is used in this thesis research is a user friendly device. Previous research shows that FSA pressure mats are accurate to measure clinical data. We were even able to measure small cyclic changes during breathing. Ferguson-Pell and Cardi (1993) have compared different kinds of pressure mapping systems with advantages and disadvantages of each. They found the 19% hysteresis error for FSA pressure mats, which is close to what is found in chapter 3 of this thesis. They also investigated a 4% creep for FSA pressure mats. Data collection in the operating room is continuous and minimal creep in pressure mats occurs in this time. Based on the research in chapter 3, creep occurs at the beginning of the data measurement and before electro cautery. This means that although creep is a kind of error in FSA pressure mats, it can be reduced and eliminated. Due to the results from chapter 3 experiments, the mats should be left to warm up for 20 minutes, if possible, to reduce the effect of creep. Calibrating FSA pressure mats is a way to have more precise and accurate data. Dey et al. (2013) examined the accuracy of pressure mats before and after calibration. They used the FSA pressure mats' whole area to compare the pressure results before and after calibration. They found that calibrated

pressure mats provide more accurate data and suggest calibration every two months. Although the pressure mats' error reduction is small after calibration in the results section in chapter 3, it is still recommended. The creep effect decreases after the first 20 minutes so it is recommended to plug in the system at least 20 minutes before patient positioning. One limitation of this work is that the error for pressure mats is still relatively high. Moreover, the FSA pressure mats do not measure the shear force which may play a role. Regardless, FSA pressure mats are reliable and comfortable devices to measure intraoperative pressure during scoliosis surgery.

5.1.2 Future work

When positioning the patient over FSA pressure mats in the operating room, the hip area is not always in the center of the FSA pressure mat. It is suggested to test the pressure mats by placing the subject in different regions of FSA pressure mats to see if there is any error. The Instron study can be repeated to find the accuracy in different parts of the pressure mats. Additionally, the error of these mats is still large. This is a limitation of this work and an alternate pressure measurement system may need to be designed and integrated directly into the cushions.

5.2 Discussion, conclusion and future work chapter 4

5.2.1 Discussion and conclusion chapter 4

Tingling, redness and numbness are the symptoms of LFCN compression after scoliosis surgery. Some patients suffer from these side effects for weeks after the operation. The incidence of LFCN injury varies between 18% and 23.8% in research (Yang et al. 2005, Mirovski and Neuwirth, 2000, Tejwani et al. 2006) and in our work 4 of 23 or 17% had LFCN injury.

Many factors including BMI, age, surgeon, positioning and pressure interface may cause this problem. Previous researches have suggested that shorter surgery duration may decrease the probability of LFCN injury in scoliosis patients. Yang et al. (2005) examined 252 patients before and after surgery and they have found that 60 patients (23.8%) had LFCN problems. They focused on patients' BMI and length of surgery and determined that the patients with longer surgery duration (3.7 hours) as well as higher BMI (23.6 kg/m2) have experienced LFCN injury. It is concluded from Yang et al. (2005) that BMI and surgery time can affect the LFCN compression. Looking at the surgery duration and LFCN injuries in the research of this thesis, it seems the patients with longer surgery time suffered from redness or numbness on LFCN area. However, we found no relation between BMI and LFCN injury.

The idea of intraoperative pressure monitoring was developed based on previous research on buttock ulcers in wheelchair patients and its relation with external pressure. Previous

studies have suggested the probability of external pressure relationship with LFCN compression but intraoperative pressure monitoring was not considered in any other work. Based on the results from this research, the intraoperative pressure may cause the LFCN injury after scoliosis surgery. During the scoliosis surgery procedure, an increase in pressure was observed during screw and rods insertion as the surgeon pushes hard on the back of the patient. Patient positioning and the pads used on the surgery table are also the factors that can increase pressure in hips.

Tejwani et al. (2006) performed research on the effects of surgical table pads in LFCN injury. They believe that using thigh pads and a leg support table helps to reduce the pressure on hips. The Jackson table was used during data collection of this thesis research. Results for pressure and LFCN injury were not statically significant for this work. However, we did notice a trend and the average overall and maximum pressures were greater in the redness and LFCN group than the normal patients. Unfortunately, at this point in time we cannot confidently set a threshold for dangerous pressure as there would be too many false positives and false negatives using our current data.

Another way of detecting LFCN injury was to directly monitor the SSEP during surgery. LFCN SSEPs during scoliosis surgery might not be the best way to identify LFCN compression. It seems that LFCN SSEP's can be measured when the patient is awake but after anaesthesia, the signals lose their sensitivity. The LFCN signals are weak and not reproducible for most of the patients. More investigations and more samples are needed to demonstrate if there is any change in LFCN SSEP on the patients with LFCN injury. There were also limitations

with this study. The groups of patients who had LFCN injury and normal patients are unequal and we did not see as many patients as expected in the patients with LFCN injury group.

5.2.2 Future work

In addition to more data collection and further investigations to determine the relationship between intraoperative pressure and LFCN compression, alarming the pressure amounts that exceed a certain threshold may help to decrease the effect of intraoperative pressure on LFCN incident. Average pressure collected from the patients who had LFCN injury can be a reference and a system can be designed to alarm the surgeon when pressure rises more than the reference.

5.2.3 Somatosensory evoked potentials future work

Hypothetically, there should be abnormality in SSEP signal for patients with LFCN problems especially during the mid-surgery as LFCN compression is more probable to occur. In this experiment, LFCN SSEPs were recorded intermittently during scoliosis surgery. As a future work it is suggested that recorded LFCN SSEP signals be analysed for all patients to see if monitoring evoked potentials can help to identify the LFCN injury during the surgery and alarm the surgeon.

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Appendix A

A.1. Ethics information sheet

Glenrose Rehabilitation Hospital

INFORMATION SHEET

Title of Research Study: **Understanding the Implications of Pressure at the Patient Cushion Interface During Posterior Spine Surgery**

Principal Investigator: Kajsa Duke PhD 780-492-4710
Co-Investigator: Doug Hill, P.Eng. MBA, Jim Raso, P.Eng. MASc,
Douglas Hedden, MD, Marc Moreau, MD,
Jim Mahood MD, Sarah Southon, BScN, RN, MN
Jonathan Norton PhD, Francois Roy PhD
Kathleen Shearer RN, Negar Bezadi Fard BSc

Background: During spine surgery the patient is usually placed prone on the operating table to improve exposure to the spine. Surgery tables can vary, but the patient is generally supported on the hips and upper chest in order to allow the abdomen to remain pendulous as this reduces blood loss. In this position, injuries to the lateral femoral cutaneous nerve (LFCN), located on the upper anterior portion of the thigh, have been reported as well as pressure sores near the iliac crests. The relationship between patient-cushion interface pressures and injury risk is not presently known. Pressure mats will be used to study pressure as it relates to the incidence of LFCN damage and pressure sores occurring during spine surgery.

Objective: This project is to perform a pilot study to quantify the pressure at the patient cushion interface and determine if there is any correlation with pressure and increased risk of developing pressure sores or damage to the LFCN.

Procedure: The project coordinator will explain the study. A written consent form will be signed if you or your child agrees to participate. The patient's age, gender, weight, height, length of surgery, type of surgery, and hospital the procedure occurred at will be recorded. A pressure mat, commonly used to measure seating pressure in wheel chair users, will be used to measure the pressure at the patient cushion interface when lying prone on the operating table. The pressure mat, which is made of a thin flexible material, will be draped over the cushions. A clean plastic cover as well as a clean sheet will be placed on top. Surface electrodes will be placed on the front of the patient's thighs to stimulate the dermatomal distribution of the LFCN. The patient will then be positioned as usual by the surgical staff. Average and peak pressure measurement data will be collected throughout the surgery by the pressure mat operator. Finally, data will be analyzed to see if there is any correlation with the amount of pressure measured or the duration of the surgery to the presence of any nerve damage or reddening of the patient's skin around the iliac crests. If redness of the hips is present the day following surgery, photos may be taken of the area contingent on consent.

Confidentiality/Freedom to Withdraw: During the study we will be collecting health data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the study office or published by

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the researchers. Sometimes, by law we may have to release your information with your name and so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private

The study staff may need to look at your personal health records. Any personal health information that we obtain from these records will be only what is needed for the study. By signing this consent form you are agreeing to allow the study staff to collect, use and disclose information about you from your personal health records as described above.

After the study is completed we will still need to securely store your health data that was collected as part of the study. At the University of Alberta we keep data stored for 5 years. If you leave the study, we will not collect new health information about you, but we will need to keep the data that we already have.

You/ your child are free to withdraw from this study at any time, and doing so will not affect any treatment received by your/ your child's physician, the Hospital or its staff

Risks/Benefits: The risk of participating in the study is extremely small. The test procedures are non-invasive and do not add any time onto surgery. The pressure mat will be covered with disposable coverings, and neither the equipment nor its operator will enter the sterile field. The risk of infection is marginally higher since increasing the amount of equipment and personnel in the operating room always carries a slight risk; however, these risks will be mitigated wherever possible. There are no known short and long term risks associated with the use of pressure monitoring mats. This study will not affect you/ your child's current or future treatment. The research findings will help to support further research and design into improved operating tables that provide integrated pressure monitoring which can reduce the risk of these nerve or pressure sore complications.

Contact Names and Telephone Numbers: If you have concerns about your rights as a study participant, you may contact the Patient Relations Office of Alberta Health Services, at 780 342-8080. This office has no affiliation with the study investigators.

Please contact any of the individuals identified below if you have any questions or concerns:

Dr. Kajsa Duke, Assistant Professor	(780) 492-4710
Sarah Southon, Nurse Practitioner	(780) 407-1560

University of Alberta
5-1K Mechanical Engineering
Tel: 780-492-4710, Email: kajsa.duke@ualberta.ca

Figure A.1: Consent form

Appendix B

B.1. Matlab programs

FSA simulator

```
%%----------------------------------------
function inp = calc_fsa(COL,LIM1,LIM2)
% Simulation of FSA in matlab
if nargin == 0
    % Check the number of input arguments (nargin)
    COL = input('Enter the column number: ');
%     LIM1 = input('Enter the starting limit: ');
%     LIM2 = input('Enter the end limit: ');
title='FSA calculator';
% The main title of your input dialog interface.


end

%%-----------------------------------------------------

filename = 'rods.xlsx';
a = xlsread(filename);

[num,txt,raw]=xlsread(filename);

data_mat1=num(14:269,:);

M = zeros(16,16);
l=1;
i=1;
%LIM1=281
%LIM2=520
%COL=1
 %%FIRST PLOT
  LIM1 = 14 ;
  LIM2 = 269;


for k = LIM1:LIM2;
    if l == 17
        l = 1;
        i = i +1;
```

```
    end
    M(l,i) = num(k,COL);
    l =1+l;

end
 g0 = nonzeros(M);
 [numbercells, col] = size (g0);
%numbercells = count(g0)
activearea = numbercells*1.119531
subplot(2,2,1);

contourf(M);
[C,h] = contourf(M);
xlabel('FirstMat')
clabel(C,h);
hold on
camroll(-90);



%%SECOND PLOT

l=1;
i=1;
  LIM1 = 281;
  LIM2 = 536;

for k = LIM1:LIM2;
    if l == 17
        l = 1;
        i = i +1;
    end
    M1(l,i) = num(k,COL);
    l =1+l;

end
g = nonzeros(M1);
[numbercells, col] = size (g);
%numbercells = count(g)
activearea = numbercells*1.119531
subplot(2,2,2);
plot(filter(k,g,data_mat1));
contourf(M1);
[C,h] = contourf(M1);
xlabel('Chest')
clabel(C,h);
hold on
camroll(-90);




%%THIRD PLOT
l=1;
```

```
i=1;
  LIM1 = 548 ;
  LIM2 = 803;

for k = LIM1:LIM2;
    if l == 17
        l = 1;
        i = i +1;
    end
    M2(l,i) = num(k,COL);
    l =1+l;

end
g1 = nonzeros(M2);
[numbercells, col] = size (g1);
%numbercells = count(g1)
activearea = numbercells*1.119531
subplot(2,2,3);
contourf(M2);
[C,h] = contourf(M2);
xlabel('Hip')
clabel(C,h);
hold on
camroll(-90);




%FOURTH PLOT
 l=1;
i=1;
  LIM1 = 815 ;
  LIM2 = 1070;

for k = LIM1:LIM2;
    if l == 17
        l = 1;
        i = i +1;
    end
    M3(l,i) = num(k,COL);
    l =1+l;

end
g2 = nonzeros(M3);
[numbercells, col] = size (g2);
%numbercells = count(g2)
activearea = numbercells*1.119531
subplot(2,2,4);
contourf(M3);
[C,h] = contourf(M3);
xlabel('Thigh')
clabel(C,h);
hold on
camroll(-90);
end
```

Appendix C

C.1. Patients follow up form

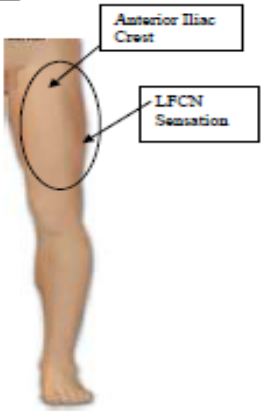
Understanding the Implications of Pressure at the Patient Cushion Interface
During Posterior Spine Surgery- **Patient Data Record**

Patient ID_____

Demographic Data

Sex (M/F)		Age (yr+mo)		Date of Surgery	
Height (cm)		Weight (kg)		Traction in OR (Y/N)	
BMI		Diagnosis		Skin-Skin Time	
Cushions used		Days in hospital		Surgeon	

Post-Operative Data



POD 1

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

POD 2

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

POD 3

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

POD 4

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

POD 5

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

POD 6

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

POD 7

		LEFT	RIGHT
Anterior Iliac Crest Skin Check	Redness (Y/N)		
	Blisters (Y/N)		
	Other		
LFCN Sensation	Normal		
	Decreased		
	Numb		

This patient is part of a research study. Please complete this form.
Contact kajsa.duke@ualberta.ca or Sarah.Southon@albertahealthservices.ca with any questions.

Figure C.1: Patients post-operative follow up form

Appendix D

D.1. Additional pressure over time graphs during different procedures

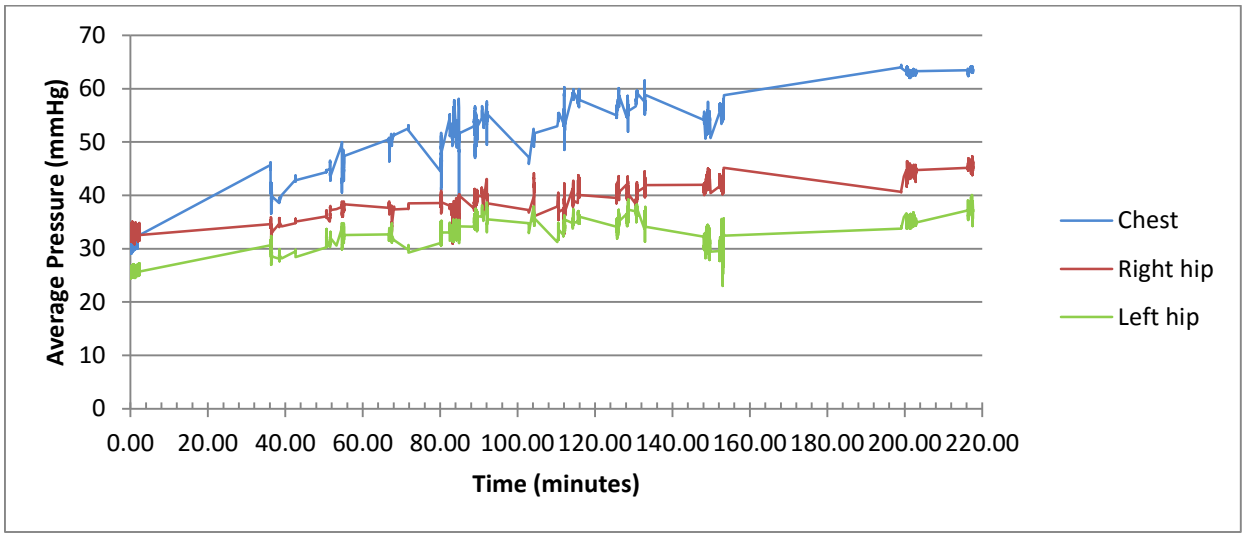


Figure D.1: Average pressure for Case# 2. Screw insertion

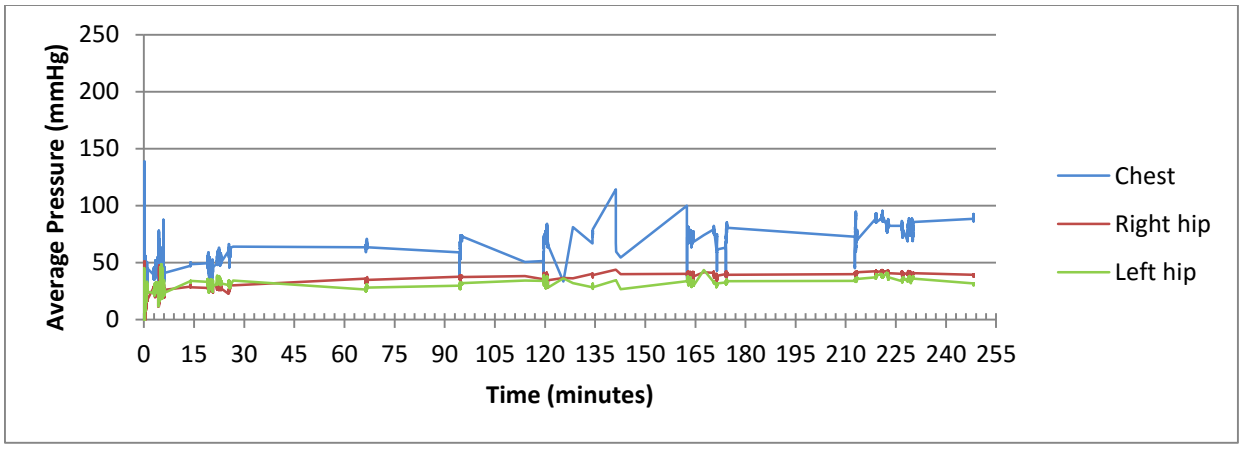


Figure D.2: Average pressure for Case# 5. Screw and rod insertion

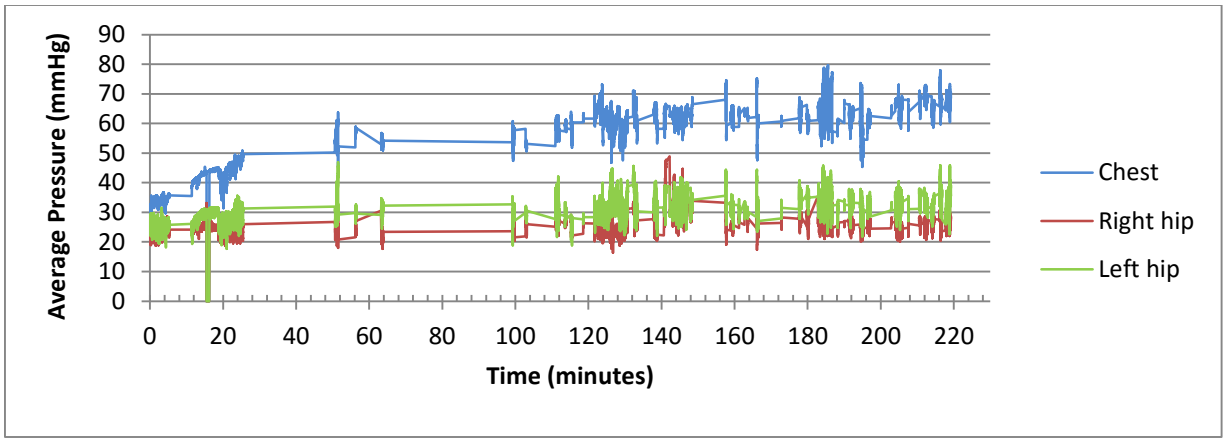


Figure D.3: Average pressure for Case# 4. Surgery starting and screw insertion