Evaluation of Effectiveness of Brace Treatment in Scoliosis Patients

by

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Dedication

This thesis work is dedicated to my mother Usha Prabhakar, who was a source of motivation to me. Although she is no longer in this world, her motivation always drives me to push the limits of technology and strive for innovation.

This work is also dedicated to my loving husband Vishnu, who has been a constant source of support and encouragement during the challenges of my graduate school and life. I'm thankful for having you in my life.

This work is also dedicated to my father Prabhakar Rao, and brother Vijay who always love me and whose good examples have taught me to work for the things I aspire to achieve.

Acknowledgements

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This study was conducted in collaboration with the C.S. Mott Hospital, University of Michigan, and the Orthotics and Prosthetics Center, University of Michigan. I would like to thank Dr. Ying Li, who is a fellowship-trained pediatric orthopedic surgeon at the C.S. Mott Children's Hospital, University of Michigan, Ann Arbor, since 2011. A large portion of her clinical practice and research focuses on the treatment of pediatric patients with scoliosis and other spinal disorders. All subjects are patients of Dr. Li at the C.S. Mott Children's Hospital. I would also like to thank Jeffrey Wensman, who is the Director of Orthotic and Prosthetic Services. Mr. Wensman is involved in the teaching of orthotic and prosthetic residents as well as resident physicians in Physical Medicine and Rehabilitation and Orthopedics. Mr. Wensman partners in research with engineering, kinesiology and medical faculty. His current research topics include: additive manufacturing of orthotics and prosthetics, scoliosis management and powered lower limb prosthetics. He specializes in the treatment of scoliosis and other pediatric

conditions as well as lower limb prosthetics. All back braces (TLSOs) were designed at the Orthotic and Prosthetic Center at the University of Michigan, Ann Arbor.

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Abstract

Scoliosis is a medical condition which occurs in adolescents, where an individual's spine develops curvature. Monitoring the effectiveness of brace treatment of scoliosis is an ongoing challenge that many physicians face today. A Thoracolumbosacral orthosis (TLSO) is a type of brace used to control the lateral curvature of the spine in scoliosis. It is a non-surgical treatment with the goal of preventing curve progression in patients with idiopathic scoliosis. To successfully monitor compliance with brace treatment, a wearable multi-modal sensor solution is embedded into the patient's brace. The custom-designed hardware consists of a sensor board, a force sensor, an accelerometer and a gyroscope. The force sensor collects the force being exerted on the patient's back, while the accelerometer and gyroscope generate cues to determine the patient's activities and lifestyle. In this dissertation, a novel data-mining method is proposed, to identify patient activities and evaluate the effectiveness of the brace treatment pervasively based on fusion of continuous force and inertial motion recordings. The proposed method evaluates three main factors: 1) The compliance to the brace treatment or duration of brace wear through the process of segmentation, 2) The level of tightness of brace by estimating the baseline force per segment and 3) The quality of brace fit in the presence of different activities including sitting, standing, climbing, walking, running and lying. The aim is to design a context-aware remote monitoring system for ubiquitous evaluation and enhancement of brace treatment compliance of adolescent idiopathic scoliosis patients. Two experimental scenarios have been investigated: 1) Semi-supervised scenario in which, the patient performs a series of pre-defined

activities at home during day long segments of brace wear, and 2) Unsupervised scenario in which, there is no knowledge of the patient's activities and other circumstances during pervasive sensor data recordings. The experimental results demonstrated that we achieved an overall accuracy of a 100% for activity detection. The level of tightness of brace-fit reduced gradually over a period of 4 weeks by 33%. Initially, at the beginning of the treatment, patients were instructed to wear the brace for 2 hours, and the compliance with the brace treatment was 7.8%. The duration of the brace wear increased gradually during the period of 4 weeks. At the end of week 4, the compliance reached 80%.

Chapter 1 Introduction to Scoliosis

1.1 Introduction to Idiopathic Scoliosis

Idiopathic scoliosis is an abnormal curvature of the spine that can worsen throughout growth, making it vital for doctors to treat it during the early stages. For that reason, physicians focus on skeletally immature adolescents who show signs and symptoms of idiopathic scoliosis. If the condition is seen in patients between 10 to 18 years of age, it is known as adolescent scoliosis [1]. Today, 3% of children below the age of 16 years are diagnosed with adolescent idiopathic scoliosis (AIS).

1.2 Causes of Idiopathic Scoliosis

There are no identifiable causes for AIS today. There are many theories about the cause of AIS including asymmetric growth, muscle imbalance, hormonal imbalance and genetic causes. About 30% of the patients have a family history of the condition. Many researchers are working towards finding the cause of AIS [20].

1.3 Symptoms of Adolescent Idiopathic scoliosis

The severity of scoliosis in a patient is measured by the Cobb angle [21]. The Cobb angle refers to magnitude of the spinal curvature as measured on a posteroanterior plain radiograph of the spine. The most common form of treatment of AIS in skeletally immature individuals is a Thoracolumbosacral orthosis (TLSO) [22]. While the brace does not provide a solution to fix the curvature, it helps prevent worsening of the curve throughout the adolescent's growth. If progression of the spinal curvature is prevented, then surgery can be avoided and this is considered a brace treatment success [7].

1.4 Treatment of Scoliosis

To ensure that the treatment is successful, it is important to monitor the quality and duration of brace-wear. The total number of hours of brace-wear correlates to the lack of curve progression [7] [12]. A braced curve that remains 45°-50° at skeletal maturity is considered a treatment success, as bracing is no longer effective once patients are skeletally mature. Curves that are 45°-50° at skeletal maturity are not likely to progress during adulthood [2]. Several studies provided convincing evidence about the effectiveness of this treatment given appropriate usage [14]. A Dose-response curve has been demonstrated that the duration of brace-wear is positively associated with the rate of treatment success [11]. Patients who wore the brace for 0 to 6 hours daily had a success rate of 42%, whereas patients who wore the brace for at least 12.9 hours had success rates of 90 to 93% [5]. Therefore, the effectiveness of treatment depends on the duration of wear and tightness of the brace. However, monitoring brace compliance is a challenging task. Previous studies have demonstrated that when brace-wear is accurately monitored with a temperature sensor, adherence to brace-wear is frequently overestimated [7][2]. Patients wore the brace for only 47% of the prescribed time, even though physicians, orthotists, parents, and patients estimated that the brace was worn for 64%, 66%, 72%, and 75% of the prescribed time, respectively. Patients wore the brace for the same number of hours a day regardless of whether the prescribed time was 16 hours or 23 hours [18].

Chapter 2 Related Work

There have been tremendous advancements in the areas of wearable devices providing significant opportunities in monitoring patients and improving personalized healthcare. The electronics are now much smaller, flexible, consume low power, have a higher memory for data storage and have networking capabilities making enabling ubiquitous monitoring of the patients [13]. In this chapter, a detailed study of different works in the existing literature is presented. Section 2.2 discusses in detail about existing work on activity recognition.

2.1 Related work on camera based activity recognition

Researchers have been working on developing efficient methodologies to monitor physical activities of individuals and patients. Depth video sensors have been used to monitor the daily activities of elderly [8]. Hidden Markov Models have been used to train the predictive model and identify different types of activities including smart home activities, smart office activities and smart hospital activities. Accuracy of 92.33% has been achieved for recognition of home activities, 93.58% for recognition of office activities and 90.33% for recognition of smart hospital activities [8]. Researchers have also been working on developing systems to differentiate abnormal activities from normal activities. Such systems have been extremely useful to detect falls in the elderly. Activity analysis framework has been developed to detect normal and abnormal activities using RGB-D cameras. Abnormal activities include those which are dangerous to the elderly including fall from sitting and standing. An accuracy of 98.1% has been achieved for the identification of such activities [17].

2.2 Related work on Activity Identification

Monitoring day to day activities of patients affected by scoliosis is quite important to physicians. In this study, we aim to monitor and evaluate the duration and quality of brace wear in during day to day activities of the patient by correlating the force, acceleration and angular velocity collected by a multi-modal sensor solution.

There has been extensive research in the areas of activity detection from accelerometer and gyroscope readings [6] [17] [19] [3]. Researchers have been working on developing methodologies using data from different sensors for activity identification. The data from 3D accelerometer placed on the subject's wrist, hip and a GPS receiver was used to record the unsupervised data for activity identification [6]. A new hybrid classifier, which combined a tree structure with a priori knowledge and artificial neural networks was trained for activity identification. Using the hybrid classifier, the accuracy achieved was 97% for lying, 87% for rowing, 18% for exercise bike, 97% for sitting/standing, 89% for running, 70% for nordic walking, 71% for walking, 78% for football and 72% for cycling with real bike. The total classification accuracy achieved was 89%.

MHARS or Mobile Human Activity Recognition System, was developed to monitor day to day activities of patients with ambient assisted living [17]. Two accelerometers, one from the smartphone and other embedded into the wearable device was used to collect data. The smartphone was placed on the waist and leg of the patient. The wearable device was placed on the chest. Data was collected from 10 different subject subjects. 70% of the data was used for training purposes. An accuracy of 90.2% was achieved for running, 67.1% for climbing upstairs, 86.7% for walking, 91.2% for standing, 90.1% for sitting and 89.1% for lying. An overall accuracy of 83.3% was achieved for activity recognition.

Smart phones which contain accelerometer, gyroscope and GPS sensors have been quite useful in monitoring day to day activities. Researchers worked on developing a hybrid classifier that used linear acceleration and gravity signals from Blackberry smartphone to collect the data from 30 subjects [4]. They extracted 7 different features including moving average of sum of range of linear acceleration over 4 windows, Difference of x and z acceleration from y, sum of range of linear acceleration, standard deviation of linear acceleration, maximum slope of moving average sum of variances of gravity, range difference and sum of range of x and z gravity components. A specificity of 99.4% was achieved for standing, 98.4% for sitting and 97.9% for lying.

Android smart phones are commonly used in monitoring the day to day activities of individuals [9]. The accelerometer and GPS data collected from an Android smart phone can be used for identification of activities. Features including mean acceleration, standard deviation for each axis, average absolute difference, mean resultant acceleration, time between the peaks of sinusoidal waves, and binned distribution have been used to train the predictive model. An accuracy of 93.6% has been achieved for walking, 98.3% for jogging, 61.5% for climbing upstairs, 55.5% for climbing downstairs, 95.7% for sitting, 93.3% for standing and an overall accuracy of 91.7%.

Researchers have also been working on designing and implementing software and hardware tools that could provide users with insights on day to day activities. Fit bit is a tool that helps users to track their physical activity during the day [19]. MotionSynthesis is another toolset for data collection and algorithm development. It has a custom hardware which is used to collect Accelerometer and Gyroscope data [3]. It also has a java based diary generation tool that allows users to select relevant aspects of the motion in their day to day activities, and to visualize their activity data.

In this dissertation, a novel system is designed and developed that could help physicians to evaluate the effectiveness of treatment of patients with scoliosis, by monitoring the tightness and duration of the brace wear in addition to the day to day activities of the patient.

Chapter 3 Overview of the work and contribution to the thesis

In this dissertation, I intend to discover an innovative and effective treatment-monitoring methodology by implementing a context-aware remote sensing solution. The subject size for this study was three patients, all of whom were females in the age group of 10-13 years. The experiments were conducted in three different scenarios: 1) supervised, 2) semi-supervised and 3) unsupervised. In the supervised scenario, all three patients volunteered to perform pre-defined activities including sitting, standing, walking, running, lying and climbing consecutively for two minutes per activity daily. This results in 12 minutes of supervised data collected over a period of 6 days. Furthermore, under the semi-supervised scenario, all three patients recorded the activities they performed for six days and wrote notes on brace wear duration in a log book. In the unsupervised setting, the first patient's data was collected for additional 20 days and conducted the compliance study. The effectiveness of the treatment in patients with scoliosis was evaluated using three main parameters: 1) Compliance of the brace wear 2) The level of tightness of the brace 3) Quality of the brace fit.

3.1 Compliance of brace wear

The compliance study indicated the amount of time the patient wore the brace, as compared to the duration of wear prescribed by their doctor. We developed a unique method of segmentation of the force sensor readings to evaluate the duration of brace wear during the day. Two methodologies for segmentation were developed, Segmentation by average force and Segmentation of average power of force.

3.2 The level of tightness of brace

The force sensor data also contains breathing patterns of the patient. A moving average filter was designed to determine the level of tightness of the brace.

3.3 Quality of brace fit

To determine the quality of brace fit, the patient data was classified into six different activities. The extracted data was annotated by the patient from the logs used for training a predictive model for activity identification. The proposed solution consists of two stages: 1) remote sensing and data acquisition and 2) data mining. For the remote sensing module, a sensor board consisting of accelerometer, gyroscope and force sensor to capture data from the patient's body, was designed and fabricated. The data mining module handles processing and the analytical procedure performed on the captured data. After filtering out the noise from the sensor data, relevant features were extracted including resultant acceleration, number of footsteps in a window and average value of the resultant x-axis acceleration in a window. In this thesis, a unique methodology to detect the number of footsteps using the power density spectrum was developed. Sequential feature select methodology was used to select the relevant features, which were used to train the predictive model to identify six different activities including sitting, standing, walking, running, lying and climbing.

Chapter 4 Architecture of the system

The proposed method for pervasive and context-aware monitoring of brace treatment includes four main modules: 1) Hardware Architecture and 2) Data pre-processing 3) Signal processing and predictive modeling 4) Predictive Analysis, as shown in Figure 4.1. It illustrates the end-to-end architecture of our methodology.

4.1 Hardware Architecture

In this dissertation, a multi-modal sensor solution is developed with accelerometer, gyroscope and force sensor. The hardware architecture is discussed in detail in Chapter 5.

4.2 Data Pre-processing

In this dissertation, a multi-modal sensor solution is developed with accelerometer, gyroscope and force sensor. The hardware architecture is discussed in detail in Chapter 5.

4.3 Data Pre-processing

The inputs from the accelerometer, gyroscope and force sensor are sampled at a sampling frequency of 40Hz. The data collected from the PCB is noisy and contains non- numeric characters. Data cleaning modules are implemented using python script. The script reads input data character by character. The non-numeric samples are replaced by ‘NAN’. The ‘NAN’ values are replaced with the average of previous value and the next values in the attribute.

4.4 Signal Processing

In the signal processing and predictive modeling system, the sampled signal is filtered using a 5Hz low pass filter to remove high frequency noise. Features are extracted from the data and relevant features are selected from the sequential feature-select module.

4.5 Predictive modeling

The selected features are used to train the predictive model, and the trained model is used to identify activities in the semi-supervised data scenario.

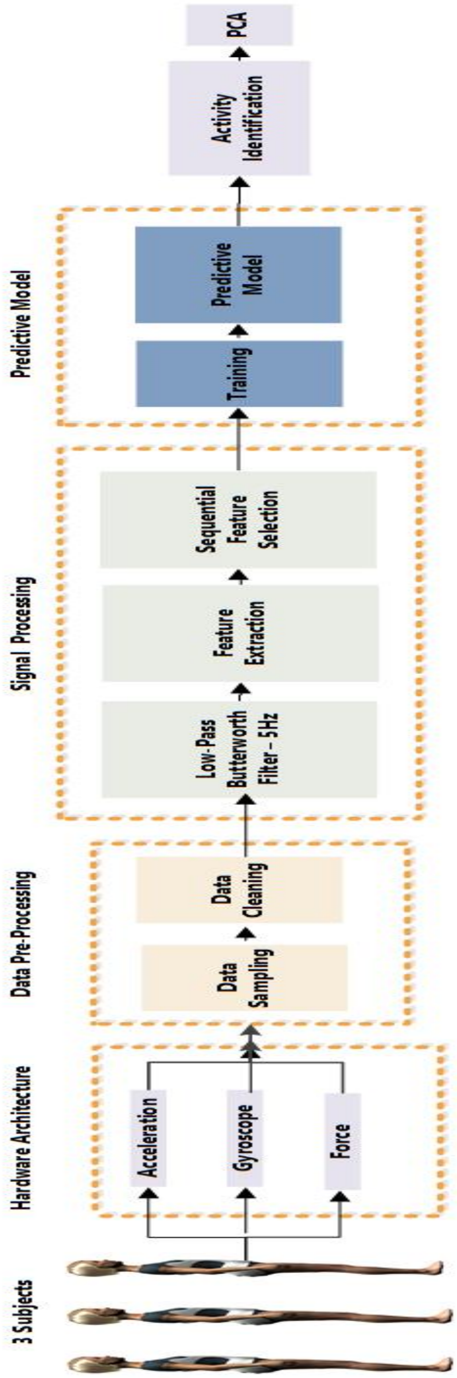


Figure 4-1 End to End Architecture of the system

Chapter 5 Hardware Architecture

The hardware design of the system consists of a multi-modal sensor data acquisition board, a force sensor and a motion sensor. The equipment is embedded in the brace, and data is continuously collected for analysis. The specifications of the sensor data acquisition board and the components associated with it are explained in detail further in this thesis.

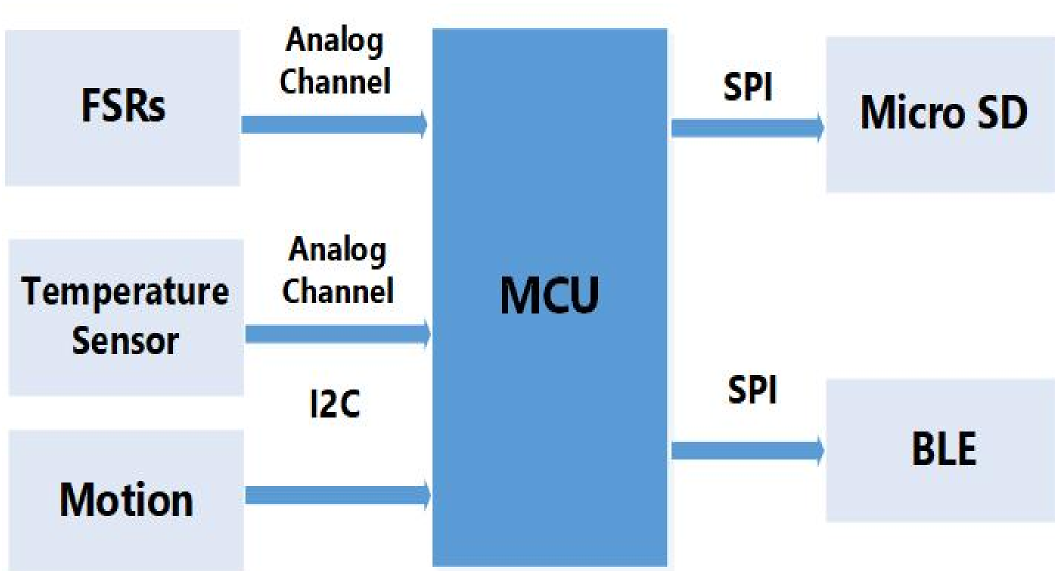


Figure 5-1 Hardware architecture

The sensor board contains Atmega32u4, Atmel as a baseband data processor; MPU-9250 motion sensor from InvenSense, which is a 9 axis MEMS sensor using the I2C channel; a custom-designed Honeywell FSB1500NSB force sensor placed at the analog channel using 10-bit resolution A/D converter; and communication channels, which include a micro SD card as a data logger and nRF8001 from Nordic® as a Bluetooth low energy module, BLE. Figure 5.2 displays the hardware schematic and Figure 5.3 displays the sensor board that the proposed hardware architecture is implemented in it.

The FSB1500NSB sensor has a range of measuring force between 0 to 15N. Since this is not a

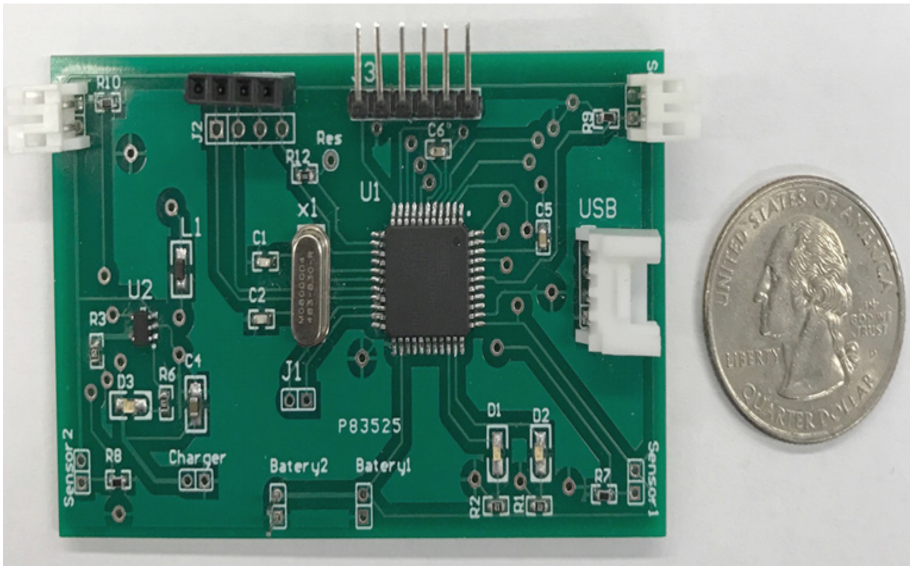


Figure 5-2 PCB sensor board

significant range for measuring changes in force readings, we have amplified this range. We use an INA2322 CMOS TI Instrumentation Amplifier with two resistors of values, *R_1=27k*Ω, and *R_2=87k*Ω, to amplify the numerical value of the force sensor. Using these resistor values in Equation 1, we can determine that the gain is 21.1. This is done to provide higher-density and more precise analysis to the physician about changes in force readings. Figure 5.3 shows the electronic schematic for the amplifier. The value of Gain can be used in Equation 2 to determine the output voltage of the amplifier.

$$Gain = 5 + 5\left(\frac{R_2}{R_1}\right) \tag{1}$$

$$V_{out} = (V_{in}^{+} - V_{in}^{-}) \times Gain \tag{2}$$

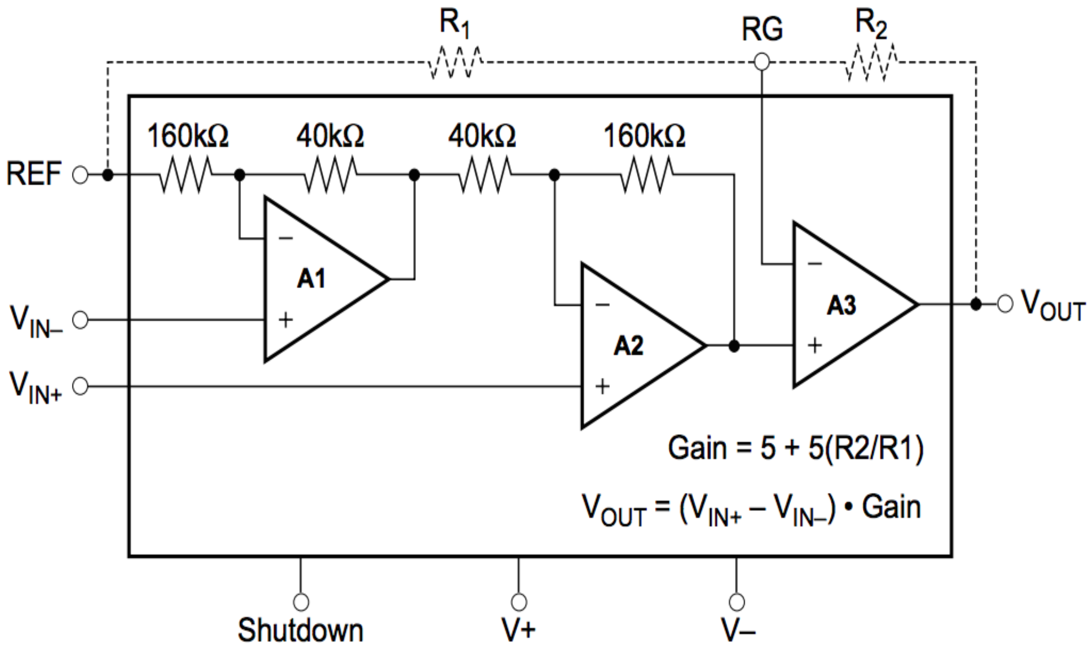


Figure 5-3 TI amplifier for boosting force sensor values

Ultimately, the maximum value that can be recorded with the modified force sensor is 1048. Given that the maximum value the force sensor can output is 15N, and the amplification factor is: 69.867, which can be rounded to 70 for documentation purposes. The proposed solution consists of our hardware design system embedded in a Boston-type TLSO. Figure 5.4 shows the customized brace with direction of axes of the motion sensor. The x-axis readings of the accelerometer indicate upward movement of the patient.

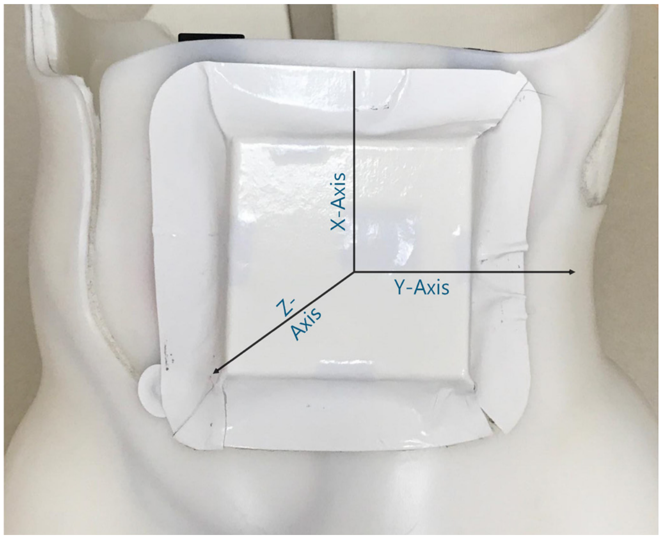


Figure 5-5 PCB sensor embedded into the brace


Figure 5-4 Force Sensor Embedded into the brace

The y-axis and z-axis readings give sideways and forward movement of the patient respectively. Figure 5.5 shows the position of force sensor inside the customized brace. Force sensor measures the force exerted by brace on the patient's back.

A major challenge was to design and incorporate the most suitable sensor for this study. We tried several types of force sensors to ensure a highly reliable force measuring sensor. We conducted day long tests on force baseline changes and durability. After conducting a thorough research, we chose the Honeywell FSB1500NSB force sensor as one of the most commonly used force sensor in medical applications. Due to the restriction of the Honeywell force sensing area, we designed and developed a custom housing and assembly with the sensor to aggregate the force on the padding inside the brace to the sensor. We designed a 3D force aggregation mechanism in the housing, as shown in Figure 5.6. Figure 5.7 illustrates the force sensor fitted in the housing. This housing was custom-designed to make sure that the sensor does not cause any discomfort to the patient.

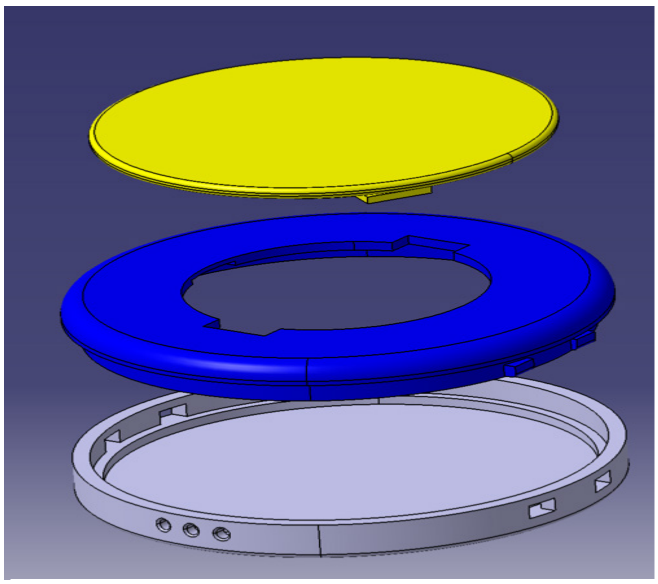


Figure 5-6 Force sensor housing

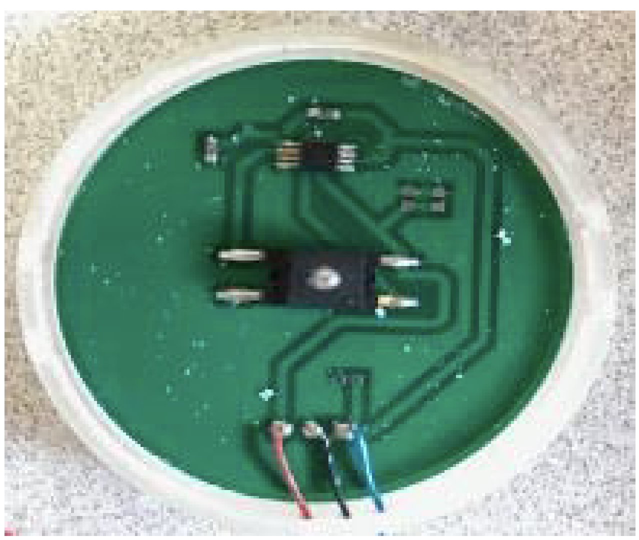


Figure 5-7 Force sensor PCB fitted in mechanical housing

Chapter 6 Data Acquisition

For this study, 3 patients were recruited to date. The hospital follows a process and has certain guidelines before patients can be allowed to participate in the study. For instance, some of the eligibility requirements to recruit patients for this study is that they must be in the age range of 10-16 years, and have a Cobb angle in the range of 25°-40°. The data collected was analyzed in semi-supervised, and fully pervasive data from the patients.

6.1 Data Acquisition in semi-supervised setting

During semi-supervised data collection, the patients were asked to perform the pre-defined activities: LIE, SIT, SND, WLK, RUN and STR for duration of 2 minutes each. The patients were required to wear the brace for either approximately 23 hours a day, or the amount of time prescribed by the orthotist. During this time, data was being continuously recorded in a secure, digital SD card. The patients downloaded data from SD card and uploaded to a secure on-line drive, once a week. They recharged the battery for one hour or more when they had taken off the brace daily or once every two days (the battery lasts for three days). They noted down the timings of specific activities they did each day, in a logbook provided. This helped us to make a connection of the data collected to the activities of patient for evaluation purposes. Treatment continued for several months. The only supervised conditions are monthly-based visits to the Orthotist. The data is sampled at 40 Sample/Sec with 10-bit resolution. This data is passed through a Low Pass filter with cut off frequency of 10Hz to filter high frequency noise. In this work, the analysis is carried out during 6 days of semi-supervised data for all the three patients.

6.2 Data Acquisition in Unsupervised setting

After the first 6 days of semi-supervised data collection, the patients continued the treatment in an unsupervised home environment. The patient did not provide the any details about brace wear. The remote sensing brace was worn as prescribed by the Orthotist. The patients downloaded data from SD card and uploaded to a secure on-line drive, once a week.

Chapter 7 Determination of compliance of brace treatment

Duration of the brace wear is one of the major factors that impacts the treatment of patients with scoliosis. Compliance to the brace treatment is defined as the time for which the brace is worn relative to the prescribed time [13]. Compliance is important to physicians and patients as it provides important information about the patient's ability to wear the brace. If the patient has difficulties in wearing the brace, physicians can have a conversation and develop strategies to help increase the compliance. With higher compliance, curve progression of the spine and chances of requiring surgery are much lower [14]. In this dissertation a new methodology is designed to segment the force sensor data to estimate the number of hours of brace wear in a day. The segmentation process allows in-brace data to train the predictive model. Two different techniques are discussed to segment the filtered force sensor data of a window: 1) Segmentation by average force and 2) Segmentation by average power of the force signal. The patient data is non-stationary in nature, as the patient is involved in day to day activities at different instances of time. Walking, running and climbing stairs have a higher frequency, while standing, sitting or lying have a lower frequency. The patient data is divided into rectangular windows of 4 seconds each, assuming the signal is stationary in that window. The breathing pattern of the patient, which is captured from the force sensor, is quasi periodic, with peaks which are about 1.5 seconds apart. By choosing a smaller window size of 1 second, it's not possible to extract the frequency content of the signal. A larger window may contain more than two different activities of the patient and will not generate accurate results. An optimal window size of 4 seconds is chosen for the purposes of analysis. The window can be represented using the Equation 3, where *N* is the number of samples in a window which is 160.

7.1 Segmentation by average force

For each 4 second window of the data, the average value of force sensor data is in the window of N samples is calculated using Equation 3, where each window starts at k^{th} sample and μ is the average value of force sensor values in that window and *x[i]* is the i^{th} sample. Each window is incremented by 10 seconds or 40 samples. Figure 6.1 shows the details of segmentation by average force. Markers are generated to show the segments of data when the brace was worn.

$$\mu = \sum_{i=k}^{N-1+k} x[i] \qquad (3)$$

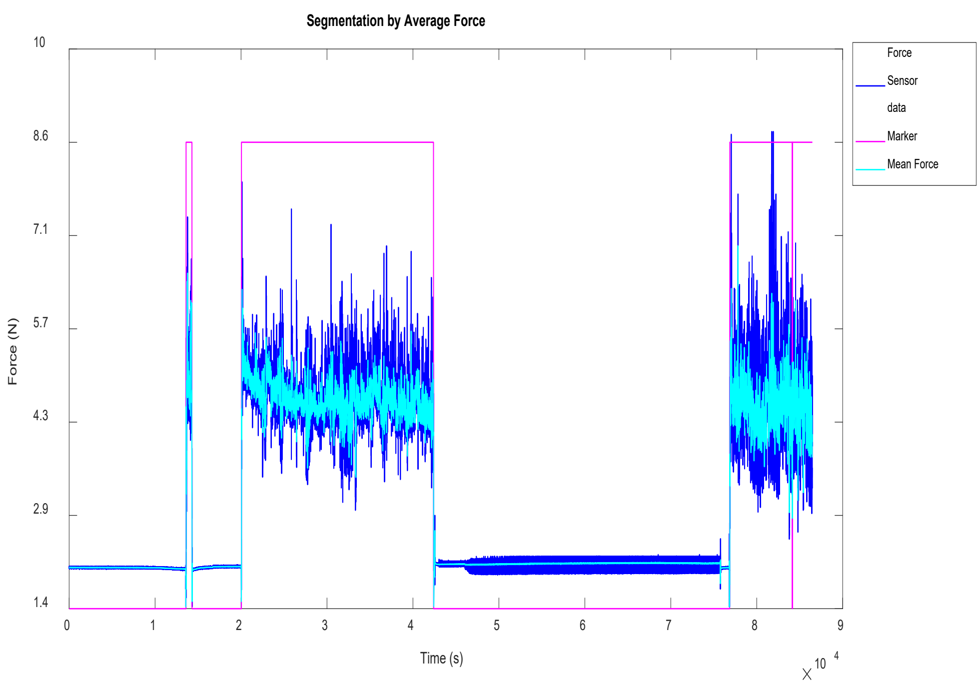


Figure 7-1 Segmentation by average force

7.2 Segmentation by average power of force

For each of the 4 second window of the data, the average power of the force sensor data is in that window is calculated using Equation 4, where each window starts at k^{th} sample and P_k is the average power of force sensor data in that window and *x[i]* is the i^{th} sample. Each window is incremented by 10 seconds or 40 samples. Figure 6.2 shows the process of segmentation using average power. The power values are scaled to a factor of 1/10 to compare it to the original force sensor values.

$$P_k = \frac{1}{N}\sum_{i=k}^{N-1+k} x[i]^2 \qquad (4)$$

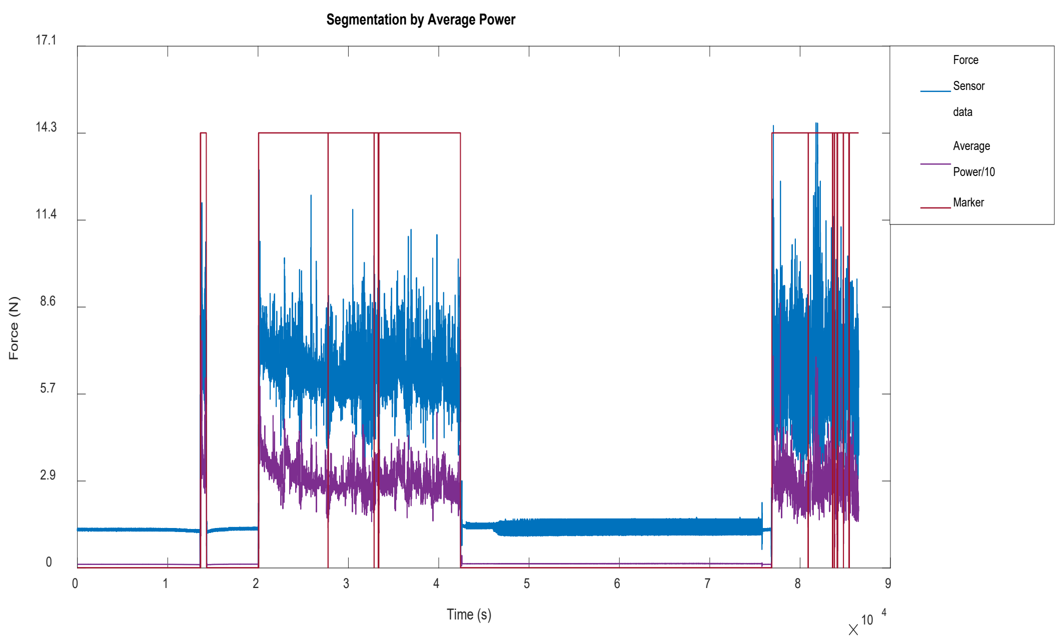


Figure 7-2 Segmentation by average power of force

Chapter 8 Calculation of baseline force

Tightness of the brace wear is one of the major factors that impact the brace treatment. The force sensor measures the force exerted by the patient's back on the brace. In this thesis, the tightness of the brace is estimated from the force sensor data. The force sensor data contains the patient's breathing patterns and high frequency noise. Two methods are employed, to calculate the baseline force exerted on the brace by the patient: 1) Moving average filter over each segment of data to calculate the baseline force; and 2) Employing activity specific principle component analysis.

8.1 Baseline Force using moving average filter

In this method, the baseline force for each day is calculated using the moving average filter. This filter is simple and fits online applications and is effective in smoothing out the patient's breathing patterns or the peaks of waveforms during different activities. It computes the n^{th} sample of the output sequence as the average of $M_1 + M_2 + 1$ samples of input sequence around the n^{th} sample. In the equation form, it is written as [1]:

$$y[n] = \frac{1}{M_1 + M_2 + 1} \sum_{k=-M_1}^{M_2} x[n-k] \tag{5}$$

In this dissertation, a moving average filter was applied on 10-second segments of data. Therefore, M is chosen as 400. Figure 8.1 shows the estimation of baseline force for 20 seconds of walking data. The moving average filter removes the high frequency components which indicate the walking pattern, to calculate the baseline pressure.

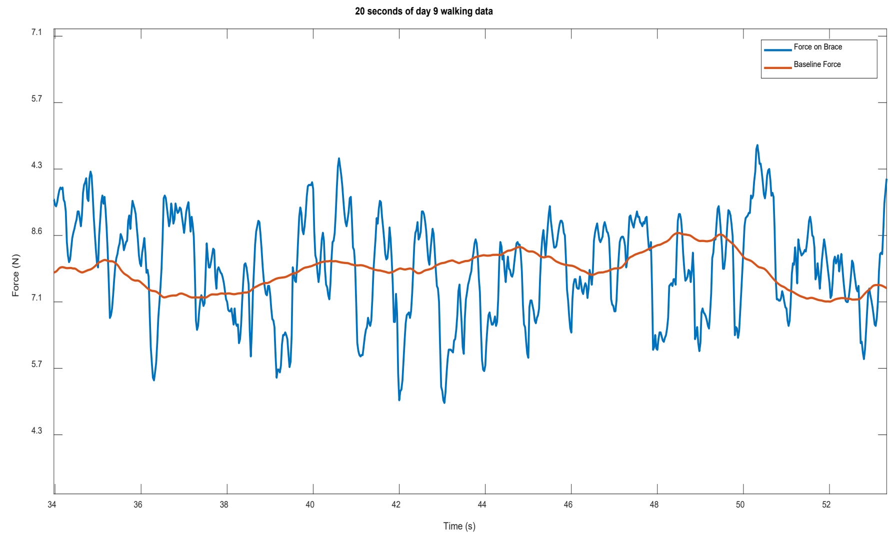


Figure 8-1 Calculation of baseline force using Moving Average for 9 seconds of walking data.

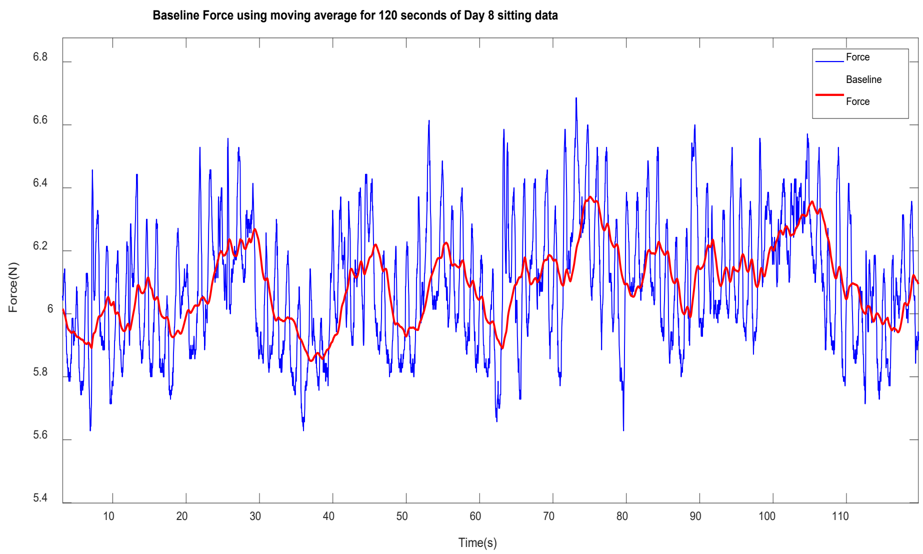


Figure 8-2 Calculation of baseline force using Moving Average for 120 seconds of sitting data.

In this method, the baseline force for each day is calculated using the moving average filter. This filter is simple and fits online applications and is effective in smoothing out the patient's breathing patterns or the peaks of waveforms during different activities. It computes the n^{th} sample of the output sequence as the average of $M_1 + M_2 + 1$ samples of input sequence around the n^{th} sample. In the equation form, it is written as [1]:

$$\mathrm{y[n]} = \frac{1}{M_1 + M_2 + 1} \sum_{k=-M_1}^{M_2} \mathrm{x[n-k]} \tag{5}$$

8.2 Calculation of Baseline force using PCA

PCA is a linear transformation technique that aims to simplify the data by decomposing the original multivariate data into an orthonormal space while preserving relevant information (e.g. variance). Data is transformed into a new coordinate system where principal component are linear functions of the original variables and are uncorrelated. The largest variance of the projection lies on the first coordinate, the second largest variance lies on the second coordinate, and so on. This process is achieved by calculating the covariance matrix and the eigenvectors and eigenvalues of the covariance matrix as shown in Equation 6.

$$\mathrm{cov(x,y)} = \frac{1}{N-1} \sum_{k=-M_1}^{M_2} (x_i - \bar{x})(y_i - \bar{y}) \tag{6}$$

Let x_i be the eigenvector which corresponds to the Eigen value ϕ_i, the eigenvectors-eigenvalues are calculated as shown in Equation 7.

$$\mathrm{R}x_i = x_i \varphi_i \tag{7}$$

The number of eigenvalues of the covariance matrix represents the rank of this matrix. We employ transform PCA to the data segments and analyze the resulting principle components (PCs) to detect and remove activity artifacts. Since the PC space is orthonormal, then we can simply remove a basis vector without affecting others. Figure 8.3 shows the architecture of the PCA analysis used.

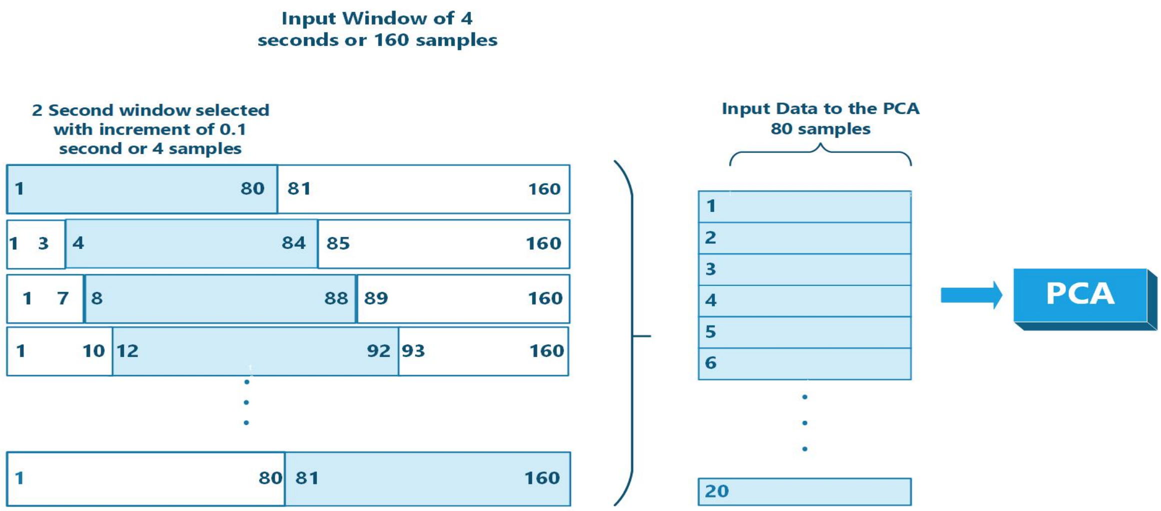


Figure 8-3 PCA Architecture

The 4 second window containing 160 samples is divided into two sections of 80 samples each. The section is incremented by 0.1 seconds or 4 samples. The data which is input to the PCA has 20 such sections with 80 samples each. Figure 8.4 illustrates the resulted PCs by decomposing the running data segments using PCA transform. We used the elbow point to remove the high energy PCs to estimate the baseline pressure. The elbow point is marked in red in Figure 8.4. Both methods generated similar estimations.

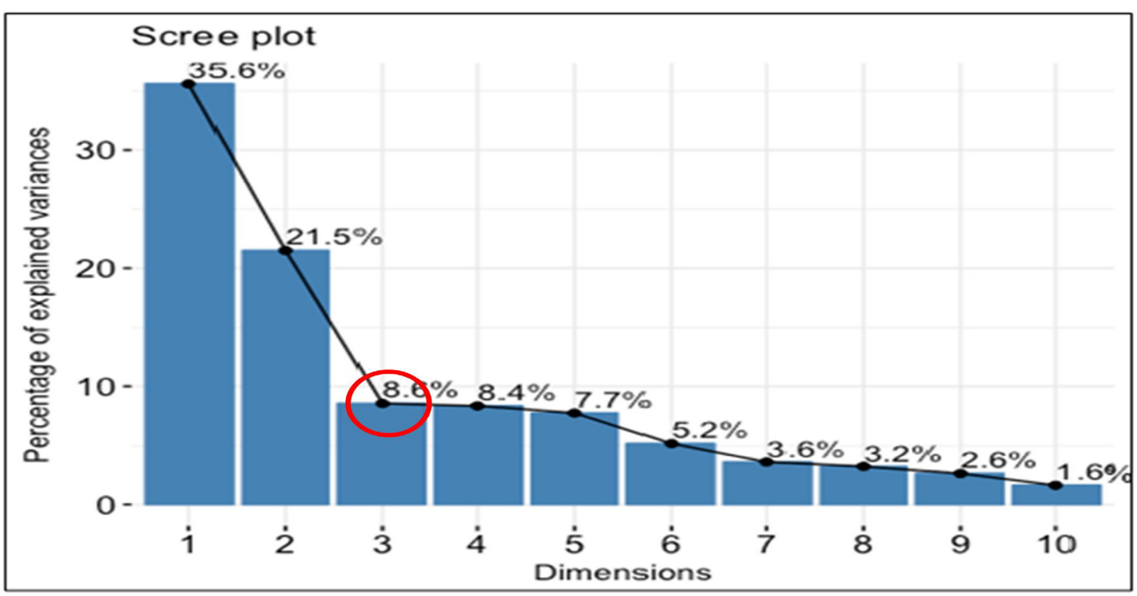


Figure 8-4 Estimation of baseline force using PCA

Chapter 9 Feature Extraction

After segmentation, the in-brace data is passed to the feature extraction block. Thirteen different features were used for the analysis including resultant acceleration, resultant gyroscope, force values, acceleration along x, y and z axis, gyroscope values along x, y and z axis, mean x axis acceleration in a window, mean gyroscope vales in a window, mean pitch and number of footsteps. Figure 9.1 shows the x, y and z axis and the acceleration along the three axes. x-axis represents upward movement of the brace. Movement along y-axis or pitch represents the forward and backward movement of the brace and is a discriminative feature to differentiate lying from sitting and standing.

9.1 Orientation of brace or pitch

Euler angles are the angles that are used to represent the orientation of the body [10]. The roll, pitch and yaw represent the orientation of the brace with respect to x, y and z axis respectively. Pitch has a tremendous importance as it represents if the patient is leaning forward or lying down. The pitch ranges from -90° to +90°. For better analysis and readability in the scatter plots, we try to normalize the angle by adding 90° to the pitch. Pitch can be calculated by Equation 8 [10]:

$$Pitch = \frac{A_y}{\sqrt{A_x^2 + A_z^2}} \tag{8}$$

This is one of the most important features as it is the angle at which the patient leans forward. This is feature is important to differentiate climbing from walking as the patient must lean forward a little to climb up the stairs. This feature can also help us to differentiate between sitting and standing from lying [11].

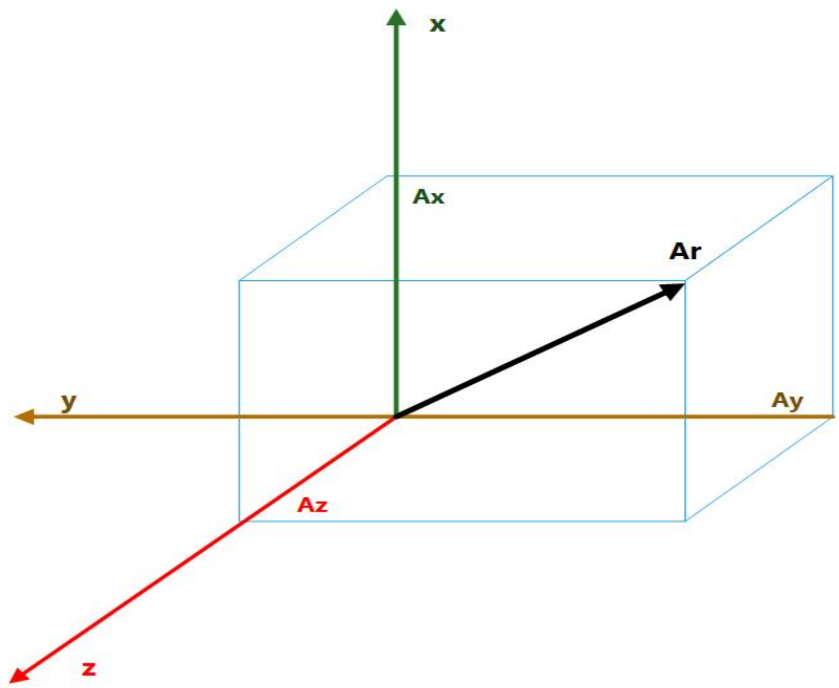


Figure 9-1 Acceleration along x, y and z axis

9.2 Resultant Acceleration

If the vector A measures the acceleration in the accelerometer, the projections of A are A_x , A_y and A_z respectively, the magnitude of the acceleration can be calculated as using Equation 9 [12]:

$$A_r = \sqrt{A_x^2 + A_y^2 + A_z^2} \tag{9}$$

The resultant acceleration represents the walking, running or climbing pattern of the patient. The accelerometer signal contains acceleration due to gravity. To calculate the acceleration of the brace and remove the effects of gravity, the mean of resultant acceleration is subtracted from the resultant acceleration.

$$\mu_n = \sum_{k=1}^{n} A_r[k] \tag{10}$$

$$A_f[k] = A_r[k] - \mu_n \tag{11}$$

9.3 Resultant Gyroscope readings

If the vector *G* measures the orientation in the Gyroscope, the projections of *G* are G_x, G_y and G_z respectively, the magnitude of the gyroscope readings can be calculated using Equation 12:

$$G_r = \sqrt{G_x^2 + G_y^2 + G_z^2} \tag{12}$$

9.4 Determination of number of footsteps using power density spectrum

The Fourier transform provides a better analysis when the signal is deterministic and is not corrupted by random noise. As the data from the accelerometer is corrupted by random noise, Welch's method is used to calculate the PSD as the noise due to small movements in the brace are smoothed out. PSD is calculated to evaluate the changes in the power of the signal with frequency. The most dominant frequency in the periodogram gives information about activities including walking, running and climbing. Using the Welch's method of calculation of periodogram, a unique equation is derived to calculate the number of footsteps in each window. The resultant acceleration A_f is divided into *L* overlapping segments. A rectangular window *w* is applied to each segment. Fast Fourier Transform is applied to the windowed data. The periodogram is applied for each windowed segment. The periodogram computed is then averaged to compute the spectral estimate *S(k)*.

$$A_f(m) = A_f(n + (l - 1)M) \tag{13}$$

Where

$$n = 0, \ldots, N - 1 \tag{14}$$

$$l = 1, \ldots, L \tag{15}$$

L represents the number of overlapping windows and *N* represents the number of data points in each window, *(l-1)M* is the starting point of l^{th} window. The windowed periodogram $A_f(k)$ can be estimated using Equation 16:

$$A_l(k) = \sum_{n=0}^{N-1} A_f(\mathrm{n})\mathrm{w}(\mathrm{n})\mathrm{e}^{-\frac{j2\pi nk}{N}} \tag{16}$$

$$\phi_l(k) = \frac{1}{NP}|A_l(k)|^2, l = 0, \ldots, L \tag{17}$$

A_l is the FFT of the windowed segment, ϕ_l is the periodogram, and *P* denotes the power of window *w(n):*

$$P = \frac{1}{N}\sum_{n=0}^{N-1}|w(k)|^2 \tag{18}$$

The Welch's estimate of Power Density Spectrum is given by Equation 19:

$$S(k) = \frac{1}{N}\sum_{l=1}^{L}|\phi_l(k)|^2 \tag{19}$$

For each window, the power density spectrum can be calculated as Equation 20:

$$N_f = f_d N \tag{20}$$

Where f_d is the dominant frequency and N_f is the number of footsteps in each window.

Figures 9.2 shows the power density spectrum of resultant acceleration with different activities. For PSD of sitting data, the peak is at 0Hz. PSD for walking and running have the peaks at 3.3Hz and 4.3Hz respectively.

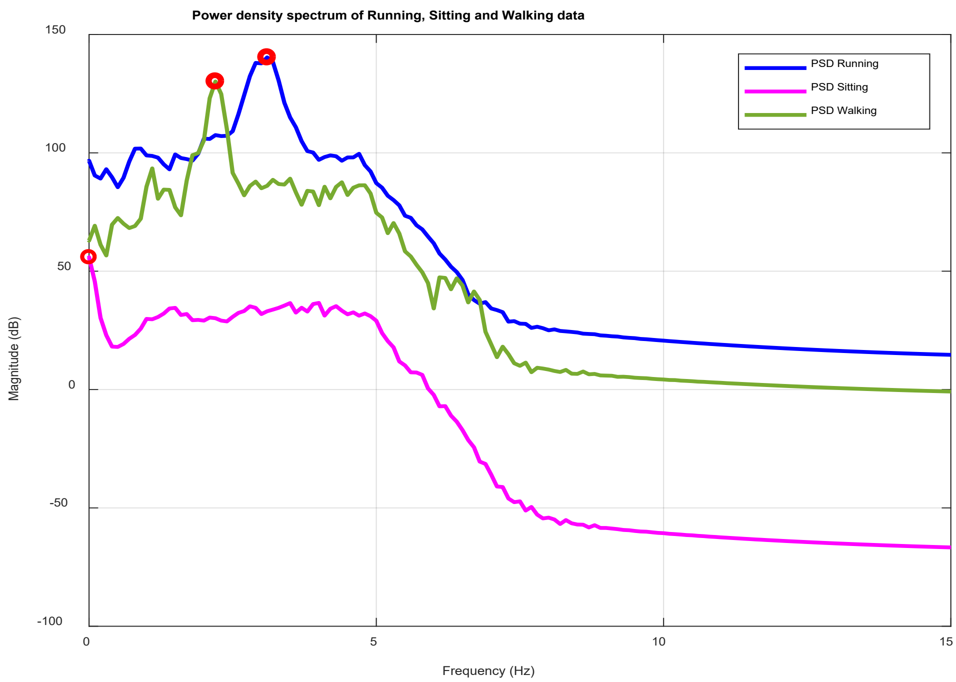


Figure 9-2 Power density for sitting, running and walking data.

9.5 Sequential Feature Selection

The acceleration is along a specific axis is important to identify the day-to-day activities of the patient. For instance, when the patient climbs up or down the stairs, the direction of acceleration is mainly on the x-axis. When the patient walks, the acceleration along z-axis is dominant. For stationary activities including sitting, standing or lying down, orientation of the brace or the angle of rotation of y-axis (pitch), can be used as a discriminative feature. For lying, the normalized pitch is almost 180°, whereas for sitting and standing, the normalized pitch is approximately 90°. The number of footsteps in a 10-second window is another discriminative feature that we employ in this work. To improve the identification accuracy of the predictive model, we used sequential feature select methodology to select different features which are important to identify the activities. These features are used to train the predictive model.

Chapter 10 Experimental results

The experimental results in this thesis are examined in semi-supervised and unsupervised scenarios. In this section, we discuss the results of three different phases. In the first phase, we discuss the results of sequential feature select. In the second phase, we discuss the results related to training the predictive model, cross validation results and the activity identification results in semi-supervised scenario. In the third phase, we discuss the experimental results of the compliance of brace treatment and the tightness of the brace in both, semi-supervised and unsupervised settings.

10.1 Sequential Feature Select Results

We used sequential feature selection to extract a different combination of features for all patients, as depicted in Table 1. These features are used for training the predictive model for each patient. We observe that the average x-axis acceleration in a window, pitch and the number of footsteps in a window are three most important discriminative features for activity identification. The x-axis acceleration represents the upward movement of the patient and is used as a discriminative feature to differentiate climbing from walking and running. Pitch represents the orientation of the brace along y-axis. This is used as a discriminative feature to differentiate sitting and standing from lying.

Patient	Features Selected using Sequential Feature Select methodology
Patient-1	Number of footsteps (1) Gyroscope values along y-axis (2) Acceleration along x-axis (3) Acceleration along y-axis (4) Gyroscope values along x-axis (5) Average x-axis acceleration in a window (6) Pitch (7)
Patient-2	Number of footsteps (1) Gyroscope values along y-axis (2) Acceleration along x-axis (3) Acceleration along y-axis (4) Gyroscope values along x-axis (5) Average x-axis acceleration in a window (6) Pitch (7)
Patient-3	Number of footsteps (1) Acceleration along y-axis (2) Force sensor values (3) Gyroscope values along z-axis (4) Pitch (5)

Table 1: The features selected for activity identification.

10.2 Training and Classification Results

For each day, there is a 12-minute window in the accelerometer and the gyroscope data, where the patient carried out activities including sitting, standing, walking running, lying and climbing. Patient wrote the duration, time and sequence of activities in the logbook provided. From the training data collected in the clinic, we observed that data collected from the stationary activities of sitting, standing and lying capture the breathing pattern of the patient. The data is quasi-periodic with a frequency of about 1.5 seconds apart. Frequency of resultant acceleration data is found to be highest for running. The activity detection accuracies of all three patients using different classifiers can be compared in Table 2, 3 and 4. It can be noted that the highest overall accuracy achieved was that of patient 2. Their overall accuracy is 100% using bagging and boosting, with a 10-fold cross-validation methodology.

Accuracies	KNN with K=1	KNN with K=3	KNN with K=5	Complex decision Tree	Boosting	Bagging
Sitting	99%	99%	99%	99%	99%	99%
Standing	99%	99%	99%	99%	99%	99%
Walking	95%	96%	96%	99%	99%	99%
Climbing	86%	82%	79%	100%	100%	99%
Lying	99%	99%	99%	99%	99%	99%
Running	99%	99%	99%	96%	96%	90%

Table 1: 10-CV performance for patient-1

Accuracies	KNN with K=1	KNN with K=3	KNN with K=5	Complex decision Tree	Boosting	Bagging
Sitting	95%	95%	95%	95%	99%	99%
Standing	95%	94%	94%	89%	99%	99%
Walking	92%	90%	89%	96%	99%	99%
Climbing	90%	85%	9%	98%	99%	99%
Lying	99%	99%	99%	99%	100%	99%
Running	79%	75%	74%	95%	100%	100%

Table 2: 10-CV performance for patient-2

Accuracies	KNN with K=1	KNN with K=3	KNN with K=5	Complex decision Tree	Boosting	Bagging
Sitting	99%	98%	98%	98%	99%	99%

Standing	98%	98%	97%	94%	99%	99%
Walking	97%	95%	93%	96%	100%	100%
Climbing	96%	92%	91%	91%	99%	99%
Lying	99%	99%	99%	99%	99%	99%
Running	93%	93%	90%	98%	100%	100%

Table 3: 10-CV performance for patient-3

After training the predictive model, Ensemble learner is used with Ada-boost to classify semi-supervised data. The classification results for semi-supervised data are shown in Table 2. During the entire 6 days of both, semi-supervised and unsupervised data, the maximum duration of running is 12 minutes in an entire day for all the three patients. The patient was advised to take the brace off during intense physical activities like playing soccer. The duration of lying is about 5.3 hours every day for patient-2, which indicates that patient-2 sleeps with brace worn. The two-minute data extracted for each of activity for the first 6 days is used for training the predictive model. Sequential feature select is used to select the relevant features to train the predictive model. The cross-validation results are as shown in Table 2. Lying shows the highest classification accuracy among all the activities as the angle of rotation of y axis helps differentiate it from other activities. To get a better idea on which of the features are more suitable for creating a model, a confusion matrix. Figures 10.1, Figure 10.2 and Figure 10.3 show the confusion matrices for patients 1, 2 and 3 respectively. The matrices show true positive rates for different activities.

		PREDICTED CLASS					
		Sitting	Standing	Walking	Climbing	Lying	Running
TRUE CLASS	Sitting	>99%					<1%
	Standing		>99%	<1%		<1%	
	Walking		<1%	>99%			
	Climbing				100%		
	Lying		<1%			>99%	<1%
	Running	3%				<1%	96%

Figure 10-1 Confusion matrix for Patient-1

		PREDICTED CLASS					
		Sitting	Standing	Walking	Climbing	Lying	Running
TRUE CLASS	Sitting	>99%	<1%			<1%	
	Standing	<1%	>99%		<1%	<1%	
	Walking			>99%	<1%		
	Climbing			<1%	>99%		
	Lying	<1%				>99%	
	Running						100%

Figure 10-2 Confusion matrix for Patient-2

		PREDICTED CLASS					
		Sitting	Standing	Walking	Climbing	Lying	Running
TRUE CLASS	Sitting	>99%	<1%			<1%	
	Standing	<1%	>99%		<1%	<1%	
	Walking			>99%	<1%		
	Climbing			<1%	>99%		
	Lying	<1%				>99%	
	Running						100%

Figure 10-3 Confusion matrix for Patient-3

Days	Sitting	Standing	Walking	Climbing	Lying	Running
1	0.9	0.1	0.3	0.2	0	0
2	1.3	0.3	0.8	0.1	0.5	0
3	1.9	0.7	0.6	0	0.6	0.1
4	2.1	0.7	0.8	0.1	0.5	0.1
5	0.9	0.4	0.4	0.1	2.2	0.2
6	2.8	0.7	0.9	0.2	4.6	0.0

Table-4: Classification results for patient-1

Days	Sitting	Standing	Walking	Climbing	Lying	Running
1	1.1	0.3	0	0	0.1	0
2	0.4	0.2	0.5	0	1	0
3	3.1	1.3	0.1	0.1	5.6	0

4	4	1.5	0.2	0	4.7	0
5	3.9	0.8	0.3	0.1	5.3	0
6	1.3	1.1	0	0	2	0

Table-5: Classification results for patient-2

Days	Sitting	Standing	Walking	Climbing	Lying	Running
1	3.6	3.5	0.4	0.3	0.8	0.1
2	5.3	1.5	0.1	0	0.6	0
3	3.9	0.6	0.2	0.1	0	0
4	7.1	4.1	0.6	0.2	1.6	0.2
5	1.4	1	0.1	0.1	4.4	0

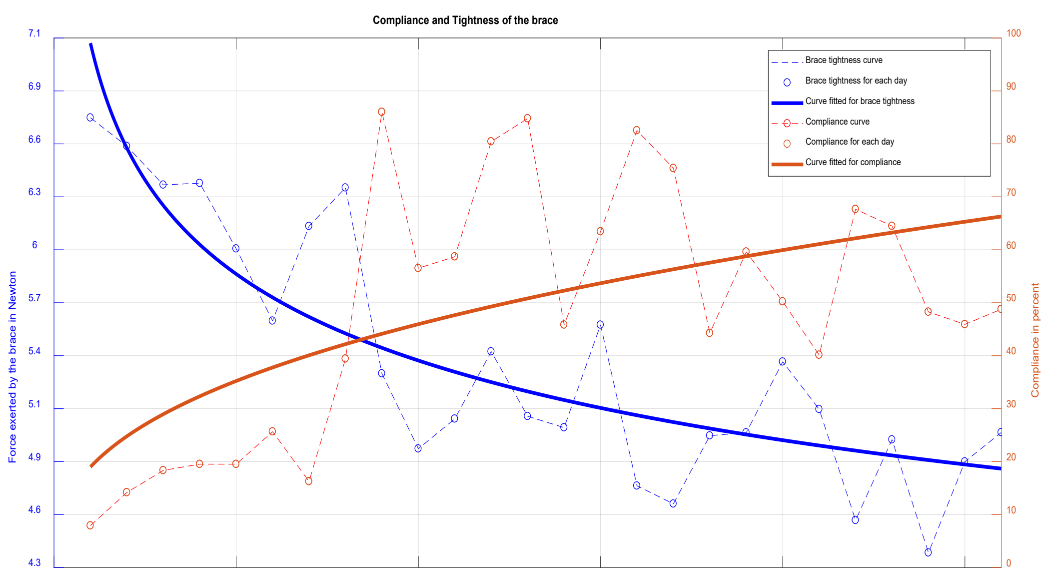
Table-6: Classification results for patient-3

Days	Force on brace	Compliance (%)	Days	Force on brace	Compliance (%)
1	6.7	7.9	14	5	45.8
2	6.6	14.1	15	5.6	63.4
3	6.4	18.3	16	4.7	82.5
4	6.4	19.5	17	4.6	75.4
5	6	19.5	18	5	44.3
6	5.6	25.6	19	5	59.6
7	6.1	16.2	20	5.4	50.2
8	6.3	39.4	21	5.1	40.1
9	5.3	86.5	22	4.5	67.7
10	4.9	56.2	23	5	64.5
11	5.1	58.6	24	4.4	48.3
12	5.5	80.4	25	4.9	45.9
13	5.1	84.7	26	5	48.8

Table-7: Results of compliance and force on the brace for 6 days of semi-supervised and 20 days of unsupervised data for Patient-1

10.3 Results of force and compliance studies

Table 3 shows the duration of brace wear in hours, while Table 4 shows the force exerted by the brace or tightness of brace wear in Newton and the compliance in percentages for patient-1. The relation between compliance to brace treatment and tightness with which the brace is worn is shown in Figure 10.4. It was observed that, for the first 4 days the patient begins to become accustomed to the brace. On day 1, they wear the brace for 2 hours. From Week 2 onwards, compliance with the treatment had increased and reached almost 50%, as the patient is able to wear the brace for longer than 10 hours a day. A gradual reduction in the force exerted by the brace is observed, which indicates that the brace is getting looser, which could be due to the patient's wearing the TLSO more loosely or due to patient's curve reducing while wearing the TLSO. This information is quite important for the physician as a loose brace may not be able to adequately control the spinal curvature.



10-4 Compliance and duration of brace wear for 26 days

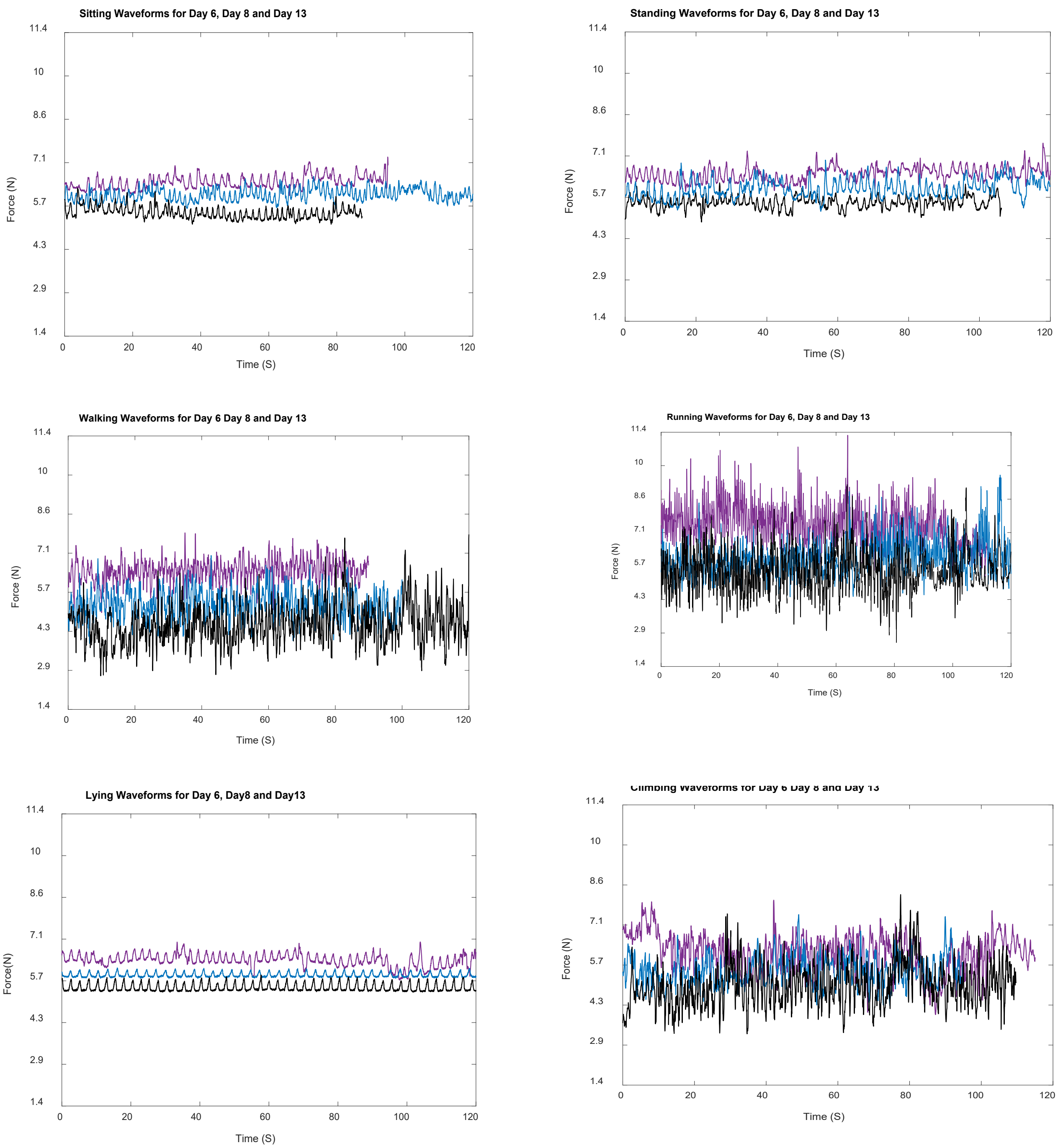


Figure 10-5 Waveforms for sitting, standing, walking, running, lying and climbing for Day 6, Day 8 and Day 13.

The waveforms generated for different activities, are shown in Figure 10.5. The figure shows training data for 3 days for better visualization. The baseline force was observed to be higher for Day 6, while it is much lower for Day 8 and Day 13. The brace was tighter during the first week, as the force exerted by the brace is significantly higher. As observed from the Figure 10.5, all activities follow a unique trend and pattern that can be further justified by observing the force readings associated with the respective activity. The breathing patterns of the patient can be observed for stationary activities like sitting, standing and lying. The frequency of waveforms is much higher for walking. Running data shows highest frequency for the force sensor data. During the entire 6 days, it was observed that the maximum duration of running is about 12 minutes in a day. The patients were advised to take the brace off during intense physical activity like playing soccer. It was also observed that the duration of lying is about 4 to 5 hours every day for patient-2, which indicates that the patient sleeps at night with the brace on. The scatter plot in Figure 10.6 shows the distribution of training data over x-axis acceleration (upward acceleration), pitch (which represents orientation of the brace with respect to y-axis) and, the number of footsteps during a 10-second window. The pitch is in the range of -90° to +90°. For better visualization of data, the pitch value is normalized by adding 90°. For running, the number of footsteps are in the range of 30 to 45, and the pitch is about 90°. For walking the number of footsteps is between 10 and 30. Climbing is a slightly slower activity with the number of footsteps between 10 and 20. Pitch is roughly 20° for walking, climbing and running. Lying has 0 footsteps but the pitch is close to 100°. The number of footsteps are 0 for sitting and standing

Figure 10-6 Scatter plot for training data

as well, but the pitch is much less than lying, thus, making it easy to differentiate lying from sitting and standing.

Conclusion

In this thesis, a new data-mining methodology to evaluate the effectiveness of brace treatment pervasively based on accelerometer, gyroscope and force readings is proposed. Three main aspects of brace treatment are evaluated 1) Compliance of brace treatment by evaluating the duration of brace wear through segmentation 2) Level of tightness of the brace by calculating the baseline force exerted by the patient on the brace 3) The quality of brace-fit by estimating the duration of activities: LIE, SIT, SND, WLK, RUN and CLB performed daily. The quality of brace fit for 6 days of semi-supervised data for 3 patients is investigated. An overall accuracy of 99.8%, 100% and 99.9% for patients 1, 2 and 3 respectively for semi-supervised activity detection is achieved. The study continued compliance and tightness for Patient-1 for the remaining 20 days of unsupervised data. Patient was instructed to wear the brace for 2 hours a day initially, gradually increasing to 23 hours a day. This was proven by the analysis as compliance was observed to increase from 20% to 80% after 4 weeks. Naturally, the brace is tightest when the patient begins treatment. As they continue wearing the brace daily, they start to "break-in", making the brace more comfortable to wear. This can be calculated by measuring the baseline force exerted on the brace. The analysis showed that the force decreased by 33% after 4 weeks.

Appendix

This appendix describes the user protocol provided to the patients when they sign up to participate in the study. The protocol is as follows:

The purpose of this back brace is to monitor the force being exerted by your back. The force would be collected from the force sensor placed inside the back brace. Below you can find the main steps and procedures related to the back brace. After your visit with the Doctor, you are ready to follow the instructions listed below.

Charging

To charge the battery, you must connect the USB charging cable to the board. The USB charger and cable will be provided to you. Plug the USB charger into any wall power outlet for 2-3 hours a day. Once you are done charging, you may remove the USB charging cable from the board.

Daily Activity Log

Each day, you would be required to complete at the six activities listed below. Each activity is scheduled to last for 2 minutes. Below you will find instructions on procedure to conduct these tests. These activities should be recorded in the activity log each day. These activities should be done every day for 6 days. Remember: Each test is 2 minutes long!

Sitting: You may sit on a chair or a couch. Try to limit any movement.

Standing: Stand still - try to limit any movement.

Walking: Walk in a straight line or circle, indoors or outdoors.

Running: Try to run at your normal speed.

Lying down: Lie down on a flat surface, like a bed or a couch. It is all right to lie on your side. Try to limit any movement!

Climbing stairs: Climb up and down the stairs at your normal speed.

In order to record specific activities, the data button located on the brace must be pressed. This button will be shown to you during your visit. There are two buttons on the board so make sure not to mix them up. This button must be pressed each time the activity begins and ends. Before beginning a specific activity, press and hold the button for 2-3 seconds. Now you may begin your activity. Be certain to monitor the time when the activity is started and ended. This also means that the time should be noted when the button is pressed once at the beginning and once at the end of the activity. Example: You are about to go for a jog at 10:45 am. You press and hold the button for 2-3 seconds when you are about to start jogging. You should note the time at this point in the log. You end the jogging session at 11:52 am. You must now press and hold the button for 2-3 seconds. You must now note the time that the button was pressed. For that time window, you must also write down the activity you did. In this example, the log should say:

Activity: Jogging

Start Time: 10:45 am

End Time: 11:52 am

In addition to the six timed activities listed above, please note down any other activities you do. Examples may include: Reading a book, studying, or playing sports outdoors. The more details that you write down, the better we can understand what you did when you were wearing your brace!

Data download

Once a week, it will be necessary to transfer the data on the SD memory card to the Drive folder. The SD card must be removed from the brace and connected to the computer once a week. You will then open the Drive link provided to you. You must now upload all files to the Drive.

To upload files from the SD card, click on the link Drive Link provided. Now select Week 1 for the activities done in the first week. A window will pop up which allows you to select multiple files. Select and upload all files in the SD card. You will see a small box on the bottom right of the screen showing the status of the files being uploaded. Once the files are successfully uploaded, you may now delete the files on your SD card. Before uploading the files however, make sure that the files were in-fact successfully uploaded. To do so, log out and log back in to your Drive. Then, click on the link provided above. Enter the folder you just uploaded the files to. If the files are still there, you have successfully uploaded the files. You may now delete the files after confirmation. To delete the files on the SD card, open the SD card drive on your computer. Once you enter the SD card folder, you may now select all files and delete them. Remember: only delete the files once you have confirmed that they have been uploaded. After deleting the files, plug the SD card back into the brace. Once the SD card is plugged back in, press the reset button to reset the board. Each week, the brace needs to be reset. This button will be shown to you. You must remember what each button does. In this case, the second button would reset the circuit. It is very IMPORTANT to reset the board in order to collect data each week. Remember to note down the timings of your activities.

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