Measurement of sagittal imbalance in patients with lumbar degenerative pathology

Dr Wickus Neethling

Research report to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfilment of the requirements for the degree of Master of Medicine in Neurosurgery.

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Declaration

I, Wickus Neethling, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in branch of Neurosurgery at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Signed:__________________________ on this 15th day of November 2024.

Acknowledgements

Professor John Ouma for his guidance, mentorship and leadership during my years in his department.

Dr Prince Boungou-Poati for his supervision with my topic and compilation of protocol.

Abstract

Introduction: Degenerative diseases of the lumbar spine (DSD) are a major cause of disability worldwide characterized by degeneration associated with age leading to low back pain and functional impairment. The study of lumbar degenerative spine diseases has increased the significance of sagittal balance. Sagittal imbalance occurs when there is disturbance in alignment between spinal and pelvic parameters, which triggers compensatory mechanisms that subsequently fail leading to significant disability. Understanding these relationships provides insight into improving patient management and outcomes in LBD.

Primary Objectives: This was a descriptive study aimed at: Describing sagittal balance in patients presenting for treatment for lumbar degeneration by measuring sacral slope (SS), pelvic tilt (PT), pelvic incidence (PI), lumbar lordosis (LL), and sagittal vertical axis (SVA) on standing sagittal x-rays of the lumbar spine. Comparing sagittal balance among patients with a pathology of the lumbar area against control subjects to determine if they differ significantly from each other.

Methods: This was done as a prospective cross-sectional study undertaken at Chris Hani Baragwanath Hospital's Department of Neurosurgery in Johannesburg, South Africa. A total of sixty participants comprising fifty patients with known lumbar degenerative pathologies (Group 1) and ten healthy volunteers (Group 2) were included. Standing lateral full spine radiographs were taken for all participants, while PACS software was used to measure parameters related to sagittal balance. Data analysis included logistic regression, chi-square, independent t-tests with p<0.05 being considered statistically significant.

Results: The findings pertaining to the study's variables indicated significant results regarding sagittal balance parameters.Pelvic tilt emerged as one crucial predictor of sagittal balance where higher PT values were significantly associated with an imbalanced sagittally profile (p=0.0023). Group 1 had mean PT = 23.9° compared to the mean of 11.3° in Group 2. In addition, thoracic kyphosis (TK) was significantly higher in patients with lumbar degenerative disease compared to healthy subjects (p=0.03), though it failed to significantly differentiate balanced from unbalanced profiles within the group of patients. Other parameters including pelvic incidence, sacral slope and lumbar lordosis exhibited no statistically significant differences between the two groups. Multivariate analysis demonstrated a significant overall difference in sagittal balance parameters between the groups (p=0.0289).

Conclusion: The study has established that there are several factors to be taken into consideration for assessing and managing patients with lumbar degenerative diseases, and this can be a complex task. Pelvic tilt and thoracic kyphosis are compensatory mechanisms which impact sagittal balance greatly. Findings imply the need for comprehensive and individualized assessment of patients having LDD. Clinicians must consider multiple parameters while ensuring successful diagnosis and treatment planning. Further research is required to address these limitations, like larger sample sizes and dynamic assessments amongst others, so as to gain deeper insights into the intricate relationship between sagittal balance parameters and lumbar degenerative diseases.

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List of Abbreviations

CHBAH	Chris Hani Baragwanath Academic Hospital
DDD	Degenerative disc disease
DH	Disc herniation
DSD	Degenerative spine disease
IQR	Interquartile range
LBP	Low back pain
LDD	Lumbar degenerative disease
LL	Lumbar Lordosis
“p”	p-value
PI	Pelvic Incidence
PT	Pelvic Tilt
SB	Sagittal balance
SD	Standard Deviation
StdDev	Standard Deviation
SS	Sacral Slope
SVA	Sagittal Vertical Axis
TK	Thoracic Kyphosis

Introduction

Lumbar degenerative spine disease (DSD) is known to be a noteworthy cause of disability worldwide. DSD refers to a syndrome in which age-related wear and tear on the spinal components causes low back pain (LBP).[1] In-between each spinal vertebral body are the intervertebral discs - pads of fibrocartilage-based structures that provide support, flexibility, and minor load-sharing.[2] When the natural structure of these discs is disrupted, it can result in a disc herniation or a protrusion of the content, which may exert pressure on the spinal cord, a nearby nerve root, or an adjacent vertebral body and cause pain radiating down the buttocks and lower extremities, or potential weakness.[2] However, some patients' complaints include being unable to stand up straight, stooping while walking, and finding it difficult to lift large objects in front of them. Spinal sagittal imbalance is similar to this clinical picture.[4]

Recently, the study of the sagittal balance has been noted to be important in the management of lumbar degenerative spine diseases[3]. Sagittal balance refers to an individual's optimal alignment of the spine in the sagittal plane and ability to maintain a stable standing position with minimal physical effort [3,7]. It necessitates the interaction of various elements, including bone morphology (spine and pelvis), disc and ligament mechanical behaviour, muscle strength and resistance, and compensating ability – and sagittal imbalance arises when one of the components is interrupted.[4,5] The cascade of compensating mechanisms manifests progressively with increasing spine imbalance until compensation is no longer possible and the individual is unable to maintain the standing position.[15] Sagittal balance can be evaluated in a variety of methods, employing different bony landmarks and angles to determine whether or not the axial skeleton is subject to a normal distribution of weight and stresses.

Standing films are the mainstay of spinal alignment imaging. Patients should stand with the upper limbs resting on a support, the shoulders flexed 30° forward, and the elbows slightly flexed.[16] Certain parameters are measured to determine sagittal balance indirectly.[6]

The interaction of the spine and the pelvis is a critical factor in the analysis of spinal deformities. Spinal degeneration can lead to sagittal imbalance being triggered by a maladjustment between the pelvic incidence and lumbar lordosis. Reduced lumbar lordosis causes anterior flexion of the trunk, which is characterized by an increase in the sagittal vertical axis, resulting in a curved posture and a downward tilt of the head, with the inability to see above the horizon. When this imbalance happens, compensatory mechanisms kick in to restore a compensated balance. [7]

The pelvic tilt measures the compensatory mechanisms of the pelvis. A high pelvic incidence is thought to be associated with a high sacral slope and pronounced lumbar lordosis, indicating a greater capacity for spinopelvic compensation. Whereas a low pelvic incidence is thought to be associated with a lower sacral slope and subtle lumbar lordosis, and a lesser capacity for spinopelvic compensation. The sagittal vertical axis and pelvic tilt are spinopelvic parameters that reflect the severity of the adult spine deformity, and the magnitude of one affects the magnitude of the other.[7]

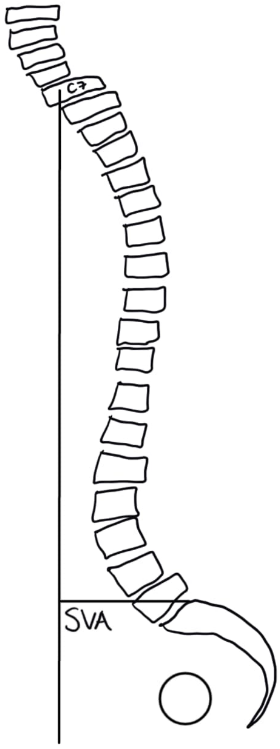


Figure 1:

Sagittal vertical axis (SVA) and C7 plumb line

The first parameters to study are sagittal vertical axis (SVA) and C7 plumb line, see Figure 1. The horizontal distance between the C7 plumb line and the vertical line passing through the upper posterior edge of S1 is measured as the sagittal vertical axis. The C7 plumb line is a radiographic reference for determining the sagittal vertical axis, which is the most traditional measurement of the spine's sagittal balance. A caudal vertical line is drawn from the center of the C7 vertebral body. The line should connect with the superior-posterior endplate of S1 or be within 5mm of it.[6, 18] A positive, neutral, or negative balance can be determined from these lines.

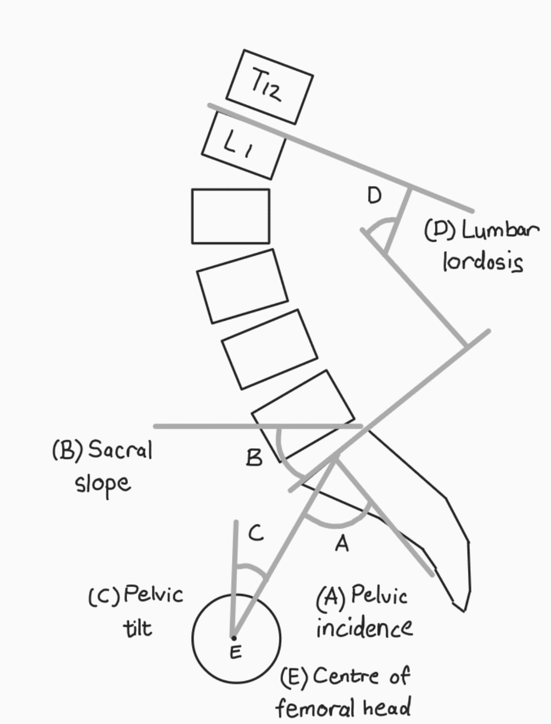


Figure 2:

Sagittal balance parameters

The important pelvic parameters to study to determine compensation, include pelvic incidence (PI), see (A) in Figure 2, which is defined as the angle between the perpendicular line to the sacral plate and the line connecting the midpoint of the sacral plate to the bi-coxo-femoral axis. The PI is a morphological parameter, considered as a constant, independent of the spatial orientation of the pelvis. The sacral slope (SS), see (B) in Figure 1, corresponds to the angle between the sacral plate and the horizontal plane. The SS is also a positional parameter, varying according to the pelvis positioning.[3] It varies between 20° and 65°, with an average of 40°.[7] The pelvic tilt (PT), see (C) in Figure 1, corresponds to the angle between the line connecting the midpoint of the sacral plate to the bi-coxo-femoral axis and the vertical plane. The PT is a positional parameter.[3] It varies between 5° and 30°, with an average of 12°.[7]

There is a relationship between these three parameters: The PI represents the algebraic sum of the SS and the PT:PI=SS+PT. [3] It is directly related to the value of the lumbar lordosis and ranges from 34° to 84°, with an average of 52°.[6,7]

The lumbar lordosis, see (D) in Figure 1, is defined as the extension spinal segment above the sacral plate. Thus it was measured using Cobb's method from the sacral plate to the upper endplate of the most incline vertebrae into the thoracolumbar junction zone (corresponding to the inflection point where the spine transitions from lordosis to kyphosis).[3] As much as 75% of lumbar lordosis occurs between L4 and S1 with 40-50% occurring at L5/S1.[6] It normally ranges between 30° and 79° [7], and an average value of 60 degrees noted.[6]

Spinal sagittal imbalance is a familiar and well documented issue: according to studies, patients with lumbar degenerative disease have anterior sagittal imbalance, loss of lumbar lordosis, decreased sacral slope, and increased pelvic tilt, and it compares directly with disability and pain[7]. The radiologic parameters to evaluate the state of spinal sagittal imbalance and the relationships between the pelvic incidence, sacral slope and the sagittal curves, have been well noted in the normal population, but there is inadequate familiarity with its incidence.[3,4]

Literature Review:

A retrospective analysis of the spino-pelvic alignment in a population of 85 patients with a lumbar degenerative disease, found that patients with disc herniation (DH) and those with degenerative disc disease (DDD) had sagittal profiles that were quite comparable and featured a normal or low pelvic incidence.[3]. The two groups had extremely similar values for the sacral slope, pelvic tilt, and lumbar lordosis. Therefore, these patients have a flat spine and lumbar lordosis significantly reduced.[3] Similar results were reported by a French study that examined the spinopelvic characteristics of 50 patients with herniated lumbar discs, and compared them to the same measurements made on 30 healthy volunteers. The lumbar lordosis score was lower, and the sacrum was more vertical. [8]

A retrospective study published in 2020 analysed the sagittal spino-pelvic alignment and compared these parameters between 68 patients with and without degenerative spondylolisthesis (DS) – 34 in the first group suffering from DS, and 34 in the second group not. They found that pelvic incidence, sacral slope and lumbar lordosis were significantly greater in the patients in the first group as compared to those in the second group. There was a strong correlation between PI and SS, rather than with the PT in the first group, while there was no significant difference in PT between the two groups.[9]

After reviewing 25 adults with LDH and measuring pelvic incidence, pelvic tilt, sacral slope and lumbar lordosis amongst others, a study done in China in 2016 on spinal sagittal imbalance in patients with lumbar disc herniation (LDH), concluded that a loss of lumbar lordosis, an increase in thoracic kyphosis, and pelvic tilt, are the key compensatory mechanisms for spine sagittal imbalance.[4]

A comparative retrospective study published in 2016 in Europe also analysed spinopelvic parameters and symptoms in individuals receiving either conservative or surgical care for a single-level LDH. The study included 71 patients, and characteristic changes in spinopelvic parameters identified in patients with lumbar degenerative disc disease were a reduction in pelvic incidence, sacral slope and lumbar lordosis, with an increased pelvic tilt.[10] A 102-patient case-control study published in Iran on spinal sagittal balance and spinopelvic parameters in patients with degenerative lumbar spinal stenosis, also found a decrease in sacral slope and lumbar lordosis in patients with lumbar spinal stenosis. However, they did not find a significant difference in pelvic incidence between patient groups.[11]

It is well recognized that evaluating these radiographic spino-pelvic parameters of sagittal balance to prevent functional disability, is now a standard aspect of many degenerative spinal disease therapies.[12]

Despite the growing body of literature on sagittal balance, there is still disagreements regarding the published spino-pelvic parameters and the correlation with patients suffering from degenerative lumbar disease. Notably, no such studies have been published South Africa in particular.

In patients with lumbar degenerative pathology, it is generally expected that they will have a positive sagittal vertical axis (SVA), low lumbar lordosis, high pelvic tilt, and low pelvic incidence. By comparing the sagittal balance of patients with lumbar degenerative pathology to healthy patients, it can be determined if these expected findings are supported by this study and if they align with the international literature on the subject.

The results of the study can highlight the importance of evaluating the sagittal balance in our unit, and therefore lead to better predicting the development of lumbar degenerative pathologies, and improved management for these patients. Preventative measures such as lifestyle management can also be addressed if a patient has been evaluated as being at risk.

AIM:

The aim of this study is to describe the relationship between sagittal balance parameters and degenerative lumbar pathology in our South African population.

STUDY OBJECTIVES:

The objectives of this study are as follow:

- To describe the sagittal balance in patients presenting with degenerative lumbar pathologies, by measuring various parameters, including sagittal vertical axis, pelvic incidence, pelvic tilt, sacral slope and lumbar lordosis on standing sagittal lumbar x-rays.

- To compare the sagittal balance of patients with lumbar degenerative pathology to healthy volunteers to determine if there are any differences between the two groups.

Methods:

This is a prospective cross-sectional study, reviewing two groups of participants: patients with isolated complaints regarding lumbar spinal disease and known lumbar degenerative pathologies, and the control group: healthy volunteers not known with or any complaints relating to lumbar spinal disease. This study was conducted in a single centre, at the Department of Neurosurgery at Chris Hani Baragwanath Hospital, located in Soweto, Johannesburg, South Africa. The data collected were from patients seen at the Neurosurgery Outpatient Department, and patients admitted to our neurosurgery ward **(see appendix 1)**.

Standing X-rays (lateral sagittal full spine from C2 to the pelvis, including the femoral heads) for above mentioned patients were obtained at CHBAH's radiology facilities on the same day as patient's clinic appointment/follow-up, and sagittal balance measurements were taken using PACS software thereafter.

Measurements:

Degeneration of the spine was characterized using X-rays, and the following features were evaluated: osteophytosis, thickened facet joints, sclerotic/irregular endplate surfaces of the vertebral bodies, or narrowing of the disc spaces, caused by the intervertebral discs' decreased height.[17] Regarding sagittal balance measurements, the SVA/C7 plumb line was measured. [18] The position of this line is can be positive, neutral or negative. A <u>positive balance means</u> the plumb line passes more than 2 cm in front of the posterosuperior corner of the S1 vertebral body. A <u>neutral balance means</u> the plumb line passes within 2 cm of the posterosuperior corner of the S1 vertebral body. A <u>negative balance means</u> the plumb line passes more than 2 cm behind the posterosuperior corner of the S1 vertebral body. And lastly, to determine spinopelvic compensation, pelvic incidence, sacral slope, lumbar lordosis were measured.

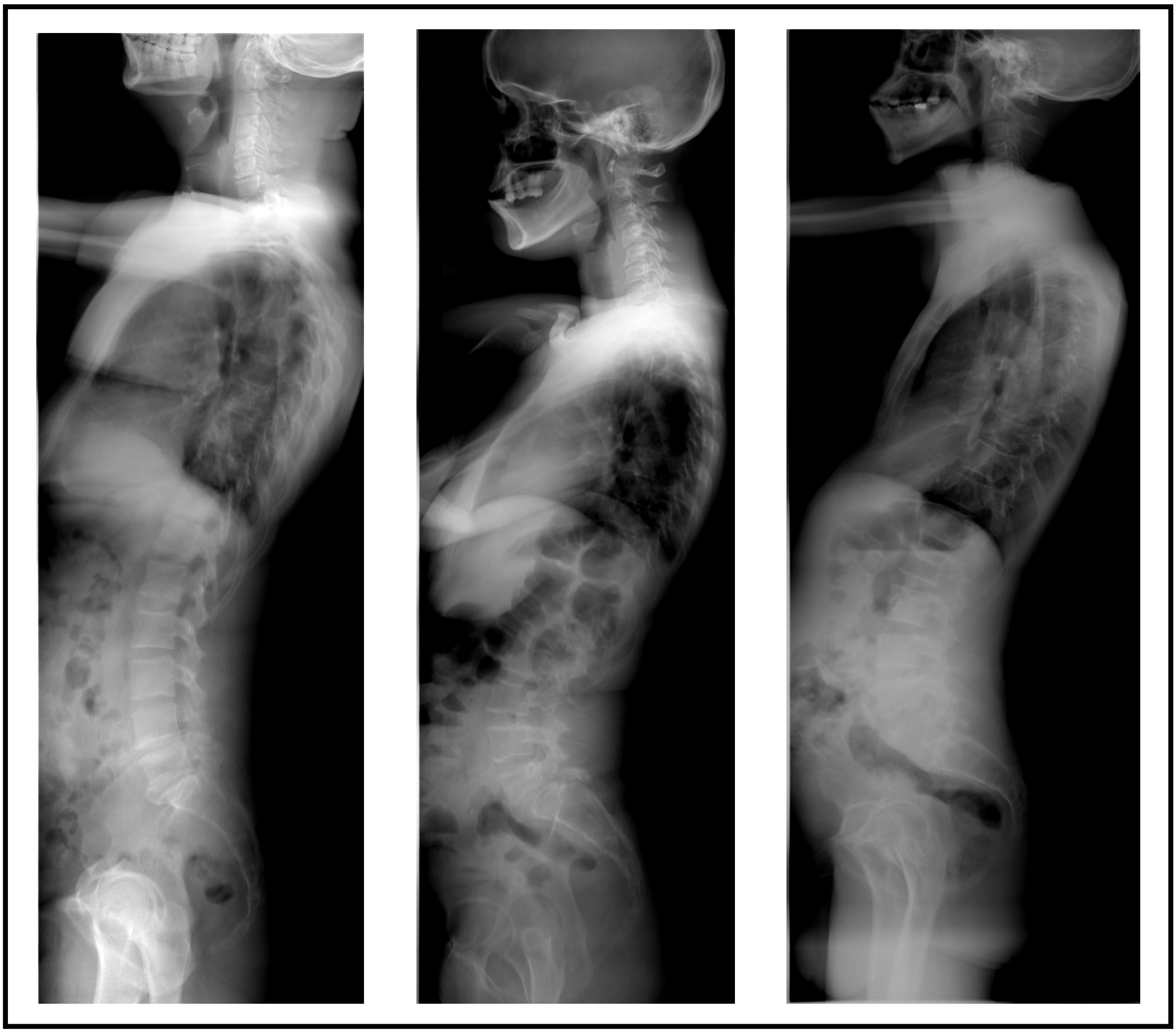


Figure 3 below is three standing x-rays taken during this study, to demonstrate the ideal imaging for evaluation of the relevant parameters:

Inclusion and Exclusion Criteria:

The population for this study consists of two groups of participants at Chris Hani Baragwanath Hospital. “Group 1”: patients known with degenerative lumbar pathologies, and “Group 2”: (Control group) healthy volunteers not known with or any complaints relating to lumbar spinal disease, selected from the health care workers at Chris Hani Baragwanath Hospital.

Patient with established scoliosis, history of any previous spinal surgery, spinal trauma, spinal disease, or pregnant patients were excluded from this study.

Sample Size:

Close to 300 million individuals worldwide were found to have lumbar degenerative spine disease and lower back pain annually, and over 6 million of this total were found in Africa.[14] Given the population size of Johannesburg being over 5,6 million, the ideal sample size to have a confidence level of 95%, with a margin of error of +-5%, will be 385. The goal sample size is however 50 patients for group 1, and 10 patients for group 2 (control). This will be due to the limitations of a larger number of patients being seen at the outpatient department meeting exclusion criteria, the long follow-up periods for patients meeting inclusion criteria, and the limitations of how many patients can be radiographically investigated within the time period allocated to the project. The smaller size control group is due to the cost involved for obtaining an x-ray in these volunteers, and the possibility of some volunteers not meeting the inclusion criteria if incidental findings of degenerative lumbar disease is radiographically evident.

Data Analysis

Data analysis was done using Python (macOS) and STATA software packages.

Linear regression analysis was used to evaluate how the presence or absence of lumbar degenerative pathology affects the sagittal balance parameters measured.

Chi-square and Independent t-test were also used to analyse data points.

A p-value of <0.05 was used to determine statistical significance.

The independent variable was lumbar degenerative disease, with answers as Yes (present) or No (absent). The dependent variables (sagittal balance parameters) included:

(i) sagittal vertical axis: positive (+1), negative (-1) or neutral (0);

(ii) pelvic incidence (which normally ranges from 34° to 84°);

(iii) pelvic tilt (which normally varies between 5°and 30°);

(iv) sacral slope (which normally varies between 20° and 65°);

(v) lumbar lordosis (which normally ranges between 30° and 79°)

And (vi) thoracic kyphosis.

Ethical Considerations

Ethical clearance for this study was obtained from the University of Witwatersrand Human Research Ethics Committee prior to data collection for this study, with approval date 23-08-2023, and clearance certificate number M230617 MED23-05-035 **(see appendix 2).**

Permission was given from the superintendent and chief executive officer of Chris Hani Baragwanath Hospital to conduct this study on the premises **(see appendix 3).**

Permission from participants was obtained with approved consent forms for data collection (x-rays; pelvic-and spinal parameters).

All of the information gathered was deidentified to ensure confidentiality, and a research number was provided to each patient's data sheet and measurements - this was entered on spreadsheet and analysed.

Only the researcher and supervisor have access to this data, and is stored on a password-protected Google Drive account.

Results

60 participants were included in this study. 50 patients known with degenerative lumbar disease in Group 1, and 10 participants as healthy volunteers with no lumbar disease, in Group 2. For group 1, the minimum age for a participant was 31 years, and 83 the maximum age. For group 2, the minimum age was 21, and the maximum age was 47. Convenience sampling was used in this study and each consecutive patient seen in the outpatient department, or admitted to the neurosurgery ward, meeting the inclusion criteria, was used in this study.

(A.) Descriptive Statistics:

Group	Participants	Male	Female	Mean Age	StdDev Age
1	50	17	33	55.96	11.34
2	10	8	2	38.10	10.37
Total:	60	25	35	52.98	12.97

Table 1 above reveals the participant demographics in Group 1 and Group 2, with a slight majority in females, with an overall mean age of 52 years.

(B.) Primary Outcome (First Objective):

The first primary objective for this study included the aim to describe the sagittal balance patients presenting with degenerative lumbar pathology. Sixty patients had standing x-ray's, from their cervical to lumbar spine, including their femoral heads. Sagittal parameters were measured with the aid of PACS software, as well a sagittal balance software package[13]. For the first objective, each parameter will be discussed to describe the sagittal balance in the fifty patients in Group 1. Nineteen participants of those known and whom presented with lumbar degenerative pathologies, presented with spines in balance, while 31 presented with compensated unbalanced spines.

(B.1) SVA:

The first parameter measured is the sagittal vertical axis. A positive balance indicates the C7 plumb line crosses the posterosuperior corner of the S1 vertebral body (more than two centimetres in ahead of it); a neutral balance indicates the posterosuperior corner of S1 is intersected by the C7 plumb line, while a negative balance indicates the plumb line is more than two centimetres below the S1 vertebral body's posterosuperior corner.

SVA	Result
Neutral	16
Negative	22
Positive	12

Table 2 above shows the results of these measurements.

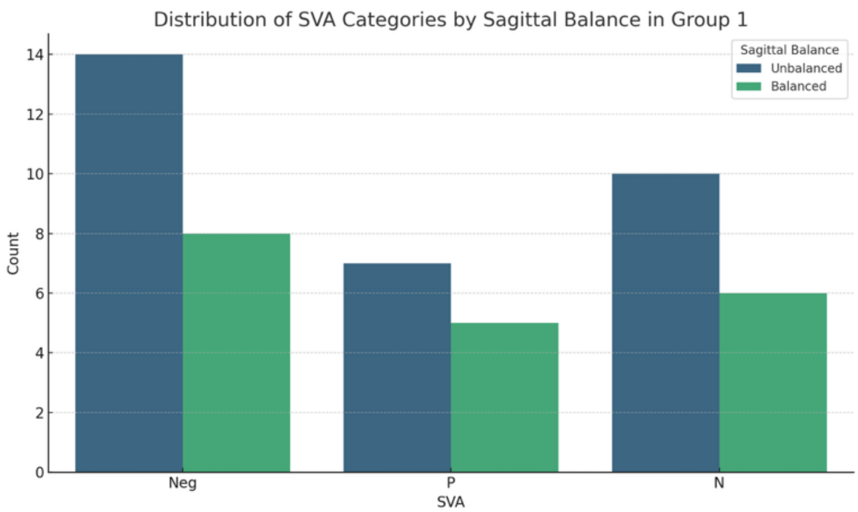


Figure 4 above is a bar plot graph, that shows how SVA distribution in Group 1 (patients with lumbar degenerative disease) is affected by Sagittal Balance (Balanced vs. Unbalanced).

Based on the data obtained from logistic regression analysis, SVA does not significantly determine whether a person has balanced sagittal profile among patients with lumbar degenerative diseases. The SVA coefficient is 0.1058 and p-value of 0.771 implies insignificance between them. A chi-square test of independence was also conducted in order to affirm this claim; however, based on the provided data, there was no relationship between SVA and sagittal balance in group 1 as indicated by P-value equaling to 0.954 which meant no association at all.

(B.2) Pelvic Tilt:

The second parameter corresponds to the angle between the line connecting the midpoint of the sacral plate to the bi-coxo-femoral axis and the vertical plane. The PT is a positional parameter.[3] It varies between 5° and 30°, with an average of 12°.[7]

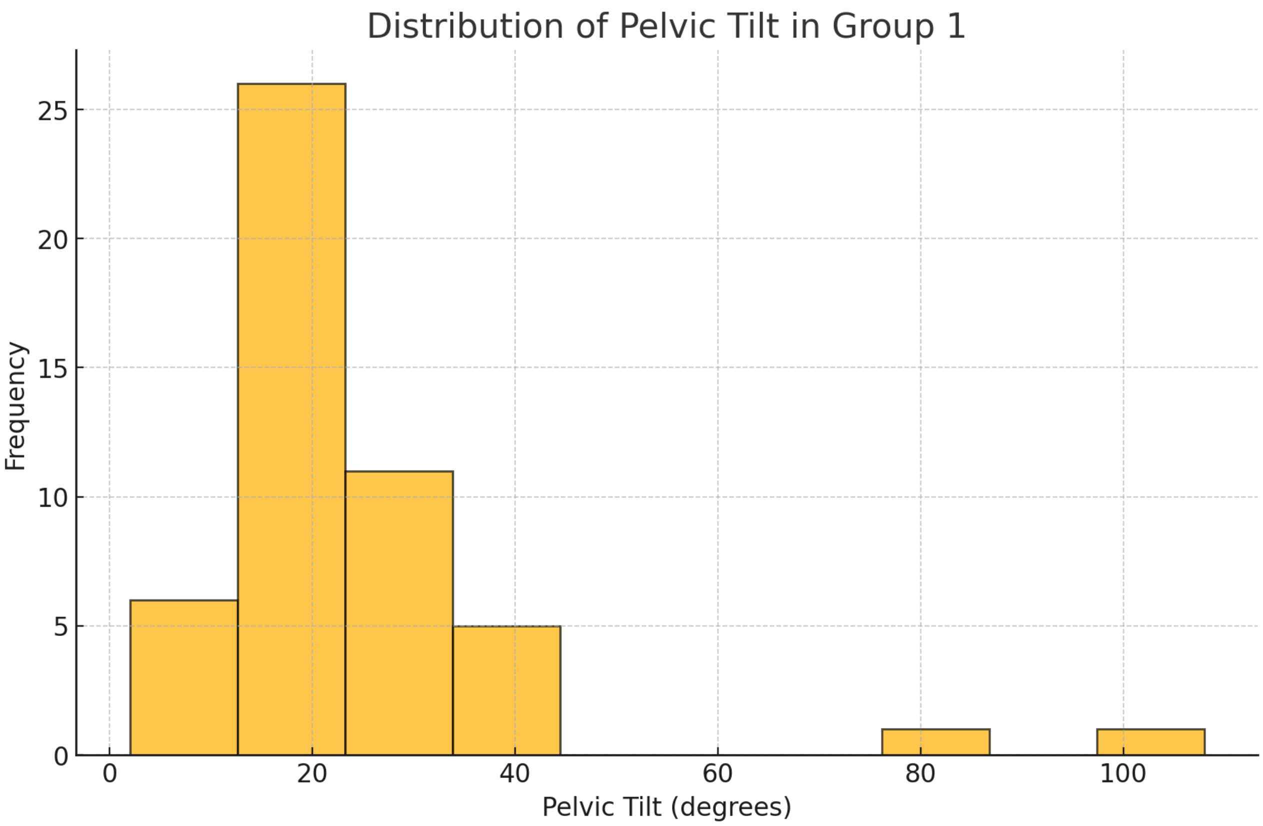
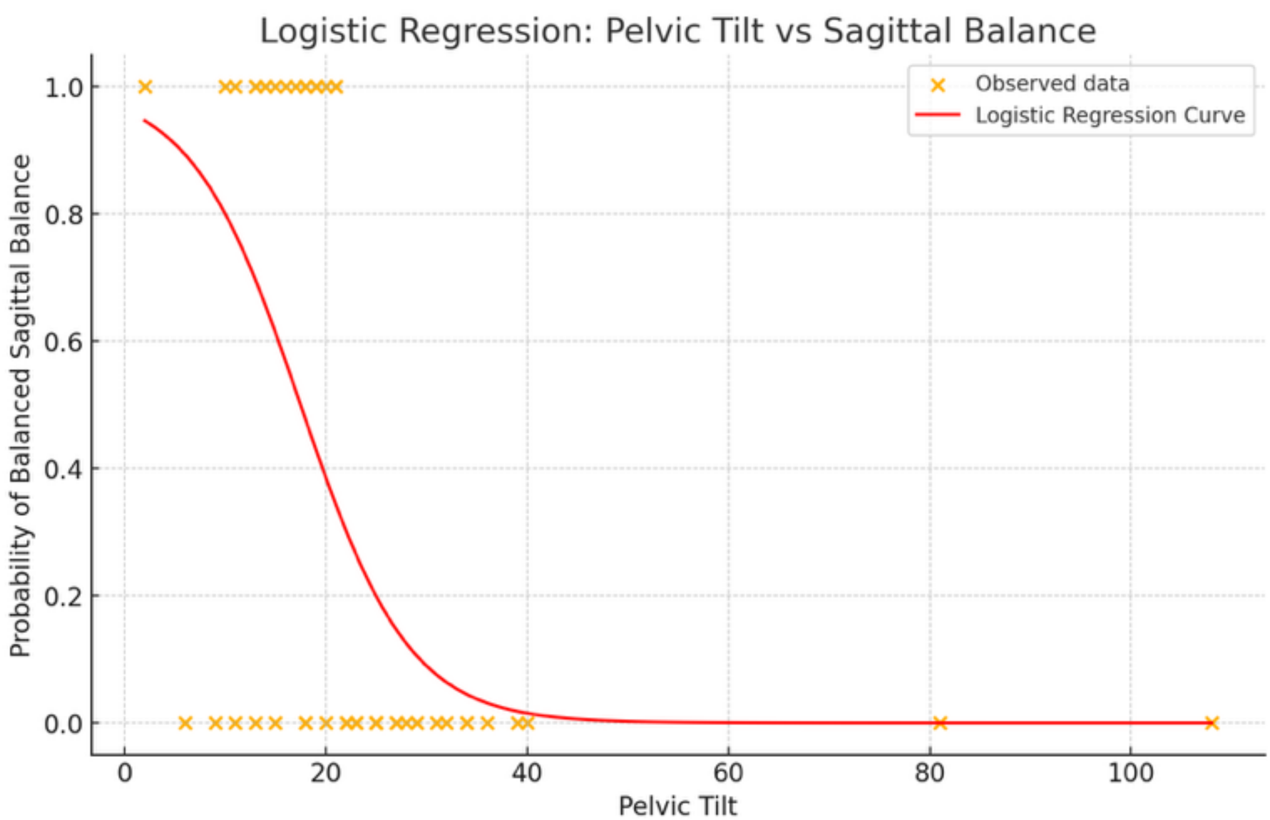


Figure 5 above shows the distribution of the PT parameter in patients in Group 1.

The descriptive statistics for Pelvic Tilt in participants with degenerative lumbar pathology showed mean PT of 23.9° (StdDev 16.94°; Med 20.5°; range 2-108°), thus giving a detailed account of pelvic tilt distribution across Group 1 members.
The relatively high standard deviation and wide range indicate a significant variability while regarding the result of the participant's pelvis tilt values (PT).

PT emerged as the most significant predictor for sagittal balance with a logistic regression analysis. A negative coefficient on PT implies that if Pelvic Tilt rises then the likelihood of having sagittal balance will decrease. This finding is statistically significant illustrated by a P-value of 0.0023 which is less than the usual significance level, 0.05.



In **Figure 6** above, a scatter plot graph is used to represent logistic regression curve that represents the probability of balanced sagittal balance depending on Pelvic Tilt.

The same data set was analysed using t-test and this confirmed the results indicating that there exists a statistically significant difference in Pelvic Tilt between balanced and unbalanced sagittal balance groups (P-Value = 0.00596 < 0.05).

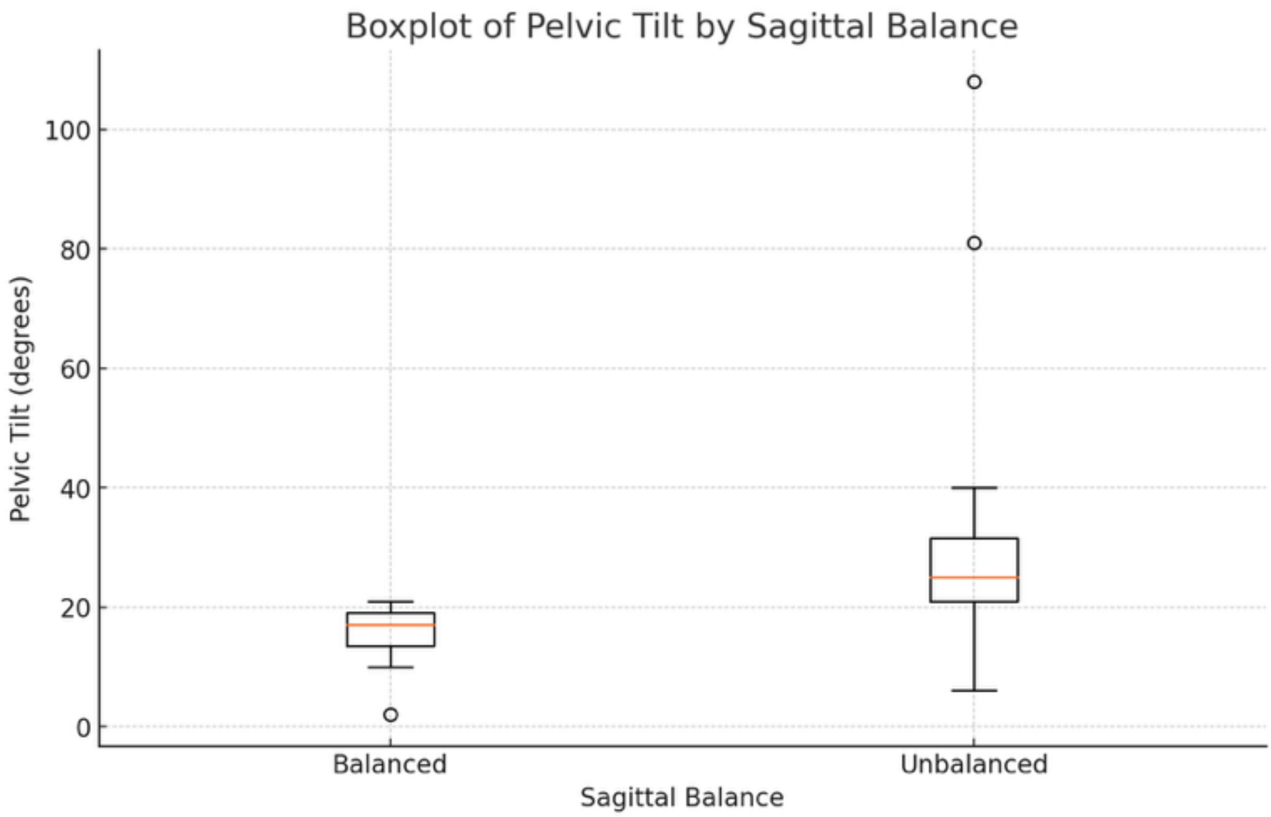


Figure 7 above is a boxplot graph illustrating the distribution of Pelvic Tilt values for both balanced and unbalanced sagittal balance groups.

(B.3) Pelvic Incidence:

The third parameter is defined as the angle between the perpendicular line to the sacral plate and the line connecting the midpoint of the sacral plate to the bi-coxo-femoral axis. The PI is a morphological parameter (a constant).

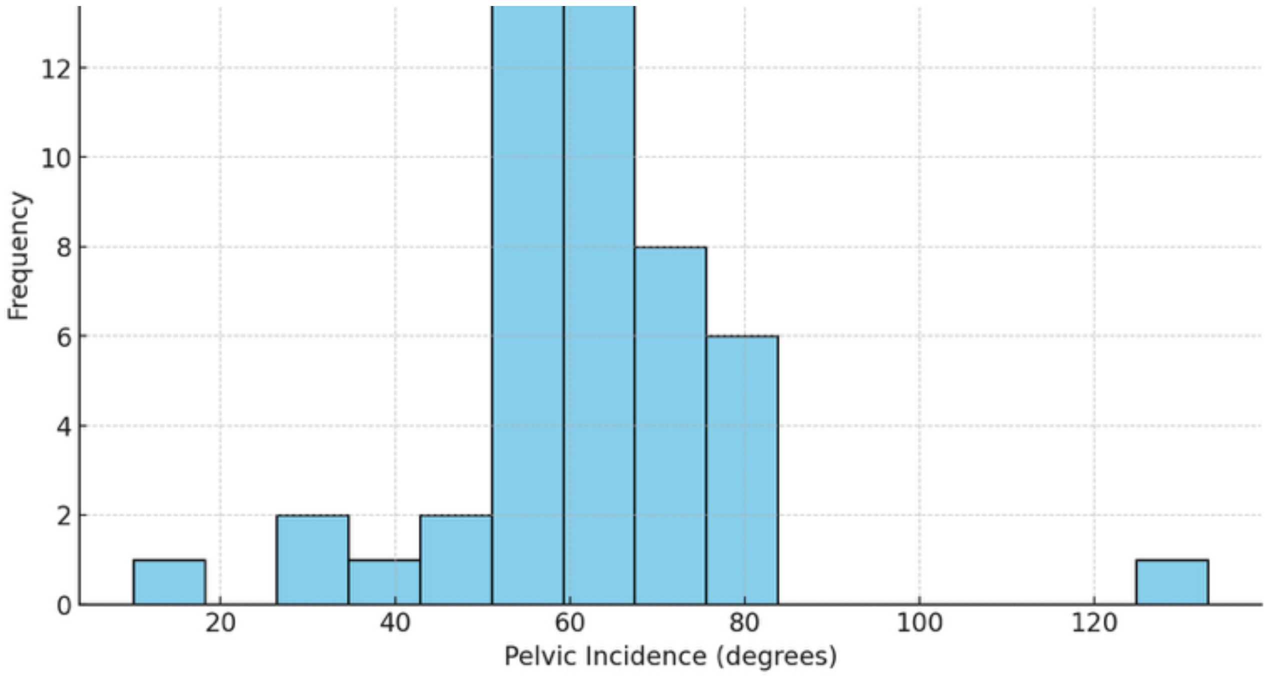


Figure 8 above is a graph that shows the distribution of Group 1's Pelvic Incidence values with a normal distribution depiction and some skewness toward higher value.

The mean for Pelvic Incidence in Group 1 is shown to be 62.14 degrees with a standard deviation of 16.92 degrees. A wide spread in pelvic incidence among the participants is indicated by the minimum and maximum values of 10.00 degrees and 133.00 degrees respectively.

According to logistic regression analysis, there was no significant association between Pelvic Incidence and sagittal balance (p=0.434). Thus, this means that in this dataset Pelvic Incidence does not significantly predict sagittal balance when using typical significance level of 0.05 as cutoff.

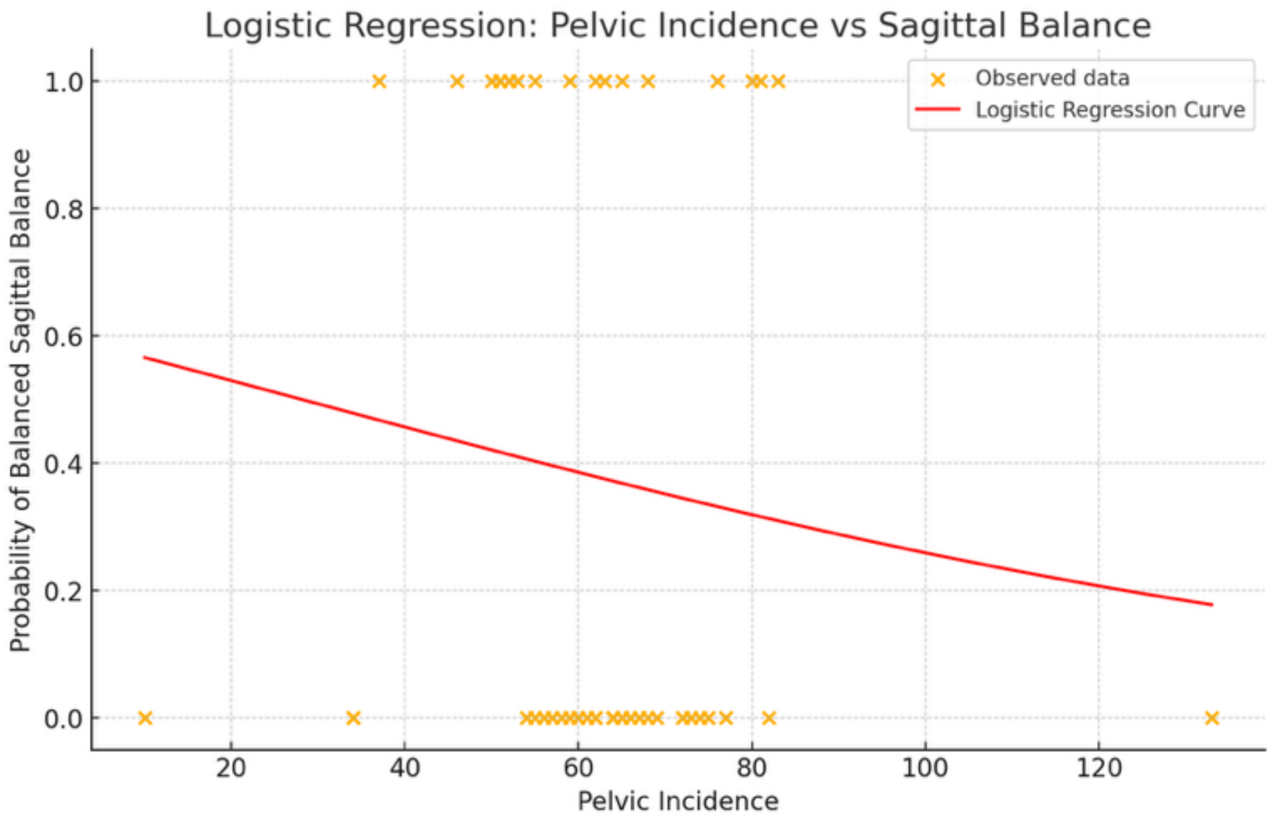


Figure 9 above displays a scatter plot showing the probability of balanced sagittal balance based on different levels of Pelvic Incidence according to logistic regression curve.

The results of t-test confirmed that there is no statistically significant difference between balanced and unbalanced groups on sagittal balance regarding their pelvis incidences (p-value = 0.4374 > 0.05), which means that mean pelvis incidence values are not significantly different between both groups of patients involved in the study.

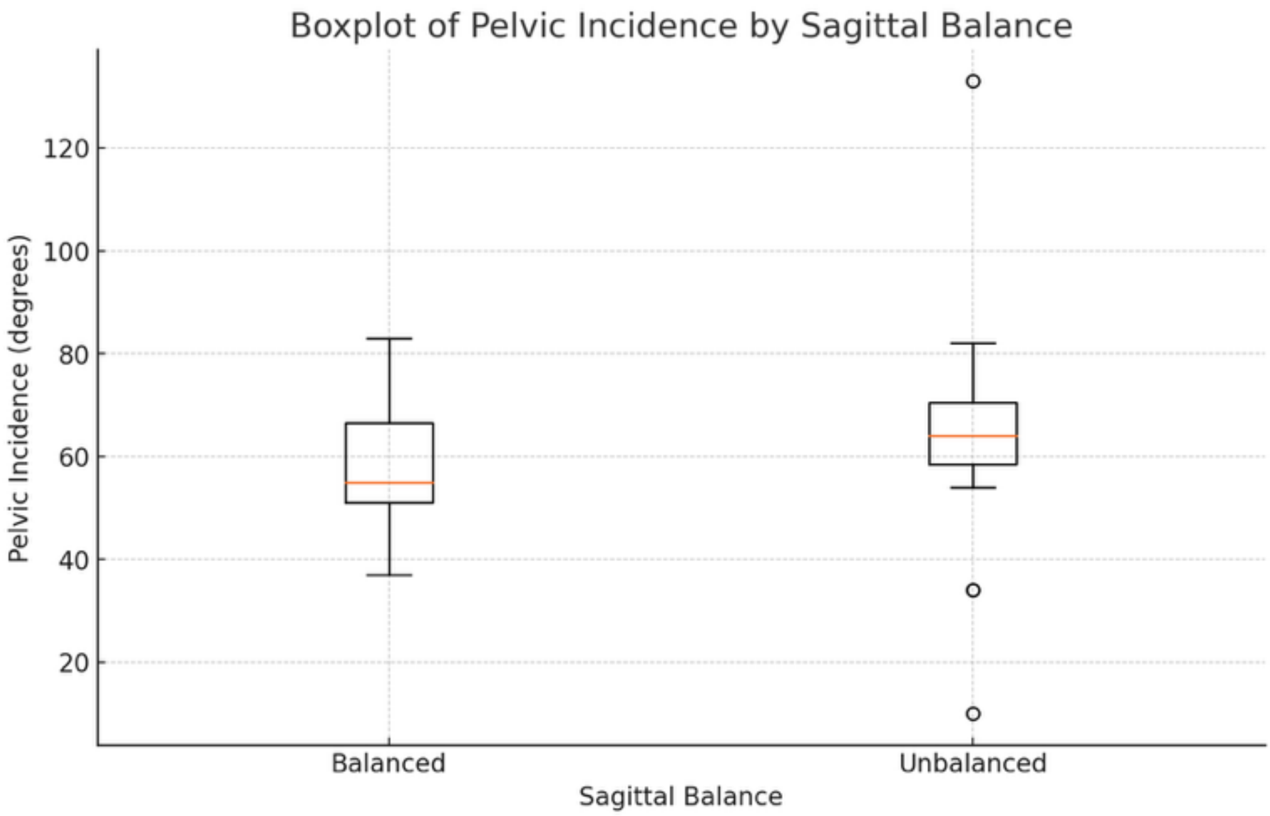


Figure 10 above illustrates a boxplot graph showing the distribution of PI values in both the balanced and unbalanced sagittal balance groups.

(B.4) Sacral Slope (SS):

The fourth parameter, SS, corresponds to the angle between the sacral plate and the horizontal plane.

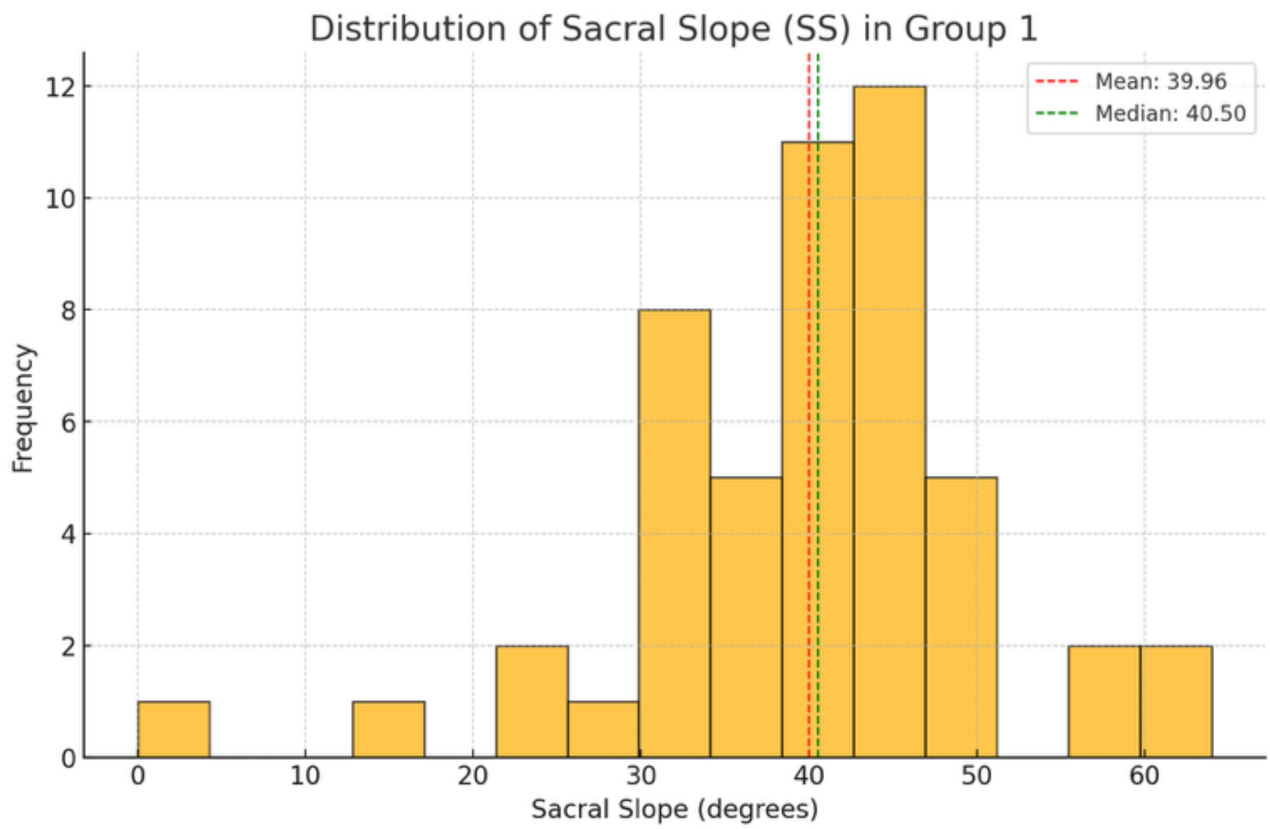
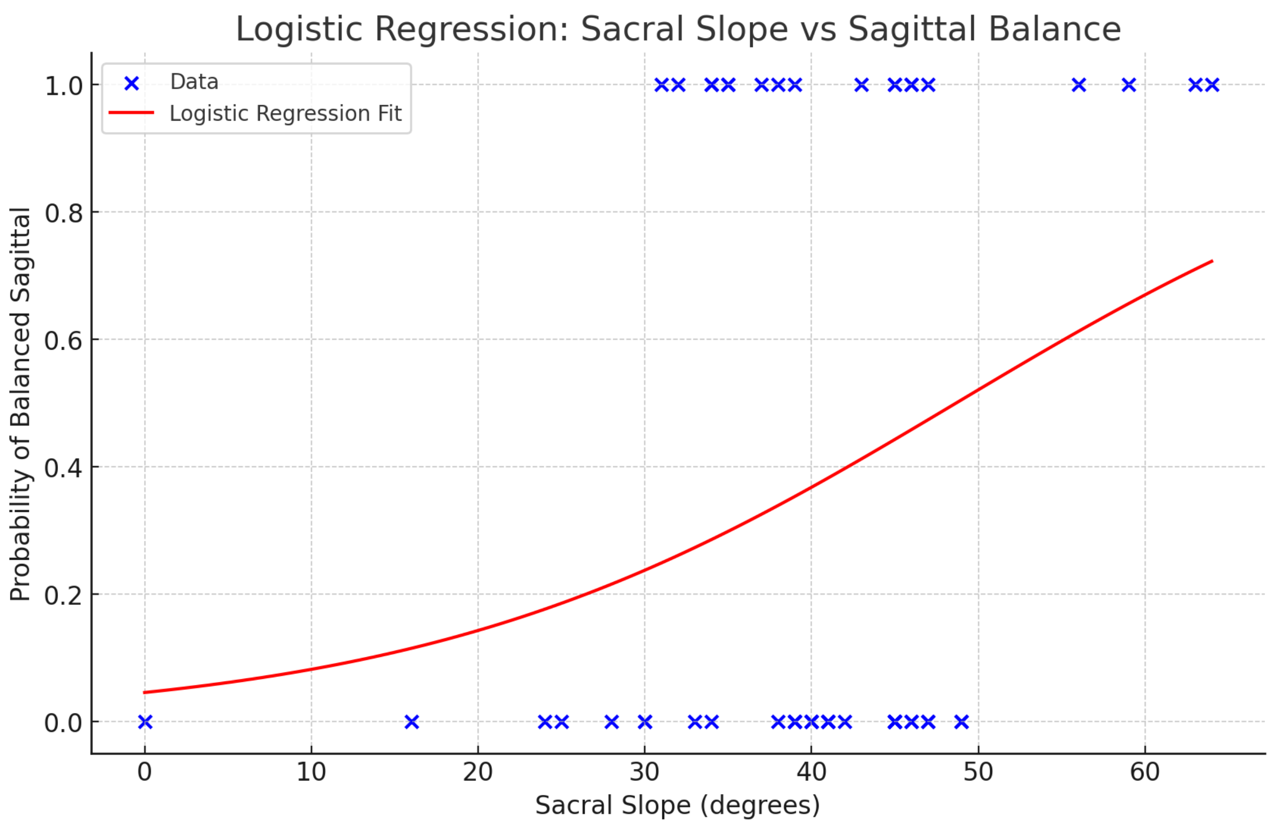


Figure 11 above is a histogram showing the distribution of sacral slope values in Group 1. The distribution is relatively spread out, with most values clustered around the mean and median, indicating a diverse range of sacral slope angles among participants with lumbar degenerative disease.

The mean value of SS in Group 1 is 39.96 degrees with a standard deviation of 10.82 degrees, while the minimum and maximum values are 0 degrees and 64 degrees respectively. These statistics suggest a moderate level of variability in SS among participants Group 1. The mean and median values are almost equal, which means that there is a relatively symmetrical distribution for SS scores. Nevertheless, the wide range and standard deviation indicate that some individuals have much higher or lower SS than the average.

Logistic regression analysis indicated a positive coefficient for SS, implying that as the SS increases, so does the probability of maintaining sagittal balance increase. However, due to its p-value (0.07) being slightly above typical significance level (0.05), this result cannot be considered statistically significant. In fact, since zero falls within the confidence interval it implies that our relationship might also not be significant. This trend suggests that sacral slope alone may not be a strong predictor of sagittal balance in this group, although it might be interesting to explore this further with respect to sample size.



The scatter plot graph on **figure 12** above shows the relationship between sacral slope and sagittal balance in group 1.

T-test results show that there is a trend towards differences in sacral slope between patients with balanced and unbalanced sagittal balance but such difference does not have statistical significance at p=0.05 level (p = 0.059). This implies that while there may be certain relationship between sagittal balance and sacral slope; however, in this current sample it has not been established to be different enough to be considered important.

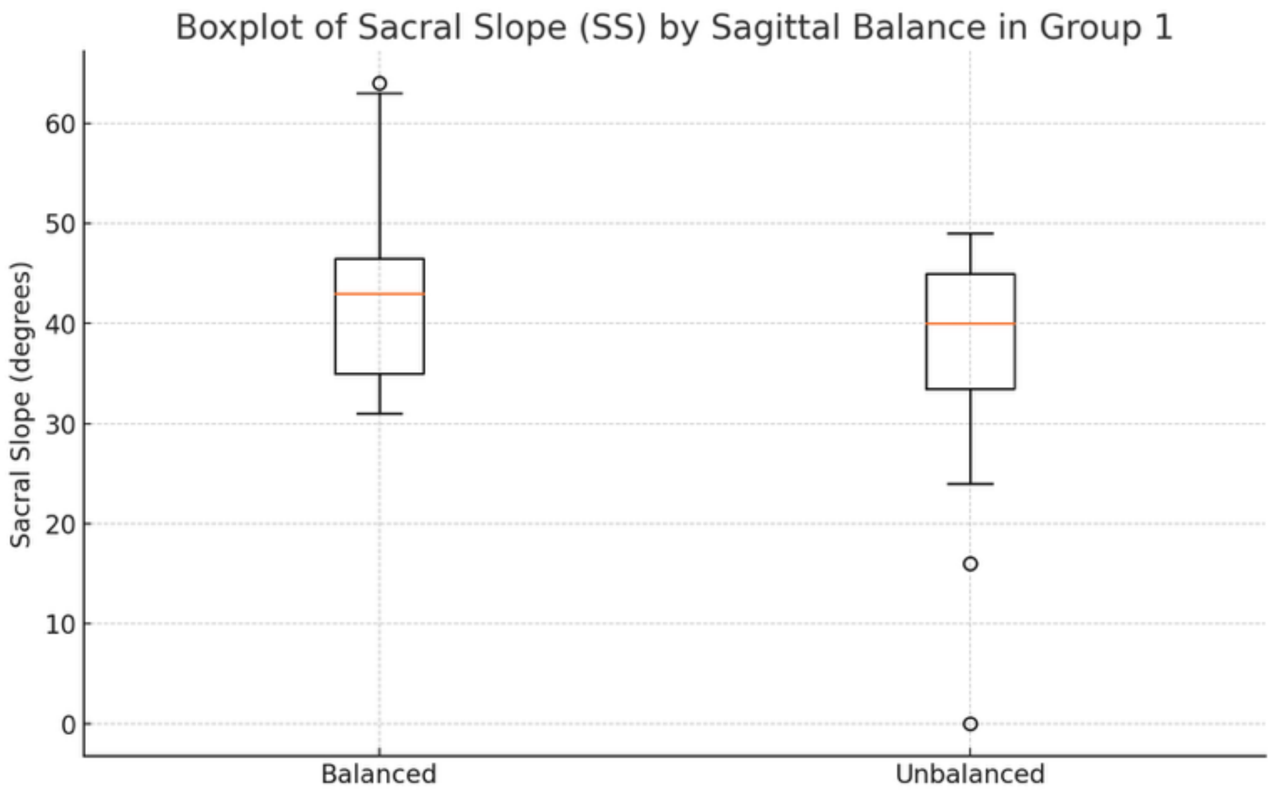


Figure 13 above, a boxplot graph, shows the distribution of sacral slope values for patients with balanced and unbalanced sagittal balance (Group 1):

(B.5) Lumbar Lordosis:

The fifth parameter, LL, is defined as the extension spinal segment above the sacral plate.

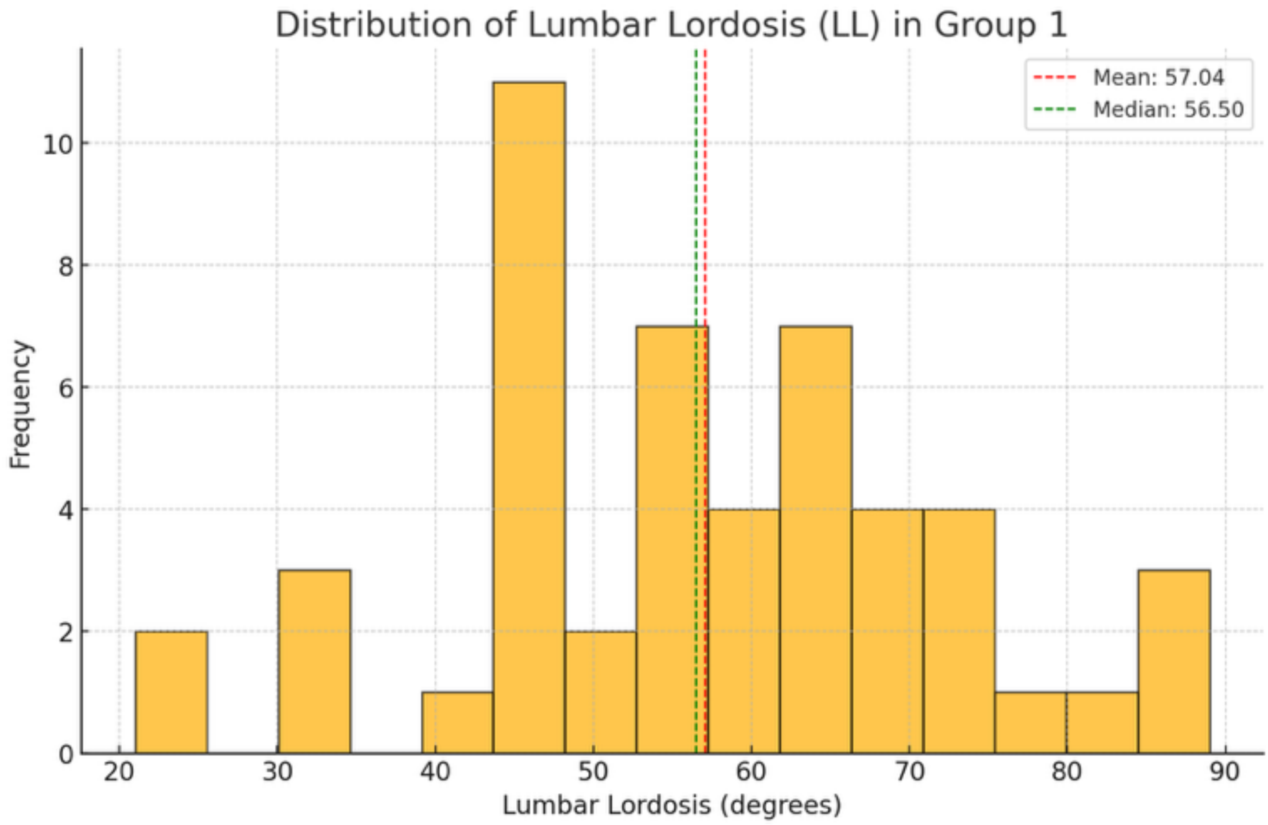
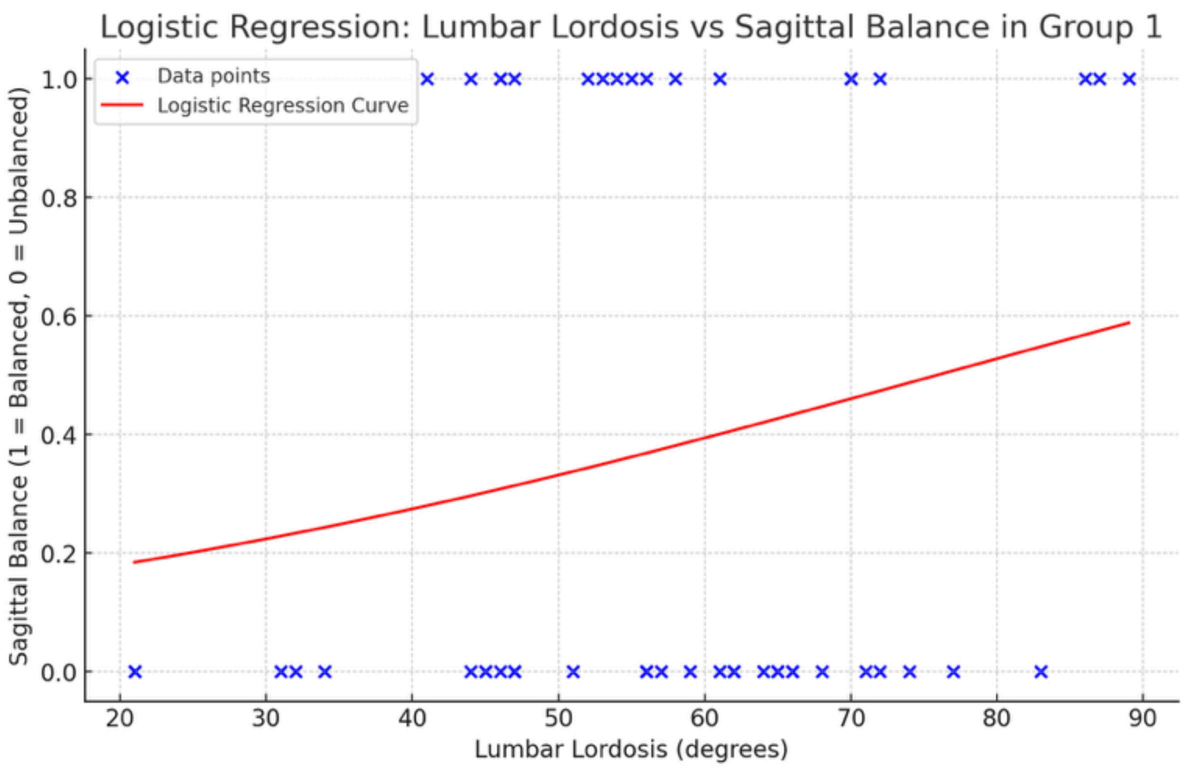


Figure 14 above is a histogram illustrating the distribution of lumbar lordosis values in Group 1. The distribution is relatively spread out, with most values clustered around the mean and median, indicating a diverse range of lumbar lordosis angles among patients with lumbar degenerative disease.

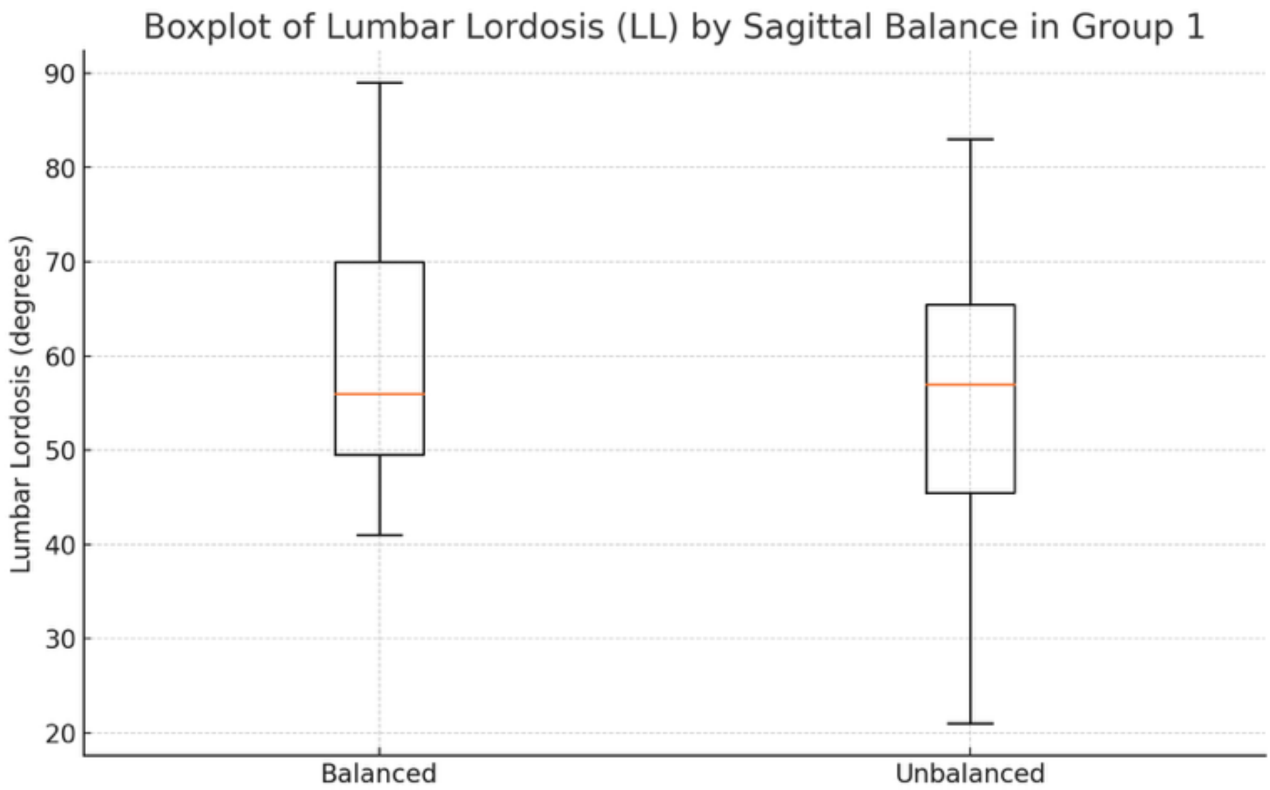
However, descriptive statistics for LL reveal a mean lumbar lordosis of 57.04 degrees among participants with lumbar degenerative disease, which implies that the lumbar spine in this group has typical curvature. The median value of 56.5 degrees means that half of the participants have a lumbar lordosis below and above this measure showing central tendency like the mean. A standard deviation of 15.64 degrees represents a wide variation about the mean reflecting on distribution among patients' lumbar lordosis. Ranging from 21 to 89 degrees, there is an immense variance in terms of curvature, some having very low or very high values.

The logistic regression results do not indicate any significant relationship between sagittal balance and lumbar lordosis. The p-value for the coefficient assigned to lumbar lordosis is 0.176 which exceeds the generally acceptable significance level of 0.05; hence it follows that in this data set; this makes lumbar lordosis not be a considerable predictor of sagittal balance.



Above is **figure 15**, a scatter plot graph illustrating how Group 1 falls within a range of sagittal balance by degree of abnormality in LL.

The results of the t-test indicate that there is no significant difference in lumbar lordosis between the group with a balanced spine and the one with an unbalanced spine ($p = 0.171 > 0.05$). It follows, therefore, that mean values for both groups are statistically equal.

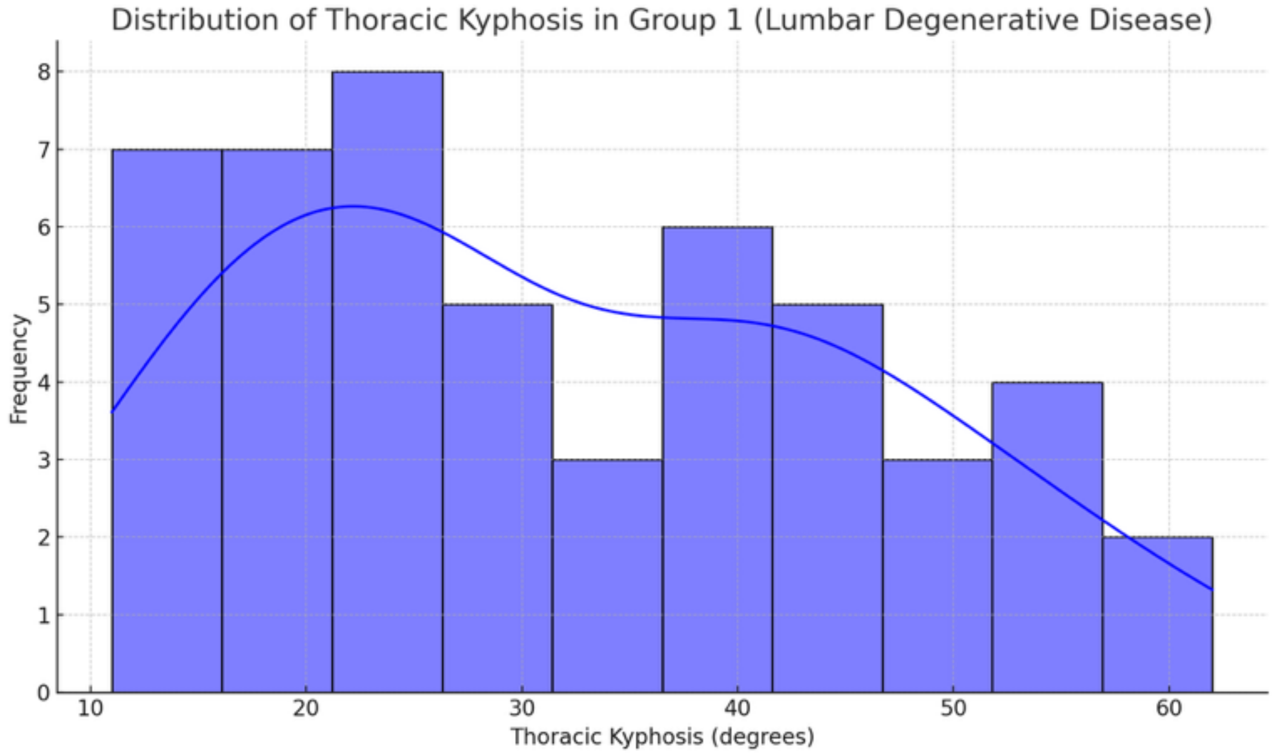


Above (**Figure 16**), a boxplot diagram illustrates distribution of lumbar lordosis values within participants belonging to Group 1 according to whether their sagittal balance was balanced or not.

(B.6) Thoracic Kyphosis:

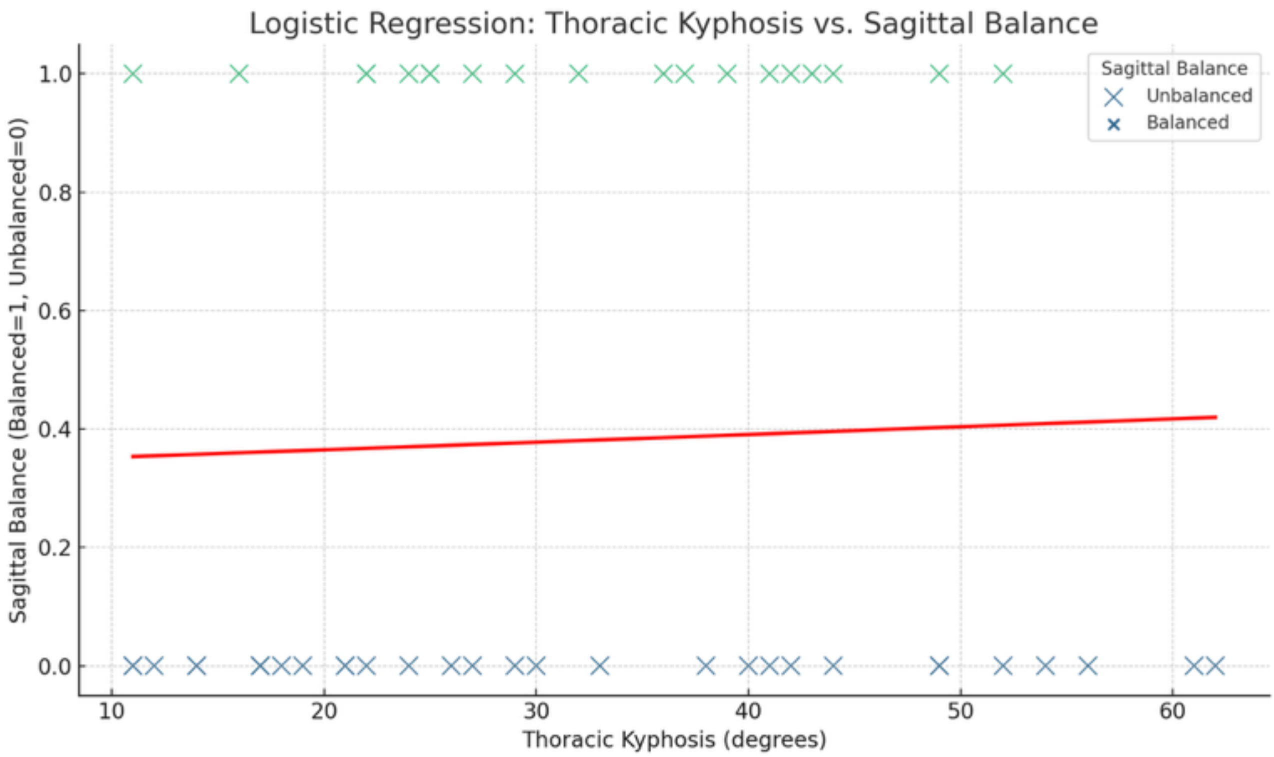
Although not part of the objective, thoracic kyphosis was easily described as an additional parameter while analysing the standing x-rays in the patients.

In Group 1 descriptive statistics of thoracic kyphosis show a standard deviation (SD) of 14.26° which indicates considerable variability around the mean value of 31.74°. The interquartile range (IQR) spans from 21.00°to 42.00°, with a minimum value at 11.00° and maximum value at 62.00° degrees. This implies that among patients suffering from lumbar degenerative disease, there exists much diversity regarding the degree of spinal curvature in this population.



As depicted in **Figure 17** above, this distribution graph demonstrates this variability, emphasising the spread of thoracic kyphosis data points, and showing a relatively normal distribution (noted some skewness towards higher values).

Logistic regression analysis revealed that Thoracic Kyphosis is not a significant predictor for balanced sagittal profile in patients with lumbar degenerative disease; p=0.790, thus suggesting no statistical significance between these two variables (coefficient=0.0055).



The scatter plot graph above **(Figure 18)** shows the distribution of thoracic kyphosis against the corresponding sagittal balance status (where balanced is represented by one and unbalanced represented by zero). The red line on this graph represents the logistic regression line - predicting probabilities of maintaining balance, based on the Thoracic Kyphosis values .

As also confirmed by t-test, there was also no statistically significant difference in the average values of thoracic kyphosis in Group 1, between those who balanced sagittal profiles, and those who did not (p-value was 0.778).

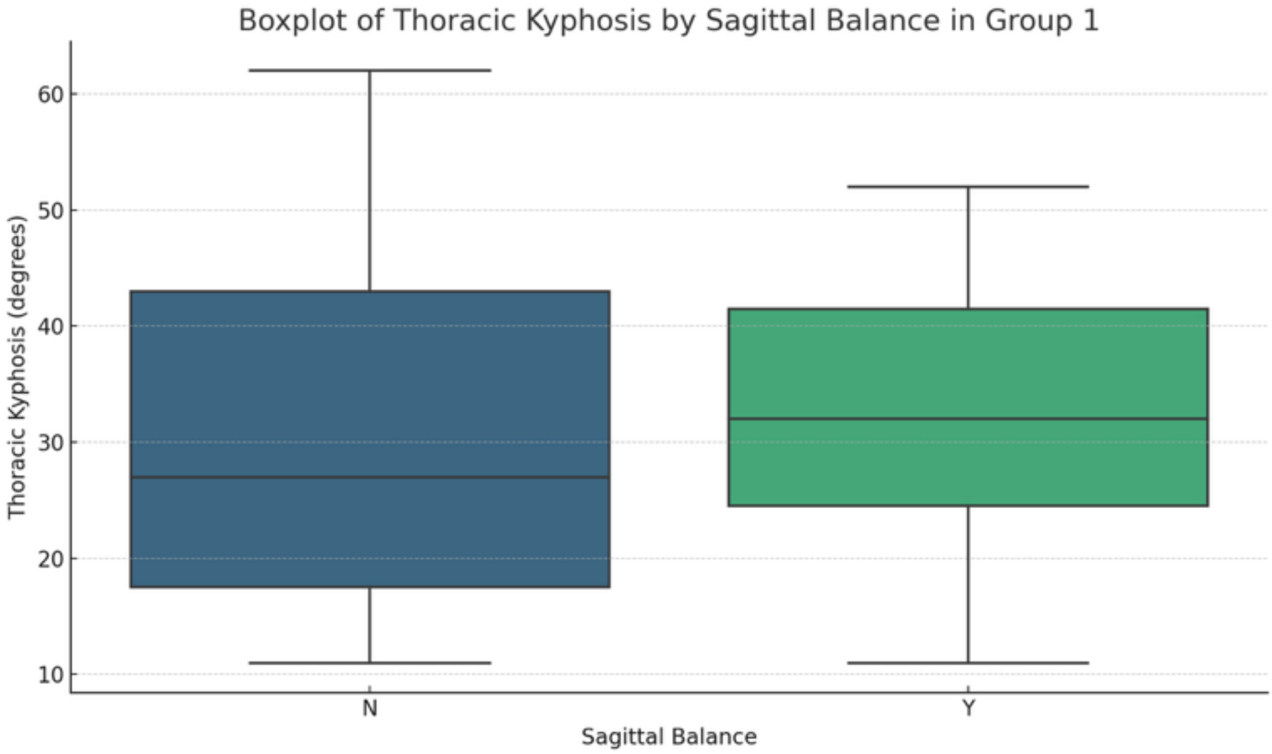


Figure 19 is a boxplot graph showing the distribution of Thoracic Kyphosis Values by Sagittal Balance (Balanced vs. Unbalanced) in Group 1.

(C.) Primary Outcome (Second Objective):

The second primary objective for this study was to compare the sagittal balance of patients with lumbar degenerative pathology to healthy volunteers (50 patients in Group 1 versus 10 control participants in Group 2). For tor the second objective, each of the parameters will be compared between the two groups for a statistical significant difference.

(C.1) SVA:

Group	Negative	Neutral	Positive	Total
1	16	22	12	50
2	5	1	4	10
Total	21	23	16	60

Table 3 shows the distribution of either a negative SVA, positive SVA, or neutral SV in both groups 1 and 2.

The Chi-Square test performed on these data points gave a p-value of 0.13 (>0.05). We can therefore conclude that there are no significant differences found in SVA categories distribution (Negative, Neutral, Positive) between Group 1 (lumbar degenerative disease) and Group 2 (healthy participants). Observed variations might be due to chance rather than reflecting the relationship between sagittal balance and lumbar degeneration pathologies.

In **Figure 20** above, the bar plot graph illustrates the distribution of SVA categories within both groups, visually confirming the lack of any substantial differences among them.

(C.2) Other parameters: PI, PT, SS, LL, TK:

For the other parameters, including thoracic kyphosis as an additional parameter interpreted, independent t-tests were used to compare the data between the groups.

Parameter	Group 1 (Mean +- SD)	Group 2 (Mean +-SD)
Pelvic Incidence	62.14 ± 16.92	59.4 ± 10.89
Pelvic Tilt	23.9 ± 16.94	11.3 ± 4.97
Sacral Slope	39.96 ± 10.82	47.6 ± 10.98
Lumbar Lordosis	57.04 ± 15.64	57.9 ± 10.62
Thoracic Kyphosis	31.74 +- 14.26	23.2 +- 9.87

Table 4 above shows the mean and standard deviation for each parameter, expressed in degrees.

(i) **Pelvic Incidence:** The independent t-test was used to compare the mean PI between Group 1 and 2; this returned a p-value of 0.52 (not statistically significant).

(ii) **Pelvic Tilt:** The independent t-test comparing the mean PT between Group 1 and 2 returned a p-value of <0.001, (statistically significant difference). This indicates that patients with lumbar degenerative pathology seems to have a higher pelvic tilt as compared to healthy volunteers.

(iii) **Sacral Slope:** The independent t-test for the average SS between Group 1 and 2 returned a p-value of 0.07 (no statistically significant difference), however, it is very close to the significance threshold.

(iv) **Lumbar Lordosis:** The independent t-test comparing the mean LL between Group 1 and 2 returned a p-value of 0.83 (not statistically significant).

(v) **Thoracic Kyphosis:** The independent t-test was lastly used to compare the average TK between Group 1 and 2; this returned a p-value of 0.03 (statistically significant).

The independent t-test results suggest that pelvic tilt is significantly higher in individuals with lumbar degenerative disease than healthy controls, implying these patients depend more on rotating the pelvis to maintain balance. Other parameters including pelvic incidence, sacral slope and lumbar lordosis show no statistically significant difference between the groups. Chi-square test results for sagittal balance between the two groups (p=0.0012) indicate a significant difference exists in this variable among those diagnosed with LDD as compared against healthy participants where by patients suffering from lumbar degenerative pathologies are more likely to have an imbalanced sagittal profile than their counterparts - 31 subjects in group 1 had an unbalanced spine with compensatory mechanism. Such marked variation emphasizes the impact of LDD on maintenance of Sagittal Balance which highlights such importance for clinical assessment and treatment planning.

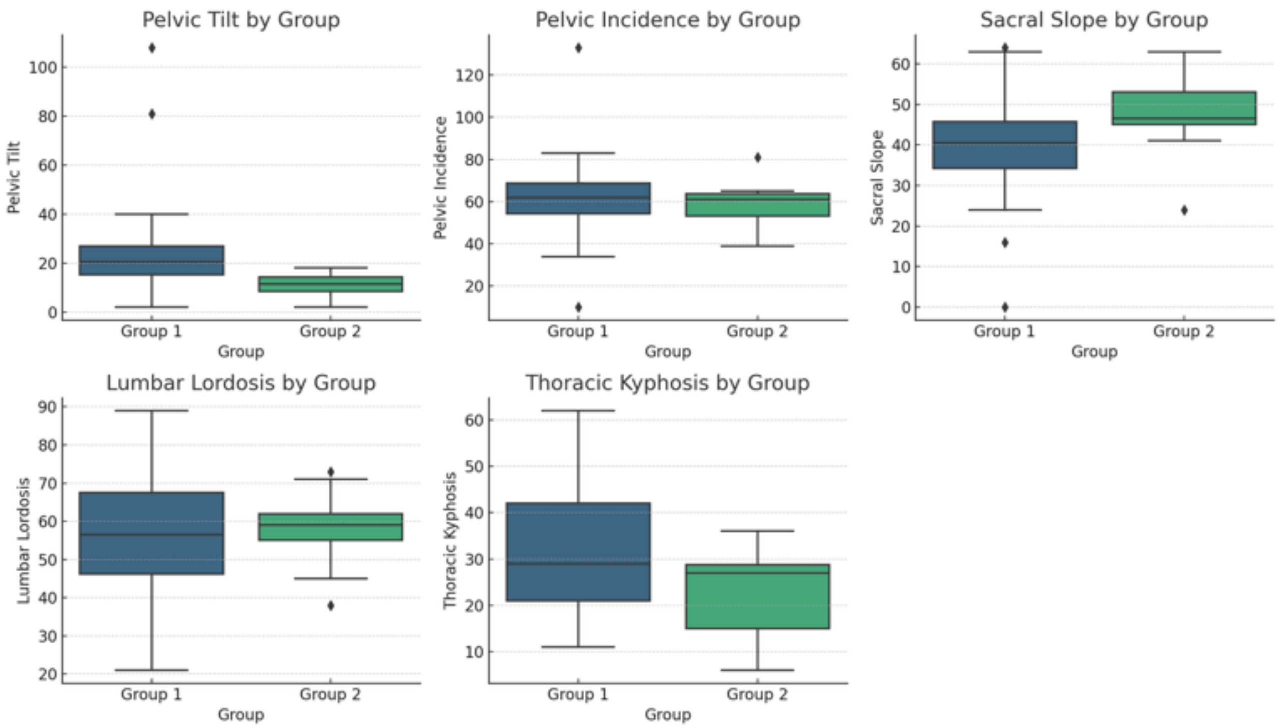


Figure 21 above is a series of box plot diagrams representing the distribution of values for each parameter between Group 1 and Group 2; hence visually confirming findings from the statistical tests.

(C.3) Multivariate Test Results:

In terms of the MANOVA results, there is a statistically significant difference in all sagittal balance parameters when regarded together (Pelvic Tilt, Pelvic Incidence, Sacral Slope, Lumbar Lordosis, Thoracic Kyphosis) between Group 1 (lumbar degenerative disease) and Group 2 (healthy participants). The p-value recorded was 0.0289 (<< 0.05). In addition, MANOVA shows that there exist multivariate effects on sagittal balance parameters due to grouping variables - this means that the overall profile differs across various individuals having different health statuses (in particular when it comes to people suffering from LDD). This affirms that a comprehensive examination should be performed when consulting these patients, taking as many of the parameters into regard.

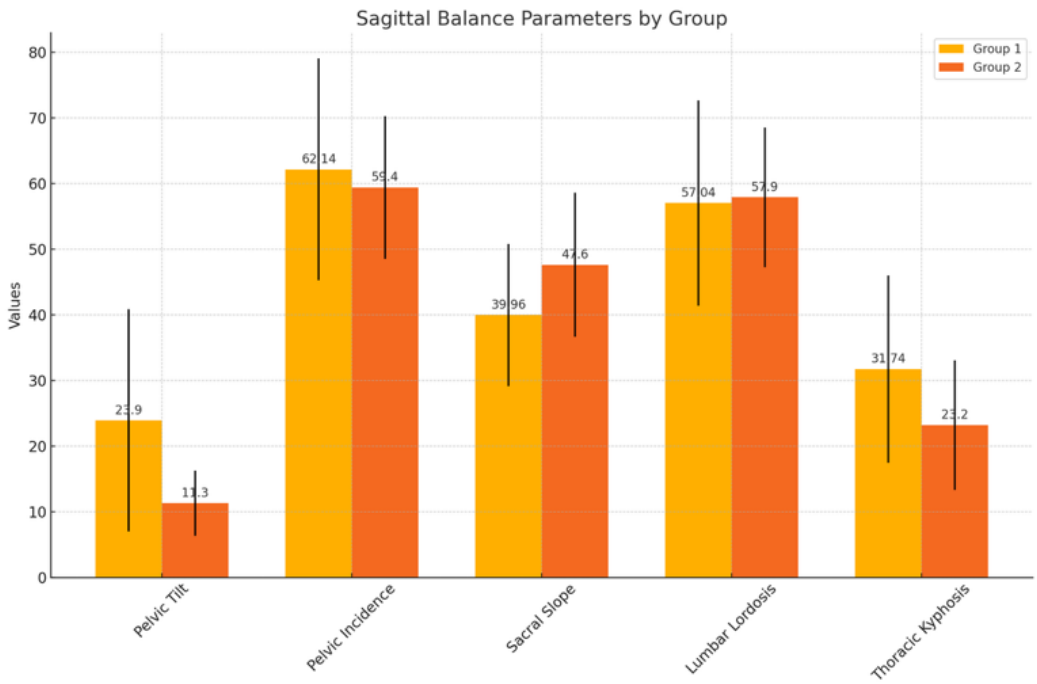


Figure 22 above is a bar chart showing the mean values and standard deviations for the sagittal balance parameters (Pelvic Tilt, Pelvic Incidence, Sacral Slope, Lumbar Lordosis, Thoracic Kyphosis) between Group 1 (lumbar degenerative disease) and Group 2 (healthy participants).

Mean values for each parameter are represented by bars, while error bars indicate standard deviation. This gives an idea of of the variation that exists within every category considered here. For instance PT and TK are greatly different, which is in line with the previously mentioned significant t-test results. However, PI, SS and LL do not demonstrate any noticeable dissimilarity (as predicted by these same tests).

(D.) Pelvic Harmony:

After measuring the parameters in the primary objectives, the pelvic harmony between the two groups could also be assessed. The LL should be within 9 - 10 degrees of PI to be regarded as having "pelvic harmony"

Group	Abnormal	Normal
1	22	28
2	0	10

Table 5 above clearly illustrates the differences between the pelvic harmony in groups 1 and 2. Pelvic harmony is regarded as "Abnormal" when the equation PI minus LL reveals a value less than -10 degrees or more than +10 degrees. A "Normal" pelvic harmony is regarded as a value between -10 and +10 degrees.

A chi-square test was conducted, and it showed that there is statistical difference in the distribution of pelvic harmony between Group 1 and Group 2 according to the results ($p = 0.02$). A higher number of patients suffering from degenerative lumbar pathologies (Group 1) showed abnormal pelvic harmony, while healthy volunteers (Group 2) did not. It implies therefore that those suffering from lumbar degenerative pathologies are more likely to have no harmonious relationship between their pelvic incidence and lumbar lordosis values.

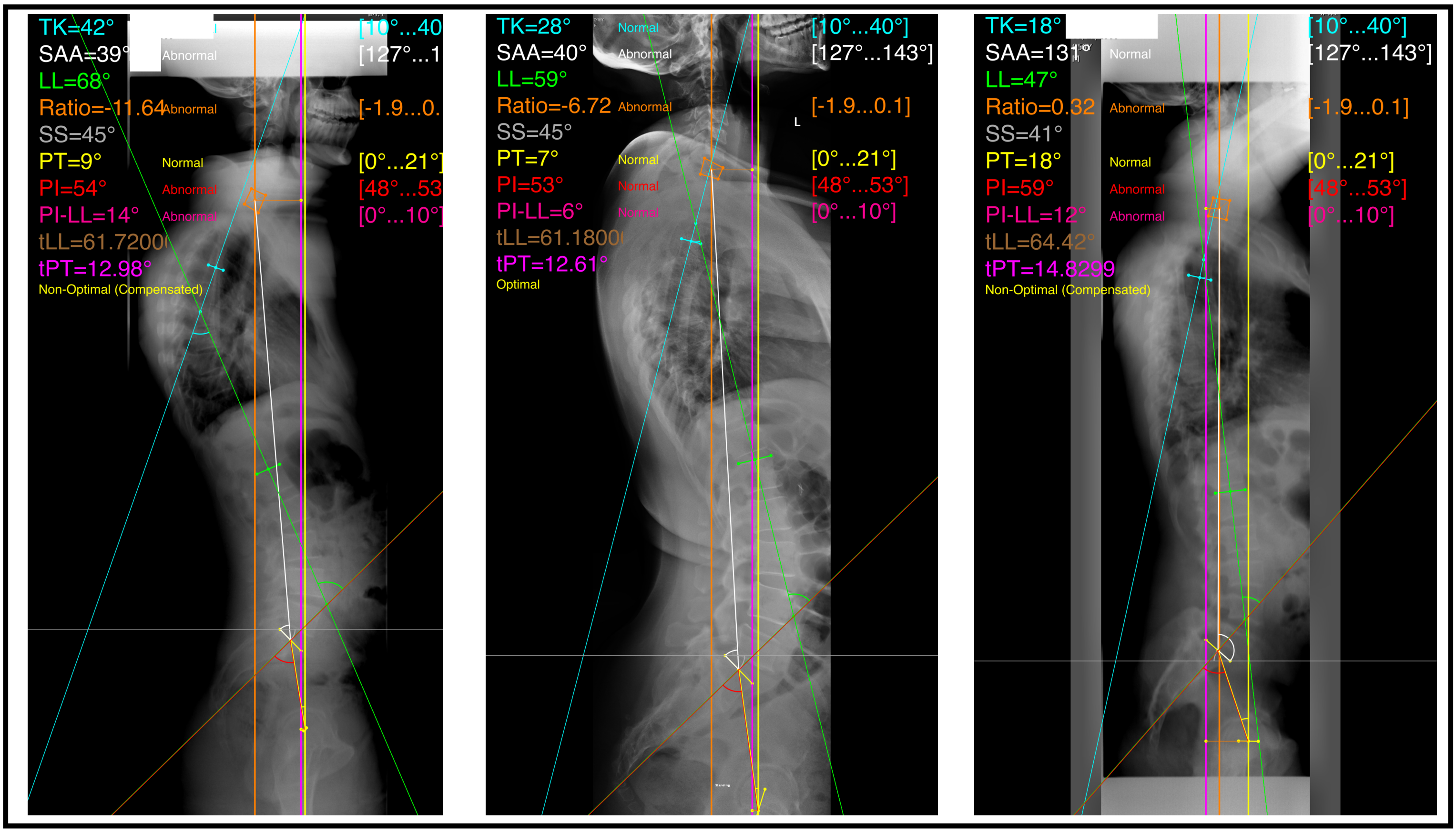


Figure 23 above illustrates the sagittal parameter measurements done on 3 participants in this study.

Discussion

The degenerative spinal disorders are characterized by abnormal spinal structure, and loss of normal spine functions mostly at the lumbar spine[19]. Physical aging is the prime cause of spinal degeneration, which has become a major source of chronic disabling disease. These conditions include lumbar disk disease (LDDD), stenosis, spondylolisthesis, facet joint arthropathy, and degenerative scoliosis[20].

Jean Dubousset first described the notion of spinopelvic alignment as a “cone of economy.” This concept states that the axial skeleton must be balanced directly over the pelvis, lower extremities and feet[25]. From this principle, light has been shed on many significant sagittal alignment parameters in spinal deformity literature over the past few decades, which ultimately underscores the importance of a harmonious spine[26]. However, a new paradigm has emerged and sagittal alignment is increasingly being recognized for its significance in evaluating and managing patients with degenerative spinal conditions - these spinopelvic parameters have become popular in predicting outcomes among patients with degenerative spinal diseases (DSD)[21].

For instance, abnormal sagittal balance parameters are observed in degenerative diseases like LDD and low back pain. However, it is important to distinguish these from age related changes. Numerous compensatory mechanisms were described by Barrey et al[22]. Degenerative spondylolisthesis is described as being a major factor behind imbalance; while degenerative scoliosis was also always associated with having a compensated balance. Both these conditions can be associated with patients complaining of backache, thus indicating that correcting this imbalance and sagittal profile had the potential to relieve backache.

Little attention has been paid to sagittal balance in relation to patients with symptomatic lumbar degenerative spondylolisthesis (especially when one looks at pelvic incidence as a possible predictive factor). High PI seems to be indicative of occurrence of degenerative disease[21]. In fact, people with higher pelvic incidences (PI) run higher risks of suffering from spondylolisthesis, and patients with extremely high PI values are more likely to develop two level diseases[24]. The application of sagittal alignment principles could enhance results in lumbar degenerative disease. Improvement in postoperative PT implies good clinical outcome[23]. The importance of compensatory changes in pelvic attitude and their possible functional consequences on sagittal balance are widely recognized.

Primary Outcome and analysing the Parameters:

Our SVA analysis shows that it does not predict sagittal balance among patients with lumbar degenerative diseases. Variations in SVA observed did not reveal any statistically significant relationship with sagittal balance. This suggests that even though SVA is a widely used parameter in clinical settings, this might not be the most important aspect for assessing sagittal balance in such patients. The absence of a significant association implies other factors could contribute more to achieving or maintaining sagittal balance, and the assessment of multiple parameters in clinical practice is vital.

Pelvic tilt was identified as one of the key factors affecting the stability of spinal alignment in people suffering from lumbar spine degenerative changes. A large number of individuals had different PT values within their group, signifying diverse postures, orientations of their pelvis, and compensatory mechanisms. It is also worth noting that there was significant correlation between PT and sagittal balance, meaning high values indicate an imbalanced sagittal state. This therefore implies that PT should be closely monitored during clinical assessments aimed at establishing whether or not someone has a balanced profile.

The range exhibited by PI values among participants was quite variable, but none correlated significantly with sagittal balance.

Among participants, SS showed a large variation, meaning a diverse number of pelvic orientations in these groups. No statistical correlation was found between SS and SB; a trend suggested a possible association, however it was not regarded as significant alone. SS therefore can’t bet regarded as a strong single parameter to predict sagittal balance in this group of patients, and thus again necessitating the need for a more comprehensive approach to clinical management strategies.

Lumbar lordosis also had considerable variability reflecting various degrees of spinal curvatures among participants in this study. However, no significant correlation could be found between LL and SB. Although vital to assess for spinal curvature, LL may not be a critical factor in assessing the sagittal balance profile in patients presenting or known with lumbar degenerative disease.

TK has wide variations across patients suffering from LDD, but it does not have significant influence over sagittal balance. This study therefore emphasizes on the importance considering multiple indices during evaluation of the sagittal balance profile.

Literature Review:

The findings of this study offer some understanding between lumbar degenerative pathologies and sagittal balance parameters. Existing literature can be compared with our conclusions so as to put them into context.

What we discovered was that PT is significantly higher in patients who have lumbar degenerative diseases as compared to healthy individuals; also an unbalanced sagittal profile is associated with increased PT. It has been recognized that pelvic tilt serves as a compensatory mechanism for maintaining sagittal balance in patients having spinal pathologies. Lafage explained how increased PT helps to realign the center of gravity by compensating for anterior displacement due to lumbar degeneration[28]. This finding supports our observation too that PT increases with lumbar degeneration in order to keep balance.

TK was found to be significantly higher among patients than in healthy volunteers but within patient group TK does not significantly differentiate balanced from unbalanced profiles. Several studies indicate that increased thoracic kyphosis is common compensation mechanism in those suffering from lumbar degenerative pathologies. According to Glassman, higher values of TK are often accompanied by lumbar degenerative diseases as the spine tries adapting itself so that overall sagittal alignment can be maintained[29]. Our results confirm this finding, showing higher TK values among patients, but lack significant distinction within the patient group. This implies that alone it cannot determine sagittal balance, as also noted by Schwab et al[30].

PI did not show any significant effect on sagittal balance within the patient group either. PI it is known to be an anatomical constant which does not change with posture or disease process. Jackson emphasized that PI is a morphological constant which remains unchanged no matter how much degeneration occurs in the spine[31]. Our result support this view point, since PI appeared as an inherent stable parameter.

SS had some variability, yet there were no statistically significant differences between groups, neither did it have any correlation with sagittal balance status. But then again, sacral slope is a complex factor in sagittal balance. Rajnics et al discussed its variability and indirect effect on sagittal alignment through the relationship with pelvic tilt and lumbar lordosis[8]. Our finding supports these facts. Thus alone, SS may not be a sufficient determinant for achieving sagittal balance.

LL showed no significant difference between patients and healthy individuals; also within this patient group, LL did not correlate with sagittal balance either. Schwab et al mentioned that LL may remain stable due to compensatory changes in other spinal regions[30]. This agrees with our result which shows little impact of lumbar degenerative pathology on LL.

SVA had no significant difference among patients as compared to normal subjects; moreover SVA did not associate itself with any aspect of sagittal balance within the patient group. Vialle et al indicated that SVA is an important measure but should be used together with other parameters so as to give a comprehensive evaluation of the situation[32]. We therefore conclude from our findings that SVA alone cannot determine whether there is imbalance or not; multiple factors are required for assessment.

The study's outcomes correlate with earlier publications, which essentially means they support the fact that PT and TK are important ways of compensating in patients who have lumbar degenerative disease. This also shows that PI and LL's inherent anatomical properties contribute to their stable parameter values. The fact that SS has a subtle effect, and SVA cannot be relied upon alone to measure sagittal balance, emphasises the need for a comprehensive and holistic approach when evaluating a patient's sagittal balance.

Clinical Implications:

The outcomes of this study has various clinical implications that can be utilised in clinical practice.

Pelvic tilt is a concept in which one can think of it as an adjustment made by the body in its pelvis so as to keep an upright posture. In case there is lumbar degeneration, the patient's spine may bend forward, causing the pelvis to counterbalance this by tilting backwards, thus ensuring that centre of gravity remains stable. It is important to keep track of PT among patients suffering from lumbar degenerative disease as it plays a significant role. High PT values indicate compensatory mechanisms at play, therefore interventions should be designed towards reduction of excessive pelvic tilting. In turn this can alleviate back strain.

Thoracic kyphosis refers to curvature found on upper back regions. When lower parts of spine degenerate, upper curvatures might occur so that overall balance can still be maintained. This works just like leaning forward when carrying heavy loads behind. Increased TK in patients with lumbar degeneration signifies a compensatory change. Recognizing this can assist healthcare providers better caring for their patients' spines holistically–they need not only address upper spinal curvatures but also those at lower levels if global spinal balance has to be preserved during treatment programs.

Pelvic incidence is like the built-in angle of the pelvis that doesn't change. It's a foundational part of our anatomy which determines how the spine aligns, but remains constant even if there is any developing spinal problems. Since PI does not change with pathology, it serves as an excellent baseline measurement. Establishing the patient's PI helps clinicians understand the spinal alignment, enabling proper intervention and planning based on this unchangeable anatomical landmark.

Sacral slope is the angle at which the base of spine meets the pelvis; it can vary depending on how much the pelvis tilts. Imaging adjusting a chair's backrest until you find the most comfortable position; similarly does sacral slope change in order to preserve balance. There were variable SS values observed, but none of them alone acted as decision makers during diagnosis or treatment planning for patients with spinal and pelvic misalignments. Therefore alongside SS, healthcare providers should always look into PT as well as LL, so that they may have complete understanding concerning these matters and come up with appropriate and effective interventions.

Lumbar lordosis refers to an inward curve located in lower parts of back. It serves as a shock absorber for the spine, just like springiness present inside a good pair of shoes that helps one walk more comfortably. We found LL to be a stable parameter despite LDD, and therefore only focusing on increasing or decreasing LL might not be sufficient during treatment planning. Again, regarding LL along with the other parameters during sagittal balance profile evaluation becomes necessary during management process for such cases.

SVA represents the vertical line drawn from base neck down towards spines; it represents how much the spine is leaning forward or backward. If one imagines a plumb line hanging straight off the top of your head , then the SVA will tell where such a line would fall with respect to the pelvis. Alone, SVA cannot be relied upon when determining whether the sagittal plane is balanced; clinicians should use other parameters together with SVA while assessing person's sagittal alignment and planning intervention accordingly.

An excellent example of a more global consideration of these parameters, is the pelvic harmony as also assessed in this study. For many years before Schwab et al. and Lafage et al.[28, 30], proposed matching PI to LL within 10° leading to improved outcomes even in surgeries for degenerative pathology; one of the main goals was "as much lordosis as possible"[24]. Low PI may be corrected up to PI + 10° while high PI can be treated as high as PI − 10°[27]. It has been suggested that low PIs should be corrected up to PI + 10° whereas correcting high PIs may extend to PI − 10°[27]. Patients with low Pelvic Incidence should undergo a correction surgery where their lordosis should increase up by ten degrees while those with large Pelvic Incidence requires a surgical intervention that will reduce their lordosis by ten degrees[27]. This simple concept of PI–LL has since evolved into targeting the ideal lumbar apex and distribution of lordosis between cephalad and caudal segments[24]. These measurements are crucial in the degenerative lumbar spine, where patients may have poor LL distribution despite normal global lordosis.

Limitations:

The following are some limitations of the study, and should be taken into account when interpreting the data analysis and results:

- Sample Size: The overall sample size was small. This makes it difficult to apply the results more widely. Bigger samples would yield stronger data.

- Radiographic Measurements: For assessing static parameters, radiographic measurements are accurate, but they cannot capture dynamic aspects of sagittal balance. Therefore, including dynamic assessments may help us understand sagittal balance better.

- Exclusion of Other Factors: Muscle strength, flexibility and patient-reported outcomes have not been considered by this study as possible factors affecting sagittal balance. In order to get a more holistic view point, these variables need to be included in future researches.

Future Research:

Future research should focus on sagittal alignment in degenerative spine diseases. It is possible that future studies will look at the role of PI-adjusted relative spinopelvic measurements with regards to short-segment lumbar fusion outcomes as this parameter has already shown positive results for adult spinal deformity corrections[24]. Additionally, segmental sagittal plane realignment targets need to be evaluated further in spinal degeneration patients regarding patient-reported outcomes, long-term complications, and revision surgery rates. To restore lumbar spine shape requires careful lumbar fusion operation planning, interbody selection tailored to a patient’s needs, rod contouring based on pelvic morphology and segmental correction.

Future studies should aim at addressing the identified limitations, while looking into other causes of lumbar degenerative pathologies among patients with different types of sagittal imbalances.

- Larger Sample Sizes: These findings should be confirmed through larger scale investigations which will also increase generalizability. Thereby increasing the number of people participating both those who are sick (patient) and those who aren’t (control).

- Longitudinal Studies: Long term trends need to be tracked so that one gets clear understanding about how this imbalance progresses over time and what factors contribute most towards its occurrence vis-a-vis establishing a relationship between sagittal balance parameter(s) and lumbar degeneration pathology.

- Dynamic Assessments: It may also help if we include some kind motion analysis tests in our assessment tools, because currently there is not much information available concerning functional activity influence on sagittal balance during daily living. Incorporating different conditions under which such imbalances occur will help us achieve this.

- Exploring Additional Factors: In future researches, it would be important to look at muscle strength and flexibility, as well biomechanical factors affecting sagittal balance. Then we can have a better understanding of how they relate with one another, including patient reported outcome measures which may give more insight into their clinical relevance.

- Advanced Imaging Techniques: These should involve the use of MRI- and CT scans, since they are capable of providing more detailed information about the anatomical- and biomechanical changes associated degenerative spinal diseases.

Conclusion

Ultimately, this study gives us a better understanding of how complex sagittal balance is in patients who suffers from lumbar degenerative disease. Among these findings were that Pelvic Tilt (as well as Thoracic Kyphosis) act as compensatory mechanisms, while other factors like Sacral Slope or Lumbar Lordosis don’t seem to significantly affect sagittal balance.

The results suggest that there should be a comprehensive and holistic approach when assessing and treating patients with regards to their sagittal balance. A wide variety of parameters needs to be considered by the clinician, along with how they might interact together given someone’s lumbar degeneration pathologies. Health care workers must identify any limitations and engage in more inclusive research over time, especially if we are going to advance our understanding about this complex field of spinal care; ultimately helping to improve patient outcomes accordingly.

That being said, what this study emphasises is the need for individualised management and treatment plans. These should be specific for each patient based off their own unique sagittal balance profiles. In cases where the imbalance is caused by some kind of a lumbar degenerative disease, it would make sense then that interventions are designed primarily around fixing Pelvic Tilt and Thoracic Kyphosis - as they are most strongly associated with sagittal balance in such patients.

This report also highlights how important it is to detect any spinal parameter change, and to intervene early, especially in patients suffering from LDD. Monitoring various aspects related to sagittal balance on a regular basis can help identify those individuals at risk of developing marked imbalances. Steps should then be taken to intervene early, possibly preventing severe progression, incapacitating deformities, or causing disabilities.

All things considered, these findings contribute even further to the expanding knowledge on sagittal balance, especially within the context of lumbar degenerative pathologies. By identifying the limitations while incorporating suggested future research directions into practice, medical practitioners alongside researchers will be enabled to achieve better outcomes for patients living with spinal imbalance due to their lumbar degenerative conditions. Therefore we can conclude that measuring radiographic spinopelvic parameters involved in sagittal balance, can be used in preventing functional disability, and should become part of routine clinical practice in the management of patients with degenerative spinal diseases.

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APPENDICES:

Appendix 1: Data collection sheet

Group 1:

Study Number:		
Age:		
Gender:		
Do you have back pain?		
Is lumbar degenerative disease present?	Y	N
Sagittal balance:		

	SVA (+/-/N)	
	Pelvic Tilt	
	Sacral slope	
	Pelvic Incidence	
	Lumbar lordosis	

Group 2 (Control):

Study Number:		
Age:		
Gender:		
Do you have back pain?		
Is lumbar degenerative disease present?	Y	N
Sagittal balance:		

	SVA (+/-/N)	
	Pelvic Tilt	
	Sacral slope	
	Pelvic Incidence	
	Lumbar lordosis	

Appendix 2: Ethics Certificate

M230617 MED23-05-035

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Wickus Neethling

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M230617 MED23-05-035

NAME: (Principal Investigator)	Dr Wickus Neethling
DEPARTMENT:	Neurosurgery Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Measurement of sagittal imbalance in patients with lumbar degenerative pathology
DATE CONSIDERED:	30/06/2023
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof John Ouma and Dr Prince Boungou-Poati
APPROVED BY:	Prof P Ruff, Chairperson, HREC (Medical)
DATE OF APPROVAL:	23/08/2023 **EXPIRY DATE:** 23/08/2028

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report** in January each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in June and will therefore be due in the month of June each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Email signed copy of this ethics clearance certificate prior to commencing with the study hrec-medical.researchoffice@wits.ac.za

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 3: COO permission letter

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 19th April 2023

TITLE OF PROJECT:

Measurement of sagittal imbalance in patients with lumbar degenerative pathology.

UNIVERSITY: Witwatersrand

Principal Investigator: Dr W Neethling

Department: NEUROSURGERY

Supervisor : Prof J Ouma / Dr P Boungou-Poati

NHRD Number: GP_202304_033

Permission Head Department (where research conducted): Yes

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Academic Hospital. The CEO / management of Chris Hani Baragwanath Academic Hospital is accordingly informed and the study is subject to:-

- **Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.**
- The Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- The MAC will be informed of any serious adverse events as soon as they occur
- Permission is granted for the duration of the Ethics Committee Approval.

....
Recommended
(On behalf of the MAC)
Date: 19/04/2023

....
Approved/~~Not Approved~~
Hospital Management
Date: 24/04/2023

Appendix 4: Plagiarism report

Turnitin Originality Report

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