NOVEL TECHNIQUE FOR S1 PEDICLE SCREW FIXATION- SAFE ZONE & MORPHOLOGY IN THE MALAYSIAN POPULATION

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Dissertation Submitted in Partial Fulfillment of the Requirement for the Degree of Master of Medicine

(ORTHOPAEDICS)

UNIVERSITI SAINS MALAYSIA

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STUDY VENUE:

HOSPITAL UNIVERSITY SAINS MALAYSIA

ACKNOWLEDGEMENTS

The author would like to express his deepest gratitude and heartfelt thank you to the following individuals for their advice, guidance, comments and support during the preparation of this dissertation.

- Dr Joehaimey Johari, supervisor of this study and my mentor, lecturer of Orthopedics Department, HUSM for his guidance and teachings during the course of this study and completion of this paper.
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- Dr Azizul Akram Salim, lecturer of Orthopaedics Department, HUSM, for his time and guidance in reviewing this paper towards completion.
- Dr Revati Pandurengan, my beloved wife, who was there by my side through all my ups and downs and supported me throughout the process of completion of this paper. She was also a huge help to the family during my graduate studies.
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- Last but not the least, my fellow colleagues and staffs in the Orthopedics Department, HUSM.

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ABSTRAK

Pengenalan

Instrumentasi lumbosacral digunakan dalam penetapan patah tulang, tumor, skolilosis dan ketidakstabilan degeneratif. Adalah penting untuk memahami anatomi dan morfologi sakrum terutamanya pedikel S1 yang biasa dilakukan dan dikaitkan dengan komplikasi neurologi, vaskular dan visceral. Matlamat kajian ini adalah untuk mengkaji dan membandingkan morfologi pedikel S1 penduduk Malaysia dengan populasi lain dan mencadangkan pintu masuk baru untuk penetapan skru pedikel S1.

Metodologi

Kajian keratan rentas ini meneliti imej imbasan CT 100 pesakit (78 lelaki dan 22 perempuan) yang dilakukan di Hospital Universiti Sains Malaysia kerana pelbagai tanda. Tahap pemotongan paksi imej imbasan CT yang diingini ke atas faset artikular L5/S1 dipilih dari satu titik dalam pandangan sagittal menggunakan Pembinaan Semula Multi Planar dalam sistem PAC. Titik masuk baharu pada sisi artikular L5/S1 digunakan untuk mengukur parameter berikut: 1) Sudut optimum untuk memasukkan skru, 2) Panjang skru pada trajektori 0 darjah,
3) Panjang skru maksimum pada sudut optimum

Keputusan

Purata panjang skru pada trajektori 0 darjah ialah 2.63cm ± 0.36 pada lelaki dan 2.40cm ± 0.25 pada perempuan. Purata sudut optimum untuk memasukkan skru ialah 21.09 ± 3.20 pada lelaki dan 20.90 ± 2.90 pada perempuan. Panjang skru maksimum pada sudut optimum ialah 4.03cm ± 0.68 pada lelaki dan 3.92cm ± 0.63 pada wanita dengan julat panjang skru dari 2.9cm hingga 5.92cm pada lelaki dan 3.16cm hingga 5.41cm pada wanita masing-masing.

Kesimpulan

Terdapat perbezaan morfologi sakrum dalam populasi Malaysia berbanding populasi lain. Pintu masuk kami yang dicadangkan selamat digunakan dalam penetapan skru pedikel S1 dengan panjang skru maksimum 4.5cm dan sisipan 20 darjah bersudut tengah ke tanjung sakral. Walau bagaimanapun, kestabilan dan kekuatan biomekanikal perlu dinilai dengan kajian kadaverik.

(278 perkataan)

Kata kunci:

Penetapan skru pedikel S1, zon selamat, morfologi, penduduk Malaysia

ABSTRACT

Introduction

Lumbosacral instrumentation is used in fixation of fractures, tumours, scolilosis and degenerative instability. It is important to understand the anatomy and morphology of the sacrum especially S1 pedicle which is commonly performed and is associated with neurologic, vascular and visceral complications. The aim of this study is to study and compare morphology of the S1 pedicle of the Malaysian population to other populations and propose a new entry point for S1 pedicle screw fixation.

Methodology

This cross sectional study examined CT scan images of 100 patients (78 males and 22 females) done in Hospital University Sains Malaysia due to various indications. The desired level of axial cut of CT scan image over L5/S1 articular facet was selected from a point in the sagittal view using Multi Planar Reconstruction in the PAC system. The new entry point over the L5/S1 articular facet was used to measure the following parameters : 1) Optimum angle for screw insertion, 2) Screw length at 0 degree trajectory, 3) Maximum screw length at optimum angle

Results

The mean length of screw at 0 degree trajectory is 2.63cm ± 0.36 in males and 2.40cm ± 0.25 in females. The mean optimum angle for screw insertion was 21.09 ± 3.20 in males and 20.90 ± 2.90 in females. Maximum screw length at optimum angle was 4.03cm ± 0.68 in males and 3.92cm ± 0.63 in females with the range of screw length from 2.9cm to 5.92cm in males and 3.16cm to 5.41cm in females respectively.

Conclusion

There is difference in morphology of sacrum in the Malaysian population as compared to other population. Our proposed entry point is safe to use in S1 pedicle screw fixation with a maximum screw length of 4.5cm and 20 degrees insertion angled medially to the sacral promontory. However, the biomechanical stability and strength should be evaluated with cadaveric studies.

(307 Words)

Key Words:

S1 pedicle screw fixation, safe zone, morphology, Malaysian population

CHAPTER 1: INTRODUCTION

1.1 INTRODUCTION

Lumbosacral instrumentation and fusion is being performed more frequently in Malaysia. It is used in various disorders of spine, including fractures, tumours, scoliosis, spondylolisthesis and degenerative instability. The goals of the surgery are to limit dissection and fusion of the motion segment, avoid sacroiliac joint penetration, maintain lumbosacral angle, stabilize the spine and obtain a rigid fixation. Complications associated with misplaced pedicle screws include neurologic, vascular and visceral injury.

The sacrum is unique as it does not have a true pedicle as the other vertebraes. So, it is essential to understand the anatomy and morphology of the sacrum when performing fixations in and around it. The S1 pedicle screw is the most commonly performed for sacral fixation. There have been few studies describing the safe zone in the S1 for screw fixation in the western population but very few in the Asian particularly Malaysian population.

The most commonly used approach was described by Roy-Camille et al. in 1986[(1)]. The entry point proposed to enter the screws on the lateral aspect of the S1 facet. This was later modified by Smith et al. and Carlson et al. where the starting point was 2mm lateral to and below the lower end of the S1 facet joint. The drawback of this technique is poor definition of the starting point[(2)]. Factors affecting the stability of the lumbosacral instrumentation are bicortical fixation, pilot hole size and diameter, depth of anchoring and angle of insertion.

Morphometric features of the sacrum determine the size and length of pedicle screw as well as the ideal direction and angulation of the screw during instrumentation. This is to

avoid injury to the pedicle cortex, nerve roots, facet joints or adjacent vascular structures[3]. The aim of this study is analyze the morphology of the S1 pedicle in the Malaysian population and propose a new entry point for S1 pedicle screw fixation as an alternative to current methods. The aim of the new entry point is to provide an easier approach to spine surgeons as well as providing a stable fixation with less complications.

1.2 OBJECTIVE

General Objective:

To determine a 'safe zone' for S1 pedicle screw fixation according to the proposed technique of screw fixation and study the morphology of S1 pedicle in the Malaysian population.

Specific Objective:

1. To compare the morphology of S1 pedicle between Malaysian population and other countries population.
2. To measure the optimum screw angle using the new proposed entry point
3. To measure the maximum screw length in optimum angle using the new proposed entry point.

CHAPTER 2: STUDY PROTOCOL

DISSERTATION PROPOSAL

TITLE: NOVEL TECHNIQUE FOR S1 PEDICLE SCREW FIXATION- SAFE ZONE & MORPHOLOGY IN THE MALAYSIAN POPULATION

NAME: DR PRADEEP SHUNMUGAM

MATRIK NO: P-UM0230/19

MMC No: 64794

SUPERVISOR:

DR JOEHAIMEY JOHARI

3.1 INTRODUCTION

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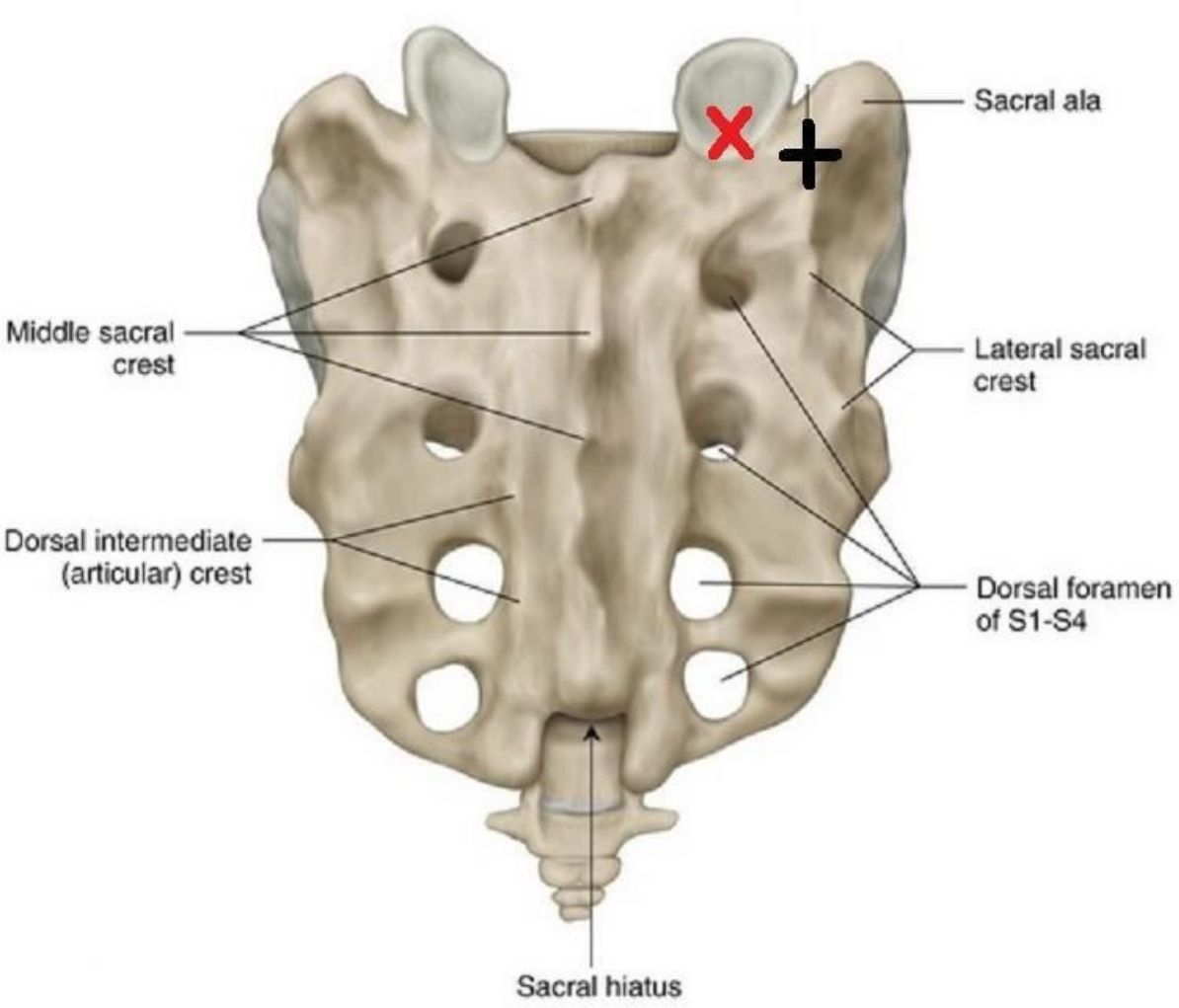
Morphometric features of the sacrum determine the size and length of pedicle screw as well as the ideal direction and angulation of the screw during instrumentation. This is to avoid injury to the pedicle cortex, nerve roots, facet joints or adjacent vascular structures[3]. The aim of this study is analyze the morphology of the S1 pedicle in the Malaysian population and propose a new entry point for S1 pedicle screw fixation as an alternative to current methods. The aim of the new entry point is to provide an easier approach to spine surgeons as well as providing a stable fixation with less complications.



. **Figure 1 :** Posterior view of sacrum

+ : Conventional entry point by Roy-Camille

X : Proposed new entry point

2.2 RATIONALE OF STUDY

There are very limited studies describing the morphology of sacrum in the Malaysian population. S1 pedicle screw fixation can be challenging as the anatomy of sacrum varies and can be complex. We aim to propose a new entry point for S1 pedicle screw fixation to ease and guide spine surgeons especially in the Malaysian population and also compare the morphology of sacrum of Malaysian population to other populations.

2.3 LITERATURE REVIEW

The sacrum is a trapezoidal structure and has no true pedicle. The pedicle is defined as the areas between the transverse process and the sacral body. Any breach in cortex can increase the risk of neural, visceral or vascular injury and failure of fixation. [4] Pedicle breach is more common in the medial than lateral in lumbosacral segments [5,12]. There are two main screw trajectories for posterior sacral fixation, including anteromedial trajectory through the pedicle to the promontory and the anterolateral trajectory to the sacral wing. Arman et al concluded there are no significant difference in the distances for anteromedial or anterolateral directed screw paths. Anteromedial screw is more popular due to its biomechanical advantage and less likely to cause injury to the neurovascular structures but has an anatomic pitfall. [8,13,14] Medially directed screws are significantly stronger and carry minimal risk of injury than laterally directed ones. [12]

The main factor affecting the length and angle of the screw is the location of entry point.[6] Several entry points are known at the S1 level as described by Harrington, Asher and

Zindrick et al. Wittenberg et al tested biomechanical influence of different operation sites at S1 level. They evaluated that insertion of a pedicle screw at level S1 through the S1 facet resulted in higher pull-out forces than Harrington's approach. The entry point which was described is oblique and below the lumbosacral facet joint and the screw has to be directed ventrally and 30^{o} to 40^{o} caudally. [(9)] Meng Jun et al described the S1 pedicle entry point was located at the intersection point of the basal lateral part of articular process and median line of transverse process. [(7)]

Meyer et al concluded that the "safe zone" for bicortical screw placement in S1 could be defined between 7^{o} and 38^{o} of convergence. Maximum possible screw length was possible at 25^{o}. Screw diameter should be selected according to pedicle height not pedicle width.[(10)] Xu, et al. demonstrated that safe zone for S1 pedicle screw was located between lower lateral potion of the L5-S1 facet and the lateral sacral crest. [(11)] ‘

Tiwari et al[(12)]. conducted a survey among 136 spine surgeons and concluded that S1 pedicle screw technique was most difficult due to an inadequate medial angulation due to paraspinal muscle mass tension and an overhanging iliac crest. Lumbosacral fixations have a high rate of complications including pedicle screw loosening or pseudoarthrosis. This was due to S1 pedicle being shorter and had a larger diameter than lumbar pedicle, leading to screw lacking holding power[(13)].

Quality of fixation is influenced by lumbosacral anatomy, bone mineral density, entry point, trajectory and length of screws. Poor fixation may lead to screw loosening, pull-out, breakage or migration[(14)]. Kwan et al. also mentioned several factors that contribute to failure of sacral screw fixation, such as inadequate sacral bone purchase, inappropriate direction of screw or depth of screw and osteoporotic bone. They also recommended S1 pedicle screw which is aimed towards the sacral promontory.

2.4 OBJECTIVE

2.4.1 General Objective:

General Objective:

To determine a ‘safe zone’ for S1 pedicle screw fixation according to the proposed technique of screw fixation and study the morphology of S1 pedicle in the Malaysian population.

2.4.2 Specific Objective:

1. To compare the morphology of S1 pedicle between Malaysian population and other countries population.
2. To measure the optimum screw angle using the new proposed entry point
3. To measure the maximum screw length in optimum angle using the new proposed entry point.

2.5 STUDY DESIGN

This is a cross-sectional study using secondary data based on Picture Archiving and Communications System(PACS) database from Department of Radiology registry in Hospital Universiti Sains Malaysia(HUSM).

2.6 STUDY AREA

The study will be conducted in HUSM which started operation in the year 1983. HUSM is a tertiary referral centre and a teaching hospital in Kelantan, at the east coast region of Peninsular Malaysia.

2.7 STUDY POPULATION

Any patients who have done lumbosacral/sacral Ct scan in HUSM from 2015 to 2021

2.8 SELECTION CRITERIA

A. Inclusion criteria

1. Lumbosacral/sacral CT scan images of patients done in HUSM
2. Patients above 18 years old

B. Exclusion criteria

1. Any patients with spinal deformity or pathologies such as congenital anomalies, spinal metastasis, infection and traumatic lesions.
2. Patients under 18 years of age
3. Non Malaysian patients

2.9 SAMPLE SIZE ESTIMATION

1. The estimated sample size for objective 1 using single mean formula

- $n = (Z*\alpha/\Delta)^2$
  - Z : 1.96
  - α : 5.04 (SD of medial angulation of screws on the transverse plane based on thesis by Chu et al. 2017)
  - Δ : 1
- n = 98

2. The estimated sample size for objective 2 using single mean formula

- $n = (Z*\alpha/\Delta)^2$
  - Z : 1.96
  - α : 3.55(SD of distance from posterior to anterior cortex of sacrum based on thesis by Chu et al. 2017)
  - Δ : 1
- n = 49

3. No drop out calculated as the study is using data from the PACS database. Therefore, the required sample size is 98 patients.

2.10 SAMPLING METHOD

Non- probability sampling is used to select patients from the PACS database, patients who have undergone lumbosacral/sacral CT scans from January 2015 to January 2021 which fulfill the inclusion and exclusion criteria. Subject recruitment is not required as data is obtained from the system.

2.11 RESEARCH TOOL

Normal lumbosacral/sacral CT scan are used to measure the parameters using the measurement tools in the PACS system by Pradeep Shunmugam under supervision of Mohd Ezane Aziz. All measurements are documented in centimeter(cm) & degree and rounded up to one decimal point.

2.12 OPERATIONAL DEFINITION

i. Normal lumbosacral/sacral CT scan are defined as images without any congenital anomaly, fracture or infection

ii. Entry point as S1 pedicle level identified by using Multi-Planar Reconstruction in the PACS software

iii. Length of screw at 0 degree trajectory is defined as anteroposterior diameter of screw at 0 degree trajectory from the entry point to anterior cortex of sacrum

iv. Optimum angle for screw insertion defined as the angle measured between a line at 0 degree trajectory at entry point and a line from entry point to sacral promontory 5mm from lateral border of spinal canal.

v. Screw length at optimum angle is defined as the length of the line from entry point towards sacral promontory at the optimum angle

2.13 DATA COLLECTION METHOD

Data will be collected by measuring lumbosacral/sacral CT scans from the PACS database. Patient's participation is not required and data will be collected with strict confidentiality. Normal CT scan (Figure 1) will be measured.

Point X will be set as the proposed new entry point. To measure the screw length at 0 degree trajectory, a line will be drawn from point X to anterior cortex of sacrum at 0 degree trajectory (Line 2). Optimum angle for screw insertion will be angle Y which is a line drawn from point X towards the sacral promontory which is 5mm from the lateral border of spinal canal. Screw length at optimum angle is a line drawn from point X to the anterior cortex of sacral promontory (Line 1).

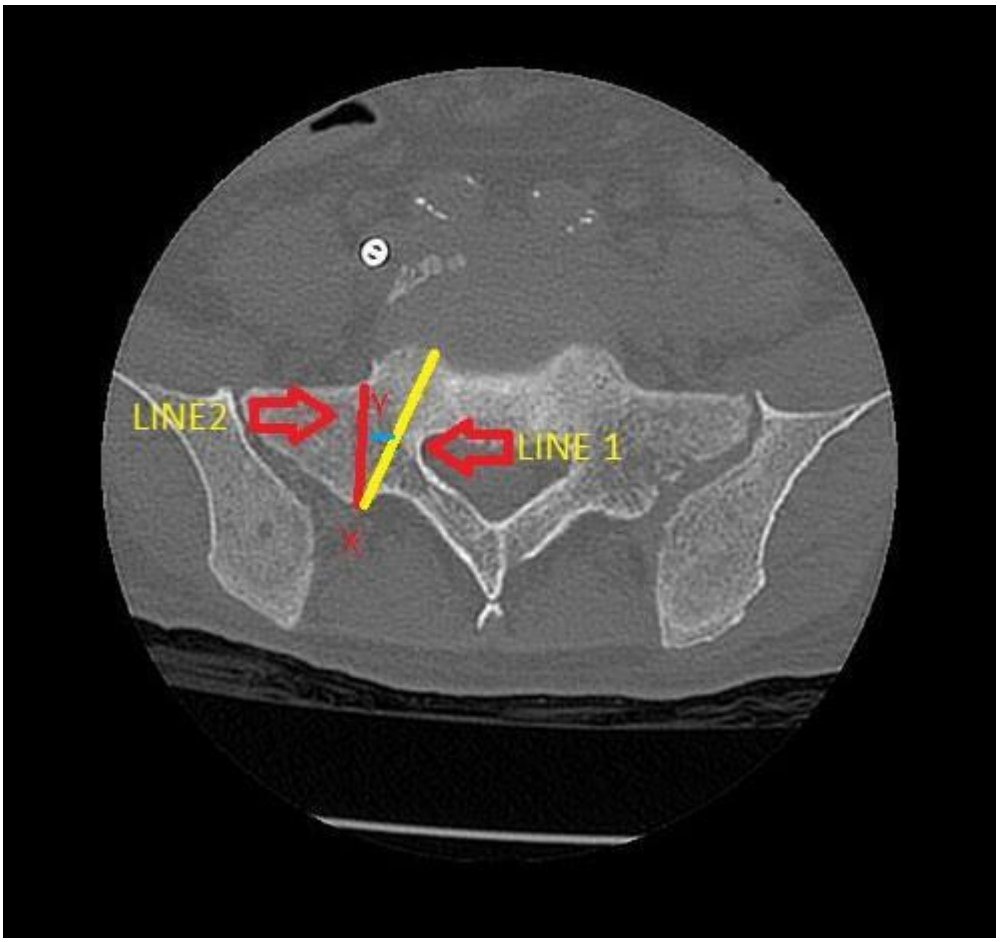


Figure 2 : CT scan at S1 pedicle at desired entry point level ; X is proposed new entry point; Y is optimum angle for screw insertion; Line 1 : Screw length at optimum angle ; Line 2: Screw length at 0 degree trajectory.

2.14 DATA ANALYSIS

Data will be entered and analyzed using SPSS version 24. Descriptive statistics will be used to summarize the socio-demographic characteristics of subjects. Numerical data will be presented as mean (SD) or median (IQR) based on their normality distribution. Categorical data will be presented as frequency (percentage). Independent t-test will be used to compare

parameters between genders. We consider p value less than 0.05 to be statistically significant, with 95% of confident interval.

2.15 BENEFIT OF STUDY

This study finding may benefit the individual and community by providing them a clear information on morphology of sacrum in the Malaysian population compared to Western population. The proposed new entry point could also be helpful in future lumbosacral/sacral fixation . This study may elevate the name of Hospital Universiti Sains Malaysia as a trusted centre of spine surgery

2.16 ETHICAL CONSIDERATION

Ethics approval will be obtained from the Research and Ethics Committee of Hospital Universiti Sains Malaysia.

The details of the patient will be assured of confidentiality. Each of the data gathered is for study purposes only and will be deemed anonymous. The author will be fully responsible for the content of the publication.

1. **Subject vulnerability**

   No patients' will be invited or called for this study. CT scan imaging of the patient will be obtained retrospectively via PACS hospital information system. The CT scan obtained is based on previous CT imaging that was done for other medical reasons.

There is no direct contact with the patients nor any effect to their management as the data is obtained from CT scan only.

2. **Declaration of absence of conflict of interest**

I declare no 'Conflicts of Interest' from any financial or benefits of any form in relation to this study.

3. **Privacy and confidentiality**

All datas and forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the subjects individually.

4. **Honorarium and incentives**

This study is not bound to any form of research grant and any minor portion of spending will be borne by the principal researcher.

5. **Community sensitivities and benefit**

This study is beneficial to our community as it provides crucial information of sacrum morphology for fixation of S1 pedicle screw. This study doesn't involve any questionnaire or interview question, hence there is no issue or sensitivities to the patient or society.

6. **Participant Information Sheet and Consent Form (PIS and CF Assessment)**

Not Applicable

7. **Collaborative study terms of reference**

There is not collaborative study terms of reference.

2.17 LIST OF ABBREVIATIONS

i. HUSM refers to Hospital Sains Malaysia

ii. PACS refers to Picture Archiving and Communications System

iii. CT refers to Computed Tomography

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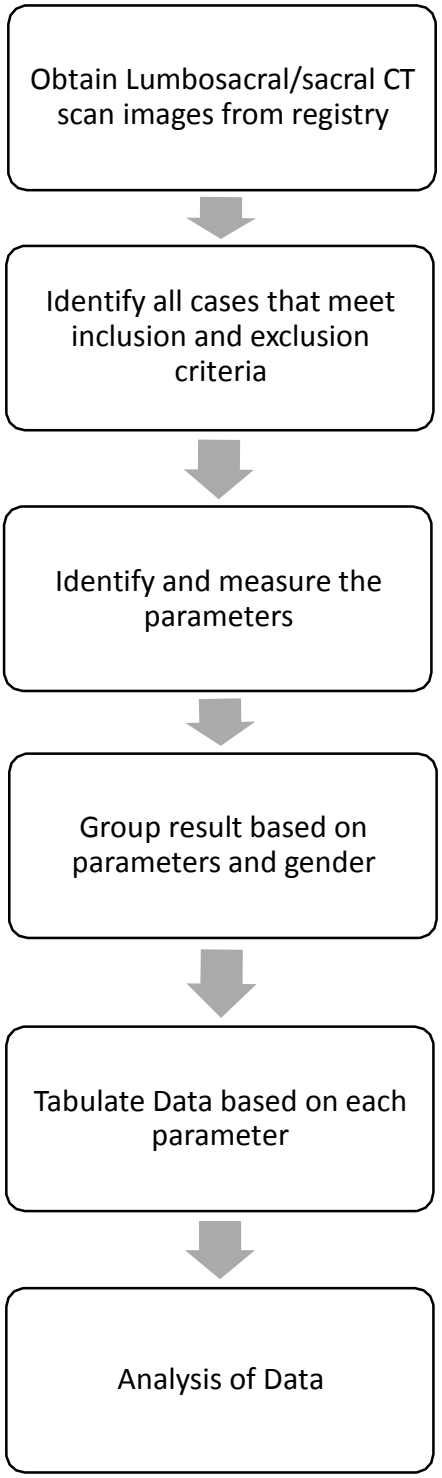
Flow chart of study



Gantt Chart

Timeline		April 2021-May 2021	June 2021-July 2021	August 2021-Sept 2021	Oct 2021-Nov 2021	Dec 2021-Jan 2022	Feb 2022-Mac 2022	Apr 2022-May 2022
Data Collection								
Data Processing								
Statistical Analysis								
Final Review								
Supervisor								
Review								
Approval Process								

ETHICAL APPROVAL LETTERS

Jawatankuasa Etika
Penyelidikan Manusia USM (JEPeM)

Human Research Ethics Committee USM (HREC)

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10th November 2021

Dr. Pradeep Shunmugam
Department of Orthopaedics
School of Medical Sciences
Universiti Sains Malaysia
16150 Kubang Kerian, Kelantan.

JEPeM Code : USM/JEPeM/21090628
Protocol Title: Novel Technique for S1 Pedicle Screw Fixation – Safe Zone & Morphology in the Malaysian Population.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/21090628**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **10th November 2021** until **9th November 2022.**

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:
1. Dr. Joehaimey Johari
2. Assoc. Prof. Dr. Mohd Ezane Aziz

The following documents have been approved for use in the study.
1. Research Proposal

While the study is in progress, we request you to submit to us the following documents:
1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form.**
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: **www.jepem.kk.usm.my**

JEPeM
JAWATANKUASA ETIKA PENYELIDIKAN MANUSIA

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Sincerely,

ASSOC. PROF. DR. AZLAN HUSIN
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia