FINITE ELEMENT ANALYSIS OF PULL-OUT PERFORMANCE OF BONE SCREW

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FINITE ELEMENT ANALYSIS OF PULL-OUT PERFORMANCE OF BONE SCREW

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DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed……………………………………………………….… (Tan Yong Quan)

Date…………………………………………………...……………. (25/07/2022)

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This thesis is the result of my own investigations, expect where otherwise stated.

Other sources are acknowledged by giving explicit references.

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TABLE OF CONTENTS

LISTS OF TABLES

LISTS OF FIGURES

LISTS OF APPENDICES

LISTS OF ABBREVATION

3D	3-Dimensional
ASTM	American Society of Testing and Materials
CAD	Computer Aided Design
CAE	Computer Aided Engineering
FE	Finite Element
FEA	Finite Element Analysis
ORIF	Open Reduction Internal Fixation
PU	Polyurethane
SRPU	Solid Rigid Polyurethane
STP	Stress-Transfer Parameter
USM	Universiti Sains Malaysia

ANALISIS UNSUR TERHINGGA TERHADAP PRESTASI SKRU TULANG SEMASA DITARIK-KELUAR

ABSTRAK

Skru tulang kerap digunakan dalam pembedahan ortopedik terutamanya pembedahan pengurangan terbuka dan penetapan dalaman (*open reduction internal fixation*, ORIF) untuk memposisikan tulang patah di kedudukan asalnya dengan daya mampatan dan membantu penyembuhan tulang patah. Ia adalah sangat penting untuk mengkaji secara terperinci terhadap parameter skru, terutamanya daya tariknya, untuk mencepatkan pemulihan tulang dan mengurangkan kecederaan tambahan. Kajian lepas mengenai sifat tulang, rekaan skru, dan teknik penyisipan skru telah dibuat melalui pendekatan uji kaji atau pengiraan. Sudut penyisipan skru kerap dikaitan dengan parameter menjejaskan daya tarik skru tulang, tetapi kurang diberikan perhatian dan jarang dijadikan topik utama dalam sebarang penyelidikan terutamanya yang berkaitan dengan pendekatan pengiraan berangka. Tujuan projek ini adalah mengkaji kesan sudut penyisipan skru terhadap daya tarik skru melalui pendekatan analisasi berangka. Medan stres dan regangan selepas penyisipan skru dan medan baki selepas skru ditarik keluar telah dikaji dan dianalisis. Model 3D unsur terhingga (*finite element*, FE) kepada skru tulang kortikal dan blok buih poliuretana yang padu dan tegar telah direka dan dikira dalam simulasi ujian tarik keluar berlandaskan piawaian ASTM F543. Deformasi keseluruhan, regangan elastik sepadan, dan stres sepadan telah dinilai daripada hasil kedua-dua simulasi penyisipan skru dan tarik keluar. Daya tarik skru yang telah dimasukan ke tulang manusia sintetik telah diukur. Kajian ini berkeputusan bahawa pertambahan sudut penyisipan skru tulang akan mengurangkan daya tariknya. Medan stres dan regangan terkumpul di zon hubungan antara skru dan blok selepas penyisipan skru, memberi kekuatan fiksasi yang lebih baik, walaupun di sudut penyisipan skru yang tinggi, isipadu zon hubungan antara skru dan blok akan berkurang dan menyebabkan pembaikan tersebut tidak nyata dan bermakna. Medan baki blok buih selepas skru ditarik keluar membantu dalam pertumbuhan tulang.

FINITE ELEMENT ANALYSIS OF PULL-OUT PERFORMANCE OF BONE SCREW

ABSTRACT

In orthopaedic surgery, bone screws were frequently used in open reduction internal fixation (ORIF) to keep the broken bones in place by screw's compression force to cure the bone fracture. It was critical to thoroughly examine its parameters, especially the pull-out strength, to accelerate bone healing and minimise additional injury. Previous studies focused on bone properties, screw design, and insertion techniques of bone screw, through experimental or computational approach. The insertion angle of bone screw was often mentioned as one of the potential parameters influencing pull-out strength of the bone screw, yet it had received comparatively little attention and was not the key element on any research particularly with numerical approach. The purpose of this project was to numerically examine the effect of insertion angle of bone screw on its axial pull-out strength. The stress-strain field after the screw insertion and residual field after the screw pull-out were examined and analysed. 3-dimensional finite element (3D FE) model of a cortical bone and solid rigid polyurethane foam block were modelled and were computational simulated for pull-out test complying ASTM F543 standards. The total deformation, equivalent elastic strain, and equivalent stress were evaluated from the simulation results for both the screw insertion and pull-out. The pull-out force of the screw inserted into synthetic human bone was measured. The study concluded that the increase in bone screw insertion angle will reduce the pull-out strength. The stress-strain distribution was concentrated at screw-block contact zone after the insertion, providing better fixation to the screw despite having lesser contact volume at high insertion angle, leading to insignificant improvement. The residual field of the foam block after the bone screw was pulled out promoted bone cure.

CHAPTER 1

INTRODUCTION

This chapter provides a succinct overview of the final year project. An introduction of bone screws and polyurethane foam blocks, followed by the project background with the problem statement, project objectives, and project scope is presented. The outline of the thesis is summarised.

1.1 Overview of Bone Screw

Bone screws, also known as orthopaedic screws, is a cylindrical device with helical threads along its outer surface, that is commonly used in orthopaedic treatment. The main function of the screw is to connect two components by compressing them. In bone fracture, this will aid in healing the bone damage as the compression force keeps the injured bones in place and enable faster recovery, which is very useful in bone implants or fixation of bone or soft tissue. (Rajesh Purushothaman, 2013)

Orthopaedic screws consist of head, body, thread, and tip. Several design parameters of screws such as length, diameter and the pitch of screw are modified to comply with the various density of human bones so that the screw can hold the bones in place. The commonly used bone screws are the cortical bone screw and the cancellous bone screw. The bone screw can be made from titanium, stainless steel, or bio-absorbable material, ranging from a diameter of 1.5 mm to 6.5 mm, and a length of 10 mm to 90 mm, based on its application. The screw tip may be non-tapping, self-tapping, or self-drilling. (UTESHIYA MEDICARE, 2017)

Figure 1-1 Various Design of Bone Screws (Sofia Surgicals Pvt. Ltd, n.d.)

Bone screws are often found in open reduction and internal fixation (ORIF), which refers to a surgical procedure of relocate the bone fragments to its correct alignment (open reduction), then reconnecting them using implant tools such as screws, plates, nails, or wires to mend the bones (internal fixation). (Jason Allen Lowe, 2019) Another treatment of using bone screws is called external fixation, in which the bone screw is fastened to the bone fragments and a metal bar outside the skin.

The implant is often anticipated to remain permanently inside the body to hold the bones in place and permit bone growth and healing. However, there are several cases which the removal of implant is crucial, such as infection, pain, and inflammation. Normally, the removal of a bone screw might be the best course of action. Care should be taken during the implant removal process to prevent further damage to the bone, nerve, and blood vessels. (Jonathan Cluett, 2021)

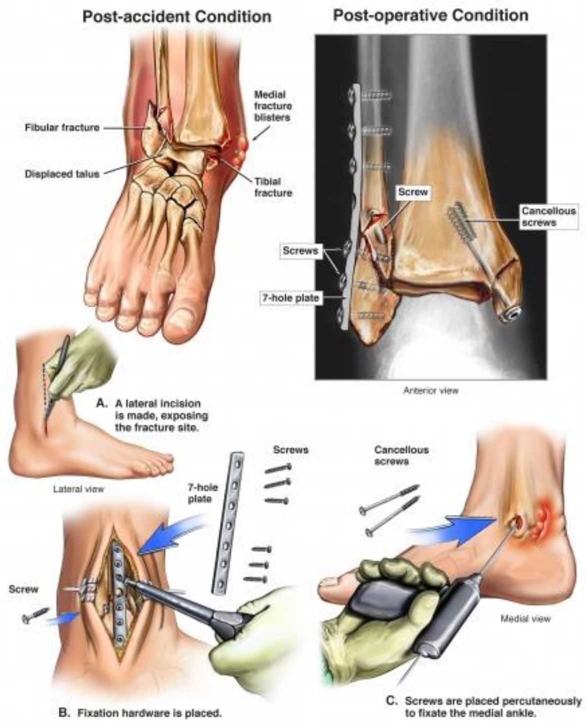

Figure 1-2 Example of Open Reduction and Internal Fixation Surgery of the Ankle (Winchester Hospital, n.d.)

Since the bone screw is crucial to bone treatment, it is vital to thoroughly research all its specifications, particularly mechanical properties, to facilitate bone healing and prevent further damage. One of the mechanical properties is the pull-out strength of the screw which is the amount of force needed to pull out a screw inserted into a bone. This force is commonly referred as screw fixation strength or screw anchorage which indicates the screw’s gripping capability. (Patel et al., 2009)

There have been many different designs and surgical methods used to get optimal bone treatment using bone screws. Bone screws have been improved in a few ways, including adding bone cement to screw, changing the screw’s specifications, altering the screw’s trajectory, and adding supporting parts on the screw. (Shea et al., 2014) The insertion angle of bone screws is one of the potential parameters influencing pull-out strength that has received comparatively little attention. This sparked the curiosity about the relationship between the two. The purpose of this research is to study the relationship between the insertion angle of a bone screw to its pull-out strength and impact on the bone through finite element analysis.

1.2 Problem Statement

The use of bone screws in the treatment of bone fractures may cause further injuries for a variety of reasons. (Kim et al., 2020) One of the possible factors will be the bone screw’s insertion angle, as this angle may alter the distribution of stress and strain and the development of crack tips in the bone, which will lessen the screw’s grip on the bone and result in pain for the patient. To prevent such failure from happening, research aims to establish a correlation between a bone screw’s insertion angle and pull-out performance using finite element analysis.

1.3 Objectives

The objectives of the final year project are

- To numerically examine the effect of insertion angle of bone screw on its axial pull-out strength
- To numerically characterize the stress and strain distribution in the vicinity of bone screw insertion in relation to insertion angle
- To numerically analyse the residual field of the screw-bone contact zone after the screw pull-out

1.4 Scope of Project

The final year project consists of the following tasks as listed in Table 1-1 below.

Table 1-1 Scope of Work Done Throughout the Final Year Project

Task	Description
Review On the Research Made	Perform literature review through several journal or research articles that have been published to study about the thesis title and research gaps
Property Identification on The Bone Screw and PU Foam Block	Identify the properties of the bone screw and the PU foam block used in the market, and its standards
CAD Modelling	Create 3D model of the bone screw and PU foam block based on the survey made using CAD software
Numerical Simulation	Setup screw insertion and pull-out test at various angles using CAE software and perform simulation
Data Analysis	Analyse the results obtained from the simulation and discuss the pull-out performance of the bone screw at various angles

1.5 Thesis Outline

There are five chapters in this thesis. Chapter 1 covers the introduction of the final year project with its background, including an overview of bone screws and a PU foam block used in the pull-out test of bone screw, along with the problem statement, project objective, scope of work and thesis outline. Chapter 2 discusses the literature reviews that have been done in relation to the thesis title, giving a summary of earlier research and identifying research gaps. Chapter 3 focuses on the methodology designed for the final year project, particularly about 3D modelling and simulation setup, to investigate the problems found and accomplish the project objectives. Chapter 4 presents the findings of the numerical analysis with a thorough description and explanation. Chapter 5 concludes and summarizes the whole project work and discuss the improvement can be made for future study. All the references are cited throughout the thesis and are listed in References section after Chapter 5, followed by the CAD drawing of the model generated appended in the Appendices section.

CHAPTER 2

LITERATURE REVIEW

This chapter presents the literature review about the most recent and pertinent studies conducted related to the final year project. The majority of the journals and publications were published between 2012 to 2022. The reviews provide a brief discussion of the factors influencing the pull-out performance of bone screw, and the research methodology taken. Out of 96 journal publications and technical papers being reviewed, only 28 are concerned with variables affecting pull-out strength. During the searching of the literature on online publication platforms like ScienceDirect, ResearchGate and PubMed, the terms “bone screw”, “pull-out strength”, “insertion angle” and “finite element analysis” are used as the keywords.

2.1 Overview of Factors Affecting Pull-Out Performance of Bone Screw

From the papers reviewed, the factors affecting pull-out strength of screws being investigated are categorized into three aspects, which are (1) bone properties such as density and porosity, (2) screw’s design parameter such as screw thread, core design, major diameter, and screw material, and (3) the screw insertion technique involving insertion torque, depth, and angle, and cement augmentation of a screw. Table 2-1 below summarized the factors found, and the number of papers focused on the variables.

Table 2-1 Summary of the Factors Affecting Pull-Out Strength of Bone Screw Found Throughout the Literature Searching

Factor	Description	Number of Papers Mentioned
Bone Properties	Density	9
Screw Design Parameter	Thread	6
	Core	3
	Material	2
	Major diameter/Pitch	2
	Auxetic Structure	2
	Tip	1
Insertion Technique	Insertion Angle	4

	Insertion Depth	4
	Pilot Hole Size	3
	Cement Augmented	2
	Reinsertion of Screw	2
	Torque	1
	Osteon Alignment	1

2.1.1. Bone Properties

The effects of bone materials on the pull-out strength of bone screw were investigated through three-dimensional finite element analysis (3D FEA) in Zhang et al.'s study. The study revealed that the stability of the inserted bone screw is dominated by bone material as it also influences other screw parameter like length and thread design.(Zhang et al., 2006) The effect of synthetic bone density on the pull-out performance of self-tapping bone screws were investigated in Wu et al.'s study through an analytical, FE and experimental study. From the study, the pull-out strength had significant relations with bone density as it will alter the other mechanical properties of a bone screw. (Wu et al., 2011) Krishnan et al. studied at how bone density affected the pull-out strength of single and two pedicle screws. For the pull-out test, different densities of PU foam blocks were employed in both screw arrangements. Regardless of the bone screw arrangements, the results demonstrated that the pull-out strength increased with increasing foam density. (Krishnan et al., 2016) Varghese et al. conducted experimental study to analyse the effects of density on the pull-out strength of pedicle screw. This research concluded that there is significant correlation between bone density and pull-out strength, with p-value less than 0.05, contributing up to 8 percent of pull-out strength. (Varghese et al., 2017)

A stress analysis was done by Zain et al. in determining the stress distribution of the bone and the bone's porosity. In this study, a significant relationship between stress distribution around the inserted screw and the density of bone. (Zain et al., 2019) Einafshar et al. performed experimental pull-out tests on forty-five titanium pedicle screws inserted in three different blocks with different materials, porosity, and insertion depth. The results of the experiments were validated using homogenised FE models. The findings showed that the homogenous FE simulations of porous materials did not agree with the experimental findings, even though both results showed an increase in pull-out strength with decreasing porosity. (Einafshar et al., 2021) To investigate the impact of PU foam block with varies density and the insertion method on the pull-out performance of a bone screw, Weilding et al. conducted several pull-out tests using PU foam blocks with varied apparent density grades. The research demonstrated that a small variation in apparent density resulted in significant differences in pull-out strength. (Weidling et al., 2022) Thus, the bone density is the main contributors to the bone screw's pull-out strength.

2.1.2. Screw Design Parameter

The screw's design parameter is also one of the factors affecting its pull-out strength. A 2D FEA study on the effect of various design parameters of a bone screw was carried out by Gefen. The screw-bone load sharing was quantified using a dimensionless set of stress-transfer parameters (STP), made it more convenient to rate the biomechanical suitability of any given screw design. The findings showed that the newly proposed screw designs – composite screw with reduced-stiffness-titanium-core, outer polymeric threads and 'active compression' hollow screw had better performance in terms of STP criteria, than conservative screw designs. (Gefen, 2002) To improve screw pull-out performance, one of the screw design characteristics that should be taken into account is screw material. Ali BİRCAN & Çetin designed and fabricated a new bone screw using a new composite material. To determine the pull-out forces of the screw, an ASTM F543-02 standard pull-out test and a 3D finite element analysis were performed. The findings demonstrated that pull-out strength was mainly influenced by screw thread design instead of material used. (Ali BİRCAN & Çetin, 2016)

Using FEA, the impacts of various parameters on the bone screw pull-out strength were examined in Zhang et al.'s study. The threaded connection of bone and the surgical screw was modelled in 3D using FE. An investigation on determining the relation between screw parameters and pull-out strength was established. The findings demonstrated that bone shearing, which happened along a cylindrical area determined by the outer perimeter of the screw and penetrated length, was the cause of the connection failure. The major diameter had a greater impact on the strength of the screw pull-out than the minor diameter and pitch. (Zhang et al., 2004) The effect of the screw size on the pull-out performance of self-tapping bone screws were investigated in Wu et al.'s study through an analytical, FE and experimental study. From the study, the pull-out strength increased with the screw size in a nonlinear pattern. (Wu et al., 2011) In Weilding et al.'s study, the parameters of pedicle screw which is commonly found in spinal treatment are studied to examine its relationship with the screw fixation ability. The study focuses on the screw design variables influencing the insertion torque and pull-out strength of the screw. The study found a relation between the pull-out strength and insertion torque, and the screw's major diameter, which had an impact on the screw's thread design, the bone-screw contact area and bone's displaced volume and diameter after the screw insertion. Such relations derive an equation with the major diameter as the scaling factor to predict the screw fixation. (Weidling et al., 2020)

The design of the screw core is also one of the focuses of study in its relationship with pull-out strength, as conclude by Hsu et al.'s research in the pedicle screws with a conical core. 3D FEA was performed to predict the pull-out strength of both the conical pedicle screw and conventional cylindrical pedicle screw before conducting mechanical test using two PU foam blocks with various density. His research showed the pull-out performance is better in the case using the conical pedicle screw with effective foam compaction, achieving p-value of less than 0.05. The FEA results behave similarly with the result obtained from mechanical test, validating the result is reliable. (Hsu et al., 2005) In Chao et al.'s study, the pull-out strength of a bone screw was improved by adjusting the core tapering and core diameter of ten pedicle screws. Pull-out tests were conducted with PU foam blocks, as well as 3D FEA, and the outcomes were compared. It was found that conical screws had greater pull-out strength, smaller core diameters, and higher foam densities. (Chao et al., 2008) Rather than changing the shape of the screw core from traditional cylindrical shape to conical, Kubiak et al. proposed using a dual-core pedicle screw which has two different core diameters and thread profiles in a single screw. The results of several pull-out tests with PU foam blocks showed that dual-core screws had higher pull-out strengths than commercial cylindrical screws, even the differences were not statistically significant. (Kubiak et al., 2019)

On the other hand, the screw thread was claimed to be one of the critical design parameters of the screw that affecting the pull-out strength. Wang et al. carried out a study focused on this parameter, particularly on the proximal half angle of the screw thread. The pull-out test was conducted at 30 mm/min, focusing on the cancellous bone screw with varying proximal half angle ranging from 0 to 60 degrees. The result showed that the pull-out strength is the maximum at an angle of 30 degrees and minimum at 60 degrees. (Wang et al., 2009) Meanwhile, pull-out strength of four different pedicle screws varied in thread design were determined by Takenaka et al. The screw design of which its proximal portion was double-threaded, and its distal portion was single threaded, was used as the basic screw design. The other screw designs altered the basic screw design by having inter-thread double-core shape, a longer proximal portion, or both. The results showed that the screw thread design with both design alterations had the highest pull-out strength among the four screw thread designs. (Takenaka et al., 2020) This indicates that screw thread is one of the major contributors to pull-out strength of bone screw.

In order to achieve optimal pull-out performance, screw tip design is one of the key design considerations for a bone screw. Three tip designs—a flat tip, a conical tip, and a novel elastomeric tip—were suggested by the Kulper et al.'s study. The designed-tip screws were placed into PU foam blocks and allowed to migrate axially. The elastomeric tips were determined to require the most force for axial migration, followed by conical and flat tips. (Kulper et al., 2018) Meanwhile, a novel structure on the bone screw can be implemented in obtaining better pull-out performance. An auxetic structure is a collection of unit cells structured in a way that allows them to expand during stretching or contract during compression. The bone screw with this structure were designed and fabricated for the tensile test, while the pull-out test was conducted computationally. The study concluded that the auxetic structure was beneficial in improving the bone screw mechanical properties. (Yao et al., 2020) In addition, a screw with an auxetic structure was created by Yao et al., and its mechanical properties were altered by wall thickness and the re-entrant angle of the auxetic unit cell. To assess the screw with auxetic structure's pull-out performance, both the FE approach and pull-out tests were developed. The findings demonstrated that by improving the screw's auxiticity at a constant elastic modulus, it is possible to improve the pull-out performance of screws with auxetic structures. (Yao et al., 2021)

2.1.3. Screw Insertion Technique

Cement augmentation of a bone screw as one of the bone screw insertion technologies enhance the stability of the bone screw. Oberkircher et al. designed an experiment to compare the iliac screw fixation with and without cement augmentation using biomechanical testing. The pull-out test was conducted on thirty female and osteoporotic human iliac bones under three different operation treatment groups. The study shown that the screw fixation with cement augmentation has higher pull-out strength than one without. (Oberkircher et al., 2021) The physical properties of cement used in this technique also play an important role in bone screw's pull-out strength. The study performed by Pujari-Palmer et al. suggests that the screw fixation failure can be prevented by using cements with lower porosity and high compressive strength, which boost the pull-out strength of the inserted bone screw. (Pujari-Palmer et al., 2018)

In addition, the osteon alignment corresponding to the bone screw insertion axis plays an important role in its pull-out performance. In Feedrick & McGarry's study, the pull-out strength of a bone screw at the screw axis corresponding to osteon alignment was measured. Longitudinal pull-out which the screw axis is parallel to osteon alignment, and transverse pull-out which the screw axis is perpendicular to osteon alignment, were simulated by FEA software. According to the findings, transverse pull-out will have higher pull-out forces than longitudinal pull-out. (Feerick & McGarry, 2012) Other than the osteon alignment, insertion torque is also one of the parameters affecting the pull-out performance of bone screw, although it is frequently treated as the outcome of other factors. Addevico et al. suggested that the bone screw insertion torque will have an impact on its pull-out strength. With referencing ASTM F543, an experimental test was performed using three screws with different pitch design, on PU foam blocks with differing densities. The results supported Addevico's claim as the correlation between the torque and pull-out strength obtained from the experiment achieving R value of 0.979. The test concluded that the bone density was the main factor affecting the torque and pull-out strength, where the pitch determines the screw holding capacity. (Addevico et al., 2020) However, Varghese et al.'s study in the factors influencing the pull-out strength of pedicle screw yielding a different result, which pull-out strength and insertion torque had no significant correlation in the case of the extremely osteoporotic bone model. (Varghese et al., 2017)

The effect of the pilot hole size on the pull-out performance of self-tapping bone screws were investigated in Wu et al.'s study through an analytical, FE and experimental study. From the study, the pull-out strength had no significant correlation with pilot hole size. (Wu et al., 2011) Similar research was conducted by Stewart et al. utilising a demineralized animal bone model to simulate the human cancellous bone with randomised pilot hole size. The outcome demonstrated that pull-out force is greatly decreased in lower density screw holes, but that this decrease can be countered by shrinking the diameter of the pilot hole for cancellous screws. (Stewart et al., 2020) In Affes et al.'s study, FE models are used to examine the effect of changing the size of the pilot hole on the biomechanical environment at the screw-bone interface of the fractured bone, both before and after the screw has been inserted and under the immediate pressure of body weight. For analysis, four pilot hole sizes ranging from 71% to 85% of the screw external diameter were taken into account. An experimental pull-out test was performed with a synthetic bone to validate the numerical models. The findings of the insertion process showed that the pull-out force was enhanced by relatively smaller holes. (Affes et al., 2018)

The effect of the insertion depth on the pull-out performance of self-tapping bone screws were investigated in Wu et al.'s study through an analytical, FE and experimental study. From the study, the pull-out strength had almost linear relation with screw insertion depth. (Wu et al., 2011) Einafshar et al. performed experimental pull-out tests on forty-five titanium pedicle screws inserted in three different blocks with different materials, porosity, and insertion depth. The results of the experiments were validated using homogenised FE models. The findings showed that the homogenous FE simulations of porous materials did not agree with the experimental findings, even though both results showed an increase in pull-out strength with increasing insertion depth. (Einafshar et al., 2021)

Krishnan et al. studied regarding the relationship between the single and two pedicle screws pull-out strength and the screw reinsertion technique. Different densities of PU foam blocks were employed in both screw arrangements for pull-out test. Reinsertion reduced the pull-out strength in the single screw by 18 %, but the effect was not significant in two-screw configuration. (Krishnan et al., 2016) In order to evaluate the pull-out strength of a cancellous screw, the pull-out strength of a loosened cancellous screw, and the pull-out strength of a loosened cancellous screw revised with a larger diameter cancellous screw, a biomechanical study using synthetic PU foam was conducted by Seng et al. The outcome revealed that the pull-out strength is reduced by 79.1% as a result of the loosening cancellous screw. The pull-out strength of a loosening cancellous screw is improved to 59.3% of the baseline by reinserting it with a bigger diameter screw. (Seng et al., 2021)

The angle of insertion of the bone screw should be taken into account in analysing the screw’s pull-out strength. A study is done by Jomha et al. to investigate the effect of angles on the pull-out strength of interference screw fixation. The interference screw is a direct tendon-to-bone interference fixation tool. Changes in the interference screw’s angle with respect to the bone plug, from 0° to 30°, were studied to see how they affected pull-out strength. The results show that interference screw fixation’s tensile strength was not significantly different for angles up to 10 percent, but that fixation was significantly weaker with p-value equals 0.0010 for screw angles more than 20 degrees. (Jomha et al., 1993) In contradiction, study done by Varghese et al.

proposed the angled pull-out strength is better than axial pull-out strength up to 34 percent, in the osteoporotic bone model. (Varghese et al., 2017)

Patel et al. had conducted a study in determining the effect of varying angle of insertion of bone screws in normal and osteoporotic bone models to its pull-out strength. The bone screws were inserted at an angle of insertion ranging from 10 degree to 40 degree, into PU foam blocks at various densities. Both cancellous and cortical bone screws were used to observe the factor of thread type. The results stating that cancellous screw had better pull-out performance than cortical screw. For both screws, the increasing density of PU foam and the angle of insertion suggest better pull-out strength. (Patel et al., 2010) Krishnan et al. studied on the effect of the screw insertion angle on the pull-out strength of single and two pedicle screws. For the pull-out test, different densities of PU foam blocks were employed in both screw arrangements. In single-screw configuration, the pull-out force decreased with the increasing insertion angle. However, in two-screws arrangement, the pull-out strength was the maximum at 10-15 degree. (Krishnan et al., 2016)

2.2 Research Method Used

Among the 28 papers being reviewed, 15 research was conducted only laboratory experiments in determining the factors affecting pull-out strength of the screw, whereas 7 studies were using FEA only. There were 6 investigations established using both the experimental and computational method. Among the studies done using FEA approach only, the factors discussed were bone density, screw core design, screw size, pilot hole size, insertion depth, and auxetic structure. There were no relevant papers related to both the bone screw insertion angle and finite element analysis found throughout the literature review.

CHAPTER 3

METHODOLOGY

This chapter briefly explains the methodology of this final year project. The procedure taken is sub-sectioned into two components. The first section presents the 3D modelling of the components required, which are the bone screw and the synthetic substitution for human bone. The second section presents the simulation setup for the insertion of the screw and the pull-out test.

3.1 CAD Modelling of Bone Screw and Solid Rigid Polyurethane Foam Block

3.1.1. Bone Screw

The bone screw used in medical field are cortical screw and cancellous screw. Cortical screw was modelled for this final year project since it is the most used bone screw in ORIF as the cortical bone covered around 80 % of a healthy adult skeleton. (Clarke, 2008) From the market survey, the dimension and design of the bone screw used was referring the cortex screw available in Narang Medical Limited as stated in Table 3-1 below. (Narang Medical Limited, 2022)

Table 3-1 Parameter of the 3D Cortical Bone Screw Model

Parameter	Dimension (mm)
Head Diameter	8.00
Thread Length	45.00
Major Diameter	4.38
Core Diameter	3.50
Pitch	1.75

Based on the dimensions mentioned in Table 3-1, the cortical screw was modelled using SolidWorks 2021, one of the CAD software from Dassault Systemes available in Computer & CAD Laboratory, School of Mechanical Engineering, USM. The 3D CAD model of the cortical bone screw was shown in Figure 3-1. The CAD drawing of the cortical bone screw was attached in this thesis as Appendix A.

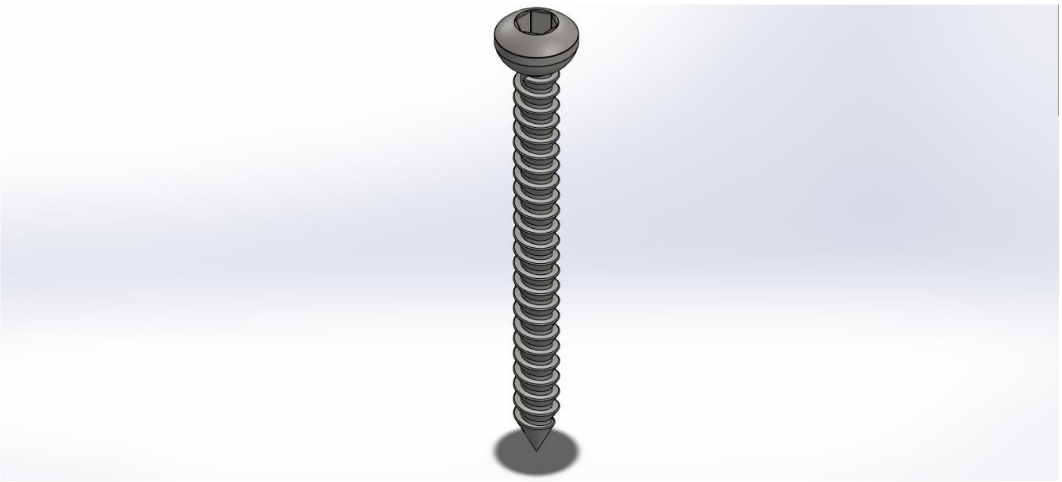

Figure 3-1 3D CAD Model of Cortical Bone Screw

3.1.2. Solid Rigid Polyurethane (SRPU) Foam Block

From the literature review made, most studies used synthetic polyurethane (PU) foam as a substitute for human bone in pull-out test. Solid rigid polyurethane (SRPU) foam block provided by Sawbones offered a consistent structure with a tolerance of 10 % density variation, covering a wide range of human bone qualities, having a density ranging from 0.08 g/cm3 to 0.80 g/cm3. The foam block complied to ASTM F-1839-08 “Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments”, and the related standards which are ASTM D1621, ASTM D1622, ASTM D1623, and ASTM C273. The dimension and design of the SRPU foam block used was referring the biomechanical products available in Sawbone as stated in Table 3-2 below. (Sawbones, 2022)

Table 3-2 Parameter of the 3D Solid Rigid Polyurethane Foam Block Model

Size	Length (mm)	40
	Width (mm)	40
	Height (mm)	50
ASTM D1622 Density	(PCF)	20
	(g/cm^3)	0.32
ASTM D1621 Compression	Strength (MPa)	8.4
	Modulus (MPa)	210
ASTM D1623	Strength (MPa)	5.6

Tension	Modulus (MPa)	284
ASTM C273 Shear	Strength (MPa)	4.3
	Modulus (MPa)	49

Based on the dimensions mentioned in Table 3-2, the SRPU foam block was modelled using SolidWorks 2021. A hole with 3.2 mm in diameter and 20 mm of depth was created on the SRPU foam block to act as the pilot hole for the screw insertion. Meanwhile, a plane parallel to the top surface of the SRPU foam block was created to enable generating the screw insertion at angles of 0°, 15°, 30° and 45°. The 3D CAD model of the SRPU foam block with pilot hole of insertion angle at 0° was shown in Figure 3-2. The CAD drawing of the SRPU foam block with pilot hole of insertion angle at 0° was attached in this thesis as Appendix B.

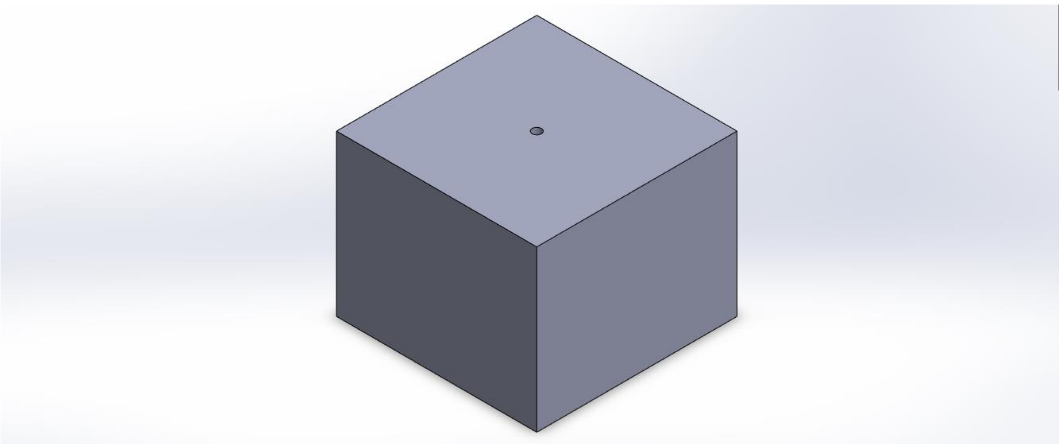

Figure 3-2 3D CAD Model of The SRPU Foam Block with Pilot Hole of Insertion Angle At 0°

3.1.3. Assembly of the Components

Both the 3D model of cortical screw and SRPU foam blocks were important into SolidWorks 2021 Assembly to place the screw tip at the pilot hole on the SRPU foam block. The assembly of the components at screw insertion angle of 0°, 15°, 30° and 45° were shown in Figure 3-3, 3-4, 3-5 and 3-6, respectively. The assembly was then exported to .STP214 format to enable ANSYS software read the CAD assembly model.

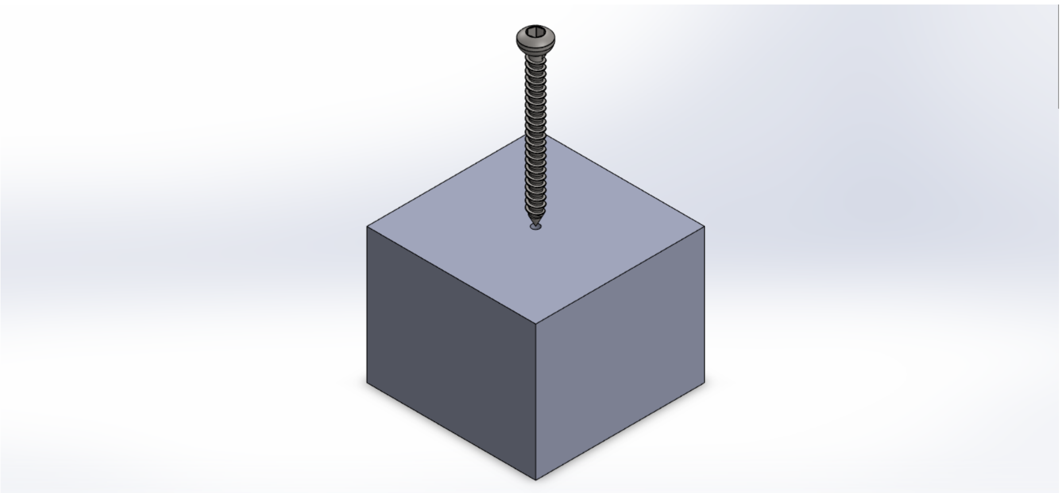

Figure 3-3 Assembly of Cortical Screw and SRPU Foam Block at Screw Insertion Angle of 0°

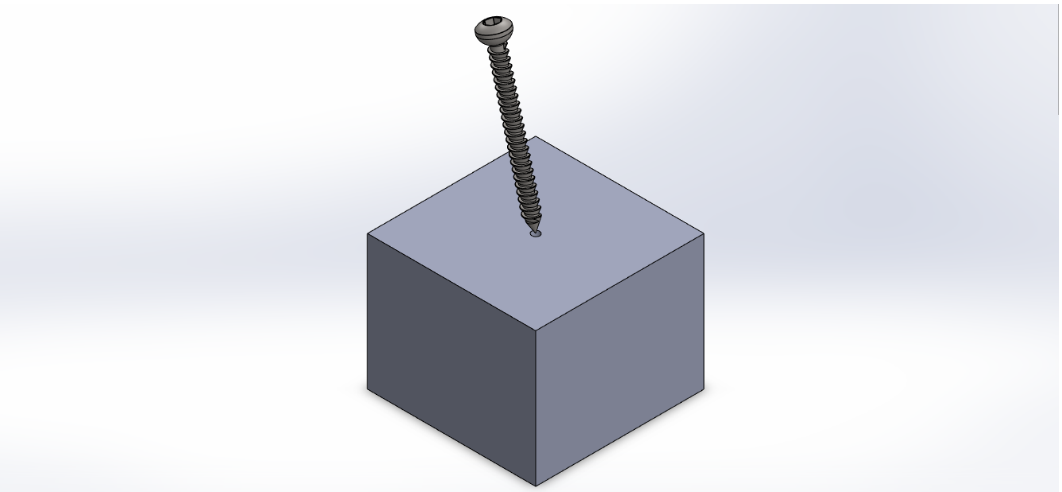

Figure 3-4 Assembly of Cortical Screw and SRPU Foam Block at Screw Insertion Angle of 15°

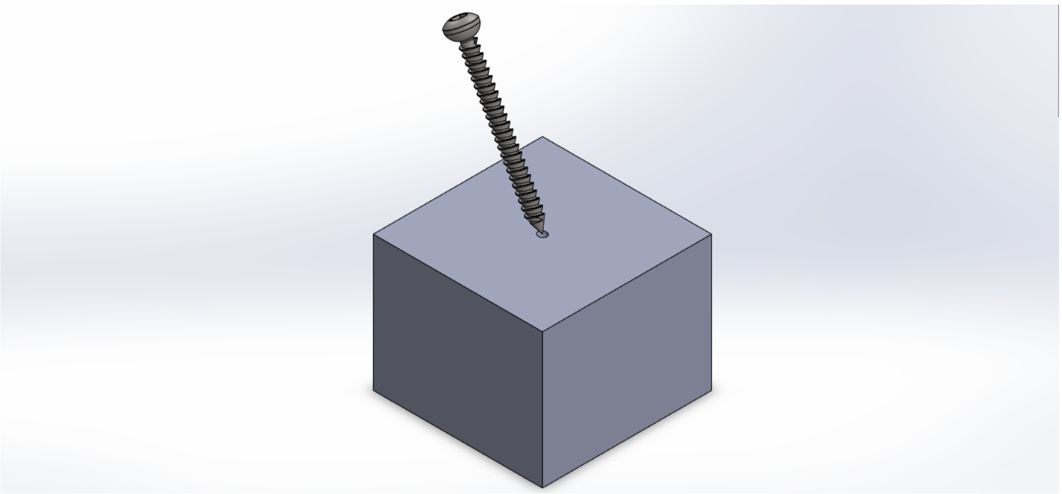

Figure 3-5 Assembly of Cortical Screw and SRPU Foam Block at Screw Insertion Angle of 30°

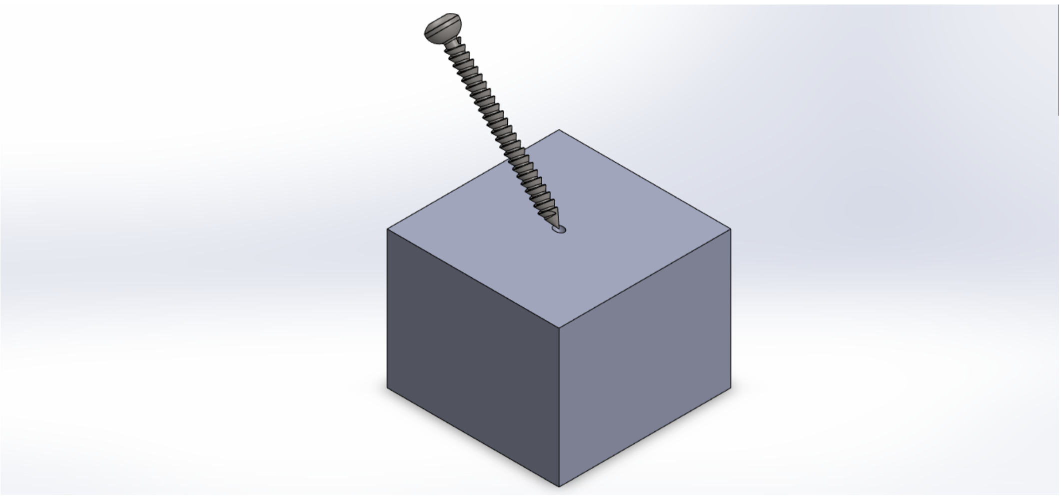

Figure 3-6 Assembly of Cortical Screw and SRPU Foam Block at Screw Insertion Angle of 45°

3.2 Simulation Setup of Screw Insertion and Pull-Out Test

According to ASTM F543 “Standard Specification and Test Methods for Metallic Medical Bone Screws”, to determine the pull-out strength of medical bone screws, the bone screw was first inserted into the test block designed to ASTM F1839, at an insertion speed of 3 rpm for 20 mm or 60 % of the thread length. After the screw insertion, the screw head was pulled out of the test block at a rate of 5 mm/min. The maximum tensile force to pull out the screw was measured. Similar setup was performed using ANSYS, a FEA software available in Computer & CAD Laboratory, School of Mechanical Engineering, Universiti Sains Malaysia, to comply with the ASTM F543 standard.

3.2.1. Insertion of Screw into SRPU Foam Block

With ANSYS Workbench, the mechanical properties of the SRPU as stated in Table 3-2 were inserted into the Engineering Data component. Stainless steel was added to the Engineering Data Sources: General Material Library as the material assigned for cortical screw. The mechanical properties of stainless steel found in ANSYS Engineering Data Sources: General Material Library was shown in Table 3-3.

Table 3-3 Mechanical Properties of Stainless Steel in ANSYS Engineering Data Sources: General Material Library

Property	Value
Density (kg/m^3)	7750
Isotropic Young Modulus (MPa)	1.93 E5
Isotropic Poisson's Ratio	0.31
Isotropic Bulk Modulus (MPa)	1.693 E5
Isotropic Shear Modulus (MPa)	0.737 E5
Tensile Yield Strength (MPa)	207
Compressive Yield Strength (MPa)	207
Tensile Ultimate Strength (MPa)	586

To simulate the insertion of screw, Explicit Dynamic analysis system was used. The .STP214 file of the CAD assembly model of cortical screw and SRPU foam block was imported into ANSYS DesignModeler under Geometry component and was undergone simulation modelling in ANSYS Mechanical. In ANSYS Mechanical, cortical screw and SRPU foam block were detected as two solid bodies. Materials were assigned to both the solid bodies which the cortical screw was pre-defined stainless steel whereas the SRPU foam block was selfdefined PU. A frictional connection was created under ‘Connections’ tree between thread body of cortical screw and pilot hole on the SRPU foam block with static and dynamic frictional coefficient of 0.5 and 0.2, respectively, to allow torsional shearing and distortion occur during the simulation.

The model was then undergone meshing by inserting two body sizing meshing to the screw and SRPU foam block, respectively, to prevent the meshing failure due to the incorrect interpretation of ANSYS Meshing on the model as the position of the screw was closed to the pilot hole on the SRPU foam block. The meshing element size was set to default value to allow ANSYS generate the optimal mesh for the model automatically. The meshed model of cortical screw at an insertion angle of 0° was shown in Figure 3-7.

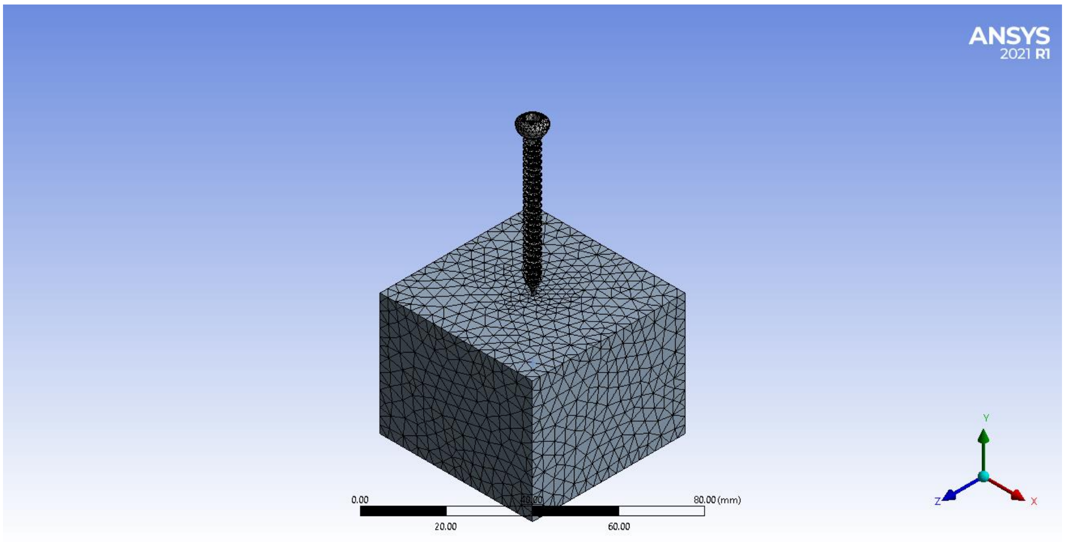

Figure 3-7 Meshed 3D CAD Model of Cortical Screw at Insertion Angle of 0°

The meshed model of cortical screw and SRPU foam block was ready for simulation setup. In Explicit Dynamics, the initial conditions were set to have no pre-stress, an angular velocity of 3.0 rpm (counterclockwise direction from z-axis to x-axis) along the axial axis of screw body, and a velocity of 25 mm/s along the axial axis of cortical screw towards the pilot hole. A fixed support was set on the bottom surface of the SRPU foam block to resist angular and translational force from the screw insertion. The analysis settings of the simulation were set according to the Table 3-4. Some adjustments on the analysis settings were made accordingly with the mesh of the angled screw insertion to allow a success simulation. The solutions of the simulation were set to be focused on total deformation, equivalent elastic strain, and equivalent stress, and were presented in Chapter 4.

Table 3-4 Analysis Settings for ANSYS Mechanical Explicit Dynamics Analysis System

Step Controls	Value/Setting
Number of Steps	1
Current Step Number	1
Load Step Type	Explicit Time Integration
End Time	1 E-6 s
Maximum Number of Cycles Per Step	1 E5
Initial Time Step	1 E-12
Minimum Time Step	1 E-12
Maximum Time Step	Program Controlled

3.2.2. Simulation Setup for Pull-Out Test

The simulation setup for the pull-out test of cortical screw was prepared after the completion of simulation for the screw insertion. The model of SRPU foam block with cortical screw inserted was generated in SolidWorks and was imported to ANSYS DesignModeler. Most of the parameters were set to be the same as the setup used in the insertion of screw. The setup of the simulation for pull-out test of cortical screw inserted at an angle of 0° was shown from Figure 3-8.

There were two differences between the simulation setup for the screw insertion and pull-out test, which were the applying of initial condition and the result obtained. A translational velocity of 5 mm/min or 0.08333 mm/s along the axial axis of screw body was applied in the direction away from SRPU foam block as initial condition on the head of cortical screw, whereas there were both translational and angular velocity applied on the screw during screw insertion simulation. Meanwhile, there was an extra result being calculated for the pull-out test simulation, that was the probe of force reaction on the screw. This force reaction probe was to measure the upwards pulling force (positive y-axis) applied on the bone screw during the pull-out test simulation, as suggested in Patel et al's study. The peak value of the force reaction measured from the probe throughout the simulation was defined as the pull-out force required.

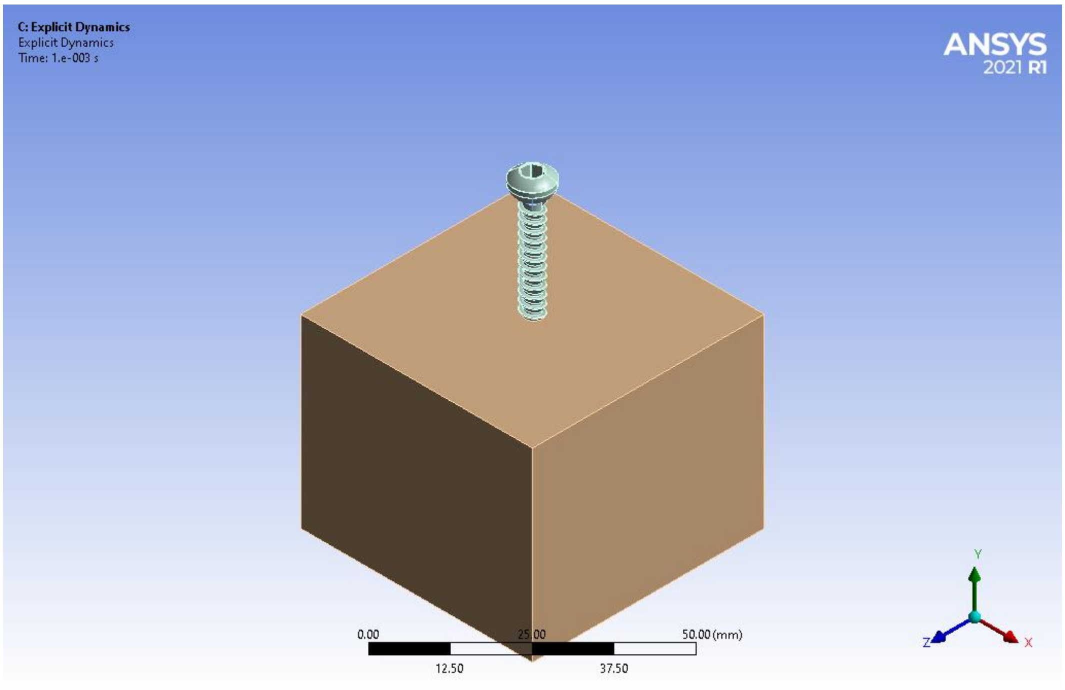

Figure 3-8 Setup of The Simulation for Pull-Out Test of Cortical Screw Inserted at an Insertion Angle of 0°

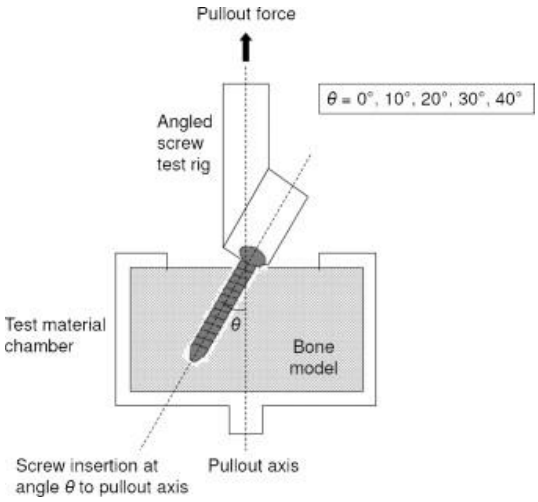

Figure 3-9 Direction of the Pull-Out Force Used in Patel et al's Study (Patel et al., 2010)

CHAPTER 4

RESULT AND DISCUSSION

In this chapter, all the findings obtained from FEA simulation made are presented with brief descriptions, explanations, and discussions. A summary of issues found limiting the progress of the final year project is presented at the last section of this chapter.

4.1 Finite Element Simulation Results

4.1.1. Insertion of Screw

The process of inserting the cortical screw into the SRPU foam block complying ASTM F543, at an angle of 0°, 15°, 30° and 45°, was simulated by ANSYS Mechanical. The solution of the FE simulation yielded the total deformation, equivalent elastic strain, and equivalent stress. The contour plot of both isometric view and cross-section view from positive z-axis were presented below.

4.1.1.1. Total Deformation

The maximum total deflection for the screw was approximately 55.949 mm, 24.967 mm, 24.801 mm, and 24.800 mm, for 0°, 15°, 30°, and 45° insertion angle configuration, respectively. There were deformed chips of SRPU foam block found in all the configurations.