EXPERIMENTAL AND NUMERICAL EVALUATION OF THE PULLOUT STRENGTH OF SELF-TAPPING BONE SCREWS IN NORMAL AND OSTEOPOROTIC BONE

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EXPERIMENTAL AND NUMERICAL EVALUATION OF THE PULLOUT STRENGTH OF SELF-TAPPING BONE SCREWS IN NORMAL AND OSTEOPOROTIC BONE

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ABSTRACT

Self-tapping cortical screws (STS) are being increasingly used for fracture fixation in metaphyseal region due to their advantage over the other bone screws. The objective of this study was to compare the pullout index and loading energy of the STS inserted in normal and osteoporotic bone blocks. A 3D model of the bone-screw interface was developed to numerically evaluate the effect of bone quality on pullout strength. Previous studies indicated the significance of pilot hole, insertion torque, screw size and cutting flutes in normal bone. This study evaluated their effects in osteoporotic bone model and compared them experimentally and numerically.

For the pullout study the screws were divided into five groups each representing a depth of insertion in normal and osteoporotic bones (six screws per group), respectively. The effects of pilot hole size, cutting flutes, manufacturer, material and screw size on the pullout index (PI) were also evaluated in this study by categorizing the screws into different groups (six screws per group). The pullout protocol specified by ASTM F.543-02 standard for metallic screws was experimentally implemented on a sample size determined by power analysis. Synthetic bone models were used for experimental evaluation. ANOVA was used to statistically analyze the effect of screw size and cutting flutes on the pullout strength.
Experimental values indicated that the PI of screws inserted into normal bone blocks was significantly different ($p < 0.05$) from that of osteoporotic bone blocks. The results also demonstrated that the PI of the screws increased with the depth of insertion in both normal and osteoporotic bones. The performance of stainless steel screws was observed to be significantly different from that of titanium screws in osteoporotic bone but not in normal bone blocks. It was also observed that there was no significant difference in PI and loading energy (LE) for screws from different manufacturers in normal and osteoporotic bone.

A finite element model, with non-linear material properties, was analyzed to investigate the interaction of the bone quality and depth of insertion on the pullout characteristics. Bone quality was observed to have a significant effect on the PI as in the experimental testing. The model was validated with the experimental data for the effect of depth of insertion on the PI for normal and osteoporotic bones.
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CHAPTER I
INTRODUCTION

1.1. Outline and Purpose

The purpose of this study was to determine the pullout index (PI) of self-tapping screws (STS) in bone materials representing normal bone and osteoporotic bone for applied linear uni-axial load. Pullout strength had been the primary variable in previous studies to characterize the performance of the screws in bone. In this study, loading energy (LE) and stiffness were also determined with experimental pullout protocols. Effects of screw size and pilot hole on the PI, LE and stiffness in osteoporotic bone were also investigated using identical test conditions. The study also involved the development and validation of a finite element model (FEM) to simulate the pullout of the screw from normal and osteoporotic bone materials. A solid model of bi-layered bone representing the cortical and cancellous layers of human bone and commercially available self-tapping bone screws along with their material properties was developed. The model developed was based on linear geometry and non-linear material properties making it a small-strain model.

1.2. Significance of the study

Bone screws are commonly used implants for fracture fixation and also for stabilization of bone transplants. Currently, self-tapping cortical bone screws (STS) are
used more frequently than other types of bone screws (non-self-tapping, etc.). The use of STS reduces the operation time; number of instruments required and blood loss. The STS also have a higher screw-to-bone interface compared to the non self-tapping screws. The presence of cutting flutes in STS is a salient feature that eliminates the need to use a tap and facilitates insertion of the screws. Cutting flutes are also considered to have a detrimental effect on the holding power of the STS as the purchase of the bone in the region of the flutes is lesser than that in the fully threaded region that may lead to the reduction in fixation strength [78].

A reduction in the stability of the bone-screw construct has been observed for some of the fracture fixation procedures. One of the factors that determines the performance of the STS is PI. Screw loosening has been observed to occur at the bone-screw interface due to mechanical failure or instability in osteoporotic subjects [43]. PI of the screws inserted in osteoporotic bone becomes a crucial quantity as osteoporosis deteriorates the bone tissue enhancing the possibility of fracture and also poses problems for fracture treatment. The reduction in modulus of elasticity, tensile modulus and tensile strength in osteoporotic bone clearly impacts the fixation strength, stiffness and durability of orthopaedic biomaterials.

Osteoporotic bone is characterized by low bone density and structural deterioration of bone tissue making it more susceptible to pathologic failure. This often results in fractures of the hip, spine, etc., after a normal fall. Internal fixation of osteoporotic fractures can be difficult due to severe reduction of density and structural properties of bone. Osteoporosis has gradually become a major public health threat for postmenopausal
women and aging individuals of both sexes, Ten million people are estimated to have the
doctrine and 34 million more are at a risk for osteoporosis [1]. Thus arises a need to
prevent osteoporosis and also for effective osteo-fixation for its associated fractures.

Any osteo-fixation using plates and screws, especially in the metaphyseal region,
involves anchoring of screws in either bone or augmented material. Effectiveness of
osteo-fixation can be quantified in part by the force required to pull the screw from bone
into which it is inserted. Pullout strength has been considered to be a significant factor in
determining the mechanical stability of the screw fixation as any load exceeding the
pullout limit when transferred between screw and bone might lead to complications in
fracture healing. Axial pullout strength has been extensively researched to evaluate the
effect of parameters like screw size (diameter), depth of insertion (DOI), screw thread
profile, pitch and insertion torque for STS inserted in normal bone [1,3,5,15,52,53,55,
60,62,78]. But only a few investigators have studied the effect of deterioration of the
bone quality on the pullout strength of STS [9,18,62]. Though a number of studies
quantified the performance of STS in normal bone, the uncertainty of expecting a similar
performance of the STS in osteoporotic bone remains. With the increase in the aging
population of the world, osteoporotic fractures will have profound implications on the
orthopedic community. Hence, to aid the research on treatment of fractures in
osteoporotic bone, this study investigates the influence of depth of insertion, cutting
flutes, screw size (outer diameter), insertion torque and pilot hole size on pullout strength
of STS.
In this study, an attempt was made to develop a numerical model to simulate screw pullout. Current mathematical (finite element) models of the screw pullout simulation are simplified in their geometry, material properties and definition of the bone-screw interface [23,82,83]. Some of the limitations of these models include the use of 2D models, linear material properties and ideal bonding at the bone-screw interface. The model in this study was developed to overcome some of the above-mentioned limitations. To date, no study has incorporated non-linear material properties of the bone and screw into a 3D model of the bone-screw interface and no model of the screw pullout has been validated for osteoporotic bone. The goal of this study was to evaluate the effect of depth of insertion (engagement length), bone quality (density), cortical thickness and cutting flutes on the pullout strength of STS used for implant fixation in the metaphyseal region.

1.3. Statement of hypothesis:

Several null and research hypotheses were developed for this study. Due to the qualitative nature of the research hypotheses involving the finite element model, statistical analyses were not deemed suitable.

1.3.1. Null Hypotheses

1. There is no significant difference between the PI of the STS in normal and osteoporotic bone material.

2. There is no significant difference between the PI of the STS inserted to different depths in bone material.

3. There is no significant difference between the PI of the STS of different manufacturers.

4. There is no significant difference between the PI of the STS made of Stainless Steel (SS) and Titanium (Ti).
5. There is no significant difference between the PI of the STS when the cutting flutes are completely inside or outside the bone material.

6. There is no significant difference between the LE of the STS in normal and osteoporotic bone material.

7. There is no significant difference between the LE of the STS inserted to different depths.

8. There is no significant difference between the LE of the STS of different manufacturers.

9. There is no significant difference between the LE of the STS when the cutting flutes are completely inside or outside the bone material.

1.3.2. Alternate Hypotheses

1. There is a significant difference between the PI of the STS in normal and osteoporotic bone material.

2. There is a significant difference between the PI of the STS inserted to different depths in the bone material.

3. There is a significant difference between the PI of the STS of different manufacturers.

4. There is a significant difference between the PI of the STS made of SS and Ti.

5. There is a significant difference between the PI of the STS when the cutting flutes are completely inside or outside the bone material.

6. There is a significant difference between the LE of the STS in normal and osteoporotic bone material.

7. There is a significant difference between the LE of the STS inserted to different depths.

8. There is a significant difference between the LE of the STS of different manufacturers.

9. There is a significant difference between the LE of the STS when the cutting flutes are completely inside or outside the bone material.
1.3.3. Research hypothesis

1. It is possible to construct a geometrically accurate model of the bone blocks and screw and employ it to solve a finite element model.

2. It is possible to demonstrate, using the FEM, a difference in the PI of the STS in normal and osteoporotic bone.

3. It is possible to substantiate the findings from the FEM with that from the experimental testing.

1.4. Specific Aims

The following specific aims were formulated to achieve the goals and objectives of this study. They summarize the scope of this dissertation:

1. To determine the PI of the STS inserted in normal and osteoporotic bone.

2. To determine the PI of STS for different depths of insertion with respect to the far cortex.

3. To determine the effect of the manufacturers on the PI of STS inserted in normal and osteoporotic bone material.

4. To determine the effect of screw material (SS or Ti) on the PI of STS in normal and osteoporotic bone.

5. To determine the influence of cutting flutes on PI of STS in normal and osteoporotic bone.

6. To determine the effect of pilot hole on the PI of the screw inserted into osteoporotic bone.

7. To determine the effect of screw size on the PI when inserted to different depths in osteoporotic bone.

8. To develop a three-dimensional solid-model of the bone screw.
9. To develop a FEM to simulate screw pullout from normal and osteoporotic bones using the solid model of the screw.

10. To substantiate the FEM with the experimentally obtained pullout data.

1.5. Flow

The dissertation has been organized in the order of significance of the study, previous studies and their limitations, methodology for evaluating effects of different parameters on pullout index, results from the experiments and simulations, discussing the results and the limitations of the study and concluding remarks. The flow is as follows:

- Chapter 2 describes previous studies and concepts pertaining to screw pullout and finite element modeling.
- Chapter 3 describes experimental protocols for evaluating the effect of various parameters on the PI of STS and development of finite element model that includes the bone-screw construct model and simulation methodology.
- Chapters 4 and 5 focus on the results and discussion of the screw pullout from normal and osteoporotic bone, the effect of screw size, the effect of a pilot hole size, the FEM and its validation and also indicate the limitations of the study.
- Chapter 6 concludes the dissertation with final conclusions and addresses the future outlook of the study.

1.6. Assumptions and limitations

This study investigated the effects of different variables during screw pullout on the PI of the screws inserted into normal and osteoporotic bone blocks but it represented an
idealized clinical situation with a few limitations. Some of the limitations and assumptions made to accommodate the limitations are listed as follows:

- Synthetic blocks were used to represent the normal and osteoporotic bone blocks.
- Bone was assumed to be an homogenous and isotropic material and was modeled accordingly.
- Micro-architectural deterioration in osteoporotic bone was not simulated.
- Thermal necrosis could not be simulated, hence the surrounding bone during insertion was assumed to be healthy and intact.
- Screw size study was limited by the lack of availability of the screws and variation of more than one screw parameter between the groups.
- Cancellous bone in the finite element model was assumed to be a uniform material with low porosity.
CHAPTER II
LITERATURE REVIEW

2.1. Bone

The skeletal system is a mechanical system that transmits forces from one region of the body that is in contact with the external environment to another and also prevents these forces from damaging organs. Bones not only provide mechanical integrity for the skeletal system but also serve as calcium and phosphorus reservoirs. Bones facilitate blood cell formation in their marrow cavities and are used as levers by muscles to move different body parts. Bones were considered to be static tissue but they are dynamic tissues that continually sense the mechanical loads and adapt their physiological structure, composition and internal architecture to withstand those loads. Martin et al. hypothesized about the mechanical adaptability of the bone that “bone structure is regulated so as to minimize fracture risk and bone mass while simultaneously optimizing stiffness” [46].

2.2. Classification of Bones

Bones come in various sizes and shapes based on their anatomical location and load bearing characteristics. They can be classified as long, short, flat and irregular bones. All
the bones have two distinct types of tissues known as (outer) cortical bone and (inner) cancellous bone, based on their porosity and architecture.

a) *Long bones* are primarily constructed of compact bone and they also have some cancellous bone at each of the ends. The length of these bones is greater than their width hence they are referred to as long bones. They mainly consist of the shaft (diaphyseal) region that is predominantly comprised of compact bone and two end-regions (epiphyseal regions) that have a trabecular structure enclosed in a thin cortex. They have a inner medulla called the intramedulary canal which contains bone marrow, vascular and lymphatic supply and hematopoietic cells. Femur, humerus and tibia are examples of long bones.

b) *Short bones* are found in the wrist and ankle. Majority portions of short bones are comprised of endosteum-covered spongy bone and periosteum-covered compact bone forms a thin outer layer. The width of these bones is greater than or equal to their length giving them a cube-like appearance.

c) *Flat bones* are thin bones that are found in the skull, ribs etc. They are formed as two parallel layers of cortical bone sandwiching a thin layer of cancellous bone.

d) *Irregular bones* are shaped complexly and are found in hip and spine bones. All the bones that are not classified in any of the above categories can be considered to be irregular bones that primarily contain cancellous bone with a thin layer of compact bone [44].
2.3. Structure of Bone

Bone can be classified into cortical and cancellous bone based on structure and micro-architecture. Long bones can further be classified into epiphyseal, metaphyseal and diaphyseal regions based on their anatomical location and physiological functions.

2.3.1. Cortical Bone

Cortical bone, also known as compact bone, is a dense bone with low porosity (5 – 10%). It is primarily found in the shaft (diaphyseal region) of the long bones and also forms the outer (shell-like) cortex around vertebrae and trabecular bone in epi- and metaphyseal regions (Figure 1). Compact bones constitute approximately 85% of the bone mass of human skeleton. The primary unit of compact bone is a longitudinally arranged osteon or haversian system, which has a cylindrical structure and can be considered to be a weight-bearing pillar. The pores of the cortical bone are comprised of:

a) Resorption Cavities are pits created by osteoclasts for the osteoblasts to fill them with new bone during remodeling. Osteoclasts are multi-cellular bone resorbing cells and osteoblasts are mononuclear bone forming cells.

b) Haversian Canals that run along the length of the bones and house capillaries, lymph vessels and nerves. They run through the core of an osteon.

c) Volkmann’s Canals are channels that provide an oblique path for blood vessels and nerves to interconnect haversian canals and periosteum or endosteum and with each other [14,44,46,79,81].
Figure 1. Femur illustrating different types of bone and classification of regions in long bones.

2.3.2. Cancellous Bone

Cancellous bone also known as trabecular bone or spongy bone, is a low density or highly pororous (75-95%) structure in contrast to compact bone (Figure 1). Vertebral bodies, metaphyseal regions of long bones and flat bones are primary locations to find cancellous bone. The trabecular structure of the cancellous bone is comprised of honeycomb of individual trabeculae formed from bone matrix. Cancellous bones constitute approximately 15% of the bone mass of human skeleton. Trabeculae, considered to be the primary unit of cancellous bone, are aligned along the direction of stress to support the bone in resisting that stress. The pores in the honeycomb structure
give the a bone a sponge like appearance and the space between the trabeculae is filled with red or yellow marrow [44,46,79,81].

2.3.3. Diaphyseal region

The diaphyseal region is the central tubular region of long bones, also referred to as the shaft that, constitutes the longitudinal axis of the long bone. It comprises of a thick layer of periosteum-covered compact bone that surrounds the medullary cavity. The medullary canal contains red or yellow marrow along with vascular and lymphatic supplies [44,46].

2.3.4. Epiphyseal region

The region at the end of the long bones is called the epiphyseal region with the end being referred as epiphyses. The epiphyseal region is wider than the tubular diaphyseal region with an outer layer of compact bone and interior spongy bone region. The epiphysis of adult bone is separated from the diaphyseal region by the epiphyseal line and metaphyseal region. The epiphyseal line is also called as the growth plate [44,46].

2.3.5. Metaphyseal region

The metaphyseal region is the segment that bridges the diaphyseal shaft and the epiphyseal region. It primarily contains spongy bone with a relatively thick (compared to epiphysis) compact layer that shapes the bone during the modeling phase. This region gradually narrows into the diaphyseal region that only contains the compact bone and medullary canal [44,46]. Most of the hematopoietic cells are housed in the cancellous region of the metaphysis.
2.4. Osteoporosis

Osteoporosis is a pathologic disorder that effects the skeletal system and is characterized by the reduction in bone mass and micro-architectural deterioration of the bone [21,40,79]. Osteoporosis is known as the “silent” disease that primarily affects the aging population by increasing their susceptibility to break bones even with small amounts of stress. Osteoporosis is one of the most common musculo-skeletal disorders of the elderly that may lead to breaking a hip or fracturing a vertebra from a minor trauma (normal fall) that would only bruise a younger person and this can be attributed to the loss of bone [77]. Most fractures in osteoporosis are due to falls: 92% of hip, 96% of distal radius, 95% of proximal humerus, 82% of foot and toe, and 68% of hand fractures. In recent years the severity and frequency of osteoporosis related fractures has increased considerably, diminishing the quality of life, increasing morbidity and elevating the costs for treatment substantially.

Osteoporosis can be considered to be the result of the imbalance created by the increase in bone resorption compared to that of formation in both the trabecular (cancellous) and cortical bone. Osteoporosis is characterized by the thinning of the trabeculae (material resorbed from plates and struts that constitute trabecular bone), Figure 2, and diaphyseal resorption that changes the diameter of the inner and outer cortices. This structural change affects the bending and torsional characteristics of the bone and makes it susceptible to low-energy fractures [28]. The thinning of the cortices in ribs may make them as fragile as eggshell. These changes in the morphology in osteoporotic bone lead to complications in osteosynthesis. Fracture fixation challenges
that arise are due to anchoring of the implants in weak bone and probable loosening and failure of the implants in the future due to bone resorption [79].

![Trabecular structure of normal and osteoporotic bones illustrating the thinning of trabeculae in osteoporotic bone](image)

Giannoudis et al. and Johnell et al. reported an estimate of 40% of white women in the United States and 14% of white men over the age of 50 experienced at least one osteoporosis related fracture in their lifetime. The International Osteoporosis Foundation estimates that 30-50% of women and 15-30% of men will suffer a fracture related to osteoporosis in their lifetime. With the increase in the number of elderly people in the near future (so called baby-boomers), both in the United States and around the world, an estimated 200 million people are at a risk of sustaining fragility fractures globally. According to the estimates published by The National Osteoporosis Foundation in the USA, by 2010 about 12 million people over the age of 50 are expected to have osteoporosis and another 40 million to have low bone mass. The annual direct medical cost for treatment of osteoporotic fractures was calculated to be approximately $17.5 billion based on the treatment costs reported for the previous years [64].
Figure 3  Trabecular bone thinning is observed in both men and women with aging but there is a removal of bone plates in women (With Permission of Prof. Seeman) [64].

2.4.1. Women vs Men: Who is more affected?

The skeletal mass begins to deteriorate at 0.5 % per year after skeletal maturation in both sexes. Involution of bone mass and mineral density proceeds at a constant rate in the absence of any disorder/ deficiency. The bone loss rate remains constant and lower in males as compared to females enabling them to reach fracture threshold at a later age. This constant bone loss in women leads to severe thinning of the trabeculae and removal of complete plates compared to that in men as shown in Figure 3 [64]. This disparity between males and females can be attributed to lower peak bone mass and acceleration of
bone loss (~3% per year) with the onset of menopause which leads to estrogen deficiency [79]. It can also be observed that the rate of endosteal thinning of the cortical bone is similar for men and women (Figure 4) but the rate of peripheral bone formation is higher in men than in women. This phenomenon also contributes to the faster weakening of bone in women than in men.

Figure 4  Difference in the rates of peripheral bone formation and endosteal thinning leading to weakening of bones at an earlier age in women than in men.

2.4.2. Bone Mineral Density

The most common diagnosis of osteoporosis is based on bone mineral density (BMD) measurement. BMD is usually the amount of mineralized tissue in the scanned area, its units are g/cm$^2$, but in some of the technologies it is measured as amount per volume of bone (g/cm$^3$). Hip BMD is considered the best predictor of hip fracture and appears to predict other types of fractures as well as measurements made at other skeletal
sites do. The World Health Organization (WHO) [40,61] provided the following base operational definitions based on BMD to predict the severity of osteoporosis:

a) Measured value for BMD < 1 standard deviation (SD) below the gold standard value (GSV) of young adult: Normal

b) Measured value for BMD > 1 SD below the GSV of young adult but not > 2.5 SD below: Osteopenia

c) Measured value for BMD > 2.5 SD below the GSV of young adult: Osteoporosis

d) Measured value for BMD > 2.5 SD below the GSV of young adult and presence of one or more fragility fractures: Severe osteoporosis

There are different modalities for measuring the BMD values that characterize osteoporosis. X-rays are the simplest form of radiographs but have shortcomings for diagnosing osteoporosis. Single Photon absorptiometry was also considered for detecting osteoporosis but the most commonly used methods are dual x-ray absorptiometry (DXA) and quantitative computed tomography (QCT).

2.4.3. Dual X-ray Absorptiometry

Diagnosis of osteoporosis prior to a fracture is very important clinically as there have been a number of studies that show a significant increase in risk of fractures after the first fracture. Simple bone radiographs are not sufficient to diagnose the bone loss at an early stage, as a significant amount of bone loss would have occurred before it could be detected. DXA is a diagnostic test used to assess BMD in spine, wrist, hip or total body. Radiation exposure is minimal and the procedure is short and easy to perform. DXA measures area density (g/cm²) rather than true volumetric density.
DXA bone density studies of the spine and hip are considered the “gold standard” for diagnosing osteoporosis and following changes in bone density over time. Previously known as dual energy x-ray absorptiometry (DEXA), this technique uses two low dose x-rays of different energies to distinguish between bone and soft tissue, giving a very accurate measurement of bone density at scanned sites. The software of DXA devices enables automatic detection and identification of major anatomical landmarks. This feature of DXA scans enables the analysis of the clinically most important site, the proximal femur, Figure 5. The presence of trabecular bone in abundance in the intertrochanteric region and the Ward’s triangle with small amount of cortical bone (shell) makes this a key site clinically. It has been established that hip densitometry predicts the risk of fragility fracture at other sites along with being the best predictor of hip fractures.

DXA bone density testing is the most accurate method available for the diagnosis of osteoporosis and is also considered an accurate estimator of fracture risk. DXA scanning equipment is widely available and is a commonly used tool for measuring bone density. It is a simple non-invasive procedure that doesn’t require anesthesia. DXA scans expose the patient to extremely small amount of radiation (1/10th the dose of standard chest x-ray). DXA scans utilize x-rays which do not have side effects and do not leave a residue of radiation after an examination.
2.4.4. Quantitative Computed Tomography

This diagnostic tool can be used to assess bone density and can represent the bone mineral density three dimensionally. It measures the volumetric density and can be limited to specific regions of interest (trabecular bone in the spine) unlike DXA, but the dosage of radiation is larger than DXA. QCT is fast, patient friendly and has the unique ability to image a combination of soft tissue, bone and blood vessels.

2.4.5. T-score

T-scores are commonly used to define osteoporosis and osteopenia. T-score is the number of standard deviations the BMD measurement is above or below the young normal mean bone density. WHO has defined the following categories bases on T-scores [40,61]:

![Normal and Osteoporotic Bones](image)
a) Normal : T-score greater than –1  
b) Osteopenia : T-score between –1 and –2.5  
c) Osteoporosis : T-score less than –2.5

T-score is calculated as:

\[
T\text{-score} = \frac{\text{BMD}_{\text{peak}} - \text{BMD}_{\text{measured}}}{\text{SD}_{\text{peak}}} \quad \text{(Eq 2. 1)}
\]

2.4.6. Z-score

Z-score is the number of standard deviations the measurement is above or below the age-matched mean bone mineral density. Z-score is commonly used but may be helpful in identifying persons that need to undergo a work-up for secondary causes of osteoporosis. A Z-score changes over time in relation to the T-score.

T- and Z- scores were developed because of variation of BMD measurement technology among different manufacturers. Therefore, the BMD results are expressed as standard deviations from a comparison to the referent mean, Figure 6. The prediction of fracture risk from T- and Z-scores is not possible unless the risk of an average person is known. Fracture risk is difficult to predict because it is dependent on age, gender, race and other parameters that may not be directly related to BMD.

2.5. Screws

Screws are devices used to fasten or hold two segments (bone-plate, bone-bone) together by converting the applied torque into compressive force between the segments. Screws are broadly categorized by the type of bone they are inserted into (cortical and cancellous screws) and insertion technique / biomechanical function (STS, NSTS) [48,79].
2.5.1. Cortical Screws

Cortical screws are fully threaded screws intended for insertion in cortical bone. Cortical bone screws are primarily used in the diaphyseal region of the bone. They have a wide core, fine thread pitch and shallow thread depth. The large core diameter increases the bending and torsional strength of the screw which are important for inter-fragmentary compression using a bone-plate-screw construct to offer resistance to the deformation loads [16,49]. They can be STS, NSTS or SDS.

2.5.2. Cancellous Screw

Cancellous screws are either fully or partially threaded and are intended for insertion in cancellous bone. Cancellous screws are used in epiphyseal and metaphyseal regions and also as lag screws (partially threaded). They have a smaller core, deeper thread, coarse thread pitch compared to cortical bone screws. The wider and deeper
thread enhances the holding power by compressing the trabeculae together during insertion. Cancellous bone screws do not require the pilot hole to be tapped as they can cut a thread while being inserted due to the weak material characteristics of cancellous bone [48].

2.5.3. Non-self Tapping Screws

NSTS require a predrilled pilot hole, the size of the screw core, which is tapped corresponding to that of the screw profile. The insertion torque and heat generated during the insertion of the screw are low due to minimal resistance offered. Tapping process removes the bone chips and debris from the threads thus avoiding their accumulation that results in increased insertion torque and heat generation during screw insertion. The positioning of the screws is very accurate due to absence of wobble and removal and reinsertion of screws is easier as they follow the threaded path [48].

2.5.4. STS screws

Self-tapping screws (STS) have become a common choice for the orthopedic surgeon during osteosynthesis and are being more frequently used than other types of screws. STS are characterized by the presence of cutting flutes that eliminate the need for tapping a screw hole (Figure 7).

The use of STS reduce the number of steps involved during fracture fixation thus reducing the number of instruments, blood loss and operating time [9]. The STS creates a tight fit of the screw in bone by compacting the debris that stays behind to fill the area around the screw threads [7]. This increase in the bone-screw interface is believed to increase the pullout strength. This tighter fit of the STS may reduce the micro-motion and
hysteresis during cyclic loading of the screw head [74]. Some researchers [11,55] criticize the use of STS as they contend that the presence of cutting flutes is detrimental to the pullout strength of the screw. On the contrary, the studies of Schatzker et al and Koryani et al [41,60] report no significant difference between the self-tapping and pretapped screws.

2.5.4.1. Cutting flutes

STS are characterized by cutting flutes that facilitate the screw to cut threads during insertion into a pilot hole drilled in the bone. Cutting flutes are built into the tip of the screw and have smaller threaded area compared to the rest of the screw (Figure 8), but
they also provide clearance for the newly formed bone chips [78]. The cutting flutes do not extend along the length of the screw hence the cut chips accumulate and compact around the screw threads. The pilot hole drilled for self-tapping screws is larger than the core diameter of the screw facilitating the compaction of the bone chips in the clearance between the screw core and tapped core [73]. The design, length and number of cutting flutes has a significant influence on the insertion torque, soft tissue irritation, thread stripping, patient comfort, insertion accuracy [48,78].

Cutting flutes are considered to be the cause for increased insertion torque in STS compared to NSTS [48,55,78]. Ansell et al [3] suggested that the following factors might influence the insertion torque:

a) properties of the surrounding bone and tissue
b) pilot hole size
c) unicortical or bicortical fixation
d) insertion technique (continuous and intermittent).

Few of the earlier studies recommended that the presence of cutting flutes results in the reduction in holding power when compared to the fully threaded regions which led the physicians to extend the cutting flutes past the far cortex. Such protrusion may lead to muscle and soft tissue irritation, interfere with the functioning of tendons, complicate the removal of the screws due to bone growth into the flutes, create a potential site infection and increase patient discomfort [78]. Cutting flutes in STS may lead to additional trauma to the bone owing to the wobble related to initiation in an untapped hole and may also cause misalignment [74].
2.5.4.2. Failure and Infection

Infection has been observed to be a problematic factor for fracture treatment and plays a significant role in the long term outcome of the fracture fixation, for severe open fractures in particular, even though there has been an improvement in internal fixation of fractures over the years [33]. The rise in incidence of infections, despite the developments in prevention and treatment of infections related to implants, can be attributed to the lifelong risk for developing into potential sites of infection due to bacterial seeding. The infection rates in orthopaedic implants have been observed to be 0.5-5 % depending on the type of surgery. The infection rates were observed to be lower for fixation of closed fractures (0.5 – 2 %) than for open fractures (~30%) [1,70]. In the future, the incidence of infections is expected to rise due to growing number of implants used in aging population, increasing the time of residence in the body, thus increasing the risk for infection [70].
The three key features that have been identified for susceptibility of the implant to infection are type of injury, quality of surgery and nature of the device. Type of injury determines the severity (open/close fracture; degree of vascular and soft-tissue damage; potential for contamination; low/high energy injury) and circumstances (farming injury; drug / alcohol abuse) of the injury. Quality of surgery entails the skill and expertise of the surgeon, choice of surgical procedures (minimally invasive; lavage to minimize bacteria inoculum; debridement of the dead muscle; tissue necrosis; removal of contaminants; blood supply to the fracture site) and surgical and post-operative facilities at the hospital. Nature of the device used for implantation is determined by the biocompatibility of the material used, implant design and surface properties that govern inhibition/prohibition of tissue adhesion and bacterial growth [57].

The infections at the implant site can be categorized as either early or late phase infections. The early infection may be due to the bacterial contamination at the fracture site and/or the surgical procedure itself. Late infection may be of hematogenous origin which can occur due to the bacterial seeding in the sites around the implant. Dead space is created around the implant that has a deleterious effect by preventing access to mobile cellular defense. Dead soft or hard tissue that promotes infection may result due to the accident, necrosis of bone due to implant insertion and/or surgical procedure or dead space around the implant. Biocompatibility of the implant, proper implant design, and good surgical practice are factors that favor the resistance to infection [61].
External fixation devices are used to stabilize severely comminuted fractures but have a persisting problem of pin tract infections that may lead to osteomyelitis in some cases. Some of the influential factors for pin tract infection are poor implantation technique, duration for which pin remains in contact with the skin, transfixation of pin through muscle and poor drilling technique that leads to tissue necrosis. Staphylococci aureus and Staphylococci epidermidis are the common causes for implant-associated infections and can be treated with antibiotics. Metal-biomaterial, joint-bone, and soft tissue related infections are caused by virulent micro-organisms, S. aureus and polymer related implant infections by S. epidermidis. Both these bacteria form multiple layer biofilms on the implant surface in which the initial bacteria layer adheres to the implant surface and the other layers are formed by bacteria-bacteria adhesion that shield the bacteria-implant surface making it difficult to treat with antibiotics [31].
2.5.5. Comparison of STS and NSTS

The debate whether STS is superior to pretapped or non-self-tapping screws (NSTS) has been going on for decades with some studies reporting favorably towards STS and others towards NSTS. Both STS and NSTS have their own advantages and disadvantages as pullout strength of the screw is a function of the quality of bone surrounding the screw. In vivo studies demonstrated that the pullout strength can be dependent on screw design, reaction of the bone and surrounding tissue to the trauma during insertion, biological response of the bone to the implant and remodeling and loading of the bone during fracture healing. Schatzker et al observed microfractures created during the insertion of both STS (due to cutting flutes) and NSTS (due to tapping) that healed during the remodeling process without affecting the pullout strength of the screws [60].

STS generate greater stresses in the bone surrounding the screw due to the increase in insertion torque when compared to pretapped NSTS. The process of tapping thus avoids potential damage to tissue surrounding the bone and decreases the complex forces (torsional and tensile) experienced by the screw [7]. Bechtol suggested two alternatives to obtain maximal pullout strength with STS. One was to extend the screw through the far cortex such that the cutting flutes are driven out of the bone and lie in the surrounding soft tissue. This might interfere with muscle and tendon actions, cause pain, irritate the surrounding tissues and also lead to infection. The other alternative Bechtol suggested was to use the NSTS as they seemed to be the ideal solution considering the drill-tap-screw situation (Figure 10).
Figure 10 Difference between STS and NSTS fixation in bone. It can be observed that the bone purchase is greater in STS due to the pilot hole size that is equal to the core diameter than in NSTS where the purchase of bone is only between the threads cut by the tap (ID₁, ID₂ are diameters of the pilot holes) [48].

But drawbacks of NSTS such as lengthened time of insertion, tight tolerance requirement between the tap and screw threads, corrosion and damage to the tap during autoclaving diminish its advantage over STS [11]. Tolerance between the tap diameter and screw diameter plays a crucial role as larger tapped holes reduce the contact between screw threads and bone thus affecting the holding power. Damage to the tap during
autoclaving with other metal instruments might reduce its ability and efficiency to tap the drilled holes thus producing stress risers.

STS are not recommended for inter-fragmentary compression as fracture displacement might occur due to additional torque and axial load required for insertion. This is one reason why NSTS are recommended for inter-fragmentary lag screw fixation. The torque and axial load applied during insertion of NSTS is less that that required for STS [47]. The presence of cutting flutes enables the STS to cut a new channel during removal and reinsertion of screws. NSTS screws can be replaced accurately as they cannot form their own threaded path but follow the path formed by prior tapping.

2.6. Previous Pullout Studies

Pullout studies have been the benchmark or gold standard for evaluation of the screw designs for fracture fixation. ASTM standard and the FDA consider pullout strength to be one of the critical factors to evaluate the orthopedic screws. The question that researchers over the years have tried to seek an answer to is “how relevant are the screw pullout tests to real clinical failures?” [75]. In clinical situations, the screws are subjected to complex forces, a combination of axial, shear and cyclic loads. These complex loads are not tested by the pullout tests but pullout tests do provide a good estimation of the strength of fixation. Uniaxial pullout tests provide a protocol to evaluate the effect of different factors related to screw fixation, i.e. pilot hole size, insertion torque, screw type etc. [41,75]. Pullout strength is an important factor to consider in internal fixation as it is a measure of the ability of the screw to achieve stable inter-fragmentary fixation by holding the bone firmly and the resistance offered to pullout that
relates the stable attachment of the plate. Prior to cyclic loading and micromotion effects, pullout strength is a good estimate of the magnitude of bone purchase [16].

Koryani et al. [41] evaluated the holding power of orthopaedic screws in canine femurs. Pullout tests performed on screws inserted into the diaphyseal shaft (bicortical fixation) established a near-linear relationship between the thickness of bone and holding power, no significant difference in holding power between V-shaped and buttress threads and also no difference in holding power between STS and NSTS.

Vangsness et al. [74] determined the pullout strength of cortical bone screws before and after application of shear loads. They observed that the cyclic loading (closer to clinical loading) decreased the pullout strength in both STS and NSTS. Their tests corroborated findings of other studies demonstrating no significant difference between the pullout strength of STS and NSTS.

Westmoreland et al. [75] contended that in a screw-plate fixation of fractures screws should provide sufficient holding power to maintain the plate’s principal function of acting as a buttress and not detach from the bone. They investigated the influence of screw diameter on the pullout strength using paired human tibia. Their findings suggested that there was no significant difference between the pullout strength of 3.5mm screws and 6.5mm screws inserted into small fragment subchondral tibial plateau bone. Their study reiterates that the screw pullout strength is not the only factor to be considered during screw insertion but the surrounding bone quality and location have to be considered. They suggested that the smaller bone screws provided better fixation in small fragments
due to their smaller pitch (facilitates access) and size as more screws can be inserted to provide a scaffold to avoid collapse in severely comminuted fractures.

Schatzker et al. [60] conducted pushout tests to determine the holding power of orthopaedic screws in diaphyseal region of canine tibia. The results of the study indicated no difference between the holding power of STS and NSTS in vivo in an unloaded system. The study also investigated the histological aspect of tissue death due to necrosis and tissue reaction to the implant. The findings demonstrated that there is no histological difference between STS and NSTS.

Harnroongroj et al [30] determined the effect of cancellous bone in generating holding power of the cancellous screw in the metaphyseal region using intact cadaveric distal femur specimens. The findings of their study suggest that there is a significant difference in the pullout strength of the screw in the presence and absence of cancellous bone in the metaphyseal region. This contradicts the results of studies of Schatzker et al. [59,60] that predicted the holding power of the screw in metaphyseal region is generated as a summation of the forces in cancellous bone and proximal and distal cortices.

Decoster et al. [20] tested a bone-screw thread design using synthetic bone material to optimize the bone screw pullout force. The synthetic model eliminated the sample variability in specimen that had been the cause for the wide range of results obtained in the other studies. The use of synthetic bone with consistent material properties yielded a tight distribution of pullout forces with less than 10% standard deviation of the mean values. Their data indicated that pitch of the threads is of more clinical relevance than
major diameter. They demonstrated that variation in pitch for the same outer diameter has a significant effect on the pullout strength.

Phillips et al. [55] conducted experiments to evaluate the stripping torque measurements based on increased cases that reported microfractures during screw insertion and a subsequent reduction in holding power for STS when compared to NSTS. Their study illustrated NSTS to be the ideal technique for screw insertion as that would decrease the shearing forces on the surrounding tissue and the screw thus increasing screw efficiency in fracture fixation. Combination of tensile and torsional forces lead to screw failure at lower tensile forces than when the screw is subjected to only uniaxial tensile forces. But they also indicated that for thin midface bones, maximum compression is obtained through STS and that NSTS allow for micromotion that might lead to bone resorption at bone-screw interface and compromise of system stability.

Nunamaker and Perren [53] conducted *in vitro* experiments on fresh bovine femurs to determine the relationship between screw type and screw size. Their findings illustrated that larger screws had significantly higher holding power compared to smaller ones and that the core diameter determines the failure torque for screws (torque varies as the cube of core diameter).

2.7. Factors affecting the pullout strength

There are several factors have been considered to effect the pullout strength of the screw when inserted into cortical or cancellous bone. Factors demonstrated by the previous studies to have significant effect on the pullout strength are explained in this section.
2.7.1. Thread depth (Ratio: Major Dia / Minor Dia)

Pullout strength is considered to be proportional to the contact surface area at the bone-screw interface. The contact area between the bone and screw thread can be maximized by increasing the ratio of major diameter to root diameter (or increasing the difference between the OD and RD). The increase in contact area between the screw thread and bone results in stronger fixation due to the increase in the bone volume engaged between the threads, Figure 11 [47].

![Diagram of bone volume engaged between the threads](image)

Figure 11. The difference in the volumes of bone engaged between threads with same pitch but different heights.

2.7.2. Pitch

Contact surface area at the bone-screw interface can also be increased by increasing the pitch of the screw (increase the number of threads per inch). Increasing the pitch increases the number of threads engaged in bone thus increasing the amount of bone chips and debris engaged between the threads, Figure 12. Hence it can be concluded that
screws with coarse threads have a lower pullout value than those with fine threads when inserted into similar bone specimens [20,47].

Figure 12. The bone volume engaged in finely threaded screws is more than that in the coarsely threaded one, $V_B > V_A$.

2.7.3. Thread Design

Pullout strength of the screw and its resistance to breakage have a high correlation with thread design. Bad design of the screw threads can lead to stress risers that increase the possibility of screw failure. A stress riser can be formed if the threads intersect the core of the screw at a sharp angle, hence to minimize the stress risers it is important to incorporate curves at the core-thread intersection [47]. Koranyi et al tested the effect of the shape of the threads on the pullout strength using buttress shaped and v-shaped threads (Figure 13). The results yielded no significant difference of pullout strength between the two types of threads [41].
2.7.4. Bone Density

The density of bone varies with age, from soft bones in childhood to stronger bones in youth to fracture-susceptible relatively weaker bone in old age. Previous studies provide data to indicate the density and strength of bone are affected with age and osteoporosis. Osteoporosis occurs as a result of the imbalance between the osteoclastic and osteoblastic activities which considerably reduce the bone mineral density (BMD) and mechanical strength [81].

Halvorson et al. investigated the influence of bone mineral density on the holding power of pedicle screws. The results of the study showed that there is a significant difference (700%) in the average pullout force withstood by the pedicle screws in normal and osteoporotic bone samples. Based on their results, which showed a substantial impact of the BMD on the holding power in the vertebrae, they emphasized the need for
specially designed screws based on the microstructural strength and density of the victims of osteoporosis [29].

Bone density determines the bone shear strength and can be defined by the following relationship:

\[ S = 21.6 \times \rho^{1.65} \]

Where,

S is the bone shear strength (MPa)
ρ is the apparent bone density (g/cm³)

Based on the above stated relationship it can be calculated that a reduction of the bone density to 50% of its original value results in the deterioration of the shear strength to 31.8% of its original value. In the case of severe osteoporosis the bone density reduces by 75%, which translates into a 90% loss of shear strength [79].

2.7.5. Engagement Length

Engagement length is the length of the bone-screw interface; it plays a significant role on the holding power of the screw. Longer length of engagement of the screw in the bone results in greater volume of bone engaged between the screw threads which translate into higher resistance offered to screw pullout [81].

2.7.6. Shear / Failure Force

Screw pullout occurs due to the failure of the bone material at the bone-screw interface due to the shear force it is subjected to. This shear failure force can ideally be estimated using Eq 2.3 [5,15]. This equation accounts for the ultimate shear strength of the synthetic bone material, TSF and thread shear area.
\[ F_s = \sigma_s \times A_s \] \hspace{1cm} \text{(Eq 2.3)}

\[ A_s = L \times \pi \times D_{\text{major}} \times TSF \] \hspace{1cm} \text{(Eq 2.4)}

\[ TSF = 0.5 + 0.57735 \times (d / p) \] \hspace{1cm} \text{(Eq 2.5)}

Where,

\[ F_s: \overline{\text{predicted shear failure force}} \]

\[ \sigma_s: \overline{\text{material ultimate shear strength}} \]

\[ A_s: \overline{\text{thread shear area}} \]

\[ L: \overline{\text{length of engagement}} \]

\[ TSF: \overline{\text{thread shape factor}} \]

\[ d: \overline{\text{thread depth}} \]

\[ p: \overline{\text{thread pitch}} \]

2.7.7. Unicortical and Bicortical fixation

Cortical bone with higher density contributes significantly to the pullout strength of the bone-screw fixation compared to the lower density cancellous bone. Harnroongroj et al [30] determined that cancellous bone has no significant influence on the pullout strength of the screw. Their study indicated that the cortical bone makes the primary contribution for the resistance offered during pullout. In unicortical fixation the threads are engaged in only the near cortex of the bone but in bicortical fixation they are engaged in both the near and far cortex, Figure 14. Studies show that the bicortical fixation has
higher pullout strength compared to the unicortical fixation due to the increased purchase in the cortical bone.

Figure 14 Unicortical and bicortical configurations of a screw in bone

2.7.8. Insertion Torque

Torsional forces transmitted through the screw during the insertion have been shown to influence the pullout strength. Some studies showed that there is a correlation between the heat generated during insertion, pullout strength, pilot hole size and insertion torque [9,19,24,61]. It has also been observed that the tapped holes generate less heat and require lower insertion torque compared to pilot holes drilled for STS [55,81]. But most
of these studies were performed on composite bone material with uniform material properties. Cadaveric pullout studies did not yield high correlation between the insertion torque and pullout strength [39]. Determination of the optimal insertion torque is challenging in cadaveric bones as the bone quality varies among specimens and varies between anatomic locations.

2.7.9. Pilot Hole Size

Theoretically, the smaller the pilot hole drilled in the bone the greater the pullout strength due to the increase in bone-screw purchase. But, the smaller the pilot hole, the higher the insertion torque and the higher the temperature rise due to the frictional forces acting during screw insertion [24,54,61]. Gantous and Phillips investigated the effect of pilot hole size on the insertion torque. Their findings indicate a critical pilot-hole size that decreases the insertion torque without compromising the pullout strength [24].

2.8. Use of synthetic bone as a substitute for cadaveric bone

Cadaveric bones have been used over the years to evaluate biomechanical characteristics of fracture fixation devices and procedures. The use of cadaveric bone is diminishing due to the difficulty and expense involved in acquiring normal (disease-free) bones. Some studies reported a high inter-specimen variability (in some cases standard deviations in excess of 100%) that would ideally require a large sample size to compensate for these variations, which is practically difficult to fulfill. Inter bone variations lead investigators to measure the biomechanical parameters prior to and post implant placement in the same bone. It was also observed that the mechanical properties of the cadaveric bones varied with specimen location, sex, age, metabolic condition and
specimen geometry [55,69]. The handling and storage (freeze-thaw cycles) have been observed to change the properties of the specimen thus influencing the outcome of the study. Biomechanical testing with cadaveric bones involves a risk of contamination hence can be performed only in the facilities that can handle such risk and dispose the biohazard waste. Limitations of the cadaveric bones led the research towards developing a bone substitute material with structural and mechanical properties similar to human cancellous bone [6, 55,69].

Synthetic bone is frequently used in research as a substitute for cadaveric bone due to its low intra- and interspecimen variance, low cost, ease of availability and storage [1,3,9,20,25,32,54,55,69]. In the synthetic model, cancellous bone with trabecular structure is mimicked by homogeneous rigid polyurethane foam with uniform matrix [25,32,55,61,69]. Polyurethane foams have a cellular structure, strength and stiffness values similar to that of human bone. Uniform, consistent, controllable and reproducible material and mechanical properties similar to human bone and availability in a range of densities (including osteoporotic models) make it a suitable bone substitute for screw pullout tests [81]. The consistency and reproducibility of the synthetic bone models also facilitates the reuse of fixtures. Synthetic bone properties can be changed by varying the ratio of the resin to isocyanate.

Though synthetic bone models can determine the pullout strength of the screw precisely, clinically they have limited applicability due to the inhomogeneous nature of bone specimens [81]. Palissery et al. indicated the analog bone materials selection should be based not only on static characteristics but also on fatigue characteristics [55].
Use of rigid polyurethane foam has been standardized for biomechanical evaluation of orthopaedic devices (bone screws, intermedullary reamer, medical drills, etc.) [6]. Commercially, rigid polyurethane foam is used as an analogous material for cancellous bone and glass fiber-reinforced epoxy as analog for cortical bone.

2.9. Metals

Metal implants assist in and enable fracture fixation by protecting the fractured bone without affecting the bone modeling, growth or healing process [47]. A number of metals are available for manufacturing orthopaedic implants, important factors that need to be considered during the selection of implant material are [11,47]:

a) ability to provide mechanical stability
b) biocompatibility, ease of osseointegration and corrosion resistance to body fluids
c) resistance to degradation
d) effects on imaging
e) cost and material availability
f) ease of machinability

2.9.1. Stainless Steel

316L stainless steel (SS) used for surgical implants are primarily comprised of iron and chromium (ASTM F-138, F-139). 316L represents the AISI classification for iron in 300 series based on its chromium and nickel components. Nickel (13-15.5%) is added to iron crystals to increase corrosion resistance, austenitic range and capacity to accept more chromium and molybdenum. Chromium (17-19%) is added to iron for its corrosion resistant properties, ability to form a passive surface oxide and ease of solubility.
Molybdenum and manganese (2-3%) are added to improve pitting and crevice resistance and crystal stability respectively [11,47]. SS crystal has a face-centered cubic structure.

2.9.2. Titanium

Titanium (Ti) used in surgical implants is commercially pure (CP). CP Ti is differentiated into four different grades based on the amount of impurities present. CP Ti has a hexagonal close-packed crystal structure with relatively low mechanical strength but high ductility. But the mechanical characteristics can be improved by increasing the amount of oxygen (impurity) in CP Ti. Hence Grade 4 CP Ti has the best mechanical characteristics of all CP titaniums. Ti has the lowest density of all the surgical implants used. Ti6Al4V is a common Ti alloy used for manufacturing implants. Aluminum and Vanadium stabilize different phases of Ti crystal and allow annealing of Ti (CP Ti cannot be heat treated due to its single phase constitution) that improves its mechanical properties [47].

2.9.3. Compare the two materials based on supporting papers

The implants used for fracture fixation need high yield strength and fatigue resistance. The mechanical properties of pure metals differ from those of alloys significantly and they can be altered by cold working, annealing etc. 316 L SS and Ti alloys are best suited for implant material due to their mechanical properties and hence are used for implants designed to withstand high stresses [16,47].

SS when cold worked has moderate yield and ultimate strengths, high ductility, low cost, good low-cycle fatigue resistance and is easy to machine making it a versatile material for use in orthopaedic implants. But the elastic modulus of a SS implant is 12
times that of cortical bone that results in stress shielding and potential sites for stress risers [16,47].

Ti alloy on the other hand is expensive, difficult to machine, but has good high-cycle fatigue resistance. The elastic modulus of a Ti implant is 6 times that of cortical bone, its modulus is closer to bone than SS and hence is considered to be a better choice for implant material to prevent stress shielding. But clinical investigations indicated no significant difference in the healing time between SS and Ti implants [47].

Ti alloy implants are more favorable to imaging modalities than SS implants. CP Ti and Ti alloys produce less attenuation and scatter in X-rays and CT scans than SS implants thus leading to minimal image disruption. CP Ti and Ti alloys do not have any magnetic characteristics and can hence be imaged using magnetic resonance imaging (MRI) with minimal imaging concerns and better image resolution. SS implants on the other hand have magnetic characteristics that could move the implant or cause signal attenuation or interference and image disruption or loss of resolution [47].

ASTM F-361 standard evaluates the biocompatibility of the metal implants by assessing the effects of implantation. Two of the major causes of concern are corrosion and osseointegration. The standard requires the implant to corrode minimally and evoke minimal inflammatory reaction and also evaluates the bone growth around the implant. Ti and Ti alloys form an oxide layer on the surface of the implant that has high corrosion resistance. SS implant’s corrosion resistance is dependant on the amount of nickel and chromium in the material. But a small percentage of the population is allergic to nickel and chromium. That prevents the use of SS and encourages the use of Ti implants in
those people. Ti promotes bone growth and has a remarkable ability to form an interface with the bone (good osseointegration) by promoting adhesion of osteoblasts; but this ability can also be considered a drawback as the osseointegration (mechanical binding) makes the extraction or removal of the implant difficult (higher removal torque). SS on the other hand forms a thin fibrous capsule, a poor and mechanically weak interface with the bone, and also does not promote bony ingrowth. But these shortcomings of the SS implants make the removal of the implant easy (lower removal torque) [4,47].

2.10. Numerical Analysis

Experimental pullout tests have some limitations with respect to the information that can be provided on the bone-screw interface; they cannot provide information pertaining to the internal forces, stresses and strains experienced by the bone and the screw independently and at the interface between the two [23,83]. Inter- and intra-specimen variation in the mechanical properties of the bones makes it difficult to achieve reproducible results experimentally. The pullout strength is affected by a number of parameters like screw diameter, bone quality, pitch etc; hence it would be difficult to investigate the effect of each of the parameters. The insertion technique and experimental setup for the specimens change from operator to operator introducing another source of variation into the experiments [82].

Theoretical or mathematical models are employed to overcome some of the above-mentioned limitations. Mathematical models quantify structural behavior and provide information on force, stress and strain distributions for physiological loads [42]. Mathematical models offer the ideal opportunity to analyze the study with absolute
repeatability and ability to vary any of the parameters that affect the pullout strength [82]. Mathematical models, like FEM, provide detailed information on deformation and internal stress distribution that is not accessible with experimental models.

2.10.1. Finite Element Analysis (FEA)

FEA is a numerical analysis method in which a material or structure is loaded and analyzed for specific results by discretization. The basic concept of FEA is that a structure is analyzed by sub-division into small, interconnected sub-regions or finite elements. The behavior of each of the elements is governed by functions representing stresses and displacements in that region. These functions are chosen such that there is a continuity of the described behavior throughout the structure [23]. This discretization process is similar to numerical integration in that the finer the elements, the more accurate the results yielded by the model [44]. FEA models have a unique capability that is not readily possible in analytical and experimental models, the potential to run a parametric study that allows variation of one parameter keeping the others constant.

FEA uses a grid (mesh) comprised of nodes placed at the ends of the elements for analyzing the structure. Density of nodes in a region is dependent on the anticipated stress levels and geometrical complexity. Regions that are considered to be critical for analysis are assigned a high density of nodes than the ones that are anticipated to experience low stresses. The movement of the nodes can be described by three orthogonal displacements and three rotations hence they can be considered to be analogous to the structure’s degrees of freedom [44]. The mesh is governed by equations that represent material and structural properties that define the behavior of the individual
finite elements and the whole structure when subjected to required loads. FEA can be
summarized in simple steps as follows:

Step 1. The region to be analyzed is modeled by substituting or replacing it with a
number of discrete elements.

Step 2. These elements are assigned with nodes and the governing equations to
represent the variation of the field variable over the element.

Step 3. Matrix equations that determine the properties of each of the elements are
developed.

Step 4. Global stiffness matrix is constructed by assembling all the element matrix
equations.

Step 5. Boundary conditions for the nodes are specified

Step 6. Unknown nodal displacement values are computed from the simultaneous
linear algebraic equations

Step 7. Element strains are calculated from nodal displacements and element
stresses from strains. [1,23,35].

FEA can be performed on 2D models and 3D models. 2D modeling can be used to
analyze simple structures in which accuracy is not critical. 2D modeling can be
performed on normal non-dedicated computers. 3D modeling on the other hand is more
complex and requires dedicated high-speed computers for optimum performance.

2.10.1.1. Theory of FEM

For a plane strain problem the unknown nodal displacements can be represented as
a column vector $u_{ij}$ as shown follows [1,23,35,44]:

48
where \( ij \) indicates nodal representations. The unknown displacements are determined by minimizing the potential energy of the solid with respect to the nodal displacements. The displacements within individual elements can be computed using the elemental governing equations as listed below:

\[
\begin{bmatrix}
    u_1 \\
    u_2 \\
    u_3 \\
    \vdots \\
\end{bmatrix}
\]  

……………………………………(Eq 2. 6)

Where,

\[ w_i \] is the governed by the element type

Strain can be calculated from nodal displacements \( u_e \) and strain interpolation matrix \( (B) \) as:

\[
\varepsilon = [B]u_e
\]  

……………………………………(Eq 2. 8)

Stresses can be calculated using Hooke’s law from strains, proportionality matrix \( (D) \) (comprised of elastic constants) as

\[
\{\sigma\}=[D]\{\varepsilon_e\}
\]  

……………………………………(Eq 2. 9)
Element equilibrium equations can be calculated using the principle of minimum potential energy. Total potential energy for the element can be calculated as:

\[ \{ P_e \} = U_e - E_e \] ....................(Eq 2. 10)

Where,

\( U_e \) is the strain energy

\( E_e \) is the work done by the external applied forces

Strain energy can be computed from the element stress and strain distribution as:

\[ U_e = \frac{1}{2} \varepsilon^T \sigma \iiint dv \] ....................(Eq 2. 11)

\[ U_e = \frac{1}{2} \varepsilon^T [D] \varepsilon \iiint dv \] ....................(Eq 2. 12)

\[ U_e = \frac{1}{2} \left( \begin{bmatrix} B \end{bmatrix} u_e \right)^T [D] \left( \begin{bmatrix} B \end{bmatrix} u_e \right) \iiint dv \] .......(Eq 2. 13)

\[ U_e = \frac{1}{2} u_e^T \left( \begin{bmatrix} B \end{bmatrix}^T [D] \begin{bmatrix} B \end{bmatrix} \right) u_e V \] ....................(Eq 2. 14)

Work done by external applied forces can be calculated as:

\[ E_e = [u] \{ F \} \] ....................(Eq 2. 15)

Combining the two equations

\[ \{ P_e \} = \frac{1}{2} u_e^T \left( \begin{bmatrix} B \end{bmatrix}^T [D] \begin{bmatrix} B \end{bmatrix} \right) u_e V - [u] \{ F \} \] ....................(Eq 2. 16)
For equilibrium
\[
\begin{bmatrix} \frac{\partial P_e}{\partial u} \end{bmatrix} = 0 \tag{Eq 2.17}
\]

Simplifying the above equation
\[
([B]^T[D][B])\{u\} = \{F\} \tag{Eq 2.18}
\]

Defining element stiffness matrix (ESM) \( K_e \) as:
\[
([B]^T[D][B])\{u\} = \{K_e\} \tag{Eq 2.19}
\]

It can be observed that the proportionality / material property matrix is symmetric hence the ESM is also symmetric. Total strain energy of the structure can be computed by assembling the strain energies of all the elements in the structure as:
\[
U_T = \sum_{\text{elements}} U_e = \frac{1}{2} \sum_{\text{elements}} u_e^T K_e u_e \tag{Eq 2.20}
\]

Converting the local nodal displacements into global nodal displacements the above equation can be rewritten as:
\[
U_T = \frac{1}{2} u^T [K] u \tag{Eq 2.21}
\]

where [K] is known as the global stiffness matrix (GSM). Each of the elements have only a few nodes compared to the total number of nodes and each node is shared by several elements making the GSM a sparsely populated matrix. One of the characteristics of GSM is that its non-zero coefficients are clustered about the diagonal and the zeros are
away from it making it a banded matrix. GSM is also a symmetric matrix as each of the
ESMs are symmetric enabling efficient storage of the matrices [1,23,35,44].

2.10.1.2. Linear vs Non-Linear

Linear models are based on Hooke’s theory (Eq 2.22), which demonstrates a
linear relationship between force and deflection of a spring using stiffness as the
coefficient of proportionality. Linear analysis of FEM is also based on the same principle
of calculating the unknown nodal displacements from known force and stiffness matrices
for each of the elements and assembling them into a GSM to determine the nodal
displacements, strains, stresses. But most of the practical systems exhibit non-linear
behavior that demonstrates a change in stiffness with loading based on material and/or
structural properties. This deviation of the relationship between force and corresponding
displacements is characterized by (Eq 2.23). Linear models can be applied for relatively
small displacements and loading in elastic of stress-strain curve. Linear models are
computationally less intensive compared to complex non-linear models but lack the
accuracy of the non-linear models.

\[ f = Ku \] .......................................................... (Eq 2.22)

\[ f \neq Ku \] .......................................................... (Eq 2.23)

2.10.1.3. Non-linear Analysis

In structural mechanics, generalized Hooke’s law is not valid if the stress-strain
relationship is non-linear (NL). NL models are more complex to execute than the linear
models as some of the linearising relationships, such as, superposition principle, stress-
strain relationship, contact analysis and strain-displacement relationships are violated. The non-linearity may be due to geometric or material related. When the deformations are large the problem is considered to be a geometric non-linearity problem and when the deformations are small the problem is considered to be a material non-linearity problem [50]. The factors that influence NL FEA are:

a) Geometric accuracy
b) Meshing and element selection
c) Material properties (stress-strain relationship)
d) Boundary conditions
e) Contact definition (interaction characteristics)
f) Convergence criteria
g) Solution method
h) Validation

2.10.1.3.1. NL Material Properties: Stress-Strain Relationship

Stress-strain relationship is considered to be the strain experienced by the structure under incremental or progressive loading conditions. Plasticity can be considered to be the most common example of material non-linearity. A material exhibiting elastic-plastic properties is characterized by the initial elastic region where there is a linear stress-strain relationship that gradually changes into a non-linear relationship. In the elastic region the displacement experienced is proportional to the applied load and when the load is removed the initial stress state is restored. Non-linearity is introduced into the stress-strain relationship after the yield point when the load carrying capacity of the material is reduced significantly. At this stage the unloading
of the material will result in a permanent, irreversible deformation accompanied by a loss of energy. The material demonstrates plasticity past this point when a small increase change in load is accompanied by a large increase in strain (displacement) [1].

Yield stress is considered to be the key value past which plastic deformations are observed in elasto-plastic materials. This stress value is determined by uniaxial test but the structure experiences multi-axis stresses hence the uniaxial stress value is referred to as the von Mises yield criterion.

2.10.1.3.2. Von Mises Stresses and Yield Criteria

Previous FEA studies reported stress and strain values in terms of von Mises stresses and strains [1,23,27,82,83]. In von Mises theory, also known as maximum distortion energy theory, “failure by yielding occurs when, at any point in the body, the distortion energy per unit volume in a state of combined stress becomes equal to that associated with yielding in a simple tension test” [61]. Von Mises theory relates distortion energy in three-dimensional state of stress to that in a uniaxial stress state.

Von Mises stress relation can be determined by resolving the 3D stress state into deviatoric and dilatational stress states. Dilatational component is responsible for change in size of the sample and deviatoric component is responsible for change in shape of the sample.
The relationships can be defined in terms of principal stress state as [44]:

\[
\begin{bmatrix}
\sigma_{xx} & 0 & 0 \\
0 & \sigma_{yy} & 0 \\
0 & 0 & \sigma_{zz}
\end{bmatrix} = \begin{bmatrix}
p & 0 & 0 \\
0 & p & 0 \\
0 & 0 & p
\end{bmatrix} + \begin{bmatrix}
\sigma_{xx} - p & 0 & 0 \\
0 & \sigma_{yy} - p & 0 \\
0 & 0 & \sigma_{zz} - p
\end{bmatrix} \quad \text{--------- Eq 2.24}
\]

Where,

\[ p = \frac{1}{3}(\sigma_{xx} + \sigma_{yy} + \sigma_{zz}) \quad \text{------------------------ Eq 2.25} \]

For three-dimensional state of stress, generalized Hooke’s law for isotropic homogenous material is:

\[
\varepsilon_{xx} = \frac{1}{E} \left[ \sigma_{xx} - \nu (\sigma_{yy} + \sigma_{zz}) \right] \quad \text{------------------------ Eq 2.26}
\]

\[
\varepsilon_{yy} = \frac{1}{E} \left[ \sigma_{yy} - \nu (\sigma_{xx} + \sigma_{zz}) \right] \quad \text{------------------------ Eq 2.27}
\]

\[
\varepsilon_{zz} = \frac{1}{E} \left[ \sigma_{zz} - \nu (\sigma_{xx} + \sigma_{yy}) \right] \quad \text{------------------------ Eq 2.28}
\]

Total strain energy can be determined in terms of principle stress by substituting Hookean relationships as,

\[
U_T = \frac{1}{2} \sigma \varepsilon = \frac{1}{2} \sigma_{xx} \varepsilon_{xx} + \frac{1}{2} \sigma_{yy} \varepsilon_{yy} + \frac{1}{2} \sigma_{zz} \varepsilon_{zz} \quad \text{------------------------ Eq 2.29}
\]

\[
U_T = \frac{1}{2E} \left[ (\sigma_{xx}^2 + \sigma_{yy}^2 + \sigma_{zz}^2) - 2\nu(\sigma_{xx} \sigma_{yy} + \sigma_{xx} \sigma_{zz} + \sigma_{yy} \sigma_{zz}) \right] \quad \text{------------------------ Eq 2.30}
\]
SED due to dilatational stress component can be derived to be

\[ U_{dil} = \frac{1}{2E} \left( 3p^2 - 2\nu(3p^2) \right) \]  \hspace{1cm} \text{Eq} 2.31

\[ U_{dev} = U_T - U_{dil} \]  \hspace{1cm} \text{Eq} 2.32

\[ U_{dev} = U_T - \left\{ \frac{1 - 2\nu}{6E} \left( \sigma_{xx} + \sigma_{yy} + \sigma_{zz} \right)^2 \right\} \]  \hspace{1cm} \text{Eq} 2.33

Von Mises stress can be determined by solving the above equations

\[ \sigma_{VM} \propto \left( (\sigma_{xx} - \sigma_{yy})^2 + (\sigma_{yy} - \sigma_{zz})^2 + (\sigma_{zz} - \sigma_{xx})^2 \right) \]  \hspace{1cm} \text{Eq} 2.34

In terms of principal stresses and strains it can be represented as

\[ \sigma_{VM} = \frac{1}{2} \left( (\sigma_{p1} - \sigma_{p2})^2 + (\sigma_{p2} - \sigma_{p3})^2 + (\sigma_{p3} - \sigma_{p1})^2 \right) \]  \hspace{1cm} \text{Eq} 2.35

\[ \varepsilon_{VM} = \frac{2}{9} \left( (\varepsilon_{p1} - \varepsilon_{p2})^2 + (\varepsilon_{p2} - \varepsilon_{p3})^2 + (\varepsilon_{p3} - \varepsilon_{p1})^2 \right) \]  \hspace{1cm} \text{Eq} 2.36

Von Mises stresses are a useful way to analyze the bone-implant interface during axial loading of the bone as the principal stress state \( (\sigma_{p1}) \) that represents the component perpendicular to bone axis yields peak stresses and principal stress state \( (\sigma_{p3}) \) that represents the transverse component yields minimum stresses from axial loading. Von
Mises yield condition matched closely with experimental values of many of the commonly used ductile metals and hence is widely used in material nonlinearity problems [44,1].

2.10.1.3.3. Contact / Interference Definition

Changes in contact conditions need to be continually monitored to update the model with latest changes in contact relationship between two bodies in contact. Though this characteristic is a geometric non-linearity it behaves and is monitored similar to the changes in boundary conditions hence it can also be considered a boundary condition non-linearity that is monitored continuously for changes in loads and constraints [1].

Early contact models required pre-defining the potential contact areas and connecting the contact surfaces with connecting elements. The loads are transferred through the connecting elements hence the transmitted loads were dependent on the stiffness of those elements. These shortcomings were overcome using “slideline” technology that monitors the complete structure and potential contact regions continuously and automatically updates transmitted loads and contact conditions. The method of contact analysis uses stick-slip contact model based on coulomb or shear friction that transmit shear forces across the area of contact. They utilize a regularization procedure to enhance the stability of the transitions of sliding and sticking contacts [1]. In coulomb friction model the contact surfaces experience tangential forces to prevent relative motion between the surfaces [44].
2.10.1.3.4. Solving Procedure

FEA is a numerical method that produces approximate and not exact solutions. The method employed to solve the multitude of simultaneous equations involved is the important aspect of NL analysis. These equations need to ensure that equilibrium is maintained between the internally generated stresses and externally applied loads. This is achieved by automatically updating the force-displacement (indirectly stress-strain relations) relationship during the incremental-iterative solving process.

Early NL analysis solvers were based on an incremental approach that accounted for the NL stress-strain (force-displacement) relationships by applying sequentially increasing loads in a series of steps. But this approach wasn't very accurate and diverged from the true behavior as it was heavily dependent on the incremental step-size, geometric complexity and degree of nonlinearity. The current methods based on Newton-Raphson numerical techniques use the incremental-iterative approach in which within each increment of the load the equilibrium is achieved by iteratively correcting the internal stress till the external forces are balanced with predefined tolerance levels known as "convergence criteria".

The convergence tolerance is calculated as Euclidean norm of changes in traction between the contact regions using the following ratio [71]:

\[
\frac{\left( \Delta v_1 \right)^2 + \ldots + \left( \Delta v_n \right)^2}{\left( v_1 \right)^2 + \ldots + \left( v_n \right)^2}^{1/2}
\]

.......................... Eq 2.37
where, \( V \) could be substituted with 3D strain, stress, displacement or force. If the above ratio is less than the predefined convergence tolerance value the solver considers the solution to have converged.
CHAPTER III
MATERIALS AND METHODS

3.1. Block preparation and screw insertion

The bone coupons (Pacific Research Laboratories, Vashon, WA) were obtained in a single sheet that was cut into smaller blocks that were 76 mm long and 25 mm wide. The solid polyurethane bone coupons used were in accordance with the American Society for Testing and Materials (ASTM) F 543-02 specification for metallic bone screws. Synthetic models of the bone are used instead of cadaveric bones to eliminate the variability between the samples and also to establish control and maintain uniform material properties for all the tests. The bone coupons representative of osteoporotic bone had a density of 0.24 g/cc, tensile modulus of elasticity of 143 MPa, shear modulus of 44 MPa and \(BMD \approx 0.45 \text{ g/cm}^2\). Normal bone was mimicked by bone coupons with a density of 0.64 g/cc, tensile modulus of elasticity of 696 MPa, shear modulus of 247 MPa and \(BMD \approx 1.16 \text{ g/cm}^2\). Cortical bone was simulated by e-glass filled epoxy sheets with 1.7 g/cc density and 12.4 GPa tensile modulus (determined by ASTM D-638). Dual Energy X-ray Absortiometry (DXA) scans were performed on the bone blocks to determine the BMD values. The BMD values suggested that the osteoporotic synthetic bone blocks represented a state of moderate osteoporosis.
Commercially available Synthes® (Synthes Inc., Paoli, Pennsylvania) stainless steel and titanium self tapping screws were randomized and inserted into synthetic bone coupons representing “osteoporotic” bone. These screws were intended to be used in both metaphyseal and diaphyseal regions. Three holes (19mm apart) were drilled per bone coupon in accordance with St. Venant’s principle, which states that the difference between stresses caused by statically equivalent load systems is insignificant at distances greater than the largest dimension of the area over which the loads are acting [61]. Based on this principle a safety factor of 5 was incorporated into the separation between the screws to ensure that the pullout trial of one screw did not have an adverse effect on the trial of adjacent screws in the block. The holes for insertion were prepared using a Bridgeport milling machine (Bridgeport, CT) for minimal bit wobble and to ensure a perpendicular hole and a dial indicator depth gauge sensitive to 0.025 mm was used to ensure accurate insertion depth.

Figure 15  Bone coupon comprising of polyurethane foam (for cancellous bone) and e-glass-filled epoxy sheets (for cortical bone) with its specifications and the dimension between the drilled screw holes.
3.2. Grouping of Screws

The screws were grouped into different categories based on the variables (depth of insertion, screw size, pilot hole size, depth of cutting flutes, etc.) for investigating the effect of different parameters on screw pullout index.

3.2.1. Depths of Insertion Study

One hundred and fifty self-tapping bone screws were evaluated for the insertion depth study. Cortical bone screws with 40mm length, 1.25mm pitch, 3.5mm outer diameter and 3.9 ± 0.15 mm cutting flute length were inserted into the bone coupons. The screws were grouped with 24 screws per depth in the osteoporotic bone and 18 screws per depth in the normal bone to study the effect of the depth of insertion. Each group in the normal bone comprised of six Synthes SS screws (SS) and six Zimmer SS screws (Z) and each of the groups in osteoporotic bone were made up of six Synthes SS screws (SS), six Zimmer SS screws (Z) and six Howmedica SS screws (H).

The screws were randomly inserted into the pre-drilled pilot holes (2.5 mm) to different depths. The five depths of insertion were based on the position of the tip of the screw being –1mm (Grp I), 0mm (Grp II), 1mm (Grp III), 2mm (Grp IV) and 3mm (Grp V) with respect to the far cortex measured with the help of a dial-indicator depth gauge.

3.2.2. Pilot Hole Study

Seventy-two Synthes (Synthes Inc., Paoli, Pennsylvania) stainless steel self-tapping cortical bone screws were inserted into synthetic bone coupons representative of osteoporotic bone. The pilot holes were drilled with four different diameters: Group A - 2.45 mm (70% of screw outer diameter [OD]), Group B - 2.50 mm (71.5%), Group C -
2.55 mm (73%), and Group D - 2.80 mm (80%). All pilot holes were prepared using a Bridgeport milling machine (Bridgeport, CT). Six screws were inserted to depths of 0, 1 or 2 mm past the far cortex (Grp I, II & III respectively) in each pilot hole group. Insertion torque during screw placement was monitored with a digital torque screwdriver (Figure 16). A dial indicator depth gauge was used to ensure accurate insertion depth.

![Digital Torque screw driver](image1.png)

**Figure 16.** Insertion of STS into bone coupon using digital torque screw driver with electronic readout

3.2.3. Screw Size Study

Fifty-four (Synthes Inc., Paoli, Pennsylvania) stainless steel self-tapping cortical bone screws were inserted into synthetic bone coupons representative of osteoporotic bone. The screws were randomly divided into three groups, with six screws per group of the types 2.7mm (A), 3.5mm (B) and 4.5mm (C). Group I had its screws inserted with the tips flush with the far cortex, and Groups II & III had their screws inserted with the tips 1mm and 2mm beyond the far cortex, respectively. Pilot holes, in accordance with
the surgical technique guide, were drilled for each of the screw types, 2 mm, 2.5 mm & 3.2 mm respectively.

3.2.4. Cutting Flutes Study

One hundred and twenty SS screws were evaluated to determine the effect of the cutting flutes on the HP in normal and osteoporotic bone. Stainless steel screws were randomly grouped in to five different depths based on the position of the tip of the screw with respect to the far-cortex, -3, 0, 1, 2 & 5 mm (Groups I, II, III, IV & V respectively). Each group was comprised of 24 screws, 12 each for normal and osteoporotic samples. The screws were further sub-categorized into 6 screws per manufacturer (Synthes and Zimmer). Pilot holes, 2.5 mm in diameter, in accordance with the surgical technique guide were drilled for each of the screws.

3.2.5. Stainless Steel vs Titanium Study

One hundred and twenty Synthes screws, sixty SS and sixty Ti, were evaluated to analyze the pullout characteristics of SS and Ti screws at different depths of insertion in normal and osteoporotic bone. The screws were randomly grouped into five different depths based on the position of the tip of the screw with respect to the far-cortex, -3, 0, 1, 2 & 5 mm (Groups I, II, III, IV & V respectively). Each group was comprised of 24 screws, 12 each for normal and osteoporotic samples. The screws were further sub-categorized into 6 screws per screw material (SS & Ti). Pilot holes, 2.5 mm in diameter, in accordance with the surgical technique guide, were drilled for each of the screws.
3.3. Test Protocol

A servo-hydraulic Instron 8511 materials testing system (Canton, MA) was used to measure peak force and stiffness. The material testing system was comprised of a control tower, servo-hydraulic head housing the linear variable displacement transducer (LVDT), load cell (capacity: 22.24 KN), analog-to-digital conversion system, Gould amplifiers to amplify the output signals from the force actuator and LVDT (Figure 17).

Figure 17 Instron 8511 material testing system (1) Control Tower (2) Servo-hydraulic Head (3) Load Cell (4) A/D conversion system (5) Gould Amplifiers
The screws were pulled out with a test fixture (Figure 18), designed according to the ASTM F 543-02 specification that slipped over the screw head and a load train that employed a universal joint [2]. The incorporation of the universal joint into the load train was essential to eliminate residual stresses and to ensure that only axial pullout occurs. This setup was essential in ensuring that only axial pullout forces were applied to the screws (Figure 19). During the testing process it was also ensured that the test-setup for pullout was parallel to the screw axis.

Figure 18  Experimental setup comprising of the mechanical construct to hold the block and the pullout device to seat the screw head.
Figure 19 Schematic representation of the experimental set-up to pull-out the screw from the coupon

Figure 20 S-ramp profile used for the pullout of screws
Testing was conducted under displacement control at a rate of 0.1 mm/s, as specified in ASTM F 543-02 standard, using an S-ramp with 6mm maximum displacement settings (Figure 20). Data from two channels, representing maximal load and displacement, were collected at a sampling rate of 30 Hz for 60 seconds (total 900 samples per channel) and stored on a personal computer. The force-displacement data was digitally recorded for each of the pullout tests and the maximum value of the applied tensile force was determined as the pullout strength of the screw.

<table>
<thead>
<tr>
<th>Screw Type</th>
<th>Outer Diameter (mm)</th>
<th>Root Diameter (mm)</th>
<th>Pitch (mm)</th>
<th>Screw Length (mm)</th>
<th>Cutting Flute Length (mm)</th>
<th>Thread Depth (mm)</th>
<th>TSF</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>2.7</td>
<td>1.9</td>
<td>1</td>
<td>40</td>
<td>5</td>
<td>0.40</td>
<td>0.73</td>
</tr>
<tr>
<td>S2</td>
<td>3.5</td>
<td>2.4</td>
<td>1.25</td>
<td>40</td>
<td>5</td>
<td>0.55</td>
<td>0.75</td>
</tr>
<tr>
<td>S3</td>
<td>4.5</td>
<td>3</td>
<td>1.75</td>
<td>40</td>
<td>5</td>
<td>0.75</td>
<td>0.75</td>
</tr>
</tbody>
</table>

Table 1 Basic screw parameter measurements

3.4. Block Preparation for Basic Screw Measurements

Basic screw parameters were measured by embedding the screws in Polymethyl Methacrylate (PMMA) blocks. The PMMA-screw assembly was milled to the centerline of the screw to obtain the optimum specimen as shown in Figure 21a. The assembly was imaged under a microscope to get the accurate measurements using 3D Doctor (Figure 21b). The measurements from the screws are listed in Table 1.
3.5. Statistical Analysis

Standard statistical techniques were used to determine the sample size for the study and for analyzing the data obtained from the experimental testing of screw pullout.

3.5.1. Sample Size Determination

Sample size required for this study was determined using the following equation:

$$n \geq 2 \times \left( \frac{\sigma}{\delta} \right)^2 \left( t_{\alpha[v]} + t_{2(1-P)[v]} \right)^2 \quad \text{Eq 3.1}$$
where, \( n \) : sample size

\( \sigma \): true standard deviation

\( \delta \): smallest true difference to be detected

\( \nu \): degrees of freedom

\( \alpha \): significance level

\( P \): power of the test

\( t \): two-tailed t-table value [65]

The number of samples was calculated to be eight using 356 degrees of freedom. A true standard deviation of 15% was assumed, the smallest true difference to be detected was proposed to be 30%, the power of the test was assumed to be 85% and a significance level of 0.05 was assumed in order to determine the sample size.

3.5.2. Statistical Models

The statistical models assumed for this study were one-factor, two-factor and multifactor analysis of variance (ANOVA) – fixed effects models. The multifactor fixed effects model was defined with 3 main effects as condition of the bone, manufacturer and depth of insertion (DOI). The model definition was:

\[
Y_{ijkl} = \mu + \alpha_i + \beta_j + \gamma_k + \alpha\beta_{ij} + \alpha\gamma_{ik} + \beta\gamma_{jk} + \alpha\beta\gamma_{ijk} + \delta_{ijkl} \quad \text{............... Eq 3.2}
\]

where: \( Y_{ijkl} \): dependent variable

\( \mu \): parametric mean of the population

\( \alpha_i \): fixed treatment effect for the \( i^{th} \) group
\( \beta_j \) : fixed treatment effect for the \( j^{th} \) group

\( \gamma_k \) : fixed treatment effect for the \( k^{th} \) group

\( \alpha \beta_{ij} \) : first-order interaction effects in the sub groups represented by the indicated combinations of the \( i^{th} \) group of the condition of the bones and the \( j^{th} \) group of the manufacturers.

\( \alpha \gamma_{ik} \) : first-order interaction effects in the sub groups represented by the indicated combinations of the \( i^{th} \) group of the condition of the bones and the \( k^{th} \) group of the DOI.

\( \beta \gamma_{jk} \) : first-order interaction effects in the sub groups represented by the indicated combinations of the \( j^{th} \) group of the manufacturers and the \( k^{th} \) group of the DOI.

\( \alpha \beta \gamma_{ijk} \) : first-order interaction effects in the sub groups represented by the indicated combinations of the \( i^{th} \) group of the condition of the bones and the \( j^{th} \) group of the manufacturers and \( k^{th} \) group of the DOI.

\( \delta_{ijkl} \) : error term of the \( l^{th} \) item in the subgroup \( ijk \).

\( I \) : number of diseased conditions of the bone

\( j \) : number of manufacturers.

\( K \) : number of DOI.
Two factor ANOVA was defined for the pilot hole study, screw size study with main effects being DOI and screw size / pilot hole size. The model was defined as follows

\[ Y_{ijk} = \mu + \alpha_i + \beta_j + \alpha\beta_{ij} + \delta_{ijk} \]  

where: \( Y_{ijk} \) : dependent variable

\( \mu \) : parametric mean of the population

\( \alpha_i \) : fixed treatment effect for the \( i^{th} \) group

\( \beta_j \) : fixed treatment effect for the \( j^{th} \) group

\( \alpha\beta_{ij} \) : first-order interaction effects in the sub groups represented by the indicated combinations of the \( i^{th} \) group of the condition of the bones and the \( j^{th} \) group of the manufacturers.

\( \delta_{ijk} \) : error term of the \( k^{th} \) item in the subgroup \( ij \).

\( i \) : number of pilot hole sizes / screw sizes

\( j \) : number of DOI.

Two-factor ANOVA was defined for the cutting flutes study and SS vs Ti study with the main effects being DOI and condition of the bone / screw material respectively. The model was defined as follows:

\[ Y_{ijk} = \mu + \alpha_i + \beta_j + \alpha\beta_{ij} + \delta_{ijk} \]  

where: \( Y_{ijk} \) : dependent variable
\[ \mu \] : parametric mean of the population

\[ \alpha_i \] : fixed treatment effect for the \( i^{th} \) group

\[ \beta_j \] : fixed treatment effect for the \( j^{th} \) group

\[ \alpha\beta_{ij} \] : first-order interaction effects in the sub groups represented by the indicated combinations of the \( i^{th} \) group of the condition of the bones and the \( j^{th} \) group of the manufacturers.

\[ \delta_{ijk} \] : error term of the \( k^{th} \) item in the subgroup \( ij \).

\[ i \] : number of diseased conditions of the bone / screw materials

\[ j \] : number of DOI.

The order of insertion, DOI and testing order of the screws were randomized to eliminate any bias. The Student- Newman Keuls post priori test were conducted to determine where the difference existed between the groups. Statistical analysis using SAS software package (SAS Institute, Cary, NY.) were performed.

3.6. Finite Element Model

Finite element model of the bone screw interface was developed by assembling the 3D models of screw and bone-mimicking bi-layered foam blocks.

3.6.1. Screw Geometry

A standard 3.5 mm cortical screw with spherical under-surfaces was modeled using the dimensions derived from the microscopic images and conforming to ASTM F 543-02 specifications for metallic medical screws. Figure 22 shows the cross-sectional
profile of the thread and Table 2 lists the principal screw dimensions. The geometry of the screw was created using UGS PLM-I-DEAS Nx software. Figure 24 illustrates the three-dimensional model of the screw, a single thread profile and the cutting flute design. Material properties listed in Table 3 were derived from the stress-strain curves (Figure 23) and assigned to the screws. The stress-strain data of the materials defined their non-linear material properties with plasticity.

Figure 22 Profile of a screw depicting the important parameters for screw design (parameters a-I are described in Table 2).
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Trailing Edge Angle</td>
<td>3°</td>
</tr>
<tr>
<td>b</td>
<td>Leading Edge Angle</td>
<td>35°</td>
</tr>
<tr>
<td>c</td>
<td>Pitch</td>
<td>1.25 mm</td>
</tr>
<tr>
<td>d</td>
<td>Thread Height</td>
<td>0.55 mm</td>
</tr>
<tr>
<td>e</td>
<td>Leading Edge Crest</td>
<td>0.80 mm</td>
</tr>
<tr>
<td>f</td>
<td>Trailing Edge Crest</td>
<td>0.20 mm</td>
</tr>
<tr>
<td>g</td>
<td>Root Radius</td>
<td>1.20 mm</td>
</tr>
<tr>
<td>h</td>
<td>Outer Radius</td>
<td>1.75 mm</td>
</tr>
<tr>
<td>i</td>
<td>Crest Width</td>
<td>0.05 mm</td>
</tr>
</tbody>
</table>

Table 2 Specifications of the screw designed for this study in accordance with ASTM F 543-02.

Figure 23 Stress-strain curves of screw materials

(a) Stainless Steel
Figure 23. continued.

(a) 3D model of the screw

(b) Single thread profile

Figure 24 Geometry of the screw developed for the FE model.
3.6.2. Bone Modeling

Bone-mimicking bi-layered foam block were modeled similar to those used in the experimental evaluation of the PI. The bone model comprised of a layer of cancellous bone sandwiched between two layers of cortical bone.

3.6.2.1. Material Properties

Bones have anisotropic material properties but for simplicity of the model, they were assumed to be isotropic materials. The material properties of the cadaveric bones are not uniform hence a synthetic bone coupon comprised of solid polyurethane foam and e-glass epoxy sheets representing the cancellous bone and the cortical layers of the bone was modeled. The modulii of elasticity of the bone material, listed in Table 3, were determined from the stress strain curves shown in Figure 25 & Figure 26. Poisson’s ratio (ν) was chosen to be 0.3 based on the literature [82,83]. The cortical bone was considered to be much stiffer than the cancellous bone and this was further confirmed by the 75% and 2% strains to failure for the cancellous and cortical bone materials respectively. The stress-strain data of the materials defined their non-linear material properties with plasticity.
Figure 25 Stress-strain curve for cortical bone

Figure 26 Stress Strain curves for cancellous bones

(a) Normal Bone
Figure 26 continued.

<table>
<thead>
<tr>
<th>No.</th>
<th>Material</th>
<th>Ult Strength (MPa)</th>
<th>Tensile Modulus (MPa)</th>
<th>Poisson’s Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Stainless Steel</td>
<td>862</td>
<td>200,000</td>
<td>0.3</td>
</tr>
<tr>
<td>2</td>
<td>Grade 4 Titanium</td>
<td>680</td>
<td>120,000</td>
<td>0.3</td>
</tr>
<tr>
<td>3</td>
<td>E-glass Epoxy</td>
<td>90</td>
<td>12,400</td>
<td>0.3</td>
</tr>
<tr>
<td>4</td>
<td>Normal Cancellous Foam</td>
<td>16</td>
<td>1190</td>
<td>0.3</td>
</tr>
<tr>
<td>5</td>
<td>Osteoporotic Cancellous Foam</td>
<td>3.9</td>
<td>143</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Table 3 Material properties of stainless steel, titanium, cortical bone, normal and osteoporotic cancellous bones
3.6.2.2. Bone Geometry

A separate simple geometry, shown in Figure 27, was developed to represent the bone coupon using UGS PLM-I-DEAS Nx software. The model, based on the bone coupons used in the experimental evaluation, comprised of two cortices with 2 mm thickness and an 18 mm cancellous region. The octagonal shape was chosen to facilitate the use of axisymmetry and for anchoring the bone by applying appropriate boundary conditions.

A partitioned surface model as shown in Figure 27a was extruded to 22mm length to generate the 3D solid model (Figure 27b). The 3D model was further transversely partitioned to define the cortical regions towards either ends of the bone. The model was partitioned to make possible the use of different mesh densities, with finer mesh closer to the bone-screw interface. Partitions P2, P3 and P4 were 4, 5 and 7mm respectively in diameter (Figure 27a). Partition P4 represents the pilot hole (2.4mm) drilled in the bone before the insertion of the screw. The threads were cut in partition P3 to match the profile of the above-mentioned screw (Figure 27c). The position of the threaded hole was assumed to be centrally located with respect to the bone block, with its axis parallel to the length of the bone block.
Figure 27 Bi-cortical bone block developed for the FE model

(a) Cross-section of the partitions in the bone

(b) Bone block geometry

(c) Threads cut into the bone block
3.6.3. Bone-Screw Assembly

The bone and screw models (described in section 3.6.2) were combined to generate a final assembly representative of the experimental bone-screw construct (Figure 28). Bone-screw interface was assumed to have perfect contact such that a uniform transfer of force occurred between the screw edge and bone. A total of eighteen threaded joints were modeled to simulate an engagement length of 22mm between the screw, bicortical layer and cancellous region of the bone. A global coordinate system was defined with Y-axis along the longitudinal axis of the screw and X- & Z-axes acting radially outward (Figure 28). An axisymmetrical model was generated, to save computational time and resources, from the solid bone-screw assembly such that only a quarter model was employed for bone and screw as shown in Figure 28.

Figure 28 Quarter model of the 3D bone-screw construct developed using UGSPLM IDEAS-Nx software.
3.6.4. Meshing

The assembled quarter model bone-screw construct was then meshed using the free-form meshing and maximum area plane methods. 3D Solid Parabolic Tetrahedral (SPT) elements (Figure 29) were used to mesh the assembly as they are the most versatile 3D solid elements used in finite element modeling. These elements are 10-node 4-face elements as shown in Figure 29, they are very adaptable elements used in linear, creep, fatigue and non-linear analysis. A finer mesh was chosen for the regions with high stress gradient, threaded bone-screw interface, and a coarser mesh was chosen for the regions with low stress gradient, regions away from the threaded region. More elements were used in the partitions representing bone than those representing the screw as it was predicted that bone would deform more than the screw.

Figure 29 3D Solid Parabolic Tetrahedral Element from the IDEAS® element library [71]
Figure 30 Partitions illustrating the different mesh densities.

The meshing was performed in the partitioned regions of the bone, P1 – P3, and screw using SPT elements of different sizes. The different regions of the model were meshed, as shown in Figure 30 as follows:

- Screw Head: Element size = 1 mm
- Screw Threads: Element size = 0.5 mm
- P1: Element size = 3 mm
- P2: Element size = 1 mm
- P3: Element size = 0.5 mm

In all, the bone-screw model was comprised of 35,090 nodes and 18,862 elements. The screw and bone regions were modeled with 16,915 & 18,175 nodes and 8,314 & 10,728 elements respectively. The fine mesh at the bone screw interface increased the total number of elements in the model. The region representing the bone material at the
bone-screw interface was predicted to be the area of critical failure hence was represented by 14,920 nodes and 8,924 elements (fine mesh: 0.5mm) which comprised of the majority of the nodes and elements in the bone model. The material properties of SS, Ti, cortical bone and normal & osteoporotic cancellous bone were assigned to these partitioned areas from Table 3. Stress-strain data was added to the material properties to calibrate the plasticity model.

Figure 31. Partitions with different mesh densities.
3.6.5. Loading and Boundary Conditions

The boundary conditions (BC) were applied such that the outer surfaces of the bone block were anchored and weren’t allowed to move in any direction, Figure 32. This BC was chosen to simulate the holding of the bone coupon in place by the faceplates during the screw pullout. Translational and rotational displacements of inner and upper surfaces of the axisymmetric model were appropriately restricted in X and Z directions in accordance with Table 4.

<table>
<thead>
<tr>
<th>Plane</th>
<th>Degrees of Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TrX</td>
</tr>
<tr>
<td>X=0</td>
<td>Constrained</td>
</tr>
<tr>
<td>Z=0</td>
<td>Free</td>
</tr>
</tbody>
</table>

Table 4 Boundary condition configurations for axisymmetry about X and Z axes

Quarter incremental loads (Force (N) / 4) were applied, due to the use of a quarter model of the threaded bone-screw construct, along the axis of the screw in Y-direction to simulate a uniaxial pullout. The load was incremented by 400 N after every iteration hence the total simulation involved five steps or five time intervals.

3.6.6. Contact Definition

The bone and screw contact each other when screw is subjected to pullout force and would together experience compressive forces due to the contact. Contacts were defined in terms global search distance, d, which detects all the element free faces (outer surfaces) that are $-0.05 \leq d \leq 0.05\text{mm}$. The coefficient of friction was assumed to be 0.2
at the contact surface between the bone and screw [82,83]. 8479 contact elements were defined based on the search distance and a preview of those elements is shown in Figure 34.

Figure 32 Boundary conditions used to simulate axisymmetry of the model

Figure 33 Uniaxial loading condition, with incremental loads from 0 –2000 N with a step-size of 400 N, applied normally to the screw head.
3.6.7. Model Solution

The software solver for nonlinear statics analysis solves for the displacements, strains, and stresses of the finite element model at discrete time intervals in the history of the structure. A nonlinear solution proceeds incrementally with equilibrium iterations performed at every solution point. The software computes plastic strain increments using a backward Euler technique without any sub-increments. It computes a consistent tangent modulus for use in generating the tangent stiffness matrix. This procedure is used with a full Newton-Raphson iteration to obtain quadratic convergence [71].

Non-linear Solver recreates the contact elements after every iteration of the solver as the geometry deforms and changes. The procedure for the contact analysis is described by the flowchart shown in Figure 35, it explains the computational aspects of the solver.
and the convergence checks performed during the computations. For a nonlinear analysis, the software calculates convergence by creating a ratio that compares the incremental value of displacement, forces, stress, or strain for the iteration to the total value of displacement, forces, stress, or strain (Eq. 2.37). For this study, strain energy (calculated as the area under the force-displacement curve) was selected as the convergence check parameter and the tolerance limit was chosen to be 0.005. The other convergence limit variable that is built into the model is the maximum limit on the number of iterations the solver can perform prior to considering the solution to be non-convergent. For this study, the limit was set for a maximum number of iterations of 40. There are other user defined variables like the maximum number of iterations for the inner force loop (loop 1 in Figure 35) and the outer contact loop (Loop 2 in Figure 35). The traction convergence at the contacts is checked in the inner force loop and if satisfied, the location of the next contact surface is computed using the outer contact loop.
Figure 35 Flowchart describing the procedure for solving the contact algorithm by checking the convergence of the selected parameter.
CHAPTER IV
RESULTS

The screw pullout trials were performed in accordance to ASTM 543-02 specifications, as mentioned in section 3.3, using the Instron material testing system. All the trials resulted in screws being pulled out successfully without any visible damage to the screws and bone coupons hence no additional trials were performed. There were no visible indications of cracks or fissures extending to the adjacent screws holes in the synthetic bone coupons. All the bone blocks were from a single batch hence there was no block-to-block variance as was observed in some of the studies [12]. In all the cases of pullout, failure of bone was observed and force-displacement curves representative of the screw pullout tests for normal and osteoporotic bones were plotted as shown in Figure 36. Pullout index (PI) was calculated as the ratio of the maximum pullout force for each of the trials to the length of screw-bone engagement. Loading energy (LE), N-mm, was calculated as the area under the normalized load-displacement curve to the peak value.

4.1. Depths of Insertion Study

The experimental test data from the depth of insertion study illustrated the difference in the pullout index of the screws inserted in normal and osteoporotic bone blocks.
4.1.1. Normal Bone

Mean PI values of SS screws in S and Z groups for different DOI in normal bone blocks are illustrated in Figure 37. These values indicate that there is a difference between the PI at different depths of insertion but no significant difference for different manufacturers of SS self-tapping screws inserted into normal bone coupons. ANOVA yielded no statistically significant difference between the means of the two groups ($p>0.05$).

The mean PI values for SS screws inserted to different depths are shown in Figure 38. Lowest PI and highest PI were observed for screws in Grp I & Grp V respectively. The mean PI was calculated for each depth of insertion: Grp I 155.6 N/mm ($\pm$ 12.9), Grp II 164.4 N/mm ($\pm$ 10.8), Grp III 174.7 N/mm ($\pm$ 12.6), Grp IV 178.4 N/mm ($\pm$ 9.6) and
Grp V 183.4 N/mm (± 8.1). These values indicate that the PI of the screws inserted past the far cortex is greater than that of the screws that do not penetrate the far cortex. ANOVA and SNK tests yielded a statistically significant difference ($p<0.05$) between Grp I and Grps II, III, IV & V, Grp II and Grps III, IV & V, but indicated no such difference between Grps III, IV & V.

Figure 37. PI of SS STS of different manufacturers inserted in normal bone coupons (S: Synthes; Z: Zimmer; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

Mean values of LE, area under the load-displacement curve, and stiffness, slope of the linear region of the normalized load-displacement curve, for the groups S and Z are shown in Figure 39 and Figure 41. These values indicate that there is no significant difference between the LE and stiffness values for different manufacturers of SS self-
tapping screws inserted into normal bone coupons. ANOVA yielded no statistically significant difference between the means of LE and stiffness of the two groups \( (p>0.05) \).

The mean LE and stiffness vals for SS screws inserted to different depths are shown in

Figure 38 PI of SS STS at different depths of insertion in normal bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

![Graph showing PI of SS STS at different depths of insertion](image)

The mean LE and stiffness vals for SS screws inserted to different depths are shown in

Figure 40 & Figure 42. The mean LE was calculated for each depth of insertion: Grp I 81.5 N-mm \( (\pm 47.3) \), Grp II 91.4 N-mm \( (\pm 68.8) \), Grp III 111.2 N-mm \( (\pm 51) \), Grp IV 117.1 N-mm \( (\pm 58.3) \) and Grp V 108.7 N-mm \( (\pm 51.8) \). Grp I was 89.2% and Grp III, IV & V were 121.6%, 128.1% \& 118.9% of the mean LE value of control Grp II (0 mm). The values indicate an increase in LE of the bone-screw construct with the increase in depth of insertion. ANOVA and SNK tests performed for LE values yielded a statistically
significant difference \((p<0.05)\) between Grp I & II and Grps III, IV & V but indicated no such difference between Grps III, IV & V.

Figure 39. Loading energy of self-tapping bone screws from different manufacturers inserted to different depths in normal bone coupons ( S: Synthes; Z: Zimmer; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

The mean stiffness (N/mm) was determined for each depth of insertion: Grp I 184.6 N/mm (±41.2), Grp II 190 N/mm (±57.4), Grp III 199.8 N/mm (±54.9), Grp IV 210.0 N/mm (±37.4) and Grp V 212.1 N/mm (±48.3). These values indicate that the stiffness of the screws inserted past the far cortex is greater than that of the screws that do not penetrate the far cortex. ANOVA and SNK tests for stiffness values yielded a statistically significant difference \((p<0.05)\) between Grp I & II and Grps III, IV & V but indicated no such difference between Grps III, IV & V.
Figure 40  Loading energy of self-tapping bone screws inserted to different depths in normal bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

Figure 41  Stiffness of self-tapping bone screws from different manufacturers inserted in normal bone coupons (S: Synthes; Z: Zimmer; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)
Figure 42 Stiffness of self-tapping bone screws inserted in normal bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

Figure 43 Displacement at peak pullout strength for STS inserted to different depths. (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)
Displacement at peak, the displacement at maximum pullout force, was determined and the mean values for each of the depths of insertion are reported in Figure 43. Lowest and highest displacements were observed for screws in Grp I & Grp V, 0.93 and 1.2 mm respectively. These values correlate to the pitch of the screw, 1.25 mm, and correspond to \( \frac{3}{4} \) and one turn rotation. The data indicated that peak pullout force was attained at lower displacements for the screws that do not penetrate the far cortex when compared to those that penetrate it.

4.1.2. Osteoporotic Bone

Mean PI values of SS screws in S, Z and H groups for different depths of insertion in osteoporotic bone blocks are illustrated in Figure 44. A trend representing the
increase in PI with insertion depth was observed from these values but no significant difference was observed between the PI of different manufacturers for SS self-tapping screws inserted into osteoporotic bone coupons. ANOVA yielded no statistically significant difference between the means of the three groups ($p<0.05$).

![Figure 45 Mean Pullout Index during the pullout of self-tapping bone screws in osteoporotic bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)](image)

The mean PI values for SS screws inserted to different depths are shown in Figure 45. Lowest PI and highest PI were observed for screws in Grp I & Grp V respectively. The mean PI values calculated for each depth of insertion were: Grp I 31.1 N/mm (±4.7), Grp II 34.8 N/mm (±5.4), Grp III 44.4 N/mm (±6.4), Grp IV 49.7 N/mm (±4.2) and Grp V 51.3 N/mm (±4.4). These values indicate that the PI of the screws inserted at least 2mm past the far cortex is greater than that of the screws that do not penetrate the far cortex. ANOVA and SNK tests yielded a statistically significant difference ($p<0.05$)
between Grp I and Grps II, III, IV & V, Grp II and Grps III, IV & V, Grp III and Grps IV & V but indicated no such difference between Grps IV & V.

Mean values of LE and stiffness for the groups S, Z and H are shown in Figure 46 and Figure 48. These values indicate a positive correlation for LE & stiffness values with depth of insertion but not a significant difference between the LE and stiffness of different manufacturers for SS self-tapping screws inserted into normal bone coupons. ANOVA yielded no statistically significant difference between the means of LE and stiffness of the three groups ($p > 0.05$).

Figure 47 and Figure 49 summarize the findings concerning LE and stiffness values for SS screws inserted to different depths. The mean LE was calculated for each depth of insertion: Grp I 9.4 N-mm ($\pm 2.5$), Grp II 10.3 N-mm ($\pm 2.7$), Grp III 14.6 N-mm ($\pm 3.3$), Grp IV 20.1 N-mm ($\pm 2.9$) and Grp V 21.5 N-mm ($\pm 2.3$). Grp I was 91.3% and Grp III, IV & V were 141.8%, 195.2% & 208.7% of the mean LE value of control Grp II (0 mm). The values show that the LE of the bone-screw construct for different depths of insertion are different from one another such that there is an increase in the LE values with greater screw engagement in the far cortex of osteoporotic bone. ANOVA and SNK tests yielded a statistically significant difference ($p<0.05$) between Grp I & II and Grps III, IV & V but indicated no such difference between Grps III, IV & V.
Figure 46 Loading energy during pullout of self-tapping bone screws of different manufacturers inserted in osteoporotic bone coupons (S: Synthes; Z: Zimmer; H: Howmedica; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V).

Figure 47 Comparison of the loading energies during the pullout of self-tapping bone screws inserted to different depths in osteoporotic bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V).
Figure 48 Stiffness during pullout of self-tapping bone screws from different manufacturers inserted in osteoporotic bone coupons (S: Synthes; Z: Zimmer; H: Howmedica; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

Figure 49 Stiffness during the pullout of STS inserted to different depths in osteoporotic bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)
The mean stiffness (N/mm) was determined for each depth of insertion: Grp I 81.8 N/mm (± 7.1), Grp II 87.9 N/mm (± 7.7), Grp III 94.9 N/mm (± 5.9), Grp IV 95.7 N/mm (± 6.9) and Grp V 100.7 N/mm (± 6.2). These values indicate that the stiffness of the screws inserted in osteoporotic bone increases with the depth of insertion such that it was greater when far cortex was penetrated. ANOVA and SNK tests yielded a statistically significant difference ($p<0.05$) between Grp I & II and Grps III, IV & V but indicated no such difference between Grps III, IV & V.

![Figure 50](image-url) Displacement of LVDT at peak pullout force of STS inserted to different depths in osteoporotic bone (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

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Displacements at peak pullout force of STS were recorded and the mean values for each of the depths of insertion are shown in Figure 50. Lowest and highest displacements were observed for screws in Grp I & Grp V, 0.57 and 0.78 mm respectively. These values correlate to the pitch of the screw, 1.25 mm, and correspond to $\frac{1}{2}$ and $\frac{5}{8}$th turn rotations respectively. The data indicated that peak pullout force was attained at lower displacements for the screws that do not penetrate the far cortex when compared to those that penetrate it.

4.1.3. Comparison between normal and osteoporotic bones

Figure 51, Figure 52 and Figure 53 summarize the findings for the screw pullout in normal and osteoporotic bone blocks in terms of PI, LE and stiffness. The difference in the PI for normal and osteoporotic blocks was found to be 400% in Grp I, 372 % in Grp II, 293 % in Grp III, 259 % in Grp IV and 258% in Grp V. These values indicate the increase in difference in PI for normal and osteoporotic bone with increased cortical engagement of the screw. ANOVA and SNK tests yielded a statistically significant difference ($p<0.05$) between the means of PI, LE and stiffness in normal and osteoporotic bone blocks.
Figure 51 Pullout Index of STS inserted to different depths in normal and osteoporotic bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V).

Figure 52 Comparison of loading energies for the pullout of STS from normal and osteoporotic bone coupons (Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V).
Figure 53 Comparison of stiffness for pullout of STS from normal and osteoporotic bone coupons (Depth of insertion: -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V).

Figure 54 Profile graph for torque in the pilot hole study (R1, R2: Regions for engagement in proximal and distal cortices of the bone block)
4.2. Pilot Hole Study

A typical torque profile for the insertion of STS into synthetic osteoporotic bone block is illustrated in Figure 54. Regions R1 and R2 represent the resistance offered to the engagement of the screw in the near and far cortices respectively. Penetration of the far cortex generated peak torque during insertion regardless of the size of the pilot hole.

Peak insertion torques for each of the screws from the four pilot hole size groups were recorded for engagement of the screws in both the cortices for all depths of insertion (Figure 55). Mean insertion torque values (± standard deviation) for the pilot hole size groups were: Grp A 0.54 (± 0.07) Nm, Grp B 0.58 (± 0.06) Nm, Grp C 0.52 (± 0.06) Nm & Grp D 0.35 (± 0.04) Nm. These values indicate that the insertion torque reduced with a significant increase in the pilot hole size. No statistically significant difference was found between Grp A, Grp B, and Grp C (\(p=0.06\)), but there was a statistically significant difference between these three hole sizes (A,B,C) as compared to hole D (\(p<0.001\)).

Mean PI values for all the pilot holes at different insertion depths are compared in Figure 56. When compared to control Grp B, Grp A had 92.5%, 94.5% & 96.3%, Grp C had 97.8%, 98.3% & 94.2% and Grp D had 81.1%, 76.5%, & 81.6% PI values for 0, 1 and 2 mm insertion past the far cortex. These values indicate a reduction in the PI of the screw for pilot hole size D when compared to A, B & C thus illustrating the compromise of PI with the increase in pilot hole size. The PI of the screws inserted flush with the far cortex were found to be statistically different (\(p < 0.001\)) from those that were advanced 1 and 2mm past the far cortex regardless of pilot hole size. ANOVA and SNK tests yielded a statistically significant difference in PI of pilot holes A,B & C when compared to hole D at all depths of insertion (\(p= 0.012\)).
Figure 55 Comparison of the insertion torques for different pilot hole sizes (A: 2.45mm; B: 2.5mm; C: 2.55mm; D: 2.80mm).

Figure 56. Pullout Index comparison for difference size pilot holes (A: 2.45mm; B: 2.5mm; C: 2.55mm; D: 2.80mm; Depth of insertion 0: Grp I; 1: Grp II; 2: Grp III).
Figure 57 and Figure 58 summarize the results of the loading energy and stiffness of the pullout test of STS inserted in osteoporotic bone blocks for each of the different insertion depths and also for all the pilot hole sizes. A significant decrease in stiffness and LE values can be observed with the increase in pilot hole size. ANOVA and SNK tests yielded statistically significant difference between loading energy and stiffness values of pilot holes A, B & C as opposed to hole D \((p<0.001)\), irrespective of insertion depth.

![Graph showing loading energy comparison for different size pilot holes.](image)

**Figure 57 Loading energy comparison for difference size pilot holes** (A: 2.45mm; B: 2.5mm; C: 2.55mm; D: 2.80mm; Depth of insertion 0: Grp I; 1: Grp II; 2: Grp III).
Figure 58 Stiffness comparison for difference size pilot holes (A: 2.45mm; B: 2.5mm; C: 2.55mm; D: 2.80mm; Depth of insertion 0: Grp I; 1: Grp II; 2: Grp III).

Figure 59 Pullout index of screws of different sizes inserted to different depths (Screw Size A: 2.7mm; B: 3.5mm; C: 4.5mm; Depth of insertion D0: Grp I; D1: Grp II; D2: Grp III)
4.3. Screw Size Study

Pullout index for each of the screw groups, inserted into osteoporotic bone blocks, was determined and tabulated based on the depths of insertion (groups I, II & III) and screw size (A, B & C). Differences of 26%, 25%, 27% between groups I & II, 32%, 30%, 43% between groups I and III and 6%, 6%, 12% between groups II and III were observed for screw sizes A, B & C respectively. PI of the screws (all sizes) was observed to be highest for those inserted 2mm past the far cortex and lowest for those inserted flush with the far cortex (Figure 59). No significant differences were observed for different screw sizes for each depth of insertion. Mean LE and stiffness values of all the groups for each of the screw sizes are illustrated by Figure 60 and Figure 61 respectively. It was observed that the energy absorption was greatest and stiffness was lowest for the 4.5mm screw for all depths of insertion.

Based on PI and LE as independent variables a statistically significant ($p<0.05$) difference was observed between Groups I and II, I and III, and II and III. When the corresponding groups of different screws were compared no statistical difference was observed. SNK classified the PI and LE of group III being significantly different from groups I and II and group II being significantly different from group I.
Figure 60: Loading Energies of screws of different sizes inserted to different depths (Screw Size A: 2.7mm; B: 3.5mm; C: 4.5mm; Depth of insertion D0: Grp I; D1: Grp II; D2: Grp III)

Figure 61: Stiffness of screws inserted into different size pilot holes to different depths (Screw Size A: 2.7mm; B: 3.5mm; C: 4.5mm; Depth of insertion D0: Grp I; D1: Grp II; D2: Grp III)
4.4. Cutting Flutes Study

The mean PI values, for the cutting flutes study, at each depth of insertion in normal and osteoporotic bone blocks are illustrated in Figure 62. When compared to control group (Grp II), mean PI of Grp I was 86.9% & 81.5%, Grp III was 106.3% & 127.7%, Grp IV was 108.5% & 142.8% and Grp V was 112% & 145.8% in normal and osteoporotic bone blocks respectively. The results indicate the decrease in pullout strength of the screws when the cutting flutes are engaged in cancellous/cortical bone and do not penetrate the far cortex. The PI values for screw pullout from normal bone blocks were 503.8%, 472.3%, 393.2%, 358.9% and 362.8% greater than the values in osteoporotic bone blocks for their respective depths of insertion. These values reiterate the findings from the above mentioned depth of insertion study that the pullout strength of STS in osteoporotic bone is significantly lower than that in normal bone.

Figure 63 and Figure 64 illustrate the mean LE and stiffness values for each of the cutting flute depths in normal and osteoporotic bone material. ANOVA yielded a significant difference ($p<0.05$) between the groups for both PS and LE based on the depth of cutting flutes and also bone quality. Grps III, IV & V were classified by SNK test to be different from Grps I & II in both normal and osteoporotic bones. The test also yielded a difference between Grps I & II but no difference between III, IV & V groups.
Figure 62 Pullout Index of self-tapping bone screws in normal and osteoporotic bone coupons for different cutting flute configurations (Depth of insertion of the cutting flutes with respect to the far cortex -3: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 5: Grp V)

Figure 63 Loading energy comparison for pullout of STS from normal and osteoporotic bone coupons for different cutting flute configurations (Depth of insertion of the cutting flutes with respect to the far cortex -3: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 5: Grp V)
Figure 64 Stiffness comparison for pullout of STS from normal and osteoporotic bone coupons for different cutting flute configurations (Depth of insertion of the cutting flutes with respect to the far cortex: -3: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 5: Grp V)

4.5. Stainless Steel vs Titanium

Mean values of PI of stainless steel and titanium STS in normal and osteoporotic bone blocks are compared in Figure 65 and Figure 66 respectively. The values for different depths of insertion for SS and Ti had mean differences of 4.2%, 0.7%, 7.8%, 1% & 4.2% in normal bone and 16.7%, 27.3%, 15.2%. 9.9% & 0.0% in osteoporotic bone blocks. ANOVA yielded no significant difference in PI between SS and Ti in normal bone but yielded a significant difference ($p<0.05$) in PI between SS and Ti in osteoporotic bone.
Figure 65 Pullout Index comparison for SS and Ti screws in normal bone coupons. (SS: Stainless steel; Ti: Titanium; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V)

Figure 66 Pullout Index comparison for SS and Ti screws in osteoporotic bone coupons (SS: Stainless steel; Ti: Titanium; Depth of insertion -1: Grp I; 0: Grp II; 1: Grp III; 2: Grp IV; 3: Grp V).
4.6. Finite Element Model (FEM)

The finite element models of different bone-screw interface configurations yielded results that were similar to that of the experimental values.

4.6.1. Screw pullout from normal bone

Figure 67 & Figure 68 show the von Mises stress profiles for the bone and screw at failure load during the simulation of screw pullout from normal bone, respectively. It was observed that at peak load the bone at the bone-screw interface (Figure 67) experienced high stress gradient (≥ yield stress) that led to the failure (non-convergent model) of the cancellous bone at edges of screw thread. The corresponding peak von Mises stresses (< yield stress) in the screw were also observed in the thread region at the bone-screw interface (Figure 68).

Figure 67 von Mises stress values for normal bone
A decrease in stress values was observed as the bone was traversed from the bone-screw interface to the outer circumference of the bone illustrating a large stress gradient. Hence, it can be deduced that the failure (non-convergence) of the model occurred in the bone around the outer diameter of the screw. The stress values were the highest in the first two and last two threads that were engaged in cortices at both the ends and the failures stresses in the cancellous bone were evenly distributed at the bone-screw interface. The stress values in the cancellous bone were relatively smaller than those in the cortical bone thus illustrating the influence of cortical bone in establishing fixation stability. It was observed that at peak load the elements representing cortical and cancellous bone near the thread tip region experienced high stresses that resulted in non-convergence.

The stress values in the screw were different from that of the bone in that they were not as evenly distributed as in the bone. It was observed that stress values in the
screw decreased for threads away from the head as compared to those near the head. The stress experienced by the screw was much lower than its yield stress i.e., it can be considered that the screw experienced stresses in the linear region of the stress-strain curve that led to a small elastic deformation. Hence it can be concluded that failure during pullout testing occurs in the bone at the bone-screw interface without plastically deforming the screw threads. The high strain values in the bone at the bone-screw interface as observed in Figure 69 reiterate the above finding. Figure 70 (a) & (b) illustrate the strain energy and element displacement profiles. The displacement of the head of the screw was the largest as in the experimental evaluation. Difference in strain energy values for successive iterations was used as the convergence criteria for the non-linear analysis.

Figure 69 Strain values (in the Y-direction) at bone screw interface for normal bone
4.6.2. Screw pullout from osteoporotic bone

Figure 71 shows the stress distribution in the screw during the pullout simulation in osteoporotic bone. High stress values can be observed in the screw threads engaged in proximal and far cortex but these values were lower than the yield values for the screw hence no plastic deformation was observed. Unlike the stress distribution in the normal bone, the stresses in osteoporotic bone were concentrated in the cortices due to the lack of load sharing capacity of the deteriorated cancellous bone in the osteoporotic model.
The corresponding von Mises stress distribution in osteoporotic bone may be found in Figure 72. It can be observed that the cortical shell contributes most of the resistance offered to screw pullout as very low stresses can be seen in the cancellous bone region. The region around the threads in cortical shell can be seen to experience high stresses ($\geq$ yield stress) that led to failure (non-convergence of the model). Figure 73 and Figure 74 show the strain and displacement distributions for the pullout simulation demonstrating the higher strains in the cortical region of the bone and high displacement of the screw respectively. Figure 75 illustrates the difference in the stress distributions during the pullout from the normal and osteoporotic bones. High stress concentration was observed in the cortical shell of osteoporotic bone during the pullout due to the minimal load sharing between the cortical and cancellous bones. On the contrary, in normal bone due to the loading sharing between the cortical and cancellous bones a uniform stress distribution was observed.
Figure 72 von Mises stresses in the osteoporotic bone

Figure 73 Displacement profile during screw pullout from osteoporotic bone.
Figure 74 Strains (in the Y-direction) at the bone screw interface in osteoporotic bone

Figure 75 Stress distribution illustrating the stress concentration in the cortical bone of osteoporotic model and more uniform stress distribution in normal bone
4.6.3. Depths of insertion

Figure 76 shows the FE models of screws inserted to different depths and Figure 77 shows the computed force-displacement curve for the pullout simulation. Bone, being the weaker material at the bone-screw interface, failed at the peak of the curve and demonstrated the non-linear behavior of the pullout simulation with a marked decrease in the resistance offered to the applied force. This phenomenon is similar to that seen in the force-displacement curve for experimental pullout. It was observed that the FE model of the screw pullout does not replicate the experimental pullout, in that no tearing or crushing of the bone could be simulated, but the non-linear trend in the force-displacement curve was represented.

![Figure 76: Different depths of insertion with respect to the far cortex.](image)

-1mm  0mm  1mm  2mm  3mm
Figure 77. Typical force-displacement curve for the FE model of screw pullout (Reference line included in the figure to indicate the pullout values for force and displacement).

Figure 78. Comparison of the computed pullout strength of the screw inserted to different depths in normal bone.
Finite element models for pullout of screws inserted to different depths with respect to the far cortex in normal and osteoporotic bone yielded results that followed a trend similar to that of experimental pullout. It can be observed from Figure 78 & Figure 79 that the pullout strength of the screws increased with the increase in engagement in the
far cortex in normal and osteoporotic bone and it can also be observed that the pullout values for normal bone are greater than that for osteoporotic bone.

Figure 80 Screw inserted to 0, 1, 2mm past far cortex for 1mm cortical thickness; (d) 2 mm past the far cortex for 2 mm cortical thickness.

4.6.3.1. Effect of Cortical Thickness

Osteoporosis has been defined to be the diseased state of the bone that results in structural deterioration with reduction in bone mass. Cortical thinning and loss of lattice structure of the trabeculae demonstrate the structural deterioration. Reduction in bone
mass and loss of trabecular structure were represented by low density foam with material characteristics similar to that of moderately osteoporotic bone but cortical thinning couldn’t be simulated due to the limitation of thickness ≥ 2 mm for commercially E-glass filled epoxy sheets that mimicked cortical bone in the synthetic bone blocks. Hence, a FE bone model (Figure 80) with 1 mm cortical thickness was developed to evaluate the effect of cortical thinning. It can be observed in Figure 80, that there was no thread engagement at the far end for 0 and 1 mm past the far cortex.

4.6.4. Validation

Table 6 and Figure 81 compare the pullout values from the finite element model to those obtained experimentally. It can be observed that values for pullout obtained numerically and experimentally are not significantly different from one another and the trend of increase in the pullout strength with the increase in depth of insertion past the far cortex is maintained. All the FEA values were within two standard deviations of the experimental data and the minor difference between the two sets of values could be attributed to the applied boundary conditions and assumption of contact friction at the screw and bone interface in the model. The results indicate that by defining proper boundary conditions, material properties and contact parameters, the FEA results can mimic the experimental findings.
Table 6 Pullout values from the FEA model and the experimental testing.

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4.6.5. Effect of Cutting Flutes

The linear FE model developed to evaluate the effect of cutting flutes on the screw pullout strength in normal bone yielded stress distributions similar to that of above-mentioned non-linear model. Table 7 lists the pullout values from the linear FE model and the experimental data. The stress distribution in the screw was, Figure 82, reduced as one traversed along the length of the screw from the head towards the cutting flutes. Stress concentration areas could however be observed in the cancellous bone surrounding the cutting flutes in Figure 84(a) though the stresses in the screw near the tip are low when compared to those near the head. But these values were still lower than the yield stress value of the screw as illustrated by strain distribution in the screw in Figure 85.
Figure 81 Comparison of experimental pullout with FE model results for normal and osteoporotic bone. (EPON: Experimental Pullout from Normal Bone, FEAN: Finite Element Pullout from Normal Bone, EPOO: Experimental Pullout from Osteoporotic Bone, FEAO: Finite Element Pullout from Osteoporotic Bone)

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<td>3</td>
<td>185.49</td>
<td>5.08</td>
</tr>
</tbody>
</table>

Table 7 Pullout values from the linear FEA model and the experimental testing.
Figure 82 Stress profile for screw for the linear cutting flutes model

Figure 83 von Mises stress distribution in the bone region for the linear cutting flutes model.
Figure 84 High stresses around the cutting flutes

Figure 85 Strain distribution (in the Y-direction) of the cutting flutes model
Figure 83 and Figure 84(b) illustrate the stresses experienced by the bone during screw pullout. It was observed that stresses were distributed uniformly in the cortical and cancellous bone regions around the screw threads. When stresses in the cortical bone, observed to be greater than that in the cancellous bone, reached yield stress value the bone-screw construct was led to failure. The stress concentration areas in the bone surrounding the cutting flutes can be observed in Figure 84(b). Figure 85 illustrates the strain distribution during the screw pullout and the enlarged segment shows the high strain areas in the bone around the cutting flutes that can be identified as stress risers. It was observed that the pullout forces in the linear model with cutting flutes were not significantly different from that of the model without the cutting flutes (p < 0.05).

Figure 86 Displacement profile for the screw with cutting flutes inserted into the normal bone.
The effect of cutting flutes in the osteoporotic bone can be observed from Figure 87 and Figure 88. Figure 87 shows the stress distribution in the screw and bone regions that indicated a trend similar to that observed in the non-linear model. The enlarged segments indicate the high stress and strain regions in the area around the cutting flutes that act as stress risers. It was observed that the pullout strength of screws in osteoporotic bone was not affected by the presence of cutting flutes as the values were not different from screws without the cutting flutes.

Figure 87 *von Mises* stresses in the cutting flutes model in osteoporotic bone
Figure 88 Strains (in the Y-direction) in the cutting flutes region for osteoporotic bone
CHAPTER V
DISCUSSION

This study was designed to examine the effect of axial pullout on the PI of self-tapping cortical bone screws inserted to different depths in normal and osteoporotic bone materials. Axial loading was chosen as it loads the bone in its weakest (transverse) orientation and to follow the ASTM standard protocol for screw pullout of metallic bone screws. Axial loading mimicked the worst clinical situation of screw pullout hence investigating its effects would provide information to estimate or predict the pullout strengths in other orientations [63]. In a clinical setting the screw experiences complex loads that are dominated by the axial component, normal to the longitudinal axis of the screw, with cyclic loads playing a significant role in screw loosening. However, the pullout test can still be considered to be a good measure of the holding power of the screw in bone [75].

Several studies reported failure of the screws in a clinical setting and identified bone stripping, screw loosening, improper placement or insertion, screw breakage, during removal due to bony ingrowth and bone density to be some of the factors that cause failure [41, 59, 60, 74]. Such failure of the screws in a clinical setting may require additional surgical intervention or may lead to poor fixation across the fracture site [58]. Most of these factors that lead to failure are related to or can be quantified by the pullout
strength of the bone-screw construct hence PI plays a significant role in evaluating the performance of the screw in bone.

Some of the other factors that affect the performance of the screws inserted in bone are the tissue trauma, thermal necrosis and torque generated during insertion. Baumgart et al. and Phillips et al. [9, 55] observed that the screws failed at tensile stresses less than tensile strength if they were subjected to torsional shear and tensile stresses simultaneously. They indicated that the screws were subjected to complex loads involving torsional (due to the clockwise rotation of the screw), tensile (pressure exerted by the screw driver) and flexion (tensile load at an angle) loads that might lead to their failure which made insertion torque a significant factor in the evaluation of the pullout strength bone screws. Schatzker et al. [60] investigated the effects of trauma and thermal necrosis during the insertion of screws into cortical bone. They observed that the pullout strength was minimal immediately after the insertion due to tissue trauma from drilling operations and / or thermal necrosis but they also observed a gradual increase in pullout characteristics during the healing stages.

Osteoporosis is a disease state of the bone and is characterized by the reduction in bone mass and micro-architectural deterioration of the bone [21,40,79]. The deterioration of the bone mass, BMD and structural characteristics, loss of trabecular connectivity, make the bone susceptible to fracture and challenging to repair. Osteo-fixation challenges that arise are due to placement of the implants in deteriorated bone and probable loosening and failure of the implants in the future due to bone resorption [79]. With the increase in the aging population that is affected by osteoporosis, fracture
fixation in the elderly has assumed a significant role in determining the quality of life. Hence osteosynthesis in osteoporotic bone is fast becoming a topic of prime importance due to the intrinsic challenges involved in attaining fracture fixation.

Stromsoe et al. [67,68] demonstrated the dependency of the holding power of the bone screws on the BMD values and material properties of bone. They observed and correlated the deterioration in the strength of fracture fixation to the loss of bone mass, thus indicating that the reduced modulus of elasticity and other mechanical properties of osteoporotic bone impact the fixation strength of the osteo-fixation hardware (plates, screws etc).

Self-tapping bone screws facilitate the insertion with fewer surgical instruments and steps than NSTS due to the presence of cutting flutes. Though the STS offer greater bone-screw interface area, with the compaction of bone debris between the screw threads during thread cutting, than the NSTS, the major concern related to their usage in surgery is the fact that the cutting flutes, at the tip of the screw, must be advanced past the far cortex into the soft tissue to maximize the bone-implant interface area thus improving its fixation strength. This might cause soft tissue irritation, cause hindrance to the gliding of the tendons and ligaments and also provide potential site for bacterial infection [9,52,78]. Very few studies have evaluated the performance of STS with respect to the depth of insertion past the far cortex and in osteoporotic bone. This study compared the performance of the STS in normal and osteoporotic bone by investigating the effects of depth of insertion with respect to the far cortex, screw material, pilot hole, screw size and cutting flutes on the PI.
5.1. Depth of insertion

Protrusion of the screw tip past the cortex has been considered an important factor during insertion of STS but there are no biomechanical studies to quantify and support the above theory. Current screw pullout studies have not addressed the effect of depth of insertion in normal and osteoporotic bones. This study employs synthetic bone coupons with high and low strengths to mimic the normal and osteoporotic bone materials respectively. The use of synthetic bone for biomechanical evaluation of metallic bone screws has been approved by ASTM and has been accepted by many researchers for its advantages over the cadaveric bones (previously discussed).

Material properties of high and low density polyurethane foams representing the normal and osteoporotic cancellous bone and that of e-glass epoxy sheets representing cortical bone were evaluated in-house and were observed to closely mimic the cadaveric bone properties. DXA scans of the foam materials were obtained to confirm their representation of normal and osteoporotic bones by the means of BMD values. Based on the BMD values the low density synthetic bone material was categorized to be moderately osteoporotic bone.

Findings from the study by Berkowitz et al. [12] indicated that the protrusion of the screw tip past the far cortex of normal bone material provided higher pullout strength than when the tip is within the far cortex. However, the study was limited in that it had a low value of power and only a few samples were evaluated. The results of our study involving the evaluation of the effect of depth of insertion on PI in normal and
osteoporotic bone reinforced the findings of Berkowitz et al. for normal bone and also show a similar trend for osteoporotic bone.

The purpose of the study was to investigate the influence of bone density, insertion depth, screw material and vendor on the pullout strength of STS while keeping the screw dimensions constant. All the screws used for testing were of the same major and root diameters, pitch, length and thread design. The results indicate that the PI, LE and stiffness of the screws inserted past the far cortex were higher that those flush with and inside the far cortex in both the normal and osteoporotic bone. It was also observed that there was no statistically significant difference in PI and LE between 1 mm, 2 mm and 3 mm penetration past the far cortex. These findings confirm that the presence of screw tip with cutting flutes within the far cortex is detrimental to the pullout strength of the screw. It can also be observed that though the cutting flutes were 3.9 (± 0.2) mm long, their protrusion of 1mm and 3mm past the far cortex provide similar fixation strength in spite of cutting flutes being partially engaged in the far cortex. This indicates that the presence of cutting flutes in the tip region is detrimental to the pullout strength but their presence at the distal end of the screw, where OD is equal to OD of the screw, is not detrimental. Based on this biomechanical finding it can be recommended that protrusion of the screw tip 1 mm past the far cortex is sufficient to provide optimal screw fixation contrary to the anecdotal recommendation of penetration of the screw tip 2 mm past the far cortex.

The results show that the PI, LE and stiffness of bone screws inserted in normal and osteoporotic bones are different. It was observed that the PI and LE in normal bone
were significantly different from that in osteoporotic bone (> 250 %) for all the depths of insertion. The study by Harnroongroj et al. [30] indicated that the pullout resistance is offered by the engagement of the screw in the cortices and not by their engagement in cancellous bone. The findings of our study contradict the results of Harnroongroj et al’s study in that the material and geometrical characteristics of the e-glass epoxy sheets that represented the cortical bone were similar for normal and osteoporotic bone coupons. Hence the difference in the PI and LE values for normal and osteoporotic bone coupons cannot be attributed to cortical engagement only. The contribution of the cancellous bone to the screw fixation strength was observed from the difference in the PI values for normal and osteoporotic bone coupons, as they only differed in the material properties of the polyurethane foam representing cancellous bone. The results indicate that the pullout strength of the screw is not only dependent on the cortical bone properties of the bone but also on the cancellous bone. These results confirm the observations made by Seebeck et al. that anchorage strength was dependent on density of cancellous bone and cortical thickness and not only on the screw engagement length in case of bi-layered bone models [63]. The bone coupon model used in the study is representative of the clinical osteoporosis in that the cancellous bone is affected more by the disease than the cortical bone; hence the low density foam was used to represent the deterioration of the bone quality and strength due to osteoporosis. The results of this study indicated that for the osteoporotic bone model the cortical layer contributed to / offered most of the pullout resistance and low density foam offered little resistance unlike the normal bone model in which the high density foam also contributed to the pullout resistance significantly.
The study also compared the performance of screws from different manufacturers (Synthes, Zimmer and Stryker). Screws from Synthes and Zimmer were evaluated in both normal and osteoporotic bone but due to limitation of availability, Stryker STS were used only in osteoporotic bone. In normal bone, it was observed that there was no statistically significant difference in PI and LE of the screws from Synthes and Zimmer for all depths of insertion. In osteoporotic bone, it was observed that there was no statistically significant difference in PI and LE of the screws from the three manufacturers for all depths of insertion past the far cortex. These findings indicate that the performance of bone screws from the three manufacturers is similar.

5.2. Pilot Hole Study

Insertion torque generated by the STS has long been considered an important factor in the evaluation of the bone screw performance due to the high torques applied to the screw, thermal necrosis and tissue damage that accompany the high insertion torques. The torque applied to the screw by the surgeon during the insertion of STS is also transmitted through and experienced by the bone into which the screw is inserted; hence high insertion torques may lead to screw failure or iatrogenic fracture [3,24,55]. One of the factors that influence the insertion torque is the size of pilot hole drilled for screw insertion. Inappropriately drilled pilot holes (with respect to root diameter of the screw) lead to the application of high forces that exceed the elastic limit of the screw resulting in failure of the screw and/or trauma to the bone and surrounding tissue.

Gantous et al. [24] suggested that the insertion torque could be reduced without compromising of the pullout strength by increasing the size of the pilot hole. They
determined a critical pilot hole size to which any increase in pilot hole size was not
detrimental to the pullout strength but any further increase of the pilot hole size more
than the critical size decreased the pullout strength dramatically. Baumgart et al. [9]
indicated that the insertion torque and thermal necrosis could be limited by tapping the
pilot hole to appropriate size. Ansell et al. [3] enlisted mechanical strength of the
surrounding bone, mode of insertion (continuous or intermittent), mode of engagement
(uni- or bi-cortical) and pilot hole size to be the factors that influenced the insertion
torque.

The goals of this study were to determine the effects of pilot hole size on the insertion
torque and pullout characteristics of STS when inserted in osteoporotic bone while
maintaining the other influential parameters constant. The screws with three cutting flutes
were chosen for the study based on the recommendation from Yerby et al. [78] that three
was the minimum number of cutting flutes required for optimal insertion with relative
ease and minimal possibility of thread stripping. The results of this study demonstrated
that pilot hole size does influence the insertion torque and pullout strength of STS in
osteoporotic bone. It was observed that as the pilot hole size was increased to the critical
size as recommended by Gantous et al. (80% of OD) the pullout strength reduced
dramatically due to the decrease in the bone-screw interface area and reduced contact
between screw threads and bone, resulting in loss of compression between them. The
difference in the results for our study from Gantous et al. might be due to the fact that
they evaluated mini and micro fixation screws (1 mm, 1.5 mm and 2 mm) of short lengths
(used in oral and plastic surgeries) compared to the 3.5 mm screws used in this study.
Their tests were conducted on Delron blocks that did not have a cortical bi-layer unlike
the test blocks, in this study, that mimicked a bi-cortical fixation with the presence of two cortices and cancellous region. The use of osteoporotic material might have also contributed to the disparity in the findings as osteoporotic bone has a reduced capacity of withstanding shear forces experienced during screw pullout. The decrease in the LE values of the larger sized pilot hole further supports the finding of reduction in pullout strength in osteoporotic bone with the increase in pilot hole size to 80 % of OD of the screw. The findings of the study (IT, PI, LE and stiffness) appear to support the surgical use of the pilot hole size of 2.5 mm (Grp B, 71.5 % of OD) thus confirming the observations of Ansell et al. that optimal pilot hole size helps achieve maximal pullout strength.

The insertion torques were observed to be greatest while penetrating the far cortex for all pilot hole sizes. Hence it can be suggested that the surgeon inserting screw be cautious while estimating the purchasing capacity of the bone as use of high tensile and torsional forces might lead to tissue damage and might not result in an optimal fixation. The decrease in insertion torque with the increase in pilot hole size may be explained by the reduction in the bone volume to be displaced for cutting thread cutting or forming. It was also observed that similar trends of increase in PI were demonstrated with increase in depths of insertion regardless of pilot hole size. The recommendations from this study though are limited by the use of synthetic foam material which represent ideal bone conditions without any variations that are encountered in cadaveric bones and also in that its an in vitro study that approximates an in vivo clinical situation. The results of this study are unique and demonstrate that the findings of previous studies cannot be applied to osteoporotic bone.
5.3. Screw Size study

It had been observed by many researchers that geometrical properties of the screw and the quality of the surrounding bone tissue were the main parameters that influenced the fixation [36,75,76]. Geometrical parameters like outer diameter of the screw, root diameter, thread pitch, thread shape, ratio of ID/OD have been found to effect the pullout strength [20,41,47,75] of which thread depth and major diameter have been indicated to be the main constituents of pullout resistance. Some of the studies suggested that screw size (OD) and bone density to be the most influential parameters for pullout strength and that only minimal gains could be obtained with the modifications to screw thread design [5,20]. Theoretical studies conducted by Chapman et al and Decoster et al. [15,20,63] reported an increase in the shear force required for screw pullout, hence an increase in pullout resistance offered by the screw, with the increase in screw size. It has also been established that the forces involved in the pullout of the screw inserted into bone were related to surface area of the cylinder in contact with the bone, determined by the screw diameter, and the engagement length [82].

The objective of this study was to evaluate the effect of the screw size of STS on the holding strength of the screw when inserted in osteoporotic bone while maintaining the depth of insertion and length of engagement constant for each screw size. The results of this study indicated that regardless of screw size the PI increased with insertion depth which is consistent with the prior findings of this study. The results though differed from the theoretical studies of Decoster and Chapman in that there was no significant difference in the PI for different screw sizes inserted to similar depths. This difference can be attributed to the material characteristics of osteoporotic bone as the theoretical
calculations were validated with normal bone values. The deteriorated properties of osteoporotic bone, with loss of bone mass and structural integrity, might have caused the screws with different diameters to perform comparably. Fixation strength is influenced greatly by the bone density surrounding the screw hence the low density foam mimicking osteoporotic cancellous bone might have influenced the pullout resistance with its reduced shear strength. The screws used in the study were not all of the same pitch, Decoster et al. indicated that low pitch screws generated higher pullout resistance than high pitch screws, which may also have influenced the results such that the increase in diameter was compensated with increase in pitch resulting in having similar PI values for all screws. The pitch of the screws with OD’s 2.7 mm and 3.5 mm was similar but the pullout resistance did not increase with the screw size which can be attributed to the low shear strength of osteoporotic bone. The thread depth (ratio of ID/OD) was not the same (71%, 68% and 66% respectively) for all the screws which might have also influenced the results and might have contributed in attaining similar pullout strengths for all the screws (though of different OD’s). The results obtained in this study, though were limited by small differences in thread design parameters and lack of isolation of individual screw parameters, demonstrate that the pullout strength in osteoporotic bone is more influenced by the bone density than by the screw size as it had been established in previous studies that the thread design provided minor improvement to pullout strength compared to bone density and screw size.
5.4. Cutting Flutes Study

The presence of cutting flutes increases the insertion efficiency of the STS due to the reduction in the number of surgical steps and operation time [78]. Some studies indicate that the presence of cutting flutes inside the bone to be detrimental to the pullout strength due to the reduction in the interference area between the screw and the bone near the flutes [41]. Based on anecdotal recommendation the cutting flutes are extended 2 mm past the far cortex to maximize the pullout strength of the screw. This recommendation though might lead to the irritation of soft tissue and increase the potential for bacterial infection [78]. It was also reported that cutting flutes provide a favorable surface for bony in growth making the screw removal difficult [3,41,78]. Seeback et al. [63] observed a relationship between the pullout strength and bone density such that a reduction in bone density by a factor of two decreased the pullout strength by 4 times. This finding makes the presence of cutting flutes more significant in osteoporotic bone.

The goal of this study was to investigate the effect of presence of cutting flutes in the bone on the pullout characteristics while keeping other parameters the same for all the screws. The depths of insertion to evaluate the effect of cutting flutes were chosen so as to include extreme cases, depths of 3 mm inside the far cortex and 5 mm past the far cortex which represented the cases in which the cutting flutes either did not engage in the far cortex or completely penetrated the far cortex respectively. Other depths of insertion were chosen based on anecdotal recommendations and the above mentioned findings. The results yielded no statistical difference between the three depths past the far cortex confirming the findings of the earlier study (depths of insertion study) that optimal pullout resistance can be obtained by penetrating the far cortex. With the penetration of 5
mm past the far cortex not being significantly different from penetration of 1 mm past the far cortex the later case can be recommended during the insertion of STS as it causes lesser irritation of soft tissue and also offers a lower surface area for bacterial infection than the former. The group that represented the depth of insertion to 3 mm inside far cortex offered minimum resistance to pullout and, as predicted, was significantly different from the other groups. These results demonstrate the advantage of bicortical fixation over unicortical fixation and also the detrimental effects of the presence of cutting flutes / tip of the screw inside the far cortex.

5.5. Stainless Steel vs Titanium

Titanium is being increasingly used in orthopaedic implants due to the lower modulus of elasticity (closer to that of bone), better imaging characteristics (produces less attenuation and scatter), high corrosion resistance (due to formation of oxide layer) and better osseointegration characteristics compared to SS [47]. But SS provides better mechanical stability, is less expensive and easily machinable compared to titanium. With both the materials having their advantages and disadvantages this study endeavored to investigate the effect of these materials on the PI in normal and osteoporotic bones.

The results indicated that there was no significant difference in the pullout resistance offered by the screws manufactured from either of the materials when inserted in normal bone to different depths. This can also be attributed to the quality of the bone surrounding the screws as it plays a significant role in determining the pullout characteristics. The results from the pullout of SS and Ti screws from osteoporotic bone differed dramatically as they indicate higher pullout strength for SS screws than the Ti
screws. This difference in the pullout characteristics can be attributed to the mechanical strength of the material of the screw and deterioration of the material properties of the osteoporotic bone.

In normal bone the screw gains purchase from cortical and cancellous bone materials which provide the pullout resistance. The stresses experienced by the bone are distributed in the cortical layers and the cancellous bone that provide an uniform distribution of forces along the length of the screw that are lower than the yield strength of the material of the screw which results in elastic deformation. On the contrary, in the osteoporotic bone the screw did not gain a lot of purchase from the low density foam material. The pullout resistance was offered primarily from the cortices hence there is an uneven stress distribution along the length of the screw with the threads engaged in the cortical bone bearing most of the load. Due to the high loads applied to the threads in the cortical region they experience high stress which might have exceeded the yield strength of the less stronger Ti screws thus causing the screw to pullout at a lower PI than that of the relatively stronger SS screws. The difference in the PI values for the two materials might have also been due to the surface interactions between the screw material and foam representing bone. The results thus recommend the use of SS bone screws for fracture fixation in osteoporotic bone.

5.6. Finite Element Model

Pullout strength of the bone screws has been evaluated mechanically by many researchers using cadaveric, animal and synthetic bone models. Though the experimental data provides useful information about the relationships among different screw
parameters and helps compare the performance of different screws it is limited in giving
details about the bone-screw interface and local stress distributions. The investigation of
these factors is made feasible by computational models using FEA. This approach is
being preferred due to its ability to perform parametric analysis, capacity to evaluate
stresses in structures of complex shape, low cost involved, reduced time for analysis and
reduced effort from mechanical testing [27,34,37]. Mathematical models defined by
structural aspects, geometrical properties, material properties, boundary and loading
conditions and contact parameters are being frequently used to mimic complex structures
like bone (due to non-linear and anisotropic properties) [37]. Purely mathematical models
are limited in their evaluation of the pullout strength because of the limited number of
design factors included in the formula but FEA can be used to independently evaluate the
effects of each of the screw design parameters and is also not limited to screw with
homogeneous geometry [34].

The current study developed 3D finite element models of STS in normal and
osteoporotic bone to evaluate the effects of bone density and depths of insertion on the
holding power of the screws. Previous studies involved the development of linear models
of screw-bone interface which were limited in their capacity to evaluate a non-linear
structure like bone (most of the studies assumed bone to be a homogeneous and isotropic
material) [27,34,82]. To the best of our knowledge at the time of the study, no non-linear
models of the bone-screw interface that characterized the pullout behavior of the
bicortical bone using FEA were available. FE models representing different bone
densities were validated by comparing their results with those obtained experimentally.
The FE model was also used to determine the effects of depth of insertion and cutting flutes, screw material.

The results showed that the pullout strength of the screw was significantly affected by the density of the bone around the screw. The pullout strengths of the two models were directly proportional to the density of cancellous bone as cortical bone of similar material properties and thickness was used for both the models. The material properties of the cortical bone material and cancellous foam (normal and osteoporotic) were evaluated in house and stress-strain data from material testing experiments was used to define the non-linear material properties of each of the materials in the FE models. The material properties of the screw were defined based on the literature. The models illustrated a linear relationship in the elastic region and non-linear relationship in the plastic region of the screw pullout profile that was compatible with that observed in the mechanical pullout of the screw from the foam. Validation of the model confirmed the applicability of the FE model, assumed boundary, loading and contact conditions for the screw pullout model.

The FE model met all the requirements for a comprehensive model in that it had [13]:

- sufficiently refined mesh to define the geometrical characteristics of the involved structures
- appropriate and well defined material properties for all the elements involved
- relevant boundary conditions representing the constraints and loading analogous to experimental setup
- proper contact definition between mating / intersecting parts
demonstrated convergence with change in mesh refinement
been validated with experimental findings.

The internal stress distribution indicated that bone experienced high stresses (greater than yield strength) around the circumference of the threaded region unlike the screw which experienced stresses lower than its yield strength. The distribution of the stresses was different for bone and screw in that the screw threads experienced high von Mises stresses only in the regions of cortical engagement and threaded region of the bone experienced similar magnitudes of stress along the length of engagement for cancellous and cortical regions. Though higher stresses were observed in the cortical region than in the cancellous regions the failure strength of cancellous was much lower than that of cortical resulting in the failure of that material. Hence it can be established that the pullout strength of the bone-screw fixation is limited by the failure strength of the weakest link (cancellous bone) of interface. The findings from the simulations also confirm the significant contribution of the cortical shell to the resistance offered during pullout. The effect of cortical shell was observed in osteoporotic bone when the contribution of the cancellous bone was very small unlike the normal bone where cancellous bone contributed significantly to the pullout resistance. This finding is consistent with the above mentioned experimental results.

The computational simulations were in agreement with the experimental data in that they also showed the increase in pullout strength with the penetration past the far cortex. The simulations, like the experimental data, indicated that the pullout strength of the screw inserted such that the tip of the screw is 1 mm past the far cortex is greater than
that inserted flush and inside the far cortex. The FE model also demonstrated that there was no significant difference in the pullout strength for 1, 2 and 3 mm penetration past the far cortex. It was also observed that the mean pullout strength in normal bone was greater than that in osteoporotic bone with reduced bone density. Clinical scenario of osteoporosis, reduction in cancellous bone density and thickness of cortical shell, indicated a further decrease in the pullout strength. But this model could not be validated with experimental data due to the limitation of the thickness of the commercially available cortical shell mimicking e-glass epoxy sheets. Thus, it can be concluded that the model does represent the significance of the bone density and cortical thickness on the pullout strength of the screw.

The non-linear solution did not converge for the model with cutting flutes due to the complex geometry of the flutes which might have led to some stress risers on the cutting edge of the flutes. A linear model was thus developed to evaluate the effects of the cutting flutes. The results from the linear FE model indicate that the pullout resistance offered to the screw pullout increases with the increase in protrusion of the screw tip past the far cortex (findings are similar to that of the non-linear model without the cutting flutes). These findings also agree with the trend in the experimental values supporting the applicability of the simplified model. The failure values, though, were higher for the linear model compared to that of the non-linear model due to the linear material properties of the bone and screw. The definition of linear material properties led to higher values for pullout due to the absence of yield / failure criteria. Hence 30 % strain was considered to be the criteria for failure or screw pullout and thus the force value satisfying the criteria for strain was regarded as the pullout strength of the screw. The
findings of the linear model show a significant difference in the pullout strengths for normal and osteoporotic bone emphasizing the deterioration of the bone quality and fixation strength in the later.

Previous studies involved only cancellous bone models (no cortical engagement) and validation was conducted with values from literature limiting the scope of the model [83]. The models validated with values obtained from literature were based on assumed loading and boundary conditions and material properties of the bone model. Experimental data obtained from literature varies over a wide range due to variation in the cadaveric bone, screw specifications and testing protocols. The current model is more comprehensive in its evaluation of screw pullout in a clinical setting due to bicortical fixation (metaphyseal region), depth of insertion with respect to the far cortex and non-linear material properties. The validation of the current model was conducted with the values obtained through mechanical testing, allowing better definition of loading and boundary conditions and also the mechanical properties of the materials used.

5.7. Limitations of the study

While the findings of the study yielded important results pertaining to the depth of insertion of the STS past the far cortex in normal and osteoporotic bone, effects of pilot hole size and screw size on the holding power of the screw in osteoporotic bone and effect of the screw material and insertion torque on the pullout strength, this study remains an idealization of the clinical situation with several limitations. The experimental test blocks and FEA model used in the study represented the insertion of the screw only in the metaphyseal region. The use of synthetic blocks to represent the normal and
osteoporotic bones can also be considered a limitation due to the fact that they can only
approximate an in vivo clinical setting and also because of the assumption that the
c cancellous bone was comprised of solid, homogeneous and isotropic material. This
idealized model of the bone might have affected some of the results due to the limitation
of representing the micro-architectural deterioration of the trabeculae in osteoporotic
bone. The bone blocks could not mimic the cortical thinning that is observed in the
osteoporotic bone due to the unavailability of blocks with 1mm thick cortical layer. The
test blocks with 2mm cortical thickness were not milled to 1mm thickness to avoid
introducing cracks and milling errors during the preparation of the test block. This model
was fashioned to represent osteoporotic bone based on its mechanical properties and T-
scores from DXA scans, hence it cannot be considered to be misrepresentation of the
osteoporotic state.

The findings of this study might have provided higher values of pullout strength
compared to the cadaveric osteoporotic bone models due to the solid and low porosity
material used to represent the cancellous bone instead of its highly porous and trabecular
nature, but a significant difference in the PI was observed between the normal and
osteoporotic bones, hence the recommendations from this study can be applied to
cadaveric osteoporotic bone. The limitation of synthetic bone blocks, both normal and
osteoporotic, was that they were homogenous isotropic materials and could not
demonstrate the anisotropic and viscoelastical material properties of the bone. But this
limitation was partly compensated for by pulling the screw in the transverse direction, the
orientation in which the bone is weakest, thus mimicking the worst case scenario during
screw pullout. The advantages of the synthetic bone such as less inter-specimen
variability, cost, availability, minimal specimen preparation and sterile environment, and non-degradation characteristics (longer shelf life) compensate for the above mentioned limitations.

One of the detrimental effects of self tapping screws is the increase in temperature of the bone surrounding the screw during insertion, this results in thermal necrosis which might have led to the reduction of pullout strength in cadaveric bone, but with synthetic blocks used as a substitute for cadaveric bone in this study, effects of temperature and thermal necrosis on the pullout strength could not be evaluated. The other common mode of screw failure in bone is due to loosening, but that aspect could not be evaluated in this study as the objective was to determine the screw pullout immediately after insertion. In future studies loosening of the screw could be simulated by applying a bending load on the screw head (cantilever loading) prior to pullout.

The pilot hole study was limited by the availability of the screws; hence the performance of STS in osteoporotic bone could not be compared to that of normal bones. The screw size study was also limited by the availability of the screws and differences in the screw design characteristics between each of the groups. These limitations can be overcome with the availability of more screws and use of screws by varying one of the design parameters (OD) keeping the others constant. The results of this study demonstrated that, even with these limitations, the unique relationship (not evaluated in previous studies) between the pilot hole size and screw size independently on the pullout strength in an osteoporotic environment.
The FE model also had potential limitations in that the bone was modeled as a homogenous and isotropic material when it has been widely accepted that bone behavior is anisotropic with different material properties in each direction of loading. A perfect interaction between the bone and screw was assumed which may not be the case in a clinical setting. Osteoporosis was defined only through mechanical properties cancellous bone when it is also accompanied by cortical thinning which, as shown, also has a significant effect on the holding power of the screw. The current FE model though mimicked the experimental material used for testing; it was an idealized representation of cancellous bone. Trabecular structure of cancellous bone was not taken into account, but rather assumed that cancellous bone had a uniform material density and low porosity. This limitation might have had also affected the simulated results for osteoporotic model as the micro-architectural deterioration of the trabeculae during osteoporosis could not adequately be represented. Osseointegration, considered to be the key factor to be considered during fracture healing, was not accounted for in the model, as the simulation represented the clinical setting immediately after insertion. Osseointegration could be incorporated into the model by mathematically representing the chemical and biomechanical changes at the bone-screw interface. A model defining the osseointegration would be dependent on the healing time, bone growth / resorption rate, infection rate, load distribution at the bone-screw interface which in turn would affect the stability of the screw fixation [81].
CHAPTER VI
CONCLUSIONS

Based on the experimental results from mechanical testing and numerical results from the 3D finite element model of the bone-screw interface, the following conclusions were made.

6.1. Study of Hypotheses

1. It was hypothesized that little difference would be observed in the pullout characteristics between normal and osteoporotic bone materials.

   Hypothesis #1: There is no significant difference between the PI of the STS in normal and osteoporotic bone material.

   For the first hypothesis tested, it was determined that there was a significant difference (p < 0.05) in PI of the STS inserted in normal and osteoporotic bone material. Hence the null hypothesis was rejected.

2. It was hypothesized that little difference would be observed between different depths of insertion in normal and osteoporotic bone materials.

   Hypothesis #2: There is no significant difference between the PI of the STS inserted to different depths in bone material.
For the second hypothesis tested, it was determined that there was a significant
difference (p < 0.05) in PI of the STS inserted to different depths in both normal
and osteoporotic bone material. Hence the null hypothesis was rejected.

3. It was hypothesized that little difference would be observed between the screws
manufactured by Synthes, Zimmer and Howmedica.

Hypothesis #3: There is no significant difference between the PI of the
STS of different manufacturers.

For the third tested hypothesis tested, it was determined that there was no
significant difference (p > 0.05) in PI of the STS manufactured by Synthes and
Zimmer when inserted in normal bone material (Howmedica screws were not
tested in normal bone due to their limited availability) and in the STS
manufactured by Synthes, Zimmer and Howmedica when inserted in osteoporotic
bone material. Hence the null hypothesis was accepted.

4. It was hypothesized that little difference would be observed between stainless
steel and titanium screws.

Hypothesis #4: There is no significant difference between the PI of the
STS made of Stainless Steel (SS) and Titanium (Ti).

For the fourth hypothesis tested, it was determined that there was no significant
difference (p > 0.05) in PI of the stainless steel and titanium STS inserted in
normal bone material but a significant difference was observed in PI of stainless
steel and titanium STS inserted in osteoporotic bone material. Hence the null
hypothesis was accepted.
5. It was hypothesized that little difference would be observed when cutting flutes are inside or outside the bone.

   Hypothesis #5: There is no significant difference between the PI of the STS when the cutting flutes are completely inside or outside the bone material.

For the fifth hypothesis tested, it was determined that there was a significant difference ($p < 0.05$) in PI of the STS between cutting flutes inside and outside the bone for both normal and osteoporotic bone materials. Hence the null hypothesis was rejected.

6. It was hypothesized that little difference would be observed between normal and osteoporotic bone materials.

   Hypothesis #6: There is no significant difference between the LE of the STS in normal and osteoporotic bone material.

For the sixth hypothesis tested, it was determined that there was a significant difference ($p < 0.05$) in LE of the STS inserted in normal and osteoporotic bone material. Hence the null hypothesis was rejected.

7. It was hypothesized that little difference would be observed between different depths of insertion.

   Hypothesis #7: There is no significant difference between the LE of the STS inserted to different depths.
For the seventh hypothesis tested, it was determined that there was a significant
difference (p < 0.05) in LE of the STS inserted to different depths in both normal
and osteoporotic bone material. Hence the null hypothesis was rejected.

8. It was hypothesized that little difference would be observed between the screws
manufactured by Synthes, Zimmer and Howmedica.

   Hypothesis #8: There is no significant difference between the LE of the
   STS of different manufacturers.

For the eighth hypothesis tested, it was determined that there was no significant
difference (p > 0.05) in LE of the STS manufactured by Synthes and Zimmer
when inserted in normal bone material and in the STS manufactured by Synthes,
Zimmer and Howmedica when inserted in osteoporotic bone material. Hence the
null hypothesis was accepted.

9. It was hypothesized that little difference would be observed for screws inserted
into bone blocks when cutting flutes were positioned inside or outside the far
cortex of the bone.

   Hypothesis #9: There is no significant difference between the LE of the
   STS when the cutting flutes are completely inside or outside the bone
   material.

For the ninth hypothesis tested, it was determined that there was a significant
difference (p < 0.05) in PI of the STS between cutting flutes inside and outside
the bone for both normal and osteoporotic bone materials. Hence the null
hypothesis was rejected.
10. It was hypothesized that models of bone blocks and screw could be accurately constructed and could be employed to numerically investigate the bone-screw interface.

   Research hypothesis #1: It is possible to construct a geometrically accurate model of the bone blocks and screw and employ it to solve a finite element model.

For the first research hypothesis tested, it was determined that it is possible to construct geometrically accurate models of the bone blocks and screw. Furthermore, it was determined that it is possible to employ the designed bone-screw model to investigate the bone-screw interface using a finite element model.

11. It was hypothesized that the numerical bone-screw model would able to quantitatively demonstrate a difference in the pullout characteristics in normal and osteoporotic bone materials.

   Research hypothesis #2: It is possible to demonstrate, using the finite element model, a difference in the PI of the STS in normal and osteoporotic bone.

For the second research hypothesis tested, it was determined that the finite element model employing the 3D bone-screw model was indicated a significant difference in PI of the STS inserted in normal and osteoporotic bone material.

12. It was hypothesized that the experimental results of the pullout study would validate the results from the finite element model that simulated a numerical pullout.
Research hypothesis #3: It is possible to validate the findings from the finite element model with that from the experimental testing.

For the third research hypothesis tested, it was determined that the experimental results from mechanical testing validate the results from the numerical simulation of the bone-screw interface using a finite element model.

6.2. Summary

This study was conducted to investigate the pullout characteristics of STS in normal and osteoporotic bone materials. The results indicate that the PI of screws in normal bones is much higher than in osteoporotic bones. The results also indicate an increase in PI with depth of insertion, with respect to the far cortex, in both normal and osteoporotic bones. Cutting flutes were demonstrated to be detrimental to the pullout characteristics in normal and osteoporotic bones. It was also demonstrated that the increase in pilot hole size for STS though would decrease the insertion torque but also reduced the PI of the bone-screw construct in osteoporotic bone. An attempt was made to determine the effect of screw size on the PI of STS in osteoporotic bone but the study was limited by the lack of availability of screws. Specifically, screws with different outer diameters and consistent other parameters could not be obtained. A finite element model of the bone-screw interface was also developed to simulate the screw pullout numerically. The model was validated by the experimental results and was used to overcome some of the limitations encountered in the mechanical testing.

This study presents a new approach to the development of a computer-aided model of the bone screw interface and to employ the bone-screw construct, with non-linear
material properties, in a finite element model to analyze the pullout characteristics. The approach presented here further asserts current trends of incorporating finite element analysis into biomechanical testing. This study advocates the use of the new generation of algorithms to solve finite element models that can substantiate the prototype design. Finite element models, validated by the experimental data, can increase the efficiency and reduce the time and cost involved in the product design and verification process.
REFERENCES

1. *An introductory guide to non-linear analysis.* MSC Software documentation.


APPENDIX

NOMENCLATURE

ASTM: American Society for Testing and Materials
BMD: Bone mineral density
DOI: Depth of insertion
DXA: Dual X-ray absorptiometry
FDA: Food and Drug Administration
FEA: Finite element analysis
FEM: Finite element model
LE: Loading energy
NSTS: Non self-tapping screws
OD: Outer Diameter
PI: Pullout index
QCT: Quantitative computed tomography
RD: Root Diameter
SS: Stainless steel
STS: Self-tapping screws
Ti: Titanium
WHO: World Health Organization