Biomechanical evaluation of novel expanding pedicle screws suitable for osteoporotic lumbar spine

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Biomechanical Evaluation of Novel Expanding Pedicle Screws Suitable for Osteoporotic Lumbar Spine

by

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An Abstract of

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Pedicle screw fixation is the most common treatment method for correction of spine disorders such as deformity, disc degeneration, and trauma. However, traditional screw designs suffer from inadequate fixation in patients with osteoporosis. The objective of this study was to develop several novel expanding screw concepts to address the loosening of screws in osteoporotic bone. To achieve this goal, four new expanding designs, each offering different features, are proposed. Three are reversible and collapsible in case the need arises to remove the screws. FE simulations were carried out for all screw designs and for traditional screws. Based on the FE results, the two best screw designs were prototyped for axial pullout in lumbar vertebrae. FE results showed improved pullout force for all the designs. In an osteoporotic bone, the failure load dropped to 170 N (38 percent decrease) for the conventional screw, while it was restored by the new designs. For the cancellous expanding screw, the failure load was 360 N, which is almost twice the value for a conventional screw in osteoporotic bone and 33 percent greater than for a conventional screw in normal bone. Screws providing anchorage in the cortical shell yielded significantly better results. Window expanding
screws showed the largest pullout force (840 N, an increase of 196 percent) compared to a conventional screw in normal bone. Cortical and transverse expanding screws also performed better, increasing the failure load to 660 and 540 N, respectively. Cadaver study of the two transverse and bottom expanding screw showed similar pull-out strength to the conventional screw.
I dedicate my dissertation to my family. Special gratitude to my loving parents, Rahim Asadollahi and Farzaneh Ravanbarzin—this could not have been achieved without their material and spiritual support. My sisters, Zahra and Sepideh, have never left my side and are very special.
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# Table of Contents

Abstract ........................................................................................................................................ iii

Acknowledgements .................................................................................................................. v

Table of Contents ...................................................................................................................... vi

List of Tables .............................................................................................................................. ix

List of Figures ............................................................................................................................. x

List of Abbreviations .................................................................................................................. xiv

List of Symbols ........................................................................................................................... xv

1 Introduction .......................................................................................................................... 1

1.1 Introduction to the human spine ......................................................................................... 1

1.1.1 Anatomy of the spine .................................................................................................... 1

1.1.2 Loading on the lumbar spine ........................................................................................ 8

1.2 Surgical instrumentation of the pedicle ............................................................................ 9

1.2 Objective of this study ......................................................................................................... 13

2 Literature review .................................................................................................................. 15

2.1 History of the pedicle screw ............................................................................................ 15

2.2 Implant materials ............................................................................................................. 19

2.3 Screw design ...................................................................................................................... 22

2.4 Finite element analysis of human implants ....................................................................... 28

3 Materials and methods ......................................................................................................... 32
3.1 Design controls and design requirements .........................................................32

3.2 Implant design .................................................................................................37

  3.2.1 Cancellous expanding screw .................................................................38
  3.2.2 Bottom expanding screw .........................................................................39
  3.2.3 Transverse expanding screw .................................................................41
  3.2.4 Window expanding screw .........................................................................42

3.3 Finite element analysis .....................................................................................44

  3.3.1 Lumbar finite element model ......................................................................44
  3.3.2 Implantation of the model with designed screws .......................................49
  3.3.3 Loading and boundary conditions ............................................................53

    3.3.3.1 RoM testing .........................................................................................53
    3.3.3.2 Pull out testing .....................................................................................56

  3.3.4 Analysis criteria .........................................................................................57

3.3 Cadaver study ..................................................................................................57

  3.4.1 Implant preparation ....................................................................................57
  3.4.2 Specimen preparation ................................................................................59
  3.4.3 Testing ........................................................................................................60

4 Results and discussion .......................................................................................62

  4.1 Finite element results ....................................................................................62

    4.1.1 Expansion of screw ..................................................................................62
    4.1.2 RoM results ..............................................................................................65
    4.1.3 Pull out results ..........................................................................................73

  4.2 Cadaver study results ....................................................................................75
List of Tables

2. 1 summary of different techniques proposed to improve the pull-out strength of pedicle screw in osteoporotic bone. [77] ................................................................. 23

2. 2 Summery of different metallic materials being used for manufacturing of spinal implants and their material properties [77] ............................................................................................. 26

3. 1 A qualitative comparison of four proposed designs in this study. ......................... 49

3. 2 Material properties and element type of bony structures, ligaments, intervertebral disc, and facet joint [107, 108] ............................................................................................................. 51

3. 3 Geometrical dimensions of the screws that used in FE for simulation .................. 55

3. 4 Specimens conditions used for the cadaveric study ............................................. 65

4. 1 Required torque for expansion of each screw design calculated from axial force result from FE simulation. ......................................................................................... 69

4. 2 Stress values for all screws in different physiological loading at 10 N.m .......... 77

4. 3 Safety factor for all screws in different physiological loading at 10 N.m calculated from stress values from table 4-2 ......................................................................................... 77

4. 4 Pull out simulation data in FE ............................................................................. 80
List of Figures

1-1 General overview of human spinal body showing from left: Anterior view, Lateral view, and posterior view. Curvature of each section is illustrated in lateral view. Reprinted from http://www.aboutcancer.com........................................2

1-2 Geometrical shape variation of vertebrae in different sections of spine (cervical, thoracic, and lumbar). Reproduced from http://www.edu.xunta.es/........................................4

1-3 Anatomy of a lumbar vertebra showing vertebral body and posterior elements. Reprinted from http://www.c2forum.com .................................................................4

1-4 Schematic of an intervertebral disc with its various components including AF, NP, and EPs [2]..................................................................................................................5

1-5 A functional spinal unit (FSU) with seven corresponding ligaments. Reprinted from http://www.coloradospineinstitute.com/.................................................................7


1-7 Nerve root compression due to the extrusion of NP in disc herniation. (a) Healthy intervertebral disc and (b) herniated intervertebral disc. Reprinted from http://www.yoganatomy.com/.................................................................10

1-8 Lateral x-ray view of a L4-L5 level instrumented with pedicle screws and intervertebral cage to provide stability for fusion of adjacent levels and pain relief........11
a) A radiological photograph showing the test block and the inserted screw following cement augmentation b) The average ultimate pullout strength of fully inserted conical and cylindrical pedicle screws with various screw fixation techniques [76].

a) Pull-out strength comparison of (Top) standard 6.5-mm titanium pedicle screw and (Bottom) expandable titanium pedicle screw b) Representative load-displacement curve of the expandable screw compared with the standard pedicle screw [78].

Pull-out strength comparison of conventional pedicle screw without augmentation, expansive pedicle screw without augmentation, conventional pedicle screw with calcium-based cement augmentation, and expansive pedicle screw with calcium-based cement augmentation.

Basic Screw and Thread Terminology. Key feature of the screw design are labeled: A = screw head or tulip, B = head body junction, C = pitch, D = thread angle, E = major diameter, F = minor diameter and G = screw length [78].

Pedicle screw designs. (a) Cylindrical threading and cylindrical core and (b) cylindrical threading and conical core [82].

Effect of screw design on pull-out strength. The percentages are with respect to a classic pedicle screw of otherwise similar dimensions: TSRH: Texas Scottish Rite Hospital (conical screw), CD: Cotrel-Dubousset (conical screw), MM: Moss Miami (cylindrical screw), Cy/Cy: cylindrical thread with cylindrical core, Cy/Co: cylindrical thread with conical core, Co/Co: conical thread with conical core, V: standard thread, and Ti: titanium [82].

Eight different geometries that have been used for FE modeling of lumbar spine including those by (a) Kim and Park, (b) Puttlitz and Labus, (c) Chen and Wang, (d)
A design process waterfall showing the application of design controls and its influence on design and product development process .............................................................40

Cancellous expanding screw before expansion (right) and after expansion (left).45

Bottom expanding screw design ..........................................................................46

Transverse expanding screw design ....................................................................48

Window expanding screw design ..........................................................................49

Top and side views of the FE geometry that was used in this study [109] ............53

Different sections of the FSU in the FE model. Cortical, cancellous, posterior bones are distinguished with different colors in this figure. AF and NP are also shown [109] ......................................................................................................................................53

FE model of L4-L5 FSU where all the ligaments that were considered in the FE model are shown in red [109]. ......................................................................................................................................54

Intervertebral disc components where AF and NP are distinguished [109]. .......54

Screw and rod assembly configuration in the model .............................................57

Placement of the cage in the model. LLIF cage put using lateral approach .........57

Configuration of Pull out test model ....................................................................58

Configuration of each screw after expansion in the model a) Cancellous expanding screw b) Bottom expanding screw c) Transverse expanding screw and d) Window expanding screw ..................................................................................................................60

Boundary condition for FE simulations. The inferior surface of the L5 was rigidly fixed ..................................................................................................................61
3-15  (a) Compressive loads were applied in a symmetric manner as follower loads; (b) moments were applied to a reference point in the center of the superior surface of L4 by kinematic coupling ..............................................................62

3-16  CT scans of the specimens were taken to measure the pedicle length. Pedicle length was measured from the start of the bony part from anterior where pedicle starts along the pedicle axis to the posterior cortical shell .........................................................65

3-17  Screw was aligned to the MTS machine axis to make sure a pure axial load ......67

3-18  Attachment of screw to the MTS machine via a hook .....................................67

4-1   Load displacement data for expansion simulation of screws ................................70

4-2   Stresses on the screw after expansion a) Cancellous expanding screw b) Bottom expanding screw c) Transverse expanding screw and d) Window expanding screw ......71

4-3   RoM results for all screw designs compared with intact FSU extracted from FE simulation with normal bone ...........................................................................................................72

4-4   RoM results for all screw designs compared with intact FSU extracted from FE simulation with osteoporotic bone ..............................................................................................................73

4-5   RoM results for all screw designs compared with intact FSU extracted from FE simulation differentiated by design .................................................................74

4-6   Stress distribution on the endplates and FSU with osteoporosis at 10 N.m flexion for a) Cancellous expanding screw b) Bottom expanding screw c) Transverse expanding screw and d) Window expanding screw .................................................................75

4-7   Stresses on the implant construct at 10 N.m flexion in the FSU with osteoporotic bone for a) Cancellous expanding screw b) Bottom expanding screw c) Transverse expanding screw and d) Window expanding screw .................................................................76
4-8  Pull out simulation results in FE for a model with normal bone.
89

4-9  Pull out simulation results in FE for a model with osteoporotic bone.
89

4-10 Screw insertion steps with final configuration after expansion a) Bottom expanding screw b) Transverse expanding screw
81

4-11 Pull out test results on the L4 level of specimen 56226 for bottom expanding and normal screw
82

4-12 Pull out test results on the L4 level of specimen 66166 for transverse expanding and normal screw.
82

4-13 Screws after pull out a) bottom expanding screw b) Transverse expanding screw
78

5-1  comparison of pull-out study between FEA and experimental
91
## List of Abbreviations

- **AF**: Annulus Fibrosus
- **ALL**: Anterior Longitudinal Ligaments
- **BMD**: Bone Mineral Density
- **CT**: Computed Tomography
- **DEXA**: Dual-Energy X-ray Absorptiometry
- **DIS**: Draft International Standard
- **EP**: End Plate
- **FDA**: Food and Drug Administration
- **FE**: Finite Element
- **FOA**: Flank Overlap Area
- **FSU**: Functional Spinal Unit
- **ISL**: the Interspinous Ligaments
- **ISO**: International Organization for Standards
- **ITL**: Intertransverse Ligaments
- **LLIF**: Lateral Lumbar Interbody Fusion
- **LF**: Ligamentum Flavum
- **MTS**: Mechanical Testing System
- **MRI**: Magnetic Resonance Imaging
- **NP**: Nucleus Pulposus
- **PLL**: Posterior Longitudinal Ligaments
- **ROM**: Range of Motion
- **SSL**: Supraspinous Ligaments
List of Symbols

C1.............................First cervical vertebra
C2.............................Second cervical vertebra
T5.............................Fifth thoracic vertebra
L4.............................Fourth lumbar vertebra
L5.............................Fifth lumbar vertebra
Tr.............................Torque induced by expansion
Tf.............................Frictional torque
T.............................Required torque for expansion
Dp.............................Effective pitch
C1.............................First cervical vertebra
Dmaj...........................Major Diameter
FA.............................Axial load
P.............................Pitch

\( \theta \)..........................Screw tip’s angle
\( \mu \).............................Friction coefficient
Chapter 1

Introduction

Lower back pain is a common health problem that in severe situations requires spinal surgery. Despite breakthroughs in spinal instrumentation, challenges remain. To achieve a successful instrument design, a thorough understanding of spinal anatomy and surgical techniques used for the treatment of spine disease is needed. In this chapter, a brief anatomical background of the spinal body is provided. A short description of surgical instrumentation of the spine using pedicle screws follows.

1.1. Introduction to the human spine

1.1.1. Anatomy of the spine

The human spine is a complex bony structure in the back of the body, which is intended to support the weight of the upper body, provide posture while allowing for movement and flexibility, and protect the spinal cord [1]. The spinal column consists of 33 vertebrae and 23 intervertebral discs that are interposed between the two adjoining vertebral bodies along the spine. In addition, the spinal body is divided into four main
regions based on curvature of the column in the sagittal plane. The first seven vertebrae, called cervical vertebrae, are lordotic. Below the cervical spine are twelve kyphotic thoracic vertebrae, then five lumbar vertebrae with lordotic curvature, and, finally, five fused sacral and three to four coccygeal vertebrae with kyphotic curvature (Figure 1). The coccyx initially consists of four tiny vertebrae that fuse during adolescence and convert to a single bone in the adult skeleton.

**Vertebral Column**

![Vertebral Column Diagram](image)

**Figure 1-1:** General overview of human spinal body showing, from left, anterior view,

The smallest vertebrae belong to the cervical region in the spinal column; it provides great flexibility to the neck. The first two cervical vertebrae have a unique shape named atlas and axis, which provides up and down movement and rotation to the left and right to the skull, respectively. The thoracic region consists of larger and stronger vertebrae than those found in the cervical region and has less flexibility. The main feature of this region is the spinous processes pointed inferiorly to help lock the vertebrae together. Next is the lumbar level, with larger and stronger vertebrae with greater flexibility. The sacrum contains flat and triangular bones found in the lower back, followed by the coccyx, which bears the body’s weight while seated. Figure 2 illustrates this geometric variation in different regions of the vertebral column.

Vertebrae, excluding C1/C2 and the coccyx, have numerous features in common. Each vertebra can be divided into two regions: the anterior region, which includes the vertebral body, and the posterior region, which includes the arch that protects the spinal cord and the connecting processes. The vertebral body itself is composed of a hard outer shell of cortical bone filled with a spongy structure of cancellous bone. The pedicle is a thick cortical tube filled with cancellous bone that connects the posterior arch and processes to the vertebral body (Figure 3). Spinal surgeons take into account the special anatomic structure of the pedicle, because its special anatomy allows them safe posterior instrumentation via the pedicle channel through the vertebral body by purchase of pedicle strong bone fixation for screw implants.
Figure 1-2: Geometrical shape variation of vertebrae in different sections of spine (cervical, thoracic, and lumbar). Reproduced from http://www.edu.xunta.es/.

Figure 1-3: Anatomy of a lumbar vertebra showing vertebral body and posterior elements. Reprinted from http://www.c2forum.com.
There are 23 intervertebral discs in the entire spinal column. These discs comprise 25 percent of the height of the spinal column and are located between each two vertebrae. Their function is to absorb and distribute load over the vertebral bodies while providing stability and flexibility to the human spine. An intervertebral disc consists of an outer shell called the annulus fibrosus, which is filled with a soft, pulpy material called nucleus pulposus. Annulus fibrosus has a composite structure with tough fibrocartilages that bind the vertebrae together; however, it is flexible enough to allow for spinal movement. Nucleus pulposus acts as a shock absorber and supports the body weight. The geometry of each disc follows its related vertebra. The lumbar spine has the largest intervertebral disc, measuring 40 to 45 mm in width, 35 to 40 mm in depth, and approximately 10 mm in height in healthy discs. Figure 4 is a schematic of an intervertebral disc with its components.

Figure 1-4: Schematic of an intervertebral disc with its various components including AF, NP, and EPs [2].
Ligaments are another part of the spine that provides stability to the spinal column. Seven major ligaments are identified in the human lumbar spine. Two connect the vertebral bodies, and the rest connect posterior elements. Anterior longitudinal ligaments (ALL) and posterior longitudinal ligaments (PLL) are located in the anterior and posterior of the spinal body. The other posterior ligaments are the ligamentum flavum ligaments (LF), intertransverse ligaments (ITL), interspinous ligaments (ISL), supraspinous ligaments (SSL), anterior longitudinal ligaments (ALL), and facet joint ligaments, as shown in Figure 5.

All the elements involved in spinal column construction and discussed thus far exist in the smallest part of the spine called the functional spinal unit (FSU). The FSU that represents the properties and functions of the spine consists of two adjoining vertebrae, posterior bony elements, articular facet joints, intervertebral disc, ligaments, and the surrounding muscles. The series connecting these motion segments can construct the entire spinal column. Therefore, studying the biomechanics of FSUs is of interest because it helps to clarify the behavior of the spinal column. Figure 5 shows a lumbar motion segment with its components.

Several authors have studied and discussed the morphometry of the thoracic and lumbar spine [3, 4]. These studies were considered in the design of the screw, specifically in determining the shape, geometry, and anatomical-related parameters of the design. The studies included large populations, and they indicate that, excluding the cervical vertebrae, on average, the smallest pedicle diameter in the transverse plane belongs to the T5 level and is approximately 4.5 mm. The largest one, measuring 18 mm, belongs to the
L5 level. The pedicle's oval shape causes it to be slightly larger in the sagittal plane. These variations in pedicle size from level to level and person to person require an implant design with multiple screw sizes and lengths to best fit and cover those anatomical variations. In surgery, to balance safety and secure fixation optimally, most surgeons try to select a screw size that fits and fills 80 percent of pedicle diameter [5].

Figure 1-5: A functional spinal unit (FSU) with seven corresponding ligaments. Reprinted from http://www.coloradospineinstitute.com/.
1.1.2. Loading on the lumbar spine

Different physiological or traumatic loads can apply on the spine. These loads can be a combination of compressive loads due to gravity or lifting objects and bending or torsional moments in different directions due to common daily activities. Timing of these loads can be different and can be short term (such as normal activities), long term (such as sitting or standing for a long time), cyclic (such as walking), and/or dynamic (such as jumping).

Physiological body movements and rotations of the spine have their own terminology in biomechanics. Flexion and extension are used to describe bending forward and backward respectively (bending in the sagittal plane), left and right bending (lateral bending) are used to describe bending to the sides (bending in the coronal plane), and axial rotation is used to describe twisting to the left or right (rotation in the transverse plane). These fundamental movements are shown in Figure 6. Furthermore, muscle activities can be another source for the loads applied on the spine. The function of muscles is to prevent the spine from unwanted movements and stabilize it in a standing position. However, a high compressive load can be induced due to muscle contraction. In a healthy disc, these loads are distributed within the AF region, while the distribution pattern can change in damaged discs.

A comprehensive knowledge of the anatomy, biomechanics, and kinematics of the spine is required to create a successful spinal implant design. Without this knowledge, the design of an implant can not only fail in the clinical situation and patient body, but
also can cause other serious injuries to the patient intraoperatively or post-surgically. As an introduction to these subjects, the sections that follow focus on surgical methods used for the treatment of spinal and lower back pain, and the design and challenges of pedicle screw implants.

1.2. Surgical instrumentation of the pedicle

Aging can cause a variety of diseases in the human spinal column. In addition, deformity, trauma, cancer, and degeneration are the most common spinal disorders that usually require surgery. Lower back pain caused by nerve compression due to degenerative lumbar disc disease (Figure 7) responds well to the surgery. Pedicle screw systems are used widely as a treatment method [6, 7]. Pedicle screw implantation fuses
and decompresses the adjacent lumbar spine levels as the primary mode of stabilization to relieve the patient’s pain.

Top views of vertebrae

![Top views of vertebrae](image)

**Figure 1-7:** Nerve root compression due to the extrusion of NP in disc herniation. (a) Healthy intervertebral disc and (b) herniated intervertebral disc. Reprinted from http://www.yoganatomy.com/.

Pedicle screw implantation is the most common method of treatment among existing types and forms of spine surgery instrumentation [1]. Pedicle screw instrumentation is a posterior approach that involves the insertion of a screw from a posterior position through the pedicle in the vertebra. After screws are implanted, usually bilaterally, they are connected via rods to form a rigid construct (Figure 8). This rigid construct eliminates instrumented levels from motion and limits flexibility, and the stability provided helps the degenerated level to fuse together by allowing bone generation in the space between two endplates. Figure 7 shows a lateral x-ray view of the
fused L4-L5 level using pedicle screws and an intervertebral cage. Intervertebral cages typically are used with pedicle instrumentation to replace the disc, and are intended to restore lost vertebral disc height and improve bony fusion.

![Lateral x-ray view of L4-L5 level instrumented with pedicle screws and intervertebral cage](image.png)

**Figure 1-8:** Lateral x-ray view of an L4-L5 level instrumented with pedicle screws and intervertebral cage to provide stability for fusion of adjacent levels and pain relief.

The safest way to reach the vertebral body from a posterior approach is through the pedicle channel. The pedicle consists of a strong shell of cortical bone with a core of softer cancellous bone. The angulation of this channel determines the proper angle of
screw insertion to prevent breaking the pedicle walls. Not damaging the pedicle is important because of the spinal cord and nerve roots passing through the foramen, which is surrounded by the pedicle and lamina. Due to the lack of a clear view of the pedicle direction during surgery, surgeons need information regarding the pedicle angle in different levels, as described in several morphometric studies [3, 4]. Pedicle angle in the transverse plane ranges from approximately 10 degrees of medial angulation (from posterolateral to anteromedial) in thoracic vertebrae to 30 degrees at L5 level.

Moreover, the length of the pedicle channel, available length for use of a screw, and the selection of the proper implant size are important parameters in posterior fixation surgery. Morphometric studies show an average distance of 40 mm from the posterior edge of the pedicle to the anterior vertebral body shell along the axis of the pedicle in thoracic vertebrae. This length increases to 50 mm in lumbar vertebrae. To maximize strength and minimize complications, an ideal screw length is used in the pedicle screw systems currently available. Biomechanical studies point out that 60 percent of screw strength comes from the screw purchase of bone in the pedicle, and the remaining 40 percent relates to cancellous bone purchase in the vertebral body. In those that penetrate the anterior vertebral body (anterior cortical cortex), the strength of the screw increases by 20 percent but carries the potential risk of injuring major anterior vasculature, including the aorta. Therefore, the benefits of gaining additional strength by reaching the anterior cortex is thought to be lower than the risk associated with it [8, 9]. This strength distribution is reversed in sacrum implantation. Due to its strong anterior weight-bearing
column of bone, 60 percent of screw strength is related to the anterior region, which requires anterior wall penetration on this level [8].

By these means, a successful and ideal posterior fixation surgery would be such that the screw 1) is inserted along the axis of the pedicle channel to prevent nerve injury, 2) has the largest possible screw diameter to purchase the most bone interaction without fracturing the pedicle, and 3) retains the maximum length without penetrating the anterior cortical cortex (with the exception of the sacrum) [9]. A full consideration of the aforementioned parameters in the design of any new pedicle screw implant is required to enable surgeons to achieve successful surgeries.

1.3. Objective of this study

The pedicle screw fixation method was a breakthrough in spinal surgery. However, challenges, such as insufficient strength in instrumentation, especially in those with osteoporotic bone, remain. This insufficiency results in screws loosening before complete fusion occurs. Therefore, the development of a new fixation device is required to address this issue. By these means, the objective of this study is to propose, develop, manufacture, and test four new expanding pedicle screw designs with the intention of improving screw loosening in posterior fixation surgery.

In the following chapters, the researcher discusses the history of pedicle screws and improvements in their design until now as well as the challenges and parameters involved in screw design. In the next chapter, the new designs and the methods used in
FE to evaluate them are examined. Based on the results extracted from FE simulation, presented in last chapter, the two most effective designs were selected for cadaver pullout testing, and the results of this experiment are reported in last chapter. The author hypothesizes that by expanding the screw in the vertebral body, bony fixation will improve as the interaction surface area increases.
Chapter 2

Literature review

In this chapter, a brief introduction to the history of the pedicle screw and its developments is provided. The materials used for implants and their properties are described, followed by design parameters that affect screw outcome. Finally, the FE method is introduced as a powerful tool in the design and development of human implants, especially spinal implants.

2.1. History of the pedicle screw

The current pedicle screw design is an enhancement of a 1970 invention that revolutionized spinal surgery. Spine surgeons worldwide use pedicle screws for the treatment of spinal disease and it is a widely accepted treatment method. Harda first used surgical instrumentation for the treatment of spinal disease in 1891, employing a wiring technique to stabilize a pathologic cervical spine fracture-dislocation secondary to Pott’s disease [10, 11]. King first introduced facet screws as a technique for the fusion of a
degenerative lumbar spine, and thus is known for developing methods of screw fixation for the spine [12]. Boucher conceptualized pedicle screw fixation in spinal surgery [13] by extending the screw used by King to the pedicle to provide a pedicle-approach fixation. However, the screw he used differs from the pedicle screws used today.

Harrington and Tullose first introduced the technique of passing screws through the pedicle channel to provide improved fixation in the pedicle and vertebral body [14]. They used this technique for the treatment of spondylolisthesis in children, but it was not accepted widely in North America. Ten years later, in 1979, Roy-Camille presented a pedicle screw fixation method to surgeons at an American Academy of Orthopedic Surgeons meeting [5]. Steffee brought the next development in pedicle screw fixation, which provoked broader acceptance of pedicle screw instrumentation. He made pedicle screws compatible with various anatomies by inventing the variable-screw-placement plate [15]. Nevertheless, a high-quality internal fixation method for use in the long bones was still required [5]. Hence, significant investigations were carried out to improve and develop modern spinal instrumentation systems. One of the most successful achievements in this regard has been the addition of the “tulip” to the screw head, which allows improved screw placement by providing a larger screw head angle variation for the rod attachment.

Clinical developments in the pedicle screw fixation method and their effects on the surgical care of patients with spinal disease have been significant. Their valuable effects are reflected in a variety of spinal disorders, including scoliosis, kyphosis, spinal fracture, spondylolisthesis, degenerative lumbar disease, neoplasms, and autoimmune
disease. Improved ability of curvature correction and maintenance of alignment in scoliosis treatment and a reduced need for brace utilization have been some of the significant outcomes [16-18]. The use of pedicle screws has enabled surgeons to fuse fewer segments in trauma treatment and has generated a higher rate of success in the correction of post-traumatic kyphotic deformities [19-24]. The use of this method in the treatment of spondylolisthesis has resulted in a substantially increased fusion rate, increased surgical ability to reduce and maintain the deformity, and an increased rate of surgical success with decreased corresponding overall risk. In addition, this method is suitable for use in percutaneous and minimally invasive surgery for the treatment of spondylolisthesis and other deformities [25-30]. Furthermore, it has improved the outcomes for treatment of cancer by allowing a safe radical resection of primary spinal tumors with the use of short constructs to fuse a few levels of vertebrae [31, 32].

Despite the great success of the pedicle screw system in the treatment of spinal disease, it has challenges and limitations. These systems have to provide stability to the instrumented level for three to six months post-surgery to allow fusion to take place, but their inability to provide sufficient fixation in osteoporotic bone results in screw loosening and, therefore, the need for revision surgery. The same issue occurs in revision surgery. Moreover, pedicle screws cannot provide sufficient stability for patients who have suffered severe trauma.

The screw-bone interface is the key feature in determining screw-fixation quality and, therefore, the strength of the construct to provide sufficient stability to the instrumented vertebrae, and can dictate the failure or success of the surgery. Due to the
poor bone density in osteoporotic bone, this screw-bone interface is substantially compromised and can be problematic, causing screw loosening before fusion occurs [33-46]. In addition to bone quality, two other elements are involved in the bone-screw interface: screw design features and geometry. These parameters are investigated in various studies and include screw diameter and pedicle match (in other words, the percentage of the pedicle filled by the screw shaft), screw length, thread pitch, thread type, shape of the minor diameter, shape of the major diameter, angle of screw insertion, insertion torque, use of cross-linking, pre-tapping of the pedicle, use of bilateral construct, use of bone cement for augmentation, and the use of hollow screws [47-63]. Although the most effective aspects of each feature were investigated and implemented in the screw design, fixation in osteoporotic bone remains a concern. Similarly, elderly patients with multiple spontaneous compression fractures secondary to osteoporosis are poor candidates for pedicle screw fixation [45].

Bone mineral density as a parameter that shows the quality of bone can be used for the study of bone quality’s effect on screw fixation. Soshi et al. introduced the JIKEI index relating to bone mineral density and pedicle screw pullout strength by using an x-ray based scheme. In this grading scale, a grade of 0 represents the normal trabecular pattern and density, while the other end of the scale, grade 3, relates to poor bone quality in which the transverse trabecular has disappeared. Spontaneous compression fractures, as mentioned previously, usually occur in people with poor bone quality (grading 2 or 3 of this scale), thus the author concludes that pedicle screws are contraindicated [45]. Although other treatment options are available for patients with osteoporosis, such as the
hook-based construct, they do not improve the outcomes, and pedicle-screw fixation remains the most effective mode of fixation for spine surgery [35].

In addition to the design changes and improvements, researchers propose several other methods to resolve the issue of poor bone-screw interface in osteoporosis cases. One of these techniques is the use of bone cements such as methyl methacrylate, calcium triglyceride, and polypropylene glycol fumarate [36, 49, 60, 66, 74]. This method can increase the pullout strength of the screw significantly by cement augmentation, but it involves the risk of cement extrusion into the spinal canal and spinal cord injury. Moreover, with this technique, revision surgery is not possible because the screw is bonded to the cement and, therefore, to the bone.

In a pull-out study in human lumbar vertebra, Daniel et al. [75] showed improvement in pull-out strength of screw when augmented with cement. They used kyphoplasty type technique and transpedicular type technique to inject polymethylmethacrylate. Kyphoplasty type augmentation increased pull-out strength by 72% over intact osteoporotic controls. The transpedicular augmentation technique could improve pull-out by 28% over intact osteoporotic controls. In another similar study Chen et al. [76] compared the pull-out strength of the augmented screws with non-augmented screws using solid screws with retrograde cement pre-filling and cannulated screws with cement injection through perforation. Their results showed a significant increase in pull-out strength for augmented screws compared to non-augmented [Figure 2-1]. They also showed that solid screw method can increase the pull-out by 32% compared to cannulated screw.
A group of other investigators tried to increase the pull-out by change in the screw design. Most of these designs have tried to increase the anchorage by expansion of screw in the vertebra. In a clinical study Stephen et al. [77] reviewed the radiographic fusion of one hundred forty-five patients received one or more expandable pedicle screws from the Omega21 spinal fixation system (EBI, L.P., Parsippany, NJ) at a mean follow-up period of 35 months. Results showed 86% radiographic evidence of fusion with no instances of screw loosening or pull-out. Screw breakage was observed in four patients (2.8%). Vishnubhotla et al. [78] compared the initial pull-out strength of an expandable titanium screw (Osseoscrew; Alphatec spine, Carlsbad, CA, USA) with standard titanium pedicle screw in human cadaveric spine [Figure 2-2]. They showed that the yield load for expandable screw was nearly 25% greater than standard screw. Ultimate load was found to be statistically greater (nearly 30%) for the expandable screw compared with the standard screw. The energy required to cause bone-implant failure was also statistically greater for expanding screws.

Figure 2-1: a) A radiological photograph showing the test block and the inserted screw following cement augmentation b) The average ultimate pullout strength of fully inserted conical and cylindrical pedicle screws with various screw fixation techniques [76].
Figure 2-2: a) pull-out strength comparison of (Top) standard 6.5-mm titanium pedicle screw and (Bottom) expandable titanium pedicle screw b) Representative load-displacement curve of the expandable screw compared with the standard pedicle screw [78].

Another effort to improve the pull-out strength of pedicle screw in osteoporotic bone is been implementation of two aforementioned methods at the same time, pedicle screw augmentation while using expanding screws. To support the feasibility and effectiveness of this method Mingxuan et al. [79] proposed a protocol to compare four conventional pedicle screw without augmentation, expansive pedicle screw without augmentation, conventional pedicle screw with calcium based cement augmentation, and expansive pedicle screw with calcium based cement augmentation. They showed that combination of augmentation and expansion in osteoporotic bone can improve the pull-out strength than each method alone (Figure 2-3). They pointed out that in case of severe osteoporotic neither of these methods can significantly improve the fixation compared to conventional screw. This can be justified because of the compromised bone quality in
cancellous region. Therefore, a screw design with anchorage through cortical bone can hopefully improve the pull-out strength even in severe osteoporotic bones, which is proposed and evaluated in this study.

**Figure 2-3:** pull-out strength comparison of conventional pedicle screw without augmentation, expansive pedicle screw without augmentation, conventional pedicle screw with calcium based cement augmentation, and expansive pedicle screw with calcium based cement augmentation

Table 2-1 shows a summary of different techniques proposed to improve the pull-out strength of pedicle screw in osteoporotic bone.
**Table 2.1:** summary of different techniques proposed to improve the pull-out strength of pedicle screw in osteoporotic bone.

<table>
<thead>
<tr>
<th>Author</th>
<th>Image</th>
<th>Technique</th>
<th>Pull-out strength improvement compared to conventional screw (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daniel et al. [75]</td>
<td><img src="image1" alt="Image" /></td>
<td>kyphoplasty Cement augmentation</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Transpedicular Cement augmentation</td>
<td>28</td>
</tr>
<tr>
<td>Chen et al. [76]</td>
<td><img src="image2" alt="Image" /></td>
<td>Cement augmentation</td>
<td>900</td>
</tr>
<tr>
<td>Stephen et al. [77]</td>
<td><img src="image3" alt="Image" /></td>
<td>Expandable screw (Omega21) /Clinical follow-up</td>
<td>86% successful fusion rate</td>
</tr>
<tr>
<td>Vishnubhotla et al. [78]</td>
<td><img src="image4" alt="Image" /></td>
<td>Expandable screw (Osseoscrew)</td>
<td>25</td>
</tr>
<tr>
<td>Mingxuan et al. [79]</td>
<td><img src="image5" alt="Image" /></td>
<td>Cement augmentation</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expandable screw</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expandable screw combined with augmentation</td>
<td>43</td>
</tr>
</tbody>
</table>
2.2. Implant materials

When designing a new instrument for use in the human body, having knowledge about different material properties can be helpful in the selection of the most suitable material. Material selection is important, because despite an appropriate geometrical design, improper selection of material can lead to the failure of an implant. In the selection of a material for manufacturing an implant, several parameters are critical. These include that the material selected should 1) be as inert as possible to reduce corrosion and the release of ions and particles after implantation, 2) be visible in magnetic resonance imaging (MRI) and produce minimum noise, and 3) have a relatively low modulus of elasticity to make a less stiff construct to prevent the occurrence of stress shielding, which results in osteoporosis around implants [80].

Most implants consist of metallic alloys, which commonly include aluminum, titanium, vanadium, chromium, manganese, iron, cobalt, nickel, zirconium, niobium, and molybdenum [1]. Among these metals, titanium is the only one used in its pure form for manufacturing spinal implants. Four commercial grades of titanium are available, ranging from grade 1, which contains no contaminants and is the purest, to grade 4, which is the least pure. The higher grade of titanium has larger moduli of elasticity and greater tensile strength.

Materials currently commonly used to manufacture spinal implants, especially pedicle screws, are 316L stainless steel, 22-13-5 stainless steel, Co-Cr-Mo, and Ti-6Al-4V (a mixture of titanium, aluminum, and vanadium). Table 2-1 provides a list of
different metallic materials used to manufacture orthopedic implants, with their material properties. The alloyed form of titanium is the most widely used material in orthopedic implants and is ideal for spinal implants, meeting the three critical requirements discussed previously. Besides titanium, stainless steel and cobalt chrome are also suitable options. Some manufacturers exploit the benefits of the different material properties of these metals by creating hybrid implants or constructs (such as titanium alloy for the screw and cobalt chromium for the connecting rods) [4, 81].
Table 2.2: Summary of different metallic materials used to manufacture spinal implants and their material properties [82].

<table>
<thead>
<tr>
<th>Material</th>
<th>Principal alloying elements (weight %)</th>
<th>Elastic modulus (GPa)</th>
<th>Yield strength (MPa)</th>
<th>Ultimate strength (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stainless steel 316L</td>
<td>balance Fe 17–20 Cr 12–14 Ni 2–3 Mo max 0.03 C</td>
<td>205–210</td>
<td>170–750</td>
<td>465–950</td>
</tr>
<tr>
<td>CoCrMo F75</td>
<td>balance Co 27–30 Cr 5–7 Mo max 2.5 Ni</td>
<td>220–230</td>
<td>275–1585</td>
<td>600–1785</td>
</tr>
<tr>
<td>MP35N</td>
<td>balance Co 33–37 Ni 19–21 Cr 9–10.5 Mo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ti grade 4</td>
<td>balance Ti max 0.4 O</td>
<td>105</td>
<td>692</td>
<td>785</td>
</tr>
<tr>
<td>Ti4Al6V</td>
<td>balance Ti 5.5–6.5 Al 3.5–4.5 V</td>
<td>110</td>
<td>850–900</td>
<td>960–970</td>
</tr>
<tr>
<td>Ti6Al7Nb</td>
<td>balance Ti 6 Al 7 Nb</td>
<td>105</td>
<td>921</td>
<td>1024</td>
</tr>
<tr>
<td>Ti35Nb5Ta7Zr (TNZT)</td>
<td>balance Ti 35 Nb 5 Ta 7 Zr</td>
<td>55</td>
<td>530</td>
<td>590</td>
</tr>
<tr>
<td>NiTi</td>
<td>55.9–56.1 Ni balance Ti</td>
<td>20–70 (martensite)</td>
<td>50–300 (martensite)</td>
<td>755–960</td>
</tr>
<tr>
<td>TiNb</td>
<td>balance Ti</td>
<td>70–110 (austenite)</td>
<td>100–800 (austenite)</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td></td>
<td>60–85</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>
2.3. Screw design

As discussed previously, pedicle screws are the most commonly used implant for the surgical treatment of spinal disease, with the purpose of stabilization of the spine. The indications for the use of pedicle screws extend from pediatric to adult patients. They are distinguished for their ability to retain bony purchase in the treatment of deformity and trauma and the management of chronic or degenerative conditions as the primary mode of fixation. Despite their ability to provide stability in healthy vertebrae, their strength in cases such as osteoporosis, revision surgery, and severe trauma is inadequate, causing early failure of the construct due to loosening. In this section, the researcher discusses geometrical parameters in pedicle screw design that can affect and improve the strength of the construct, thus preventing loosening.

A pedicle screw can be divided into four main components that each plays a particular role in the screw-bone fixation construct. A pedicle screw with different geometrical sections is shown in Figure 2-1. The main sections of a pedicle screw are the head, core, thread, and tip, and each section has its own effect on the mechanical properties and outcomes of the screw as well as its interface with bone. Hence, any alteration to these features can affect the outcome. Different studies were completed to investigate the effects of each and to propose and establish the optimal screw design to achieve the most effective possible screw-bone fixation.
Figure 2-4: Basic screw and thread terminology. Key feature of the screw design are labeled: A = screw head or tulip, B = head body junction, C = pitch, D = thread angle, E = major diameter, F = minor diameter, and G = screw length [83].
Tulip is a common name for the head of a spinal pedicle screw. The role of the tulip in the screw construction is to resist the translational force induced by the rotation of the screw. In addition, in modern screws the tulip acts as an anchor point for fixation of the rod to provide a rigid and stable construct by connecting all the screws along the spinal column. Previous designs of the screw tulip have confirmed that the existing design is effective and does not cause complications or failure post-surgery. Therefore, in this study, the researcher does not attempt to change the tulip design, and it is not the point of interest.

The core of the screw, referred to as the main shaft or minor diameter of the screw, is the primary factor in determining the strength of the screw in bending and torsion. Based on the mechanical equations, screw strength is proportional to the cube of the minor diameter. Hence, it should increase exponentially as the minor diameter increases \[84\], and it can be concluded that the best option for selection of screw minor diameter is the largest one that best matches the pedicle diameter.

Increasing the minor diameter raises two issues: by increasing the minor diameter, thread depth is scarified, the significance of which is discussed below, and a screw with a larger core is stiffer, with a stiffer surgical construct, which causes stress shielding of the bone and loss of bone density around the screw \[80\]. Conversely, by lowering the rigidity of the construct by decreasing the minor (core) diameter, excessive motion of the implanted level can fail to fuse post-surgery \[85\].

Furthermore, the shape of the screw shaft has a significant effect on the screw-bone interface that should be considered. Two different shapes for screw core are
proposed: cylindrical and conical with the end closer to the tip having a smaller diameter (see Figure 2-2). The conical screw showed better results in improving the pullout strength of the screw (Figure 2-3). The conical shape compresses the bone as it screws in, and this produces a stronger screw-bone interface while sacrificing the thread depth near the screw head [56]. The Xia® instrumentation system (Stryker®, Spine Michigan, Kalamazoo) is one example of such a screw available on the market.

Screw thread is another feature in the screw design that, if designed properly, can improve the outcome of the design. Variable parameters in the selection of thread type are thread depth, pitch, and type (shape). Thread depth, a parameter that shows the difference between the minor and major diameters, is measured from the shaft to the thread’s tip. Larger thread depth can improve screw pullout by increasing the bone purchase, especially in softer bone (in other words, cancellous bone) in the vertebral body. However, it should be considered that increasing the thread depth would not sacrifice the minor diameter, which is critical in the determination of screw strength (fracture or failure of screw). Thread pitch is the distance between two adjacent levels in metric measurements and is defined as the number of threads per inch in the standard measurement system. In this thesis, the metric definition of pitch is used. Thread type or thread shape has nearly infinite options, including buttress, square, and standard. The most common shapes are V-shaped (mostly 60 degree), buttress, and square thread.

The type of screw should be selected based on the bone in which it is going to be inserted (cortical bone vs cancellous bone). If it is being used for instrumentation in a cortical bone, which is a hard material, a machined screw is ideal. Machined screws have
a low thread pitch and low thread depth to gain the best bone purchase and fixation. For instrumentation in soft bone, such as cancellous bone, a wood screw type can provide improved fixation due to its larger thread depth and larger thread pitch. Larger thread depth and pitch allow a larger amount of bone to be between each thread, thus increasing fixation. For the design of a pedicle screw, a wood screw type is preferred because it is interfacing mostly cancellous bone [86].

Previous studies have highlighted the ideal characteristics for the thread type, shape, pitch, core shape, and size of a pedicle screw [1, 4, 5, 56, 70]. Thus, the ideal design to gain maximum pullout strength is a screw with a V-shaped thread that has a pitch of approximately 2.8 mm and thread depth of approximately 1 mm, and a conical core. The screws on the market that utilize these ideal parameters (such as the Xia® screw from Stryker®) have been shown to have a successful clinical outcome, which means any new pedicle screw design should consider these ideal variables to be successful.

In addition to changes in the screw design, several researchers have attempted to propose a new mechanical design of screws to address the deficiency for use in osteoporotic bone. One example, expandable screws, attempts to increase fixation by increasing the screw-bone interface and, therefore, screw anchorage. This showed an approximately 30 percent increase in pullout while being safe for in-vivo use [36, 83-87]. OsseoScrew-Zodiac® (Alphatec Spine Inc, Carlsbad, California) is a titanium expandable screw available in the North American market, made for use in patients with osteoporosis. Biomechanical studies on this screw have shown a 30 percent increase in
ultimate failure load compared to the standard screw. In the next chapters, four novel expanding screws are introduced and their biomechanical testing results are compared.

Figure 2-5: Pedicle screw designs. (a) Cylindrical threading and cylindrical core and (b) cylindrical threading and conical core [82].

Figure 2-6: Effect of screw design on pullout strength The percentages are with respect to a classic pedicle screw of otherwise similar dimensions. TSRH: Texas Scottish Rite Hospital (conical screw); CD: Cotrel-Dubousset (conical screw); MM: Moss Miami (cylindrical screw); Cy/Cy: cylindrical thread with cylindrical core; Cy/Co: cylindrical thread with conical core; Co/Co: conical thread with conical core; V: standard thread; and Ti: titanium [87].
2.4. Finite element analysis of human implants

The finite element method has been used in spinal biomechanics for nearly four decades. Recent developments have expanded its scope to simulate a wide range of clinical and experimental situations, and to make it possible to study parameters that are difficult to measure in a clinical setting. Finite element (FE) is a computational method of solving complicated physical problems by dividing the body into a finite number of elements. Those elements can be different in shape and size, and are connected to each other through common nodes. Loads and boundary conditions are applied on the nodes, and the solution of interest is derived based on the governing equations for each node. The FE method has been a low-cost, useful, and effective tool in the study of biological sciences, especially in spinal research. It has been valuable in a variety of areas, from dynamics and biomechanics to spine implantation and corresponding disease treatments, as well as in the evaluation of unknown in-vivo and in-vitro forces (for example, ligaments and facet joint forces [88, 89]). Furthermore, a cadaveric testing model typically is used to validate results and to strengthen the ability to make clinical decisions from the simulations [90].

FE is a powerful computational tool in a variety of biomechanical fields [91], and it has been used widely to describe spinal biomechanics [92]. It is superior to in-vivo and in-vitro studies in that it offers cost-efficient, robust solutions and avoids the necessity of using live animals or postmortem human or animal samples. Nevertheless, the results extracted from FE depend on the geometry, material model, and material properties used
in the simulations and can vary in different models. Dreischarf et al. [93] completed a comparison study on eight different existing models of the lumbar spine (L1-5) in a variety of research centers. These models are shown in Figure 2-4. They concluded that the median response of all the models’ predictions was in better agreement with reported data than the individual model predictions.

The use of FE models is especially important when examining parameters that are difficult to measure, such as loads across the sacroiliac joint [99]. Another important utility of FE modeling is that it makes parametric studies feasible (in other words, those in which the effects of isolated changes in one individual parameter are measured). The applications of FE models in spine studies are far reaching, and include investigations into spine physiology (spine biomechanics), treatment, and instrumentation. Kumar et al. [100] compared the stress pattern in adjacent vertebra for four common spinal cages and found high stress concentration and abnormal stress patterns for all cases. They point out that a successful bony fusion could restore a physiological pattern of stress distribution.

In a parametric study, Chatzistergos et al. [101] used the FE method to investigate parameters affecting pullout strength of the pedicle screw. The FE results show that the deepest threads carry most of the pullout load, and the material surrounding these threads fails first. They further conclude that the major parameter influencing pullout force is the outer radius (increasing its value by 36 percent increases the pullout force by 34 percent), while the respective dependence on the thread inclination, depth, and pitch is significantly weaker. In this study, the FE method was used as a tool for primary...
evaluation of the designs. The results were used for the selection of the two best designs and further experimental evaluations
Figure 2-7: Eight different geometries that have been used for FE modeling of the lumbar spine, including those by (a) Kim and Park, (b) Puttlitz and Labus, (c) Chen and Wang, (d) Little and Adam, (e) Schmidt and Wilke, (f) Shirazi-Adl, (g) Rohlmann and Zander, and (h) Goel and Kiapour. Figure is reprinted from [102].
Chapter 3

Materials and methods

In this chapter, the method and procedure followed in designing the four novel pedicle screws are reviewed first. These designs are then described with their specific features for their intended use. In addition, the finite element (FE) method used for biomechanical evaluation of the screw designs is discussed in detail. Moreover, to validate the two best designs—distinguished by FE results—a clinical pullout test was performed in single vertebra. This clinical protocol is described in the last section of this chapter.

3.1. Design controls and design requirements

For any design and product development to be successful and efficient, a procedure known in industry as design control must be followed: Design control increases the likelihood that device production and product development are appropriate for the intended use of the device, and affords both managers and designers improved visibility of the design process. This allows managers to lead the design process more effectively; that is, to recognize problems earlier, make corrections, and adjust resource
allocations. Design control benefits designers by providing an enhanced understanding of the conformity of a design to user and patient needs as well as improving communications and coordination among all participants involved in the process.

Design control and quality system requirements are proposed and discussed by the Food and Drug Administration’s (FDA) quality system regulation and is cross referenced to the International Organization for Standards (ISO) draft international standard ISO/DIS 13485. Figure 3-1 illustrates a schematic of design control and its influence on the design process. The development process depicted in the figure is a traditional waterfall model, which expresses that requirements are developed (design input) and a device design is proposed to meet those requirements. After evaluation of the design and verification of outputs, design is transferred to the production stage for manufacturing. Design control does not end with the transfer of the design to the manufacturing stage, however; it applies to all changes of device design, including activities after a device has been introduced to the market. Performance enhancement activities and corrective actions resulting from the analysis of the failed product are two ways in which design control extends into the life of the device. Design control covers not only device design but also packaging, labeling, storage, installation, and servicing of all finished devices.
Figure 3-1: A design process waterfall showing the application of design controls and its influence on the design and product development process.

Because the objective of this study has not been marketing of an implant but rather clinically relevance, the author has attempted to implement design controls in the design and development process of a novel expanding pedicle screw as much as the application and author’s knowledge allows. For the purpose of this design process, Dr. Vijay K. Goel, a design reviewer and supervisor with a broad knowledge of orthopedic and implant design; Dr. Anand K. Agarwal, an orthopedic spine surgeon, design reviewer, and design consultant specializing in proposing user and patient needs; and a
designer (the author), with a background in mechanical engineering and experience in designing several patented devices, collaborated. As an initial step in the design, through literature review and meetings with the design advisors, critical user and patient needs were defined, including:

1) Screw design and material should be biocompatible;
2) Screw should be implantable with standard surgical techniques or a proper instrument should be designed;
3) New design should provide comparable stability to traditional pedicle screw designs;
4) The implant should withstand static and dynamic physiological loads until fusion occurs (six to 12 months);
5) The implant expansion should be reversible so it can be extracted for revision surgery if needed;
6) The amount of expansion should be adjustable by the surgeon;
7) Design should be implantable and cover all anatomy variations (should be able to be manufactured in different lengths and diameters); and
8) Design should improve screw loosening, especially in osteoporotic bone, compared to traditional screws.

As the purpose of this study was to improve pedicle screw design by changing the geometry and design of the screw, the material used remains unchanged. The most common material used by the industry for manufacturing pedicle screws is Ti4Al6V, and
its biocompatibility has been confirmed. Thus, the same material was used to manufacture the novel pedicle screws. The second design input, compatibility of the design with existing instruments, was addressed in the designs. The screw head and tulip remain unchanged, but an extra part was added to the bottom of screw. It requires an additional instrument to drive the inner screw and is discussed in the following sections.

The third requirement represents the main goal of using pedicle screws in the human body. Design should be such that the screw provides adequate stability and prevents the motion of respective levels to allow fusion to occur within three to six months. Range of motion (ROM) study is one of the methods used to examine the stability of a pedicle screw construct. This testing was done in FE for all new and traditional designs in an FSU, and results were compared to evaluate the designs. In addition, stress across the screw parts was extracted, and the safety factor for each design was reported.

Furthermore, the reversibility and controllability of expansion, discussed in the sections that follow, is another important parameter that was considered in these designs. The limitation of each design from an anatomical perspective is discussed, too. Finally, the main purpose of this study was to design a novel screw that can provide stability comparable to that of traditional screws and can improve screw loosening in bony constructs, especially in osteoporotic bone. Two methods of studying screw loosening are to perform pre- and post-cyclic loading and to conduct pullout strength testing. If the stability of the construct in a post-cyclic loading ROM test is similar to its value in a pre-cyclic loading ROM test, it means it can provide stability without loosening of the screw.
The number of cycles was chosen based on the average number of physiological bending cycles a patient would have in three to six months until fusion occurs. In pullout testing, which was done in this study, the failure load in testing may be higher, which indicates that the screw could show more resistance to loosening.

After defining the design inputs, the next step in the design control process is the design process, which is the translation of design input into a device design that can address the design inputs and requirements. After the design was finalized and reviewed (which is the subject matter of this section), a prototype was created to verify the conformance of the design with the design input. Last, two of the best screw designs based on FE simulation results were selected for manufacturing and further testing to evaluate the designs experimentally, and verify and validate them with design input and user needs, respectively. In the following sections, four novel expanding screws are proposed, additional details of each design are examined, and the FE method used for simulations is discussed.

3.2. Implant design

To achieve the aforementioned goals, four different screw designs initially were taken through the conceptualization stage to prototype development. One of these designs expands in cancellous bone, while the other three expand to reach the cortical shell around the screw shaft and grip the cortical bone (Figures 3-2 to 3-5). Expansion of the screws is achieved after insertion by turning the central core, which contracts the expanding parts, increasing their diameter. The expansion is dictated by the push of the
expanding part against the screw shaft and the number of turns given to the central core. In all designs, the tulips and screw shafts remained unchanged, and the screws were redesigned and developed by adding the expanding parts to the bottom of the screws. All screws have a cannula for insertion of the inner screw, which is intended for screw expansion after screw insertion. Each screw has a different design and different geometry, giving it different features and purposes, as described in the sections that follow.

3.2.1. Cancellous expanding screw

This screw is designed to increase the flank overlap area (FOA). FOA is a parameter defined by Krenn et al. [103] that shows the contact area between screw and bone to predict the fixation of a screw in bone of poor quality. From a purely mechanical perspective, the load bearing of the screw depends on the amount of surrounding material that is in contact with the screw thread [104]. Therefore, it was expected that increasing the contact area would result in a greater distribution of forces and, thus, a greater pullout strength.

In this screw design, four expandable parts were created circumferentially along the screw shaft by cutting four slots on the outer diameter through the cannula, as shown in Figure 3-2. Driving the inner screw pushes the screw bottom and compresses the expanding parts. The angle of the wings after expansion depends on the number of inner screw turns, and is variable and controllable by the surgeon. As the slots are provided on the end of the screw shaft, wings expand in the soft bony region of the vertebral body, the
cancellous bone. Although this increased contact area increases screw anchorage, it was predicted that pullout strength would not increase much compared to that of a traditional screw due the expansion in soft bone, especially in osteoporotic vertebra with poor quality bone. Hence, the next three designs are proposed to offer an expansion that would contact the strong cortical bone and, therefore, provide improved anchorage.

Figure 3-2: Cancellous expanding screw before expansion (right) and after expansion (left)

3.2.2. Bottom expanding screw

Because cortical bone is significantly stronger than cancellous bone and, as mentioned in the literature section, most of the screw strength derives from screw-bone purchase in the cortical bone, it was expected that an expanding design providing
anchorage within cortical bone would provide greater strength and stability. To this end, a bottom expanding screw design was proposed. This screw consists of the main screw, the expanding part, and the inner screw. In this design, screw length is shorter than in a traditional screw and is such that after screw insertion, the main screw tip penetrates the cancellous bone not more than two thread pitches. This causes the expanding part to reach the cortex (cortical shell around the vertebral body) and provide a stronger anchor and increased stability.

The expanding part, as shown in Figure 3-3, consists of four prongs connected on the end and facing the screw tulip. This part assembles between the inner screw tip and main screw tip, and it is settled and stabilized by the inner screw shaft before deployment or expansion. For expansion, rotating the inner screw pushes the expanding part against the screw tip, making it expand around the screw shaft until it reaches the cortical shell. An advantage of this design is providing anchorage with the stronger bone, but it loosens the screw-bone interface in the cancellous bone in the vertebral body, which can increase the stresses on the screw and failure or breakage. In addition, because the bottom of the expanding part is connected all around, it would cause a major strain and, therefore, stress on this part after expansion, possibly causing a fracture. Due to the strain required to expand the part, it would cause resistance to expansion and require higher torque on the inner screw to make it possible. This higher torque can cause inner screw failure due to the tiny geometry of the part. To create such a design with less resistance to expansion, the transverse expanding screw was proposed.
3.2.3. Transverse expanding screw

Due to the high predicted resistance to the expansion of the screw, a transverse expanding screw was proposed. The design concept is identical to that of the bottom expanding screw, which involves expansion around the main screw shaft to reach the cortical shell and provide a stronger anchorage. A minor change in the design of the expanding part, as shown in Figure 3-4, made it less stiff in the radial direction while providing the same axial strength. The axial strength of the expanding part is important because it is in the direction of the load flow from the cortex to the expanding part and to the inner screw. An extra radial edge was added to the bottom of the expanding part, fitting in the radial slit provided on the inner screw. This mechanism was added to make the expansion reversible if the need arises. The advantage of this design compared to the bottom expanding design is its ease of expansion. Although this is intended to be reversible, which means being able to collapse the expanding part to the original position to withdraw the pedicle screw if needed, it may not return fully to its original shape.
because of deformation of the plastic after contraction. The last design, the window expanding screw, was proposed to provide an assured reversible mechanism.

![Transverse expanding screw design](image)

**Figure 3-4:** Transverse expanding screw design

### 3.2.4. Window expanding screw

This screw concept design is similar to the last two designs, with the difference of having an assured reversible mechanism. The expanding part consists of three prongs placed inside the screw shaft that expand outward through the slits provided on the screw wall, as shown in Figure 3-5. When the expansion is reversed, the screw walls push the expanding parts inward, ensuring that it collapses to the original shape and providing a secure pullout even if its plastic is deformed after expansion. A disadvantage of this design is the small cross section of the ramus of the expanding parts due to the geometric limitation, which may lead to the failure or breakage of the part under loading. Nevertheless, an advantage of this design is keeping the threaded screw length and bone
purchase in the cancellous bone, which reduces the potential of high stresses on the main screw. A qualitative comparison of the four proposed designs is provided in Table 3-1.

![Window expanding screw design](image)

**Figure 3-5:** Window expanding screw design

**Table 3.1:** A qualitative comparison of the four designs proposed in this study.

<table>
<thead>
<tr>
<th>Design</th>
<th>Cortical anchorage</th>
<th>Screw cancellous bone interface</th>
<th>Reversibility</th>
<th>Ease of expansion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancellous expanding screw</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Bottom expanding screw</strong></td>
<td>✓</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Transverse expanding screw</td>
<td>✓</td>
<td>✗</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Window expanding screw</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✗</td>
</tr>
</tbody>
</table>

### 3.3. Finite element analysis

#### 3.3.1. Lumbar finite element model

An experimentally validated 3D finite element (FE) model of the intact ligamentous L4-L5 FSU was used for biomechanical evaluation of the designs. This
model was created, developed, and validated in prior studies [105-109]. For the analysis, Abaqus 6.11 was used (175 Wyman Street, Waltham, Massachusetts 02451). The geometry of the model was obtained from the computed tomography (CT) scan of a cadaveric spine segment with a 1.5 mm transverse slice thickness [105]. This spine segment was free from abnormalities and defects to ensure proper geometric results. The material properties used in the model were chosen from the literature review.

Each vertebra, including posterior elements, was modeled by C3D8-type mesh. This type of mesh is a hexagonal linear element with eight representative nodes on the edges. Subsequently, the vertebral body was encased in a 0.5 mm thick cortical shell covering inner cancellous bone elements. The other segment of FSU, the intervertebral disc, was modeled into two parts: the inner part, or nucleus pulposus, and outer part, or annulus fibrosis. The nucleus pulposus was modeled by C3D8 elements, which were used for the bone also. To simulate its hydrostatic characteristics, a material property with Poisson’s ratio of $\nu = 0.4999$ and Young’s modulus of $E= 9 \text{ MPa}$ was assigned to it. Furthermore, the composite property of annulus fibrosis was considered in the model, and the matrix of the composite was simulated by 3D hexagonal elements with neo-hookean hyperelastic material properties. This matrix includes fibers modeled with REBAR elements and oriented $\pm30$ degrees to the horizontal alternatively in each layer. Fibers are active only when in tension, and their thickness and stiffness increase as the distance from the nucleus increases.

For simulation of the facet joints, a 3D GAP element was used, and the elements were spaced 0.5 mm from each other. GAP element material properties are defined by
contact behavior. By decreasing the opening between the GAP elements, the force created by the contact increases exponentially until it reaches maximum stiffness of the posterior bone elements.

Ligaments in this model were simulated by T3D2 elements, a 3D truss element defined by two end nodes. All seven interspinous, supraspinous, intertranservse, capsular, posterior longitudinal, anterior longitudinal, and ligamentum flavum ligaments were included in the model. These elements were modeled by hypoelastic material properties. The mechanical properties of the materials vary along with the strain magnitude for a predetermined strain rate. For simplification, all ligaments initially are at rest (no pretension on ligaments), although this is not physiologically the case.

For simulation of the osteoporotic bone, material properties of bony elements were changed accordingly. Smith et al. [111] indicate a linear relationship between BMD and the material properties of the bone. Thus, the Young’s modulus for the cancellous and cortical bone was changed to 69.7 and 10200 MPa respectively.

Overall, the L4-L5 FSU model contains 15,136 elements and 19,148 nodes. The model was considered symmetrical with respect to the mid-sagittal plane of the spine. Table 3-2 shows the material property used in the model for healthy and osteoporotic bone, respectively, and Figures 3-6 to 3-9 show different components of the intact model.
Table 3.2: Material properties and element type of bony structures, ligaments, intervertebral disc, and facet joint [112, 113].

<table>
<thead>
<tr>
<th>Material</th>
<th>Element Type</th>
<th>Constitutive Relation</th>
<th>Material Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bony Structures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertebral Cortical Bone, Endplates &amp; Posterior Cortical Bone</td>
<td>8 nodes brick element (C3D8)</td>
<td>Isotropic, elastic</td>
<td>E = 12000 MPa (\nu = 0.3)</td>
</tr>
<tr>
<td>Vertebral Cancellous Bone &amp; Posterior Cancellous Bone</td>
<td>8 nodes brick element (C3D8)</td>
<td>Isotropic, elastic</td>
<td>E = 100 MPa (\nu = 0.2)</td>
</tr>
<tr>
<td><strong>Ligaments</strong></td>
<td></td>
<td></td>
<td>Elastic modulus MPa (strain %)</td>
</tr>
<tr>
<td>Anterior Longitudinal</td>
<td>Tension-only, Truss elements (T3D2)</td>
<td>Hypoelastic</td>
<td>7.8 (&lt;12%), 20.0 (&gt;12%), (\nu = 0.3)</td>
</tr>
<tr>
<td>Posterior Longitudinal</td>
<td>Tension-only, Truss elements (T3D2)</td>
<td>Hypoelastic</td>
<td>10.0 (&lt;11%), 20.0 (&gt;11%), (\nu = 0.3)</td>
</tr>
<tr>
<td>Ligamentum Flavum</td>
<td>Tension-only, Truss elements (T3D2)</td>
<td>Hypoelastic</td>
<td>15.0 (&lt;6.2%), 19.5 (&gt;6.2%), (\nu = 0.3)</td>
</tr>
<tr>
<td>Intervertebral Disc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nucleus Pulposus</td>
<td>8 nodes brick element (C3D8)</td>
<td>Isotropic, elastic</td>
<td>E = 2 MPa, (\nu = 0.499)</td>
</tr>
<tr>
<td>Annulus Fibrosus</td>
<td>8 nodes brick element (C3D8)</td>
<td>Hyperelastic anisotropic (HGO)</td>
<td>Table 3.2</td>
</tr>
<tr>
<td><strong>Apophyseal Joints</strong></td>
<td>GAPUNI elements</td>
<td>Non-linear Soft contact</td>
<td>Pressure overclosure = 12000 MPa</td>
</tr>
</tbody>
</table>
Figure 3-6: Top and side views of the FE geometry used in this study [114].

Figure 3-7: Sections of the FSU in the FE model. Cortical, cancellous, and posterior bones are distinguished with different colors in this figure. AF and NP are also shown [114].
Figure 3-8: FE model of L4-L5 FSU, where all the ligaments considered in the FE model are shown in red [114].

Figure 3-9: Intervertebral disc components where AF and NP are distinguished [114].
3.3.2. Implantation of the model with the screws designed

As discussed previously, the objective of spinal surgery with use of the posterior fixation method is to provide permanent stability to the adjacent levels. The loosening of screws due to poor bone-screw fixation in patients with osteoporotic bone is a challenging issue in fixation with pedicle screws. Two common testing methods that show the stability and strength of the construct are range of motion (ROM) and pullout strength tests, respectively. ROM usually is conducted on an implanted FSU with pedicle screws connected to each other with rods, or implanted with standalone cages, or a combination of both. Cages are used to restore the lost intervertebral disc height. Pullout is done in a single vertebra fixed in an MTS machine. An axial load is applied on the screw head to extract a load-displacement plot for the screw, and higher pullout failure load represents stronger bone-screw fixation and, therefore, a lower possibility of screw loosening. Accordingly, an ROM study and a pullout test were simulated in the model with both healthy and osteoporotic bone.

Each study was carried out in three steps: insertion of the screw and other implants (such as rods and a cage), expansion of the screw, and application of load based on the testing being done. After the design of each screw was completed in SolidWorks (four novel expanding screws as well as a traditional screw with features similar to other screws), assembly of each screw was exported as a STEP file. The geometrical dimensions of each screw used in the FE modeling are provided in Table 3-3. These assemblies were imported to Abaqus into the L4-L5 FSU model. For the ROM testing,
four of each screw were imported and moved to the pedicles such that they aligned with
the pedicle axis. The researchers attempted to place them in the center of the pedicle as
much as possible. Then, rods were assembled to connect the tulips of screws on each
side, as shown in Figure 3-10. Elements of the model (representing the cancellous and
cortical bone) that were interfering with the screw geometry were removed.

The model was assumed to have a disc degeneration disease, and so a banana-
shaped lateral lumbar interbody fusion (LLIF) cage was used to replace the disc in all
four screw models. The position of the cage was maintained in all models to avoid the
effect of the disc on the results. As an LLIF cage was used, a lateral surgery approach
was assumed for the insertion of the cage, so right posterior elements of the annulus
fibrosis as well as all nucleus pulposus elements were removed, and the cage was placed
between the endplates anteriorly (Figure 3-11). In the case of the pullout test, an isolated
L5 vertebra was cut off from the model. Each screw was imported to the model and
placed in the right pedicle, as was done for the ROM model (Figure 3-12).

**Table 3.3:** Geometrical dimensions of the screws used in FE for simulation.

<table>
<thead>
<tr>
<th></th>
<th>Main screw-shaft length (mm)</th>
<th>Minor diameter (mm)</th>
<th>Major diameter (mm)</th>
<th>Expanding part length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancellous expanding screw</td>
<td>21</td>
<td>6</td>
<td>7.2</td>
<td>15</td>
</tr>
<tr>
<td>Bottom expanding screw</td>
<td>22</td>
<td>6</td>
<td>7.2</td>
<td>12</td>
</tr>
<tr>
<td>Transverse expanding screw</td>
<td>25</td>
<td>6</td>
<td>7.2</td>
<td>12</td>
</tr>
<tr>
<td>Window expanding screw</td>
<td>38</td>
<td>6</td>
<td>7.2</td>
<td>12</td>
</tr>
</tbody>
</table>
Figure 3-10: Screw and rod assembly configuration in the model.

Figure 3-11: Placement of the cage in the model. LLIF cage placed using lateral approach.
After assembling the construct, the next step was expansion of the screws in the bone. Each screw was imported in unexpanded form, as it would be used in surgery, before expansion was simulated in the bone accordingly. To do so, the screw head was encastered (constrained in all six degrees of freedom) and the inner screw was constrained to move only in the direction of the screw’s axis. A surface-to-surface interaction with rough contact properties was assigned to the surfaces that were in contact (in other words, between the inner screw and expanding part, and main screw and expanding part). To make the screw expand, a displacement control was applied on the top of the inner screw toward the tulip such that when it reached its maximum displacement, the expanding part touched the cortical shell of the vertebra, except in the
case of the cancellous expanding screw that is designed to expand in cancellous bone. Figure 3-13 shows the configuration of each screw after expansion in the model. The ultimate force required to expand each screw was extracted for comparison and calculation of the torque required for rotation of the inner screw intraoperatively. The results obtained during this step were used for the ROM and pullout testing simulation, which is explained in the next sections.

3.3.3. Loading and boundary conditions

3.3.3.1. ROM testing

The inferior surface of the L5 vertebra was fixed rigidly in all six degrees of freedom for the analysis, as shown in Figure 3-14. In all the analyses conducted in the current study, compressive forces to simulate body weight were applied as follower loads, as suggested in literature; it was 200 N on each side and called “preload” in this study [110] (Figure 3-15a). By using follower loads in a motion segment, the compressive load is tangential to the spinal curve, and, thus, the intervertebral disc would be loaded in almost pure compression. Bending moments were applied to a reference point that was connected to all of the nodes of the superior surface of L4 by kinematic coupling (see Figure 3-15b). These loadings include 10 N m of flexion, extension left and right bending, left and right rotation, and flexion and extension with preload (or simulated body weight).
Figure 3-13: Configuration of each screw after expansion in the model. a) Cancellous expanding screw, b) bottom expanding screw, c) transverse expanding screw, and d) window expanding screw.
For simulation of interactions, the rod and screw tulip were tied together to mimic their rigid interaction. The inner screw’s head also was tied to the screw cannula to keep the inner screw in place, and to support the expanded part and avoid contraction. Surface to surface contact similar to what was assigned for expansion simulation was assigned to the interacting parts of the screw. For the cancellous expanding screw, the surface of the expanded parts was connected to the surrounding nodes of cancellous bone elements. For the other expanding screws, the tip of the expanding part, where it was in touch with the posterior cortical shell, was tied to the nodes of the cortical shell. This tie interaction makes the screw grip the strong bony cortical shell, which is the purpose of designing these expanding screws. Then the model was applied in a static domain, and the results were exported.

**Figure 3-14:** Boundary condition for FE simulations. The inferior surface of the L5 was fixed rigidly.
3.3.3.2. Pullout testing

For the pullout test, inferior and superior endplates of the L5 vertebra were constrained in all six degrees of freedom. Interactions between screw parts as well as the screw and vertebra were defined, as in the ROM testing. Then, a new coordinate having the x-axis along the screw axis was identified. A reference point was coupled to the surface of the tulip head, and an axial load was applied on the reference point along the x-axis (screw’s axis) of the newly defined coordinate. Finally, the model was implemented in a static domain, and load displacement for the reference point was reported.
3.3.4. Analysis criteria

For the finite element model analysis, the maximum von Mises stress was determined on each screw to establish the strength and safety factor of each design. A stress counter on each screw showing the location of maximum stress can aid in modifying the design to propose a stronger screw with a higher safety factor. In addition, von Mises stress at the superior and inferior endplates of the L5 and L4 vertebrae were reported. These endplates are of interest as they can indicate an increased risk for subsequent post-operative vertebral fracture.

The torque required to spread the expanding part of the inner screw in the bone was calculated from the axial load applied on the inner screw. This torque can be used for evaluation of inner screw strength as well as designing a strong inner-screw driver. ROM and pullout testing results also show the success of the design in providing stability and addressing the poor screw-bone interface in osteoporotic bone.

3.4. Cadaver study

3.4.1. Implant preparation

A cadaver study was planned to perform pullout testing for the two best designs as well as for a conventional screw for comparative evaluation. Based on the FE results of ROM testing, pullout testing, and stress on the screw (safety factor), the bottom expanding screw and transverse expanding screw were selected as the two best designs for further cadaveric evaluation (these results are reported and discussed in the Results
Because the intention of the new designs was not to change the feature designs of the main screw (thread length, thread depth, and so forth), eight pedicle screws were bought from Spinal Balance, Inc. The screws were 40 mm long, with 6.5 mm and 4.8 mm major and minor diameters, respectively. They had a 1.7 mm cannulation and were made of titanium. Drawings of expanding parts and inner screws were then prepared, and two sets of each design were manufactured from titanium. The screw cannula was threaded to host the inner screw, and the screw length was shortened based on the pedicle length of the specimens measured from the CT scans of the vertebrae (Figure 3-16). Length was adjusted based on the pedicle length such that after screw insertion, it provides a 4 mm gap for expansion before reaching the cortical shell. The manufactured parts (expanding parts and inner screws) were assembled to the main screws and were used for the experiments.
Figure 3-16: CT scans of the specimens were taken to measure the pedicle length. Pedicle length was measured from the start of the bony part, from the anterior where the pedicle begins along the pedicle axis to the posterior cortical shell.

3.4.2. Specimen preparation

Four L4 vertebrae were selected for the testing. These vertebrae were scanned with DEXA to determine the T-score. Table 3-5 shows the condition of each specimen. These vertebrae were dissected carefully from an L1-S1 cadaver leaving the posterior elements intact, and the vertebrae were cleaned while ensuring no damage was done to
the endplates. CT scans of each vertebra were taken to measure the pedicle length and diameter (Table 3-4). The vertebrae were refrigerated and thawed 24 hours before the experiment. Each vertebra was potted using Bondo to enable installation in the fixture.

**Table 3.4:** Condition of specimens used for the cadaveric study.

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Age</th>
<th>Sex</th>
<th>T-Score</th>
<th>Condition</th>
<th>Cause of death</th>
<th>Pedicle length (mm)</th>
<th>Pedicle diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Left</td>
<td>Right</td>
</tr>
<tr>
<td>56226</td>
<td>64</td>
<td>Male</td>
<td>-2.2</td>
<td>Osteopenia</td>
<td>Hanging</td>
<td>20.9</td>
<td>21.0</td>
</tr>
<tr>
<td>66166</td>
<td>77</td>
<td>Female</td>
<td>-1.9</td>
<td>Osteopenia</td>
<td>Colon cancer</td>
<td>19.3</td>
<td>18.9</td>
</tr>
<tr>
<td>66207</td>
<td>59</td>
<td>Male</td>
<td>-1.3</td>
<td>Osteopenia</td>
<td>Liver failure</td>
<td>19.9</td>
<td>19.9</td>
</tr>
<tr>
<td>66291</td>
<td>70</td>
<td>Male</td>
<td>-0.4</td>
<td>Normal</td>
<td>Cardiovascular disease</td>
<td>16.2</td>
<td>16.2</td>
</tr>
</tbody>
</table>

**3.4.3. Testing**

Each individual specimen was tested for failure in axial pullout using an MTS testing machine. The test block with a screw inserted was placed on a specially designed universal fixture. The screw was aligned to ensure a pure axial load was being applied on the screw (Figure 3-17), and the pedicle screw was attached to the testing machine by a rod attached to a hook (Figure 3-18). After the specimens were mounted, pullout force was applied at a constant crosshead rate of 5 mm/min [116]. The force acting on the screw during testing was continuously recorded in 0.2 second increments until the peak
pullout resistance was reached, displacing the screw outward. The peak force recorded during the pullout test was defined as the maximum pullout strength for comparison.

**Figure 3-17:** Screw was aligned to the MTS machine axis to ensure a pure axial load.
Figure 3-18: Attachment of the screw to the MTS machine via a hook.
Chapter 4

Results and discussion

In this chapter, the initial results of the FE simulation are reported. This includes the expansion simulation and related required torque, the ROM study of the implanted FSU for both normal and osteoporotic bone, and the pullout test results. The results of the cadaveric pullout test for two expanding designs are reported and discussed subsequently. The simulation results indicated that all the new screw designs could provide similar stability compared to conventional screws while increasing the pullout strength of the screws. However, experimental result did not show an increase in pullout strength value for the new screw designs.

4.1. Finite element results

4.1.1. Expansion of screw

After each screw was inserted in the pedicle, an axial load was applied on the inner screw head to expand the screw. This load displacement was recorded and is given in Figure 4-1. To calculate the torque required to drive the screw intraoperatively,
Equation 4-1 was used, with $T_r$ being the torque required for expansion, and $T_f$ being the torque induced by friction. In this equation, $T$ is the required torque to drive the screw, $D_p$ is the effective pitch diameter derived from Equation 4-2 using $D_{maj}$ (major diameter, which is 3 mm for the inner screw) and $P$ (screw pitch, which is 0.5 mm). $F_A$ is the axial load on the screw induced by screw expansion, $\mu$ is the friction coefficient for the titanium, which is 0.52 [117], and $\theta$ is derived from Equation 4-3. $B$ is the screw tip angle, which is 60° in this design.

\[
T = T_r + T_f = D_p F_A (\sin \theta + \mu \cos \theta) \frac{2}{2(\cos \theta - \mu \sin \theta)} + \sin \left(\frac{\beta}{2}\right) F_A \mu D_{min}
\]  \hspace{1cm} (4-1)

\[
D_p = D_{maj} - 0.649519 P
\]  \hspace{1cm} (4-2)

\[
\theta = \tan^{-1} \left( \frac{P}{\pi D_{maj}} \right)
\]  \hspace{1cm} (4-3)

Substituting the amounts into the equations yields:

\[
T = 1.85 \times 10^{-3} F_A
\]  \hspace{1cm} (4-4)

In addition, by substituting the axial load ($F_A$) extracted from FE simulation into Equation 4-4, one can calculate the required $T$, which is given in Table 4-1.

A self-locking screw is a screw that does not turn or move backward due to the axial force on its shaft until an external torque is applied. Equation 4-5 is the governing equation on self-locking screws. In this design, since $\mu$ is 0.52 and is greater than $\tan \theta$ (that is, 0.052), that is a self-locking mechanism, which means that the screw would not collapse or turn back to the initial position after expansion or under physiological loads in the human body.
\[ \mu > \tan \lambda \]  \hspace{1cm} (4-5)

To compare the designs in terms of strength, stress distribution after screw expansion with the maximum value is shown in Figure 4-2.

**Figure 4.1:** Load displacement data for expansion simulation of screws.

**Table 4-1:** Required torque for expansion of each screw design calculated from axial force result from FE simulation.

<table>
<thead>
<tr>
<th></th>
<th>Cancellous expanding screw</th>
<th>Bottom expanding screw</th>
<th>Transverse expanding screw</th>
<th>Window expanding screw</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Axial load, ( F_A ) (N)</strong></td>
<td>1110</td>
<td>900</td>
<td>50</td>
<td>315</td>
</tr>
<tr>
<td><strong>Required torque, ( T ) (N m)</strong></td>
<td>2.05</td>
<td>1.67</td>
<td>0.1</td>
<td>0.58</td>
</tr>
</tbody>
</table>
Figure 4-2: Stresses on the screw after expansion in a) cancellous expanding screw, b) Bottom expanding screw, c) transverse expanding screw, and d) window expanding screw.

4.1.2. ROM results

After insertion of screws in the L4-L5 FSU, a 10 N m moment was applied on the superior endplate of the L4 vertebra. For each 2.5 N m increment, the location of three predefined nodes on each vertebra was exported to the macro Excel sheet, and
ROM was calculated for each case. The results for all the designs as well as the conventional screw are given in Figures 4-3 and 4-4 for an FSU with normal bone and osteoporotic bone. For an improved comparison, the ROM for an intact (non-implanted) model with a healthy disc is provided. Results show similar stability to traditional screws for all new designs in both normal and osteoporotic bone. Both the transverse and bottom expanding screws were able to reduce motion compared to a conventional screw in all physiological loadings (flexion, extension, and so forth), with an average of 2.2 percent greater reduction in motion. This means that despite losing bone purchase in cancellous bone, added cortical bone anchorage could restore the rigidity of the construct and provide similar stability. The window expanding screw showed the least motion and the most stability, averaging 6 percent higher reduction in motion. This could be expected due to the cortical anchorage of the screw, which maintains the bone purchase of the screw in the cancellous bone region.
Figure 4-3: ROM results for all screw designs compared with intact FSU extracted from FE simulation with normal bone.

Figure 4-4: ROM results for all screw designs compared with intact FSU extracted from FE simulation with osteoporotic bone.
Figure 4-5 shows the ROM for each individual screw separately in normal and osteoporotic bone compared to the intact model. As expected, these results show that the screw construct could provide greater stability in an FSU with normal bone than one with osteoporotic bone, which is due to the poor bone quality in osteoporotic bone. Stresses on the endplates as well as the entire FSU with osteoporotic bone are shown in Figure 4-6. In addition, stresses on the implant construct are shown in Figure 4-7. Stress values and the calculated safety factors in different physiological loadings (for example, flexion and extension) are provided in Table 4-2 and 4-3.
Figure 4-5: ROM results for all screw designs compared with intact FSU extracted from FE simulation differentiated by design.
Figure 4-6: Stress distribution on the endplates and FSU with osteoporosis at 10 N m flexion for a) cancellous expanding screw, b) bottom expanding screw, c) transverse expanding screw, and d) window expanding screw.
Figure 4-7: Stresses on the implant construct at 10 N m flexion in the FSU with osteoporotic bone for a) cancellous expanding screw, b) bottom expanding screw, c) transverse expanding screw, and d) window expanding screw.
**Table 4.2:** Stress values for all screws in different physiological loading at 10 N m.

<table>
<thead>
<tr>
<th></th>
<th>Cancellous expanding screw</th>
<th>Conventional screw</th>
<th>Transverse expanding screw</th>
<th>Window expanding screw</th>
<th>Bottom expanding screw</th>
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</thead>
<tbody>
<tr>
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<td>Osteoporotic bone</td>
<td>Normal bone</td>
<td>Osteoporotic bone</td>
<td>Normal bone</td>
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<tr>
<td>Flex</td>
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<td>326</td>
<td>58.2</td>
<td>59.1</td>
<td>68.9</td>
</tr>
<tr>
<td>Ext</td>
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<tr>
<td>Lben</td>
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<td>371</td>
<td>93.3</td>
<td>102</td>
<td>90.8</td>
</tr>
<tr>
<td>Lrot</td>
<td>215</td>
<td>209</td>
<td>54.3</td>
<td>52.4</td>
<td>60.2</td>
</tr>
<tr>
<td>Fwp</td>
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</tr>
<tr>
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<td>353</td>
<td>368</td>
<td>53.9</td>
<td>54.9</td>
<td>54.9</td>
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</tbody>
</table>

**Table 4.3:** Safety factor for all screws in different physiological loading at 10 N m calculated from stress values from Table 4-2.

<table>
<thead>
<tr>
<th></th>
<th>Cancellous expanding screw</th>
<th>Conventional screw</th>
<th>Transverse expanding screw</th>
<th>Window expanding screw</th>
<th>Bottom expanding screw</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Normal bone</td>
<td>Osteoporotic bone</td>
<td>Normal bone</td>
<td>Osteoporotic bone</td>
<td>Normal bone</td>
</tr>
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<td>Flex</td>
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<td>13.23</td>
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<td>2.16</td>
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4.1.3. Pullout results

Pullout testing was simulated in a model with normal and osteoporotic bone; pullout results for a conventional screw are reported for improved comparison. Pullout failure load is used as a parameter to determine the bone purchase of a screw, which determines the strength and stability of the screw in the bone. Figures 4-8 to 4-9 show the results of simulation. Failure load, ultimate load, energy to failure, total energy, and stiffness were calculated and are provided in Table 4-4. Plots stop where von Mises stress on either the screw or the bone material reached its failure value. Failure load for the conventional screw in a normal bone was 270 N, which increased in all new designs. It increased to 390 N (40 percent increase) for cancellous bone and 800 N (200 percent increase) for other designs. These results prove the hypothesis that a design with anchorage within cortical rather than cancellous bone can offer improved pullout force.

In an osteoporotic bone, the failure load dropped to 170 N (38 percent decrease) for the conventional screw, while it was restored by the new designs. For the cancellous expanding screw, the failure load was 360 N, which is almost twice the value for a conventional screw in osteoporotic bone and 33 percent greater than for a conventional screw in normal bone. Screws providing anchorage in the cortical shell yielded significantly better results. Window expanding screws showed the largest pullout force (840 N, an increase of 196 percent) compared to a conventional screw in normal bone. Cortical and transverse expanding screws also performed better, increasing the failure load to 660 and 540 N, respectively.
**Figure 4-8**: Pullout simulation results in FE for a model with normal bone.

**Figure 4-9**: Pullout simulation results in FE for a model with osteoporotic bone.
Table 4.4: Pullout simulation data in FE.

<table>
<thead>
<tr>
<th></th>
<th>Normal bone</th>
<th>Osteoporotic bone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Load (N)</td>
<td>Failure (N)</td>
</tr>
<tr>
<td>Cancellous expanding</td>
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<td>600</td>
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<tr>
<td>Bottom expanding</td>
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<td>800</td>
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<tr>
<td>Transverse expanding</td>
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<td>720</td>
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<tr>
<td>Window expanding</td>
<td>840</td>
<td>840</td>
</tr>
<tr>
<td>Traditional screw</td>
<td>270</td>
<td>405</td>
</tr>
</tbody>
</table>

4.2. Cadaver study results

To investigate the reversibility of expansion, each design was inserted in a previously used L5 vertebra and expanded, and was then screwed back to collapse the prongs and taken out of the vertebra. In all three cases, the screw successfully came out of the vertebra without causing additional damage. Figure 4-10 shows the screw insertion procedure and final configuration of the expanded screw captured with a fluoroscopy scan. The surgeon pointed out the ease of expansion without high resistance during rotation of the inner screw. Figures 4-11 and 4-12 show the pullout test results in the cadaver. Results indicate a lower pullout force for the bottom expanding screw compared to the conventional screw, while the transverse expanding screw showed even failure force. The expanding screws were pulled out completely and are shown in Figure 4-13. The bottom expanding screw came out without breaking and without damaging the
pedicle. The transverse expanding screw came out without damaging the pedicle, but one of the prongs was broken (Figure 4-13).
Figure 4-10: Screw insertion steps with final configuration after expansion for a) bottom expanding screw and b) transverse expanding screw.

Figure 4-11: Pullout test results on the L4 level of specimen 56226 for bottom expanding and traditional screws.
Figure 4-12: Pullout test results on the L4 level of specimen 66166 for transverse expanding and traditional screws.
Figure 4-13: Screws after pullout for a) bottom expanding screw and b) transverse expanding screw.
Chapter 5

Summary and Discussion

Pedicle screws are the gold standard of fixation for the thoracic and lumbar spine in the field of surgical treatment of spinal disease. Their existence has revolutionized the surgical treatment for a wide variety of spinal conditions, including deformation and degenerative, traumatic, and cancer-related diseases. The stability and bone purchase of pedicle screws are sufficient to manage patients with spinal pathologies in most cases. However, in the case of osteoporosis, the conventional pedicle screw can be limited due to insufficient bony purchase resulting in early failure. This failure could bring both catastrophic outcomes for the patient and significant challenges for the surgeon.

Current instrumentations indicate common drawbacks in maintaining patients’ alignment. In these cases, further surgeries, such as reconstruction of the anterior spinal column, are required to obtain sufficient stability for patients [118]. Hence, the need for a second, larger anterior procedure to withstand secondary deformity due to the instability caused by trauma can be limited by improving a posterior contract method.
In the case of osteoporosis, problems arise that are more significant. For example, pedicle screws tend to decrease insertional torque, pullout strength, and toggle strength [40, 42, 119]. Furthermore, early and late osteoporosis instrumentation failures have brought a major challenge and cost to the healthcare system [44]. Thirteen percent of early complication rates and 26 percent of late complication rates are associated directly with inadequate fixation, with complications including pedicle fractures, compression fractures, pseudoarthrosis, and progressive deformity [37]. There are severe limitations to treating osteoporotic patients with spinal instrumentation due to its tendency to fail. Hence, employing multilevel instrumentation to establish multiple points of fixation and longer procedures with increased complication rates in patients already compromised by age-related co-morbidities are required [37, 43].

In an attempt to improve fixation in osteoporotic patients, some surgeons recommended the use of cement. However, this approach is not an ideal solution [45]. The main problem relates to screw removal, which can result in injury to the entire vertebral body. Moreover, the cement, which is injected in a liquefied state, can penetrate the canal and potentially cause irreversible nerve injury [5, 49]. Other research groups have suggested bone mineral density testing for all patients who are susceptible to osteoporosis. Although osteoporosis can be identified by this test, the lack of existing surgical options can halt the treatment process [42]. Additionally, some research groups have used larger-diameter screws despite pullout strength not increasing by increasing
screw diameter [50, 120]. Furthermore, pedicle canal size can limit screw diameter and increase the risk of pedicle fracture.

Since the inception of pedicle screw introduction, numerous researchers have investigated various screw shapes and thread patterns to achieve more efficient screw fixation. It has been proven that a screw with a conical minor diameter and V-shaped thread containing a pitch of 2.8 mm provides the best fixation in both osteoporotic and normal bone [47, 52, 56, 57]. Yet despite commercially available pedicle screws, including the Xia® screw from Stryker®, taking advantage of these design elements, the treatment of patients with osteoporotic bone remains challenging. Furthermore, utilization of a conical minor diameter is problematic if the screw is withdrawn, resulting in decreased pullout strength [59]. The necessity of withdrawing a screw cannot be disregarded in the operating room, specifically when the connecting bar does not match the adjacent screw due to height inequality or if the screw simply is placed deeper than initially planned.

Modified methods have been employed to improve the pullout strength of the pedicle screw. These methods rely on how the screw hole is prepared as well as the screw angle during placement. However, it has been pointed out in several investigations that preparation method has little effect on the overall pullout strength [69, 71, 121]. For example, horizontal insertion generates greater pullout strength than placing the screw along the anatomic axis of the pedicle. In this study, preparation of the screw hole was accomplished using an approach similar to placing the screw along the axis of the
pedicle. In addition, a pilot hole 4.5 mm in diameter was drilled to standardize the angle of insertion. The researchers believe that this pilot hole is unlikely to affect overall screw performance.

Various approaches have been developed successfully to develop expandable pedicle screws to address their current limitations in osteoporotic bone or revision surgery. The majority of studies conducted were focused on screw expansion in the basis of the vertebral body post insertion, with a 30 percent increase in mean pullout strength and increased versatility in in-vivo applications. However, the existing clinical data does not sufficiently support the efficiency and safety of these devices. OsseoScrew-Zodiac® (Alphatec Spine, Inc., Carlsbad, California), a commercially available expandable screw, is intended for use in patients who suffer from osteoporosis. Based on the results, an only 30 percent increase in ultimate failure was observed using this screw compared to a standard screw.

The research team was able to propose four new expanding screws to address the loosening of the screw in osteoporotic bone. The first design, the cancellous expanding screw, includes a main screw like a traditional screw, with an expanding part attached to the bottom. This attached part expands in the cancellous bone intraoperatively after screw insertion. The screw is reversible and can be collapsed for ease of removal if the need arises to do so. The other three screws are designed such that after expansion in the vertebra, they reach the strong cortical shell around the vertebral body and provide stronger anchorage for the screw. Two of these screws (not the bottom expanding screw)
are reversible. The transverse expanding screw offers less resistance to expansion, whereas the window expanding design offers safer reversibility of the screw due to the specific design.

All screws were designed and drawn in SolidWorks before each screw was imported to Abaqus for evaluation. A 3D-validated model of the L4-L5 level was used. Pullout and ROM studies were simulated for all screw designs as well as traditional screws for improved comparison. Results show that all four new screw designs provide similar stability to traditional screws. The pullout study showed increased pullout failure load from 100 to 370 percent for different designs in osteoporotic bone and could restore its value for a traditional screw in normal bone. Based on the FE simulation results and screw performance, including their stability (ROM), pullout strength, and safety factor, the bottom expanding and transverse expanding screws were selected for manufacturing and further cadaveric study.

The two selected screws were manufactured out of titanium and used for the pullout study. Both screws expanded and collapsed without problems and were screwed out without damaging the pedicle, confirming their reversibility. Pullout test results showed similar pullout failure load to the traditional screw for the transverse expanding screw, while it was half the value of that of the traditional screw for the bottom expanding screw. The bottom expanding screw withdrew completely without breakage or damaging the pedicle, while one of the transverse expanding screw’s prongs was broken after complete pullout.
This unsuccessful cadaveric result could have been induced by two factors. One factor could be the tiny contact area between the prongs’ head and the cortical shell, and its sharp edges, which would cause a stress concentration on the cortex and cause it to fail under lower axial loads. The other factor could be inadequate expansion of the expanding parts. As shown in Figure 4-10, the prongs expand around the threads and do not provide adequate support in the area intended. Because the prongs expand exactly around the threads, they could enhance distortion of the bone surrounding the screw, thus neutralizing the effect of the increased contact area by the expanded part.

To compare the FEA results with cadaver study results, results were scaled in displacement relative to the failure displacement. The pedicle screw length was limited and restricted by the geometry of finite element model and also limitation in available number of specimens for cadaver study. So the pedicle screw length used in FE (22mm for bottom expanding and 25mm for transverse expanding screw) was different from the ones used in cadaver (24.9mm for bottom expanding and 23.3mm for transverse expanding screw). This could introduce 15% difference in length for bottom expanding screw and 10% for transverse expanding screw, which expected to be negligible compared to the strength gained through anchorage to the cortical bone. Figure 5-1 shows both FEA and experimental results in one plot. This shows that FEA stiffness and failure load is lower than experimental. This could have been because of the difference in osteoporosity in FEA (Osteoporotic model) and experimental specimens (Osteopenia).
Figure 5-1: Comparison of pull-out study between FEA and experimental

Regarding future work, as the design was expanded successfully and collapsed and withdrawn safely, further development of the design is worthwhile. By changing the design parameters, such as expanding the part length or screw tip angle, increased expansion can be achieved. Among the proposed designs, the transverse expanding screw has the potential to achieve greater expansion and, therefore, an increased support area without failure due to the design features. Furthermore, the addition of a soft material or absorber to the head of the prongs could avoid stress concentration and the related cutting effect.
One of the reasons for designing such tiny prongs was the limitations in the geometry. The outer diameter of the inner screw limited the inner diameter; the outer limit was the pedicle screw’s minor diameter. For screws used in bigger vertebrae, a larger screw diameter is used and, hence, a bigger area is available to increase the cross section of the expanding part. This can help to increase the support or anchorage area and, thus, possibly increase the pullout strength for some series of pedicle screws.
References


