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Localized Expansion of Pedicle Screws for Increased Stability and Safety in the Osteoporotic Spine

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Localized Expansion of Pedicle Screws for Increased Stability and Safety in the Osteoporotic Spine

by

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A thesis submitted in partial fulfillment
of the requirements for the degree of
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DEDICATION

This thesis is dedicated to my parents who have supported me more than I ever could have hoped for in my educational endeavors over the years. Though I will try, I will never be able to repay you. I also want to dedicate this to my beautiful fiancé, Melanie, who has gone above and beyond to take on any burdens that would otherwise distract from this project. This is for my friends and family who have provided words of encouragement (and sometimes free food) while they waited patiently for me finish my thesis. And I would finally like to dedicate this to my late grandfather who encouraged me years ago to pursue a degree in biomedical engineering.

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ABSTRACT

When a patient is diagnosed with various spinal injuries, deformities, or advanced degeneration, it is commonly suggested that he/she undergoes surgery for spinal fusion. Most current procedures in spinal fusion restrict mobility in one or multiple levels of the spine so that, over time, new bone will grow between the levels creating a single motionless unit of bone. The bilateral pedicle screw system (BPSS) has long been considered to be the "gold standard" in spinal fusion. However, for patients with osteoporosis, adequate fixation within the bone-screw interface has continuously been difficult to achieve or has come with high risk of other forms of catastrophic damage. Reflecting this, a new pedicle screw design was developed and evaluated against current standard pedicle screws commonly used in spinal surgery. All screw designs were also tested with a common cement augmentation technique surrounding the circumference of the screw. All tests measured pullout strength, stiffness, energy to failure, toughness, and the amount of destruction to the surrounding synthetic bone. While the newly designed pedicle screw failed to produce significantly stronger pullout forces in comparison to the standard screws, it did show evidence of a longer lasting residual axial resistance and a safer mode of failure than the standard screw, hinting that the design may benefit individuals who experience screw pullout and are awaiting reinstrumentation.

CHAPTER 1: INTRODUCTION

1.1 Research Objectives

The bilateral pedicle screw system (BPSS) has long been considered the "gold standard" in spinal fusion techniques. However, to this day, difficulties still exist in achieving adequate fixation in bone of poor quality, such as is seen in patients with osteoporosis. As a result, various screw designs and insertion techniques have been attempted in hopes of increasing the pullout strength of pedicle screws in this low quality bone. However, many of the most successful attempts have also been accompanied with an increased risk of catastrophic damage to the patient. The aim of this study was to design and test a pedicle screw which not only increases the fixation of the screw in an osteoporotic model, but also, should failure occur, controls the resulting damage to a location away from the surrounding nervous system.

1.2 General Medical Terminology

Before one can understand the anatomy of the spine, a basic understanding of the terminology used by physicians to describe both position and direction in the body is essential [1]. Location is first described by relating it to one of four planes dividing the body (Figure 1.1). The *transverse plane* separates the upper and lower halves of the body, the *frontal plane* divides the front half from the back, and the *sagittal plane* divides the left and right sides. The fourth plane, the *median plane*, is parallel to the sagittal, but rests in the exact center of the body creating a near mirror image between the left and right sides [2]. Additionally, the location that one point has in relation to another in the body is also described (Figure 1.2). For instance, a point

located above or below another would be referred to as being *superior* or *inferior*, respectively, to it. This is sometimes also referred to as being *cranial* ("towards the cranium, or head") or *caudal* ("towards the tail"). Points in the body located closer to the median plane are referred to as having a *medial* position while those closer to the left or right sides are said to be more *lateral*. Furthermore, a forward facing position is referred to as being *anterior* while a position closer to the back is described as *posterior*. Finally, when talking about limbs such as the arms or legs, points closer to the body (such as the upper arm or thigh) are described as being *proximal* while those further away from the body (like fingers and toes) are referred to as being *distal* [1, 2].

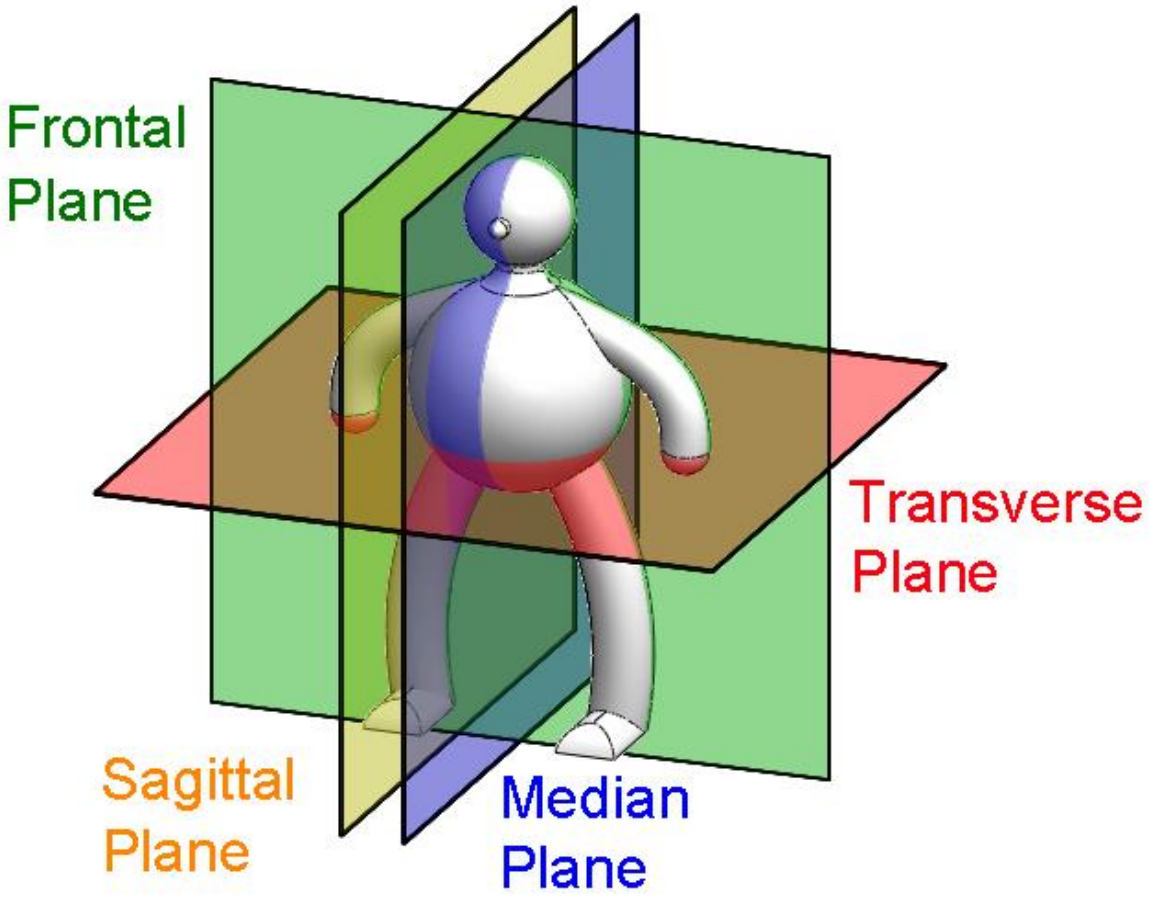

Figure 1.1. Anatomical planes of the body.

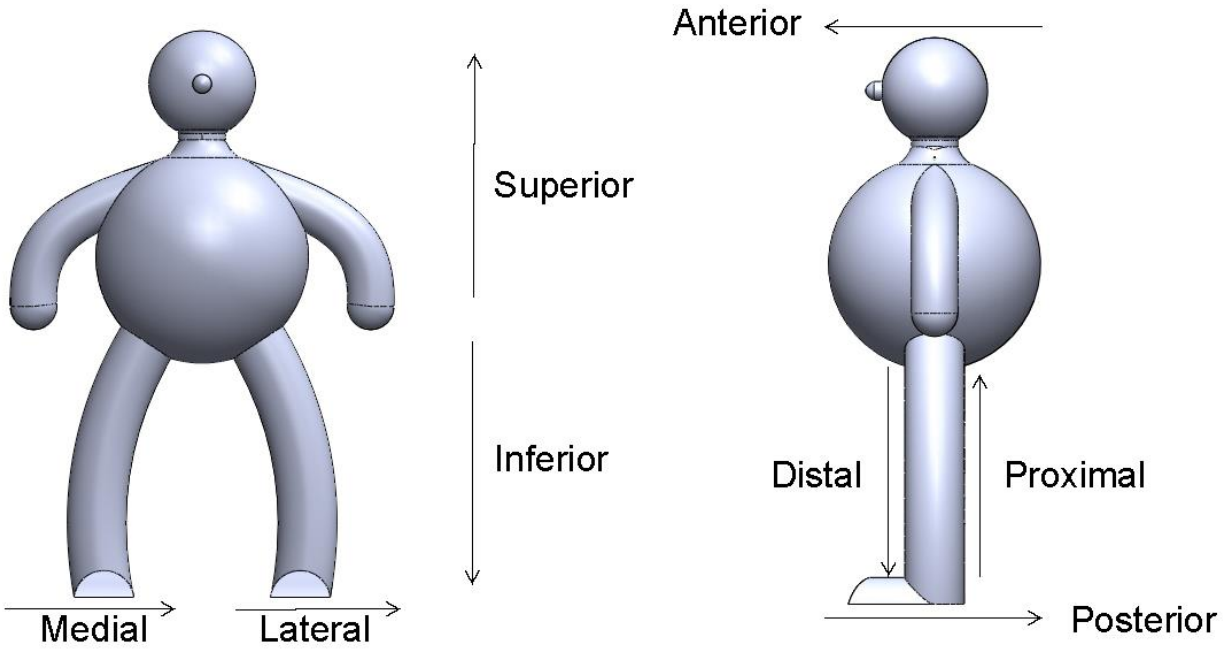

Figure 1.2. Anatomical position and relationship.

1.3 The Vertebral Column

Originating at the cranium, the human vertebral column consists of a series of 33 inferiorly extending vertebrae divided into five sections (Figure 1.3). The superior most section of the vertebral column is the cervical which consists of seven vertebrae that make up the neck, followed by twelve vertebrae in the thoracic, five in the lumbar, and five and four fused vertebrae making up the sacrum and coccyx, respectively. Each of the cervical, thoracic, and lumbar vertebrae are separated by intervertebral discs, which allow for flexibility of the spine. In general, due to the larger loads that are placed on inferior vertebrae as opposed to those more superior, the size of each individual vertebra increases inferiorly down the spine until reaching L5 and then decreases again at the sacrum and coccyx [2].

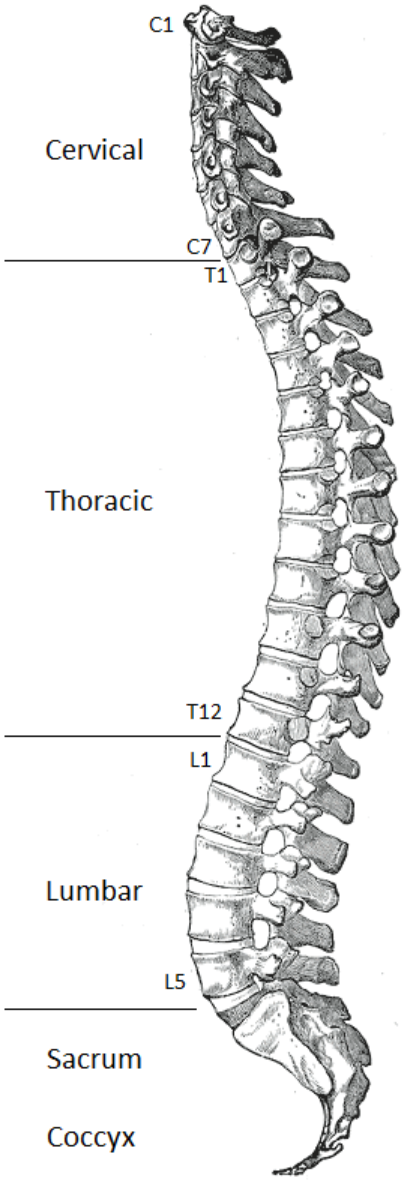

Figure 1.3. The human vertebral column. (Public Domain) Adapted [3].

1.3.1 Vertebra

Despite slight variations in size and function, each vertebra, particularly those in the cervical, thoracic, and lumbar sections, share common characteristics. Anteriorly, they are composed of a large, mostly cylindrical, structure called the vertebral body (Figure 1.4). The vertebral body is primarily composed of porous bone, known as trabecular bone. It is surrounded

by an epiphysial rim (approximately 0.5 mm thick) characterized as a more compact bone, referred to as cortical bone [2, 4]. Endplates composed of hyaline cartilage make up the majority of the superior and inferior ends of the vertebral body [2]. Physiologically, the endplates serve as semipermeable barriers that permit limited fluid diffusion between the intervertebral disc and the trabecular bone in the vertebral body [2]. Mechanically, the endplate provides a large surface through which forces placed upon the vertebral body can be distributed [4].

At the anterior side of the vertebral body lies the aorta. At its arch, the aorta makes contact with the T4 vertebra. From here, it descends down the spinal column along the anterior wall of the vertebral body [2] (Figure 1.5). Once the aorta approximately reaches the L4 or L5 vertebra, it branches into the two common iliac vessels [2, 5].

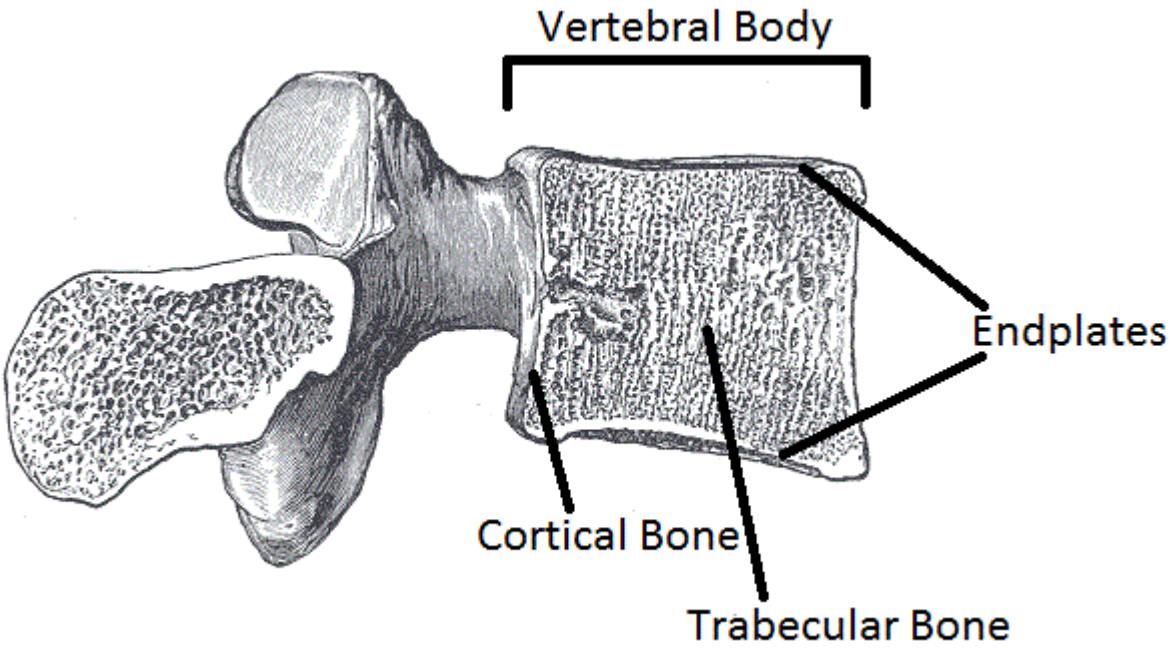

Figure 1.4. Median section of the vertebra. (Public Domain) Adapted [3].

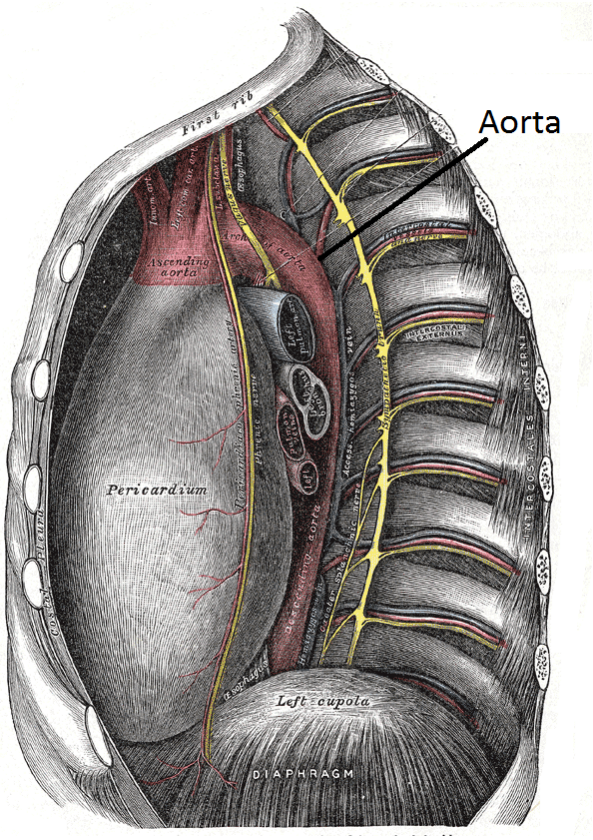

Figure 1.5. The aorta in the thoracic cavity. (Public Domain) Adapted [3].

Extending posteriorly from the vertebral body is the vertebral arch which is made up of a left and right pedicle and a connecting lamina (Figure 1.6). The vertebral body and vertebral arch combine to form an opening between them known as the vertebral foramen. Extending down the vertebral column, this opening is referred to as the vertebral canal, which is the path through which the spinal cord descends [2]. The surrounding vertebral body and vertebral arch forms a protective barrier around the spinal cord [2, 4]. At each vertebral level, spinal nerve roots extend from the spinal cord for innervation throughout the body [2]. These nerve roots, especially in the lumbar spine, will exit the vertebra nearest to the medial and inferior edges of the pedicle [6] (Figure 1.7).

Protruding from the vertebral arch are seven processes (Figure 1.8). The spinous process is located along the median plane and extends posteriorly. Two transverse processes are located where the pedicles and the lamina meet and extend posterolaterally. The spinous and transverse processes provide attachment points for musculature and are essential for movement. Four articular processes (also referred to as the facets) protrude superiorly and inferiorly from the intersection of the pedicles and lamina. Unlike the other three processes described, the facets are intended to limit motion to fall within a certain range [2].

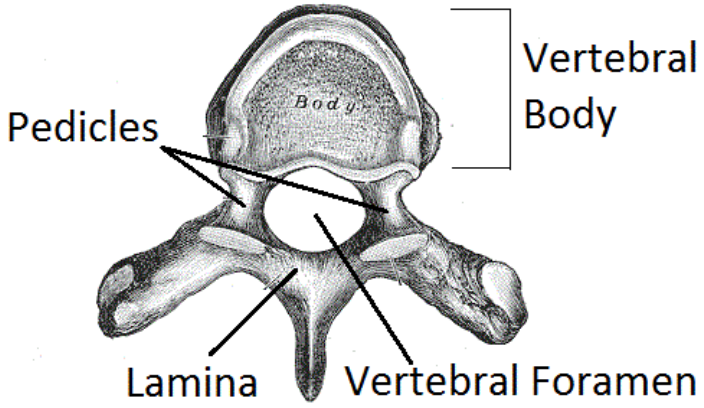

Figure 1.6. A superior view of the human thoracic vertebra. (Public Domain) Adapted [3].

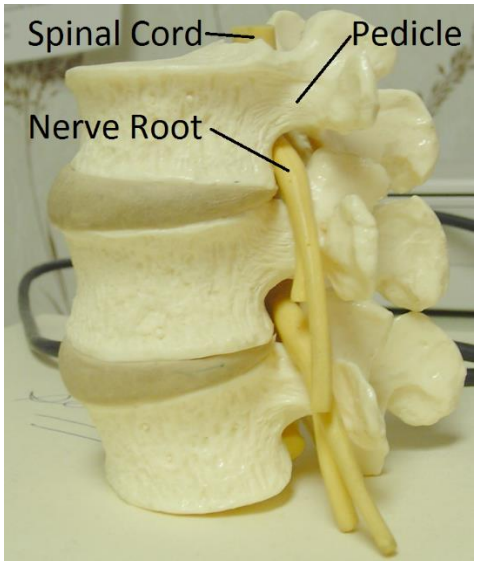

Figure 1.7. Spinal cord and nerve root location relative to the pedicle. (Public Domain) [7].

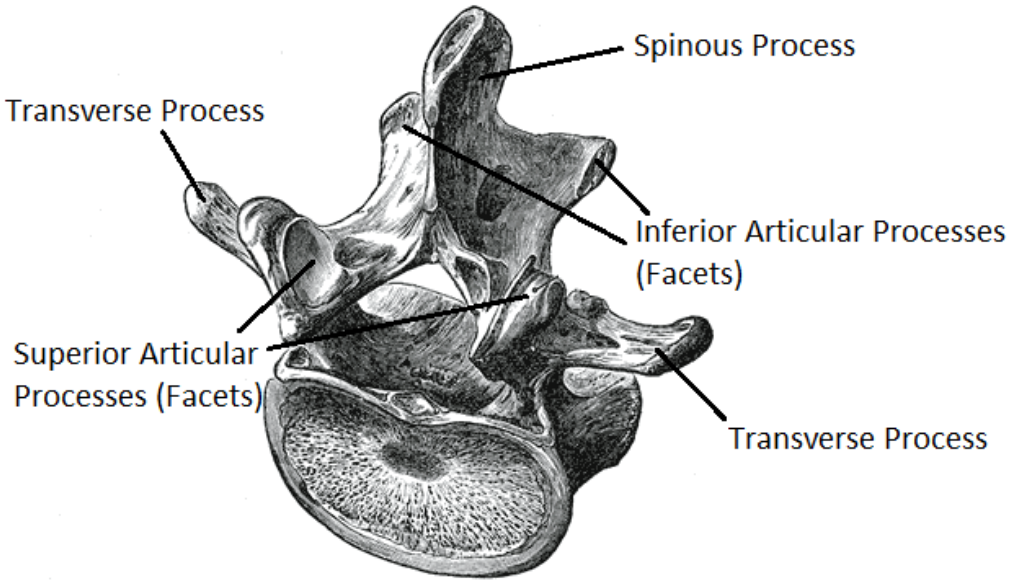

Figure 1.8. The processes of a lumbar vertebra. (Public Domain) Adapted [3].

1.3.2 Intervertebral Joints

The intervertebral discs, located between each vertebra of the cervical, thoracic, and lumbar regions of the spine, not only function as a mode of flexibility of the spine, but also helps to distribute axial loads better throughout the vertebral body (Figure 1.9). Similar to the vertebrae that they separate, the cross sectional area of the intervertebral discs increase as they progress inferiorly from the cervical to the lumbar regions. They are composed of a gelatinous core known as the nucleus pulposus surrounded by an anulus fibrous (Figure 1.10). In a healthy disc, the nucleus pulposus accepts the majority of the loads during extension and tension while the fibrous rings of the anulus assist in resisting bending and torsion [2, 4]. However, as one ages and the disc begins to degenerate, the nucleus becomes stiffer and less elastic. As this occurs, the anulus is then required to assume the brunt of the loading. If the loading becomes too great, this can result in annular rupture [2, 4].

Located on the anterior side of the vertebral body, the anterior longitudinal ligament helps to stabilize the intervertebral discs while simultaneously preventing hyperextension of the joint. Similarly, the posterior longitudinal ligament (not pictured) stabilizes the posterior side of the disc and prevents hyperflexion. Additional ligaments also help to limit excessive motion, such as the intertransverse ligaments located between adjacent transverse processes (Figure 1.9) [2].

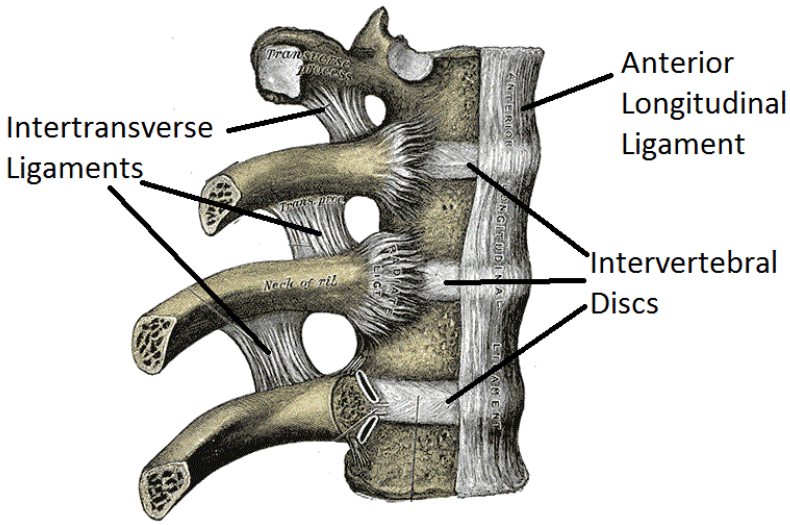

Figure 1.9. Spinal segment including intervertebral discs and ligaments. (Public Domain) Adapted [3].

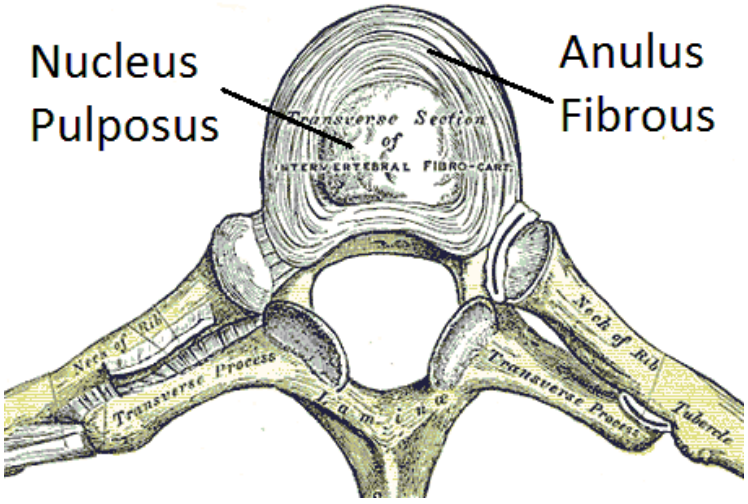

Figure 1.10. Transverse section of intervertebral disc. (Public Domain) Adapted [3].

1.4 Spinal Fusion

Spinal fusion is a procedure in which multiple levels of the vertebral body are held stationary and placed in a situation that would allow bone to form between them, thus creating a single spinal unit [8]. Adapted from arthrodesis, where joints were fused together to relieve pain, the main goal of spinal fusion is to treat spinal instability [8, 9]. In order to perform this procedure, a number of techniques can be utilized, including placing cages between endplates of adjacent vertebrae, bone grafts, bone morphogenetic proteins, and pedicle screws [8].

1.5 Pedicle Screws

Screws have been in use for spinal fusion for well over half a century. The technique was likely originated by King [10] in the mid-1940s when he attempted to stabilize a lumbar spine by placing screws through the facets. In the late 1950s, Boucher [11] furthered King's idea by placing long screws through the pedicle which, a few decades later, led to the addition of a rod to simultaneously fuse multiple levels together [12]. Since then, pedicle screws have been considered the "gold standard" in spinal fusion technology.

It was reported that over 50% of all the money put into spinal implants by hospitals in 2004 went into pedicle screws and their supplementary products such as rods, heads, and set screws [13]. Standard pedicle screws are created in a variety of lengths and diameters depending on the size of the pedicle and vertebral body for which it is to be inserted. As of 2004, the majority of these screws (75%) were placed in the lumbar levels. As a result, the most commonly used diameter of this timeframe was 6.5 mm (33%) and the two most common lengths were 40 mm (29%) and 45 mm (26%). However, screws as small as 3.5 mm in diameter and/or 14 mm in length were used, most likely for instrumentation in the smaller pedicles of the cervical spine [13]. The

shaft of the screw typically consists of a single lead thread with a pitch more akin to wood screws to accommodate the mechanical properties of the surrounding bone. The head of the screw often resembles a cup with a U-shaped cutout to fit the rod used to connect pedicle screws on adjacent levels. The head can either be fixed to the screw or it can be allowed freedom to rotate, such as with the polyaxial screws used in this study. Pedicle screws are made out of biocompatible materials such as stainless steel or titanium [13]. Similar to the anatomical directions used in the human body, the term *distal* has been used to describe a location closer to the screw's tip while *proximal* has been used to describe a location closer to the screw's head [14-18] (Figure 1.11).

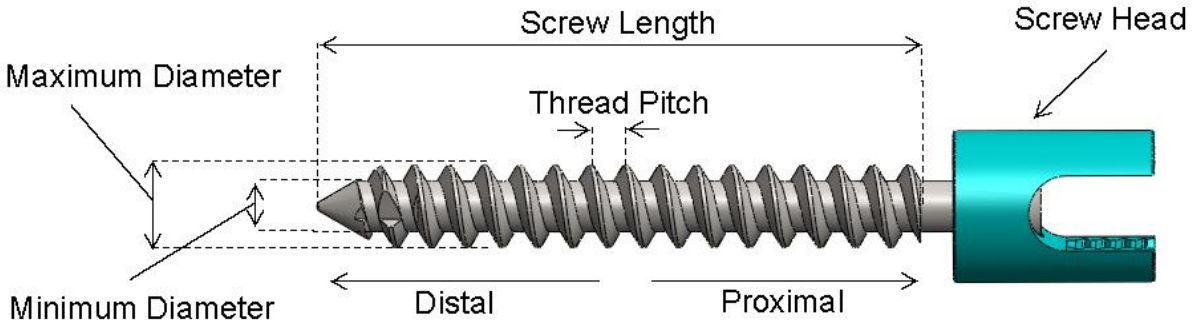

Figure 1.11. Standard pedicle screw.

1.6 Pullout Testing

One of the first steps in determining how effective a pedicle screw is at achieving adequate fixation within bone of any density is to perform a pullout test. The pullout test for pedicle screws involves applying a constant displacement to the device implanted in either a vertebra or block of "synthetic bone," thus creating a gradually increasing axial force. When this force gets large enough, the screw loses its fixation within the surrounding material. This maximum force achieved is referred to as the pullout force. While not commonly seen in a clinical

setting, pullout testing is considered to be one of the most efficient methods to test the fixation of different screw designs in bone since it is simplistic to perform and reproducible [19, 20].

While the most commonly observed parameter of pullout testing is the maximum pullout force achieved, the test can provide other useful information to describe how the device and surrounding bone interact with one another. For example, stiffness is often measured to determine how quickly axial forces within a system increase when placed under tension. Observing the load-displacement curve of a specific pullout test, the stiffness is the slope of the curve prior to the point of pullout. Recording the area under same region of the load-displacement curve can also be used to determine how much mechanical energy needs to be put into the system before pullout is reached. This is referred to as energy to failure. Additionally, though not commonly used, data can be observed past the point of pullout as well. For instance, taking the area under the entire load-displacement curve will provide information on how much mechanical energy is needed to remove the screw completely from the bone or block that it is placed in. This is referred to as the toughness.

1.7 Osteoporosis

Bone within the human body constantly undergoes a process called remodeling, where old bone cells are resorbed by cells called osteoclasts as new bone is created by cells called osteoblasts. The process is essential to keep a sufficient balance of calcium throughout the body [21]. However, an imbalance comes naturally with aging, where osteoblastic activity begins to occur at a slower rate than that of the osteoclasts. As this happens, the density of bone decreases. The maximum bone density a person will have occurs in their late teens to mid-twenties. After that point, bone mass is decreased at roughly 0.3% to 0.5% per year. However, this rate can be

exacerbated based on other conditions. For instance, women during their first five years after menopause can lose bone mass at 5% to 6% every year. Additionally, extended use of certain drugs such as corticosteroids can further induce osteoporosis [22].

Osteoporosis is defined by the World Health Organization as occurring once this loss in bone results in a bone mineral density (BMD) at least 2.5 standard deviations below the mean for a healthy young female [23]. It can be classified as being either primary or secondary in nature. Primary osteoporosis happens as a result of common physiologic processes occurring within the body [24]. This is further classified as being of one of two types: postmenopausal osteoporosis is known as type I and senile osteoporosis is type II [25, 26]. Secondary osteoporosis arises pathologically, potentially as a result of other diseases within the body, lifestyle choices, or as a side effect of certain medications [24, 26].

CHAPTER 2: LITERATURE REVIEW

2.1 Note to Reader

The contents of this chapter contain direct and adapted excerpts which have already been published from an article by Shea et al. [27] in Biomed Research International (formerly titled Journal of Biomedicine and Biotechnology). Hindawi Publishing Corporation's approval of reproduction of the paper for this use can be found in Appendix A. The contributions of each author can be found in Table 2.1.

Table 2.1. Author contribution for Shea et al. [27].

Name of Author	Review of the Literature	Initial Draft of Manuscript	Critical Review of Manuscript	Post-Review Editing	Funding
Thomas M. Shea	X	X	X	X	
Jake Laun	X	X	X	X	
Sabrina A. Gonzalez-Blohm			X	X	
James J. Doulgeris			X	X	
William E. Lee III			X		
Kamran Aghayev			X		
Frank D. Vrionis			X		X

2.2 Effect of Osteoporosis on Spinal Fusion

Osteoporosis has a great impact in spinal disorders and their treatment. Vertebral fractures are the most common type of osteoporotic fracture and responsible for 42–48% of the variation in kyphosis in patients with osteoporosis [28]. In osteoporotic patients with conditions such as kyphosis or compression fractures, complications originate with the continuous failure of

conservative, nonsurgical treatments. This often leads to surgical intervention. However, a principal obstacle that is often encountered with surgical intervention in osteoporotic patients is the possibility of hardware pullout in spinal fusion due to the fragile characteristic of the bone, which can result from either micromotions/injuries or excess force applied at the bone-metal boundary [29]. Furthermore, by-product kyphosis, adjacent level kyphosis after instrumentation (known as junctional kyphosis), can occur in a patient with osteoporosis, which may alter the number of levels involved in the surgical intervention [29]. For these reasons, fusion devices used for osteoporotic patients require specific attention and design enhancement to improve the strength of the bone-screw interface. Thus, these fusion devices are of great interest to the research community.

Despite all the advancements in spinal fusion, achieving optimal pedicle screw fixation within bone of compromised quality is still a concern [15, 30-34]. A variety of designs and surgical techniques have been implemented, both clinically and in laboratory settings, in an attempt to enhance the amount of fixation possible between the pedicle screw and the surrounding bone of osteoporotic patients. This chapter reviews different pedicle screw designs and implantation techniques that have been proposed for osteoporotic patients and have been evaluated under laboratory setup for pullout strength.

2.3 Basic Screw Design

Much needs to be considered when determining the proper pedicle screw design to be used for spinal fusion in an osteoporotic patient. Increasing the diameter and length of the screw has the potential to produce larger pullout forces, but they also increase the risk of fracturing the surrounding, fragile bone [16, 35, 36]. Tapering the diameter of the screw is believed to help

compress surrounding bone, which may in turn enhance the screw's fixation in the vertebra [15, 16, 37-40]. Different thread designs serve a diverse range of mechanical functions that must take into consideration the material properties of the bone that it is to be paired with [39-43]. Moreover, a screw material that would offer not only excellent mechanical properties but also exceptional biocompatible properties is crucial for successful long term performance [33, 44]. Design alteration is a topic of interest in the literature and the pros and cons of altering each design characteristic are individually discussed. Figure 2.1 demonstrates the relative pullout strength of the various screw designs.

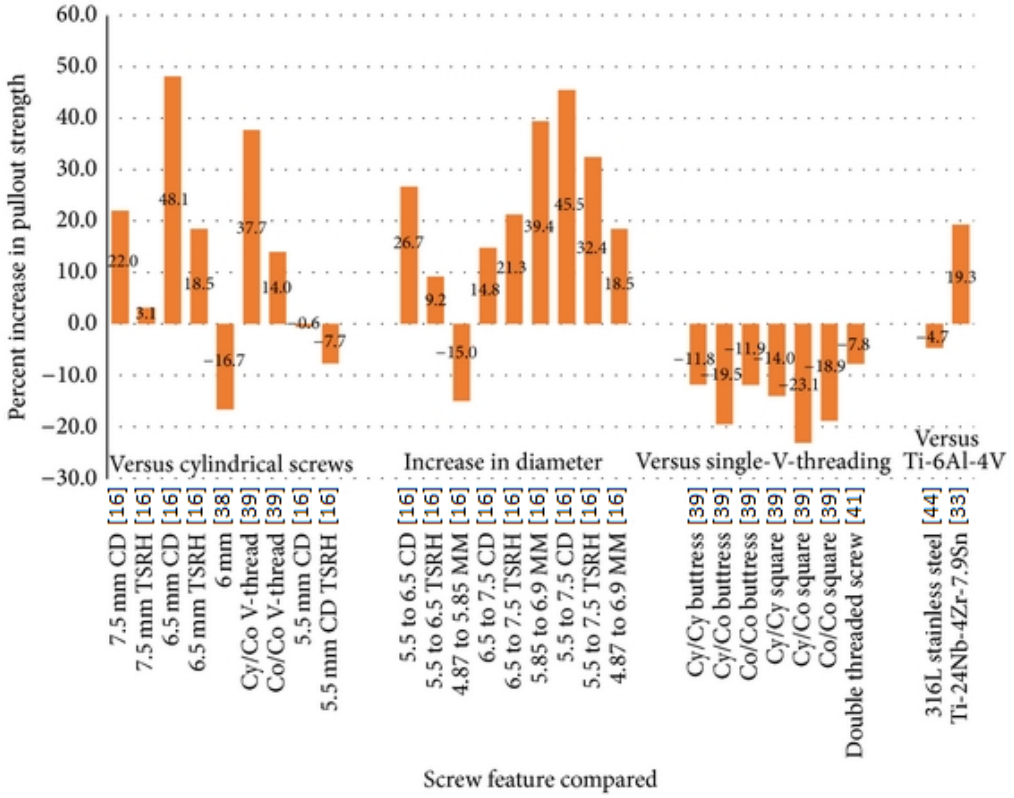

Figure 2.1. Effect of screw design on pullout strength. The percentages are with respect to a standard pedicle screw of otherwise similar dimensions. TSRH: Texas Scottish Rite Hospital (conical screw), CD: Cotrel-Dubousset (conical screw), MM: Moss Miami (cylindrical screw), Cy/Cy: cylindrical thread with conical core, Cy/Co: cylindrical thread with conical core, Co/Co: conical thread with conical core, V: standard thread, and Ti: titanium. Adapted.

2.3.1 Pedicle Screw Size

Quite possibly the most intuitive technique used to achieve a high amount of purchase, where little is expected, is to increase the diameter of the pedicle screw [16, 35, 36]. After all, it is believed that amongst the anatomical considerations of pedicle screw design, the size of the outer diameter best influences pullout strength [45]. Hsu et al. [16] showed that there was a steady increase in the pullout strength as the diameter increased by approximately 1 mm, when testing three different diameters. Zindrick et al. [36] observed significantly higher pullout forces in 6.5 mm cancellous screws than in either 4.5 mm cortical screws or 4.5 mm Louis screws. Likewise, Patel et al. [35] tested cancellous and cortical screws and found that the 2 mm larger cancellous screws significantly increased the fixation strength within a synthetic osteoporotic bone model. Special care must be taken during implantation of larger than usual pedicle screws in bone of compromised quality since the weakened pedicles are more prone to fracture upon screw insertion [46, 47].

In addition to utilizing screws of a larger diameter, adjustments in the screw's length have been made to increase the depth achieved within the vertebral body in hopes of enhancing the pullout strength. It has been suggested that, in most cases, advancing the pedicle screw to about 80% of the vertebral body will provide sufficient fixation [5]; however, Zindrick et al. [36] noted that in osteoporotic specimens, there did not appear to be much of a difference between inserting the screw 50% into the vertebral body or complete insertion, without penetrating the anterior cortex. In these tests, the differences ranged from a 4% decrease to a 16% increase in pullout strength when fully inserted.

2.3.2 Conical Screws

Much of the research being done on pedicle screws involves those with a cylindrical shape (Figure 2.2a) [14, 31, 41, 44, 47-50]. However, some have attempted to increase screw fixation by utilizing conical screws, which involve a tapering of at least the core of the screw to allow for a gradual increase in diameter in the proximal direction (Figure 2.2b) [16, 37-39]. The larger proximal diameter could lead to a decrease in fixation strength since a significant amount of stress is concentrated in the posterior portion of the screw, especially when screw turnback is necessary [38], but a conical shape could enhance pullout strength since the geometry could promote additional compression in the bone surrounding the periphery of the screw [16, 17, 40, 51-53]. Theoretically, increased localized bone density could increase the screw's purchase within the vertebra. Furthermore, from an anatomical standpoint, the conical shape of the screw conveniently matches that of the pedicle, which has an elliptically shaped cross section [36, 38, 48, 50, 53] and anteriorly decreasing diameter [54]. The complimentary geometries of the screw and bone is beneficial since roughly 60% of the pullout strength of a pedicle screw is dependent on the bone of the pedicle itself, while only 15% to 20% depends on the trabecular bone of the vertebral body [5, 55].

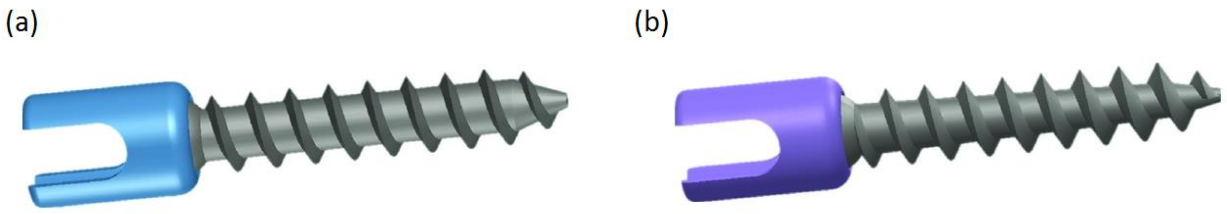

Figure 2.2. Pedicle screw designs. (a) Cylindrical threading and cylindrical core and (b) cylindrical threading and conical core.

The effectiveness of conical pedicle screws, in comparison to standard cylindrical screws, in osteoporotic specimens has been controversial. Hsu et al. [16] noticed a significant increase in pullout strength between two models of conical screws (Cotrel-Dubousset and Texas Scottish Rite Hospital) as a result of compaction of the surrounding bone than with that of a cylindrical screw (the Moss Miami). However, a follow-up study [37] that compared a number of conical screws, containing different tapering patterns with cylindrical screws of similar diameters in an osteoporotic model, could not state any significant difference between any of the conical or cylindrical screws. Moreover, Chen et al. [38] performed a number of pullout tests comparing both types of screws in the presence and absence of bone cement in osteoporotic synthetic bone. For every augmentation technique that was performed, including the lack thereof, they determined that no statistical differences in pullout forces existed through the use of conical over cylindrical screws. On the other hand, Kim et al. [39] compared true cylindrical pedicle screws with those of a conical core and cylindrical thread as well as those with both a conical core and conical thread, finding that the conical core and cylindrical thread screws performed, on average, 23–37% better in pullout testing than true cylindrical screws and 10–21% better than the screws with a conical thread and conical core.

2.3.3 Thread Type

Developing a screw with proper thread design is essential in achieving optimal results within the human body as the preferred size, shape, and pitch will vary based on particular anatomy. For instance, in traditional mechanical design, a screw with a deep thread and large pitch is preferred in softer mediums to prevent stripping, while a smaller thread size and pitch are ideal where material strength may not be a concern, but size may be a limiting factor [42].

The osteoporotic spine, however, suffers from both a decrease in material properties [30] that would require a large screw with deep threads and from the aforementioned risk of pedicular fracture [46, 47], which limits the size of the screw that can be utilized.

From a purely mechanical perspective, the allowable load placed on a screw is dependent on the amount of surrounding material that contacts the thread [42]. Therefore, it could be hypothesized that by increasing the contact area between a pedicle screw thread and the surrounding bone, there will be a greater distribution of forces and thus larger pullout strength will be obtained. Krenn et al. [40] defined this coverage between thread and bone as the flank overlap area (FOA) and tested screws of varying thread types, pitches, and screw shapes to determine if this would be a good predictor of its fixation capabilities in bone of poor quality. Three screw designs were tested: one with a constant core diameter and V-threading (FOA = 206 mm^2); another with a buttress thread and a conical core (FOA = 261 mm^2); and the third with a varying thread design, conical core, and smaller pitch (FOA = 326 mm^2). It was found that while the FOA was largest on the screw with the smallest pitch its pullout strength suffered since the bone between threads behaved more like bone fragments rather than compressed bone. On the other hand, the screw with the buttress thread and conical core outperformed the other two designs in whatever density the pullout test was performed in. Therefore, it was determined that bone compression achieved by having both a conical core and constant thread diameter, as well as an appropriate distance between threading, provided a better connection by means of friction than simply increasing the contact area between thread and bone.

Other attempts to increase fixation based on alterations of thread design could theoretically be achieved by increasing the number of threads being used. Based on the

observation that a screw with two different threads on its polar ends has the capability to significantly compress nearby bone when used elsewhere in the body [56, 57], Mummaneni et al. [41] has suggested that adding a second parallel thread of smaller height to a pedicle screw would enhance the holding strength of the screw within elderly osteoporotic patients. After performing pullout tests between standard pedicle screws and the double threaded ones described above, it was determined that there was no significant difference between the two types and therefore the use of an additional thread in hopes of better compression to the surrounding bone would not be beneficial for use in osteoporotic individuals.

Also hoping to increase the fixation of pedicle screws through the addition of more than one thread, Brasiliense et al. [58] compared a standard single threaded screw with a pitch of 2.6 mm to a screw with a pitch of 4 mm and the addition of a second parallel thread in the proximal half. They hypothesized that while the standard screw had a larger overall FOA, the dual-threaded screw had a larger FOA in the region of the pedicle, which the majority of the pullout force is dependent upon [5, 55], and therefore should increase fixation within the bone. However, the dual-threaded screw achieved a pullout force 19% less than that of the single threaded screw when being tested in high porosity (low density) polyurethane foam models and performed only slightly better (7.8%) when tested in vertebrae with a bone density of less than 0.8 g/cm^2. Both differences were determined to be statistically insignificant [58]. These results differ from those reported by Thompson et al. [43], who stated that the surface area of the screw's thread was a good predictor of its fixation strength within bone.

In addition to affecting the surface area making contact between screw and bone, the cross-sectional shape of the threading plays an important role in the function of the screw.

Standard screw threads, closely resembling V-threads, named after the shape made by their cross section, are the most popular for use as fasteners (Figure 2.3a). Other popular thread shapes include buttress and square threads, although these are used more as power screws for machine usage (nonmedical) as they are ideal for converting rotational motion to linear motion (Figures 2.3b and c) [39, 42]. However, one potential advantage that these thread shapes have over the standard V-thread is that the thread height is made up of a near 90° angle to the axis of the screw as opposed to the standard screw's 120°. Comparing the above thread types to one another, Kim et al. [39] found that despite the geometric makeup of the threads, pullout forces of cylindrical screws with a V-thread were 16.3% and 13.4% greater than either the square or buttress threaded screws, respectively, when being tested in an osteoporotic model.

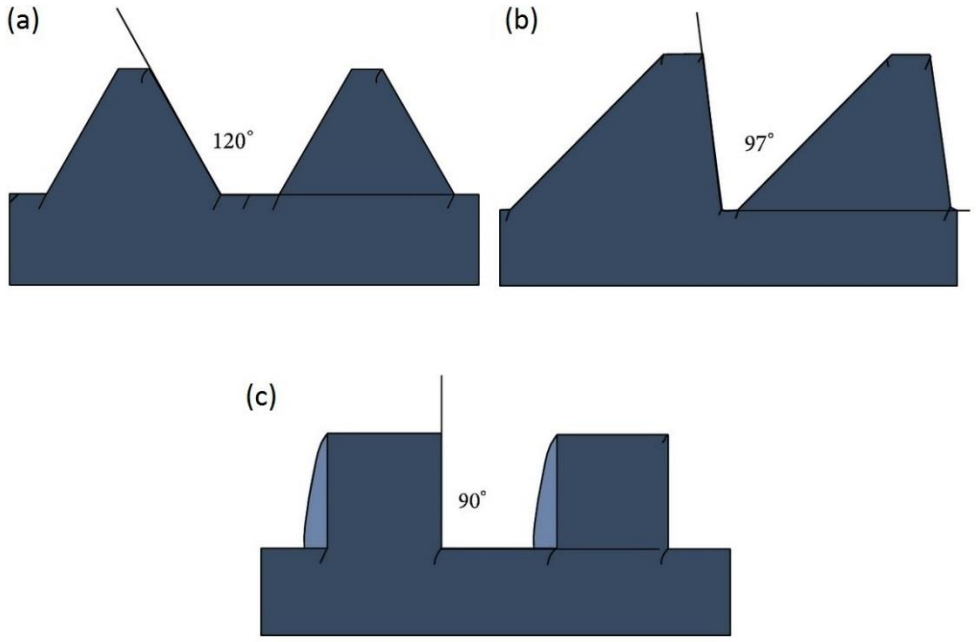

Figure 2.3. Posterior angle of various thread designs of pedicle screws: (a) standard, (b) buttress, and (c) square.

2.3.4 Material

In addition to altering the anatomical features of the pedicle screw, the screw material could also affect how well it is able to achieve proper anchorage in low quality bone. For instance, many pedicle screws are made out of stainless steel due to its biocompatibility and high strength [30, 34, 44, 59-65]; however, titanium has been considered to have superior mechanical and biological properties over stainless steel [44]. For instance, with a lower modulus of elasticity, it is more flexible than stainless steel, which would allow for a reduction in stress shielding [33, 44]. Secondly, while it is considered to be a biocompatible material, it is also classified as bioactive which will thus promote osteointegration between the bone and screw [33, 44]. Finally, titanium is a material that allows greater magnetic resonance imaging (MRI) and computed tomography (CT) resolution over stainless steel [44].

To test if these characteristics resulted in an increase in anchorage of the pedicle screw within the osteoporotic spine, Christensen et al. [44] performed an *in vivo* study involving the use of 316L stainless steel and Ti-6Al-4V titanium pedicle screws in miniature pigs. After three months, the animals were sacrificed and then prepared for pullout testing to observe the effect the materials have on pullout strength over time. Despite the fact that there was noticeably better integration between the bone and titanium screws than that of the stainless steel screws, there was still a statistically insignificant increase of less than 5% in pullout strength of the titanium screw over the stainless steel.

In 2012, Shi et al. [33] performed mechanical testing on an expandable pedicle screw made out of a new titanium alloy, Ti-24Nb-4Zr-7.9Sn, in osteoporotic sheep. They hypothesized that this new alloy, which has an elastic modulus (42 GPa) closer to that of bone (~13.5 GPa) [66],

would produce greater pullout forces than those made of Ti-6Al-4V (110–114 GPa) [33, 37]. After sacrificing the sheep six months post screw implantation, it was noticed that there was, in fact, more bone surrounding the lower elastic modulus expandable screws than the higher modulus expandable screws. Following mechanical testing, it became apparent that this provided enough strength to significantly increase the pullout force of the low elastic modulus screws by 19.3% [33].

2.4 Insertion Technique

2.4.1 Pretapped Hole versus Self-Tapping Screw

A topic of great interest in the literature is whether or not to utilize self-tapping screws or to rather have the pilot hole pretapped before screw insertion [15, 43, 67-69]. Self-tapping screws are often used in surgical applications as their ability to cut the thread path as it is being inserted greatly simplifies the procedure and, as a result, shortens the required time to perform the operation. Unfortunately, the screw will meet frictional resistance as it progresses, which will in turn increase both the installation torque and risk of fracture in low density bone [59].

The practice of pretapping a pilot hole was necessary as a means of accurately installing screws in longer bones in orthopedic surgeries, which was then implemented to spinal surgery [69], despite the controversy regarding its effectiveness. Chen et al. [15] determined that tapping the pilot hole prior to inserting the screw tends to weaken the pullout force and produce less consistent results than by utilizing self-tapping screws. Similarly, Pfeiffer and Abernathie [69] found that when testing ten different screw designs, each of which were either self-tapping or not, the majority of the self-tapping screws designs presented significantly stronger pullout forces in osteoporotic models. Alternatively, Carmouche et al. [67] reported that while the

pullout force was lesser in pretapped holes in osteoporotic lumbar spine, there were no noticeable differences between the two techniques in the thoracic vertebrae. Furthermore, Thompson et al. [43] and Mehta et al. [68] were unable to find any noticeable differences in pullout strengths between tapped and untapped pilot holes.

While mixed observations are present regarding pretapping pilot holes, Helgeson et al. [70] hypothesized that an optimal insertional torque (IT) during the tapping process exists that would help predict the ideal screw size to be used in osteoporotic patients. During the pilot study, they calculated this optimal torque to be roughly 2.5 in-lbs. In each vertebra tested, one pedicle was tapped with increasing diameters until the IT reached 2.5 in-lbs and the tapping IT in the contralateral pedicle reached 1.5 in-lbs. Once this value was reached, the screw diameter to be used was determined to be the most recent tapping diameter plus 1 mm. Utilizing this technique, they observed a significant increase in pullout force of 23% in the pedicle that was tapped with 2.5 in-lbs IT as opposed to the one that had an IT of 1.5 in-lbs. Since no breaching of the pedicular wall occurred, these results can likely be explained by the larger diameter screws that were able to be used in the pilot holes tapped with an IT of 2.5 in-lbs.

2.4.2 Insertion Angle

Another possible technique for enhancing screw fixation is altering the angle through which it is inserted [32, 35, 71]. Patel et al. [35] performed tests on varying bone screws in synthetic models representing healthy (BMD = 0.32 g/cm^3), osteoporotic (BMD = 0.16 g/cm^3), and severely osteoporotic (BMD = 0.09 g/cm^3) cancellous bone at angles ranging from 0° to 40°. They observed that while screws in healthy bone performed best at or near the angle of axial pullout, those in osteoporotic bone achieved the highest possible pullout strength around 10° to

the axial force, while severely osteoporotic bone required screws to be positioned at a 40° angle to maximize fixation strength. The explanation behind these findings is likely because the purchase within the bone-screw interface is so poor in osteoporosis that maximizing the fixation would require an increase in bone concentration around the screw, as is achieved when the screw is pulled out at an angle from which it is inserted.

During instrumentation of a pedicle screw into a given vertebra, two common trajectories exist: the straightforward (0° to 10° both in the medial and caudal directions) and the anatomic trajectories (0° to 10° medial and 22° cephalocaudal) [32, 71]. Lehman Jr. et al. [72] showed that between the two trajectories the straightforward technique produces pullout forces 27% greater than those inserted using the anatomic trajectory in an osteoporotic vertebra. While both of these have the pedicle screw simultaneously engaged in cortical and trabecular bone, a third, lesser used trajectory (known as the "cortical bone trajectory") keeps the screw completely engaged with the cortical bone of the pedicle [32]. Santoni et al. [32] performed pullout testing to compare this third method along with that of the anatomic trajectory. Despite the fact that the pedicle screws in the cortical bone trajectory were significantly smaller to avoid bicortical purchase (mean 29 mm versus 51 mm), it produced a mean pullout force 28% greater than the larger screws in the anatomic trajectory.

2.4.3 Bicortical Fixation

If poor fixation is a concern, surgeons will often obtain additional strength by inserting the pedicle screw through the vertebral body and into the anterior cortex [19, 36, 73]. Breeze et al. [19] noted an increase in pullout strength of 26% to 44% between bicortical and unicortical screws, depending on the severity of osteoporosis. Zindrick et al. [36] demonstrated that,

depending on the screw used, insertion through the anterior cortex resulted in an increase in pullout strength of 31% to 120% when compared to inserting the screw just up to the anterior cortex without penetrating it. Furthermore, Zhuang et al. [73] found that bicortical fixation within the sacrum can provide a greater resistance to pullout in the early stages of osteoporosis when being compared to a unicortical screw augmented with bone cement. However, as the level of osteoporosis worsens, this no longer remains the case.

When inserting a pedicle screw through the anterior cortex, special care must be taken. Due to the location of the aorta and iliac vessels along the anterior of the spine, incorrect placement of the screw could result in severe vascular injury [5, 46]. Additionally, Zindrick et al. [36] noticed during their testing that applying a cyclic load to the screws when attached to the anterior cortex resulted in a "windshield wiper" type motion as a result of the center of rotation shifting to the distal tip of the screw. Because of this, it was noted that there was an increased risk of pedicle fracture or screw bending. Therefore, it has been suggested that bicortical fixation should be reserved for use in the sacrum or in cases where the additional fixation achieved is desperately needed [5].

2.5 Bone Cement

The strength of the trabecular bone in the vertebral body is dramatically diminished as osteoporosis progresses [18, 30, 38, 74]. As such, the bone-screw interface within the vertebral body becomes so poor that adjustments to the screw's design alone prove to be ineffective as conditions become more severe. Therefore, in some extreme cases, the addition of bone cements has been explored to enhance the screw's fixation within the vertebral body [14, 15, 31, 34, 36, 49, 60, 65, 75-78]. Typically used in kyphoplasty or vertebroplasty procedures for restoring

height in the vertebral body following compression fractures [60, 79, 80], introducing cement to strengthen the interface between the screw threads and its immediate surroundings has proven to be a successful, albeit controversial, solution for providing increased screw stability in bone of compromised quality [48, 65, 73, 75-78, 81, 82].

2.5.1 Types of Cement

2.5.1.1 Polymethylmethacrylate (PMMA)

Quite possibly the most frequently used cement, PMMA is also the most highly debated for its use in clinical practice [48, 65, 73, 76, 77, 81]. Less serious problems associated with the use of PMMA include its inability to be seen by common medical imaging techniques, such as X-ray. This, however, can be remedied by adding small amounts of barium sulfate to the mixture [18, 83]. More severe, however, is the polymerization of PMMA via an exothermic reaction [83-85]. Therefore, as it solidifies in the body, the cement will increase its temperature to about 40°C to 110°C [85] with one study reporting a temperature as high as 113°C [84], well within the range to allow thermal necrosis to take place to surrounding osteoblasts and neural tissue such as the spinal cord [84, 86]. Additionally, its injection into the vertebral body during its liquid phase presents a very real potential for leakage, further increasing the risk of neural injury [14, 15, 31, 38, 48].

Its inability to degrade under biological conditions poses even further threats. Since PMMA will remain in the vertebra as a permanent foreign body, if pedicle screw removal is desired, drastic, potentially damaging surgery will be required on the vertebra [34, 87, 88]. Furthermore, while PMMA may be a biocompatible material, its monomer methylmethacrylate (MMA) is in fact known to be toxic. It is believed that long term exposure to PMMA can result in

MMA being absorbed into the blood stream resulting in cardiac issues such as embolic events [89] and hypotension [90].

Despite these concerns, the benefit that PMMA provides to screw stability in osteoporotic patients is often believed to outweigh the potential risks. In addition to its low cost and high availability [77], PMMA provides a mechanical strength like few other bone cements can. The literature has shown PMMA increasing the pullout strength of pedicle screws in osteoporotic vertebrae from 25% to 348%, depending on the amount used and technique of injection [14, 31, 48, 60, 76, 77].

Chen et al. [38] compared the pullout forces achieved in using conical screws alone in an osteoporotic synthetic model with standard cylindrical screws augmented with PMMA under the same conditions. While the conical screws reached a mean pullout force of only 35 N, the cylindrical screws with cement augmentation achieved forces averaging 298 N and 421 N, depending on how the cement was placed in the spine. Similarly, Liu et al. [77] found that standard pedicle screws augmented with PMMA attained average pullout forces 257% of those seen in pedicle screws without the cement but containing an expansive distal end.

2.5.1.2 Calcium Phosphate (CaP) Cement

There are alternative bone cement options to use in the vertebral body when PMMA may be considered too hazardous of a material. One particular cement recently increasing in popularity is calcium phosphate (CaP) [18, 34, 78, 82]. Unlike PMMA, CaP is a biodegradable material. Consequently, after surgery is performed and as spinal fusion occurs, the cement will gradually degrade and allow newly formed trabeculae to take its place [18, 34, 91]. Additionally, CaP hardens via a hydration reaction, thus resulting in an endothermic response [34, 87].

Therefore, there is no heat produced as a result of the cement's usage and thus no risk of thermal necrosis to the surrounding tissue. There is, however, still the potential of leakage upon insertion which can, like PMMA, cause damage to the spinal cord [82]. Nevertheless, under careful placement by a skilled surgeon, the use of CaP can prove to be a safer option than PMMA when bone cement is desired.

One important drawback of using CaP cement is the weaker pullout force it induces when compared to that achieved by PMMA [18, 92]. Regardless, Yazu et al. [82] reported a rate of increase in pullout strength of about 244% when a cannulated pedicle screw augmented with CaP cement was compared with a standard non-augmented screw in osteoporotic specimens. Furthermore, Stadelmann et al. [78] calculated that for every millimeter that CaP cement is added along the exterior of a cortically anchored pedicle screw, pullout strength will be increased by roughly 23 N (in other words, a pedicle screw with 15 mm of its shaft surrounded by CaP will increase its pullout strength by about 345 N).

As stated, a major advantage of using CaP over PMMA when choosing to augment a pedicle screw with bone cement is the fact that CaP will gradually degrade as new cancellous bone takes its place. Taniwaki et al. [34] performed a four-week study using beagles with induced osteoporosis to investigate how the use of CaP would affect the anchorage of pedicle screws over time as opposed to those being used without the bone cement. The dogs were sacrificed at one, two, and four weeks after surgery to perform a pullout test. It was noticed that, while there was an insignificant increase in pullout strength in the osteoporotic non-CaP group at four weeks compared to one week, there was a much more significant increase of 38.1% in the CaP treated osteoporotic dogs at week four compared to one week after surgery. Additionally, CaP increased

the overall stability of pedicle screws in osteoporotic dogs as opposed to those without CaP by 28.1% to 56.3% from one to four weeks, respectively.

While CaP cement has been shown to provide a significant increase in pullout strength over the non-augmented pedicle screw with less harmful side effects than PMMA, some may still be cautious of its use due to the ever present possibility of leakage outside the vertebral body. As a result, those surgeons who want to take advantage of the biocompatible characteristics of CaP while avoiding the potential hazards that could occur as a result of leakage may pack the pedicle screw's pilot hole with granular CaP particulate prior to screw insertion [75]. Knowing the advantages that it possesses, Hashemi et al. [75] performed pullout tests on screws augmented with CaP particles to see if it was still able to provide an increase in pullout resistance as opposed to non-augmented screws. Using polyurethane blocks, it was determined that CaP particulates can increase the pullout strength about 13% to 25% in low density samples and can still be used to provide some additional strength in a rescue situation where the screw pullout already occurred and needs to be replaced. On the other hand, it was noticed that the augmentation technique tended to have an adverse effect on pullout strength in high density samples, indicating that it would not be ideal to use it in normal, healthy bone.

While the nature of the test performed by Hashemi et al. was meant to determine the mechanical benefits of augmenting screws with granular CaP particles immediately following surgery, it was suggested that further investigation needed to be performed in an *in vivo* environment to fully understand the potential of particulate CaP augmentation in a clinical setting. Since the experiment was performed in polyurethane blocks, there was a natural inability to test for how the potential of bone growth over time would affect the screw's pullout strength.

An *in vivo* study would take into account the biomechanical effects that osteogenesis and cyclic loading has over time that cannot be properly tested *in vitro* [75].

2.5.1.3 Other Biocompatible Bone Cements

A novel and quickly degradable cement made up of both calcium phosphate and calcium sulfate components was tested by Gao et al. [49]. They showed that using 2 mL of the cement to augment a standard pedicle screw in osteoporotic bone was enough to increase the pullout strength by 12.6%. While this was not considered to be a statistically significant increase, it was enough to produce comparable results to that of non-augmented screws in slightly denser osteopenic vertebrae. However, the cement did little to improve the level of fixation in severely osteoporotic specimens. A standard pedicle screw augmented with the calcium based cement only produced pullout strengths 6.2% greater than its non-augmented counterpart and 38.4% less than a non-augmented screw in osteoporotic bone.

Another popular biocompatible material used for enhancing the pedicle screw purchase is hydroxyapatite (HA). Similar to the other calcium cements, HA is capable of promoting osteointegration between bone and screw. Hasegawa et al. [93] performed mechanical tests after sacrificing osteoporotic dogs who had HA coated screws implanted for ten days. Compared to the noncoated screws in each contralateral pedicle, HA increased the screw pullout strength by 60.6%. Following inspection of the screws, it was noted that there was significantly more bone growing between the threads of the HA coated screws as opposed to standard pedicle screws alone.

Similar to CaP, a bioactive cement consisting of strontium and hydroxyapatite nanoparticles (Sr-HA) that maintains a low curing temperature while promoting the formation of

new bone over time has been evaluated [65]. Unfortunately, Zhu et al. [65] showed that under cyclic loading, PMMA outperformed Sr-HA cement by producing pullout forces nearly 50% stronger. Somewhat promising, however, they noticed that upon insertion of the pedicle screw, Sr-HA cement covered 79% of the length of the screw, while PMMA only covered 43%. This was suggested to be a result of Sr-HA's longer handling time and may produce more significant bone growth long term.

Calcium triglyceride (CTG) is biocompatible cement that benefits from a release of carbon dioxide during its early stages of polymerization. This forms pores within the material which in turn results in its expansion. While this increases concerns over cement extrusion, it is also believed that it could benefit screw fixation [76]. Hickerson et al. [76] found that, while PMMA increased pullout strengths by 25% over non-augmented pedicle screws, CTG increased these forces by 89%. Furthermore, when directly compared in revision situations, CTG augmented pedicle screws had pullout forces 30% larger than those augmented with PMMA.

2.5.2 Injection Techniques

Multiple variables need to be considered when augmenting pedicle screws with bone cement in order to obtain both maximum fixation and safety. For example, it must be determined what the preferred method of applying the cement should be. One of the most popular is solid screw vertebroplasty, being the insertion of the cement into the pilot hole prior to placement of the screw [14, 34, 38, 49, 60, 61, 77, 81]. However, there are concerns over leakage occurring as the screw displaces the cement upon instrumentation [34, 38]. This led to a vertebroplasty technique involving fenestrated screws as a means of injecting the cement after the screw was already inserted (Figure 2.4) [14, 15, 31, 38, 48, 61]. Chao et al. [94] showed that, while

statistically insignificant, prefilling the pilot hole with cement produces pullout forces 40% greater than fenestrated injection. Both prefilling and injection techniques, however, were significantly stronger (461.7% and 301.5%, respectively) than non-augmented pedicle screws in osteoporotic vertebrae.

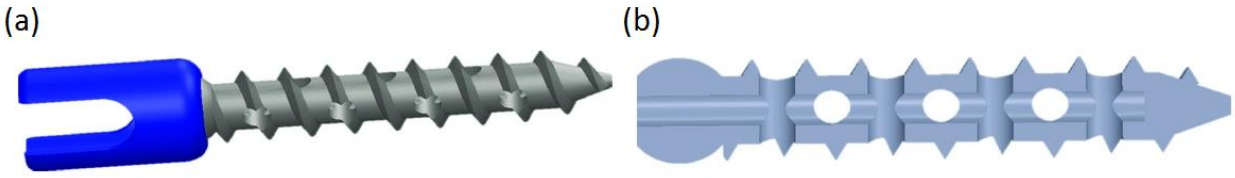

Figure 2.4. Fenestrated screws used for injection of cement after installation. (a) Model view and (b) section view (no head).

A third injection technique exists called balloon kyphoplasty. This technique involves a medical balloon placed into the vertebral body and then expanded to create a cavity in the trabecular bone. After the balloon is deflated and removed, cement is injected into the cavity followed by screw insertion [14, 60].

Becker et al. [14] determined that, of the three techniques discussed (vertebroplasty injection, vertebroplasty injection involving fenestrated screws, and balloon kyphoplasty), both vertebroplasty injections performed greater than the kyphoplasty technique from a mechanical standpoint, producing near identical results of just under an 80% increase in pullout strength over non-augmented screws. In a separate test, Burval et al. [60] found that kyphoplasty based cement injection provided more significant pullout forces than did the vertebroplasty technique of injecting the cement prior to screw insertion. However, the differences between these two studies may be a product of the variations in testing procedures. For instance, Burval et al. [60] compared the two augmentation techniques in the same specimen whereas Becker et al. [14]

limited each specimen to one of the techniques being tested. Furthermore, Burval et al. [60] used 4 mL of PMMA in the kyphoplasty augmentation and only 2.5 mL of the cement for vertebroplasty. Becker et al. [14], on the other hand, used 2 mL PMMA for all of the augmentation tests performed. They did admit, however, that a larger amount may be required for the kyphoplasty technique since using such a small amount may not be enough to properly incorporate itself into the surrounding bone after cavity formation in the vertebral body.

Becker et al. [14] also noted that, of the ten specimens that were tested via cement injection through the cannulated screw, two resulted in leakage into the epidural veins. This is in direct contrast with how this technique was expected to perform when compared to solid screw vertebroplasty [34, 38]. Chen et al. [15] reaffirmed that there is a risk of cement extrusion outside of the vertebral body when being injected through a cannulated screw with proximally located radial holes near the posterior cortex of the vertebral body. However, they also noted that the pullout forces required to remove one of these screws augmented with PMMA is significantly larger than one where the cement is extruded from the distal portion of the screw. This suggests that upon careful insertion by a skilled surgeon in a vertebra not already prone to leakage (i.e., no identifiable breaches in any of the walls), the added strength achieved by injecting PMMA through a screw with radial holes located just past the pedicle-vertebral body junction may be worth the risk associated with it if fixation is particularly difficult to achieve.

2.5.3 Optimal Volume

Another important factor to consider when using bone cement to augment pedicle screws is the optimal volume to utilize. Paré et al. [31] conducted research on the optimal amount of PMMA, by testing pullout strengths of screws augmented with three different volumes: 0.5, 1.0,

and 1.5 cc in the thoracic spine and 1.5, 2.0, and 2.5 cc in the lumbar spine. Perhaps somewhat surprising, their numbers suggested that more cement is not always better. Maximum pullout forces in the thoracic spine occurred with 1.0 cc of bone cement augmentation (186% over the non-augmented control) and in the lumbar with 1.5 cc of cement (264% over the non-augmented control). In both cases, as larger amounts of cement were added, there was a gradual decrease in the difference between its pullout strength and that of the control in the contralateral pedicle. Furthermore, when less cement was used in the thoracic spine, any mechanical advantage that was achieved over the control was so small that it was deemed statistically insignificant.

2.6 Novel Pedicle Screws

2.6.1 Expandable Screws

Since increasing a pedicle screw's diameter in an attempt to achieve better purchase will also increase the likelihood of pedicle fracture [46, 47], screws allowing their insertion into the pedicle and vertebral body in a similar fashion to that of standard cylindrical screws but expanding distally after their insertion were developed [33, 46-49, 77, 81, 95, 96]. This increase in diameter at the screw's tip concentrates fixation in the vertebral body for better anchorage in the trabecular bone without compromising the integrity of the pedicle (Figure 2.5) [46, 47, 49, 81].

Cook et al. [48] compared the pullout strengths in severely osteoporotic specimens of a conventional pedicle screw (6.5 mm diameter) augmented with PMMA with a non-augmented expansive screw that consisted of four expandable fins expanding along the distal two-thirds of the screw (7 mm diameter and 8.5 mm distal expansion). Mean pullout forces to the cement augmented screw were measured at 104.66 N. While the expansive screw alone measured at

81.12 N, this difference was not determined to be significant. This suggests that when safety is a concern, it may be a better alternative to use the expansive screw rather than taking the risks associated with cement injection.

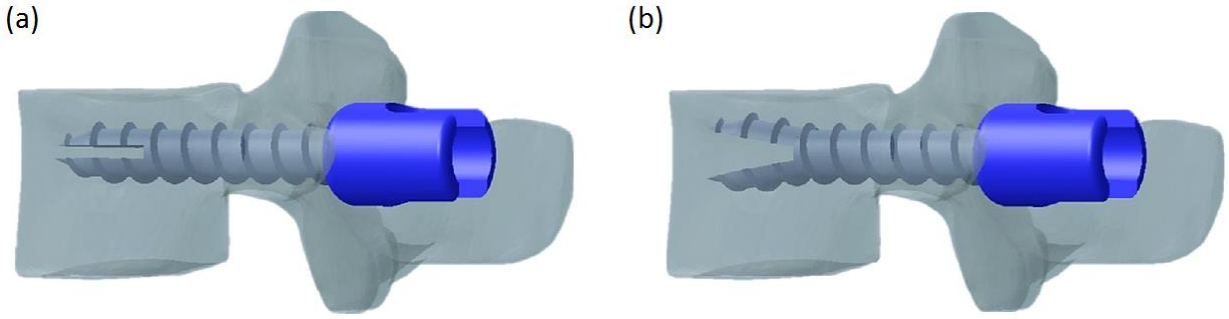

Figure 2.5. Expandable screw in the vertebral body (a) unexpanded and (b) expanded.

Koller et al. [95] also tested their own version of a four finned expandable screw, but one where only the distal most one-fifth of the shaft length expanded. Expansion in this case resulted in an increase of pullout strength of roughly 20% when compared to standard screws of similar dimensions. This difference, however, fell just shy of being considered statistically significant.

Gao et al. [49] performed pullout tests on another design of distally expansive pedicle screw that contains two expanding fins (Figure 2.5) rather than four. The fins, once fully extended, increase the distal diameter of the screw by roughly 2.5 mm. By testing this screw against standard pedicle screws, evidence suggests that the expansion mechanism significantly increases pullout strength of 27.2% and 51.5% in osteoporotic and severely osteoporotic specimens, respectively. Additionally, the expansive pedicle screw alone produced pullout forces 42.7% greater than a standard screw augmented with calcium-based cement in severely osteoporotic bone.

While still larger, the differences were less noticeable between two finned expansive pedicle screws and PMMA augmented standard screws in pullout tests performed by Wu et al. [44]; the expansive pedicle screws alone produced 7.3% greater pullout forces than standard screws with 2 mL of the bone cement in osteoporotic vertebrae and only 3.3% greater in specimens with severe osteoporosis. However, in both levels of osteoporosis, it was recorded that an expansive pedicle screw augmented with PMMA provides greater pullout strength when compared to a conventional pedicle screw, both with and without bone cement.

More recently, Liu et al. [77] tested a similarly designed two finned expansive pedicle screw (6.5 mm diameter and 7.5 to 8.5 mm distal expansion) to standard pedicle screws (6.5 mm diameter) both augmented with and without PMMA in low density synthetic bone. It was shown that the expansive pedicle screws had pullout strength 25.3% to 48.4% greater than any of the standard pedicle screws used. However, unlike the previous studies, it was determined that the pullout strength of the expansive pedicle screw was significantly lower than that of the cement augmented standard screw. They suggested that this likely has to do with the fact that the expansive screws experience a localized increase in diameter at the distal-most point only, while the PMMA augmented screw has an increased diameter uniformly throughout the entirety of the screw.

2.6.2 Expandable Anchors

While a mechanism allowing for distal expansion in pedicle screws has shown to provide promising results as a means of fixation within osteoporotic bone, there still exists concern as to whether trabecular bone of compromised quality is strong enough to take full advantage of the increased diameter generated [89]. Since only about 20% of the fixation strength of a pedicle

screw occurs in the trabeculae of the vertebral body [5, 55] and, in cases of osteoporosis, the integrity of trabecular bone becomes compromised much faster than that of the cortical bone [18, 30, 38, 74], it may benefit pedicle screw fixation to choose a design that takes advantage of the additional strength that is left from the cortex. As a result, some have questioned if expanding the diameter of the screw immediately at the posterior cortex of the vertebral body, thus allowing an increased surface area to provide anchorage to the stronger cortical bone, would help in increasing the fixation strength of pedicle screws in osteoporotic individuals [30, 89].

Lin et al. [30] found that the addition of an external shell with expandable wings, similar to a wall anchor used in drywall, performed significantly better in L1 to L4 porcine segments where the vertebral body was hollowed out to simulate osteoporosis. Interestingly, they discovered that a point is reached where further expansion of the wings causes more harm to instrument fixation as the additional distance achieved by the stainless steel anchor actually placed more stress on the surrounding bone, thereby increasing the risk of fracture. In their current porcine model, however, they determined that the optimal wing height was achieved at 3.75 mm, which increased its pullout strength by 47% when compared to standard pedicle screws alone.

Vishnubhotla et al. [89] performed pullout testing on a 6.5 mm expansive pedicle screw that opens up to a maximum diameter of 10 mm just past the opening of the pedicle-vertebral body junction. The result of this was an increase of pullout strength of 29% when being compared to standard pedicle screws of otherwise similar dimensions.

A significant advantage this technique has over other proposed fixation enhancement techniques, such as PMMA augmentation, is its reversibility. While removal of a cement

augmented screw may require some degree of vertebrectomy, the removal of expandable screws and anchors can be accomplished by simply retracting the device and then removing it as one would a standard pedicle screw.

CHAPTER 3: MATERIALS AND METHODS

3.1 Pedicle Screws

3.1.1 Design Process

The current literature strongly suggests that a screw design that utilizes the strength of the cortical bone over the more quickly degrading trabecular bone in osteoporotic individuals would be appropriate. While attempting to increase the purchase within the pedicle has been proven to be successful, the risk for fracture of the bone was too great to be considered an option to pursue. Rather, it was determined that increasing the surface area making contact with the inside wall of the vertebral body would help to prevent the instrumentation from backing out of the pedicle as forces are applied to it.

From the onset of the design process to its completion, many different concepts were considered. Early designs originated as highly mechanized screws that would expand or retract multiple wings around the screw's circumference through either the use of springs or the insertion/removal of a pin (Figure 3.1). The concept of this early stage design was similar to what would end up being used in the final device, but the mechanism was complex and difficult to manufacture, which would not have been a cost-effective design.

The design process then evaluated the use of sleeves. These sleeves would be a separate product to compliment a standard pedicle screw already on the market. The sleeve would be inserted after drilling a pilot hole of sufficient size into the pedicle and then locked in place by subsequently inserting the pedicle screw. The variations in the sleeve designs included simple

internally threaded cylinders with semi-circular arms that slid outwards as the screw was to be inserted (Figure 3.2) to a complex plug with a sliding tip where, after insertion, the tip rotated 90° and slid into a slot allowing the pedicle screw to then be inserted (Figure 3.3). Another design resembled an arrowhead or a duckbill (Figure 3.4). The piece was to be inserted with the two sides of the bill set to expand laterally. As the pedicle screw was inserted, the duckbill would open and the lip on either side would grab the cortical bone past the pedicle.

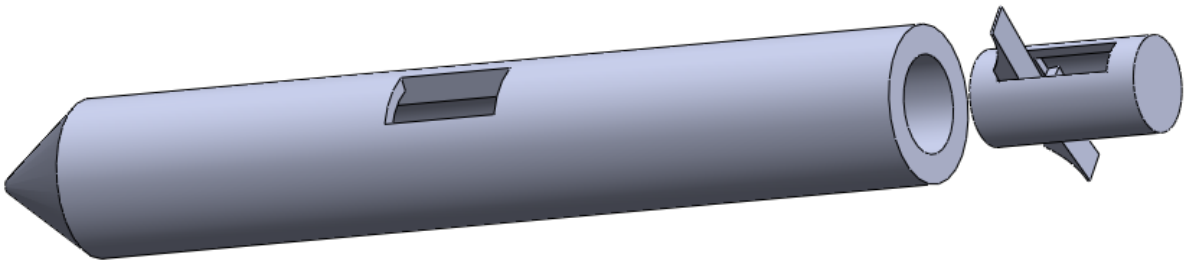

Figure 3.1. Prototype of screw with winged pod. Spring loaded wings retract when pushed distally and expand at opening. External screw threading not shown.

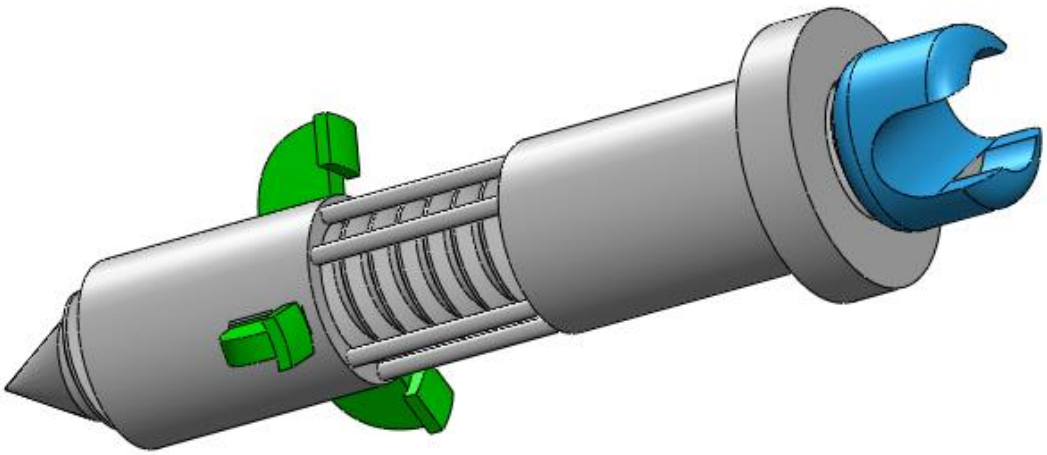

Figure 3.2. Prototype of sleeve design with adjustable length and three expandable arms.

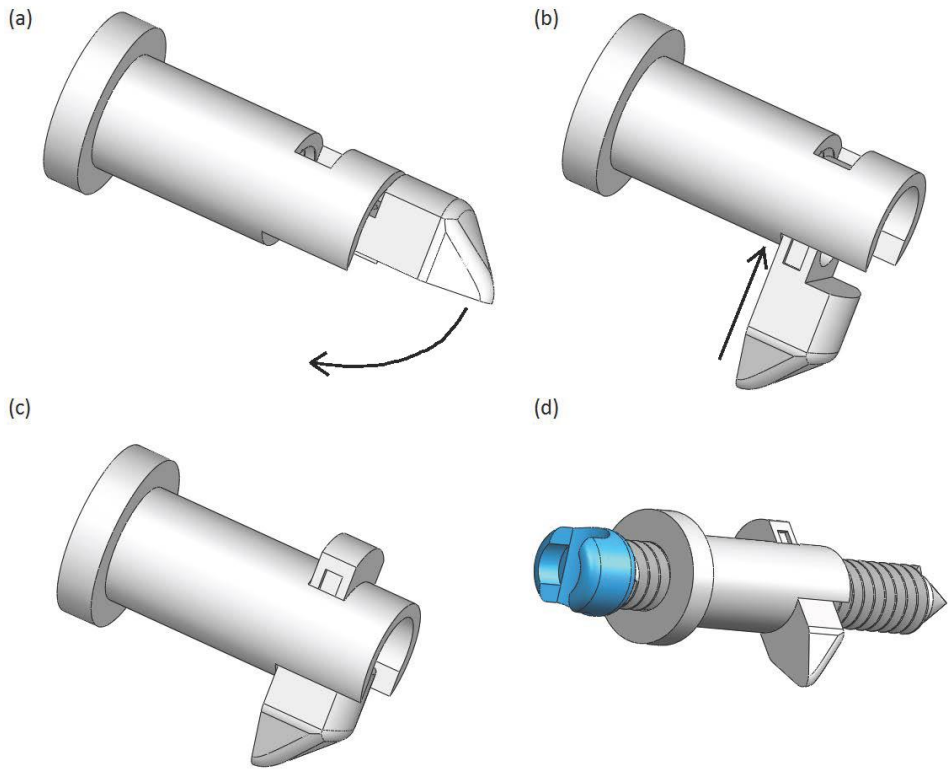

Figure 3.3. Prototype of plug with adjustable tip. (a) Tip to be rotated 90°. (b) Tip to be slid into place. (c) Plug ready for screw placement. (d) Plug with screw inserted.

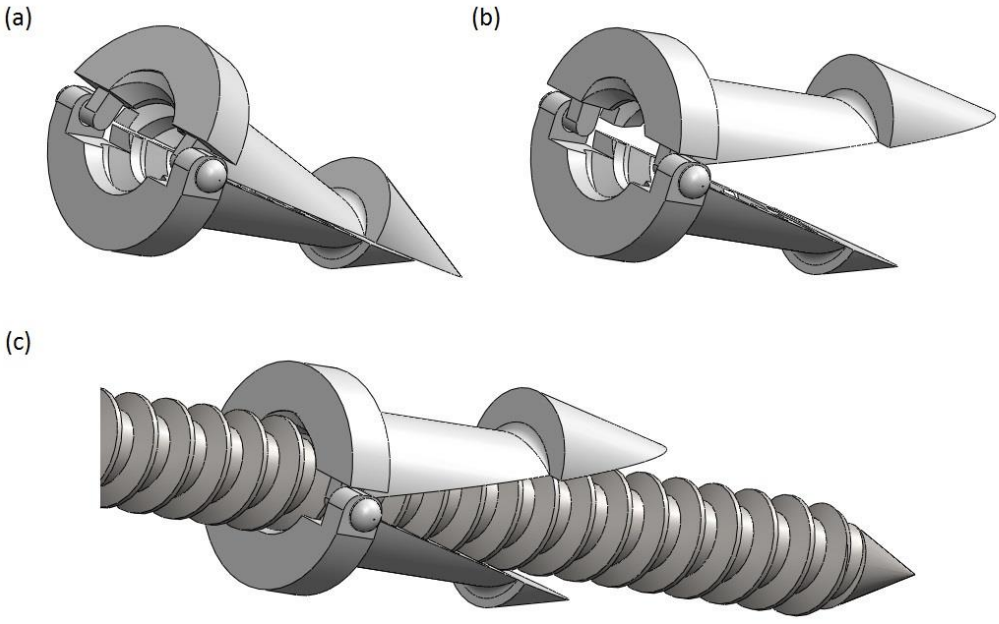

Figure 3.4. Prototype of duckbill design. (a) Closed, (b) open, and (c) with inserted screw.

In all of these cases, the external threading was removed to prevent the necessity of a pedicle screw with a small diameter as the need for internal and external screw threads on the same device requires a great deal of space and, in some instances, because the shape of the device would not accommodate for the external threading. The literature supported the use of a sleeve without external threading as a means of increasing pullout strength in both the pedicle [30] as well as in the anterior spine [62]. However, considering that the concept of the device is to utilize the cortical bone to its fullest potential, design focus shifted back to creating a singular screw rather than a supplementary piece.

The next step in the design process took into consideration some of the more successful techniques from the literature [15, 49, 77, 95, 96]. The new design featured a combination of a cannulated pedicle screw with radial holes just past the pedicle-vertebral body junction and a distally expansive screw (Figure 3.5). The idea was to inject bone cement through the cannulation and out the radial holes so that it would lay close to the cortical wall and then expand the distal wings to better hold onto and distribute the forces within the cement. The largest concern with such a design was the safety of instrumentation. With the exit points of the bone cement so close to the cortical wall, there would have been a high likelihood of cement leakage. Additionally, even if cement did not leak, removal of the screw, depending on the type of cement used and the amount of time after it was inserted, would be difficult if not impossible to do in a safe manner.

It was decided that the best course of action would be to design a screw that would not involve the use of cement augmentation as concerns over safety would be high. Furthermore, reasonable concerns exist with expandable or cement augmented screws when failure occurs

since the event may compromise the integrity of the spinal cord medial to the pedicle and the peripheral nerves inferior to it. An unexpected pullout of one of these screws may cause a large enough fracture of the surrounding bone that it would damage these nerves as well, resulting in catastrophic failure.

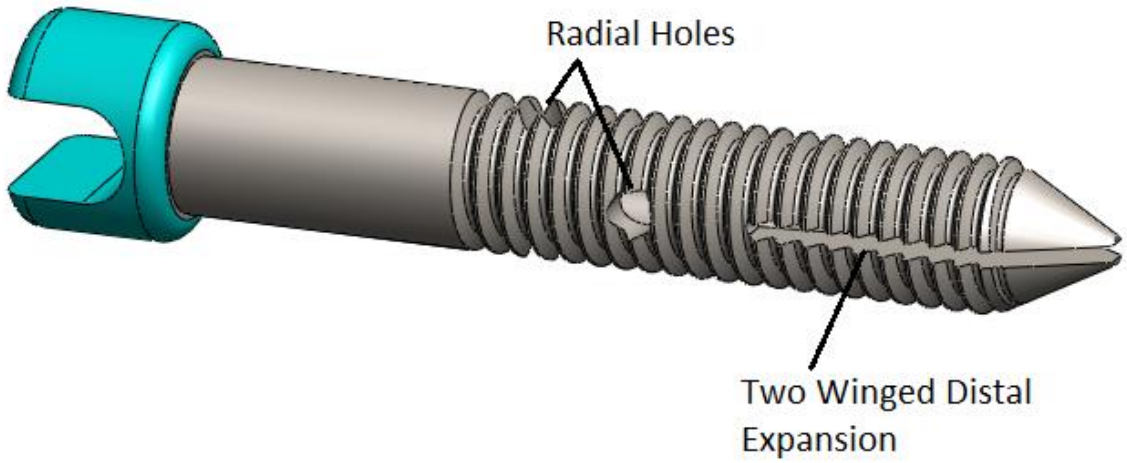

Figure 3.5. Prototype of combination screw.

Next, attention focused on utilizing the cortical bone in such a way that, should fracture of the bone occur, this failure would be done in a controlled manner that would avoid any of the surrounding nerves. This means that expansion could only occur in the superolateral direction of the pedicle. Since the location of bone cement injection would be too difficult to control on its own, the idea of the expandable arm was revisited. However, rather than positioning multiple arms or wings evenly around the circumference of the screw, only one arm was considered. Additionally, unlike what was seen in early iterations (arm positioned with the distal end of the arm nearer to the distal end of the screw and having it open 90°), this new design would be considered to be simpler, easier to manage, and significantly stronger if the distal end of the arm

was facing the proximal end of the screw prior to an expansion of 25° and expanded by insertion of a simple pin.

3.1.2 Final Experimental and Control Screws

The control for this study was a standard pedicle screw commonly used in posterior spinal fusion surgery. The screws were made out of titanium, measured 6.5 mm in outer diameter, and 45 mm in length.

For the purpose of solely testing the effectiveness of the expandable arm, a set of standard pedicle screws were modified to create the experimental expandable screws being used in this study (Figure 3.6). These modifications included: (1) a slot located at a point between the proximal and distal ends for which the pinned appendage was to be incorporated into, (2) a cannulation of 2.20 ± 0.25 mm along the longitudinal axis (extending to the most distal edge of the slot), and (3) an additional boring in the distal portion of the slot below the screw's median plane (without breaching the shaft) (Figure 3.7).

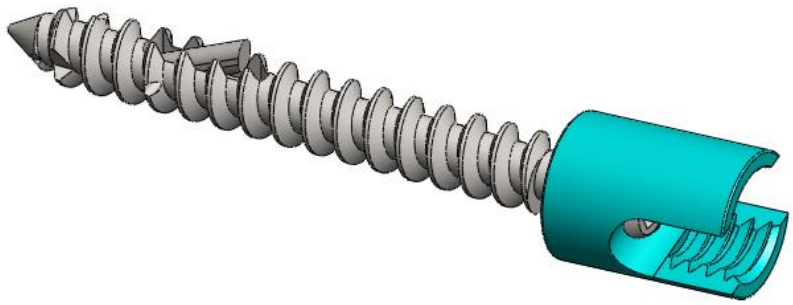

Figure 3.6. Pedicle screw with expandable arm.

The appendage, designed to fit comfortably within the opening made by the slot, bore, and cannulation, was meant to expand following implantation of the screw within the specimen. In its original resting place, the appendage lies parallel to the longitudinal axis of the screw with

its most superficial edge lying below the height of the minimum diameter of the screw. The appendage could rotate 90° from the longitudinal axis of the screw (Figure 3.8).

A pin 2.00 ± 0.25 mm in diameter and a length equal to that of the proximal portion of the screw to the first incidence of the rounded portion of the appendage is also used. Following proper instrumentation, its insertion through the cannulation will allow for an initial expansion of the appendage of 25° ± 1.5° (Figure 3.9). Keeping the pin within the screw following placement of the rod prevents accidental post-operative recession of the appendage back into the screw shaft.

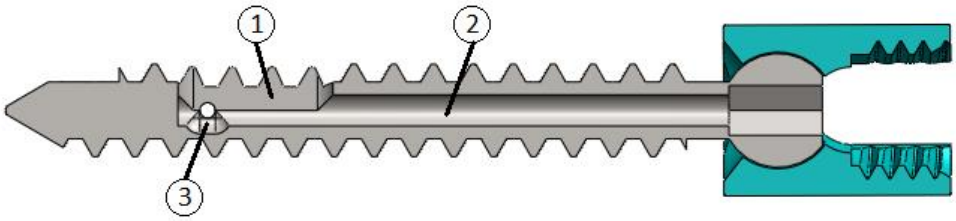

Figure 3.7. Modifications to standard screw. (1) Radial opening. (2) Cannulation. (3) Bore.

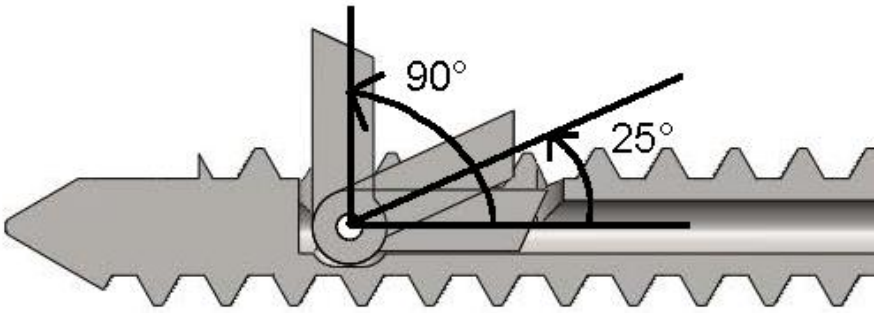

Figure 3.8. Range of motion of expandable arm.

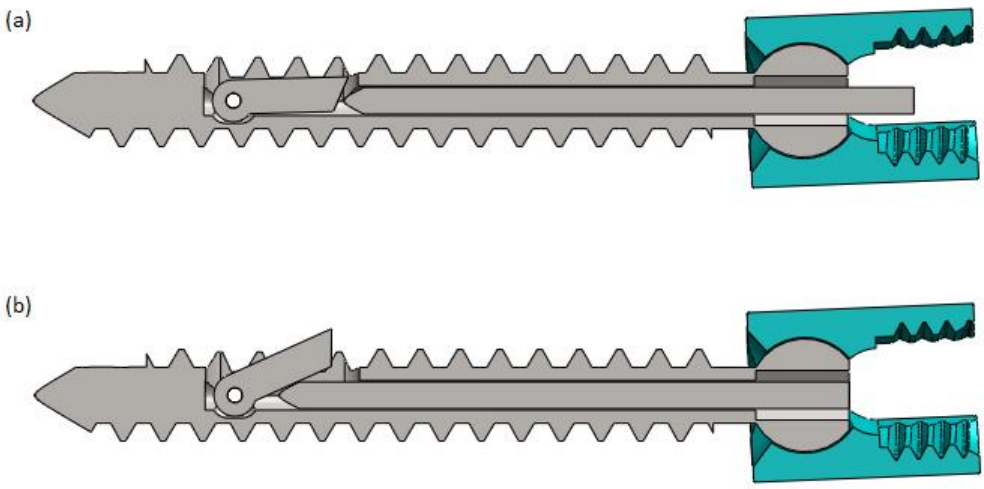

Figure 3.9. Sectional view of expandable pedicle screw with arm. (a) Pin partially inserted and arm closed. (b) Pin fully inserted and arm open.

3.2 Testing Blocks

Testing blocks were provided by Sawbones® (Pacific Research Laboratories Inc., Vashon Island, WA, USA). Two sets of polyurethane blocks of different sizes and compositions were used in the current study. One, referred to in this study as trabecular block (Figure 3.10), measured 30 mm X 30 mm X 50 mm and had a density of 0.08 g/cm^3. This density is similar to what was used by other studies to represent severely osteoporotic trabecular bone [15, 35, 38, 97].

The other block, referred to as composite block (Figure 3.11), was designed to simulate the interaction of the expandable arm as it makes contact with cortical bone. This block consisted of sections of varying densities to simulate both the trabecular and cortical bone comprising severely osteoporotic vertebral bodies. The portion of the block representing trabecular bone measured 30 mm X 30 mm X 20.25 mm and had a density of 0.08 g/cm^3. The sections of the block representing the cortical bone were 2.25 ± 0.25 mm thick and had a density of 0.64 g/cm^3. This higher density portion was layered along the top and one of the sides of the trabecular section.

The thinner design of the composite block in comparison to the trabecular is to allow the arm of the pedicle screw to open within the proximity of the cortical wall while permitting the screw to be in the center of the testing machine (Figure 3.12).

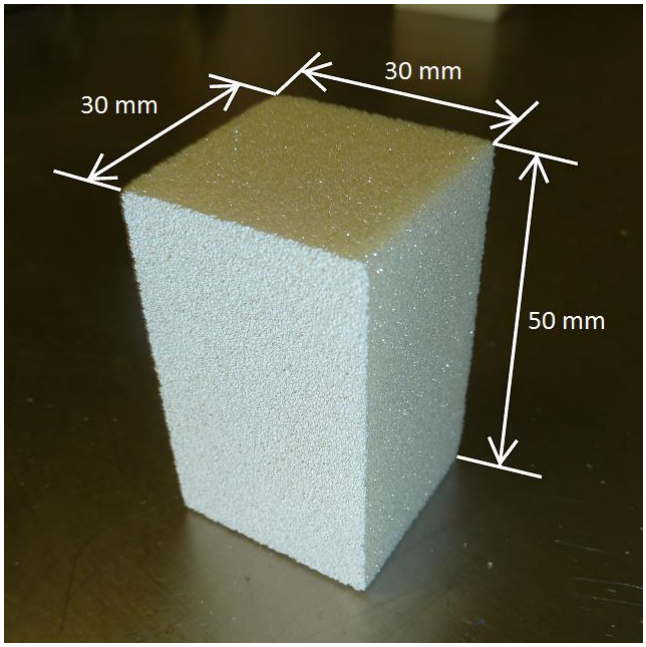

Figure 3.10. Trabecular test block.

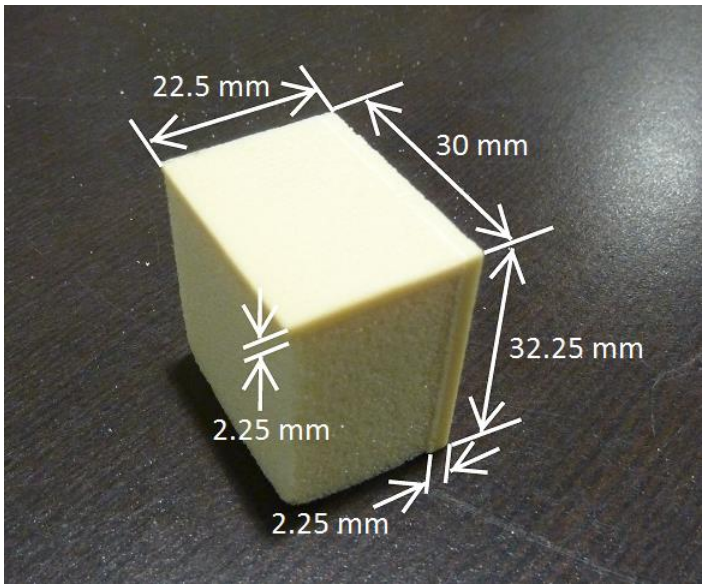

Figure 3.11. Composite test block.

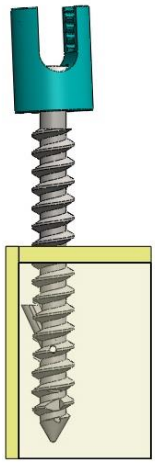

Figure 3.12. Side view of composite block with expandable screw inserted and arm open. Trabecular section made transparent for illustration.

3.3 Polymethylmethacrylate

The PMMA (DFINE, Inc., San Jose, CA, USA) was composed of 10.5 g of powder (made up of 69.5% PMMA, 30.0% barium sulfate, and 0.5% benzoyl peroxide) and 4.2 g of liquid monomer (made up of 99.5% methylmethacrylate, 0.5% N-N dimethyl-p-toluidine, and 75 ppm hydroquinone). Approximately 2 mL of PMMA was used for each test where cement augmentation of the pedicle screws was desired. The cement had a working time of thirty minutes.

3.4 Testing Machine

The machine used for providing the set displacement and recording the associated axial load was the MTS 858 MiniBionix (MTS Systems Corporation, Eden Prairie, MN, USA) (Figure 3.13). The top frame, which was attached to the load cell, was set up to allow three degrees of freedom: (1) axial displacement, (2) axial rotation, and (3) front to back bending. The hydraulic clamp, attached to the base of the machine, kept the pedicle screw stationary during pullout testing.

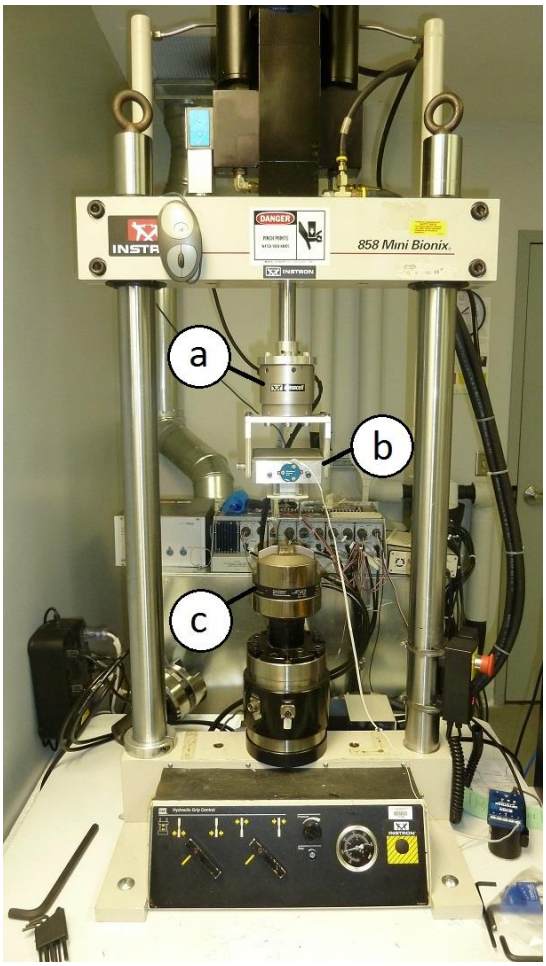

Figure 3.13. MTS 858 MiniBionix testing machine. (a) Load cell. (b) Top frame. (c) Hydraulic clamp.

3.5 Fixation Frame

In order to ensure that the test block remained stationary relative to the top frame, a fixation frame was designed to properly hold each specimen (Figure 3.14). The "skeleton" of the frame measuring 89.0 mm X 89.0 mm and 2.5 mm to 12.5 mm (with an accuracy of 0.1 mm) thick was created using SolidWorks (Dassault Systemes SolidWorks Corp., Waltham, Massachusetts, USA) and printed with the Objet24 3D printer (Stratasys, Eden Prairie, MN, USA). An opening was placed at the center of the skeleton to hold a square tube with sides measuring 38.00 mm on the outside, 32.00 mm on the inside, and a height of 57.00 ± 0.03 mm. The square tube had an

opening just large enough to hold the test block, and its centralized location ensured that the pedicle screw was placed in the exact center of the hydraulic clamp for every test while keeping both the screw and test block completely vertical. In addition to localizing the specimen, the skeleton had four openings through which four 5/16 in X 2.5 in bolts were placed. These bolts served as attachment points for the plates that would eventually be fixed, keeping the test block in place.

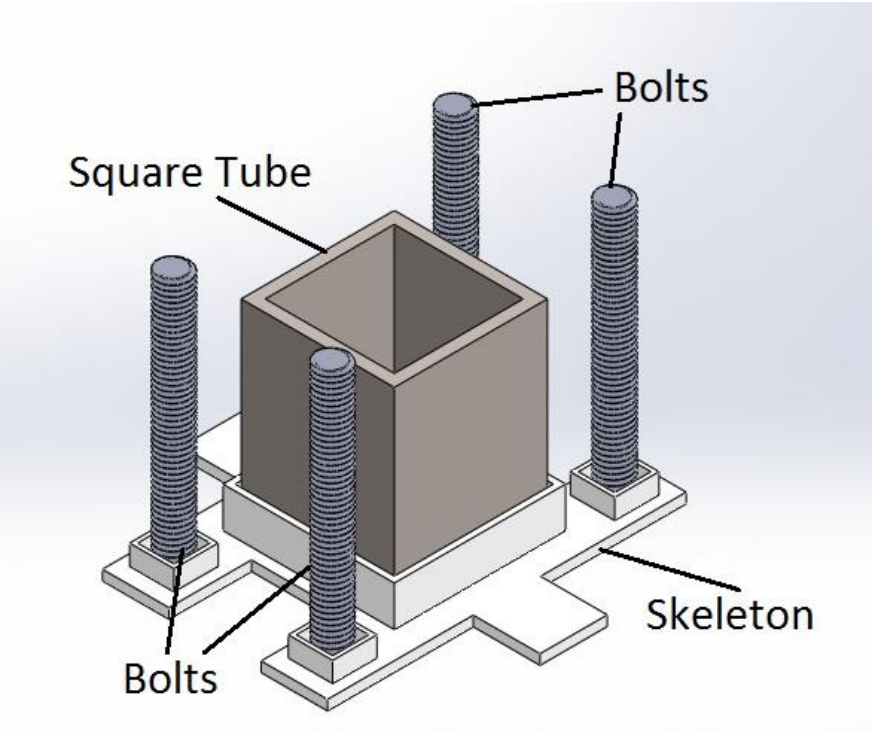

Figure 3.14. Fixation frame prior to the addition of Bondo.

Three plates were used in conjunction to keep the testing block in place. A 70.0 mm X 95.0 mm X 3.0 mm plate with a centralized 22.8 mm diameter circle (all dimensions with an accuracy of 0.1 mm) and four openings to be placed over the bolts of the frame was designed in SolidWorks and printed with the 3D printer. The design resembles a modified one gang wall plate for a circular outlet. Due to the forces that would be applied to the plate by the block during

testing, it was further reinforced by two stainless steel mending plates, which were also attached through the bolts. The plates were then fastened to the bolts with nuts.

The base of the fixation frame was held together using a combination of 3M Bondo filler, 3M red cream hardener, and 3M liquid hardener (3M, St. Paul, MN, USA). In order to keep the square tube from sliding out of the Bondo mixture during use, two small screws were drilled along the plane of two of the walls of the tube. Special care was taken to ensure that the hole did not breach either the inner or outer wall of the tube. After all the components of the frame were in place, the Bondo mixture was prepared, poured into the frame, and allowed to harden. While Bondo is known to give off heat as it hardens, no information could be found regarding the melting point of Vero White (the material used in the 3D printer). Therefore, care was taken to ensure that the components of the frame did not shift as a result of potential melting or warping of the skeleton by placing the plates over the bolts and applying a light but constant axial pressure until the material was solidified (Figure 3.15).

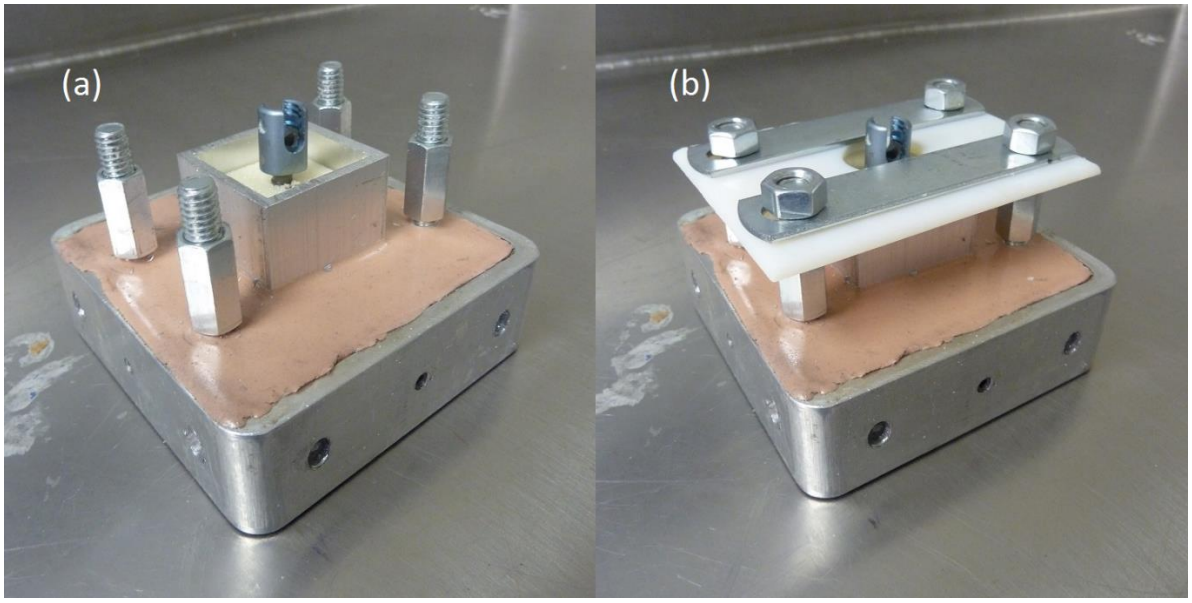

Figure 3.15. Fixation frame. (a) Containing instrumented test block. (b) With plates preventing removal of test block.

3.6 Preparation

3.6.1 Standard Pedicle Screw Instrumentation

For this study, six of each of the standard and expandable pedicle screws were used. They were tested non-augmented in both the trabecular and composite testing blocks and were finally tested with PMMA augmentation in the trabecular blocks (n=6 for every sample).

Prior to testing, each pedicle screw was assigned a number for identification purposes which was written on the head of the screw in permanent marker. For implantation of the screw into trabecular blocks, the exact center of the top of the block was found using a specialized cap/nut system, which was designed using SolidWorks and printed with the 3D printer (Figure 3.16a). Additionally, the system used the nut to increase confidence that the inserted screw was positioned perpendicular to the top surface of the block. The 10.0 ± 0.1 mm deep nut was designed to complement the dimensions (maximum/minimum diameters and pitch) of the pedicle screw and was divided into two separate halves. The two halves would piece together and fit into a sleeve on the bottom side of the cap (Figure 3.16b), which was then placed on top of the trabecular block (Figure 3.16c).

A pilot hole of 2.40 ± 0.03 mm was then drilled at the opening located at the center of the cap to a depth of 20.00 ± 0.03 mm. With the cap still in place on top of the testing block, the pedicle screw was driven through the nut and into the block (Figure 3.16d). As the screw was being driven, additional attention was given to ensure that the screw remained vertical. After the screw was inserted about halfway, the cap was removed by lifting it over the screw. This would separate the cap from the two halves of the nut which was then also removed from the threading of the screw (Figure 3.16e). At this point, the screw was driven the rest of the way to a depth of

45 mm while being closely observed to further ensure that it did not deviate to an undesirable angle (Figure 3.16f).

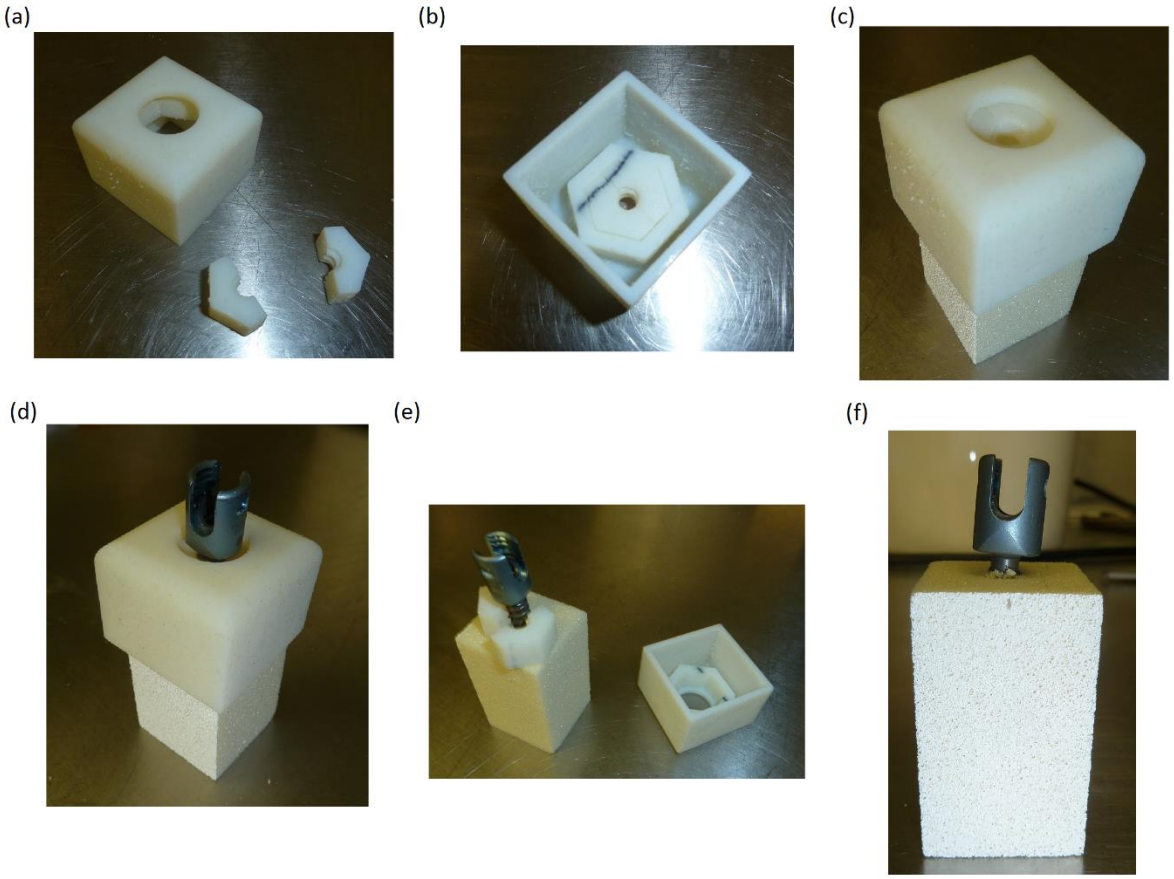

Figure 3.16. Steps for screw implantation. (a) Cap and two piece nut, (b) cap/nut system, (c) cap on top of test block, (d) partial screw instrumentation, (e) cap and nut removal, and (f) complete screw instrumentation.

The screws were inserted into the composite blocks in a similar fashion to the trabecular, however some slight adjustments were necessary due to the differences in dimension and physical properties. Prior to inserting the screws, the permanent marker was used to place a black dot on the screw shaft 30.00 ± 0.03 mm away from the tip of the screw. This marking was used as a guide for knowing how deep to insert the screw in the shorter block. Additionally, the same cap and nut system was used as was for the trabecular block. However, since the block was

thinner, the spacer was placed under the cap alongside the composite block in order to properly position the screw from the side cortical wall. Furthermore, due to the higher density in the cortical wall, the pilot hole was drilled at a diameter of 4.31 ± 0.03 mm to allow the screw to penetrate the block without placing significant, potentially catastrophic, forces to the top cortical layer.

Making the above adjustments, the pedicle screws were inserted until the marking on the screw shaft reached the surface of the composite block. Finally, to ensure that no screw was inserted at an angle greater than 5° from the vertical axis, photographs were taken of the blocks in the XZ- and YZ-planes (based on the right handed Cartesian coordinate system given in Figure 3.17). The photographs were then imported into SolidWorks and the angles of the screw in both planes were determined by sketching one line through the longitudinal axis of the screw and another line along the edge of the block and finding angle given between the two.

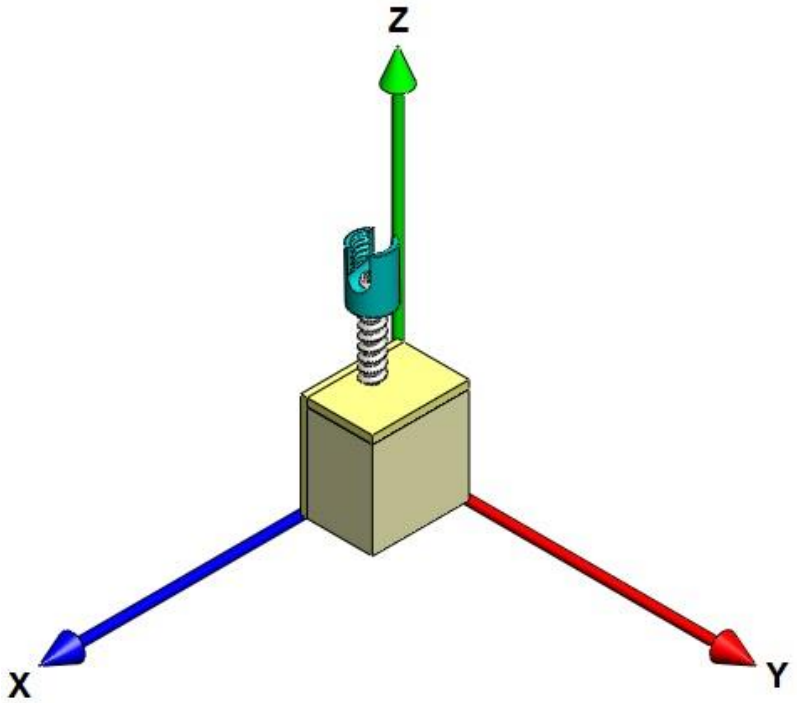

Figure 3.17. Cartesian coordinate system of composite block.

3.6.2 Expandable Pedicle Screw Instrumentation

Before the expandable screws were inserted into either of the test blocks, two markings were placed on the shaft of the screw in permanent marker, both of which were in the same longitudinal plane as the arm. The first marking was placed at the proximal most point of the threading of the screw (just under the head). The second, like the standard screws, was placed 30.00 ± 0.03 mm away from the tip of the screw. These markings were used to determine proper depth in the trabecular and composite blocks, respectively, as well as the direction the arm is facing within the block. The expandable screws were then implanted using the same techniques as were described for the standard screws. The only additional alteration (aside from expansion of the arm) was that as soon as the desired depth was reached, if the arm was not positioned towards the appropriate side of the block (as indicated by the black markings), the screw was further inserted until it reached this position. For the trabecular blocks, the arm was to directly face any of the four sides. For the composite blocks, the arm was only to face the side with the cortical wall directly.

To open the arm in the expandable screws, a 2.00 ± 0.25 mm diameter pin, designed to slide under the closed arm, was inserted into the cannulation of the screw and pushed through until the arm was expanded. Often times, the pin experienced difficulties catching the underside of the arm. In these cases, needle nose pliers were used to push the pin in place. While compressing, one end of the pliers sat on the proximal end of the partially inserted pin while the other end rested underneath the head of the pedicle screw. Special care was taken to insert the pin without producing any compressive forces between the screw and the test block as this could

potentially alter the interface between the two and produce skewed results during pullout testing.

The blocks containing the expanded screws were then imaged using an OEC 9400 C-arm (GE OEC Medical Systems, Salt Lake City, UT, USA) to ensure that the arms were in fact appropriately expanded (Figure 3.18). If not, the pin was further inserted and the test block was reimaged until the arm was expanded noticeably past the outer diameter of the threads.

Figure 3.18. OEC 9400 C-arm.

3.6.3 PMMA Augmentation

Tests involving PMMA augmented pedicle screws (of both designs) were tested only in the trabecular blocks. With the cap and nut system in place on top of the testing block, a pilot

hole of similar size and depth to the one used in other trabecular block tests was created. The PMMA was then prepared according to the manufacturer's instructions. After the cement was fully mixed the PMMA was injected into the test block at a rate of 1.3 mL per minute for 92 seconds (for a total of 1.99 mL). Once the desired amount of PMMA was inserted into the block, the pedicle screw was immediately instrumented via the same method as previously described for the trabecular block. If the screw being used was an expandable pedicle screw, the pin was immediately inserted and the arm was extended. The PMMA had a working time of thirty minutes and all screws were inserted and arms extended within this time frame. Following insertion, all test blocks were imaged using the C-arm to observe proper PMMA coverage of the screw as well as the opening of the pedicle screw arm (Figure 3.19). The specimens were then left overnight to cure for over twelve hours. After this period, the expandable screws were imaged again to confirm that the angle of arm expansion did not shift as the cement was drying.

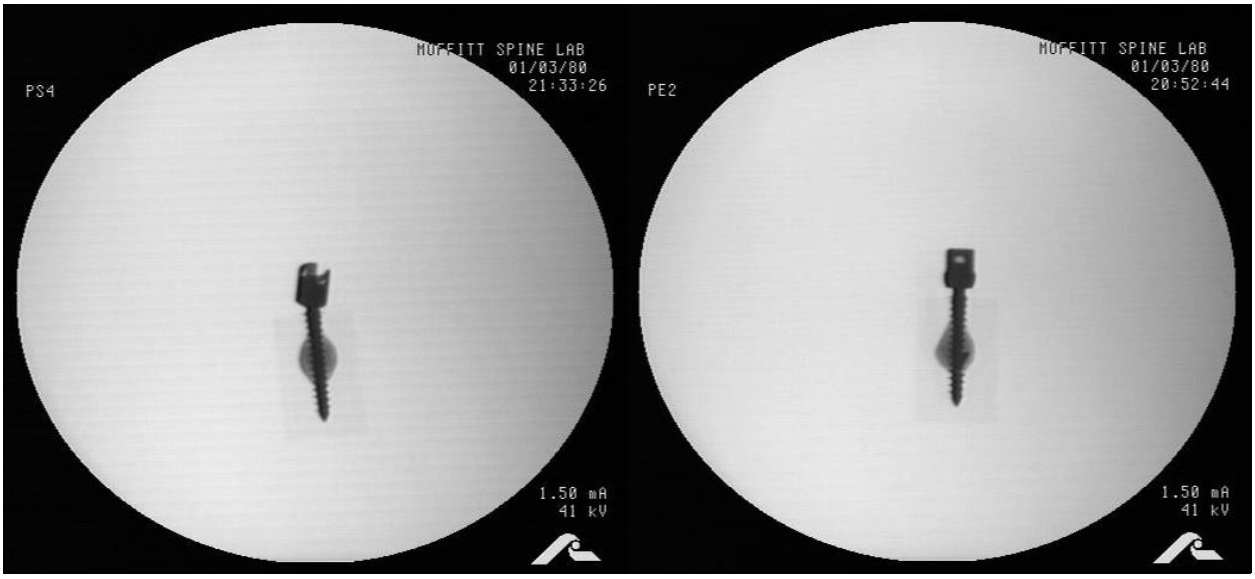

Figure 3.19. Fluoroscopic images of PMMA augmented standard (left) and expandable (right) pedicle screws in trabecular blocks.

3.7 Testing Protocol

The test block was placed in the fixation frame that was attached to the load cell on the top end of the testing machine and the 5/16 in bolts connected the inner frame of the specimen to the outer frame of the machine. The composite blocks were placed with the cortical wall facing the "inside" of the frame and were used in combination with the same spacer used for screw instrumentation (with the gap end facing the cortical wall of the block so it didn't prevent possible breaking of the harder area of the test block). This spacer helped keep the screw in the center of the testing area and to prevent the block from shifting during pullout testing.

After the block was placed in the fixation frame, a coupler was used to attach the pedicle screw to the hydraulic clamp. One end of the coupler was placed in the saddle of the pedicle screw and fixed using a compatible set screw. The other end of the coupler was carefully placed in the hydraulic clamp which closed at a pressure of 500 psi (~ 3.5 MPa) (Figure 3.20).

Once the machine was prepared, Instron WaveMatrix computer software (Instron, Norwood, MA, USA) was used to create three steps in the pullout process. The first step was to adjust the axial load so pullout would begin with the load cell reading 30 ± 1 N in tension. This value represents the approximate weight of the fixation frame and therefore adjusting the reading to this amount meant that the tension in the screw was close to 0 N. The second step in the pullout process was to apply a constant displacement of 5 mm/min on the fixation frame while holding the screw in place until the screw was fully removed from the block. Finally, the third step held the two ends in place for 5 seconds before finishing the test. An NDI data acquisition unit (Northern Digital, Inc., Waterloo, Canada) collected the axial load and

displacement data from the Instron controller at 10Hz for the entirety of the testing procedure, then NDI First Principles collated and recorded the signals.

Figure 3.20. Hydraulic clamp grips onto one end of coupler. The other end of the coupler is attached to a pedicle screw (not shown).

After testing was completed, the test block and the screw were removed from the machine. The specimens were photographed to qualitatively document the damage created as a result of pullout. Additionally, the diameter of the resulting hole in the test block was measured using a set of digital calipers (± 0.03 mm) and recorded. For the trabecular blocks, damage size was recorded in two main axes parallel to the sides of the block and passing through the center of where the screw was positioned (Figure 3.21). However, since the trabecular blocks have no distinguishable differences between any of the sides around the central screw, declaring a

specific X- and Y-direction would be arbitrary. Therefore, the damage sizes in these directions were labeled as the maximum and minimum value between the two.

The composite blocks were similarly measured in both the X- and Y-directions, however, since the block is not symmetrical about both major planes (medial and frontal) passing through the central hole, a specific X- and Y-axis could be defined. Additionally, measurements were recorded at three levels: (1) the surface of the top cortical wall, (2) the base of the top cortical wall, and (3) the surface of the trabecular section of the block (Figure 3.22).

3.8 Data Analysis

The data that was collected by the system included the load (± 1 N) and position (± 0.1 mm) of the actuator performing the pullout test. The "zero position" was determined from this data as being the point where the velocity of the top frame reached 5 mm/min. From this point, the load-displacement curves were analyzed for each test and this curve was used as the basis for calculating four main parameters: (1) pullout force, (2) stiffness, (3) energy to failure, and (4) toughness. Pullout force (N) was calculated as being the largest axial force achieved before the screw loosens from the block. Stiffness (N/mm) was determined by the slope of the load-displacement curve from the start of testing to the point of pullout. Energy to failure (N*mm) was the area under the load-displacement curve before pullout is reached. Finally, toughness (N*mm) was calculated by the area under the entire load-displacement curve. An example screenshot from a section of one of the worksheets used to calculate these values can be seen in Figure 3.23. Raw data was entered in the columns to the right and the values were presented to the left.

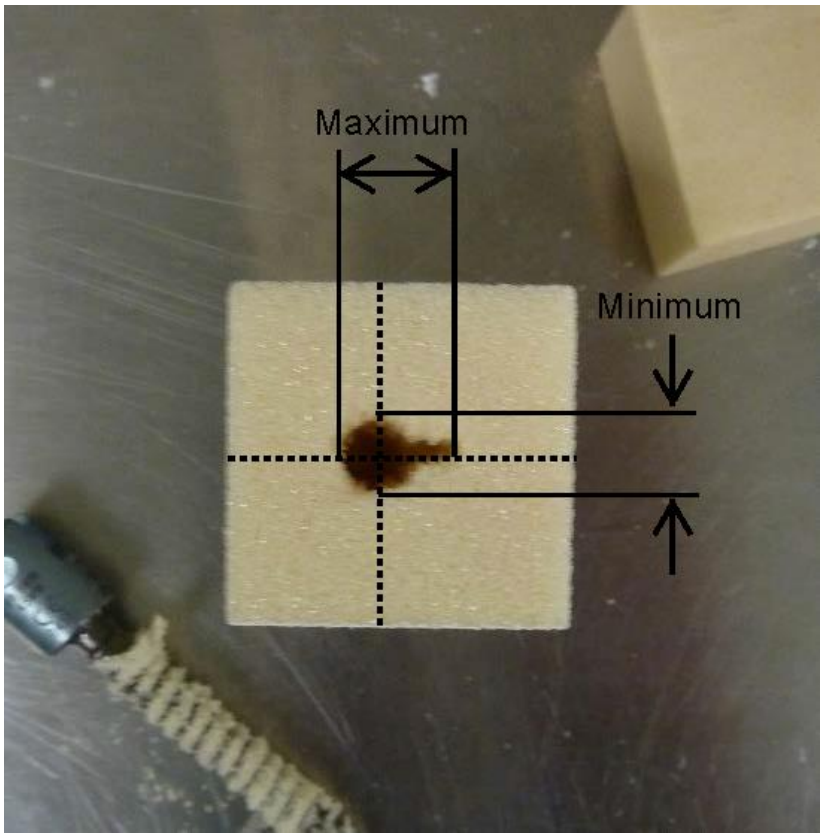

Figure 3.21. Measurements recorded following pullout in trabecular block.

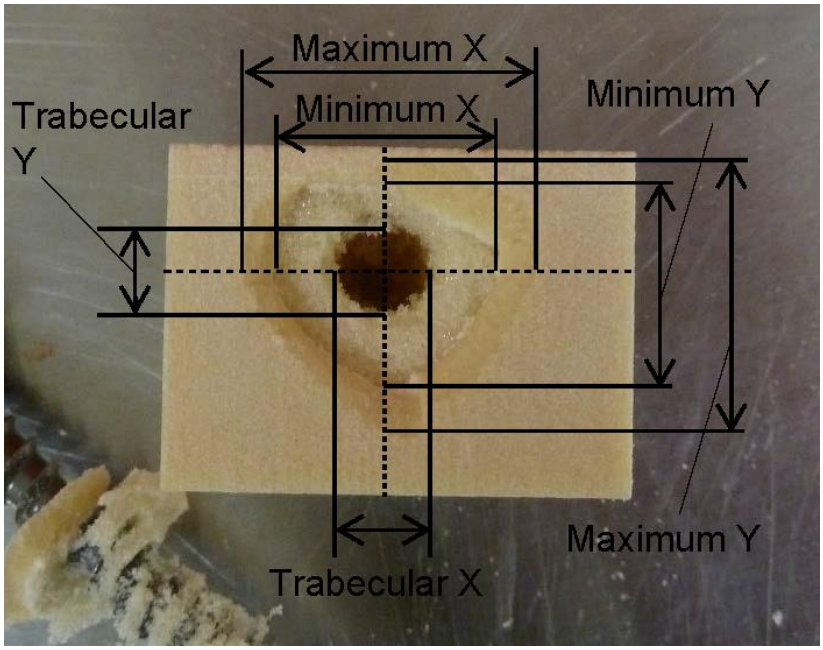

Figure 3.22. Measurements recorded following pullout of composite block.

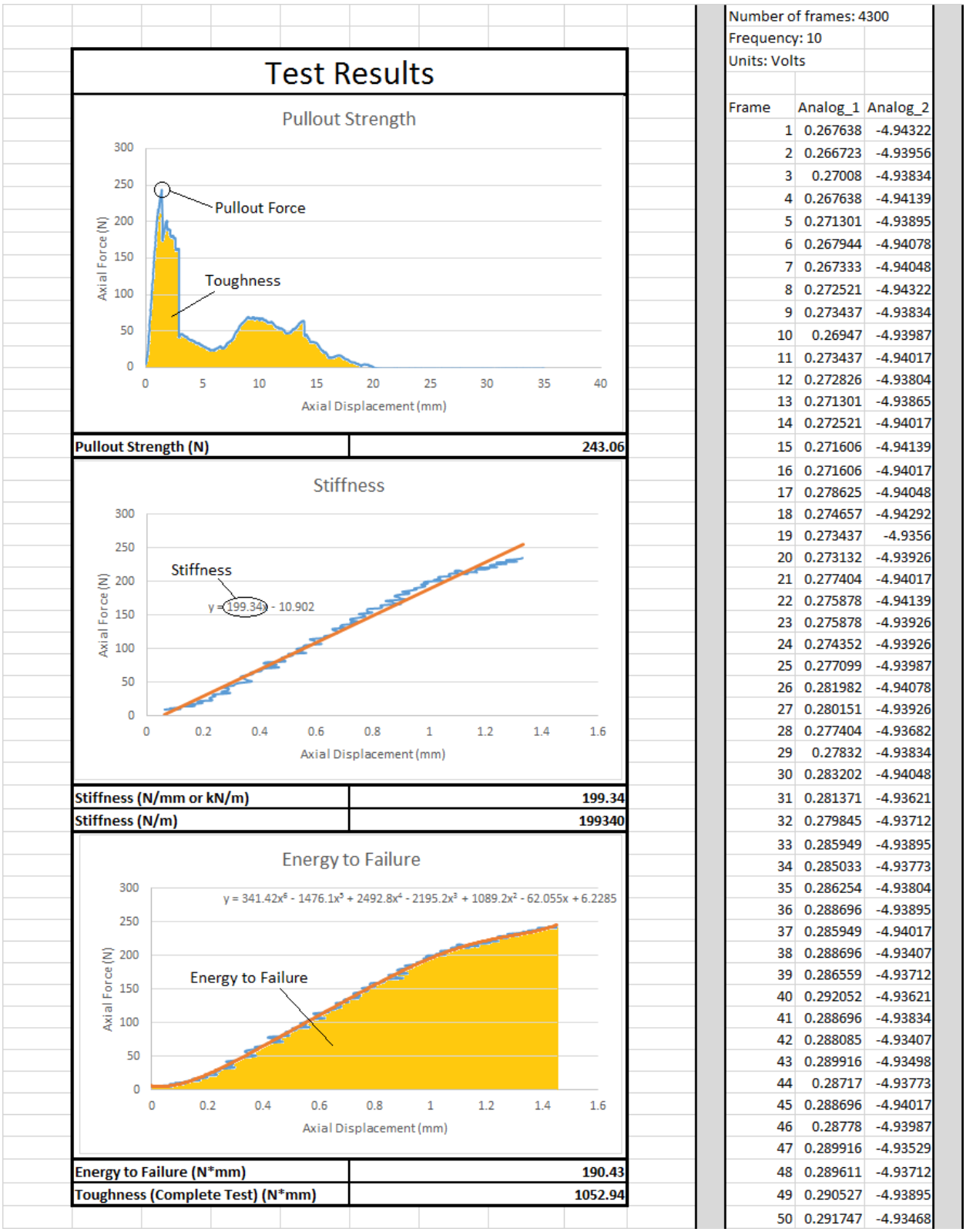

Figure 3.23. Example screenshot of worksheet used to calculate parameter values. Shading and labeling was added for clarification.

3.9 Statistical Analysis

Normality was first verified using the Shapiro-Wilk test in SAS 9.2 (Cary, NC, USA) for all four mechanical parameters (pullout, stiffness, energy to failure, and toughness) for every condition (standard, expandable, standard augmented with PMMA, and expandable augmented with PMMA). Normality was also verified for all measurements of damage caused by the standard and expandable screws in both models, however it could not be verified for the PMMA augmented screws. Considering these results, a t-test was performed for comparing values between the standard and expandable pedicle screw conditions. Additionally, tests determining differences between each of the mechanical parameters for standard screws with and without PMMA or expandable with and without PMMA were performed using a paired t-test. Differences in the measurements of damage between augmented and non-augmented screws were compared using a Wilcoxon signed rank test. A significance level of 0.05 was used for all statistical comparisons. All of the mechanical results listed are presented in the form of mean ± standard deviation.

CHAPTER 4: RESULTS

4.1 Proper Arm Expansion

Due to a malfunction of the C-arm during the testing procedure, not all of the instrumented blocks could be imaged. Therefore, to determine if the arm was properly positioned, the photographs of all the expandable screws were reevaluated after the pullout testing was performed. If the arm exited the block fully extended (the arm was open enough to "catch" the foam block as it was being pulled out), adequate placement was confirmed. On the other hand, if the arm failed to be pulled open by the surrounding low density foam, it was determined that the arm was not initially opened to an appropriate angle and the results were disregarded. There were three such instances of this happening, in which case, an alternative pullout test of the same screw was used.

4.2 Trabecular Block Tests

The values calculated for each individual screw tested in trabecular block as well as the mean and standard deviation for each condition can be seen in Table 4.1. An example load-displacement curve showing individual pullout test results for both a standard and expandable screw can be seen in Figure 4.1.

Both the expandable pedicle screws and the standard screws augmented with PMMA had average pullout forces lower than the standard pedicle screws alone. However, this difference was only significant in the expandable screws which recorded a mean pullout force 5.4% less than the standard pedicle screws alone ($P < 0.01$). While PMMA augmentation showed no statistical

difference compared to the non-augmented standard pedicle screws (P = 0.98), the PMMA augmented expandable screws reached a maximum pullout force 12.3% greater than expandable pedicle screws alone (P = 0.02).

There were no significant differences in stiffness observed between any of the comparisons made. Compared to the standard pedicle screws, however, expandable screws and PMMA augmented standard screws showed an average decrease in stiffness of 6.4% (P = 0.07) and 5.5% (P = 0.06), respectively. Conversely, PMMA augmented expandable screws performed 2.5% better than expandable screws alone, but this result, too, is statistically insignificant (P = 0.50).

When evaluating the energy to failure of the screws in the trabecular test blocks, the expandable pedicle screws had a 6.6% drop in value compared to the standard screws (P = 0.11) while adding PMMA to the standard screw increased the energy to failure by 17.6% (P = 0.43). Neither of these values, however, could be considered to be statistically significant. On the other hand, PMMA augmentation significantly increased the energy to failure of the expandable pedicle screws alone by 33.4% (P = 0.01).

The results for toughness had the largest differences between conditions. The expandable pedicle screws required 26.3% more energy to remove the screw from the test block than the standard screws did (P < 0.001). Furthermore, the addition of PMMA increased the toughness of the standard and expandable screws by 97.3% (P < 0.001) and 94.6% (P = 0.001), respectively, compared to their non-augmented counterparts. The analysis determined that these observations were significantly different.

Table 4.1. All measured values in trabecular pullout tests.

		Trabecular Block									
		Screw Number	Pullout (N)	Stiffness (N/mm)	Energy to Failure (N*mm)	Toughness (N*mm)		Screw Number	Pullout (N)	Stiffness (N/mm)	Energy to Failure (N*mm)	Toughness (N*mm)
Standard	PMMA-Standard	1	327	163	424	1330		1	359	142	643	2730
		2	332	166	431	1300		2	411	165	700	2560
		3	331	179	387	1270		3	354	179	463	2140
		4	347	168	452	1320		4	254	161	262	2760
		5	347	171	430	1300		5	252	163	247	2690
		6	348	178	424	1300		6	396	158	682	2550
		Mean	339	171	425	1300		Mean	338	161	499	2570
		Std. Dev.	9	7	21	21		Std. Dev.	69	12	208	229
Expandable	PMMA-Expandable	1	327	168	397	1630		1	314	170	393	3490
		2	308	170	345	1530		2	358	155	557	3690
		3	333	150	448	1660		3	398	166	627	2580
		4	322	164	400	1660		4	368	159	576	3410
		5	323	165	387	1660		5	346	168	458	3560
		6	310	142	403	1740		6	376	163	562	2490
		Mean	321	160	396	1650		Mean	360	164	529	3200
		Std. Dev.	10	11	33	68		Std. Dev.	28	6	86	527

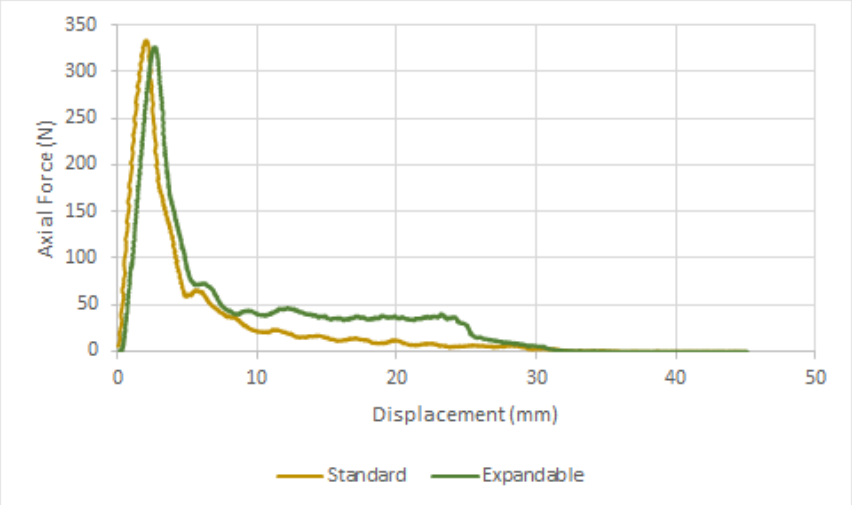

Figure 4.1. Load-displacement curves comparing individual standard and expandable screw pullout tests in trabecular blocks.

4.3 Composite Block Tests

The values retrieved for each individual screw tested in composite block as well as the mean and standard deviation for each condition can be seen in Table 4.2. An example load-displacement curve showing individual pullout test results for both a standard and expandable screw can be seen in Figure 4.2.

Table 4.2. All measured values in composite pullout tests.

	Composite Block				
	Screw Number	Pullout (N)	Stiffness (N/mm)	Energy to Failure (N*mm)	Toughness (N*mm)
Standard	1	321	163	370	832
	2	308	155	362	871
	3	296	154	284	1050
	4	293	220	215	1010
	5	306	177	363	777
	6	297	192	311	1110
	Mean	303	177	318	942
	Std. Dev.	10	25	61	133
Expandable	1	331	172	434	1540
	2	273	147	373	1600
	3	290	192	317	1420
	4	314	199	276	1260
	5	243	199	190	1050
	6	307	166	428	1390
	Mean	293	179	336	1380
	Std. Dev.	31	21	94	199

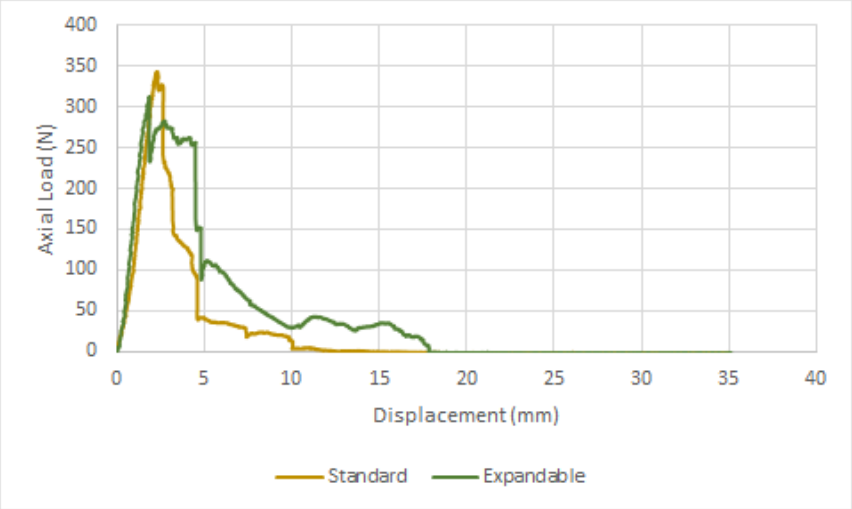

Figure 4.2. Load-displacement curves comparing individual standard and expandable screw pullout tests in composite blocks.

In the composite blocks, the expandable pedicle screws produced pullout forces 3.4% lower than the standard pedicle screws (P = 0.47). Additionally, they had average values greater than the standard screws for stiffness (1.4%) (P = 0.86) and energy to failure (6.0%) (P = 0.69), however the differences between all three of these parameters are statistically insignificant. The largest differences, once again, were seen in the toughness. Expandable pedicle screws required 46.3% more energy for screw removal than standard pedicle screws (P = 0.001), a difference that was determined to be statistically significant.

4.4 Damage to the Test Blocks

4.4.1 Trabecular Block Damage

The observations of the failed trabecular test blocks instrumented with standard pedicle screws were sheared material of the volume between the threads and extending just slightly past the maximum diameter of the screw (Figure 4.3). The expandable screws produced sheared holes similar to the ones by the standard screws. However, as the expandable screws were pulled out with the arm open to 90°, the resulting hole resembled the opening for a skeleton key (Figure

4.4). While the hole created by the threading of the expandable screw was 2.86% smaller than what was seen in the standard screw, this difference was found to be statistically insignificant ($P = 0.06$). A significant increase of 47.4% ($P < 0.0001$) was seen in the direction of arm expansion as compared to the standard screws which lacked this expansion. The mean ± standard deviation for the damage caused by standard and expandable screws in the trabecular blocks can be found in Table 4.3. A direct comparison of the maximum and minimum damage caused by the standard and expandable screws can be seen in Figure 4.5.

Figure 4.3. Standard screw damage to trabecular test block.

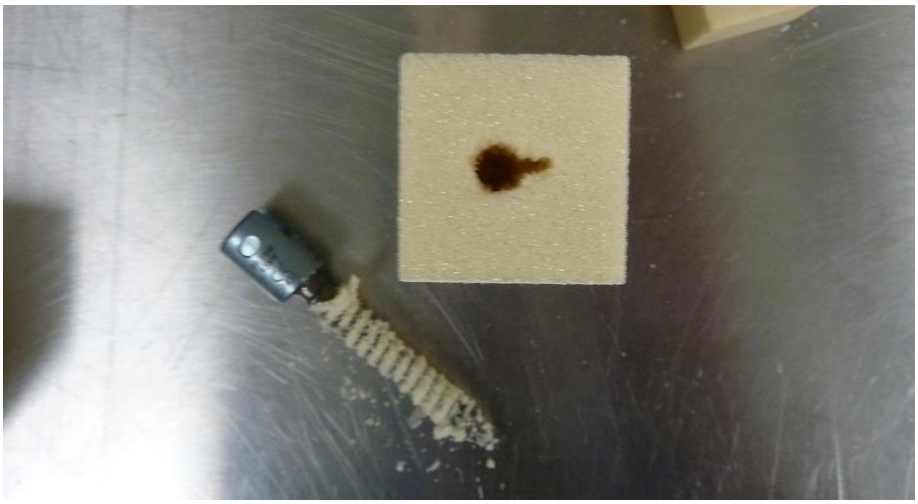

Figure 4.4. Expandable screw damage to trabecular test block.

Table 4.3. Measured damage caused by standard and expandable screws in trabecular blocks. All values for mean and standard deviation are in mm.

Trabecular Damage (Standard vs. Expandable)			
		Standard	Expandable
Max	Mean	6.93	10.22
	Std. Dev.	0.17	0.20
	Difference	47.4% Increase***	
	P-Value	0.00	
Min	Mean	6.93	6.73
	Std. Dev.	0.17	0.16
	Difference	2.86% Decrease	
	P-Value	0.06	
Note: "***" indicates statistical significance			

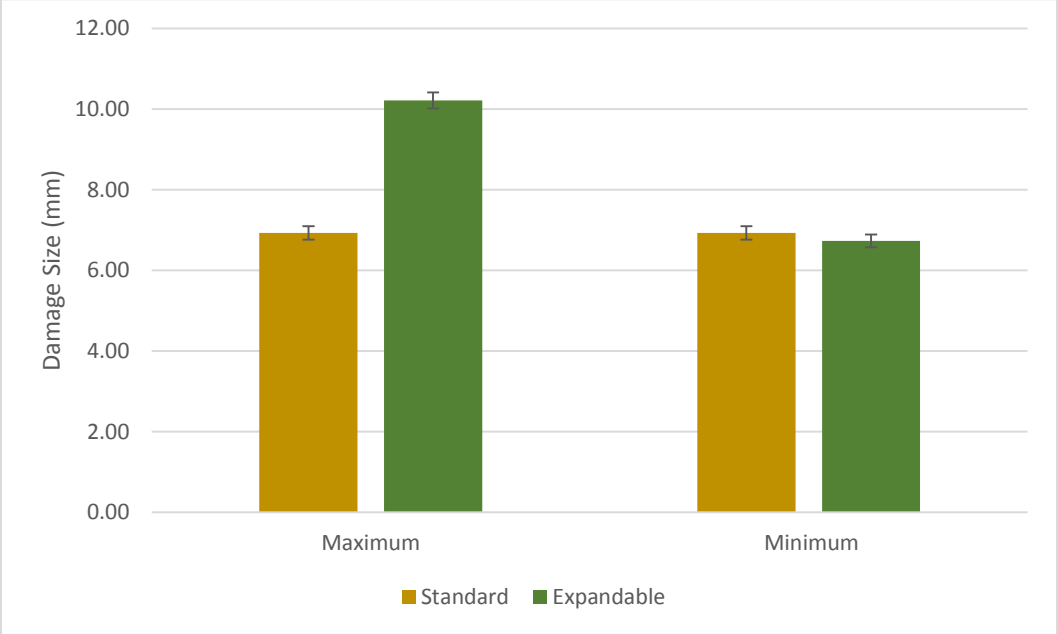

Figure 4.5. Trabecular block damage by standard and expandable pedicle screws. The error bars represent standard deviation.

PMMA augmented screws created the most damage seen in the trabecular blocks. It was apparent that following the twelve hour curing period that the cement had become fully integrated to the threads of the screw. As the pullout testing occurred, most, if not all, of the

cement that was injected into the block was removed with the screw. This resulted in large, destructive holes in the test blocks, often conical in shape (Figure 4.6).

The mean ± standard deviation for the damage caused by PMMA augmentation as compared to non-augmented screws in the trabecular blocks can be found in Table 4.4. A direct comparison of the maximum and minimum damage caused by the augmented and non-augmented screws can be seen in Figure 4.7. PMMA augmentation of standard pedicle screws resulted in damage 169% greater than standard screws alone at its maximum point and 123% at its smaller distance. Both of these differences are statistically significant ($P < 0.05$). Use of the bone cement with expandable screws also significantly increased the damage as opposed to the screws alone ($P < 0.05$). Its maximum damage was 74.91% greater than the largest measurement of destruction caused by the expandable screw alone and 133% greater than the minimum measurements between the two.

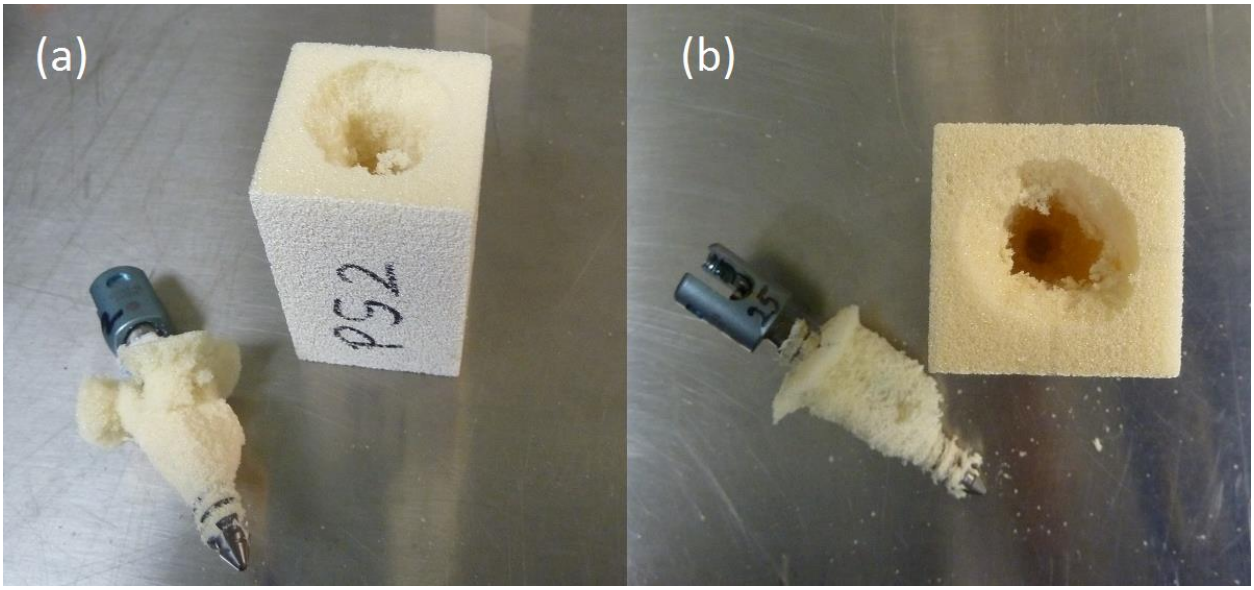

Figure 4.6. PMMA augmentation damage to trabecular test block. (a) PMMA augmented standard screw and (b) PMMA augmented expandable screw.

Table 4.4. Measured damage caused by PMMA augmented vs. non-augmented screws in trabecular blocks. All values for mean and standard deviation are in mm.

Trabecular Damage (PMMA Augmentation vs. Non-Augmentation)					
		Standard	PMMA-St	Expandable	PMMA-Exp
Max	Mean	6.93	18.63	10.22	17.87
	Std. Dev.	0.17	5.07	0.20	3.31
	Difference	169% Increase***		74.91% Increase***	
	P-Value	0.03		0.03	
Min	Mean	6.93	15.44	6.73	15.71
	Std. Dev.	0.17	4.86	0.16	4.31
	Difference	123% Increase***		133% Increase***	
	P-Value	0.03		0.03	
Note: "***" indicates statistical significance					

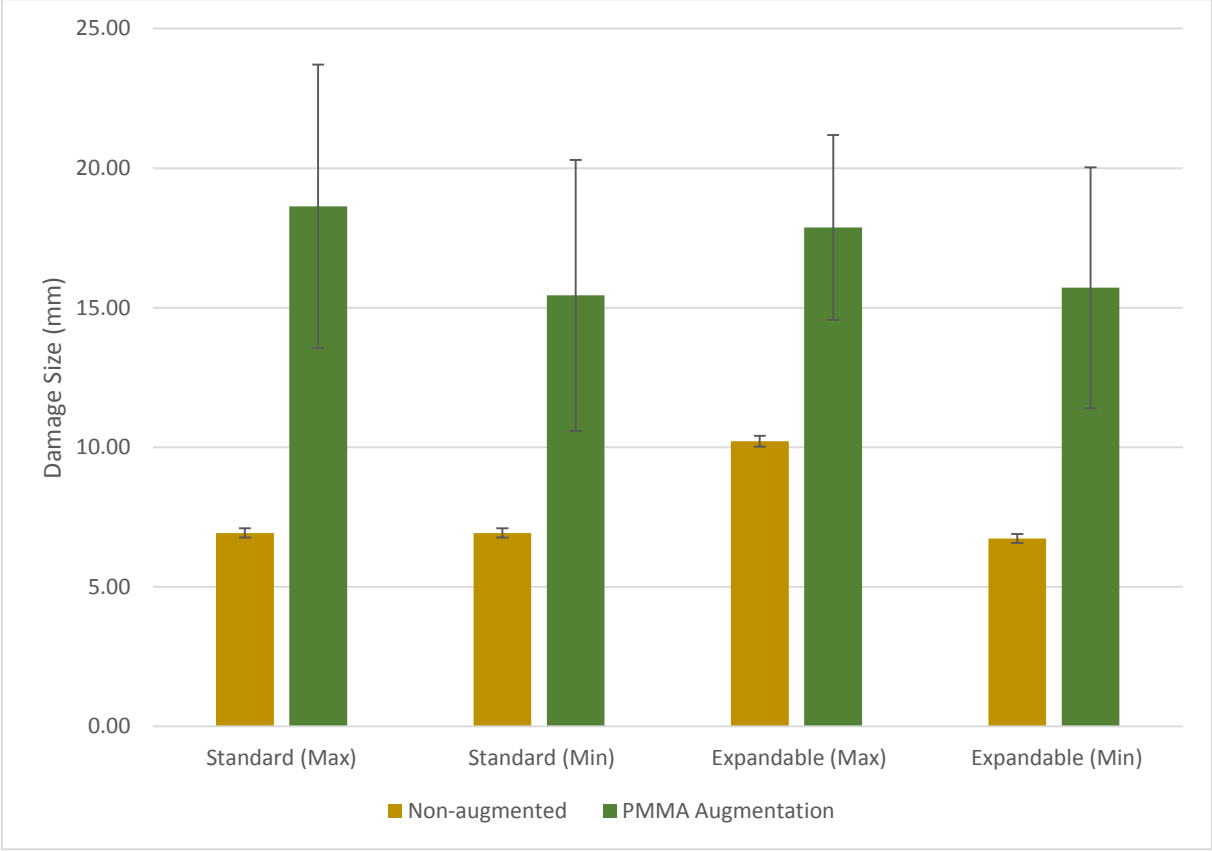

Figure 4.7. Trabecular block damage by PMMA augmentation in standard and expandable screws. The error bars represent standard deviation.

4.4.2 Composite Block Damage

As both the standard and expandable pedicle screws were pulled out from the composite blocks, the top cortical wall of the test block was separated from the trabecular section. In almost all cases, this involved complete separation as a ring of high density foam remained attached to the circumference of the pedicle screw, leaving a wider area of fracture than what was seen in the trabecular section. The hole in the trabecular section was similar in appearance to what was previously described in trabecular block with these screws. There was no damage observed to the side cortical layer in any of the tests performed. The mean ± standard deviation for every comparison made can be seen in Table 4.5. A direct comparison of the damage caused by the standard and expandable screws in every measured direction can be seen in Figure 4.8.

Table 4.5. Measured damage caused by standard and expandable screws in composite blocks. All values for mean and standard deviation are in mm.

Composite Damage					
		X		Y	
		Standard	Expandable	Standard	Expandable
Max	Mean	21.58	17.66	17.98	15.50
	Std. Dev.	2.03	1.17	2.07	0.88
	Difference	18.13% Decrease***		13.80% Decrease***	
	P-Value	0.00		0.02	
Min	Mean	19.06	13.84	16.06	12.25
	Std. Dev.	3.18	2.01	3.04	0.77
	Difference	27.41% Decrease***		23.69% Decrease***	
	P-Value	0.01		0.03	
Trab	Mean	6.85	6.76	6.85	9.51
	Std. Dev.	0.10	0.07	0.10	0.80
	Difference	1.39% Decrease		38.7% Increase***	
	P-Value	0.10		0.00	
Note: "***" indicates statistical significance					

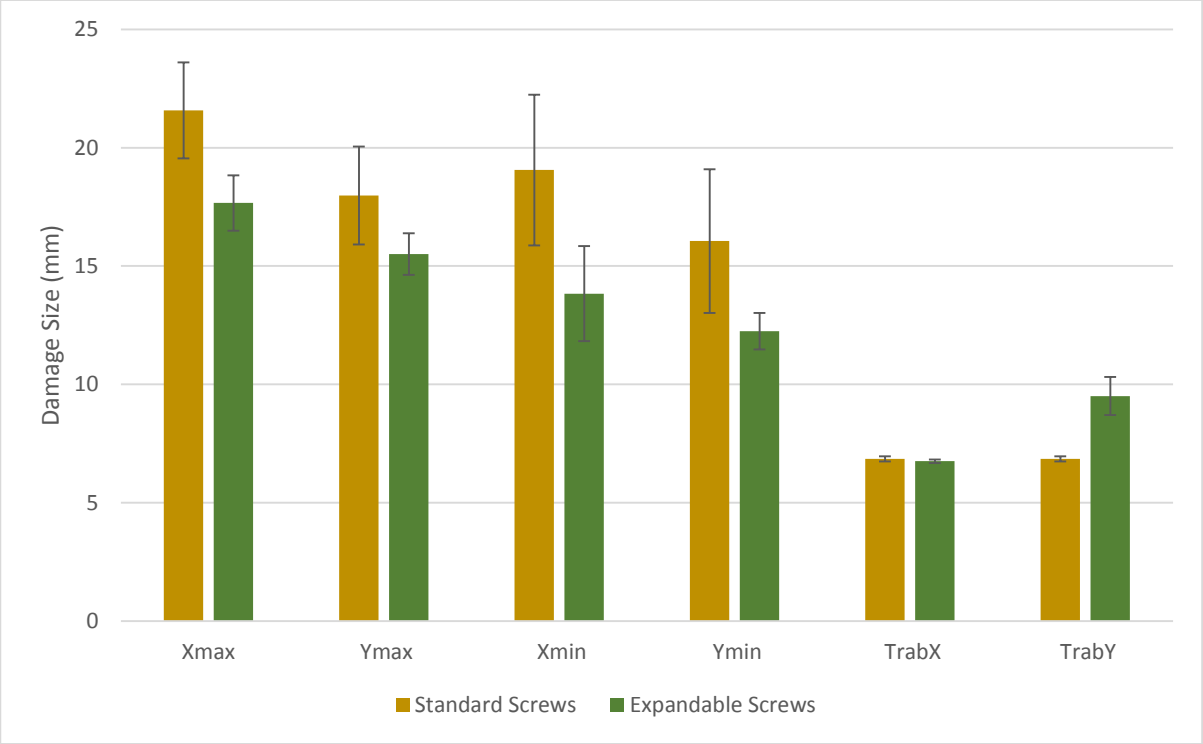

Figure 4.8. Composite block damage by standard and expandable pedicle screws. The error bars represent standard deviation.

Pullout tests involving expandable pedicle screws in the composite blocks had an average maximum removal of high density foam 18.13% smaller than that of the standard screw in the X-direction and 13.80% smaller in the Y. At the lower level of the cortical bone, expandable screws had less damage than the standard screws by 27.41% in the X-direction and 23.69% in the Y-direction. All four of these differences mentioned are statistically significant ($P < 0.05$). In the trabecular section of the composite blocks, there was no difference seen between the hole left by the screw itself (TrabX) ($P = 0.10$) and in the Y-direction the trabecular section, there was a significant increase in damage with the expandable screws of 38.7% over standard ($P < 0.001$). However, just like with the trabecular test blocks, the damage seen in this direction was expected and happened where it was intended to.

CHAPTER 5: DISCUSSION

5.1 Biomechanical Testing

Pullout testing is widely considered to be one of the best ways to determine how effective a pedicle screw is at providing adequate fixation in the human vertebra, regardless of bone quality. While it is to be acknowledged that this mode of failure is not commonly seen in a clinical setting, its simplicity and reproducibility make it ideal for comparing screws of different designs or insertion techniques. Besides pullout testing, stiffness and energy to failure can provide useful information regarding screw fixation. However, to the best of the author's knowledge, no biomechanical study has placed much, if any, emphasis on what happens mechanically after the maximum pullout force has been reached.

5.1.1 Maximum Pullout Force

In the current study, the pedicle screws with an expandable arm failed to achieve a maximum pullout force surpassing that of the standard pedicle screws in either of the test block models provided. Furthermore, the expandable pedicle screw had a statistically significant decrease in pullout force when compared to the standard pedicle screw in the trabecular block. Since the expandable arm is designed to interact with the cortical bone, it was not expected that the expandable screw would have a significantly greater pullout force in the trabecular blocks than the standard screw. Nevertheless, it was not expected that this design would perform worse than the standard screws.

It's believed that this slight, yet statistically significant, loss in pullout force is the product of two factors. First, all of the screws were inserted to the same depth for each test block so as to eliminate the role that threading plays between the tests. However, despite this, the radial opening necessary for placement of the arm in the expandable screws does eliminate some of the screw's threads that would otherwise make contact with the surrounding polyurethane foam, theoretically resulting in less resistance when an axial force is applied. Secondly, as the arm is opened, the foam surrounding the arm is pushed away and towards the distal end of the pedicle screw. While this should create a greater concentration of this material, it does so in a location that is beneficial to neither the screw nor the arm. Rather, this action creates a lack of material around the arm in the direction of pullout. Therefore, at least in the initial moments of pullout testing, the arm has very little interaction with the surrounding medium to create an increase in axial resistance. This holds especially true in the trabecular block where there is no cortical wall with which the arm can come into contact.

Even when the cortical layers are present, however, the expandable screws in the composite blocks produced statistically insignificant differences in pullout force to that of the standard screws. The expandable screw was designed to open just until it reaches the side cortical wall of the test block, keep its position as the screw is being pulled out, and then provide additional axial resistance (or a secondary pullout) when the distal end of the arm reaches the top cortical layer. This was not observed, however, as a large amount of the top cortical layer was removed from the testing blocks after initial pullout, leaving nothing but the side layer for the arm to make contact with.

Another notable result in the current study involves the pullout forces for the screws augmented with PMMA. Particularly in the instance of standard screws being augmented with the bone cement, the average pullout force was 0.29% less than those screws inserted alone. While this decrease is considered to be statistically insignificant due to the high amount of variability between tests, even the statistical insignificance is contradictory to what is seen in the majority of the literature available for both cadaveric [48, 60, 61, 81, 98] and synthetic [15, 77, 97] models.

It was found, however, that Becker et al. [14] observed no significant difference in the pullout strength between standard pedicle screws alone and those augmented via a kyphoplasty technique. In this technique, they formed a cavity in the vertebral body with a medical grade balloon and then filled this void with PMMA prior to screw insertion. They suggested that the lack of a significant difference may have been a result of using an identical volume of cement as the volume of the cavity. Because of this, little to no cement became incorporated into the pores of the trabecular bone. They did notice, however, a significant increase of 79% using a pre-injected vertebroplasty technique (injecting the PMMA without formation of a cavity) using 2 mL of cement, similar to what was done in the present study.

Another instance of statistical insignificance involving PMMA augmented pedicle screws can be seen in a study performed by Paré et al. [31], in which they attempted to determine the ideal volume of PMMA to use in pedicle screw augmentation. They found that when augmenting a pedicle screw in the thoracic vertebra with 0.5 mL of PMMA, that there was an insignificant difference in pullout strength between that and a pedicle screw inserted without the cement. However, this volume was a quarter of what was used in the current study. Additionally, they

showed significant increases in pullout strengths for all other volumes tested, including a mean increase of 221% for screws augmented with 2.0 mL of PMMA in the lumbar vertebra.

Of the studies reviewed that performed pullout testing of PMMA augmented pedicle screws in polyurethane blocks, the lowest density foam that was observed was 0.09 g/cm^3 [15, 97]. This was 0.01 g/cm^3 greater than what we used. Though specific values were not provided for one of the studies, a bar graph on each showed pullout forces of the PMMA augmented screws to be approximately equal to or less than the values seen in this study. However, these studies also showed the non-augmented pedicle screws to have mean pullout forces approximately less than 50 N. Therefore, the differences shown in these studies were significantly greater than what was seen in our results.

5.1.2 Toughness

Regardless of what was witnessed for the maximum pullout force achieved between standard and expandable pedicle screws, the interaction between the arm and the side cortical layer proved to be significant in a manner that was unexpected prior to the start of testing. By observing the load-displacement diagrams of each test, it was noticed that the expandable screws tended to have a more gradual decrease in axial loading following the incidence of pullout failure than that of the standard screws (Figure 4.2). The area under the load-displacement curve for the entirety of the test, until the screw was fully removed from the test block, was calculated. Similar to how energy to failure is used to describe the amount of energy required to reach the point of pullout, this value defines the amount of energy that is required to completely remove the screw from the test block. It was shown in this instance that the expandable screws had a significant increase of 46.3% over standard screws in composite test blocks.

The most likely explanation for this observation is that as the pedicle screw is being removed from the test block, the expandable arm scrapes against the side cortical wall. This creates a friction force opposite the direction of pullout that exists until the arm is removed from the block. It should be addressed, however, that a thin layer of adhesive glue exists between the layers of the composite test block. Therefore, the possibility exists that this frictional resistance between the arm and the cortical layer may actually be friction between the arm and glue.

A second proposed explanation for this increase in toughness is that the foam in the trabecular portion of the test block provides further resistance against the arm as the screw is being pulled out. Though this may seem to be somewhat of a contradiction to the reason of decreased pullout strength previously suggested in the trabecular block, once the arm is fully extended and overtakes the section of missing trabecular foam, the remaining foam in the way will result in a larger axial force. Evidence of this can be seen in the trabecular tests where, despite there being no cortical layer to make contact with, the expandable screws outperformed the standard by 26.3%. The load-displacement curves in Figure 4.1 shows one of the standard and one of the expandable screws being tested in the trabecular block. It can be seen that the expandable screw with its arm positioned 25 mm from the top of the block had a consistently higher axial load after pullout until the displacement of the screw reached 25 mm (the point where the arm exited the test block).

5.2 Visual Parameters

The second aspect of this study involved an investigation into how much damage is done to the block after pullout occurs. Many of the more successful techniques at increasing the pullout strength of pedicle screws in osteoporotic patients have also been accompanied by

increased risk of injury to the patient. For instance, it has been documented that, depending on the sizes used, increasing the diameter of the screw can result in an increased pullout strength of 45.5%. However, the weakened bone that the screw is inserted into can be more prone to pedicular fracture in the presence of larger instrumentation. Bicortical fixation has been shown to increase pullout strengths up to 120%, however, a slight miscalculation of screw placement may result in puncture of the aorta or iliac vessels on the anterior side of the vertebral body. Additionally, PMMA has the capabilities to produce maximum pullout forces nearly 350% larger than a similar screw inserted without the cement. However, the risk of thermal necrosis due to its exothermic polymerization, extrusion outside the vertebra resulting in neural injury, structural damage to the vertebra if reinstrumentation is necessary, and cardiac issues as a result of its toxic monomer being absorbed in the blood stream, have left many with concerns over its usage. Hesitation around its usage as well as that of some expandable pedicle screws may also exist due to the location of the spinal cord and peripheral nerves located medial and inferior, respectively, to the pedicle. The increased size of the system has to potential to cause damage to these structures should bone fracture occur.

If attempts at increasing fixation tend to come with an increased risk of damage, the goal of the experimental screw, from a safety standpoint, was to create controlled failure that would result in the least detrimental damage to the patient as possible. Therefore, the singular expandable arm on the screw was designed with the intent of being positioned in the superolateral direction to the pedicle. This way, should bone fracture occur with this screw, it was proposed that any additional damage to the vertebral body over what would normally be

seen in a standard pedicle screw would be located in an area away from potential harm of the surrounding nervous system.

Measurements of the resulting damage in the trabecular test blocks show that the expandable screw accomplished this goal. There were no differences witnessed between the hole size formed by the body of the screws for either the standard or the expandable designs. The only difference in size that was recorded was seen in the direction of the open arm of the expandable screw. In this direction, the damage extended an additional 47.4%. However, this increase was expected and occurred only where it was intended.

The damage resulting from the addition of PMMA augmentation to both screw designs, however, covered a larger, less organized area. Additionally, there was a conical shape to the damage of the block, propagating towards the surface. Not counting the direction of the open arm for the expandable screw, the addition of PMMA to the pedicle screws more than doubled the amount of foam removal at the surface of the block and this removal occurred in all directions, not just in those that were recorded.

Just as in the trabecular test blocks, the pullout tests performed in the composite blocks indicated safe methods of failure of the expandable pedicle screws when using the standard screws as a baseline. In fact, in all of the dimensions of failure measured in the top cortical layer, the expandable screws demonstrated a statistically significant decrease in damage compared to the standard pedicle screws. Additionally, in the trabecular portion of the test block, the size of the hole left behind by the body of the two screw types were statistically similar. The expandable arm once again created an expected significant increase in the damage size in the intended direction towards the side composite block.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

As proper fixation of a pedicle screw in the weakened bone of osteoporotic individuals remains a challenge in spinal fusion surgery, various screw designs and insertion techniques have been considered that increase the screw's stability in bone of compromised quality. However, this often comes at an increased risk to the patient's health as well. The expandable pedicle screw designed for this study was expected to increase pullout strength while being able to control destructive bone failure seen in a worst case scenario to a location determined to be least detrimental to the health of the patient. While pullout strength was not increased with the experimental screw over standard pedicle screws used today, the more gradual decrease in the axial load following pullout of the expandable screw shows promising results for patients waiting for reinstrumentation surgery following screw failure.

Furthermore, it was also shown that the expandable pedicle screws were successful in limiting damage to a minimum when compared to standard pedicle screws. Additional damage in the synthetic blocks representing osteoporotic trabecular bone was limited to the location directly above the arm in the direction of pullout. Considering the additional observation that damage to the cortical layer of composite blocks was statistically smaller than what was seen with standard screws, the expandable pedicle screws have been demonstrated in this study to be as safe as, if not safer than, the current standard screws used for posterior spinal fusion.

6.2 Limitations

Unfortunately, limited power minimizes the accuracy of the statistical analysis. Largely due to the high cost of pedicle screws, six standard screws and six expandable screws were used allowing for a maximum sample size of n=6 for all test conditions. While other studies of a similar nature have utilized identical sample sizes [16, 37, 51], it is still very difficult to confidently state whether significant differences between screw types are present.

Additionally, test blocks were used due to their low cost and homogeneity. As such, any differences noticed between tests can be safely assumed to be a result of variations during implantation of the screw. However, for this same reason, it should be noted that tests performed in a cadaveric model would likely produce varying results as BMD differs from person to person and even from vertebra to vertebra within the same individual. Furthermore, the composite model created for this study was proposed as a potential analog emulating how the screw would interact with not only the trabecular bone in the vertebral body, but also the cortical wall surrounding it. Mechanical comparisons have not been performed between this model and human osteoporotic vertebrae of a similar density and therefore it should not be considered an accurate representation of how the screws will perform in the human body.

6.3 Recommendations

It was noted that while the expandable pedicle screw failed to either increase the pullout strength of the system or create a secondary pullout after initial failure, the screw did present promising results from a previously unconsidered aspect. The friction created by the arm against the side cortical wall created a residual axial resistance following pullout as can be evidenced by the increased energy that was needed to be placed into the system to fully remove the screw. As

the side wall was initially only intended to serve the purpose of maintaining the position of the arm as the screw was pulled out, future research involving the current expandable pedicle screw should include a redesigned arm that maximizes contact made with the side cortical wall, thus further increasing the friction produced in this region.

Additionally, the limitations presented by the composite test block should be considered and investigated in further research. Since it is an unverified model suggested to simulate the interaction between the screw and the cortical bone of an osteoporotic vertebra, future tests involving the composite blocks should be performed in conjunction with cadaveric testing in osteoporotic vertebrae. This way, if significant differences exist between the synthetic and cadaveric models, a better understanding of how the screw will perform in a biological setting will exist even if the specimens aren't uniform in density (as is often the case in cadaveric biomechanical studies).

Finally, considering the difficulties experienced by testing with a small sample size, it would be highly suggested that future examination into the expandable pedicle screw's fixation and safety in bone of compromised quality be done with a larger number of screws in each test group. Ideally, the sample size in any biomechanical study would be significantly larger than what is seen here, such as fifty to a hundred or more. However, such a number is unrealistic considering the high cost of pedicle screws and human cadaveric vertebra, should that option be considered. Therefore, a sample size of approximately ten to twenty screws for each test group, as is seen in much of the literature reviewed [14, 15, 18, 52, 77], should still significantly reduce variability of the measurements and thus produce more meaningful results.

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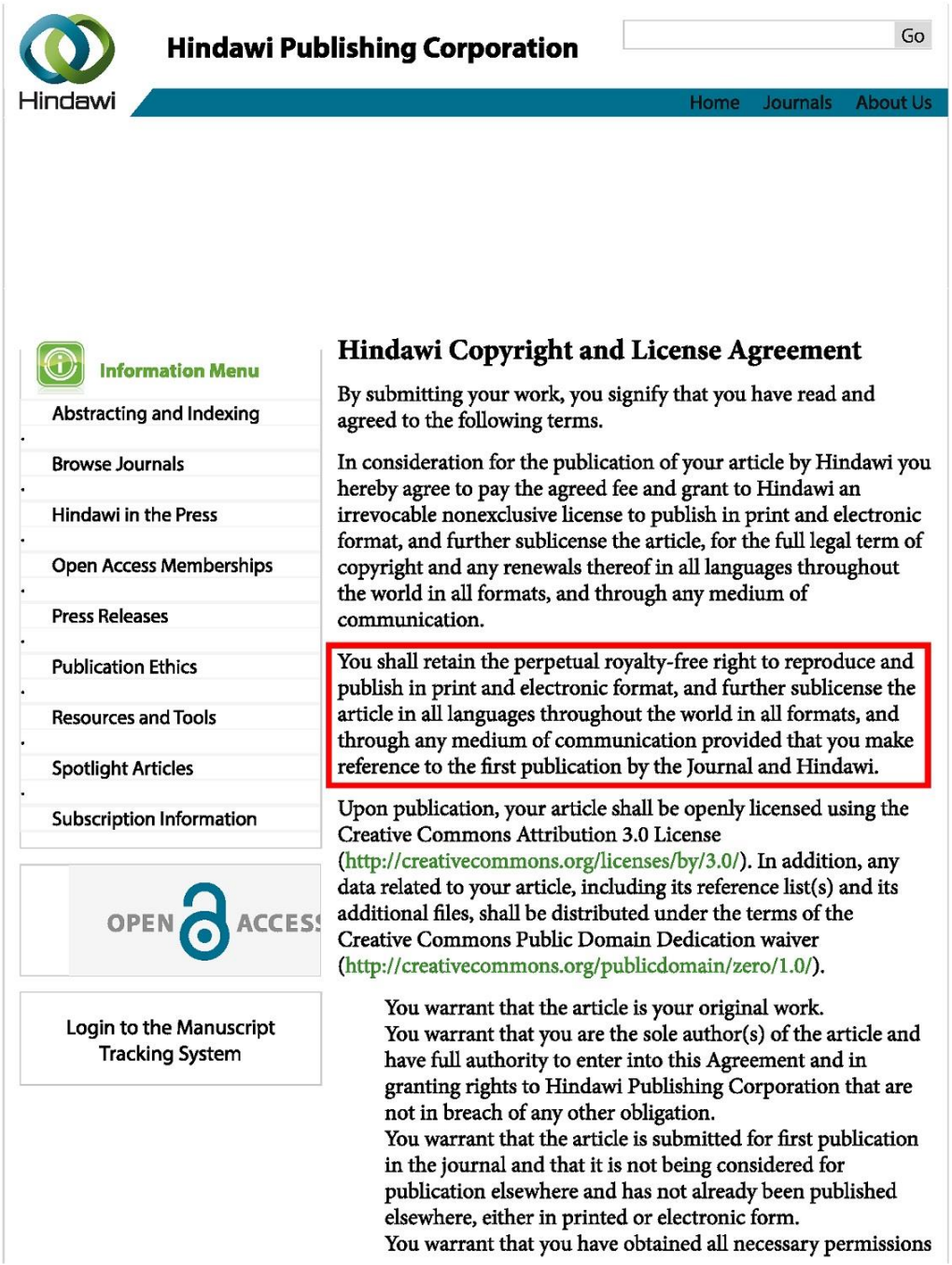

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Appendix B SAS Code for Statistical Analysis of Data

```
/* Note: The following contains a sample of the code used in SAS to */
/* perform statistical analyses of the comparisons. It is not a complete */
/* transcription of the code for all the tests performed in this study. */

/* The following code enters the datasets to be used for normality tests */

data trabpull;
input Pullout Screw $;
cards;
327.4475    Standard
331.9875    Standard
331.3825    Standard
346.785     Standard
346.635     Standard
348.42      Standard
327.24      Expandable
307.59      Expandable
333.115     Expandable
322.175     Expandable
323.49      Expandable
309.965     Expandable
359.06      PMMASt
411.03      PMMASt
354.2 PMMASt
253.98      PMMASt
252.12      PMMASt
396.29      PMMASt
314.38      PMMAExp
357.62      PMMAExp
397.57      PMMAExp
368.49      PMMAExp
346.36      PMMAExp
375.54      PMMAExp
;
run;

data comppull;
input Pullout Screw $;
cards;
320.7066667 Standard
308.01      Standard
295.69      Standard
292.495     Standard
306.26      Standard
297.03      Standard
330.615     Expandable
273.38      Expandable
289.63      Expandable
314.15      Expandable
243.06      Expandable
306.69      Expandable
;
run;
```

Appendix B (Continued)

```
data trabsurfmax;
input Specimen $ Screw $ Distance;
cards;
1      Standard    6.780
2      Standard    7.220
3      Standard    6.775
4      Standard    6.915
5      Standard    7.015
6      Standard    6.880
7      Arm   10.415
8      Arm   10.315
9      Arm   10.205
10     Arm   10.380
11     Arm   10.085
12     Arm   9.905
1      PMMAS 21.220
2      PMMAS 21.760
3      PMMAS 22.200
4      PMMAS 11.550
5      PMMAS 12.680
6      PMMAS 22.370
7      PMMAA 15.280
8      PMMAA 15.220
9      PMMAA 21.750
10     PMMAA 16.780
11     PMMAA 22.410
12     PMMAA 15.790
;
run;

data compxmax;
input Specimen $ Screw $ Distance;
cards;
1      Standard    18.540
2      Standard    20.110
3      Standard    23.090
4      Standard    23.730
5      Standard    21.000
6      Standard    22.980
7      Arm   18.530
8      Arm   18.290
9      Arm   16.550
10     Arm   19.060
11     Arm   16.110
12     Arm   17.440
;
run;

/* The following code performs normality tests on the above datasets */

proc univariate data=trabpull normal plots;
      histogram;
      class Screw;
      var Pullout;
```

Appendix B (Continued)

```
run;

proc univariate data=comppull normal plots;
      histogram;
      class Screw;
      var Pullout;
run;

proc univariate data=trabsurfmax normal plots;
      histogram;
      class Screw;
      var Distance;
run;

proc univariate data=compxmax normal plots;
      histogram;
      class Screw;
      var Distance;
run;

/* The following enters new datasets between standard and expandable */
/* screw for both blocks and all recorded measurements to prepare for */
/* statistical analysis for each mechanical set */

data trabpull_STD_EXP;
input Specimen $ Screw $ Pullout;
cards;
1 Standard 327.4475
2 Standard 331.9875
3 Standard 331.3825
4 Standard 346.785
5 Standard 346.635
6 Standard 348.42
7 Expandable 327.24
8 Expandable 307.59
9 Expandable 333.115
10 Expandable 322.175
11 Expandable 323.49
12 Expandable 309.965
;
run;

data comppull_STD_EXP;
input Specimen $ Pullout Screw $;
cards;
1 320.7066667     Standard
2 308.01    Standard
3 295.69    Standard
4 292.495   Standard
5 306.26    Standard
6 297.03    Standard
7 330.615   Expandable
8 273.38    Expandable
9 289.63    Expandable
```

Appendix B (Continued)

```
10 314.15   Expandable
11 243.06   Expandable
12 306.69   Expandable
;
run;

/* The following code runs t-tests of the above datasets */

proc ttest data=trabpull_STD_EXP;
title 'Pullout - Trabecular Standard VS Expandable Screws';
class Screw;
var Pullout;
run;

proc ttest data=comppull_STD_EXP;
title 'Pullout - Composite Standard VS Expandable Screws';
class Screw;
var Pullout;
run;

/* The following enters new datasets between PMMA augmented and */
/* non-augmented pedicle screws of the same type for both blocks and all */
/* recorded measurements to prepare for statistical analysis for each set. */
/* Note that 'Expandable' screws were renamed to 'Arm' due to issues with */
/* the code */

data trabpull_STD_PMMA;
input Specimen $ Screw $ Pullout;
cards;
1 Standard 327.4475
2 Standard 331.9875
3 Standard 331.3825
4 Standard 346.785
5 Standard 346.635
6 Standard 348.42
1 PMMASt 359.06
2 PMMASt 411.03
3 PMMASt 354.2
4 PMMASt 253.98
5 PMMASt 252.12
6 PMMASt 396.29
;
run;

data trabpull_ARM_PMMA;
input Specimen $ Screw $ Pullout;
cards;
1 Arm 327.24
2 Arm 307.59
3 Arm 333.115
4 Arm 322.175
5 Arm 323.49
6 Arm 309.965
1 PMMAarm 314.38
```

Appendix B (Continued)

```
2 PMMAarm 357.62
3 PMMAarm 397.57
4 PMMAarm 368.49
5 PMMAarm 346.36
6 PMMAarm 375.54
;
run;

/* The following code runs paired t-tests of the above datasets */

PROC SORT DATA = trabpull_STD_PMMA;
BY Specimen;
RUN;
proc transpose data=trabpull_STD_PMMA out=trabpull_STD_PMMAwide
prefix=faminc;
    by Specimen;
    id Screw;
    var Pullout;
run;
proc print data = trabpull_STD_PMMAwide;
run;

proc ttest data = trabpull_STD_PMMAwide;
  paired famincStandard*famincPMMASt;
run;

PROC SORT DATA = trabpull_ARM_PMMA;
BY Specimen;
RUN;
proc transpose data=trabpull_ARM_PMMA out=trabpull_ARM_PMMAwide
prefix=faminc;
    by Specimen;
    id Screw;
    var Pullout;
run;
proc print data = trabpull_ARM_PMMAwide;
run;

proc ttest data = trabpull_ARM_PMMAwide;
  paired famincArm*famincPMMAarm;
run;

/* The following code performs t-tests on the damage created between */
/* standard and expandable pedicle screws in both blocks. */
/* Note: the dataset for trabecular blocks are re-entered, omitting */
/* the values for augmented screws. Composite dataset stays the same. */

data trabsurfmax;
input Specimen $ Screw $ Distance;
cards;
1     Standard    6.780
2     Standard    7.220
3     Standard    6.775
4     Standard    6.915
```

Appendix B (Continued)

```
5       Standard    7.015
6       Standard    6.880
7       Arm    10.415
8       Arm    10.315
9       Arm    10.205
10      Arm    10.380
11      Arm    10.085
12      Arm    9.905
;
run;

proc ttest data=trabsurfmax;
title 'Trabecular Standard VS Expandable Surface Max';
class Screw;
var Distance;
run;

proc ttest data=compxmax;
title 'Composite Standard VS Expandable Xmax';
class Screw;
var Distance;
run;

/* The dataset for PMMA augmented screws are re-entered to prepare */
/* for comparison using Wilcoxon Signed Rank test*/

data trabsurfmax_stand;
input Screw $ Unaug Aug;
cards;
1       6.780 21.220
2       7.220 21.760
3       6.775 22.200
4       6.915 11.550
5       7.015 12.680
6       6.880 22.370
;
run;

data trabsurfmax_exp;
input Screw $ Unaug Aug;
cards;
7       10.415       15.280
8       10.315       15.220
9       10.205       21.750
10      10.380       16.780
11      10.085       22.410
12      9.905 15.790
;
run;

/* The following code runs paired Wilcoxon Signed Rank test of */
/* the above datasets */

data trabsurfmax_stand2;
```

Appendix B (Continued)

```
      set trabsurfmax_stand;
      diff= Aug-Unaug;
      run;

proc univariate data=trabsurfmax_stand2;
      var diff;
run;

data trabsurfmax_exp2;
      set trabsurfmax_exp;
      diff= Aug-Unaug;
      run;

proc univariate data=trabsurfmax_exp2;
      var diff;
run;
```