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Biomechanical Comparison of Titanium and Cobalt Chromium Pedicle Screw Rods in an Unstable Cadaveric Lumbar Spine

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Biomechanical Comparison of Titanium and Cobalt Chromium Pedicle Screw Rods in an Unstable Cadaveric Lumbar Spine

by

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of the requirements for the degree of
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Range of Motion, Intradiscal Pressure

Dedication

The following is dedicated to my family and friends. Thank you all for the support that you have given me in any way, shape or form. Furthermore, I dedicate this project and all future projects to furthering the knowledge of spine biomechanics and disorders.

Acknowledgments

I would like to thank: Alphatec Spine for providing funding and instrumentation for this investigation; Thomas Shea for helping dissect and pot the specimens; Michael Del Valle for assistance during testing; Sabrina Gonzalez-Blohm for pushing me to finish this project; Frank Vrionis for his support and advice; Kamran Aghayev for his mentoring and authentic notions; Bill Lee for helping me get to this position and guiding the project; Dan Hess for always having an ear to bounce ideas off of and Moffitt Cancer Center for hosting the spine lab.

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Abstract

Pedicle screw-rod instrumentation is considered a standard treatment for spinal instability, and titanium is the most common material for this application. Cobalt-chromium has several advantages over titanium and is generating interest in orthopedic practice. The aim of this study was to compare titanium versus cobalt-chromium rods in posterior fusion, with and without transverse connectors, through *in vitro* biomechanical testing and determine the optimal configuration.

Six cadaveric lumbar spines (L1-S1) were used. Posterior and middle column injuries were simulated at L3-L5 and different pedicle screw constructs were implanted. Specimens were subjected to flexibility tests and range of motion, intradiscal pressure and axial rotation energy loss were statistically compared among the following conditions: intact, titanium rods (without transverse connectors), titanium rods with transverse connectors, cobalt-chromium rods (without transverse connectors) and cobalt-chromium rods with transverse connectors. The novel measurement of energy loss was examined to determine its viability in fusion investigations.

All fusion constructs significantly ($p<0.01$) decreased range of motion in flexion-extension and lateral bending with respect to intact, but no significant differences ($p>0.05$) were observed in axial rotation among all conditions. Intradiscal pressure significantly increased ($p\leq0.01$) after fusion, except for the cobalt-chrome conditions in extension ($p\geq0.06$), and no significant differences ($p>0.99$) were found among fixation constructs. Energy loss, differences became significant between the cobalt-chrome with transverse connector condition with respect to the cobalt-chrome ($p=0.05$) and titanium ($p<0.01$) conditions.

There is not enough evidence to support that the cobalt-chrome rods performed biomechanically different than the titanium rods. The use of titanium rods may be more beneficial because there is a lower probability of corrosion. The inclusion of the transverse connector only increased stability for the cobalt-chromium construct in axial rotation, which suggests that it is beneficial in complete facetectomy procedures.

Chapter 1: Anatomy and Biomechanics

Note to Reader

The contents of this chapter are the author's interpretation from experience in the field and common knowledge. Contents were verified with the works of Benzel[1]. All included figures were created by the author.

1.1. Spine Anatomy

1.1.1. General Anatomy

The spine consists of 24 vertebrae, connecting the skull to the pelvis, over three sections referred to as cervical, thoracic and lumbar spine. The cervical, thoracic and lumbar sections contain seven, 12 and five vertebrae respectively. An easy way to remember this is to compare them to the typical times of meals: breakfast at 7:00 AM, lunch at 12:00 PM and dinner at 5:00 PM. In general, the sections of the spine are split up by the rib cage: the cervical spine is above the rib cage, the thoracic spine includes the rib cage and the lumbar spine is below the rib cage. Furthermore, the lumbar portion of the spine connects to the pelvis via the sacrum. The sacrum consists of five fused vertebrae and has two lateral (side) connections to the ilium.

Each vertebra of the spine contains the same basic anatomical features. The vertebral body is the most anterior (front) portion of the vertebra and is accompanied superiorly and inferiorly (above and below) by an intervertebral disc. The anatomy can be further separated into functional spinal units which are two adjacent vertebral bodies and an intervertebral disc (Figure 1.1). The vertebral body has two lateral (side) braches that extend posteriorly (back) called

pedicles. Each pedicle has two separate branches that extend medial and lateral; the medial are referred to as the lamina and the lateral branches as the transverse processes. The two medial branches coalesce to form the spinous process, which creates a foramen (hole). Lastly, the pedicle branches out, near the medial lateral junction, superiorly and inferiorly to form the articular facets. The anatomical features of the lumbar spine can be seen in Figure 1.1 and Figure 1.2.

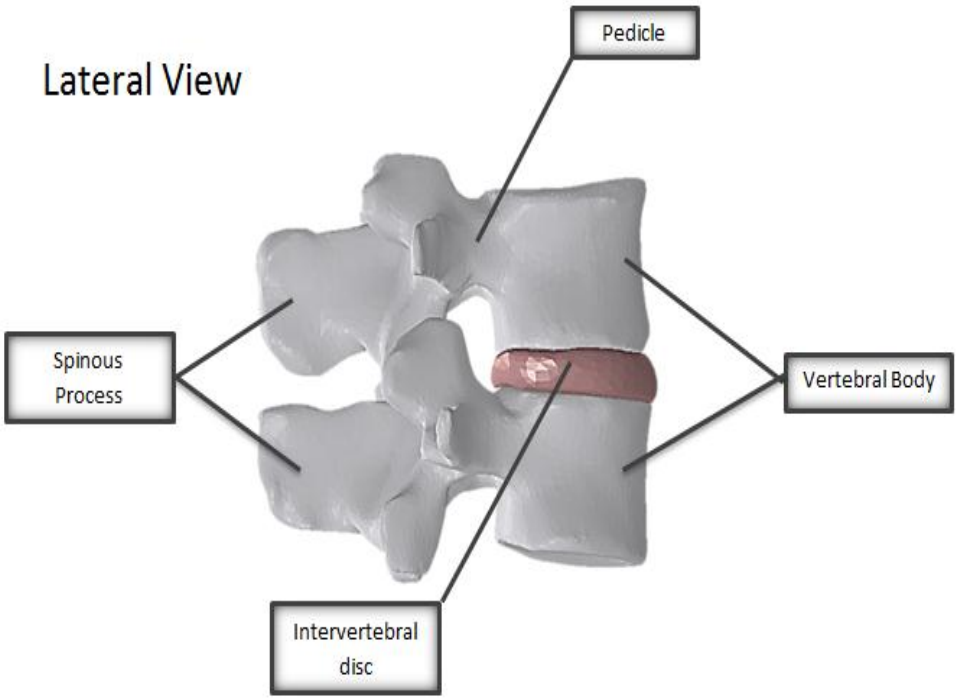

Figure 1.1. Lumbar Anatomical Features from a Lateral View

The spine naturally curves in the anterior/posterior direction or sagittal plane. Curvature in the sagittal plane is called either lordosis or kyphosis. Lordosis, found in the cervical and lumbar spine, is used to describe when the spine bends towards the posterior direction (extension). Kyphosis, found in the thoracic spine, is described by a bend in the anterior direction

(flexion). Curvature in the other lateral direction or coronal plane is called scoliosis, which is not optimal.

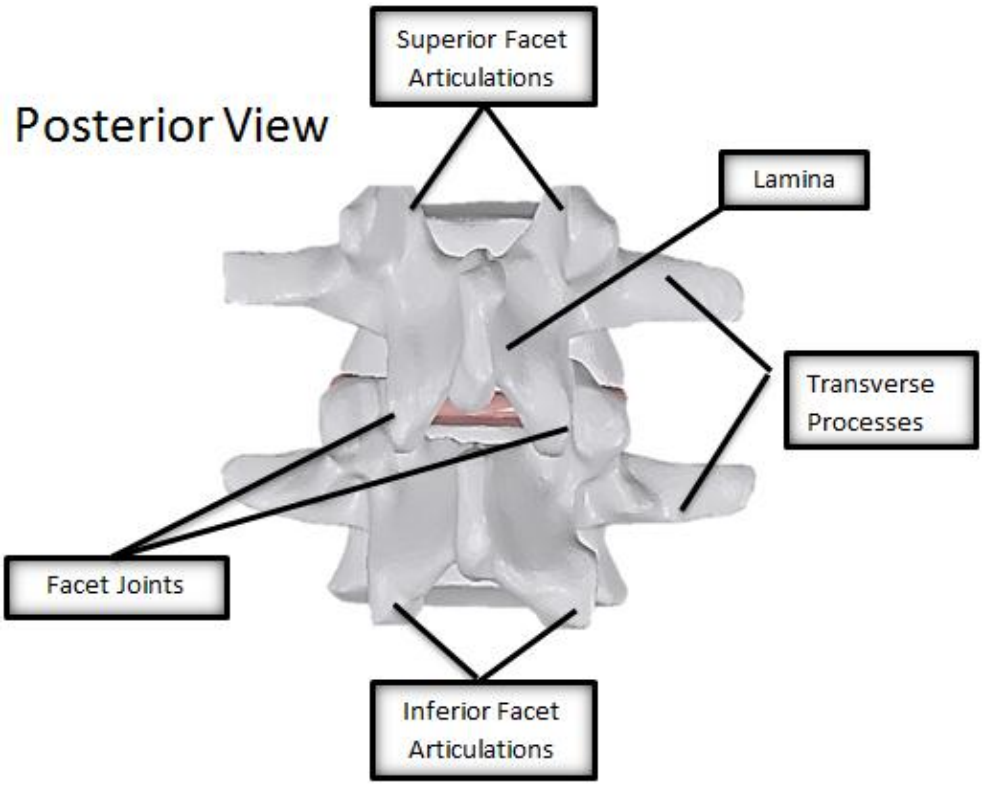

Figure 1.2. Lumbar Anatomical Features from a Posterior View

1.1.2. Intervertebral Disc

Most of the vertebral bodies of the spine are separated by an intervertebral disc. The disc is defined as a plane joint, but it also contributes to compressional load resistance. The disc is comprised of an annulus fibrosus and nucleus pulposus, both of which are made of fibrocartilage (Figure 1.3). The nucleus has a liquid consistency and is located in the center of the disc, while the annulus creates rings around the nucleus until it reaches the edge of the vertebral body.

1.1.3. Ligaments

Ligaments are made from dense connective tissue that is used to connect bones together. The function of the ligaments is similar to the function of a "door chain lock", which adds stability for motions at a set displacement and prevents excess motion. Dense connective tissues form bands between the two connecting surfaces, almost like seams of clothes. Ligaments are very strong, but if broken they can only be replaced because repairing a ligament is like stitching the bristles of two paint brushes, in the longitudinal direction, together.

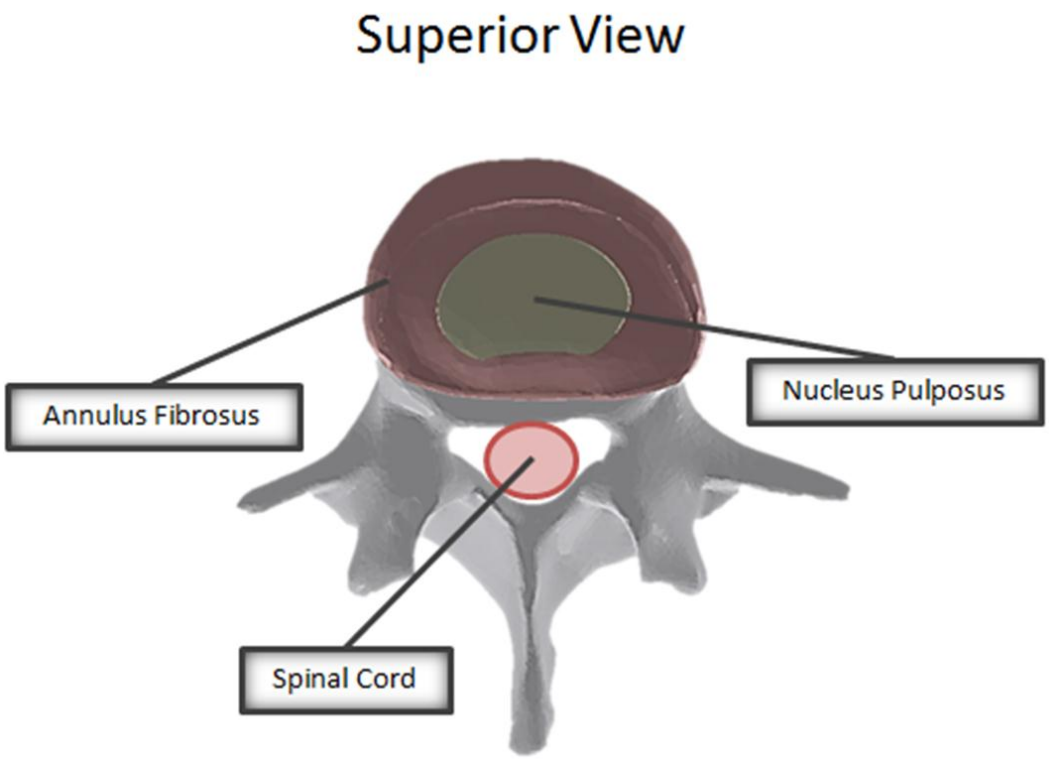

Figure 1.3. Superior View with Marked Disc Anatomy

The spine has several ligaments that connect most of the adjacent vertebras together. The names and connections are as follows: the supraspinous and interspinous ligaments connect the

spinous processes; the intertransverse ligaments connect the transverse processes; the facet capsular ligaments connect the facet joints; the ligamentum flavum connects the laminas; the posterior longitudinal ligament connects the posterior portion of the vertebral body; and the anterior longitudinal ligament connects the anterior portion of the vertebral body. All ligaments can be seen in Figure 1.4 and Figure 1.5. Each ligament is used in specific directions, which will be explained in detail later.

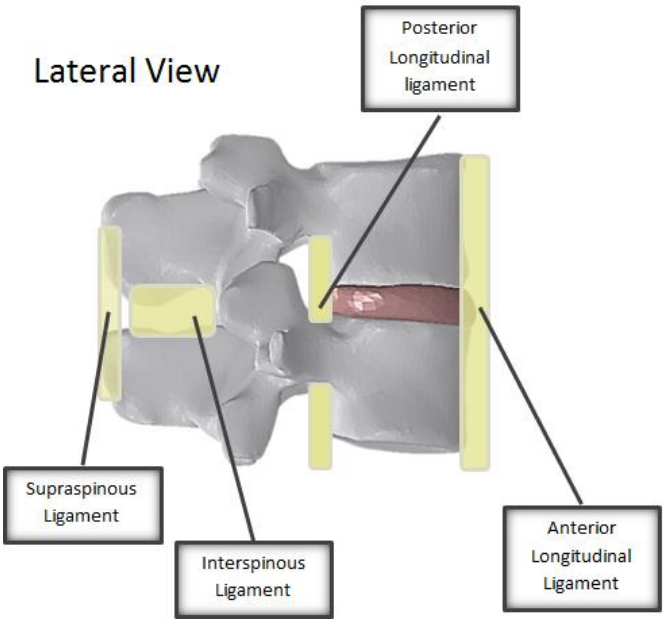

Figure 1.4. Lateral View with Marked Ligaments

1.2. Biomechanics

1.2.1. Standard Motions

Each segment of the lumbar spine can be assumed to have six degrees of freedom or motion directions; these degrees are described with the sagittal, coronal and axial planes (Figure

1.6). The three planes are all perpendicular and intersect at the "middle" of a segment. Each plane intersection creates an axis and each degree of freedom can be explained as along (translated on) or about (rotated around) an axis; thus, three axes by two degrees gives a total of six degrees of freedom. The degrees are as follows: along and about the coronal/sagittal plane are superior/inferior translation and axial rotation; along and about the axial/coronal plane are lateral translation and flexion/extension; along and about the axial/sagittal plane are anterior/posterior translations and lateral bending. The controlled motions are flexion/extension, lateral bending and axial rotation, while the rest are considered passive responses to motion.

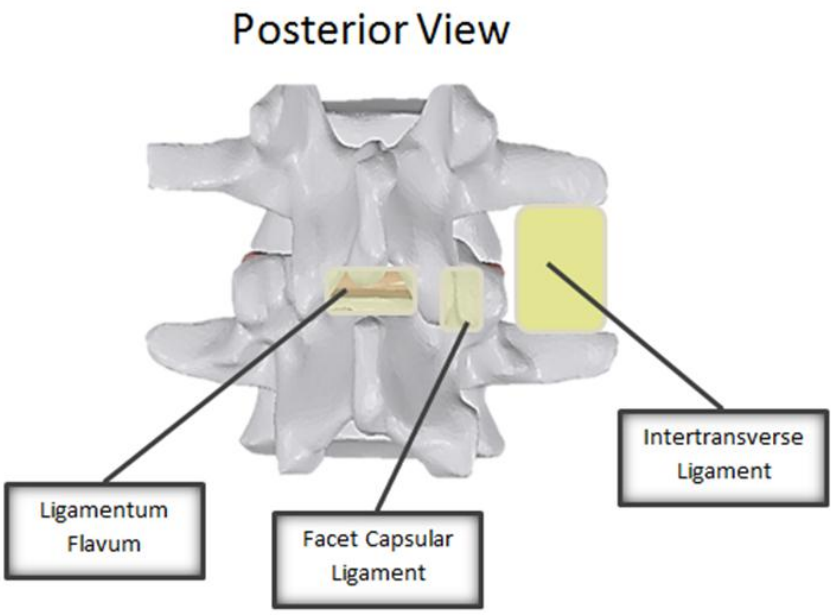

Figure 1.5. Posterior View with Marked Ligaments

1.2.2. Motion Biomechanics

Flexion is the motion that is performed when bending forward, as if to touch the toes, while extension is returning to an upright position (Figure 1.7). Flexion/extension or bending

forward/backward is a very common motion, but the biomechanics are a bit more complicated. Flexion/extension is the only standard motion that is not uniform because the anatomy is not symmetric about the coronal plane. Flexion generates compression on the disc and extension generates decompression, but both create passive translation in the superior/inferior and anterior/posterior direction. The supraspinous, interspinous, flavum, facet capsular and posterior longitudinal ligaments and the disc prevent excess flexion, while the anterior longitudinal ligaments and facet surfaces prevent hyper extension.

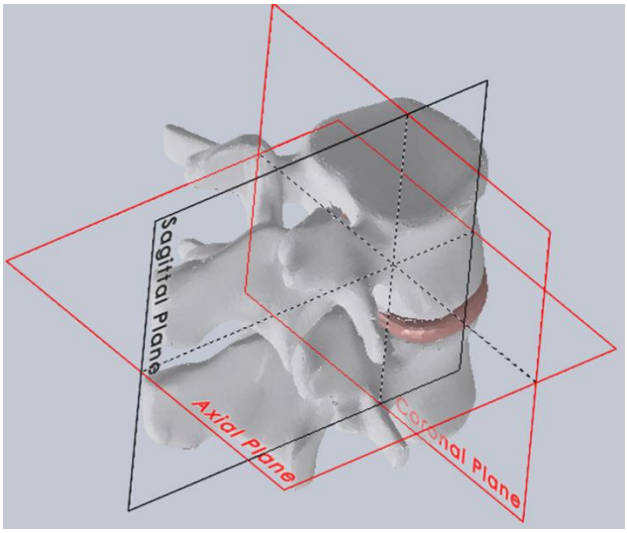

Figure 1.6. Anatomical Planes of the Spine

Lateral bending is the motion used to describe bending to either the left or right side (Figure 1.8). Right and left bending are almost identical, as long as the anatomy is relatively similar and the spine is not scoliotic, because the spine is symmetric about the sagittal plane. Lateral bending motions generate passive superior/inferior and lateral translations during loading. Furthermore, lateral bending loads create compression on the disc in the bending side, while the disc decompresses and transverse and capsular ligaments engage on the opposite side.

Axial rotation refers to the twisting of spine in the left or right direction and is the only motion that does not involve direct bending (Figure 1.9). Right and left rotations are also similar, as long as the anatomy is not deformed, because of the sagittal symmetry. Axial rotation generates all passive translations and passive flexion/extension, but passive flexion/extension is not as prevalent in the cervical and thoracic spine, where the facet angles are more parallel with the axial plane. The facets are important to the resistance of axial torques followed by the anterior longitudinal and facet capsular ligaments.

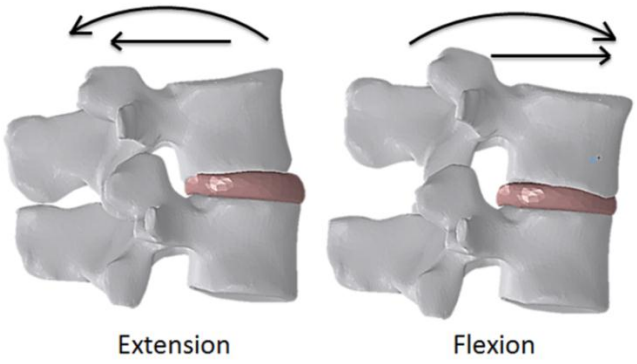

Figure 1.7. Flexion and Extension Motions

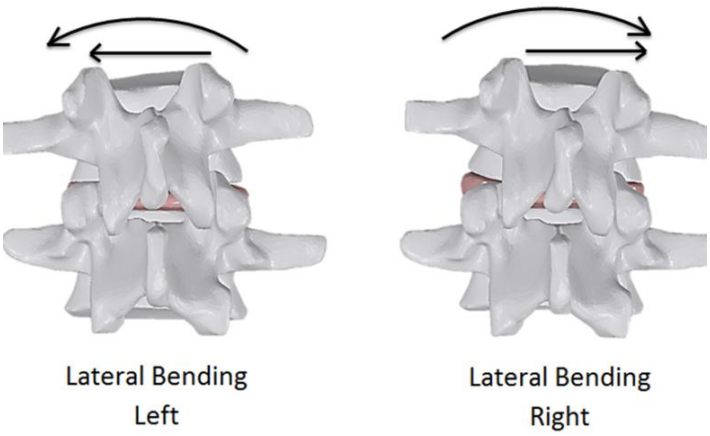

Figure 1.8. Lateral Bending Motions

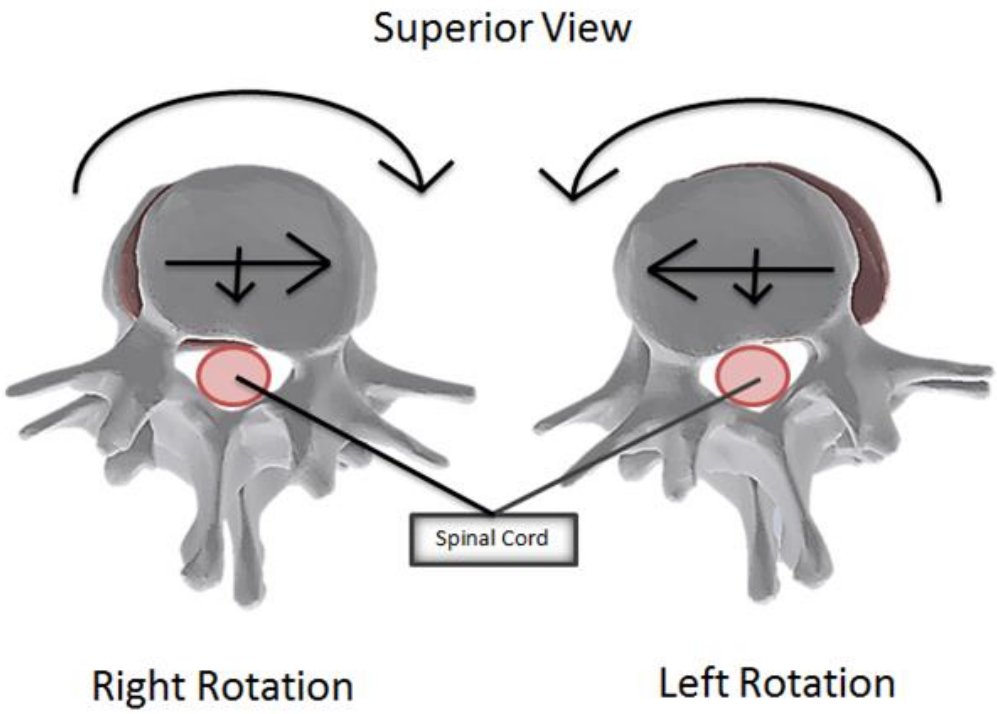

Figure 1.9. Axial Rotation Motions

Chapter 2: Introduction

Note to Reader

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2.1. Significance

The spine is a very important structure of the body. The spine has many functions, such as protection of the spinal cord, attachment site of muscular tissue, base structure of connecting anatomy, mobile support and vibration absorption. However, many of the aforementioned functions can be compromised by morbidity and require surgical intervention.

Some common disorders of the spine include stenosis, degenerated intervertebral discs, trauma, neoplastic diseases, spondylolisthesis and misalignment. Age is a factor for degenerative ailments, where instability is responsible for spondylolisthesis and misalignment. On the other hand, neoplastic diseases are cancerous with ambiguous origins. Furthermore, neoplastic diseases, such as a tumor wrapped around the spinal cord, often generate severe trauma and instability during resection, which requires reinforcement and stabilization.

The spine industry is crowded with medical devices. Generally, the devices are grouped into two categories: arthroplasties or fusion. The main difference between the two devices is the amount of expected motion after the procedure; arthroplasties maintain or increase motion after surgery, while fusion surgeries restrict motion. However, fusion interventions are more popular, especially after tumor removal, because of the versatility and success rate, but the best fusion

device is often uncertain. Therefore, biomechanical studies are needed to compare implants since the industry is crowded with surgical options.

The efficacy of spinal implants can be determined by finite element (computer simulation), biomechanical (cadaveric studies) or clinical (human trial) investigations. Finite element studies are very useful and accurate, but they require a substantial amount of time and stringent comparisons to cadaveric biomechanical models prior to implementation. Clinical spine investigations are used to determine the body's response to a surgery, but are intended to be implemented after an implant has undergone rigorous biomechanical validation. On the other hand, cadaveric biomechanical studies are very common due to the relative low cost and time investment and are the foundation for most investigations.

2.2. Clinical

Neoplastic diseases are common in the neuro-oncology field. Tumors fit in the neoplastic category and can grow is several locations in the spine. Immediate removal of tumors is recommended since prolonging excision could lead to tumors metastasizing in other locations. If the tumor were located in a convenient location, then excision would be easy; however, some common growth sites include inside the vertebral body or around the spinal cord. Complex growth sites are problematic because the approach may require removal of vital biomechanical spine structures.

The spine does reside in an anatomical cavity, like the abdominal cavity, but is surrounded by musculature and arteries which leaves the surgeon with minimal room. Often, the musculature around the spine must be manipulated to increase visualization and working volume. Therefore, excision of a tumor that is wrapped around the spinal cord requires extensive resection of posterior elements. Often surgeons are more conservative on the resection of

posterior elements to maximize the working area and view; this can include removal of the lamina and both inferior and superior articular processes. Extensive resection will ensure that the surgeon can excise the tumor completely, but will leave the spine incapable of withstanding everyday loads and unstable.

Complete posterior element resection requires stabilization. Arthroplasties would be the first choice for all surgeons in an ideal world, but these medical devices need extensive design and research before they will become a feasible option. On the other hand, fusion devices are a viable choice and are currently more reliable. The main reason fusion is more acceptable, in comparison to arthroplasties, is because of the device life expectancy. For example, if both devices are expected to survive four million loading cycles in the body, then it would be expected that both are acceptable; however, fusion needs to stabilize and prevent motion of a segment until bone grows and connects them together, while arthroplasties need to replace certain sections of the body indefinitely. Therefore, fusion is the best surgical option until arthroplasties are fully researched and developed.

2.3. Pedicle Screws

Several posterior fusion devices are currently on the market and include: interspinous spacers, facet screws, translaminar screws, facet dowels and pedicle screws. Facet screws and dowels require adjacent facet joints to remain intact, while interspinous spacers and translaminar screws need adjacent lamina to be implanted. On the other hand, pedicle screws achieve three column stabilization (anterior, middle and posterior), provide the most robust (rigid) fixation and are not limited to adjacent segments like the aforementioned alternative devices. The facets and lamina are resected in complete posterior resection; therefore, pedicle screws are the most acceptable form of stabilization and fusion.

The pedicle screw system consists of pedicle screws, interconnecting rods and locking nuts (Figure 2.1); in some cases a segment can benefit from a transverse connector, but this part is considered optional. In a segmental fusion (two adjacent vertebral bodies separated by an intervertebral disc) a surgeon will require four pedicle screws, four locking nuts, two rods and, if needed, one transverse connector.

The pedicle screws are available in an assortment of lengths (45, 50, 55, 60 or 65 *mm*), outer diameters (4.5, 5.5, 6.5 or 7.5 *mm*) and have a buttress type threading (Figure 2.1). The cross section of the threading is ideal because the strength is focused on preventing pullout. The heads of the screw can be either poly or mono axial. Mono-axial screws are stronger and have a higher fatigue life, but they are much more difficult to handle since the rods must be tailored or bent to fit. Conversely, poly-axial screws (Figure 2.1) are weaker and have a shorter fatigue life because the head capable of nutation; however, implantation is much easier because the position of the heads can be manipulated to the location of the rods.

The other components of the pedicle screw system are much less complicated. The rods are one diameter (5.5 *mm*) and can be cut and bent in the operating room to fit any length or shape. Also, the surgical set includes a variety of precut and bent rods for convenience. The locking nuts are produced in one size to save on manufacturing costs. Lastly, the transverse connectors come in a variety of qualitative lengths (20-35mm, 35-50mm and 50-65mm) because the parts are capable of telescoping and locking (Figure 2.1).

Implantation of the pedicle screw system is relatively simplistic. First, the pedicle is tapped with a smaller size screw. Then, the pedicle screws are installed into the pedicle of the vertebral body using standard operating procedures. Next, the rods are inserted into the recess on the poly or mono axial screw and set in a tentative place (Figure 2.1). Afterwards, the locking

nuts are installed in the recess of the screws and on top of the rods, and then tightened until the system is locked into place. Lastly, if additional stability is wanted, then the transverse connectors are hooked up to the rods between the screws and locked into place. However, the optimum configuration of material for the rods and screws are ambiguous and dependent on the case due to the permutations. Thus, studies that compare material selection can add to the current literature.

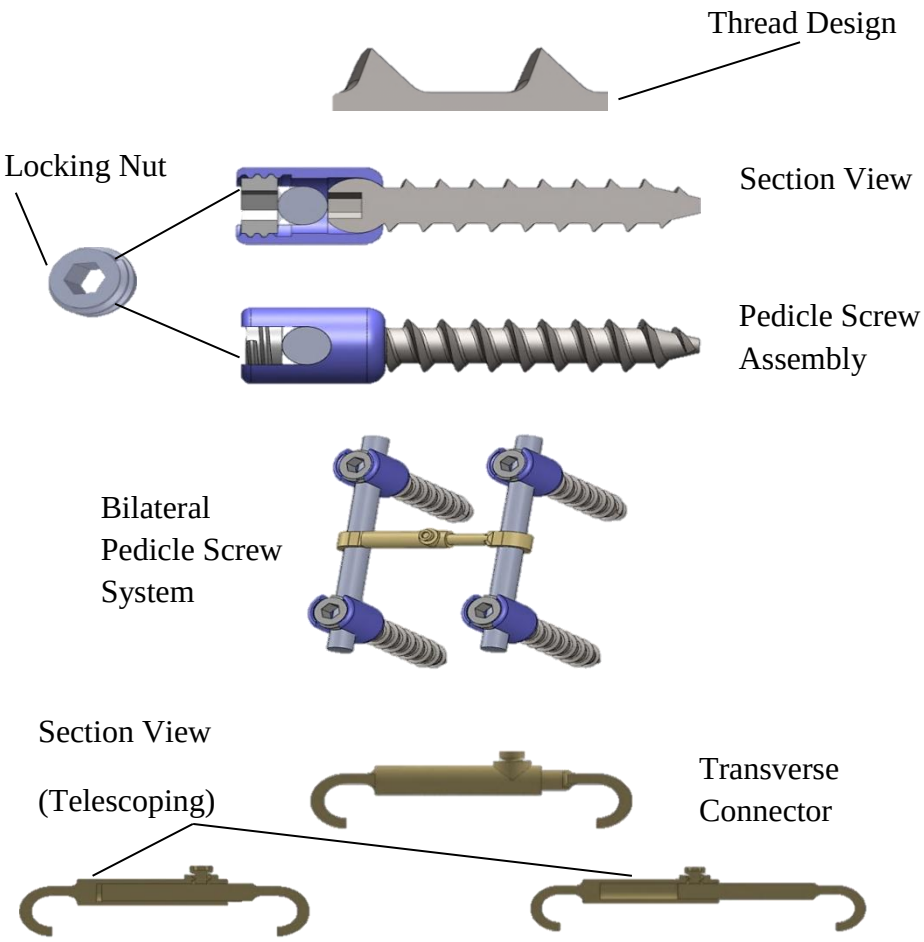


Figure 2.1. Pedicle Screw Components

Chapter 3: Literature Review

Note to Reader

The contents of this chapter have been published in previous works[2] and are used with the authorization of the publisher. The contributions of each author are shown in (Table 3.1).

Table 3.1: Author Contributions

Author Order	1	2	3	4	5	6	7
Author Initials	J.D.	K.A.	S.G.	M.D.	J.W.	W.L.	F.V.
Conception and Design	✓	✓				✓	
Acquisition and Data	✓	✓		✓	✓	✓	
Analysis and interpretation of data	✓	✓	✓				
Drafting of the Manuscript	✓						
Critical Revision of the manuscript	✓	✓	✓		✓	✓	✓
Statistical analysis	✓		✓				
Obtained funding							✓
Administrative\technical support	✓	✓	✓	✓	✓	✓	✓
Supervision	✓					✓	✓

Indication of author contributions. J.D. = James Doulgeris, K.A. = Kamran Aghayev, S.G. = Sabrina Gonzalez-Blohm, M.D. = Michael Del Valle, J.W. = Jason Waddell,W.L. = William Lee III, F.D. = Frank Vrionis

3.1. Introduction

The incidence of low back pain has consistently increased over the years and evolved into a chronic condition afflicting 70-85% of people worldwide[3]. Degenerative diseases, infections, and trauma are factors leading to low back pain, but these factors are diagnosed only in a small percentage of the cases (5-10%)[4]. Laminectomies, discectomies and facetectomies are common

procedures, in neurosurgeon's armamentarium, that provide decompression to neural elements and their effects have been addressed in previous biomechanical investigations[5,6].

3.2. Instability and Correction

Spinal instability is a common problem that originates from a variety of reasons such as traumas, tumors, infections or surgical interventions. Thus, several works discuss instability and its importance[1,7-9]. Dennis performed a series of radiological studies and subdivided the spine into the posterior, middle and anterior columns, where damage to any two columns will lead to instability[7]. For example, a middle and posterior column injury can be characterized by substantial damage to the lamina, facet joints, posterior half annulus and nucleus and classified as unstable[7] (Figure 3.1). White and Panjabi described instability as a reduction of spinal biomechanical functionality, where the spine can deform correctly, consistently, painlessly and without residual deformities[8]. Benzel described spinal instability as the limitation of extensive or aberrant motions and subcategorized instability as acute (overt or limited) and chronic (glacial and dysfunctional)[1]. Regardless, instability is very difficult to define and clinical practice often requires an amalgamation of the literature.

Injuries that are classified as unstable are typically addressed by pedicle screw instrumentation which is considered the "gold standard" treatment for spinal fixation[10,11]. A pedicle screw system is usually implemented above and below the level of injury and there is no consensus in the use of intermediate fixation or the number of cross-links used in multilevel fusion constructs[12]. Additionally, intermediate fixation is not possible in certain situations, such as tumor removal, because of compromised intermediate vertebra(e) stability (i.e. burst fracture, extended pedicle resection and advanced osteoporosis). However, the contribution of cross-links is evident when fixating more than two levels[12].

3.3. Biomaterials

New biomaterials, that improve performance, are an area of great interest for both surgeons and engineers. Two areas are considered important when evaluating materials for medical implants: biomaterial properties and mechanical performance. Common important biomaterial factors are biocompatibility, corrosion, wear resistance and osseointegration, and these correlate to successful implant integration[13]. On the other hand, mechanical properties, such as hardness, tensile strength, young modulus and elongation, are also important when deciding which material to implant[13]. Energy loss can be used to describe the plastic (permanent) deformation that occurs in a loading and unloading cycle of a material. Ductile metals loaded with minimal stresses tend to have zero plastic deformation because they can efficiently transfer strain energy, but excess loading will cause the material to permanently deform.

The surgical techniques for posterior fixation have not changed over the course of last two decades, but the constructs themselves have evolved. Historically, titanium (Ti) has replaced stainless steel due to its outstanding mechanical and biological properties. However, cobalt-chromium (CoCr) alloy has gradually become popular in the last decade. CoCr is an emerging biomaterial that has certain advantages over Ti, which has resulted in gradual replacement in several orthopedic applications[14]. Table 3.2 summarizes an overall comparison on Ti versus CoCr materials, based on previous publications[13,15].

Pedicle screw fixation typically includes Ti screws and either Ti or CoCr rods. The biomechanical characterization of both materials, as well as their biocompatibility, has been examined by Guibert et al.[16] and Marti[14] respectively. Additionally, CoCr rods have shown to have significantly larger fatigue lifespan than Ti rods during cyclic loading testing in a simulated spinal fusion construct[17]. Thus, replacing Ti with CoCr may prolong implant lifetime, especially

with cross-link connectors (TC) for cases of multilevel constructs for severe injury where intermediate fixation cannot be achieved.

3.4. Overview

From a mechanical perspective, the body is a complex dynamic environment that often performs small loads (relative to ultimate strength), high frequencies (0-5 Hz), and large cycle sizes to implants[18]. For this reason, addressing differences between material and mechanical properties is essential, but it is also important to predict their performance in activities of daily living (ADL) via *in vitro* tests.

With this background knowledge, we developed the following research objective: to compare the *in vitro* biomechanical effects of bilateral pedicle screw fixation using Ti or CoCr rods with and without TC in a two column injury model of the lumbar spine.

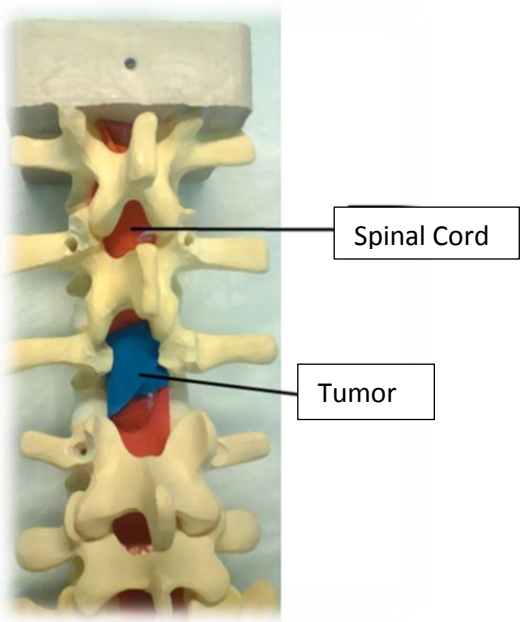


Figure 3.1. Spine with Posterior and Middle Column Injury

Table 3.2: Biomaterial Properties

Property	Ti VS CoCr	Clinical Implications
Classification *based on its interaction with surrounding Tissue*[1]	Both are classified as biomaterials	Bio-tolerant materials promote encapsulation of implant that can lead to its rejection, thus to failure. ---------- More critical in screw material.[3]
Young's Modulus[2]	Ti alloy*~116GPa CoCr Alloy† ~200-300GPa	The rods Modulus has no significant effect in quasi-static loads, but a larger Modulus will increase stresses on the screws while under dynamic loads [3]
"Stress Shielding Effect"[1]	Ti alloys < CoCr alloys	Mismatching the Young's Modulus between screws and bone lead to a reduction of bone strength ---------- Screws: High Modulus in implanted screws leads to "stress shielding effect".[3]
Shear Strength[1]	Ti alloys has poor shear strength	Maximum shear stress before failure. ---------- Critical for axial rotation motion.[3]
Tensile Strength[2]	Ti alloy* ~ 897-234MPa CoCr alloy† ~ 960MPa	Tensile strength correlates to the amount of force it takes to fracture the material. ---------- Critical for flexion, extension and lateral bending motions.[3]
Fatigue Strength[2]	Ti alloy* > CoCr alloy†	Performance of the material under cyclic loading. Life expectancy of the material
Elongation[2]	Ti alloy* > CoCr alloy†	How far a material can deform before fracturing

Relevant biomaterial properties that make titanium (ti) and cobalt-chromium (CoCr) alloys suitable for spinal fixation. Contents are published in previous works [2] and are utilized with the authorization of the publisher.

[1] Based on the works of Geetha et al.[13]

[2] Based on the works of Ratner et al.[15]

3 Author's interpretation of clinical relevance

Chapter 4: Materials and Methods

Note to Reader

The contents of this chapter have been published in previous works[2] and are used with the authorization of the publisher. The contributions of each author are shown in (Table 3.1).

4.1. Specimen Preparation

Six (6) fresh male cadaveric lumbar spines (average age of 51.7 years, age range- 35-60 years) were used in this study. Specimens were dissected into L1-S1 segments and proper care was taken to preserve all synovial capsules and ligaments. Specimens were thawed in a refrigerator at 4°C (SD 3) overnight prior to dissection and testing. 4”x 4” gauze sponges were wrapped around all exposed tissue and then moistened with 0.9% NaCl solution when the specimen was out of the testing sequence.

Six self-tapping screws (2” long) were installed into the L1 and S1 vertebral bodies to act as anchors for the mold. The specimens were potted into a custom frame via a polyester resin (Bondo Corp, Atlanta, GA, USA). Alignment was achieved by a series of leveling tools and a customized potting frame alignment tool. Natural position and ideal molding was defined by the following criterion: vertebral bodies centrally aligned into the frames, parallel top and bottom frames, symmetrical curvature through the length of the specimen and angular alignment of frames. Specimens were out of a frozen environment for a maximum of 48 hours.

4.2. Biomechanical Testing

4.2.1. Testing Machine

Specimens were mounted in a servo-hydraulic testing apparatus (MTS 858 MiniBionix modified by Instron, Norwood, MA, USA) to apply controlled torques (Figure 4.1). The testing apparatus is a four (4) degrees of freedom system that allows (1 and 2) flexion/extension or lateral bending on both superior and inferior frames, (3) axial rotation and (4) axial displacement. Axial rotation and axial displacement were transmitted on the superior frame and were constrained from these motions on the inferior frame. Axial displacement and rotation are controlled by servo-hydraulic actuators (MTS 858 Mini Bionix modified by Instron Norwood, MA, USA) and loads are measured by a two axis load cell (Dynacell Instron Norwood, MA, USA). Flexion/extension and lateral bending loads are delivered by a mass pulley system connected to the superior and inferior frames. Axial preload, magnitude of 50 *N* following previous *in vitro* biomechanical investigations[19], was delivered by the servo-hydraulic axial actuator and measured by the load cell during all simulated motions. Angular displacements were optoelectronically tracked via an Optotrak Certus System (Optotrak 3020, Northern Digital, Inc., Waterloo, Canada), by sensors located on the superior and inferior frames (Figure 4.2).

4.2.2. Pressure Transducers

A 060S pressure transducer (Precision Measurement Company, Ann Arbor, MI, USA) was inserted in the nucleus of the disc[20,21] between the L2 and L3 vertebral bodies to measure intradiscal pressure. The center of the intervertebral disc was targeted by caliper measurements in the axial, coronal and sagittal planes. A pressure transducer was sheathed in a cannulated needle and inserted laterally into the center of the disc following similar insertion protocol of Rao et al.[22]. Once in place, the sheath (cannulated needle) was removed which left the pressure

transducer in place and unscathed. Location of the pressure transducer was verified by disc dissection *ex post facto*. Pressure transducer signals were amplified by a signal conditioner (System 2100, Vishay Micro Measurements, Wendell, NC, USA) and recorded by the Optotrak data acquisition system (Optotrak 3020, Northern Digital, Inc., Waterloo, Canada). Data acquisition rate was 10Hz for all testing conditions.

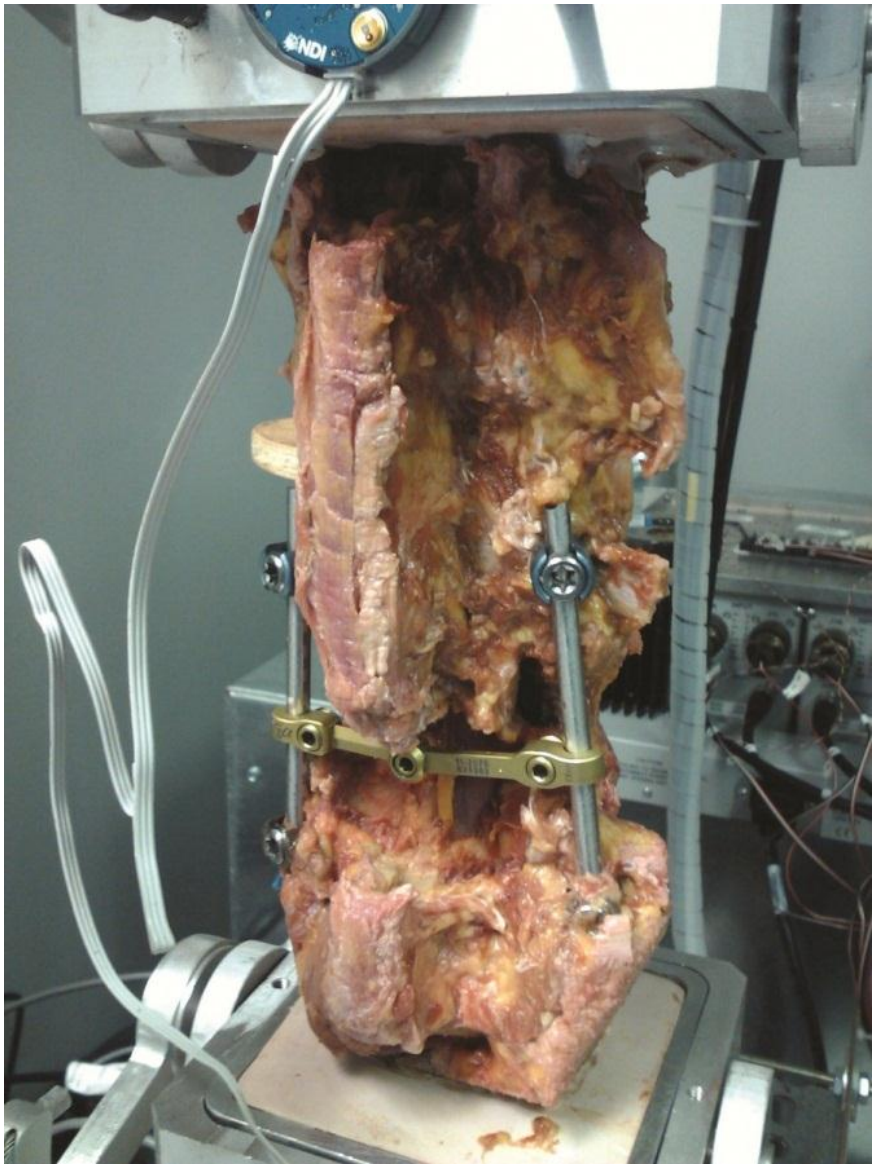


Figure 4.1. Specimen in the Testing Machine

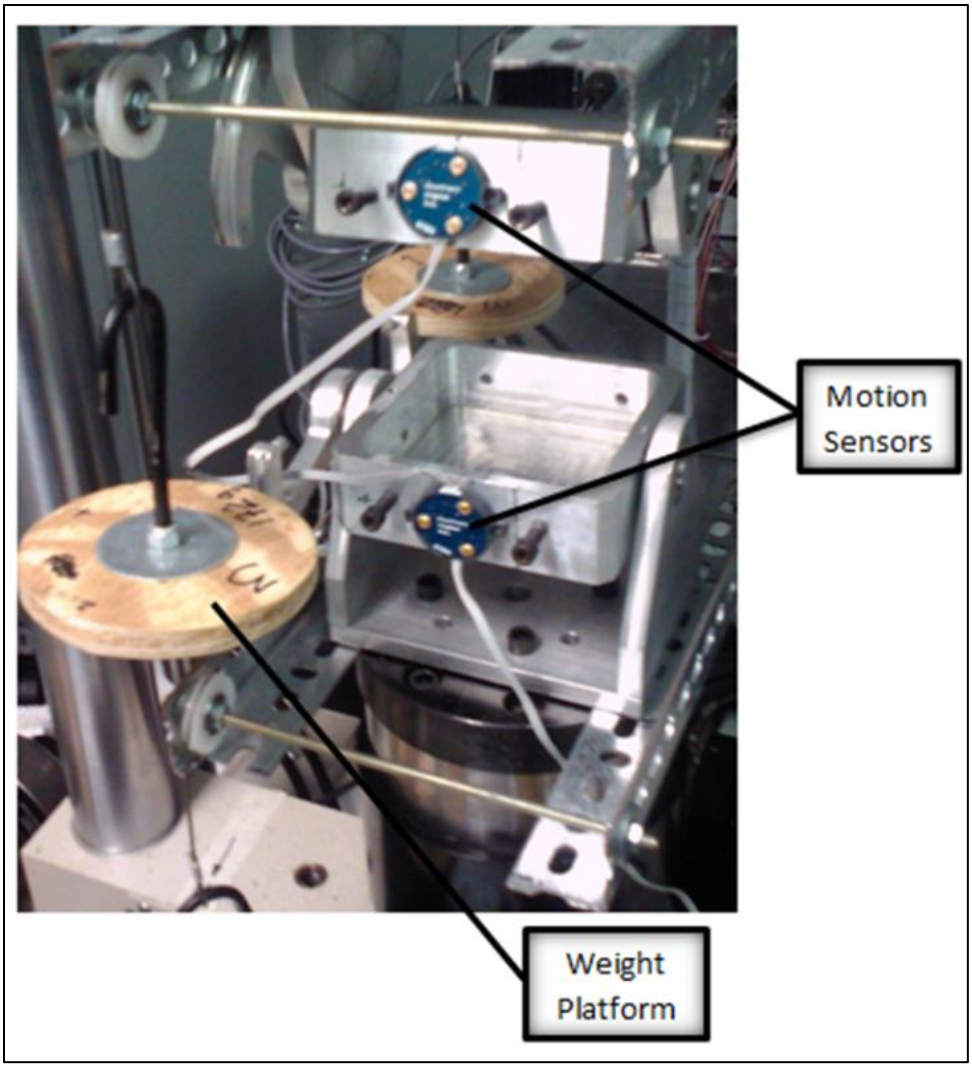


Figure 4.2. Testing Machine Setup.

4.3. Measurement Validation

4.3.1. Servo-Hydraulic and Load Cell Calibration

The measurements of the servo-hydraulic actuators and load cell were validated by an impartial and certified vendor of the machine manufacturer (Instron, Norwood, MA, USA). The linear and rotary strokes of the servo-hydraulic actuators were accurate to 0.1 *mm* and 0.1 *deg.* (1% of total motion) respectively, while the axial load and rotary torque of the load cell were

accurate to 0.1 *N* and 0.01 *Nm* (0.5% of total load) respectively. The verification methods and used equipment meet the specifications outlined in ANSI/NCSL Z540-1, ISO 10012, ISO 9001:2008, and ISO/IEC 17025:2005.

4.3.2. Optoelectronic Marker Calibration

Each marker was initially calibrated by a pivoted tip marker test, which used determined the offset of the tip. The markers, rigid bodies with three infrared light emitting diodes, were then affixed to the arm controlled by the actuators. The measurements of the markers were validated from the actuators measurements. However, if the markers were found to be inaccurate, then the process would be repeated from the beginning.

4.3.3. Hanging Weight Calibration

The hanging weights (Troemner, Thorofare, NJ, USA) were accompanied with a statement of accuracy. Each weight was validated by a scale (Pelouze, Bridgeview, IL, USA) before and after testing to confirm that mass was not lost during the process.

4.3.4. Pressure Transducer Calibration

Pressure transducers (Precision Measurement Company, Ann Arbor, MI, USA) were accompanied with statements of accuracy. The transducer was hooked up to an amplifier (System 2100, Vishay Micro Measurements, Wendell, NC, USA) and the bridge, of the transducer, was balanced at atmospheric pressure. The amplifier simulated 1000 $\mu\varepsilon$, which was used so the gain could be adjusted to match the manufacturer specifications; this process was performed before and after testing to confirm that the measurements did not drift. More intricate protocols can be used, but clinical relevance was set at 0.01MPa and comparative measurements were used in the analysis.

4.4. Testing Protocol

4.4.1. Loading Procedure

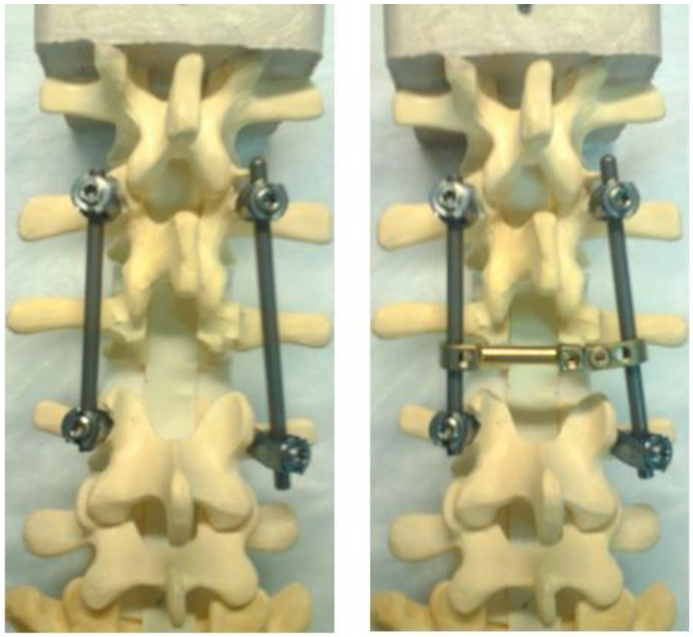
Specimens were tested under 5Nm of torque[23,24] for flexion-extension (FE), lateral bending (LB) and dynamic axial rotation (AR). FE and LB loads were delivered through a manual quasi-static procedure (+/-5.0 Nm, 4 cycles at 0.10 Hz) by a series of pulleys and masses (Figure 4.3). Axial rotation loads were delivered through an automated dynamic procedure (+/-5.0Nm, 6 cycles at 0.125 Hz) by the servo hydraulic actuator. The number of cycles selected was based upon the delivery method and motion direction. FE and LB both heavily rely on the disc space so a reduced rate and cycle procedure was used to minimize the creep throughout the study. Conversely, AR used a higher cycle provide a higher factor of safety on its repeatability. Moreover, reproducible data was obtained for the last two (2) cycles of each test hence an average of these two was considered for the analysis in FE, LB and AR.

4.4.2. Testing Procedure

The first testing cycle was performed on the "intact" (control) condition. Afterwards, posterior and middle column injuries were simulated via laminectomy and a complete bilateral removal of the superior and inferior articular processes at L4 and posterior half annulectomy and nucleus pulposus resection at L3-L4 and L4-L5 (Figure 3.1). The L3 and L5 pedicles were then bored and tapped, using standard surgical techniques and tools, and appropriate pedicle screw sizes (Zodiac, Ti, 6.5mm-diameter and 50-55mm-lengh, Alphatec Spine, Carlsbad, CA, USA) were inserted bilaterally, which has been seen in a previous publication[25]. Secondly, Ti rods (Ti-6Al-4V ELI per ASTM F136, 5.5mm-diameter and 85-110mm-length, Alphatec Spine, Carlsbad, CA, USA) were inserted and the test cycle was performed for the Ti condition (Figure 4.4A). Thirdly, a rod-to-rod TC (Ti, 40-60mm-length, Alphatec Spine, Carlsbad, CA, USA) was used to

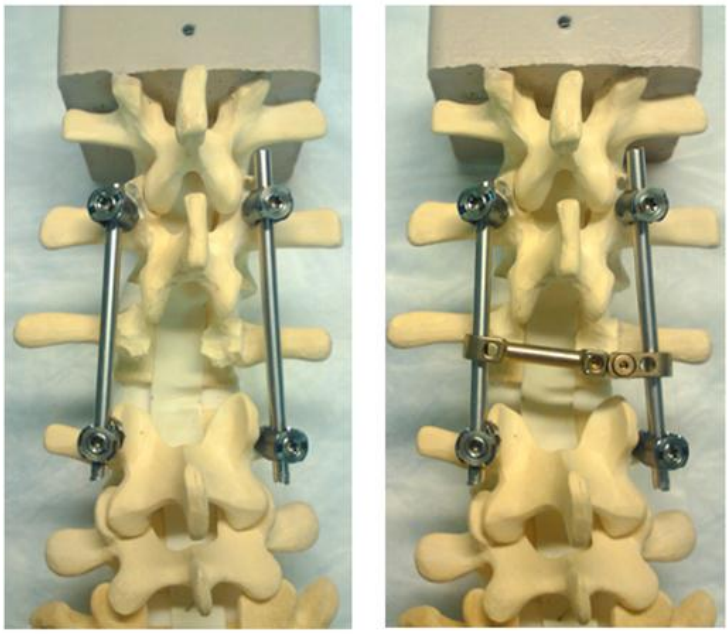
augment the implant and the test cycle was performed for the Ti-TC condition (Figure 4.4B). Fourthly, the TC was removed and rods were exchanged from Ti to CoCr (BioDur® CCM Plus® Alloy #2 per ASTM F1537, 5.5mm-diameter and 85-110mm-length, Alphatec Spine, Carlsbad, CA, USA) and the test cycle for the CoCr condition was performed (Figure 4.5A). Fifthly, the TC was included to the CoCr rods and the test cycle for the CoCr-TC condition was performed (Figure 4.5B). Lastly, all instrumentation was removed from the specimen to evaluate the "injury condition". This last test was conducted after completion of implanted tests, and not after intact condition, because the extent of the injury was classified as severely unstable[1,7] and would have jeopardized the integrity of the specimen.

Figure 4.3. Specimen Loading while in the Testing Machine



A B

Figure 4.4. Pedicle Screws and Titanium Rods in a Saw Bone Model. (A) without transverse connectors. (B) with transverse connectors



A B

Figure 4.5. Pedicle Screws and Cobalt Chromium Rods in a Saw Bone Model. (A) without transverse connectors. (B) with transverse connectors

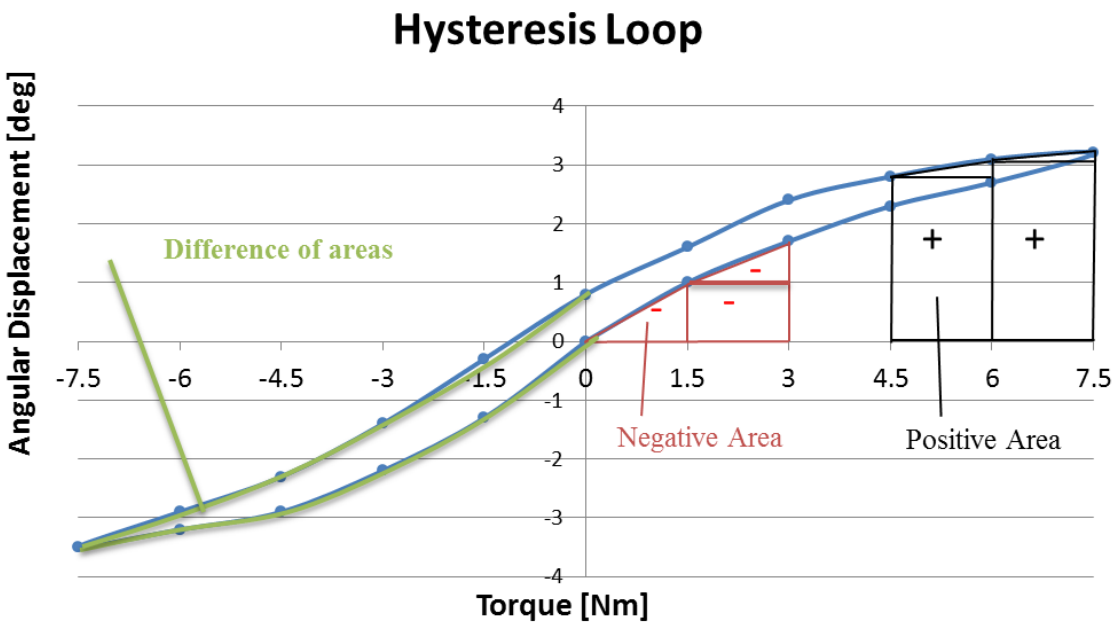
Including an "injury" condition in an *in* vitro biomechanical investigation when comparing different conditions (i.e. intact vs several constructs) is not required to established direct comparison among constructs, as it has been stated in previous publications[12]. All surgical procedures were performed by a skilled surgeon. Intermediate fixation was purposely avoided to reproduce clinical scenarios of tumor removal and to expose the construct to more critical conditions (i.e. greater loads). However, not being able to quantify the effect of the injury, due to its extent, was not considered a limitation to establish comparisons among the constructs and to address the aim of this investigation.

The former testing cycle was randomized among all implanted treatments (CoCr, CoCr-TC, Ti-TC, and Ti) to remove bias. The specimen remained connected to the testing apparatus while exchanging rods (from Ti to CoCr or vice versa) and TC's (implantation or removal) to replicate the position of the previous tested condition and to also maintain the position of the pressure transducer.

4.5. Analysis

4.5.1. Data Interpretation

Range of motion (ROM [deg.]) and intradiscal pressure (IDP [MPa]) were the dependent variables. Additionally, energy lost (EL [Nm*rad]) in the system was analyzed for dynamic AR motion via trapezoidal integration of the hysteresis loop (Figure 4.6). EL was used to measure the difference between loading and unloading of the spine (Figure 4.6). EL in FE and LB was excluded because the step sizes between the applied torques were much larger in comparison to AR. All ROM measurements were compiled together (i.e. flexion-extension, lateral bending and axial rotation), instead of treating them as separated motions (i.e. right and left bending/rotation or flexion and extension).



$$\Delta E = \sum_{i=1}^{n} \left((T_i - T_{i+1}) \left(\frac{\theta_{i+1} + \theta_i}{2} \right) \right)$$

Figure 4.6. Energy Loss Explanation

4.5.2. Statistical Analysis

A repeated measures ANOVA followed by a Bonferroni post hoc test was performed using a significance level of 0.05 to determine differences among treatments for ROM, intradiscal pressure and AR EL. Adjusted p-values were reported for multiple comparisons.

Chapter 5: Results

Note to Reader

The contents of this chapter have been published in previous works[2] and are used with the authorization of the publisher. The contributions of each author are shown in (Table 3.1).

5.1. Range of Motion Results

ROM of the different conditions is illustrated in Figure 5.1. All implanted conditions significantly reduced FE and LB ROM in comparison to the intact condition, but there were no significant differences among the implanted groups for these motions (Table 5.1).

Mean AR ROM increased after all implantations, excluding the CoCr-TC condition, but differences were not statistically significant from intact (Table 2). Also, TC conditions showed a reduction in AR ROM with respect to no-TC conditions (Figure 5.1); however, these differences were not statistically significant (Table 2). There was not enough evidence to postulate that Ti (no-TC and TC) constructs performed any different than CoCr (no-TC and TC) constructs for AR ROM. Means and standard deviations for ROM of all conditions are referenced in Table 5.2.

5.2. Intradiscal Pressure Results

In terms of intradiscal pressure (IDP), all implants significantly increased IDP for flexion ($p<0.01$), extension ($p<0.01$), LB ($p<0.01$) and AR ($p<0.03$) with respect to the intact condition (Figure 5.2), except CoCr ($p=0.06$) and CoCr-TC ($p=0.08$) conditions for extension motion. There were no significant differences ($p>0.99$) in any motion when comparing IDP among all implanted treatments. All IDP means and standard deviations are referenced in Table 5.3.

Table 5.1: Range of Motion P Values

Comparisons	Flexion-Extension	Lateral Bending	Axial Rotation
Intact with			
CoCr	<0.01*	<0.01*	0.45
CoCr-TC	<0.01*	<0.01*	>0.99
Ti	<0.01*	<0.01*	0.09
Ti-TC	<0.01*	<0.01*	>0.99
CoCr with			
CoCr-TC	>0.99	>0.99	0.29
Ti	>0.99	>0.99	>0.99
Ti-TC	>0.99	>0.99	>0.99
CoCr-TC with			
Ti	>0.99	>0.99	0.06
Ti-TC	>0.99	>0.99	>0.99
Ti with			
Ti-TC	>0.99	>0.99	0.52

Adjusted *p*-values from Bonferroni post-hoc test, after repeated measures ANOVA, for range of motion at 5.0 Nm. Contents have been published in previous works[2] and are utilized with the authorization of the publisher.
CoCr = Cobalt Chromium, Ti = Titanium, TC = Transverse Connecter,* = Statistically significant (p<0.05).

5.3. Energy Loss Results

Energy loss (EL) of the system (L1-S1) significantly increased ($p<0.05$) for dynamic AR motions in all implanted conditions with respect to intact (Table 5.2), excluding the CoCr-TC condition ($p>0.99$). There was no significant difference ($p=0.20$) between Ti and Ti-TC, but CoCr-TC significantly reduced AR EL with respect to CoCr ($p=0.05$) and Ti ($p<0.01$) conditions.

Table 5.2: Range of Motion and Energy Loss Data

Condition	Flexion-Extension *[deg]*	Lateral Bending *[deg]*	Axial Rotation *[deg]*	Axial Rotation Energy Loss *[Nm*rad]*
Intact	22.0 (4.2)	25.1 (8.1)	9.0 (2.3)	1.15 (0.38)
CoCr	14.1 (5.3)*	12.1 (4.5)*	11.2 (0.9)	1.72 (0.08)*
CoCr-TC	14.0 (5.2)*	11.6 (3.6)*	8.8 (1.8)	1.32 (0.22)
Ti	13.0 (5.8)*	12.3 (3.5)*	11.9 (1.9)	1.87 (0.10)*
Ti-TC	12.9 (5.7)*	11.8 (4.3)*	9.8 (0.6)	1.55 (0.10)*

Range of motion and energy loss mean (standard deviation) values for all conditions and motions at 5.0 *Nm* of torque. Contents have been published in previous works[2] and are utilized with the authorization of the publisher.
CoCr = Cobalt Chromium, Ti = Titanium, TC = Transverse Connecter, * = Statistically significant ($p<0.05$).

5.4. Discussion and Comparison to Literature

The main advantage of CoCr over Ti is its higher modulus of elasticity (Table 3.1), so it is expected that CoCr would be stiffer than Ti in any environment. Transverse connectors (TC) are designed to add structure to the implant by mitigating the angular displacements between the rods (keeping the rods parallel). FE and LB motions do not significantly change the angle between the rods which will result in a minimal stress on the TC. The FE and LB performance, in terms of ROM, between no-TC and TC conditions (Figure 5.1) was not significantly affected, which is consistent with previous publications[26,27]. This suggests that the contribution of one TC in a two-level fusion construct without intermediate fixation may not be substantial for these motions. Additionally, there were no significant differences between Ti and CoCr ROM or Ti-TC and CoCr-TC ROM, which suggests that, from a mechanical standpoint, both materials stabilize these motions.

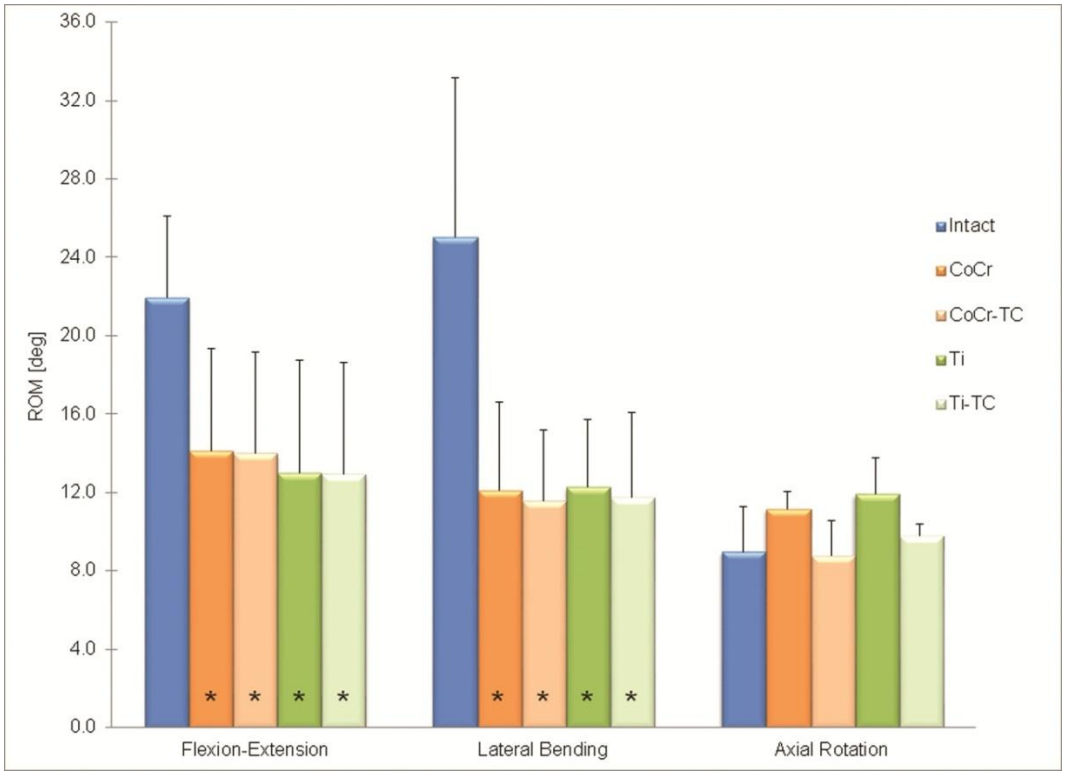
Table 5.3: Intradiscal Pressure Data

Condition	*Extension [MPa]*	*Flexion [MPa]*	*Lateral Bending [MPa]*	*Axial Rotation [MPa]*
Intact	0.16 (0.02)	0.31 (0.05)	0.19 (0.05)	0.27 (0.07)
CoCr	0.23 (0.06)	0.43 (0.07)*	0.30 (0.13)*	0.40 (0.06)*
CoCr-TC	0.23 (0.05)	0.43 (0.06)*	0.30 (0.12)*	0.41 (0.07)*
Ti	0.25 (0.06)*	0.45 (0.07)*	0.30 (0.12)*	0.38 (0.07)*
Ti-TC	0.25 (0.07)*	0.42 (0.08)*	0.30 (0.12)*	0.40 (0.06)*

Intradiscal pressure mean (standard deviation) values for all conditions and motions at 5.0 *Nm* of torque. Contents have been published in previous works[2] and are utilized with the authorization of the publisher.
CoCr = Cobalt Chromium, Ti = Titanium, TC = Transverse Connecter,
* = Statistically significant ($p<0.05$).

AR ROM is affected by the presence of the facet joints and removal of the joints reduces AR stiffness because they constrain the vertebral bodies from shear stresses[6,28]. The differences in the means between Ti and CoCr, although not significant (Table 5.1), may be explained by the fact that AR applies a shear stress on the construct[5,26,27] and that Ti is considered to have "poor shear strength"[29]. Since the absence of TC makes the construct less stable[6,27,30], it is expected that Ti construct without TC would have been the weakest in AR ROM (Table 5.2), but differences were not significantly different than other constructs (Table 5.1). On the other hand, based on the ROM mean TC provided the more stability in comparison to no-TC, but more evidence is needed to confirm a statistical difference.

When performing the "injury test", all six specimens deformed plastically to the extent of failure, and the injury was severe enough to cause failure under the axial preload alone (before testing started), which was expected due to the significant effect of axial preloads in middle columns[7]. These findings support that bilateral pedicle screw system provided the majority of the structure to the specimen after injury.



Note: Range of motion mean values for all conditions and motions at 5.0 *Nm* of torque. Error bars represent one standard deviation. Contents have been published in previous works and are utilized with the authorization of the publisher. CoCr = Cobalt Chromium Ti =Titanium TC = Transverse Connecter * = statistically significant ($p<0.05$) with respect to the intact condition.

Figure 5.1. Range of Motion Bar Chart

Measuring EL by the spinal segment provides additional information, in terms of stability. EL is an indication of the plastic deformation and is related to the disc contribution. The inclusion of EL is particularly useful in fusion because it corresponds to rigidity. CoCr-TC was expected to be the most rigid construct in AR due to material and mechanical properties of CoCr with respect to Ti alloy (Table 3.1) and the additional rigidity applied from the contribution of TC's. However, more evidence is needed to show that CoCr-TC construct would provide significantly more stability than others in terms of ROM. The lack of difference between the EL is attributed to the overlapping implants (same pedicle screws and TC) and limited sample size.

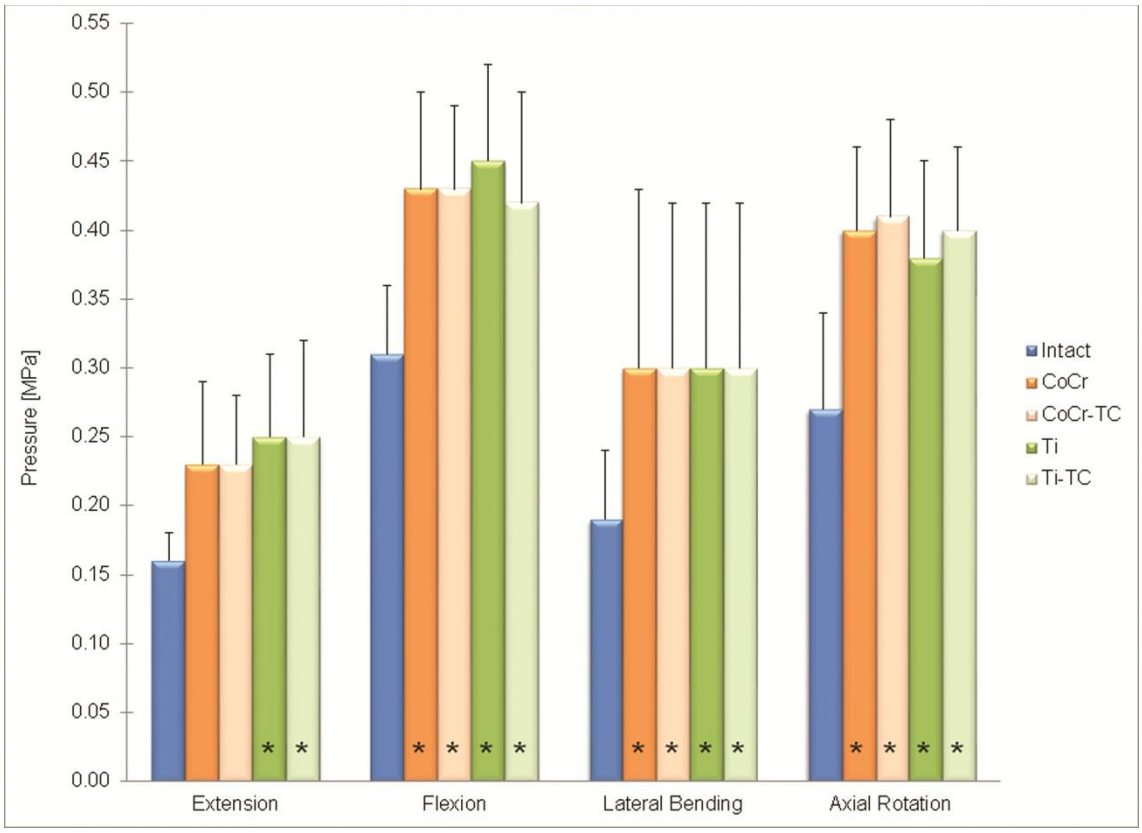
The energy lost by the segment in AR under the CoCr-TC condition was not sufficient to be statistically significantly different than the intact condition (Table 5.2), while all other conditions were. This evidence suggests that CoCr-TC was the construct that promoted the least energy loss of all fixations, which translates to greater stability. Moreover, the Ti condition had the greatest average in AR EL (i.e. least stable) and even that the increase was not enough to be statistically significantly different than the CoCr or Ti-TC conditions, it was sufficient to be significantly different than the most rigid construct: the CoCr-TC condition. However, similarities to the energy loss are attributed to the tissue damping from the adjacent unfused segments.

When comparing TC and no-TC conditions in terms of AR EL, the inclusion of TC could increase AR stability when using CoCr rods, which goes in line with similar findings postulated by other authors[5,27,30].

In terms of intradiscal pressure, an increase at superior levels is a common byproduct in fusion and has been validated in previous works[31,32]. It is thought that increased intradiscal pressure is the main factor leading to accelerated adjacent level degeneration. Changing the stiffness of the construct may seriously change load distributions and divert the load from the disc space. Therefore, it is possible that different materials may affect IDP differently. However, differences were not statistically significant in intradiscal pressures between the CoCr and Ti constructs (Figure 5.2), indicating that they may result in the same rate of adjacent disc degeneration.

Mechanical hardware will be more prone to failure if not supported by bone fusion. Osteoporosis, advanced age, malnutrition, previous radiation, poor wound healing are factors that negatively affect the bone fusion process. Instrumentation systems that are based on longer

fatigue life may provide more time to achieve bone fusion. In a recent study, Nguyen et al.[17] demonstrated superiority of CoCr over Ti rods under axial compression (700N) bending cyclic testing, where CoCr were most likely to fail around the titanium screw necks and titanium rods failed at the notch created by the French Bender (from intraoperative contouring).



Range of motion mean values for all conditions and motions at 5.0 *Nm* of torque. Error bars represent one standard deviation. Contents have been published in previous works and are utilized with the authorization of the publisher. CoCr = Cobalt Chromium Ti=Titanium TC=Transverse Connecter *= statistically significant ($p<0.05$) with respect to the intact condition.

Figure 5.2. Intradiscal Pressure Bar Chart

Differences between Ti and CoCr rods could also become more noticeable in high impact/dynamic loads, where each material will absorb strain energy at different rates. The stress magnitude on the screws under impact/dynamic loads will depend on the mechanical properties

of the rods, where rods with the greatest stiffness will concentrate more stress on the screws. Ti screw/CoCr rod junction may be a critical area that eventually leads to hardware failure in an *in vitro* environment. Therefore, under impact/dynamic loads, it is hypothesized that CoCr rods will produce more stress than Ti rods on the bone surrounding the screws.

The resulting similarities between the two rod materials are expected for certain motions. The rods mostly deform from compression or tension stresses and the screws deform mostly due to bending stresses during flexion/extension and lateral bending (Figure 5.3). The majority of deformation is due to the bending stresses on the screw and bone interface and surrounding tissue, which makes changes in rod stiffness arbitrary. However, the rods are sheared during axial rotation motions (Figure 5.4), which is a different deformation. The trend of increased stability was expected for the TC condition because it intuitively increases the shear resistance, but was not significant due to the limited number of samples.

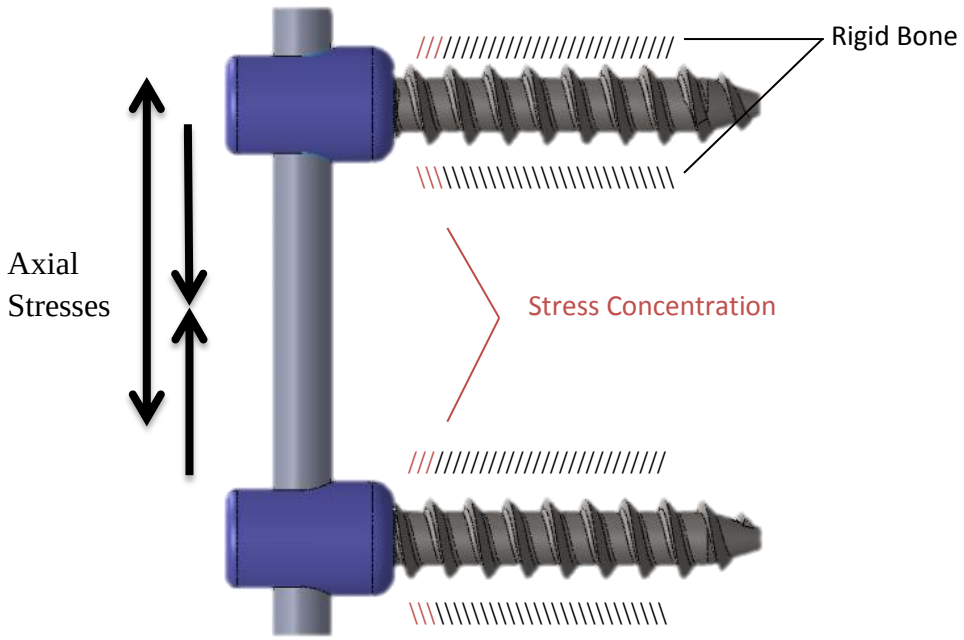


Figure 5.3. Stresses during Compression/Tension to System

In terms of biocompatibility, Pleko et al.[33] postulated that osseointegration capacity of CoCr is lower compared to Ti, but this is not a factor for "Ti screws-CoCr rods" constructs in spinal fixation since the rods are not in direct contact with the bone surface. On the other hand, metal corrosion and shredding are important aspects and the interactions of CoCr with Ti at the screw rod junction is probably the most critical area for this specific application. This interface is under significant frictional load, which causes the majority of metallosis in adjacent tissue[34]. The interfering surfaces of these two materials have been widely used in total hip arthroplasty, and it has been reported that these interaction result in a considerable crevice corrosion and metallosis in the adjacent tissues[6]. It has also been shown, on knee implants, that during CoCr-Ti interaction more debris comes from Ti[16].

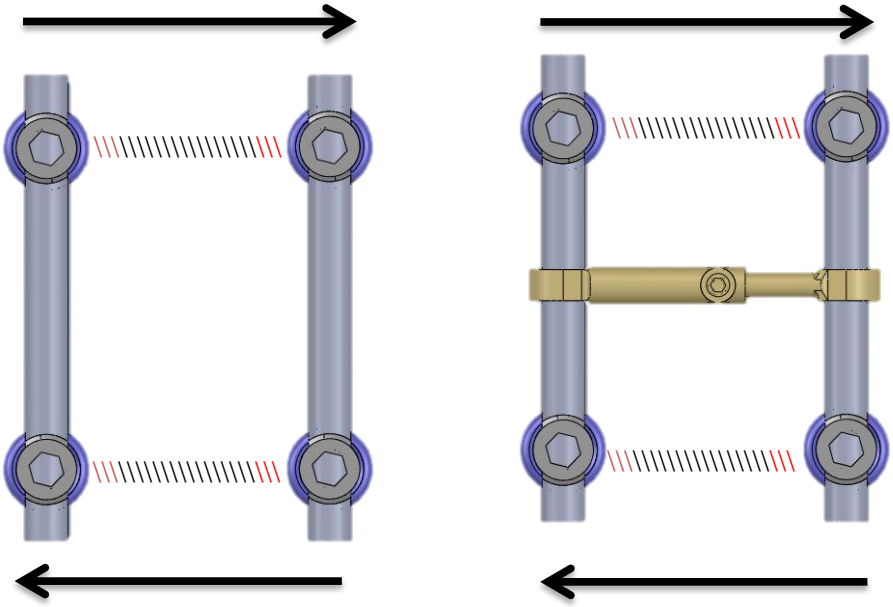


Figure 5.4. Forces and Stresses in Axial Rotation

Chapter 6: Conclusions and Recommendations

Note to Reader

The contents of this chapter have been published in previous works[2] and are used with the authorization of the publisher. The contributions of each author are shown in (Table 3.1).

6.1. Limitations

We acknowledge that the small number of samples available (6 for this study) in human cadaveric testing is always a limitation. Deriving clinically relevant conclusions from *in vitro* testing is always challenging since the number of variables that can be studied in cadaveric models are limited when compared to *in vivo* conditions. However, establishing comparisons among different treatments can provide relevant information that could be extrapolated to clinical scenarios. Intermediate motions were not quantified in terms of ROM because the extent of the injury and fusion involved half of the segments. However, intradiscal pressure readings were used to obtain additional information of the intermediate segments. The injury could not be quantified due to its extent, which impeded the evaluation of the effects of all instrumented conditions with respect to the injury itself. Quasi-static motions were measured at full torques and not incremental torques which limits the interpretation of the study because neutral zone measurements could not be incorporated.

6.2. Recommendations

A retrospective analysis of the investigation leads to several procedural and technical recommendations. The data was assumed to be normal, but non-parametric approaches are a

more appropriate for this type of research. The testing machine allowed for four degrees of freedom, which is acceptable for small segments, but for long segments (four or more discs) the inclusion of the other degrees of freedom, such as anterior/posterior and lateral translations, are recommended; otherwise, the motions that are observed may not emulate *in vivo* motions.

Global range of motion was used in this investigation, but it is recommended that rigid body markers are implanted at each level or at least on the target levels; this ensures that measurement drift and plastic deformation do not skew the data. The accuracy and calibration of the pressure transducers should be more extensive by the inclusion of testing known pressures to further validate the measurements. Pressure transducer placement should be verified by fluoroscopy in addition to *ex post facto* disc resection to ensure that the transducer is not displacing during testing. *Ex post facto* disc characterization can be a helpful additional factor to test for, especially if the testing is of a biomechanical nature.

Petroleum jelly can be coated on the specimens prior to testing to prevent desiccation[19]. The amalgamation of Bondo auto-body filler (Bondo, Bondo Corp, Atlanta, GA, USA) and fiberglass resin (3M, St. Pail, MN, USA) prior to potting simplifies the anchoring process because the resulting mixture is less viscous and can be delivered through a funnel after the specimen is in position[35]. Lastly, fluoroscopic images can help verify implant placement.

6.3. Conclusion

Our findings suggest that pedicle screw fixation above and below a two column injury without intermediate fixation is a suitable treatment for lumbar spinal instability and this fixation method, or an equivalent stabilization, is needed for tumor removal of this magnitude. There is not enough evidence to support that the rods performed biomechanically different during *in vitro* testing on lumbar cadaveric models. Also, inclusion of the transverse connector did not

significantly increase stability in FE or LB; however, evidence suggests that CoCr-TC may be more stable than CoCr in AR motions. In terms of IDP, spinal fusion significantly increases IDP post fusion in a superior adjacent disc space, and no differences were found among fixation constructs, which suggest they may contribute equivalently to adjacent segments degeneration.

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