A Dissertation

entitled

Predictive Finite Element Modeling of Artificial Cervical Discs in a Ligamentous Functional Spinal Unit

by

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Relative motion at interacting implant surfaces will generate wear debris over time. Bio-
tribological tests serve as an effective pre-clinical tool to investigate device wear 
characteristics. Wear debris evaluations for artificial discs are done in simulators using 
the currently published ASTM/ISO loading profiles. However, these tests can primarily 
compare wear related parameters of one disc design against another as opposed to an in 
vivo scenario. Additionally, these experiments are time consuming, expensive and labor 
intensive procedures. Current wear testing standards for artificial discs do not account for 
parameters such as the influence of anatomic structures and variations in the surgical 
procedures for disc placement. However, appropriate parametric mathematical modeling 
may help assess the contributions of these parameters to implant wear. The objective of 
this study is to address the above mentioned factors and to simulate in-vivo wear 
parameters as far as practicable. In this approach, the wear phenomena of the total disc 
replacement (for two different designs – metal on metal and metal on polymer) placed in 
a ligamentous functional spinal unit (FSU), as opposed the disc alone analyses conducted 
previously by other researchers was simulated. The models were further modified by
sequential addition and removal of spinal structures in order to understand the role of each element with respect to the wear outcome. Furthermore, the effect of the implant placement was studied. This was followed by comparative analyses of load versus displacement control test methodology. A significant difference was noted between the implanted and standalone condition. The standalone test cases were in agreement with the published literature, while the implanted scenario replicated some of the retrieval failure modes. Lift-off at the device interface was observed at the implant interface which was found to be a function of facets and muscle forces. This phenomenon was also reported by other researchers, thus supporting our conclusion. The design factor was found to have more effect in comparison to the material combination. Also, implant positioning demonstrated that wear is sensitive to the device placement. Additionally, during the analysis displacement control mode led to higher wear in comparison to load control for both of the implants. We can summarize by stating that this study demonstrated the need to simulate implant wear in ligamentous finite element model in order to replicate failure modes that are observed during retrievals. Surgical factors are thus crucial with respect to the wear performance of the implant and so should be planned carefully.
I would like to dedicate my work to my dear parents Uday K. Bhattacharya and Helen Bhattacharya who have always inspired me to excel at every endeavor I pursued. Thanks to my mum for teaching me how to read without which I wouldn't have been where I am today.
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CHAPTER 1

Introduction

1.1 Rationale for Studying Wear in Cervical Total Disc Replacement

In recent years, there has been a paradigm shift towards motion preserving surgeries from the previous approach of motion-eliminating (fusion) surgeries. The problems associated with fusion procedures such as accelerated adjacent level degeneration, prolonged recuperation time, pseudoarthrosis and donor site morbidity have increased the interest in alternative treatments such as total disc arthroplasty, nucleus replacement and dynamic stabilization devices[1-3]. Motion preservation devices have created additional biomechanical issues for the research community to address which are not inherent to fusion technologies. Because of the motion persevered in these new devices, cyclic loading and relative motion at interacting implant surfaces will generate wear debris over time. At present, researchers have a reasonable understanding of the mechanics and biological impact of wear in total joint arthroplasty[4]. However, the calculation and reduction of wear have become critical for the sustainability and performance of motion preserving artificial devices in-situ. Previous studies of wear related issues in hip and knee arthroplasties suggest that wear debris is capable of initiating inflammatory responses, leading to periprosthetic osteolysis.
and bone resorption at the implant-bone interface[5, 6]. These responses may induce pain and implant loosening leading to revision surgeries as shown in Figure 1-1.

Figure 1-1 Schematic representation of the biological response and potential outcome of wear particulates

The biological response to particulate debris is dependent on several factors such as the number of wear debris particles, their size or shape, surface morphology, and the rate at which they accumulate in the periprosthetic tissues[7]. Thus, bio-tribological tests serve as an effective pre-clinical tool to investigate wear characteristics of devices and improve implant performance post surgery [4]. Osteolysis can be further categorized based on causes that are implant specific, patient specific or surgeon specific, as shown in Figure 1-2[8, 9].

2
1.2 Current State of the Art

In the past two decades, bio-tribological simulations in the areas of hip and knee implants have been pursued by researchers [10, 11]. These include computational finite element modeling, as well as mechanical testing. In comparison to THR (total hip replacement) and TKR (total knee replacement), spine arthroplasty or total disc replacement is a much newer and more complicated technique. Cervical disc arthroplasty is an emerging technology that is being used post decompression to preserve motion and prevent adjacent segment stress[12]. McAfee et al.[13] have defined the clinical indications for cervical disc replacement as being the same as those of anterior cervical decompression; which is radiculopathy or myelopathy caused by one or two levels of anterior cervical compression. As the name suggests, the goal of disc arthroplasty is to
completely replace the degenerated intervertebral disc by an artificial implant, which unlike fusion has the capability to not only treat the pain causing symptoms but also potentially restore the motion.

Currently there are quite a few artificial discs available in the market based on different design concepts. Interestingly, TDR has received mixed reviews from the scientific community, based on its clinical performance. The primary deficiencies reported in this technique are risk of posterior joint degeneration, osteolysis (wear debris generation) and complicated revision surgeries. These implants are meant to be load bearing structures and hence, wear at the articulating surfaces is a common phenomenon. Studies on the retrieval of the Charité™ artificial disc by Ooij et al. [14] proved that the polymeric core failed, leading to the formation of polymeric debris. Chronic rim impingement, leading to rim fatigue and fracture, was also observed in the implant. Retrievals of Prodisc-L™ by Choma et al. [15] showed evidence of burnishing due to anterior rim impingement.

While it was previously lacking in the literature, data on polymeric wear debris has now begun to appear for spinal devices. A wear rate of 1.1 mg/million cycles has been reported for the Charité™ artificial disc while the wear rate for the Bryan™ disc was 1.2 mg/million cycles during in vitro simulation. It should be noted that the presence of wear debris in the spinal region might be more harmful due to its proximity to major blood vessels and neural tissues.

Based on our understanding of wear in hip and knee implants, test methodologies for TDA have evolved. Modern day simulators are more sophisticated and customized to evaluate wear in artificial discs. Wear debris evaluations for artificial discs are done in
simulators using the currently published ASTM/ISO loading profiles. Although the motion patterns are based on those found in the previous biomechanical literature, the clinical relevance of these profiles is under debate.[16]

Clinical failures may be a result of a unique combination of factors as stated in Figure 1-2. At present, simulators designed for disc wear-evaluations can control the loading and motion profiles and they concentrate primarily on implant specific factors. The discs must be positioned to closely match the center of rotation of the simulator station and disc components must be appropriately centered. These tests primarily compare wear related parameters among different disc designs. Current wear testing standards for artificial discs do not account for the influence of anatomic structures, variations in the surgical procedures for disc placement, misalignment and micro separation of the implant and thus are unable to simulate clinical scenarios[17]. They also do not attempt to emulate daily activity or patient specific factors, such as body weight and anthropometrics. Despite standardized testing procedures, which may replicate the worst case scenario, we are unable to emulate situations of clinical failure.

Retrieval analyses of explanted devices from humans are being conducted to understand device performance and provide information related to implant and biomaterial-related failure modes. Many of these retrievals reflect failure modes which are not observed during bench top simulations and thus direct us towards the deficiencies associated with these tests[18, 19].

For instance, *in vitro* data for the Charité™ disc was reported as having a low wear rate, demonstrating the insignificance of wear debris for lumbar discs. On the contrary, retrieved Charité™ implants reflected not only severe wear and damage but also
impingement due to subsidence, subluxation and migration of the endplates [19]. Similarly, dome burnishing and rim impingement were reported for Prodisc-L post short term retrieval [15]. In vitro simulations were also unable to predict the adverse tissue reaction for the Acroflex implant [20]. Thus, positive in vitro results might not always translate to better in vivo performance.

Additionally, mechanical simulations are time consuming, expensive, and labor intensive procedures. Data variability among different laboratories and between multiple stations in a simulator cannot be ruled out. In spite of the fact that experimental data is indispensable, alternatives need to be explored. These could range from next generation wear simulators to predictive modeling based on wear-laws and finite element techniques to simulate clinical scenarios. Numerical simulations based on Archard’s [21] wear formulation have emerged as a predictive tool for finite element modeling of wear.

This chapter provides the background information required to understand the importance of device wear as well as the tools that are being employed in understanding it. In the subsequent chapter the classical work as well as a detailed review of past studies will be described.

1.3 Goals of the Dissertation

As we move from an era of arthrodesis to joint preservation, TDA represents a new paradigm in treating disc ailments. However, it also presents new challenges such as the amount of osseointegration and wear rates at the interface. The research community has replicated the experimental protocols for discs with boundary conditions in a wear simulator (bench top testing) as per ASTM/ISO standards. Thus, in order to address the
effects of factors other than loading or motion profiles on wear, one would require a predictive wear model capable of simulating \textit{in vivo} parameters.

The approach presented in this work simulates the wear phenomena of total disc replacement in a ligamentous functional spinal unit (FSU), as opposed to the analyses done previously on the disc alone. \textit{In vivo} wear differs from machine simulated results as they are performed in a highly controlled environment. Thus our hypotheses are

a) Post-implantation resection of posterior cervical spinal elements will result in an increase in the wear rate of artificial disc cores in a standard testing protocol.

b) Standard testing protocol applied on implanted metal-on-metal artificial discs will have lower wear rates than metal-on-polymer artificial discs.

c) Displacement controlled testing will result in equivalent wear rates in comparison to load controlled testing.

We plan to further investigate this by using the following aims.

Aim1: Study the effect of anatomic structures and surgical conditions of wear.

The arthroplasty procedure involves complete or partial discectomy followed by removal of anatomic structures like the ALL/PLL (anterior longitudinal or posterior longitudinal ligaments). To understand the effects of each anatomic structure and to verify whether removal or retention of such structures will have an influence on wear, finite element (FE) test cases will be run with sequential addition/removal of such structures.

Moreover, there has been some debate on the anterior or posterior placement of the device and hence we will simulate test cases to understand the effect of device positioning on wear.
Aim2: Study the impact of implant specific factors and their effect on wear in situ using finite element analysis (FEA). We will study the effects of design and material properties of artificial discs. The design of the implant will be kept constant and the material couple will be changed to understand its effect on wear.

Aim3: Study the effect of boundary conditions on wear. Additionally the wear of the device will be simulated using the load control and displacement control boundary conditions in an FE model.

Standardized testing has many open-ended guidelines for the users to adapt according to their needs [18]. These tests suggest that users should consider other potential failure modes not listed within the guidelines. However it may not be easy to foresee clinical failure modes without retrievals [20]. In-vitro simulations are time consuming, expensive and labor intensive procedures. Previous studies have controlled the loading profiles per ISO/ASTM standards but did not account for factors such as micro-separation, surgical variability and influence of anatomic structures. Therefore, they were not able to simulate clinical scenarios. In summary, we aim to replicate a realistic predictive wear model with an FE model.

The second chapter includes a review of the existing literature that was pertinent in the development of the wear model. In the third chapter the approaches and methods utilized to replicate the wear pattern are described. The fourth chapter deals with the results of the wear simulation while the final chapter summarizes the findings and points towards future directions.
CHAPTER 2

Literature Review

The following sections describe the relevant body of clinical and experimental literature regarding wear simulation of artificial disc replacements and elucidate the existing gaps. A short description of the anatomy of the spine is presented, followed by spinal pathologies pertaining to the intervertebral disc. The treatment options are then listed, followed by brief descriptions of spinal fusion and total disc arthroplasty. Finally, there is a short excerpt on the challenges of designing an optimum disc implant, a literature review of wear testing, and analysis of spinal implants.

2.1 Basic Anatomy of the Spine

The spine comprises of thirty three vertebrae divided into five main sections. The cervical spine consists of seven bony cervical vertebrae, followed by a thoracic region which is made up of twelve vertebrae. Additionally there are five vertebral bodies in the lumbar region, five in the sacral and four coccygeal vertebrae.

A functional spinal unit (FSU) consists of two adjacent vertebrae, an intervertebral disc and the adjoining ligamentous soft tissues. The FSU is thus composed of three separate articulations: two facet joints and an intervertebral disc. The vertebral body acts as the principal load bearing member. The vertebral bodies and intervertebral discs make
up the anterior column of the spine. The posterior column is comprised of the laminae, pedicles, and articular, transverse, and spinous processes. The vertebral canal is surrounded by the posterior aspect of the vertebral body and the posterior elements of the vertebra, as depicted in Figure 2-1. This ossified canal protects the spinal cord along its entire length. There are seven ligaments present in a motion segment which are the anterior, longitudinal, posterior longitudinal, ligamentum flavum, articular capsular, interspinous, supraspinous, and intertransverse ligaments. The normal intervertebral disc is an anisotropic structure. The jelly like nucleus pulposus acts like a fluid filled bag that swells under pressure and the annulus fibrosus consists of concentric fibrous bands radiating out from the nucleus[22]. This pressure is transmitted as a circumferential tension to the annulus converting it to a load bearing structure.

Figure 2-1 (A) Load sharing in a motion segment (B) Sectional view of an intervertebral disc[23]

This whole assembly acts as a shock absorber for the spine in such a way that there is no high loading at any localized point and allows complex motion to occur. The
intervertebral disc also acts to constrain this motion, adding to the stability of the motion segment (or the FSU) as shown in Figure 2-2.

Figure 2-2 Intervertebral disc sandwiched between the vertebral bodies, posterior structures and facet joints.[23]

2.2 Degenerative Disc Disease

Back pain is a major public health problem in industrialized societies and places an enormous economic burden on the society. In adults 17 to 64 years of age, back or spine impairment accounts for a greater percentage of absence from work, extended leave and loss of productivity than any other medical ailment[24, 25]. Almost 30 million people in the United States suffer from neck or low back pain and approximately 10% of these individuals suffer from chronic disabling back pain [24]. In general, spinal disorders reduce mechanical stability leading to abnormal motion and pain during daily activities. Some spinal disorders may be associated with physical deformity [26]. Neck and back
pain related diseases account for an annual cost of approximately $50 billion dollars in the United States alone [27]. Back pain also has a strong correlation to intervertebral disc degeneration [26] [28]. Disc degeneration is often associated with disc herniation and sciatica, but is often asymptomatic [28, 29]. Degenerative disc disease (DDD) leading to spinal stenosis in elderly patients is a primary reason for age-related disabilities [30].

A degenerated annulus can have fissures, microscopic fragmentation of individual fibers, annular tears at the corners of the vertebral body that separate the annulus from the endplates (due to age, wear and tear), concentric cracks cavities and radiating ruptures as seen in Figure 2-3. Subsequently, the annulus bears higher axial compressive loads, which leads to high shear forces in the concentric lamellae [31, 32] and as a consequence, loss in the mechanical integrity of the disc. Disc bulging may also occur due to the decrease in the radial strength of the annulus.

Figure 2-3 Various disc related ailments and their schematic representations [33]
The degeneration of the nucleus occurs due to loss of water content of the nucleus. Nucleus degeneration, in association with annular degeneration, may cause disc herniation, which leads to nerve impingement. Thinning of the disc and a loss of disc height may also occur in a degenerated disc. Loss of disc height combined with gradual ossification of the endplate and protrusion of the disc tissue causes stenosis, which can also lead to back pain [34-36] as depicted in Figure 2-3. Once degeneration sets in, the intervertebral disc goes through a cascade of degenerative changes resulting in the biomechanical alteration of the load transfer through the disc, causing changes in the mechanical properties and composition of the tissue. The structural disorganization leads to the failure of the hydrostatic mechanism [36].

Even though the exact pathogenesis of the degenerative process is still unknown, the factors that may cause degeneration are: aging, mechanical factors from occupational exposure, abnormal loading conditions and the loss of nutrition to the disc [34, 36]. It has been shown that a person may have a genetic predisposition for disc degeneration [37]. A comparison of a healthy and a degenerative spine is shown in Figure 2-4.
Disc degeneration and facet joint osteoarthritis are often related, but usually disc degeneration precedes facet joint osteoarthritis [39, 40]. Biomechanically, the facet joints are the important stabilizing structures and carry about 18% of the total compressive load borne by a lumbar spine segment. Facets are mainly responsible for preventing large extension rotation and shear [41]. Higher facet loads and stresses are seen in extension rotation and shear, which may lead to facet osteoarthritis or hypertrophy resulting in spinal stenosis. Degeneration of facet joints due to mechanical factors, such as increased facet loading and wear, is called “the facet syndrome.” Spondylosis, spondylolisthesis, disc herniation, and spinal stenosis may follow these degenerative changes in the segment [42].

In the early stages of low back pain, rest, physical therapy and anti-inflammatory medications are the first line of conservative and non-surgical treatment. The detailed description of each of these conservative treatment options follows.
2.3 Conservative Treatment Options

- **Physical therapy and exercise:** Physical therapy is a long-term pain management technique that aims to enable the patient to control pain effectively and function normally, without undergoing a surgical procedure. This attempts to improve flexibility in the neck, arms and legs through stretching exercises. The therapist may also include additional strengthening exercises in the program. Under supervision, physical therapy may take three or more months and eventually the patient becomes independent and performs activities independently.

- **Neck traction:** This is a technique in which a force is applied to a part of the body to reduce muscle spasms by stretching soft tissues, and in some cases separating facet joint surfaces or bony structures [43]. Neck traction must be constant so that the muscles may tire and the strain falls on the joints. Forces between 20-50 pounds are commonly used to achieve inter vertebral separation.

- **Chiropractic manipulation:** This is a precise procedure applied to the joints of the neck, usually applied by hand. Chiropractors claim that neck adjustment improves the mobility of the spine and restores the range of motion. It can also increase movement of the adjoining muscles [44]. Patients report an improved ability to turn and tilt the head and a reduction of pain, soreness and stiffness.

- **Osteopathic manipulation:** Osteopathic manipulation claim to restore normal joint motion and can be helpful in reducing pain from a cervical herniated disc[45]. The restrictions of nerve passages are said to be released, the movement of cerebrospinal fluid through the spinal cord is said to be optimized, and misaligned bones are said to be
restored to their normal position. This therapy is used to treat mental stress, neck and back pain, migraines, TMJ syndrome and chronic pain conditions such as fibromyalgia.

- **Activity modification:** Some activities may tend to exacerbate the herniated disc pain and it is recommended to avoid these activities to prevent nerve root irritation. Such activities may include heavy lifting (over 50 pounds), activities causing increased vibration and compression to the cervical spine such as boating, snowmobile riding, and overhead activities that require prolonged neck extension and/or rotation.

- **Medications:** The primary mechanism of action in NSAIDs is a reduction of cyclooxygenase activity which leads to decreased prostaglandin synthesis. Prostaglandins are active mediators during the inflammatory cascade. A reduction in their local concentration could therefore explain the combined anti-inflammatory and analgesic properties of NSAIDs.

- **Injections:** Epidural steroid injections are delivered directly at the source of pain. Since the vast majority of pain stems from chemical inflammation, an epidural steroid injection serves to control the local inflammation by flushing out the inflammatory proteins and chemicals from the local area that may contribute to and exacerbate pain [46]. Triamcinolone acetonide, Dexamethasone, and Methylprednisolone acetate are commonly used steroids used to treat low back pain.

When conservative treatment fails to alleviate pain, surgical intervention may be the only remaining option to regain the original lifestyle. Non-surgical treatment may prove unsuccessful in the treatment of degenerative disc disease (DDD), particularly when spondylosis or spondylolisthesis is present. Thus the aim of a surgery is to alleviate
pain and restore a normal lifestyle. A simplistic algorithm to elucidate the treatment options has been depicted in Figure 2-5.

Figure 2-5 A simplified treatment option flow chart for spinal ailments.
The range of spinal ailments that are treated using instrumented spinal surgery is vast. The aim of the next section is to provide an overview of the existing surgical options that are being utilized for the treatment of degenerative condition.

2.4 Surgical Intervention

The goals of surgical intervention are to remove the diseased or injured tissue and to restore stability and function in the spinal unit.

2.4.1 Spinal fusion or arthrodesis

Spinal fusion is the gold standard of surgical treatment for DDD and is derived from experience at other joints of the body where arthrodesis (fusion) has been used to treat joint pain. For decades, fusion has been one of the most common surgical methods for treatment of degenerated discs. The main clinical problem addressed in spinal fusion is the restoration of stability in a clinically unstable spine. As the name suggests, the bony segments of the spine are fused with the goals of correcting the deformity, pain reduction and restoration of stability. Spinal fusion may be accomplished with or without the use of spinal instrumentation. External instrumentation can be used as an alignment and load sharing device until a bony fusion is achieved [47]. This instrumentation has evolved over a time and is used in combination with external braces and bone grafts to improve both the rate and degree of bone consolidation.

Harrington was the first to utilize hooks and rods to correct spinal deformity and instability and is considered to be a pioneer of posterior fixation devices for fusion [47]. Sublaminar wires were also introduced for fixation procedures [47]. However, wires were
associated with further complications and did not prove clinically successful. Pedicle screws with rod and plate systems came next. These systems were founded on the fact that the pedicles have an advantage in terms of force application as compared to the facets and laminae [47]. Apart from pedicle screw-based systems interbody cages have also become popular as an effective fusion device. Interbody cages are metallic (e.g. titanium) or polymeric (e.g. polyetheretherketone PEEK) devices with an empty central region that is packed with bone graft material and then placed in the intervertebral space. These devices have an open design to allow direct bone growth through the cage from one vertebral body into the next [48].

A common surgical approach for these devices is the ALIF (anterior lumbar interbody fusion) procedure. Yet, some cages can be inserted using a posterior approach (PLIF). Traditionally, anterior interbody fusions utilized autologous bone, harvested intra-operatively from the patient’s iliac crest. Apart from graft site morbidity, there was a high incidence of non-union with these procedures. Threaded cylindrical cages designed in the late 1990s improved the success rate of these procedures by providing a more rigid fixation within the disc space.

2.4.1.1 Challenges and drawbacks associated with fusion procedure

Although fusion was first performed over 100 years ago and still remains the gold standard of treatment for DDD, accelerated adjacent level degeneration, morbidities after spinal fusion and increased cost due to long postoperative rehabilitation still remains a concern [49]. In spite of being a successful procedure, fusion surgeries lead to decreased mobility at the surgical level thus causing the patient to cease certain activities.
Additionally, fusion has shown drawbacks such as pain at the bone harvesting site and adjacent level degeneration (ALD). After initial pain relief, pain is likely to return due to spinal stenosis, facet hypertrophy, osteophyte formation, posterior muscular debilitation or disc degeneration at levels adjacent to the fusion site. It is however unclear whether adjacent segment degeneration is an outcome of the iatrogenic reasons or if it is a progression of the natural history of the underlying degenerative disease [50]. Adjacent level disease (ALD) is a condition characterized by arthrosis of the caudal and/or cranial vertebral joint next to the fused unit. The reduced motion at the fused segments leads to an increased motion at the adjacent level. In a study by Katsurra et al. [51] the rate of ALD was found to be around 50% at the end of 10 years. A reoperation rate of 6% in addition to a 36% rate of clinical deterioration was confirmed by Goffin et al. [52] at the end of 8 yrs.

In a study by Lee et al. [3] hypertrophic degenerative arthritis of the facet joints were observed at the adjacent level. Additionally incidence of stenosis, degenerative spondylolisthesis and disc degenerative conditions were observed in 18 patients after a period of 8.5 yrs. An in vitro study by Chow et al. [53] proved increased segmental motion and intradiscal pressure for adjacent vertebrae. In another clinical study by Wai et al. [54] approximately 70% of the patients showed evidence of degeneration, while almost 30% of the patients had advanced degenerative symptoms localized to the adjacent level. Wittenberg et al. [55] concluded that long implants may give rise to strain at the adjacent level causing early degeneration and destabilization; therefore, short segment fixation is preferred in spite of its inherent shortcomings.
Reduced motion, ALD and donor site pain due to fusion have paved the way towards the quest for alternative measures. Along these lines, many non-fusion techniques are being investigated and some have emerged in recent times that are capable of replacing the conventional fusion techniques. The classification in the field of spinal instrumentation is summarized in the flow chart Figure 2-6.

![Flow Chart Figure 2-6 Classification of spinal instrumentation system](image)

Figure 2-6 Classification of spinal instrumentation system
2.4.2 Evolution of disc arthroplasty

The traditional belief that a rigid fusion correlates with successful clinical outcomes has recently come under question primarily because of the results drawn from several randomized trials [3, 51, 54]. Limited clinical success rates for spinal fusion and the success of total joint replacement for other joints in the body have motivated efforts to develop disc arthroplasty techniques in the spine [56-58]. As the name suggests, the goal of disc arthroplasty is to completely replace the degenerated intervertebral disc by an artificial implant which, unlike fusion has the capability to not only treat the pain causing symptoms but also potentially restore the motion.

The earliest clinical literature on disc arthroplasty was reported by Fernstrom in 1966, using a stainless steel ball bearing manufactured by SKF[27]. Since then there has been an ongoing quest for an artificial disc that does not compromise patient safety, maintains intervertebral height, provides an acceptable range of motion (ROM), demonstrates long term durability and stability, and restores the energy absorptive qualities of the native disc[59, 60]. The ultimate goal of such a device is to restore function with minimal detriment to surrounding tissue. At the very least, deep understanding of the clinical issues, engineering mechanics and material properties are crucial to the mechanical design of a disc prosthetic [58, 61].

The key factors that must be considered in the design of a disc implant are:

- Each spinal level contains three separate joints: Two facet joints and the intervertebral disc.
- The disc in its native state provides a combination of mobility and stability.
• Native disc’s shock absorption capabilities must be mirrored.

• The instantaneous axis of rotation (IAR) is constantly changing as the position of motion segment changes.

Various disc designs exist in the market. These devices can be categorized by two major design principles. The first group aims to replace the motion characteristic of the disc and is designed with a metal-on-polymer bearing. The second group aims to mimic the viscoelastic response of the nucleus surrounded by the annulus. These devices are designed using polymers[60]. Constraint is also important and may provide a better scheme for the classification of ball and socket devices (articulating discs) such as Prodisc-L™, Maverick™, etc. Such a classification can be broken down into constrained, semi-constrained and unconstrained designs based on the degrees of freedom [62]. The constrained design has a fixed center of rotation (COR). Moreover, the surfaces completely conform and have a retentive interface. The sliding and rolling motion of this artificial joint, in turn, defines spinal motion.

An unconstrained device has a non-conforming ball and socket interface and has a floating COR. The semi-constrained design falls somewhere in between the other two cases[63] and allows translational motion in the anterior-posterior direction. Another kind of device is the elastomeric disc such as the Acroflex™ disc. This device was designed with a unique goal of mimicking the shock absorption capacity of a natural disc. A number of disc replacement devices are summarized in Table 1.1 and illustrated in Figure 2-7 and Figure 2-8.
Figure 2-7 Different lumbar disc designs: (A) Maverick™ (B) Charité™ (C) Prodisc-L™ (D) Activ-L™ Adapted with permission from Dr A. Fahir Ozer [64]
Figure 2-8 Different cervical disc designs: (A) Prestige ST™ (B) Bryan™ disc (C) Prodisc-C™ (D) M6™ disc (E) PCM™ Adapted with permission from Dr. A Fahir Ozer [64]
Table 1.1 Types of lumbar and cervical artificial disc replacement devices [64, 65]

<table>
<thead>
<tr>
<th>Device</th>
<th>Material Couple</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LUMBAR DISCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SB Charité™</td>
<td>Metal-Polymer-Metal</td>
<td>Unconstrained polymeric core and endplates bioactively coated</td>
</tr>
<tr>
<td>Prodisc-L™</td>
<td>Metal-Polymer-Metal</td>
<td>Lordotic angle of the endplates is $6^\circ/11^\circ$. Semi-constrained device</td>
</tr>
<tr>
<td>Maverick™</td>
<td>Metal-Metal</td>
<td>COR of this device is fixed. ROM determined by radius of the ball</td>
</tr>
<tr>
<td>Flexicore™</td>
<td>Metal-Metal</td>
<td>The endplates are plasma coated</td>
</tr>
<tr>
<td>Mobidisc™</td>
<td>Metal-Metal</td>
<td>Sliding core and emulates the instantaneous COR(center of rotation)</td>
</tr>
<tr>
<td>Activ-L™</td>
<td>Metal-Polymer-Metal</td>
<td>Sliding core and endplates have spikes or keels</td>
</tr>
<tr>
<td>Kineflex™</td>
<td>Metal-Metal</td>
<td>Semi-constrained disc with a flexible COR</td>
</tr>
<tr>
<td>Acroflex™</td>
<td>Rubber core with titanium endplates</td>
<td>Elastomeric disc</td>
</tr>
<tr>
<td><strong>CERVICAL DISCS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M6™</td>
<td>Metal-Polymer-Metal</td>
<td>Polymeric fibers emulate the annulus</td>
</tr>
<tr>
<td>Bryan™</td>
<td>Metal-Polymer-Metal</td>
<td>Core encapsulated in a polymeric sheath and lubricated with saline</td>
</tr>
<tr>
<td>Prestige ST™</td>
<td>Metal-Metal</td>
<td>Two-piece ball-and-trough configuration</td>
</tr>
<tr>
<td>Prodisc-C™</td>
<td>Metal-Polymer-Metal</td>
<td>Keels on the endplates are unique</td>
</tr>
<tr>
<td>PCM™ (Porous coated motion)</td>
<td>Metal-Polymer</td>
<td>Ridges on the device endplate. Device endplates rectangular in shape and greater in width than in depth emulating the vertebral endplates.</td>
</tr>
<tr>
<td>Cervicore™</td>
<td>Metal-Metal</td>
<td>Innovative saddle shaped articulation, COR below in flex/ext; above in bending</td>
</tr>
<tr>
<td>Cervidisc™ (DISCOCERV)</td>
<td>Ceramic-Ceramic</td>
<td>Lordotic $4^\circ$ angle; endplates have teeth for fixation with hydroxyapatite coating</td>
</tr>
</tbody>
</table>

The next section provides a brief detail of the material combinations that have been listed above for the various implants.
2.4.2.1 Types of bearing couple used in total disc arthroplasty

As different material couples are being used for various disc designs it is pertinent to outline the most commonly used material combinations.

Metal-on-polymer

In 1958 Dr Charnley [66] introduced a stainless steel femoral component in combination with a polymeric socket (PTFE-polytetrafluroethane). This eventually was replaced by ultra high molecular weight polyethylene (UHMWPE). Though this material had its own shortcomings, it eventually laid the path for polymeric materials to emerge as a significant biomaterial in arthroplasty. Due to the fact that it articulates with a metallic component, the roughness of the harder surface is an important determinant of wear. Adhesive, abrasive and fatigue wear are the primary wear modes that are observed in polymeric components. In vivo oxidation as well as sterilization of polymers can lead to reduction in fatigue, strength and eventually higher wear rates. Tissue reactions and inflammation due to polymeric wear debris have emerged as an important concern among the scientific community. These materials are advantageous compared to metals and ceramics because their lower strength prevents stress shielding. Moreover, there are no allergic reactions as in metals which lead to ion release. They have excellent impact strength, low coefficient of friction and fatigue resistance. Currently the community is shifting from UHMWPE to Polyetheretherketone (PEEK) due to its excellent bio-compatibility and bio-stability properties. Its elastic modulus, which is close to that of the bone and with its radiolucent properties, qualifies it as an excellent bio material. However PEEK is being used primarily in fusion based devices while UHMWPE (cross-linked
polymers) are being used in motion preservation devices due to its better mechanical properties.

Metal-on-metal

Stainless steel, titanium and cobalt based alloys are the primary choices for orthopedic applications. Amongst all metals, titanium has much better biocompatibility properties. Apart from wear due to abrasion, adhesion or fatigue wear, corrosion is also an important concern in metallic alloys. Hall \textit{et al.} \cite{66} reported that the wear of metal on metal occurs in two phases; during the first million cycles (the elevated bedding period) and subsequently during the lower steady state. The latter occurs once the bearing surfaces have been subjected to self polishing by the action of wear particles. Low carbon content alloys produce significantly higher wear rates than high carbon ones. In comparison to metal-on-polymer couples, metal-on-metal implants are considered superior in terms of wear resistance. In spite of the superiority of metal based implants, corrosion and wear at the device interface cannot be ruled out. Metal-on-metal articulation leads to much smaller sized particulates in comparison to metal-on-polymers.

Thus for an equal volume of wear debris from both polymer and metal, the number of metallic particulates can be up to 100 times greater \cite{67}. There has also been some evidence of the carcinogenic effects of metallic ions. Accumulation of metallic debris in the periprosthetic tissue has been seen to cause proliferation of fibroblasts. This leads to the formation of a fibrous membrane, which might act as a channel for polymeric particulates \cite{68}. The metallic ions are easily transported by the body fluids away from the joint which have been often indicated by high level of ions in blood or urine.
Ceramic-on-ceramic

Ceramics are characterized by excellent biocompatibility, wear resistance, corrosion resistance and strength. Additionally, they are light weight and chemically inert by nature [69]. Alumina and zirconia are the two major types of ceramics that are being used in orthopedic applications. Zirconia toughened alumina (ZTA) combines the wear resistance of alumina with the surface toughness of zirconia. These materials are, however, brittle in nature and are prone to fracture.Stripe wear [17] due to impingement (edge loading/rim contact) and micro-separation in hip replacement has been observed in ceramic implants [70].

Moreover, the typical squeaking hips among patients with ceramic implants during activities of daily living are a serious annoyance. Additionally, edge loading might lead to higher wear rates [71]. Nevertheless, this material is perhaps much better in comparison to others in terms of wear resistance and biocompatibility.

The importance of biomechanics and other mechanical factors that contribute to the sustainability and performance of spinal implants cannot be underestimated. Stress, strain and failure analyses of these implants are performed in bench-top, animal, cadaveric or numerical studies to justify the efficacy of these devices in vivo. The next section details few pertinent biomechanical studies related to TDA.
2.4.2.2 Biomechanical evaluation of TDA

The quality and quantity of motion following total disc replacement may affect the facet joints of the motion segment and the bone-device interface. Biomechanical evaluation enables us to determine the kinematics of a motion segment as well as the adjacent segments post total disc arthroplasty (TDA). In a study conducted by Demetropoulos et al. [72] the kinematic properties of the lumbar spine were characterized following Prodisc-L™ implantation. Ten cadaveric spines (L3-L5) were tested under pure moments over a range of ±10 Nm with an applied follower load of 200 N. Load deformation curves as well as the ROM were computed in flexion-extension, lateral bending and axial rotation. This study demonstrated that Prodisc-L™ (semi-constrained) restored flexion-extension motion compared to the intact condition.

In a similar study conducted by Hitchon et al. [73] for the Maverick™ artificial disc (constrained disc design), ROM increased in all loading modes. Despite the increase, statistical significance was not established. Cunningham et al. [74] showed a 44% increase in the ROM in axial rotation using the Charité™ disc (unconstrained/浮动COR). A marginal increase in all other loading modes was also observed. In this study, the Charité™ disc was compared to the BAK cage and the BAK™ cage+ISOLA™ screw rod fixation. This study also showed that TDA preserved the kinematics at the operative and adjacent levels compared to lumbar interbody fusion devices.

Past studies have emphasized the importance of artificial disc designs that preserve the posterior elements. This is of great importance as posterior element degeneration or facet joint degeneration, is a common source of low back pain. On the other hand, some studies have reported that apart from preoperative degeneration, the posterior elements
may be abnormally stressed by disc replacement. In a computational study performed by Dooris et al.[75] the effects of facet load sharing following TDA were examined. A ball-on-socket disc design by Medtronic was utilized as the implant. Comparisons were made between the pre and post-implantation FE models. Different annular window sizes and varied anteroposterior artificial disc placement was simulated. Their findings demonstrated that an artificial disc can alter spinal bending stiffness in the sagittal plane. Changes in spinal stiffness were noted to be dependent on the position of the disc and degree of annular resection. Anterior placement of the device led to increased facet joint loads in compression and extension. These findings suggest that if the anterior longitudinal ligament is preserved and the implant is placed posteriorly within the disc, the spinal stiffness will be restored and facet loads will be maintained at pre-implantation levels. FE models are an important tool for the computation of complex motions and contact forces in cases where direct experimental measurements are not feasible.

In another numerical study by Ku et al.[76], a 3D FE model of a two-level osteoligamentous lumbar segment was built to compare cases of arthrodesis versus TDA using a metal-on-metal ball and socket design. It was found that superior adjacent segment mobility following fusion was reduced by 44% in rotation about all three axes. In contrast, superior adjacent segment mobility increased in all degrees of freedom by 52% following TDA. Interestingly, it was noted that TDA led to high ligament strain, high facet stress and heightened risk of instability. It was also suggested that the COR of an artificial disc should be located posterior to the geometric center of the endplates and that the preservation of the annulus is an important consideration in TDA [76]. In a later work by Goel et al.[77], impact of a Charité™ disc replacement at L5-S1 was
investigated using the hybrid protocol. (The hybrid protocol involves testing the intact spine to a given load level first and then repeating these tests for subsequent test conditions; such as TDR with a fixed endpoint of displacement determined by the range of motion of the intact specimen). The FE model predicted an increase in ROM by about 44% at the implanted level and a decrease in facet loads by 13.4%. ROM and facet loads also decreased in adjacent segments.

The impact of the placement of a device on the final outcome is also an important matter of debate. Based on this idea Huec et al.[78] utilized a FE model of the lumbar spine to study Maverick™ lumbar total disc replacement. ROM and facet strains were computed. It was proposed by the authors that “less-than-ideal positioning of the prosthesis, especially with an anterior offset, significantly affects the range of motion of the spine segment and cause increase of inner load in the facets”.

2.4.2.3 Detailed description of pertinent disc designs

This dissertation primarily focuses on two kinds of disc design, the Prodisc-C and the Prestige. It is necessary to understand the basic design as well as the mechanical properties of these devices.

**Prestige**: The Prestige disc (Medtronic, Inc.) features metal-on-metal articulation, in which endplates and articulating surfaces are constructed of stainless steel or titanium [Figure 2-9]. The design of metal-on-metal was used to eliminate polyethylene wear debris, which generates a more aggressive inflammatory response. The superior component is the ball component of the disc implant which is secured to the vertebral body using two fixed angle screws. The socket component or trough allows for both
translational and rotational motions. This design claims to be better than the ball on socket design as it mimics the center of rotation (COR) of the native disc.

![Figure 2-9](image)

**Prestige**

**Prodisc**

Figure 2-9 Ball on trough design of Presige<sup>ST</sup> cervical disc and ball on socket design of Prodisc-C<sup>[79, 80]</sup>

**Prodisc-C**: This is a ball and socket design with metal on polymer articulation, manufactured by Synthes Spine Solutions, West Chester, PA. It is a three part device, comprised of two cobalt chrome endplates and a polymeric core [Figure 2-9]. The inferior polymeric ball articulates with the superior metallic socket. The polymeric core fits onto the inferior endplate. The endplates are plasma-spray coated with keels for fixation and osseointegration. The COR of this device is fixed unlike the Prestige design.

The clinical indications for cervical disc arthroplasty has been defined extensively by McAfee *et al.*[13] as following

- Treatment necessary for one to three segments due to symptoms of cervical radiculopathy and/or myelopathy, with or without axial neck pain.
The patient has failed conservative treatment that has lasted for 6 wks or more due to disc herniation with radiculopathy, spondylotic radiculopathy, and disc herniation with myelopathy or spondylotic myelopathy. As per the surgical procedure for the Prestige and Prodisc-C, the artificial discs are placed after the removal of anterior annulus, entire nucleus, parts of posterior annulus and anterior longitudinal ligament at the implanted level. Additionally, the endplates are prepared so that the device sits correctly with respect to the endplates. The preparation of the endplates varies case by case and this may eventually affect the biomechanics of the implanted segment. Although the anterior approach is generally used for cervical disc arthroplasty, different disc designs may prescribe different surgical approaches for implant placement. Thus, the effect of surgical procedures with respect to the resection or preservation of a spinal structure on biomechanics is still not understood.

2.4.2.4 Challenges faced during disc design and post implantation

In spite of short term clinical efficacy cervical disc arthroplasty is still in its nascent stage of implementation. The importance of biomechanics and other mechanical factors that contribute to the sustainability and performance of spinal implants cannot be underestimated. Stress, strain and failure analyses of these implants are performed in bench-top, animal, cadaveric or numerical studies to justify the efficacy of these devices \textit{in vivo}. Currently disc designs have undergone or are still undergoing design related iterative changes. The choice of material couple has a direct bearing on the load sharing, as well as the biomechanical functionality of the implant. The stiffness of the device should be such that the implant-bone interface does not cause bone resorption or excessive bone deposition, which may eventually lead to the failure of the implant or the
endplates. The fixation interface should be able to promote optimum osseointegration. Additionally the implant should not only enable load sharing but should also replicate the normal range of motion at the implanted segment.

The minimum average age of the patient population opting for cervical disc arthroplasty is approximately 40 yrs. This would mean that the implant should be durable for at least 40-45 yrs of device usage. Thus wear and fatigue resistance are two major criteria that should be taken into account for proper functioning of the implant. The implant material should be biocompatible and not elicit any inflammatory response in the host tissue. It is important to have a reasonable understanding of the wear characteristics of an implant based on the design as well as material combination chosen. Link et al.[81] claimed that wear in disc arthroplasty was insignificant. However later studies by Anderson et al. for Bryan cervical discs revealed almost 18% loss of material in terms of gravimetric wear [81, 82].

Similarly, Serhan et al.[83] reported an average polyethylene wear of 0.11 mg per million cycles and a volumetric wear range well below the acceptable threshold for Charité™ discs. Soon after, studies by Ooij et al. and Kurtz et al.[19, 20, 84] based on explants of the Charité™ disc, depicted rim damage and wear of the polymeric core due to localized stress concentration. Thus these studies refuted the arguments presented by other researchers who claimed that polymeric wear in spinal devices might not be a clinically relevant issue. This also shows the limited understanding of the wear phenomenon in spinal implants and thus points towards the deficiencies existing in preclinical testing procedures. The subsequent section provides an overview of the wear characteristics and the corresponding outcome in orthopedic implants.
2.5 Tribology and Biotribology

All Implantable mechanical devices exhibit wear over a prolonged period of usage. Wear is not an intrinsic property of the material but is rather a function of usage. Wear in implants is caused by relative motion under load at the articulating surfaces. The word "tribos" means rubbing and friction and thus, "tribology" is the study of friction, wear and lubrication at the interacting surfaces. The term "biotribology" was coined by Dowson to include all aspects of tribology which could be applied to biological systems. Articulation of both natural (synovial joints) and artificial joints can be included under this domain [85]. Increased friction and wear can lead to debris generation at the interfaces which in-turn may be detrimental for the normal functioning of any joint. Biotribology not only includes understanding the causes of the formation of wear debris, but also the adverse tissue reaction due to wear debris formation.

Osteolysis disrupts the fine balance that exists between the bone formation and resorption processes and favors osteoclastic activities leading to bone loss. It has previously been established that host response to the particulates (wear debris) generated at the articulating interfaces of prosthetic devices leads to osteolysis and aseptic loosening [66]. Osteolysis is a particle induced disease which can be detected radiographically as endosteal radiolucencies. Initially, osteolysis was thought to be related to bone cement and was thus termed as "cement disease". This was later proven incorrect due to the presence of lesions in cementless joints. The reaction to foreign debris is dependent on various factors such as particulate morphology, shape, size, number and surface area as depicted in Figure 2-12 [86].
A host tissue responds to larger particles by the mechanism of fibrous encapsulation, while smaller particulates are phagocytosed. Particles generated from different joint replacements vary in size due to the different wear mechanisms involved in each case. For instance abrasive/adhesive wear dominates total hip replacements, leading to smaller sized particles while fatigue/delamination in knee implants leads to larger sized particles [87].

![Figure 2-10 Interrelations among wear particle characteristics, wear mechanisms and biological activity [67] (Adapted with permission from the publisher)](image)

The impact of osteolysis has been seen to increase proportionately with an increased concentration of particles. The total volume of particles generated at metal-on-metal
bearing surface is much smaller than particles generated at polymer-on-metal interface. The metallic particles being smaller in size, the number of metallic particles in the same volume might be much greater than polymeric particles [67].

2.5.1 Modes of wear in orthopedic implants

Harry Mc Kellop[88] developed a unique wear classification mode based on the contact at the bearing surfaces [Figure 2-11].

- **Mode 1**: Wear mode which is necessary for the device to function in such a way that the intended bearing surfaces are wearing against each other.

- **Mode 2**: A primary bearing surface is articulating with a secondary surface (non-bearing surface) causing unintended contact. This can lead to excessive wear and failure of the device. For example, a worn femoral polymeric component comes in contact with the metallic shell.

- **Mode 3**: When third body particulates are entrapped between two primary bearing surfaces in such a way that they act as abrasive particles. This mode may lead to very high wear rates. For instance bone cement particulates are often entrapped at the device interface which leads to third body abrasion.

- **Mode 4**: When two non-bearing surfaces rub against each other. An example is impingement of the neck against the socket.

Modes 2, 3 and 4 depict a malfunctioning prosthesis. In an ideal scenario the design of the device should be such that the wear is minimal in Mode-1 and modes 2, 3 and 4 should be prevented.
2.5.2 Factors contributing to implant wear and osteolysis

As described in chapter 1, wear of implants is multifaceted in nature and, a combination of different factors comes in to play to determine the extent of device wear. Osteolysis can be divided into several categories: patient specific, implant specific and surgeon specific factors [Figure 2-12]. These factors are not mutually exclusive and are related. Implant specific factors fall under the category of design variables; patient specific factors are categorized under environmental variables; surgical factors can be classified under both environmental and design variables. Design variables are controllable while environmental factors are uncontrollable.
2.5.2.1 Patient specific factors

Patient specific factors are those which are unique to the patient population and revolve around characteristics such as magnitude, direction of loads and joint kinematics. Patients who have an active lifestyle and are involved in various sports often have increased joint loading and thus can have a detrimental effect on the wear performance. Increased body weight can also lead to increased loading conditions and ultimately can lead to wear of the implant. It has been noted that patients who perform activities like deep flexion (kneeling activities) may be at a higher risk for wear. Female athletes have also been found to be more likely to have ACL injuries compared to their male
counterparts so it is likely that there are anatomical differences that may also contribute
to differences in wear. Moreover an increased young patient population might reflect a
new challenge for the durability of the devices [89]. Patient specific factors are listed below.

- Activity level
- Body mass index, weight and gait mechanics
- Limb Alignment
- Implant time in situ
- Preoperative diagnosis or comorbidities
- Cultural demands
- Anthropometrics
- Race

2.5.2.2 Implant specific factors

Designs, material couple and manufacturing processes are some of the inherent
implant specific factors that influence the wear characteristics of the devices [90]. For
instance, sterilization by gamma radiation reduced the wear performance of polymers.
Likewise, the shelf life of polymeric implants is an important factor on its wear
performance. Material couples such as ceramic-on-ceramic implants are preferred in
place of metal-on-metal or metal-on-polymeric implants because of their excellent wear
resistant properties [90]. Diametric clearance has been seen to play an important role in
terms of wear. Decreased wear rates have been recorded for increasing bearing radii [18].
The implant specific factors are listed as following.
- Modularity
- Component thickness/size
- Clearance
- Conformity
- Material couple
- Sterilization
- Shelf life
- Fixation methods

These factors are controllable and can be manipulated by the design engineers in order to make them tend towards better implant properties

2.5.2.3 Surgeon specific factors

Surgeons play an important role in determining the right implant size, soft tissue balance, alignment of the device, etc. These factors have a direct bearing on the wear performance of the implant. For instance, third body wear can be a result of debris generated from instrumentation, cementing techniques etc. Computer assisted surgical procedures are enabling surgeons to attain a more accurate soft tissue balance. The factors which can be listed under the following topic are as follows [89]:

- Surgical approach
- Position of the implant
- Restoration of mechanical and rotational axes
- Third body wear (due to fixation)
- Surgeon’s experience or skill
Fixation approach used

Advanced preclinical tests such as laboratory wear simulations as well as mathematical modeling techniques have given us an insight about the weight of each factor on the wear outcome of implants.

2.5.3 Mechanism of material loss in orthopedic devices

Wear can be broadly classified into the following categories: abrasive, adhesive, fatigue, fretting, erosive and corrosive wear. Detailed description of each of the wear categories has been listed in Appendix A (Section A.1). Wear at the articulating surface of an orthopedic device is visually represented by scratches, burnishing and embedded particulates. These terms are better defined as follows:

**Abrasion and scratching:** This is a manifestation of abrasive wear in devices marked by scratching and scars which could be microscopic or macroscopic [Figure 2-13]. These are caused when asperities of one surface plough against another surface.

![Figure 2-13 An example of abrasive scratching in ceramic on ceramic artificial disc post experiment (Unpublished work at ECORE, University of Toledo)](image)

**Burnishing:** Primarily caused due to the adhesive wear mechanism it is marked by a polished, glossy appearance at the surface. Burnishing of polymeric components is a common occurrence in orthopedic implants.
**Third body particulates**: Bone cement or entrapped wear particulates can accelerate the abrasive wear mechanism at the articulating surfaces.

**Fatigue wear**: Fatigue wear is commonly observed in knee implants. However rim fractures at the polymeric core of spinal devices can also be an outcome of fatigue wear.

**Chemical reactions**: Corrosion among metallic components and oxidation of polymeric parts are a common phenomenon. Tribochemical deposits or biofilms at the surface of retrieved components clearly depict this phenomenon [Figure 2-14].

![Figure 2-14 An example of corrosive wear for a cobalt chrome disc implant post experiment (Unpublished work at ECORE, University of Toledo)](image)

2.6 **Preclinical standards of wear testing**

The American Society for Testing and Materials (ASTM) and International Organization of Standardization (ISO) recently published documents for the wear assessment of artificial disc prostheses. It should, however, be noted that different kinematic profiles are suggested by these standards, which may lead to different wear paths. Recently the effect of cross-shear has been documented and thus unidirectional motion has been found to be unsuitable for wear predictions. Previous studies have confirmed strain hardening of the polyethylene during sliding and thus, linear motion can lead to wear resistance, as in the case of ASTM standards. It is therefore essential to
select test conditions that will lead to clinically relevant results, as wear is a function of relative motion. A comparative summarization for both the standards is listed in Table 2.2 which has been adapted from ISO18192 and ASTM F2423-05.

Table 2.2 Comparative chart for the test parameters of ASTM and ISO wear test standards [91, 92]

<table>
<thead>
<tr>
<th>TEST PARAMETERS</th>
<th>ISO 18192</th>
<th>ASTM F2423</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOADING PROFILES</td>
<td>Cervical</td>
<td>Lumbar</td>
</tr>
<tr>
<td>Load limits</td>
<td>50-150 N</td>
<td>600-2000N</td>
</tr>
<tr>
<td>Phase Angles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>1.0 Hz</td>
<td>2.0 Hz</td>
</tr>
<tr>
<td>Tolerances</td>
<td>± 5%</td>
<td>± 5%</td>
</tr>
<tr>
<td>MOTION PROFILES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexion Extension (FE)</td>
<td>± 7.5°</td>
<td>+6.0°/-3.0°</td>
</tr>
<tr>
<td>Lateral Bending (LB)</td>
<td>± 6.0°</td>
<td>± 2.0°</td>
</tr>
<tr>
<td>Axial Rotation (AR)</td>
<td>± 4.0°</td>
<td>± 2.0°</td>
</tr>
<tr>
<td>Phase Angles</td>
<td>LB phased by 90° from FE; AR and LB phased by 180°</td>
<td>User decides</td>
</tr>
<tr>
<td>Frequency</td>
<td>1.0±0.1 Hz (Up to 2.0 Hz)</td>
<td>2.0 Hz</td>
</tr>
<tr>
<td>Tolerances</td>
<td>± 0.5° at the peaks</td>
<td>±0.5° at the peaks</td>
</tr>
<tr>
<td>LUBRICATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature</td>
<td>37±2 °C</td>
<td>37 ±3 °C</td>
</tr>
<tr>
<td>Protein Additives</td>
<td>Sodium Azide or Other antibacterial/antimycotic and EDTA</td>
<td>Sodium Azide or Other antibacterial/antimycotic and EDTA</td>
</tr>
<tr>
<td>Protein Concentration</td>
<td>30g/l</td>
<td>20g/l</td>
</tr>
<tr>
<td>Ph Monitoring</td>
<td>Optional</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Fluid Collection</td>
<td>0.5 million cycles</td>
<td>1.0 million cycles</td>
</tr>
</tbody>
</table>

The phase differences which have been listed in the Table 2-2, specifically for the ISO-18192 defines the crossing path/multi-directional motion. There is no mention of crossing path or phase angles in the ASTM F2423-05 standard. Crossing-path motion,
occurs when a specific location on the implant is subjected to motion in different
directions over time and it is a critical factor influencing wear [8]. Metallic alloys, (CoCr)
however, exhibit wear resistance during multidirectional motion and therefore
unidirectional paths could be more realistic for this situation. However it is advisable to
use the ISO standards for polymers, which would account for this phenomenon by
specifying the phase differences between various motions and would thus be closer to an
in-vivo situation. It should also be noted that different simulators have different
combinations of Euler angles and consequently, the final orientation output might be
different from one simulator to another.

In a study by Pare et al. [8], a simple ball and socket configuration was used to
generate slide track wear pattern (which is a function of input kinematics) based on
ASTM and ISO standards. The inferior ball component was fixed while the superior
socket had pins which were used for etching these wear track. For both lumbar and
cervical test conditions, similar curves were observed from different simulators. Under
ASTM conditions, curvilinear wear path was observed while ISO represented a ribbon
shaped pattern on the surface. Also, there was a two fold increase in the sliding distance
for the ISO cervical condition. This was presumably due to an increased ROM, defined
by the cervical standards in comparison to the lumbar.

The authors also reported that the slide tracks were not sensitive to the Euler angle
sequencing, which varied from one simulator to another. It was very encouraging from
the perspective results from different types of simulators were comparable. However,
despite the fact that input conditions given to different simulators can be same, the
reproducibility of the prescribed output kinematics can change based on manufacturing
and design differences. Although the differences between simulators have been reported to be minor, one should tread carefully while comparing results from different simulators [8]. A detailed description of the standard biotribological experimental procedure, different kinds of wear simulators as well as tools and techniques utilized to measure the wear parameters have been described in the Appendix A (Sections A.2-A.5).

2.6.1 Studies on in vitro wear simulation of artificial discs

The importance of biomechanics and other mechanical factors that contribute to the sustainability and performance of spinal implants cannot be underestimated. Stress, strain and failure analyses of these implants are performed in bench-top, animal, cadaveric and numerical studies to justify the efficacy of these devices in vivo. Although there are many artificial discs which are currently available in the market, in addition to those undergoing IDE clinical trials, there is still a dearth of relevant in-vitro studies. The following section deals with such in-vitro test results based on different artificial disc designs.

2.6.1.1 Charité™ lumbar disc

Wear testing of Charité™ lumbar disc was conducted by Serhan et al. [93] based on ASTM F2423 draft standards. Three implants were subjected to a combined lateral bending and rotation, while three others were subjected to flexion/extension and rotation under sinusoidal loads. The frequency for the motion was 1.35 Hz while 2.7 Hz was used during loading. Three components were used as load soak and three others as soak components. Bovine calf serum was used as the test fluid. The load soak sample demonstrated a height loss of 0.07mm while the test samples reported a height loss of
An average polyethylene wear of 0.11 mg per million cycles was noted, followed by a value of 0.13 mg per million cycles, after accounting for fluid absorption. Particulate characterization conducted during this study reported the particulate size, shape and morphology to be similar to that of the hip, knee and shoulder replacements. The volumetric wear range was well below the acceptable threshold of 40mm$^3$.

2.6.1.2 Maverick lumbar disc

In a study by Pare et al. [94] the specimens were tested under a load of 1200N for 10 million cycles in flexion-extension followed by 10 million cycles of combined lateral bending, phased by 90 degrees with axial rotation. Alpha calf serum was used as the testing fluid at a lower protein concentration to ensure a worst case scenario. The cumulative volumetric wear from flexion/extension was $3.4\pm1.0\text{mm}^3$ after 10 million cycles, followed by an additional $4.4\pm0.3\text{mm}^3$ after an additional 10 million cycles of combined motion. Based on this data, it was concluded that the ISO loading parameters produces much more realistic wear patterns in comparison to the ASTM standards. This is primarily because the crossing path motion prescribed by the ISO standards is a predominant phenomenon that has also been observed in-vivo. Curvilinear motion as defined in ASTM standards over predicts metal-on-metal wear rates and under predicts the metal-on-polymer rates. This study also proved that metal-on-metal produces volumetric wear rates lower than that of metal-on-polymers by two orders of magnitude.

2.6.1.3 Bryan cervical disc

Results of in-vitro tests of the Bryan cervical disc was reported in a study by Anderson et al. [95]. The study was conducted prior to the existence of ASTM/ISO
standards for disc arthroplasty. The test samples were immersed in saline solution for 72 hrs prior to the test. At a constant preload of 130 N, 4.9° of flexion/extension was combined with 3.8° of axial rotation at a frequency of 4 Hz. Six test samples were tested for 10 million cycles with three devices as load control samples. Similarly three other samples were tested for 40 million cycles up to failure. The results of this test established a volumetric wear of 9.6 mm$^3$ as well as height loss of 0.75% after 10 million cycles. Particulate analysis demonstrated shapes similar to hip and knee replacements, but were larger and more elliptical in comparison to the former.

### 2.6.1.4 Prestige cervical disc

In a study conducted by Anderson et al. [96] a constant load of 148 N and flexion/extension of 9.7° was used to simulate wear in Prestige discs at a frequency of 2 Hz for a period of ten million cycles. This was followed by 5 million cycles of testing at 49N and 4.7° of bending at the same frequency. Finally 5 million cycles at a load of 49N and 3.8° of rotation was conducted to finish the study. Gravimetric wear of the samples were computed and an average wear rate of 0.18mm$^3$ per million cycles was reported. This study was also conducted prior to the existence of the current ASTM/ISO standards. An important finding of their work was that 0.1 million cycles of in-vitro testing equates to 1 year of clinical usage.

### 2.6.1.5 Activ-L lumbar discs

Grupp et al. [97] investigated the wear pattern in the Activ-L artificial disc. This study was the first of its kind to compare the effects based on ASTM/ISO standards. The samples were tested for up to 10 million cycles according to ISO18192, followed by 5
million cycles of test-run according to ASTM F2423-5. This was again followed by an additional 2 million cycles as per the ISO standard. Gravimetric wear analysis at the end of 0.5 million cycles was performed, followed by particulate analysis. A crucial finding of their work was that the ISO and ASTM simulation results differ by at least a factor of 20 or more. ISO testing led to an oval shaped wear pattern which was replaced by linear patterns in ASTM and eventually by oval traces again. Cross-shear effects due to multi-directional motion are detrimental to the wear resistance of polymeric materials. There was also no significant difference in the shape and size of the particulates that were generated during the ASTM/ISO standards. This study was a unique contribution towards understanding the effect of multi-directional motion on wear.

2.6.1.6 Prodisc-L disc

In an interesting work by Kettler et al. [98] seven presoaked implants were tested according to ISO-18192 for four million cycles at a frequency of 1 Hz, followed by a 2 Hz simulation for eight million cycles. This study was conducted primarily to understand the effect of loading frequency on the wear outcome of the devices. Gravimetric mass loss as well as height loss of the devices was recorded after twelve days of testing. These tests are time consuming and labor intensive and at a testing frequency of 1 Hz, almost 4 months are needed for completion. As a result, researchers often tend to use a frequency of 2 Hz in order to save time. Moreover, the testing standards of both ASTM and ISO prescribe a maximum frequency of 2 Hz for these tests.

Results of the test exhibited a higher wear rate at the beginning than at the end. Additionally, a frequency of 2 Hz led to an increased wear rate. This study also proved
that a test conducted at a frequency of 1 Hz is more representative of a physiological wear scenario. In another study, Vicars et al.[99] elucidated the effects of anterior-posterior (A-P) shear loads on the wear outcome of Prodisc-L. This meant employing a 5 degree of freedom (DOF) test procedure in comparison to the 4 DOF as prescribed in the ASTM/ISO standards. Addition of the anterior-posterior shear load, however did not affect the overall wear characteristics but there was a noticeable difference in the wear scar/pattern. In an interesting study by Lee et al.[100] the effect of carbon content, clearance and keels and notches were determined for an experimental metal-on-metal lumbar disc. Increase in carbon content, removal of keels and decreased clearance led to decrease in wear rate from 12.4 to 7.6 mm$^3$/million cycles. Impingement phenomenon was also observed at 1.5 million cycles. This study proved that design variables have a significant influence on the wear outcome.

2.6.2 Retrievals and explant based studies on artificial discs

Different research groups have tried to understand the wear characteristics of specific devices through in vitro simulations. These tests are primarily used to compare the performance of one disc design with another. They did not however, replicate the performance in an in-vivo setting. Without validation against retrievals or explants, it is extremely difficult to decide which load testing criteria would lead to a physiologically relevant wear pattern. Retrieval analysis is a method of understanding the in-situ device performance by examination of the removed or retrieved devices.

These devices are usually removed either due to mechanical failure of the device or during revision surgery because of painful dysfunction. Retrieval analysis enables
understanding of the host tissue response. These results can then be compared to the pre-clinical biocompatibility tests that may have been performed prior to implantation. Similar devices explanted from different countries might also give an insight into the effect of different surgeons (surgical procedure) as well as the usage of the device.

Retrievals are just another step in the iterative design process of any device and aid in improved design concepts [101].

Information that is obtained during retrieval analysis is listed as follows:

1) Examination of removed implants to understand the wear mechanism and also to compute the amount of wear.

2) Histological examination of the surrounding tissue as well as remote tissue sites, in order to understand the size, amount and distribution of particles.

3) Joint fluid analysis for wear debris

### 2.6.2.1 Retrieval of cervical discs

Two Prestige cervical discs were explanted, at 18 and 38 months due to infection and adjacent segment degeneration respectively [101]. Though no osteoclastic response was observed, the tissues showed presence of metallic wear debris. Signs of corrosion were also seen at the screw heads. The wear pattern observed was similar to the simulator studies but lesser in magnitude. The amount of wear that was predicted by simulator studies for a period of 6 months (if cycles were converted into daily usage) was greater than the device retrieved after a period of 39 months. However such comparison based on time frame should be avoided because it is difficult to predict daily spinal motions.
Moreover, as activities are variable from one patient to another, it is highly likely that these explants came from patients who have a sedentary life-style.

Eleven explants of Bryan cervical disc were examined by Anderson et al.[101]. No signs of wear, oxidation or degradation were observed in the polymeric nucleus. The device was within the dimensional range and therefore, no significant height loss was observed. No metallic debris was found but polymeric wear debris was observed in the adjacent tissue with signs of chronic inflammation. The osseointegration rate at the bone-device interface was found to be around 32% which was more than that observed in hip and knee devices.

In another study for the same device, 17 explants of Bryan discs were analyzed for wear and height loss of the polymeric wear. Though there was evidence of localized abrasive /adhesive wear, the height loss was attributed to the creep phenomenon rather than wear [102]. It should however be noted that although *in vitro* simulations reflect a linear wear rate, for an *in-vivo* setting, it may be different. Due to short term explants, it can also be said that the device may not be in the body for a sufficient time to react with the surrounding tissues.

### 2.6.2.2 Retrieval of lumbar discs

Among all lumbar discs Charité™ is probably one of the most extensively studied explanted devices; this is mainly due to the fact that it was one of the first artificial discs implanted into the human body and it has been in use since the 1980s. In a noteworthy study by Ooij *et al.* [19] evidence of polymeric wear debris was found after 6.5 -12.9 yrs of device usage. The primary reason for complication in these cases was due to improper
device sizing and positioning. Scratches and burnishing were observed at both dome surfaces of the polymer, in one case however one-sided wear was observed. Fatigue, damage and cracks were observed at the polymeric rim which was assumed to be a result of chronic rim impingement. One of the four retrievals had a completely fractured rim resulting in metallic endplate impingement. In a recent study by Kurtz et al. [103] fifteen out of 35 retrievals showed evidence of one-sided wear.

Chronic rim impingement as well as core entrapment was observed in majority of the test cases. Radial crack formation was observed due to impingement, which eventually led to rim fracture and failure in these devices. Oxidation degradation due to gamma sterilization was also thought to be one of the causes of failure. Endplate penetration had a direct correlation with the implantation time. Fractured radiographic wire markers in two of the cases led to third body wear or embedded particulates. This study concluded that clinical factors, material factors as well as design factors interplay together and lead to failure in these devices.

In a short term (2.2 years) retrieval study of 5 cases of Prodisc-L dome burnishing, scratching and chronic impingement were observed [20]. In a recent study by Choma et al. [15] evidence of anterior rim impingement as well as burnishing of the core was observed for a single retrieval case. This was caused by posterior malpositioning of the implant. Some evidence of polymeric particulates as well as early cell degeneration was also observed in the surrounding tissues. These studies demonstrate that in-vivo performance of polymers in cases of total disc arthroplasty is still not understood completely.
A metal-on-metal, ball on trough lumbar disc was explanted from a 43 yr old female patient after a year of implantation due to metal allergy. Analysis of this implant showed evidence of micro abrasion, scratching, and focal micro- plasticity on both the surfaces. Oxygen rich bio-films or coatings observed on the surfaces of this device were comparable to the one observed in hip implants[101]. Better in-vitro wear performance doesn’t necessarily mean superior in-vivo performance and thus simulations should be correlated to the explants analysis[18].

2.6.3 Previous studies on computational modeling based studies on wear of artificial discs

In vitro laboratory simulation has emerged as a powerful tool for predicting wear of orthopedic devices. Despite standardized testing procedures, which claim to replicate the worst case scenario, we still fail to emulate situations of clinical failure. Additionally, these experiments are time consuming, expensive and labor intensive procedures. Data variability among different laboratories and between multiple stations in a simulator cannot be ruled out. In spite of the fact that experimental data is indispensable, alternatives need to be explored. Numerical simulations based on the Archard’s [21] wear formulation have emerged as a wear predictive tool for finite element modeling.

Maxian and Brown et al. [104-106] were the pioneers in this discipline and implemented the classical law of wear (Archard’s equation[21]) to simulate wear in THA (Total hip arthroplasty) using the finite element method. A three dimensional, nonlinear finite element model was created. Using a validated model, the loads and the boundary conditions were determined and applied to the model. The contact stresses and the sliding
distance output was then used to model wear using a custom script. The wear coefficient was derived from a pin-on-disk experiment.

Both linear and volumetric wear were computed and compared to the existing literature. Parametric studies were conducted on three different head sizes and it was reported that although the linear wear remained same, the volumetric wear increased by 42% as the femoral head size increased by 45%. This was one of the first studies of its kind in the field of computer simulation of biotribology and thus paved the path for future researchers.

Along similar lines a probabilistic model was developed by Pal et al. [11, 107] to understand the effect of variability in alignment, constraint and such other conditions on the wear of the polymeric insert in total knee arthroplasty (TKA). An explicit finite element model was created and the loading conditions of the simulator were used. A soft tissue constraint in the simulator was recreated in the model using a set of spring elements. Archard’s [21] wear law was again used to simulate the linear wear depth for the meshed surface which was summed up over the gait cycle. A probabilistic model was further created and linked with the previous wear model. Thirteen experimental variables were introduced, Monte-Carlo and AMV methods were together used for probabilistic simulations. The simulations were in agreement with the literature reported gravimetric wear. Based on the probabilistic model, “insert alignment/tilt” was found to be the most important parameter during the wear simulation. This study however, did not include creep/plastic properties of the polymer which might have an important bearing on the wear data corresponding to the knee implants.
Based on the ideas derived from hip and knee wear simulations researchers went on to simulate wear in total disc arthroplasty (TDA). The first study to deal with polymeric wear of artificial discs was by Rawlinson et al. [108]. A finite element (FE) model of Prodisc was created, based on Archard's wear law [21] and an adaptive meshing technique was utilized to simulate wear in the polymeric core of the implant. Adaptive meshing captures the changes at the articulating surface as the surface wears and deforms. The FE analysis was conducted based on the existing wear standards and was later compared to experimental simulations. Thus, the computational model was validated against the experimental results. The wear coefficient derived from the experiment was used to calibrate this model. Effect of single peak versus double peak loading on the wear rate was analyzed. The wear rate increased to 11.7 mg per million from 9.82mg per million when double peak loading was used. Parametric studies based on design variables were also performed, however they had minimal effects on the wear.

Cross-shear effects, which have been discussed in the previous section, have been a topic of concern among researchers for quite some time. Goreham-Voss C.M et al. [109] implemented cross–shear in a computational model involving an adaptive remeshing technique. Changes in primary molecular direction and cross-shearing during the wear phenomenon was taken into consideration and executed in their model. The same group had previously demonstrated a relationship of wear factor/coefficient with the cross shear in the form of a power law. Thus the existing Archard's law [21] was modified such that the wear coefficient (k) became a function of the cross shear. The computational model was validated against experiments and an error percentage of 22 was computed. The total volumetric wear reported for low cross shear was 40% lower than the high cross shear
simulation. For unidirectional motion (without cross shear) the volumetric wear rate was 60% lower than high cross shear. Though it was unique, the study did not consider the proportion of polymeric chains that were aligned, the speed of occurrence of principal molecular orientation (PMO) or their existence under changing articulation. However this study was successful in demonstrating the differences in wear rate due to unidirectional or multi-directional articulations.

Along similar lines the same group [110] pursued finite element modeling of wear in the Charité™ device. It was reported by Kurtz et al.[103] during a retrieval study that preferential wearing of the superior-bearing surface is a common phenomenon. Theoretically the device was designed such that the COR is not constrained. However, replicating this behavior during in-vitro tests is difficult.

Parametric finite element modeling was performed by them using adaptive remeshing technique as described previously. Regardless of all the permutations that were done to constrain the COR, wear still occurred at the superior bearing surface. One sided wear existed even if the wear coefficient of the lower surface was increased. In order to predict long term wear it is thus essential to understand the in-vivo functioning of the device.

All these studies were implemented to understand the wear behavior of lumbar disc implants. There has been limited work reported in the field of cervical discs. However, in a recent paper by De Jongh et al. [82] a series of simulations were performed in understanding the wear behavior of a polymeric core. The boundary conditions at C5-C6 level were extracted from dynamic simulation software and were used as an input for finite element analysis. The slip velocities and contact stresses were then extracted to
compute the wear at the interface. Circumferential wear distribution at the polymeric core was reported by this study.

Additionally comprehensive theoretical models of wear laws for orthopedic implants have been presented by numerous authors one of them being Goswami et al. [111]. They derived a general wear equation in terms of implant dimension, body weight, femoral roughness, femoral diameter and mechanical properties of the polymer. However the equation was not validated because of limited data points existing in the literature [111].

These simulations are not intended to bypass experiments; but rather, they are powerful tools to reduce design-related costs and time. These simulations complement experimental findings. Permutations or sensitivity analysis can be expensive during experiments, which is why computational modeling can serve as an effective tool.

2.6.4 Comparison of in vitro simulations and retrieval analysis

Standardized testing procedures claim to replicate the worst case scenario; however successful in vitro tests do not always translate to better physiologic performance. Retrieval analysis often reflect failure modes which are not observed during bench top simulations and thus points us towards the deficiencies associated with these tests.

For instance in vitro results for Charité™ for 10 million cycles reported a low wear rate demonstrating the insignificance of wear debris for lumbar discs. Minor scratches as well as burnishing marks were observed as depicted in Figure 2-16 (A)[83].
On the contrary retrieved Charité™ implants at 6.5 yrs, 12.7 yrs and 16.1 yrs as seen in Figure 2-15 (B), (C) and (D) not only reflected severe wear and damage but also impingement due to subsidence, subluxation and migration of the endplates [20, 84].

Figure 2-15 Comparison of in vitro (at the end of 10 million cycles of test run) and in vivo wear patterns in Charité™ device that has been retrieved at an interval of 6.5 yrs, 12.7 yrs and 16.1 yrs from different patients [20, 84].

Preferential wear of the superior polymeric surface that was observed during retrievals were simulated by Goreham-Voss C.M et al. [110] using parametric finite element modeling. Thus wear patterns observed during retrievals which were not replicated during in vitro tests could be simulated using FE modeling methods.

Similarly satisfactory clinical results were observed for Prodisc-L implants for approximately 90% of test cases. In 9% of patient population, complications such as vertebral body fracture, transient radicular pain and implant malpositioning were reported [112]. Interestingly in either of these test cases mechanical failure of the implants or loosening was not observed.

Nevertheless in a recent study dome burnishing and rim impingement was reported for Prodisc-L after a short term retrieval by Choma et al. [15] which was attributed to the malpositioning of the implant.
Figure 2-16 Incidence of burnishing and plastic deformation of the polymeric core after the retrieval for Prodisc-L (Adapted with permission from the publisher) [15]

FE based wear study conducted by Rawlinson et al. [108] depicted a uniformly distributed wear pattern as per ISO 18192 which was not observed during the retrieval analysis [Figure 2-18]. This study was validated against experimental wear simulation of Prodisc-L implant.

Figure 2-17 Linear wear contour predicted for Prodisc-L using finite element modeling technique [108] (Adapted with permission from the publisher)
In vitro simulations were also unable to predict adverse tissue reaction in the Acroflex implant. Incidence of surface fatigue and generation of particulate debris was observed in a clinical scenario [Figure 2-18]. Initial short term clinical outcome for this device was rated as a success but long term follow-up after a period of nineteen years revealed substantial osteolysis and catastrophic failure of the device. Radiographs confirmed the loss of the elastomeric component, with the metallic end plates touching one another.

Figure 2-18 Retrieved Acroflex device showing surface fatigue and material degradation [20] (Adapted with permission from the publisher)

All these studies emphasize the importance of simulating in vivo conditions (physiologic loading and motion) rather than worst case test scenarios as described in the current test standards. This study points towards the complexity of the wear debris generation in spine and underscores the deficiencies in the current testing procedures. There is still a paucity of long term retrievals which makes it more difficult to predict the clinical failure modes. Thus, these factors lay the foundation for the current work. So keeping in mind the current scenario, the aim of this dissertation is to simulate wear contours similar to physiological test cases so as to bridge the gap between the in vitro simulations and the findings from the retrievals. The subsequent chapter deals with the approaches and methods that have been utilized in predicting in vivo wear using FE modeling techniques.
CHAPTER 3

Materials and Methods

3.1 Introduction

Numerical simulations based on the Archard’s wear formulation have emerged as a wear predictive tool for finite element modeling. This law has been used by numerous authors for total hip, total knee and total disc arthroplasty implants for the last decade [10, 11, 104-110]. However in the area of spine, for example, these current studies have simply duplicated the experimental protocols involving models of the disc alone; and used boundary conditions of a wear simulator (bench top testing) as per ASTM/ISO standards. Thus, in order to address the effects of the factors other than the loading/motion profiles on wear, one would require a predictive wear model that has the potential to simulate \textit{in-vivo} parameters.

Increased computational speed has led to the development of complex FE packages. At present, commercially available packages are capable of handling complex geometries and non-linearities with respect to geometry and materials. These capabilities are necessary in order to model physiological structures such as the cervical spine, thereby allowing for more accurate modeling of the spine with fewer modeling assumptions.
In this chapter we will present such an approach towards replicating *in-vivo* wear patterns and thus bridging the gaps present in the current literature. The current study design is represented by the following flowchart.

![Flowchart](image)

**Figure 3-1** Detailed flow chart of the study design depicting the steps and the aims of the current project
3.2 FE Modeling Approach

The cervical spine FE model used for this study consists of C5-C6 functional spinal unit derived from a previously developed and validated C2-T1 spine model in our lab[113]. The geometric data for the spinal segments were obtained from 1 mm thick computed tomographic (CT) scans of the C2-T1 segments. The cross-sectional shapes of the bony geometry depicted in the transverse slices were divided into finite regions by creating a mesh structure. The mesh structure was then digitized for nodal output and the sections were stacked serially to generate a three-dimensional (3-D) model of the C5-C6 segment as illustrated in Figure 3-2.

![Figure 3-2 The finite element model of C3-C7 cervical spine. This model contains all the relevant ligaments, facet joints, intervertebral discs, Lushka's joints and bony regions. Material properties were assigned to various structure based on available literature[113](Image)](image)

Various spinal structures within the segment were appropriately simulated to mimic their functional characteristics. The vertebral bodies were defined as cancellous bone cores surrounded by 0.5 mm thick cortical shells. The posterior region was assigned
attributes which lay between those of the cortical and cancellous regions. Three-dimensional, isoparametric solid elements (C3D8) were used to define the osseous geometry. The facet joints were modeled using surface definitions, where surface gaps between each facet region were assumed to be 0.5 mm, based on prior CT imaging. A ‘‘softened contact’’ parameter available in the ABAQUS™ software (Dassault Systems, Providence RI) was assigned to the interface. This allowed an exponentially increasing modulus as the gap distance between the inferior and superior facet closed, emulating the presence of cartilage in the facet region. The facets were oriented at approximately 45° from the horizontal plane, with some variation in the sagittal plane alignment.

The annulus fibrosis was modeled as a composite structure wherein a series of fibers simulating the lamellae of the disc were embedded in a ground substance surrounding a more gelatinous nucleus region. Every layer of the ground substance contained two alternating layers of fibers arranged at ±65° from the transverse plane with an average fiber content of 20% of the annular volume. The fibers were modeled utilizing the ‘‘rebar’’ option available in ABAQUS. A ‘‘no compression’’ parameter was enforced, which allowed the fiber elements to be activated during the tension mode only. The ground substance of the annulus was modeled using three-dimensional, 8-nodal ‘‘brick’’ elements (C3D8). The nucleus pulposus was modeled as an incompressible fluid using a fluid element definition available in ABAQUS™.

Luschka’s joints were modeled in the cervical discs as well. These were simulated around the area of the uncinate processes by creating a space between the horizontal annulus layers and placing gap elements in the resulting fissures. The elements adjacent
to the fissures were reinforced with fibers which were aligned approximately parallel to
the fissure to adequately model Luschka’s joints.

The ligaments of the lower cervical spine included the anterior longitudinal ligament
(ALL), posterior longitudinal, ligament (PLL), interspinous ligament (ISL), ligamentum
flavum (LF) and the capsular ligaments (CAP). The ligaments were modeled using three-
dimensional truss elements (T3D2). These elastic elements were allowed to behave
nonlinearly via a ‘‘hypoelastic’’ option. This option also allowed a ‘‘neutral zone’’ to be
incorporated, in which the ligament provided little stability under minimally applied
external loads. In order to completely characterize the ligament behavior, they were
modeled such that they were initially unstressed. This condition was deemed necessary
as any pre-stress in the natural ligaments is directly influenced by the geometry of the
individual spine. As a result, there exists tremendous variability among specimens and
precise, indicative values are difficult to determine. The cross-sectional and material
properties for the ligaments were taken from the literature and a previous model of a
cervical spine functional unit generated by Clausen et al.[114].

The cross-sectional areas of the ALL and PLL were specified in such a way that they
tapered from the middle of the ligament to the edges to avoid an abrupt ending to the
ligament. Validation of the intact C3-C7 model was performed by comparing model
predictions to cadaveric load-displacement data. Load cases used for validation included
0.5, 1.0, or 1.5 Nm moments in flexion/extension, lateral bending and axial rotation and a
combined load of 73.6 N plus a 1.8 Nm flexion/extension, lateral bending, or axial
rotation moment. These loads correspond to loads applied in vitro by Onan et al., Grauer
et al., Clausen et al., and Moroney et al.[114, 115] Material properties used in defining
the various entities in the C3-C7 model are summarized in Table 3.1. These were chosen from data published in the literature[113]

Table 3.1 C3-C7 FE model material and geometric property characteristics[113]

<table>
<thead>
<tr>
<th>Element Group Name</th>
<th>Number of Elements</th>
<th>Element Type</th>
<th>Young’s Modulus (MPa)</th>
<th>Poisson Ratio</th>
<th>Cross Sectional Area (mm2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical Bone</td>
<td>1440</td>
<td>C3D8</td>
<td>10,000</td>
<td>0.3</td>
<td>-</td>
</tr>
<tr>
<td>Cancellous Bone</td>
<td>6480</td>
<td>C3D8</td>
<td>450</td>
<td>0.25</td>
<td>-</td>
</tr>
<tr>
<td>Posterior Bone</td>
<td>4364</td>
<td>C3D8</td>
<td>3500</td>
<td>0.25</td>
<td>-</td>
</tr>
<tr>
<td>Annulus Ground Substance</td>
<td>3744</td>
<td>C3D8</td>
<td>4.2</td>
<td>0.25</td>
<td>-</td>
</tr>
<tr>
<td>Annulus Fibers</td>
<td>-</td>
<td>REBAR</td>
<td>-</td>
<td>0.45</td>
<td>-</td>
</tr>
<tr>
<td>Nucleus Pulposus</td>
<td>1920</td>
<td>F3D4</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Facet Joints</td>
<td>-</td>
<td>SURFACE</td>
<td>Softened-3500</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ligaments</td>
<td>1326</td>
<td>T3D2</td>
<td>NA</td>
<td>NA</td>
<td>-</td>
</tr>
<tr>
<td>Anterior Longitudinal Ligament (ALL)</td>
<td>672</td>
<td>T3D2</td>
<td>15 (&lt;12%); 30 (&gt;12%)</td>
<td>0.3</td>
<td>33</td>
</tr>
<tr>
<td>Posterior Longitudinal Ligament (PLL)</td>
<td>480</td>
<td>T3D2</td>
<td>10 (&lt;12%); 20 (&gt;12%)</td>
<td>0.3</td>
<td>33</td>
</tr>
<tr>
<td>Ligamentum Flavum (LF)</td>
<td>20</td>
<td>T3D2</td>
<td>7 (&lt;12%); 30 (&gt;12%)</td>
<td>0.3</td>
<td>50.1</td>
</tr>
<tr>
<td>Interspinous Ligament (ISL)</td>
<td>16</td>
<td>T3D2</td>
<td>5 (&lt;25%); 10 (&gt;25%)</td>
<td>0.3</td>
<td>13</td>
</tr>
<tr>
<td>Capsular Ligament (CAP)</td>
<td>138</td>
<td>T3D2</td>
<td>15 (20-40%); 30 (&gt;40%)</td>
<td>0.3</td>
<td>46.6</td>
</tr>
</tbody>
</table>
3.3 FE modeling of Wear in Prodisc-C

3.3.1 Implanted model formulation (Disc+FSU model) for Prodisc-C

The experimentally validated ligamentous intact C5-C6 FE model was modified to accommodate an artificial disc similar to Prodisc-C. The best fitting sized artificial disc at C5-C6 was chosen for this purpose. The artificial disc was placed symmetrically in the disc space.

The artificial disc was placed following removal of the anterior longitudinal ligament (ALL), anterior annulus, entire nucleus, portions of the posterior annulus and the PLL at the C5-C6 region. All of the other structures including Uncinate Processes and Luschka's Joints were preserved. The artificial disc comprised a constrained polymeric (Young's modulus = 1400 MPa, Poisson's ratio= 0.46) insert (CORE), fixed onto cobalt chrome (Young's modulus = 220 GPa, Poisson's ratio= 0.32) endplates. The diagram of the implanted FE model is depicted in Figure 3-3.

Figure 3-3 C5-C6 finite element model with artificial disc implant (Prodisc-C) placed at C5-C6 level
The polymeric core was fixed using a TIE command. This option is used to impose tie constraints between fixed surface pairings. The vertebral endplates were modified in order to match the contours of the device endplates. This was achieved by modifying the coordinates of the bony endplate's nodes to match the contours of the disc implant to be placed.

The polymeric core was meshed using 30818 hexagonal elements (C3D8) while the superior and inferior endplates comprised of tetrahedral (C3D4) elements. The superior and inferior surfaces of the artificial discs were tied to the respective device endplates using the ABAQUS TIE command. The polymeric core was also fixed to the lower endplate using the TIE command. The sliding interactions between the polymeric core and the adjoining superior endplate were simulated as a hard contact (pressure-overclosure relationship without physical softening) sliding interaction with a coefficient of friction of 0.05 at the interface. In one of our previous studies, the implanted ligamentous model's predicted kinematics under various loading scenarios was in agreement with the *in-vitro* data [116].

The human cervical spine is subjected to compressive loads[117]. Previous studies have proved that the osteoligamentous cervical spine, without any musculature, supports large physiologic compressive loads if the load is applied along the curvature of the spine [118]. A set of connector elements along the curvature of the spine were used for load propagation through the instantaneous center of rotation of the segment, as described in the next paragraph. Thus, we simulated the axial compression as a follower load, a concept proposed by Patwardhan *et al.*, [118] and that is now well accepted by the research community.
The C6 vertebra was completely constrained in all 3 degrees-of-freedom: at the inferior endplate, inferior facets and inferior portion of the spinous process. Initially, a varying compressive-follower load of 50-150 N (ISO 18192)[91] representing the weight of the head was applied using a set of connector elements passing through the flexion-extension center of rotation of the motion segment. In the next step, flexion/extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6° and axial rotation (AR) of ±4° via time-dependent amplitudes within a single loading step were applied at a point on the superior surface of the C5 vertebra at 1Hz with the specified phase difference as per ISO 18192[91] as shown in Figure 3-4.

Figure 3-4 Preload of 50-150 N, flexion/extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, and axial rotation (AR) of ±4°, with the specified phase difference as per ISO 18192[91]
3.3.2 Disc only model formulation (Disc Model - Standalone simulation)

The same artificial disc as described above was used in the model. The polymeric core was fixed to the lower endplate using the TIE command. The sliding interactions between the polymeric core and the superior endplate were simulated as "hard contact" sliding interaction with coefficient of friction of 0.05 at the interface. The superior endplate was unconstrained and could freely articulate on the polymeric surface. The preload was applied through a coupled point on the superior surface of the superior endplate. The inferior side of the inferior endplate was fixed in all directions [Figure 3-5]. The loading profile was the same as that for the Disc+FSU model. However, the time dependant amplitudes in this case were applied to the center of rotation of the implant in accordance with the literature [109].

![Figure 3-5 Finite element model of a ball on socket, metal on polymer implant (similar to Prodisc-C) Comprise of two metallic endplates, and a constrained polymeric core component](image)
3.4 Wear Simulation based on Archard’s law

Any articulating components, if placed under a compressive load, will generate debris. The wear rate can be predicted using the classical formulations of Archard’s law [108, 119, 120].

\[ V = K F x \]

where \( V \) is volumetric wear, \( K \) is a material constant or the wear coefficient of the material-couple, \( F \) the contact force, and \( x \) the relative sliding distance. The parameter \( x \) is computed in the model as relative to the tangential motion of the nodes at the contact interface, CSLIP. Its maximum value is calculated from its components CSLIP1 and CSLIP2 as follows:

\[ CSLIP = x = \left( (CSLIP1)^2 + (CSLIP2)^2 \right)^{1/2} \]

Archard’s law formulation

Numerical simulations based on the Archard’s wear formulation have emerged as a wear predictive tool for finite element modeling.

It is imperative to know the basics of this classical wear law formulation.

If two bodies are sliding under an applied load, \( L \) the relationship between the real area of contact, \( A \) and the flow pressure of the softer metal, can be written as

\[ L = pA \]

…………………………………………………………………………………………………. (1)

If the junctions at the interface are circular and are uniform in size, then

\[ A = \pi d^2/4 \] where \( n \)=number of junctions
Therefore \( n = \frac{4A}{\pi d^2} = \frac{4L}{\pi pd^2} \) ………………………………………………………………………(2)

Each junction remains in existence during a sliding distance of \( d \), after which a new junction takes over. Thus, the total number of junctions (\( N \)) formed in a sliding distance of \( x \) is written as

\[
N = \frac{nx}{d} = \frac{4Lx}{\pi pd^3}
\] ………………………………………………………………………(3)

The probability that a junction leads to formation of a transferred fragment is equated to \( k \) and it is assumed that the fragment formed is a hemisphere of diameter \( d \). The Volume \( V \) of wear per distance \( x \) of sliding distance is given by

\[
V = kN\pi d^3/12 = kLx/3p
\] ………………………………………………………………………(4)

This is the fundamental wear law, where \( k \) is a dimensionless wear coefficient. \( k/3 \) can be replaced by \( K \), as the factor of 3 is a shape factor and appears because of the assumption that circular junctions and hemispherical fragments are formed.

Thus \( V = KLx/p \) ………………………………………………………………………(5)

Based on this law, an ABAQUS supported subroutine UMESHMOTION was written in FORTRAN and the ALE technique of adaptive remeshing was utilized.

The arbitrary Lagrangian-Eulerian (ALE) adaptive meshing is a technique in ABAQUS which merges the features of pure Lagrangian analysis and pure Eulerian analysis.
ALE adaptive meshing is a tool that makes it possible to maintain a high-quality mesh throughout an analysis, despite large deformation or loss of material, by allowing the mesh to move independently of the material.

ALE adaptive meshing, however, does not incorporate changes in the topology (elements and connectivity) of the mesh. Adaptive meshing in ABAQUS is intended for use in acoustic domains and for modeling the effects of ablation or wear of materials. Adaptive meshing can be applied to an entire model or to individual parts of a model during FE simulation. A Lagrangian adaptive mesh domain will be created, so that the domain as a whole will follow the material originally inside it.

Notable features of ALE adaptive meshing are as follows:

- It can maintain a high-quality mesh under severe material deformation by allowing the mesh to move independently of the underlying material.
- It maintains a topologically similar mesh throughout the analysis (i.e., elements are not created or destroyed).
- It can be used in geometrically nonlinear static, steady-state transport, coupled pore fluid flow and stress and coupled temperature-displacement procedures.

For preliminary understanding of the adaptive meshing technique, a simplistic block-on-block model with friction being simulated at the interface of these two blocks was created [Figure 3-6 (a) and (b)]. A simple wear code was written to move the mesh in the normal direction by half of its mesh height as seen in Figure 3-6 (c). Formulation of the actual wear code was then pursued details of which are given in Appendix B.1.
Figure 3-6 (A) Simple block-on-block meshed FE model to understand the mesh movement using adaptation (B) Stress concentration at the block interface (C) Mesh movement in the lower block based on a simple wear code

The adaptive meshing using the ABAQUS code at surface nodes was done in two steps. First, the nodes were swept in the local normal direction by an amount equal to the corresponding local wear increment [119-122]. Thus, the geometry was updated followed by the next step which involved remapping the material quantities to their new positions by advecting the material quantities from the old location to the new location. The flow chart in Figure 3-7 clearly depicts the steps incorporated in the wear code.
In the actual problem, the adaptive mesh constraint node set was defined at the articulating surface of the device. A hard contact interaction (available in the software) was defined at the articulating surface; the polymeric surface was assigned as the SLAVE surface while the superior titanium component was assigned as the MASTER surface (Master-Slave interaction is a mode available in the software).
Analytically rigid surfaces are always assigned the MASTER role during interaction/tie assignments. If the contact pair involves two rigid surfaces, the assignment of MASTER and SLAVE roles is arbitrary. If contact pairs involve two deformable surfaces, then the MASTER role is assigned to the surface with the coarser mesh. If no mesh information available, the surface with the larger area becomes the master surface.

The wear was computed for the polymeric core and the values of CSLIP (contact slip variable available in ABAQUS) as well as CPRESS (contact pressure variable available in ABAQUS) were obtained from the polymeric surface. It should be noted that CSLIP (contact slip) can only be obtained from a slave surface. Thus if we need to model wear on an articulating surface, that surface needs to be assigned as the SLAVE surface with respect to the other component in order to extract the values of CSLIP.

Adaptive meshing can only work with certain element types. C3D4 elements are not supported by ABAQUS for adaptive meshing. It becomes imperative to model the wearing surface as C3D8 elements. Additionally, non-linear geometries should be used during the adaptive meshing technique. HOUR GLASS stiffness needs to be defined for the adaptive mesh elements. During Adaptation, the adaptive mesh element set, the adaptive mesh CONTROLS and the adaptive mesh CONSTRAINTS are defined.

The Adaptive mesh CONTROLS option is used to control various aspects of the adaptive meshing and advection algorithms applied to an adaptive mesh domain. The Adaptive mesh CONSTRAINTS on the other hand, are utilized to prescribe independent mesh motion for nodes in an adaptive mesh domain or to define nodes that must follow the material. In this case, a user defined mesh motion is defined, which is formulated as a user defined code in FORTRAN called UMESHMOTION.
The subroutine UMESHMOTION shifts the surface nodes in the local normal direction by an amount equal to the corresponding local wear, which itself is a function of slip/sliding distance and the contact stresses, according to the Archard’s law [120, 123]. The mesh is updated at the end of each step, based on the wear depth. The purpose of UMESHMOTION is as follows

- It can be used to define the motion of nodes in an adaptive mesh constraint node set
- It can call utility routines such as GETVRN and GETVRMAVGATNODE in order to access the results at the node points
- Using GETVRMAVGATNODE, the contact stresses (CPRESS) as well as the contact slip (CSLIP) can be extracted
- These parameters are used together in the Archard's law equation
  \[ \text{Wear (h)} = k \times \text{CSLIP} \times \text{CPRESS} \]
  and thus the wear at each nodal point is computed.

Another subroutine UFIELD (details of which are given in Appendix B.2) was written to display the wear contour based on the linear accumulative wear depth (h) of the model, which was calculated at each increment.

The purpose of using the UFIELD is as follows

- It allows us to prescribe predefined field variables at the nodes of a model that can be updated individually
- It is called whenever a user-subroutine-defined field appears
- It ignores any field variable values specified directly
• It can be used to modify field variable values read from a results file

Like previous published work [11, 108, 124] adaptive meshing was utilized to compute the wear depth on the surface of the polymeric core. The wear depth in subsequent steps was scaled by a factor of 250,000. This scaling factor was derived from a prior convergence study undertaken by us. The wear coefficient was $19.84 \times 10^{-10}$ mm$^3$/N mm derived from the work of Rawlinson et al. [108]. Thus, one million cycle of wear was divided into 4 steps, with scaling of 250,000 times occurring at each step. Each model was run for 10 million cycles, which equated to 40 adaptive meshing steps during the analysis. The linear wear depth was computed as the average wear depth for the entire adaptive mesh elements. The total cumulative wear depth at the end of each million cycles was divided by the number of adaptive mesh nodes.

### 3.5 FE Simulation of Wear in Prestige Device

The detailed description of the device is given in Chapter 2. The artificial disc comprised of a metallic ball and trough design (Young’s modulus= 220 GPa and Poisson’s ratio= 0.32). The ball component is the superior part while the trough is the inferior component. The disc design was simplified by removing the screw fixation units at both the components. The implant was imported into the ABAQUS viewport. To simulate the surgery at the implanted level, both ALL and PLL at the C5-C6 level were removed. Partial annulotomy was then followed by complete discectomy at the C5-C6 level. Translation and rotation commands were used to place the device at the disc space in a symmetric fashion [Figure 3-8]. The endplates were modified accordingly to accommodate the device. This was achieved by modifying the coordinates of the bony endplate’s nodes to match the contours of the disc implant to be placed.
The inferior endplate (trough) was meshed using 4076 hexagonal elements (C3D8) while the superior endplates comprised of 4770 hexagonal (C3D8) elements [Figure 3-9]. The two metallic components were fixed to their respective vertebral endplates using the “TIE” command. The sliding interactions between the inferior and superior endplates were simulated as “hard contact” sliding interactions with a coefficient of friction of 0.2 at the interface. Wear at the lower/inferior trough component was simulated using Archard’s wear law[21].
Figure 3-9 FE model of metal-on-metal, ball and trough implant, depicting the inferior trough and a superior ball component

The wear coefficient was $1.01 \times 10^{-11}$ $\text{mm}^3/\text{N mm}$ derived from a published article [94]. One million cycles of wear were divided into 4 steps, with scaling of 250,000 times occurring at each step. Each model was run for 10 million cycles which equals 40 adaptive meshing steps during the analysis.

The results of the simulation of Disc versus Disc+FSU were compared for both the devices. The von Mises stresses were computed for each case at the end of each million cycles. The linear wear was directly computed from the code and was recorded for each million cycles using UFIELD and UMESHMOTION. The linear wear depth was
computed as the average wear depth for the entire adaptive mesh elements. The total cumulative wear depth at the end of each million cycles was divided by the number of adaptive mesh nodes.

The VOLC command was used to compute the change in volume of the adaptive set and yielded the volumetric wear rate at the end of each step. VOLC is an ABAQUS history variable which is differentiated with respect to time to give the volumetric wear rates at various time increments.

After the simulation of Disc versus Disc+FSU for both Prodisc-C and Prestige, sensitivity analysis was performed to delineate the effect of surgical parameters, loading conditions as well as the role of the soft tissue elements on wear. The parametric study was based on study design delineated in the first chapter.

3.6 Parametric Analysis

3.6.1 Effect of surgical factors

The effect of the surgical procedure is another important aspect related to wear of devices that has not yet been analyzed. The significance of various ligaments towards providing stability is an important issue that needs attention. The effect of the resection soft tissues on the wear outcome of devices is an important question that needs to be answered. The surgical procedures employed to position the different types of disc implants may vary depending on the surgeon's preferences. Surgeons play an important role in determining the right implant size, soft tissue balance, alignment of the device, etc. These factors have a direct bearing on the wear performance of the implant. For
instance, if a device is placed with some offset from the symmetric position in the anterior-posterior direction, it may cause differences in the wear pattern. Thus, such factors can be understood in detail using FE modeling.

3.6.1.1 Effect of anatomic structures by sequential removal of each structure

Arthroplasty involves complete or partial discectomy followed by removal of the ALL and PLL. In some cases the PLL is retained and the ALL is reconstructed. However, to understand the effect of each anatomic structure and in order to verify whether removal or retention of such structures will have an influence on wear of devices, test cases need to be run with sequential addition/removal of such structures. Previous studies have shown that if the ALL is preserved then the spinal stiffness will be restored at pre-implantation levels. The surgical conditions for the disc utilized in our preliminary study calls for discectomy and removal of both ALL and PLL. The ALL and PLL were added sequentially and to try and understand the role each play in terms of lift-off and wear of the devices. Thus for both the implanted cases of Prestige and Prodisc-C, the following test cases were run in ABAQUS.

**Implanted Disc+FSU+ add ALL**: The artificial disc was placed following removal of anterior annulus, entire nucleus, parts of posterior annulus and posterior longitudinal ligament (PLL) at the C5-C6 disc region. All of the other structures including Uncinate Processes, Luschka’s Joints as well as anterior longitudinal ligament (ALL) were preserved. This model was created for both Prestige and Prodisc-C implanted cases and was run for 10 million cycles. The subroutines UMESHMOTION and UFIELD were
used during the adaptive meshing procedure to simulate wear of the polymeric core. The linear wear rate, volumetric wear and the Von-Mises stress contour were computed.

**Implanted Disc+FSU+ add PLL:** The artificial disc was placed following removal of anterior annulus, entire nucleus, parts of the posterior annulus and ALL at the C5-C6 disc region. All of the other structures including Uncinate Processes, Luschka’s Joints as well as the PLL were preserved. This model was created for both Prestige and Prodisc-C implanted cases and was run for 10 million cycles. The subroutines UMESHMOTION and UFIELD were used during the adaptive meshing procedure to simulate wear of the polymeric core. The linear wear rate, volumetric wear and the von-Mises stress contour was computed.

**Implanted Disc+FSU+ add ALL+PLL:** The artificial disc was placed following removal of anterior annulus, entire nucleus and parts of posterior annulus at the C5-C6 disc region. All of the other structures including Uncinate Processes, Luschka‘s Joints, PLL and ALL were preserved. This model was created for both Prestige and Prodisc-C implanted cases and was run for 10 million cycles. The subroutines UMESHMOTION and UFIELD were used during adaptive meshing procedure to simulate wear of the polymeric core. The linear wear rate, volumetric wear and the von-Mises stress contour was computed.

**Implanted Disc+FSU+facetectomy:** The artificial disc was placed following removal of the anterior annulus, entire nucleus, parts of posterior annulus, parts of the PLL and parts of the ALL at the C5-C6 disc region. Facetectomy was simulated by removal of the capsular ligaments (CAPS) and the facet contact interactions. Thus, there was no contact
between the superior and inferior facets and the facet joint was removed. All of the other structures, including Uncinate Processes and Luschka’s Joints were preserved. This model was created for both Prestige and Prodisc-C implanted cases and was run for 10 million cycles. The subroutines UMESHMOTION and UFIELD were used during adaptive meshing procedure to simulate wear of the polymeric core. The linear wear rate, volumetric wear and the von-Mises stress contour was computed.

**Implanted Disc+FSU+ facetectomy+ no ligaments+ no follower load:** The artificial disc was placed following removal of anterior annulus, entire nucleus, parts of posterior annulus, parts of posterior longitudinal ligament (PLL) and parts of anterior longitudinal ligament (ALL) at the C5-C6 disc region. The interspinous ligaments (ISL) and ligamentum flavum (LF) were completely removed. Facetectomy was simulated by removal of the capsular ligaments (CAPS) and the facet contact interactions. Thus there was no contact between the superior and inferior facets and the facet joint was removed. Finally the follower load, which represented the musculature was also removed. All of the other structures including Uncinate Processes and Luschka’s Joints were preserved. The subroutines UMESHMOTION and UFIELD were used during adaptive meshing procedure to simulate wear of the polymeric core. Thus this model was created for both Prestige and Prodisc-C implanted cases and were run for 10 million cycles. The linear wear rate, volumetric wear and the von-Mises stress contour was computed.
3.6.1.2 Effect of the position of the device *in situ*

Dooris *et al.*[75] suggested that anterior placement of the device led to increased facet joint loads in compression and extension. These findings suggest that if the implant is placed posteriorly within the disc, the spinal stiffness will be restored and facet loads will be maintained at pre-implantation levels. We pursued our study along this line of thought to understand whether the effect of the device position is related to the wear of the devices. The devices were placed with some offset from the symmetric position by moving it in anterior-posterior directions in order to understand the effect of position on wear. Wear is also a function of sliding or slipping at the interface, which is dependent on the overall motion of the implanted segment. Thus, to understand the effect of positioning on the overall motion characteristics of the functional spinal unit which in turn may affect the wear rate each of the test cases (anterior, posterior) were re-run for flexion/extension, lateral bending and rotation without the wear code. The input conditions of 1.5Nm moment were used for flexion/extension, lateral bending and rotation along with the follower load. The motion (in degrees) for each test case was calculated.

**Offset in the anterior-posterior direction:** Both Prodisc-C and Prestige devices were moved from the neutral position by 0.5 mm on each side in the anterior-posterior direction. The new position co-ordinates were updated in the files such that the offset was 0.5 mm on each side of the symmetrical axis. At first, a varying compressive-follower load of 50-150 N (ISO 18192) (ISO 18192)[91] representing the weight of the head was applied using a set of connector elements passing through the ext-flex center of rotation of the motion segment. In the next step, flexion/extension (Flex/Ext) of ±7.5°, lateral
bending (LB) of ±6°, and axial rotation (AR) of ±4° via time-dependent amplitudes within a single loading step were applied at a point on the superior surface of the C5 vertebra at 1Hz with the specified phase difference as per ISO 18192[91]. The subroutines UMESHMOTION and UFIELD were used during the adaptive meshing procedure to simulate wear of the polymeric core. The linear wear rate, volumetric wear and the von-Mises stress contour were computed.

3.6.2 Effect of loading (Load control versus Displacement control) test set-up

In order to achieve a standardized test protocol during an in-vitro study, the load experienced at various levels should remain constant regardless of the stiffness [125]. The loads applied should be such that it does not constrain or inhibit the motion pattern in a spinal segment. In load control mode, pure moments are applied to simulate clinical scenarios such that the load does not change across the length of the spinal segment. During displacement control, the application of a given amount of displacement (at the superior vertebral level) imposes complex loads of varying magnitude along the spine segment because of coupled motion in the spine. The displacement control method applies rotation and translations that are close to the real motions in a spine but often lead to time varying load and stress states due to stress relaxation in tissues. The current wear standards usually recommend displacement control mode. However, it would be beneficial to see the results of the load controlled mode and its affect on the wear of devices.
The displacement control mode is already specified by the ASTM/ISO standards. In order to understand the effects of the load control mode, the boundary conditions need to be modified. The C6 vertebra was completely constrained in all 3 degrees-of-freedom at the inferior endplate, inferior facets and inferior part of the spinous process. At first, a compressive-follower load of 150 N, representing the weight of the head, was applied using a set of connector elements passing through the ext-flex center of rotation of the motion segment.

While under compression, a bending moment of 2.0 Nm was applied at a point on the superior surface of the C5 vertebra to simulate physiological flexion-extension, 2.0 Nm lateral bending and 4.0 Nm of axial rotation as per ISO18192. The moments were equal in all motion planes, but they were applied with a phase difference as specified in ISO18192. The moments were applied in the form of time dependant amplitude instead of constant magnitude in the same way as the displacements were applied.

The follower load and boundary conditions were the same for both the implanted models (Prestige and Prodisc-C). The subroutines UMESHMOTION and UFIELD were used during the adaptive meshing procedure to simulate wear of the polymeric core. The simulations were run using ABAQUS for 10 million cycles. The linear wear rate, volumetric wear and the von-Mises stress contour were computed.

3.6.3 Effect of material-properties on wear

Experimental studies have proven the superiority of metal-on-metal wear couple over metal-on-polymer, in terms of wear resistance [94]. In the previous section, the methods that were utilized for finite element simulation of wear for a metal-on-metal implant
(Prestige) and a metal-on-polymer (Prodisc-C) implant were outlined. Prestige has a ball-on-trough design as compared to Prodisc-C which has a ball-on-socket design. Directly comparing the results of these two devices may not yield meaningful results. With the drastic differences in designs, it is difficult to distinguish whether the design factor or the material couple played a more major role in the wear outcome. In order to understand these results in a manner which allows for more direct comparison, the metal-on-metal ball on trough design was converted into a metal-on-polymer ball on trough design. The trough of the original Prestige device was assigned the material properties of UHMWPE, similar to the polymeric core in Prodisc-C (Young’s modulus = 1400 MPa, Poisson’s ratio= 0.46). Initially, a varying compressive-follower load of 50-150 N (ISO 18192)[91] representing the weight of the head was applied using a set of connector elements passing through the ext-flex center of rotation of the motion segment. In the next step, flexion/extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, and axial rotation (AR) of ±4° via time-dependent amplitudes within a single loading step were applied at a point on the superior surface of the C5 vertebra at 1Hz with the specified phase difference as per ISO 18192[91].

Keeping the design variable constant, the effects of the material couple could be delineated. Both implanted (Disc+FSU) as well as disc only cases were simulated. The boundary conditions were kept the same as previous models. The wear coefficient derived from the work was 1.01 x 10^{-11} mm^3/N mm [94]. Each model was run for 10 million cycles, which equals 40 adaptive meshing steps during the analysis. The subroutines UMESHMOTION and UFIELD were used during the adaptive meshing
procedure to simulate wear of the polymeric core. The linear wear rate, volumetric wear
and the von-Mises stress contour were computed.
CHAPTER 4

Results

The results obtained from predictive wear modeling using FE analysis are presented in this chapter. The chapter is divided into three major sections; the first section deals with Prodisc-C (metal-on-polymer, ball on socket) and the various test cases associated with this device. The second section focuses on the Prestige (metal-on-metal, ball on trough) implant and the parametric studies involving this implant. The last section deals with a comparative analysis of the material couple with the design aspect held constant. A detailed flowchart for the test cases is illustrated in Figure 4-1.
Figure 4-1  Detailed flowchart of the test cases run for this project
4.1 Disc versus Disc+FSU (Prodisc-C) as per ISO 18192

The maximum von Mises stresses in the Disc model were concentrated along the peripheral edges of the polymer; the maximum value being 16MPa. The maximum stresses for the Disc+FSU case exceeded the Disc case by 54MPa. In comparison to the Disc only case, the Disc+FSU model showed a much more varied and uneven stress contour as depicted in Figure 4-2. The stresses were lopsided in nature in comparison to the Disc only test case.

Figure 4-2 Von-Mises stress contour (MPa) for Disc+FSU and Disc only test simulations as per ISO 18192 (flexion/extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) for the polymeric core in the metal-on-polymer (ball-on-socket) device. Grey and red depict the maximum stress, while blue or green color means minimal stress.

Lift-off or separation phenomenon was observed at the articulating surface in the Disc+FSU model. The separation occurred in such a way that the polymeric core lost contact with the superior endplate‘s inferior surface during extension and bending modes [Figure 4-3]. Parametric studies which involved re-runs with single rotational motion
such as Flex/Ext only and bending only modes, followed by dual rotational motion such as Flex/Ext +bending and bending+ rotation, confirmed that the lift-off occurred during extension and bending.

Figure 4-3 Separation or disengagement of the superior component from the polymeric core surface during extension and bending mode as per ISO18192 (flexion/extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)

The Disc only model showed a uniform wear distribution with maximum wear occurring at the outer peripheral edges (Figure 4-4). The wear in the Disc model started at the periphery and gradually converged to the central region, spreading across the entire dome of the polymer component. In contrast, the Disc+FSU model showed single sided, posteriorly biased wear at the onset and then a wear contour gradually reaching the central region of the core. It however remained one sided within the posterior half of the polymeric core. The wear contour at intervals of 1, 3, 5, 7 and 10 million cycles, depicting the maximum linear wear depth, is depicted in Figure 4-4. For the Disc+FSU contour post 5 million cycles, the wear contour remained the same for up to 10 million
cycles.

Figure 4-4  Linear wear contour for Disc Only and Disc+FSU at 1,3,5,7 and 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, and axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N). Wear contours clearly indicate the circumferential wear pattern for the Disc only test case, while an uneven, one-sided wear pattern is shown for the Disc+FSU test case. Black denotes maximum wear, while orange or red means minimal wear.

The difference in wear contour could be attributed to the difference in the von Mises stress contour for the test cases. The maximum linear wear depth in the Disc+FSU model was less than that of the Disc model by a factor of 28. The cumulative linear depth at each million cycles was computed and is shown in Figure 4-5.
Figure 4-5 Cumulative linear wear (mm) at the end of each million cycles for (a) Disc only and (b) Disc+FSU model as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)
The predicted cumulative volumetric wear for the Disc+FSU case was about ten times lesser than the wear for the Disc only case [Figure 4-6 (a) and (b)].
Figure 4-6 Cumulative volumetric wear (mm$^3$) at the end of each million cycles for (a) Disc only and (b) Disc+FSU model as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°; lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N).

The average volumetric wear rate was 1.70 mm$^3$/million cycles for the Disc only model and 0.18 mm$^3$/million cycles for the Disc+FSU model, based on 10 million cycle data in Figure 4-6.

4.2 Effect of Facets and Ligaments on Wear (Prodisc-C) as per ISO18192

After addition of the ALL, there was no significant increase in maximum stresses. However, the stress distribution was more uniform in comparison to the Disc+FSU test case, as illustrated in Figure 4-7.
Figure 4-7 Stress distribution (MPa) for addition of ALL, addition of PLL, addition of ALL+PLL, Facetectomy and no ligaments as per ISO18192. (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive load of 50-150 N). Grey or red depicts maximum stress while blue denotes no stress at all.

On the contrary, after the addition of the PLL, the maximum von Mises stress increased by 10 MPa. However, the maximum stress was concentrated over a smaller cross sectional area in comparison to the ALL test case. On addition of both the ALL and PLL, the stress distribution resembled that of the PLL test case. The maximum stress was almost 10 MPa higher than the Disc+FSU case and was the same as after addition of PLL.
only. On removal of the facet joint, the maximum stresses increased slightly but the stress
distribution changed. The maximum stresses were concentrated more at the center of the
polymeric core in comparison to the unbalanced distribution that was observed earlier
(Figure 4-7).

After removal of all the ligaments, facet joint and follower load, the maximum stress
remained high, similar to the facetectomy test case. However, the stress distribution
changed. The stresses spread along the peripheral edge of the polymeric core in addition
to the maximum stress being concentrated in the center.

The linear cumulative wear contour was also compared among the various test cases.
On addition of the ALL or PLL, the initial wear pattern/contour was slightly different
with wear being concentrated on the outer edges. At 3 million cycles, addition of
ALL/PLL or ALL+PLL did not produce significant differences in the wear pattern
[Figure 4-8]. The lift-off at the device interface was observed for both cases. The linear
wear trend as well as volumetric wear rates was computed. The maximum linear wear
among all three test cases was recorded after addition of both ALL and PLL. The ALL
test case recorded a slight increase in linear wear in comparison to addition of PLL.
After the removal of facets, the lift-off was reduced significantly. The wear contour was no longer unbalanced as in the previous test cases. The wear eventually spread to the central part of the core [Figure 4-9 (a)]. On removal of all the ligaments, facet forces and follower load (which simulated the effect of muscle forces), the wear pattern resembled the disc only test case as the wear was no longer posteriorly biased. The wear contour
spread to the center and thus was uniformly distributed [Figure 4-9(b)]. The lift-off phenomenon, which was observed previously, was absent during this simulation.

Figure 4-9 Linear wear contour at the end of 1, 3, 5, 7 and 10 million cycles for Disc+FSU as per ISO18192 (as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive load of 50-150 N) after (a) the removal of facets (b) removal of facets + removal of ligaments + removal of follower load. Black denotes maximum wear, while orange/red denotes minimal wear.

The cumulative linear wear depth at the end of each million cycles was plotted and is depicted in Figure 4-10 (a) and (b).
Figure 4-10  Cumulative linear wear (mm) at the end of each million cycles for (a) Disc+FSU, Disc+FSU+ Addition of ALL, Disc+FSU+ Addition of PLL, Disc+FSU+ Addition of ALL+PLL (b) Disc+FSU+ Facetectomy, Disc+FSU+ Facetectomy+No Ligaments +No follower load as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive load of 50-150 N)
There was no significant increase in linear wear on addition of ALL/PLL. However, addition of both ALL and PLL together led to a slight increase in the wear depth. Post facetectomy, the linear wear depth increased by 8 times in comparison to Disc+FSU test case. Similarly, on removal of all ligaments, facets and follower load, the maximum linear wear increased by 7 times in comparison to Disc+FSU model. The cumulative volumetric wear was computed for each test case and was further compared as depicted in Figure 4-11 (a) and (b).
Figure 4-11 Cumulative volumetric wear (mm$^3$) at the end of each million cycles for (a) Disc+FSU, Disc+FSU+ Addition of ALL, Disc+FSU+ Addition of PLL, Disc+FSU+ Addition of ALL+PLL (b) Disc+FSU+ Facetectomy, Disc+FSU+ Facetectomy+No Ligaments+No follower load as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) to understand the effect of soft tissue, facet joint and follower load.

The maximum volumetric wear was predicted for the Disc only test case, while the minimum wear was computed for the Disc+FSU test scenario. There was a slight increase in volumetric wear on the addition of the ALL and PLL for Disc+FSU, however the addition of the ALL or PLL separately led to no significant increase. Post facetectomy, the volumetric wear increased up to 2.8 times in comparison to Disc+FSU. Similarly, on removal of all ligaments+ no facets+ no follower load, the wear was 4.5 times that of Disc+FSU and was still 2 times less than Disc alone test case.
4.3 Effect of Malpositioning of the Implant (Prodisc-C) as per ISO18192

Anterior positioning of the implant led to a slight increase in the maximum von-Mises stress in comparison to the neutral position as illustrated in Figure 4-12.

![Figure 4-12 Stress distribution for anterior/posterior positioning of the implant as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6 ° and axial rotation (AR) of ±4 ° and a compressive-follower load of 50-150 N) (Grey or red denotes maximum stress while blue denotes areas of no stress)](image)

Figure 4-12 Stress distribution for anterior/posterior positioning of the implant as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6 ° and axial rotation (AR) of ±4 ° and a compressive-follower load of 50-150 N) (Grey or red denotes maximum stress while blue denotes areas of no stress)

Posterior positioning of the device led to a significant decrease in the maximum stress by almost 30 MPa. The stresses were however uniformly distributed over a larger contact surface due to anterior positioning. The wear pattern for the implanted test cases was unbalanced, irrespective of their position. Lift-off/separation was also observed at the device interface for both the test cases during extension and bending. This was marked by disengagement of the superior component from the inferior component. The wear pattern for the neutral as well as anterior/posterior position was similar as shown in the Figure 4-13.
There was an increase in linear wear for all the test cases in comparison to the neutral position. The minimal wear was seen in the case of neutral positioning of the device followed by the anterior position.

Figure 4-13 Linear wear contour at the end of 1, 3 and 5 million cycles for Disc+FSU (neutral) in comparison to anterior/posterior position offset from the center as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N). Black denotes maximum wear, while orange/red denotes minimal wear.

The maximum linear wear was observed for the posterior test case while minimum wear was observed for the neutral test case. On posterior positioning of the implant, the linear wear depth increased 2.65 times in comparison to the neutral position, Figure 4-14.
Figure 4-14 Cumulative linear wear in mm for various positions, Disc+FSU (neutral), Disc+FSU (anterior), Disc+FSU (posterior) at the end of each million cycles for up to 5 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)

The posterior test case generated a maximum cumulative volumetric wear of 1.14 mm$^3$ and the neutral test case produced a value of 0.6 mm$^3$. Minimum wear was seen for the anterior test case, which was 8 times lesser than posterior placement as shown in the Figure 4-15.
The motion at the C5-C6 level was computed for each test case for flexion/extension, bending and rotation under an application of constant moment of 1.5Nm and a follower load of upto 150N. Anterior positioning of the implant led to an overall decrease in motion while posterior positioning caused an increase in motion in comparison to the neutral test case. A significant difference in motion was observed, however, during the extension mode in comparison to all other loading modes. There was also a slight decrease in motion for all other modes for the anterior position in comparison to the neutral test case. On the contrary, posterior positioning led to a slight increase in motion for all loading modes [Figure 4-16].
Figure 4-16 Comparison of motion for anterior/posterior and neutral positioning of Prodisc-C implant at the C5-C6 level on application of 1.5Nm of moment in all three bending modes (Flex/Ext, lateral bending and rotation)

4.3 Effect of Load versus Displacement (Prodisc-C) as per ASTM F2423 and ISO18192

The change in boundary condition from displacement (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) as per ISO18192) to moments (Flexion/Extension (Flex/Ext) of ± 2.0 Nm, lateral bending (LB) of ±2.0Nm, axial rotation (AR) of ±4.0Nm and a compressive-follower load of 50-150 N as per ASTM F2423) led to an overall decrease in motion of the spinal unit. The maximum von Mises stresses reduced by 3.5 times on application of moments in place of displacement as depicted in Figure 4-17. The stress
distribution changed from being a one-sided bias to peripheral stress concentration, as observed in the case of the Disc only test case.

Figure 4-17 Comparison of stress distribution for moment (Flexion/Extension (Flex/Ext) of ±2.0 Nm, lateral bending (LB) of ±2.0Nm, axial rotation (AR) of ±4.0Nm and a compressive-follower load of 50-150 N as per ASTM F2423) and displacement (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) as per ISO18192) boundary condition as seen in Prodisc-C. (Grey or red denotes maximum stress while blue denotes areas of no stress)

The amount of wear was drastically reduced for the moment based system in comparison to the displacement control input condition. Figure 4-18 shows the wear contour at one million cycle intervals.
Although the moment based test case also produced one sided wear, there was no significant difference in the patterns from 1-10 million cycles. The area depicting the wear contour was significantly less in comparison to the previous displacement controlled test case. The motion that was observed for the original model was much larger in comparison to the moment controlled test scenario. Thus, the lift-off or separation at the device interface, which was seen in the case of Disc+FSU (Displacement) model, was absent for Disc+FSU (Moment) test case. The linear wear depths for these two test cases were compared as shown in Figure 4-19 (a) and (b).
Figure 4-19 Cumulative linear wear (mm) at the end of each million cycles for (a) Disc+FSU displacement controlled (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) as per ISO18192) test case, versus (b) moment controlled (Flexion/Extension (Flex/Ext) of ±2.0Nm, lateral bending (LB) of ±2.0Nm, axial rotation (AR) of ±4.0Nm and a compressive-follower load of 50-150 N) as per ASTM F2423) test scenario.
The linear wear depth was 12.42 times less when the displacements were replaced by moments. Thus the moment test case led to a significant decrease in linear wear in comparison to displacements [Figure 4-19].

Similar to the observations for the linear wear trend, the volumetric wear for the displacement controlled test case was higher by an order of magnitude of $10^4$ in comparison to the moment controlled scenario [Figure 4-20].
Figure 4-20  Cumulative volumetric wear (mm$^3$) at the end of each million cycles for (a) Disc+FSU displacement controlled (Flexion/Extension (Flex/Ext) of $\pm7.5^\circ$, lateral bending (LB) of $\pm6^\circ$, axial rotation (AR) of $\pm4^\circ$ and a compressive-follower load of 50-150 N) as per ISO18192) test case, versus (b) moment controlled (Flexion/Extension (Flex/Ext) of $\pm2.0$ Nm, lateral bending (LB) of $\pm2.0$Nm, axial rotation (AR) of $\pm4.0$Nm and a compressive-follower load of 50-150 N as per ASTM F2423) test scenario

For better interpretation of the data for various test cases of Prodisc-C, the peak cumulative linear wear depth and the cumulative volumetric depth was summarized in the Table 4-1. The maximum value of the linear and volumetric wear was computed for the Disc Only test case.
Table 4.1 Summarization of peak cumulative linear wear and cumulative volumetric wear for various test cases of Prodisc-C

<table>
<thead>
<tr>
<th>Test Cases for Prodisc-C (Metal on poly)</th>
<th>Cumulative linear wear in mm</th>
<th>Cumulative volumetric wear in mm$^3$</th>
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</thead>
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<tr>
<td>Disc Only@ 10 million cycles</td>
<td>0.047</td>
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</tr>
<tr>
<td>Disc + FSU@ 10 million cycle</td>
<td>0.0016</td>
<td>1.75</td>
</tr>
<tr>
<td>Disc+FSU+Add ALL@ 10 million cycle</td>
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<td>1.84</td>
</tr>
<tr>
<td>Disc+FSU+Add PLL@ 10 million cycle</td>
<td>0.0019</td>
<td>1.79</td>
</tr>
<tr>
<td>Disc+FSU+Add ALL+PLL@ 10 million cycle</td>
<td>0.0022</td>
<td>2.28</td>
</tr>
<tr>
<td>Disc+FSU +Facetectomy@ 10 million cycle</td>
<td>0.0131</td>
<td>5.13</td>
</tr>
<tr>
<td>Disc+FSU+Facetectomy+No Ligaments+No follower load@ 10 million cycle</td>
<td>0.0111</td>
<td>8.16</td>
</tr>
<tr>
<td>Disc+FSU (Anterior)@ 5 million cycle</td>
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<td>1.14</td>
</tr>
<tr>
<td>Disc+FSU (Posterior)@ 5 million cycle</td>
<td>0.00106</td>
<td>0.144</td>
</tr>
<tr>
<td>Disc + FSU (moment controlled)@ 10 million cycles</td>
<td>0.00013</td>
<td>.000324</td>
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4.4 Disc versus Disc+FSU (Prestige) as per ISO18192

Unlike the Prodisc, the metal-on-metal disc displayed a higher wear rate when simulated using a ligamentous finite element model. The Disc +FSU model for the Prestige disc showed linear wear which was almost 1.5 times that of the Disc only model at the end of 10 million cycles. The wear contour for both cases was similar and maximum wear was concentrated at the center. In case of the Disc+FSU simulation, the wear contour extended along the medial-lateral direction of the implant [Figure 4-21].

![Figure 4-21 Comparison of linear wear contour for Disc only and Disc+FSU test case for Prestige-ST as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red denotes no wear, while black region denotes maximum wear)]
In the case of the Disc only model, the wear contour was concentrated at the center and the (right) lateral side of the rim. The maximum von Mises stress for the Disc only test case was less than the Disc+FSU by an order of magnitude of 10, as depicted in Figure 4-22. The stress distribution pattern was different, with the Disc+FSU exhibiting a larger surface area with higher stresses. Moreover, the stress pattern was more in the left-lateral direction for the Disc+FSU while it was the opposite for the Disc only test case. Another difference noted was a larger stress concentration surface area in the case of the Disc+FSU in comparison of the Disc only test case.

Figure 4-22 Comparison of stress distribution and maximum Von Mises stress for Disc only and Disc+FSU test case for Prestige-ST (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) as per ISO18192 (Red or grey denotes maximum wear, while blue region denotes maximum stress)
A lift-off phenomenon was also observed during bending and extension modes of the Disc+FSU model of the Prestige device; similar to what was observed in the case of the Prodisc-C. The lift-off was marked by loss of contact at the device interface [Figure 4-23].

Figure 4-23 Lift-off phenomenon that was observed during extension mode which was marked by the disengagement of the superior component as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6 °, axial rotation (AR) of ±4 ° and a compressive-follower load of 50-150 N)

The cumulative linear wear for every million cycles was plotted for both the Disc only and the Disc+FSU test case as depicted in [Figure 4-24 (a) and (b)].
Figure 4-24 Cumulative linear wear (mm) at the end of each million cycles for (a) Disc only and (b) Disc+FSU test cases for Prestige up to 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)
The cumulative wear for the Disc only test case was 1.5 times lesser than the Disc+FSU test case as illustrated in [Figure 4-24]. The cumulative volumetric wear was plotted for both test cases [Figure 4-25].

Figure 4-25 Cumulative volumetric wear (mm$^3$) at the end of each million cycles (a) Disc only and (b) Disc+FSU test cases for Prestige up to 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)
The maximum volumetric wear was 1.91 mm$^3$ and 0.267 mm$^3$ for the Disc+FSU and the Disc only test cases, respectively. The Disc only test case was 7 times lesser than the Disc+FSU in terms of volumetric wear.

### 4.5 Effect of Facets and Ligaments on Wear (Prestige) as per ISO18192

On addition of PLL, the wear contour remained the same as the Disc+FSU test case. However, when the ALL was added to the model, the posterior rim side also showed wear concentration. On addition of both the ALL and PLL, the wear contour remained the same, with additional wear at the posterior edges of the rim. The linear wear remained almost the same for all three test cases. However, addition of both the ALL and PLL together led to a slight decrease in linear wear [Figure 4-26].
Figure 4-26 Comparison of wear distribution and cumulative linear wear depth for Disc+FSU test case for Prestige-ST on addition of ALL, PLL and ALL+PLL as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) Red denotes no wear, while black region denotes maximum wear.

On removal of all adjoining ligaments, facet joints and follower load (representing the effect of muscle forces), the wear pattern resembled the standalone disc test case. The maximum linear wear almost became the same as that of Disc only test case for both the cases as depicted below [Figure 4-27]. Removal of the facet joint led to reduced lift-off, while on removing the follower load, the lift-off phenomenon was absent during the simulation.
Figure 4-27 Comparison of wear distribution and cumulative linear wear depth for Disc+FSU test case for Prestige-ST after facetectomy, and removal of all ligaments and follower loads as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive load of 50-150 N) (Red denotes no wear, while black region denotes maximum wear)

The stress plots of each of these test cases were compared. The changes in the values of the maximum von Mises stress on the addition of the ALL, PLL or ALL+PLL in comparison to the Disc+FSU test case was not significant. The stress pattern remained similar (concentrated in the center as well as the medio-lateral direction) after sequential
addition of the ALL, PLL and ALL+PLL, as illustrated in Figure 4-28.

Figure 4-28  Comparison of stress distribution and maximum Von Mises stress for Disc +FSU test case on addition of ALL, PLL, ALL+PLL, facetectomy and removal of all ligaments as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)

On removal of the facets, the maximum stresses increased by 14 MPa and the stress concentration increased over a smaller contact area (center of the trough) in comparison to the Disc+FSU test case. Similarly on removal of all the ligaments, facets and follower load, the stresses increased by 20 MPa and the stress pattern was similar to the
facetectomy test case. Maximum stresses were concentrated in the center over a much smaller contact surface of the trough. Interestingly, the stresses along the edges which were noticed for the Disc+FSU, addition of ALL, PLL and ALL+PLL test cases, were not observed in cases of facetectomy and removal of ligaments as depicted in Figure 4-28. The cumulative linear wear was plotted upto 10 million cycles for each test case as shown in Figure 4-29 (a) and (b).
Figure 4-29 Cumulative linear wear (mm) at the end of each million cycles for (a) Disc+FSU, Disc+FSU+ Addition of ALL, Disc+FSU+ Addition of PLL, Disc+FSU+ Addition of ALL+PLL (b) Disc+FSU+ Facetectomy, Disc+FSU+ Facetectomy+No Ligaments +No follower load as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive load of 50-150 N)

The maximum wear was reported for the Disc+FSU while the minimum wear was reported for the Disc only test case. On removal of the facet joint, the linear wear decreased slightly in comparison to Disc+FSU. Similarly, on removal of all ligaments, follower load and facet joint, the linear reduced by 1.4 times. There was also no significant difference in wear rate, after the addition of the ALL/PLL separately or ALL+PLL. An insignificant increase was noticeable for the ALL test case.

In terms of the volumetric wear rate, the addition of both the ALL and PLL led to an increase in volumetric wear in comparison to the Disc+FSU. Similarly addition of the ALL and PLL separately led to a slight increase in volumetric wear [Figure 4-30 (a)].
Facetectomy also led to a slight increase in volumetric wear. On removal of all ligaments, facet joint and follower load, the wear increased by 2.5 times [Figure 4-30 (b)]. Thus, the Disc only test case resulted in the minimum volumetric wear in comparison to all the other test cases while the addition of both the ALL and PLL led to the maximum amount of volumetric wear, which was 4 times that of the Disc+FSU test case.
4.6 Effect of Malpositioning of the Implant (Prestige)

In order to understand the role of malpositioning or malalignment, the artificial disc was moved from its symmetrical position. The results of malpositioning are described as follows. When the device was moved posteriorly, the wear pattern remained concentrated along the medial-lateral direction up to the rims. The posterior edge also showed wear concentration which was oriented rightwards from the center.
When the disc was moved anteriorly, even though the wear pattern was similar, the maximum wear was mostly concentrated at the center as well as (leftward biased) medially-laterally. Unlike the previous case, lateral wear concentration was not uniformly distributed towards the left and right side [Figure 4-31]. The posterior edge also showed wear concentration due to the anterior positioning of the implant. However, there was not much of a difference in the linear wear for the following test cases.

![Figure 4-31 Comparison of linear wear contour for different positions when the implant was moved anterior/posterior with respect to its neutral position as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) Red denotes no wear while black denotes maximum wear](image)

The stress contour for each of the position test cases was mapped individually. The maximum von Mises stress was recorded for the posterior position of the device which
was almost 4 times that of the Disc + FSU test case for the Prestige device depicted in Figure 4-32.

![Anterior and Posterior Stress Distribution](image)

Figure 4-32 Comparison of stress distribution and maximum von Mises stress for different positions when the implant was moved anterior/posterior with respect to its neutral position as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) Red/grey denotes maximum stress while blue denotes minimum or zero stress

Interestingly, the stress pattern was similar for all the test cases except for the posterior positioning. The posterior positioning led to greater amount of stress being concentrated on the edges of the device which was rightward biased in the medio-lateral direction. Anterior positioning showed some edge loading but it was in the leftward direction along the medio-lateral axis similar to what was observed for the Disc+FSU neutral test case.

The motion at the C5-C6 level was computed for each test case for flexion/extension, bending and rotation under an application of 1.5Nm of moment. Anterior positioning of the implant led to an overall decrease in motion except for extension [Figure 4-33]. Posterior positioning, on the other hand, caused an increase in motion in extension and
decrease in left bending in comparison to the neutral test case. For all the other modes, in the instance of posterior positioning, the motion remained equal to that of the neutral test case [Figure 4-33].

![Image](image.png)

**Figure 4-33** Comparison of motion for anterior/posterior and neutral positioning of Prestige-ST implant at the C5-C6 level on application of a moment of 1.5Nm in all three bending modes (Flex/Ext, lateral bending and rotation) and a compressive follower load of 50-150N

The maximum cumulative linear wear was plotted for each of the test cases along with the Disc+FSU (neutral position) test case. There was no significant difference in linear wear rates when the device was moved in the anterior direction while posterior positioning led to a decrease by 1.2 times [Figure 4-34].

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Figure 4-34  Cumulative linear wear in mm for various positions, Disc+FSU (neutral), Disc+FSU (anterior), Disc+FSU (posterior) at the end of each million cycles for up to 10 million cycles for Prestige-ST as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)

The volumetric wear rate reflected a trend similar to linear wear. Moving the implant in anterior posterior direction did not lead to a significant change in the volumetric wear rate. However, posterior implantation led to a slight decrease in the volumetric wear [Figure 4-35].
Figure 4-35 Cumulative volumetric wear in mm$^3$ for various positions, Disc+FSU (neutral), Disc+FSU (anterior), Disc+FSU (posterior) at the end of each million cycles for up to 10 million cycles for Prestige-ST as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N)

4.7 Effect of Load versus Displacement (Prestige) as per ISO18192 and ASTM F2423

On changing the input conditions from displacement controlled to moment controlled the wear contour as well as stresses were computed as follows. The moment controlled Disc+FSU test case was concentrated in the center, while the displacement controlled test case was concentrated both in the center and along the lateral edges [Figure 4-36].
The linear wear depth for the displacement controlled test case was 2.6 times that of the moment controlled test case. Additionally, the lift-off phenomenon which was observed in the displacement test case was absent when the input conditions were moment controlled.

Figure 4-36 Cumulative linear wear distribution at the end of 1, 3, 5, 7 and 10 million cycles for Disc+FSU displacement controlled test case as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N), versus moment controlled test scenario as per ASTM F2423 (Flexion/Extension (Flex/Ext) of ±2.0 Nm, lateral bending (LB) of ±2.0 Nm, axial rotation (AR) of ±4.0 Nm and a compressive-follower load of 50-150 N) for Prestige-ST. Black denotes maximum wear, while red denotes minimal wear.

The maximum von Mises stress was almost equivalent for both the moment controlled and displacement controlled test cases. However the area of maximum stress
concentration was larger in the case of displacement controlled in comparison to moment controlled conditions [Figure 4-37].

Figure 4-37 Comparison of stress distribution and maximum von Mises stress at the end of 1,3,5,7 and 10 million cycles for Disc+FSU displacement controlled test as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N), versus moment controlled test scenario as per ASTM F2423 (Flexion/Extension (Flex/Ext) of ±2.0 Nm, lateral bending (LB) of ±2.0 Nm, axial rotation (AR) of ±4.0 Nm and a compressive-follower load of 50-150 N). Red/grey denotes maximum stress, while orange/red denotes minimal wear.

The linear wear rate was plotted for displacement controlled and moment controlled test cases [Figure 4-38 (a) and (b)]. The displacement test case demonstrated a maximum linear wear almost 3 times larger than the moment controlled input conditions.
Figure 4-38  Cumulative linear wear at the end of each million cycle cycles for (a) Disc+FSU displacement controlled test as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N), versus (b) moment controlled test scenario as per ASTM F2423 (Flexion/Extension (Flex/Ext) of ±2.0 Nm, lateral bending (LB) of ±2.0 Nm, axial rotation (AR) of ±4.0 Nm and a compressive-follower load of 50-150 N).
The volumetric wear of the moment controlled test case was less than the displacement controlled test case by 11 times [Figure 4-39 (a) and (b)].

Figure 4-39 Cumulative volumetric wear at the end of each million cycle cycles for (a) Disc+FSU displacement controlled test as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N), versus (b) moment controlled test scenario as per ASTM F2423 (Flexion/Extension (Flex/Ext) of ±2.0 Nm, lateral bending (LB) of ±2.0 Nm, axial rotation (AR) of ±4.0 Nm and a compressive-follower load of 50-150 N) for up to 10 million cycles.
4.8 Effect of Material Combination as per ISO18192

In order to understand the effect of material couples, the Prestige metal-on-metal disc was converted into a metal-on-polymeric device. The linear wear as well as the volumetric wear was computed for both the Disc only and the Disc+FSU test cases as follows. The wear contour for the Disc only (polymer) was marked by wear concentration in the center as well as a rightward bias in the medio-lateral direction. However for the implanted test case (Disc+FSU), the wear was distributed in the center as well as along the leftward lateral edges as shown in Figure 4-40. There was no significant difference in terms of cumulative linear wear for the two test cases.

Figure 4-40 Comparison of linear wear distribution for Disc only versus Disc+FSU for polymeric Prestige design at 1, 3, 5, 7 and 10 million cycles displacement as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red denotes minimal wear while black denotes maximum wear)
The maximum von Mises stress contour is depicted in the Figure 4-41. There was little difference in the stress distribution. However, the Disc only test case had a rightward bias while the Disc+FSU reflected a leftward bias in the medio-lateral direction. The maximum von Mises stress value for the Disc only test case was 10 times that of the Disc+FSU test case at the end of 10 million cycles.

Figure 4-41 Comparison of stress distribution and maximum von Mises stress Disc versus Disc+FSU for polymeric Prestige design at 1, 3, 5, 7 and 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red denotes maximum stress while blue denotes minimal stress)
In order to understand the difference in wear patterns due to the material couples, the design was kept constant. The wear contour of the Disc only test cases were plotted for polymer as well as metal trough, side by side as shown in the Figure 4-42.

Figure 4-42 Comparison of linear wear contour for Disc only test cases for polymeric versus metallic trough at 1, 3, 5, 7 and 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red denotes minimal wear while black denotes maximum wear)
Both disc only test cases showed wear concentration in the center as well as a rightward bias in the medio-lateral direction. The order of magnitude for the maximum linear wear was the same, with no significant difference. The disc only polymeric trough, however, showed a much more uniform distribution of wear as depicted in Figure 4-41. The von Mises stress distribution was similar for both test cases. However, the maximum stress value for the polymeric Disc only test case was 10 times greater than the metallic trough. The stresses were oriented in the rightward direction along the medio-lateral direction [Figure 4-43].

Figure 4-43 Comparison of stress contour and maximum von-misses stress for meta-on-polymer versus metal on metal implant at 1, 3, 5, 7 and 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red denotes maximum stress while blue denotes maximum stress)
As a mode of comparison for the implanted cases, the Disc+FSU test case for the polymeric as well as the metallic trough coupling is depicted below. Even though the wear contour was similar, the polymeric core had a uniform wear distribution. Additionally the polymeric trough showed posterior edge wear, which was not noticed in the case of metallic trough [Figure 4-44]. On the other hand, the metallic trough showed evidence of edge wear in the leftward lateral direction. The maximum linear wear for the metallic trough was 1.13 times that of the polymeric trough test case.

Figure 4-44 Comparison of wear contour for Disc+FSU test cases for polymeric versus metallic trough at 1, 3, 5, 7 and 10 million cycles as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red denotes minimal wear while black denotes maximum wear)
The maximum von Mises stress was slightly higher for the polymeric trough in comparison to the metallic trough. The stresses were more uniformly distributed over a larger contact area (well distributed) for the metallic trough. On the other hand, the stress distribution for the polymeric trough was concentrated in the central part over a much smaller contact area [Figure 4-45].

Figure 4-45 Comparison of stress distribution and maximum Von Mises stress for Disc only test cases for polymeric versus metallic trough at 1, 3, 5, 7 and 10 million cycles displacement controlled test as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) (Red/grey denotes maximum stress while blue denotes minimum stress)
The cumulative linear wear was plotted for each of the test cases [Figure 4-46 (a) and (b)]. The maximum linear wear was reported for the Disc+FSU metallic trough, while the minimum wear was seen in the case of the polymeric disc only test case. The Disc Poly+FSU was slightly more than Disc Poly case just as Disc+FSU (metal) reported a much higher wear rate than Disc only (metal) test case [Figure 4-46 (a) and (b)]. Thus, the implanted test cases reported a higher linear wear than the stand alone test cases. However, in the case of the polymeric trough, the difference was not significant. Interestingly, the polymeric wear for both the implanted and standalone cases was lesser than the metallic wear that was reported.
Figure 4-46 Cumulative linear wear (mm) at the end of each million cycle cycles for (a) Disc only and (b) Disc+FSU displacement controlled test as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) for polymeric and metallic trough upto 10 million cycles.

In terms of cumulative volumetric wear, the maximum wear was seen in the case of the metallic trough implanted onto the FSU (Disc+FSU-Prestige) which was 1.91mm$^3$, followed by the polymeric implanted test case (Disc+FSU-Prestige-poly) with a value of 1.00 mm$^3$ [Figure 4-47 (a) and (b)]. The Disc+FSU metallic trough demonstrated a wear 9.5 times higher than the Disc only (metallic test case). Similarly the Disc Poly+FSU wear was 7 times larger than the Disc Poly standalone test case as depicted in Figure 4-47 (a) and (b).
Figure 4-47 Cumulative volumetric wear (mm$^3$) at the end of each million cycle cycles for (a) Disc only and (b) Disc+FSU for displacement controlled test as per ISO18192 (Flexion/Extension (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a compressive-follower load of 50-150 N) for polymeric and metallic trough up to 10 million cycles.
For better interpretation of the data for various test cases of Prodisc-C, the cumulative linear wear depth and the cumulative volumetric depth was summarized in the Table 4-2. The maximum value of the linear wear depth was noted for the Disc+FSU (addition of ALL) test case, while the maximum volumetric wear was computed for the Disc+FSU (Addition of ALL+PLL) test case.

Table 4.2  Summarization of peak cumulative linear wear and cumulative volumetric wear for various test cases of Prestige-ST

<table>
<thead>
<tr>
<th>Test Cases for Prestige-ST (Metal on metal)</th>
<th>Cumulative linear wear in mm</th>
<th>Cumulative volumetric wear in mm³</th>
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<tr>
<td>Disc Only @ 10 million cycles</td>
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<td>2.36</td>
</tr>
<tr>
<td>Disc+FSU +Facetectomy@ 10 million cycle</td>
<td>0.004</td>
<td>4.75</td>
</tr>
<tr>
<td>Disc+FSU+Facetectomy+No Ligaments+No follower load@ 10 million cycle</td>
<td>0.004</td>
<td>4.75</td>
</tr>
<tr>
<td>Disc+FSU (Anterior)@ 10 million cycle</td>
<td>0.0067</td>
<td>2.506</td>
</tr>
<tr>
<td>Disc+FSU (Posterior)@ 10 million cycle</td>
<td>0.0052</td>
<td>2.506</td>
</tr>
<tr>
<td>Disc + FSU (moment controlled))@ 10 million cycle</td>
<td>0.002</td>
<td>0.168</td>
</tr>
<tr>
<td>Disc Only (metal on poly) @ 10 million cycle</td>
<td>0.005</td>
<td>0.146</td>
</tr>
<tr>
<td>Disc +FSU (metal on poly) @ 10 million cycle</td>
<td>0.0057</td>
<td>1.00</td>
</tr>
</tbody>
</table>
This chapter dealt with the presentation of each of the test cases and a comparison of the results amongst the test cases. The next chapter discusses each test case in detail and provides a logical reasoning for each finding.
CHAPTER 5

Discussion

5.1 Goals

The goals of this research work were to: (1) understand the effect of ligamentous structures on the wear outcome of artificial discs (2) study the effects of positioning of the implant in-situ (3) study the importance of materials versus design factors and (4) comparison of load versus displacement control test set-up for wear predictions. This chapter deals with delineating the assumptions used during the course of the study, which is followed by discussion and understanding of each test case. At the end of the chapter, suggestions are made regarding future courses of study.

5.2 Assumptions and Limitations of the Employed Methods

Finite element (FE) analysis is a valuable tool that allows further insight into in situ biomechanics. Models that take into account the geometric properties, material properties and contact definitions, among the various components of interest in the spinal segment, are able to determine a variety of parameters including applied loads, implant and tissue stress distributions, joint contact forces, range of motion, helical axis of motion and disc pressure. These studies supplement the knowledge gathered from in vitro
experimental studies and facilitate parametric analysis[126]. FE models of intact osteoligamentous motion segments have been created by a number of investigators which have subsequently been adapted to simulate post-surgical conditions [115, 125, 127-132]. Inter-specimen variability is a problem with all biomechanical spine studies. Each spine is architecturally different from the next and material properties vary between two specimens. Thus, the FE based modeling technique has emerged as a powerful supplement to experimental procedures.

There has been considerable advancement in finite element modeling of physiologic structures, especially in the areas of spinal biomechanics. Despite the models evolution from simplistic models to ones capable of handling intricate complexities, there is still a lag in validation. Reverse engineering or estimation techniques have been used to assign material properties to various structures, primarily because of the inability to obtain in-vivo measurements[133]. Modeling physiologic structures using numerical procedures are certainly demanding and thus assumptions are necessary to reduce complexities without affecting the final outcome. It is important to delineate the assumptions and the limitations of the current modeling technique.

5.2.1 Finite element model assumptions and limitations for intact C3-C7 model

The basic C3-C7 model formulation is described in the dissertation work by J.L Scifert[134]. The following paragraphs describing the intact model are being adapted from his research work.

The bony geometry for the intact model was obtained utilizing CT images from a cadaver specimen. During process scanning and subsequent determination of osseous
borders and digitization, inaccuracies could have occurred due to the blurring of the osseous CT images. The detection of certain structures such as the endplates and uncinate processes were difficult to differentiate due to the blurring effect. They were instead created and shaped upon information available in the literature and specimen dissections [135]. The endplates were assigned a uniform thickness of 0.5 mm, though realistically, it may not be practical. The vertebral cortical shell was approximated to a specific range from 0.3-0.5 mm thickness in the model, based on the literature [136]. This could have led to variabilities in the endplate stresses and the stress value at the endplate-implant interface.

However the current study dealt with the wear at the implant interface and not at the implant-endplate interface. These assumptions would not have a direct correlation to the results that have been computed. Moreover, the endplate shape and thickness varies from one person to another and it is nearly impossible to incorporate such variabilities in a numerical model. It was also not possible to determine the structure of the intervertebral disc from the CT scans. The location of the Luschka's joints, nucleus and the structure of the annulus were derived from previous models available in the literature[137].

Partial annulotomy and complete discectomy were incorporated to accommodate the artificial disc in order to simulate the surgical procedure. The geometrical shape of the native disc did not have a direct bearing on the wear outcome of the implant. Material properties of the models were obtained from both lumbar and cervical mechanical tests [127, 128, 132, 138, 139]. The model assumed a fixed Young's modulus for cortical, cancellous and posterior element bone, which can vary among various population groups.
In any FE model, the output parameters are controlled by the loads and boundary conditions (input conditions) applied to the model. It is nearly impossible to mimic the diverse, ever changing in vivo loading scenarios in a computational model without having muscle forces defined. However, the application of a preload using a set of connector elements is a reasonable representation of the effect of muscles as described by Patwardhan et al. [118].

5.2.2 Modeling assumptions applied during predictive wear analysis

Wear is defined as the material removal at the interacting surfaces. However, the wear phenomenon can be dominated by mechanical factors or chemical factors. Finite element modeling techniques do not allow chemical interactions to be defined at the interface; therefore, wear related to chemical properties (corrosive wear) are not discussed in this dissertation. One approach towards wear modeling would be to simulate the removal of elements from the model to replicate the gouging or ploughing phenomenon. This would translate to the size of each element in the model being the same as the element being removed. However there are no options for removal of elements in the finite element modeling (ABAQUS™) software. Additionally, the size of the wear debris would be on a microscopic scale, which would mean defining a mesh size at a microscopic level. This would again translate to large amounts of computer disk space and prove to be a computationally expensive method and thus would not solve the purpose of saving time and resources[140].

The current approach is on a macroscale and the sizes of the elements are much larger than the estimated size of the wear debris. The calculations are performed within the element and thus, no new element is created or destroyed. The wear code causes the
mesh to move in a prescribed direction (normal to the surface) based on the Archard's wear law[21]. Although different wear modes—such as abrasive, adhesive or fatigue wear exist in nature, adhesive-abrasive wear is a dominant phenomenon among orthopedic implants such as metal-on-poly and metal-on-metal.[141]. The Archard's wear law, which defines a classical relationship for adhesive-abrasive wear, has been implemented in the wear code.

Although fatigue related wear may exist in some form, the current in vitro model formulation does not take it into account. The material model used in this study was purely linear elastic, and thus did not simulate creep or any type of plastic deformation. Often, existence of polymeric creep/deformation has been difficult to separate from the wear phenomenon. Thus, all these factors together would result in under prediction of the actual wear rate. A single wear equation is likely insufficient to cover all aspects of the wear phenomenon. Nevertheless, a global wear predictive model still appears to be a distant goal to achieve in the future.

Archard's law[21] states that wear volume \( V = K F x \), where \( V \) is volumetric wear, \( K \) a material constant or the wear coefficient of the material-couple, \( F \) is the contact force, and \( x \) is the relative sliding distance. The value of \( K \) denotes change in surface conditions and is derived experimentally. This law assumes that the wear rate is independent of the apparent area of contact. It also makes no assumption about surface topography or the time dependency of the wear (run-in/bed-in process) phenomenon. Hence, it proposes the linearization of the experimental results. Although Archard's law provides a true calculation of wear, it provides an order of magnitude estimate. Real time analysis cannot be run in ABAQUS quasistatic analysis; therefore, one million cycles were divided into
four steps of 250,000 cycles each. Each cycle was scaled by a factor of 250,000 assuming a linearly increasing wear phenomenon. In nature, the amount of wear decreases with an increase in the number of cycles. Due to linearization of the problem, it tends to translate to over prediction of the wear phenomenon. Additionally, the wear factor was derived from the literature which was based on a similar design. The implant in question was a lumbar implant, but the modeling approach was applied for a cervical device. As per the ISO standard, the cervical test conditions are listed as (Flex/Ext) of ±7.5°, lateral bending (LB) of ±6°, axial rotation (AR) of ±4° and a load of 50-150 N while the lumbar motion angles are (Flex/Ext) of +6°/-3°, lateral bending (LB) of ±2°, axial rotation (AR) of ±2° and a load of 600-2000 N. The differences in preload as well as displacement angles have a direct bearing on the contact stresses and the sliding distance which lead to differences in wear. The cervical disc standard specifies larger ROM (range of motion) while the lumbar disc standard specifies higher load values. It is difficult to conclude if the sliding distance or the load has a greater role to play. Nevertheless, the differences in loading values are significantly higher, which would lead to higher wear rates for lumbar discs. This is further supported by the data presented by Synthes on their product information wherein the lumbar disc wear rates are 8-9 times higher than cervical discs[142]. As the lumbar experimental wear coefficient has been utilized for this study, this would result in over prediction of the wear rates.

Due to the limitations of the predictive wear models of the disc alone, as described earlier in the literature, we developed the concept of studying the wear characteristics using the artificial disc placed within a ligamentous functional spinal unit. Unlike the wear simulator experiments and disc alone predictive models, the approach used here
permitted the study of the effects of spinal structures on the wear. Several parametric analyses were also performed to understand the significance of factors such as the effect of the addition or resection of soft tissue, placement of the implant, material combinations, etc. with respect to the wear outcome *in vivo*.

### 5.3 Disc versus Disc+FSU (Prodisc-C)

Our Disc alone model predictions are in agreement with several published studies. A linearly increasing wear trend was observed for metal-on-poly interface, which matched with the existing literature [108]. The volumetric wear value of 1.70 mm$^3$/million cycles for the Disc only test case is in agreement with the wear simulator based data of 2.0 mm$^3$/million cycles as reported by Synthes (manufacturer of Prodisc-C)[142] as depicted in Figure 5-1.
Figure 5-1  Wear data reported by Synthes Spine[142] showing comparison in amount of wear for lumbar and cervical disc (as per ISO 18192) followed by our data respectively. The data computed from this study lies within the range of Prodisc-C

The wear trend reported by Rawlinson[108] for the lumbar artificial disc (Prodisc-L) is also similar to our model predictions. Rawlinson's[108] linear wear data was 7.0 times more than our values at the end of 10 million cycles while the volumetric wear was more by 3.5 times [Figure 5-2]. This is because their simulations were conducted for a lumbar artificial disc with a maximum preload of 2000 N.
Figure 5-2 (a) and (b) depict the linear and volumetric wear as reported by Rawlinson et al. [108] for Prodisc-L as per ISO 18192 and (c) and (d) illustrate the linear and volumetric wear computed for Prodisc-C as per ISO 18192 during the course of this study.

The predicted wear pattern, marked by maximum wear at the outer periphery (circumferential wear pattern) for the Disc only model, also are in agreement with the findings of de Jongh et al. [82] as depicted in Figure 5-3.
Figure 5-3  (a) Circumferential wear pattern as reported by de Jongh[82] et al. for a metal on polymer cervical disc implant (simulations were performed as per ISO18192) (b) Peripheral edges showing maximum wear for metal on polymer cervical disc implant (Disc only cases) used in the current study (simulations were performed as per ISO18192) Adapted with permission from the publisher

The agreement of the Disc only model-based predictions with the corresponding literature in terms of the wear contour and the volumetric wear, lends confidence in our Disc+FSU model predictions. Moreover, a circumferential pattern (peripheral wear) was also observed in an experimental simulation for an artificial cervical disc which was conducted at our facility. However, it should be noted that the test implant was a ceramic on ceramic ball on socket design as shown in Figure 5-4.
Figure 5-4: Circumferential abrasive wear pattern seen in an artificial cervical disc (material: ceramic-on-ceramic, Unpublished work at ECORE, University of Toledo)

On the other hand predicted wear patterns and wear rates were different for the Disc+FSU case, as compared to the Disc alone case as illustrated in Figure 5-5.

Figure 5-5 The difference in wear pattern for the Disc Only versus Disc+FSU test case. The Disc only test case shows a circumferential wear contour while Disc+FSU depicts a lopsided pattern.

The Disc+FSU model predicted lift-off or separation at the interface during extension and bending modes which was not seen in the case of the Disc only (machine simulated) test case. Machine simulated cases predicted a uniformly distributed wear pattern while the Disc+FSU pattern seemed to be one-sided which has been observed in an explanted device.

For instance, studies on Charite™ explants by Ooij et al. and Kurtz et al.[19, 20, 84] have shown rim damage and wear of the polymeric core due to localized stress.
concentration. These explants have a non-uniform wear distribution which was not observed during the in-vitro simulations. The differences in the wear patterns for a machine simulated case versus retrieved devices are depicted in Figure 5-6.

Figure 5-6 Differences in wear pattern for an in vitro test case in comparison to the explanted devices can be seen. The device (Charité™) tested in vitro shows burnishing marks while rim fracture and failure is prominently seen in the case of explants.

Radial crack formation was observed due to impingement, which eventually led to rim fracture and failure in these devices. This study refuted the arguments presented by other researchers who claimed that polymeric wear in spinal devices might not be a clinically relevant issue based on in-vitro wear data.

The contact across the facets in extension may lead to a new fulcrum leading to the lift off/separation of the implant. Besides the facet contact, the lift off is a function of the muscle forces that are simulated as a follower compressive load in the model. Lift-off/separation at the interface meant a decreased area of contact - which is the primary reason for the high stresses in the Disc+FSU model and the corresponding one sided wear located in the posterior region.

In a study by Choma et al. [15] an explanted Prodisc-L showed the evidence of anterior rim impingement, eventual burnishing and plastic deformation at the rim leading
to periprosthetic tissue reactions. This again represents a case of non-uniform wear distribution in an *in-vivo* setting, Figure 5-7.

**Figure 5-7** Burnishing and plastic deformation occurring at the polymeric core which can be seen in the case of Prodisc-L implant that was retrieved

Despite the higher stresses in the Disc+FSU model, the predicted total wear was still lesser than the Disc alone test case. According to Archard’s law, the wear rate is not only a function of the contact stresses but also the slip/sliding distance at the interface. The slip distances were lesser by a factor of 3.3 in the case of the Disc+FSU model. The slip distances were smaller due to the stabilizing effects of the spinal structures like the facets and the ligaments and hence, a reduction in volumetric wear. Additionally, due to the disengagement of the implant surfaces, the relative slip values were reduced.

In our Disc+FSU model, although the motion profile was the same as that of the Disc only case, the presence of other spinal structures (like the facet, annulus, and ligaments) has changed the kinematics of the system. These differences most likely contributed to the differences in the wear predictions.
5.4 Effect of Facets and Ligaments on Wear (Prodisc-C)

Post facetectomy, the lift-off phenomenon reduced 20 times in comparison to Disc+FSU model. The reduction in lift-off led to an increased contact area and uniformly distributed stress pattern and subsequently, the maximum stresses went up by 10MPa. Additionally, the slip values increased by 1.8 times in comparison to the Disc+FSU test case. This resulted in increased linear as well as volumetric wear in comparison to the Disc+FSU test case.

It can be concluded that facets play a significant role in the reduction of wear. Apart from the facets, lift-off is a function of the muscle forces that was simulated as a follower compressive load in the model. If separation occurs at the device interface, it will be detrimental for the proper functioning of the device. Past studies on THA have reported the occurrence of micro separation at the articulating interface [143, 144]. Micro-separation in THA is detrimental and it cannot be ruled out at the disc interface *in-vivo*. It has been reported in a recent study [131] that lift-off is more common with larger radii implants, as smaller implants resist this, causing high shear loads at the bone-implant interface. Lift-off might eventually lead to the damage of the articulating surface, leading to excessive wear. The boundary conditions in a simulator set-up and the corresponding Disc alone simulations are well distributed and predictable, primarily because the machine‘s center of rotation is always matched to the device‘s center of rotation. However this is not the case in an *in-vivo* scenario wherein the artificial disc is affected by the remaining spinal structures and a host of other factors such as surgical variables, patient‘s activity level and changes in muscle function. Addition of the ALL/PLL or ALL+PLL did not lead to a significant difference in wear rates.
When all of the ligaments, facets and follower loads were removed, the wear pattern resembled the simulator scenario (Disc Only) and was more uniformly distributed [Figure 5-8]. The lift-off phenomenon was absent and the slip values were doubled in comparison to Disc+FSU test case.

![Disc Only vs Disc+FSU](image)

Figure 5-8 The difference in wear pattern for the Disc Only versus Disc+FSU (Facetectomy+No ligaments +No Follower load) test case. The patterns are more comparable unlike the Disc+FSU test case where the wear contour was lopsided.

This further proved our hypothesis that facets and the follower load were the primary reasons causing the differences in wear pattern. Nonetheless, for this implant, anatomical structures had a positive impact on the wear of the devices and aided in mitigating the wear phenomenon. Effective muscles and ligaments also help in reducing the wear. These differences most likely contributed to the differences in the wear predictions and hence, the surgical procedures should be planned accordingly and carefully.

### 5.5 Effect of Malpositioning of the Device (Prodisc-C)

Placement of the device anteriorly led to an increase in the maximum value of the von Mises stress. However, posterior positioning led to a uniform stress distribution over a larger contact surface. Moreover the slip/sliding distance computed was not significantly
higher in comparison to anterior positioning. Thus, maximum wear was reported during posterior positioning.

This malpositioning parametric run clearly demonstrates that wear is sensitive to the device placement. Dooris et al.\cite{75} suggested that anterior placement of the device led to increased facet joint loads in compression and extension. Incorrect positioning of the device might lead to impingement, causing a torque at the bone-device interface, increased wear and risk of dislocation\cite{145}. This has been further proved by Choma et al., wherein the device was retrieved due to malpositioning, which further led to impingement wear\cite{15}. In anterior placement, the implant would rather behave as a fusion cage system, and this would translate to reduced motion at the implanted level. On rerunning the simulations using moments (1.5Nm of constant moment and follower load used to simulate flexion, extension, bending and rotation separately) to measure the motion at the implanted level, it was found that anterior positioning led to significant decreases in motion for all the modes, especially during extension loading mode. In spite of the increase in von Mises stresses that were seen in the case of anterior positioning, the decreased slipping/sliding led to an overall decrease in wear when compared to the posterior test case.

However, the overall motion computed for the ball-on-socket Prodisc-C implant was much smaller in comparison to the values reported in the literature \cite{146, 147}; despite the implant size being chosen carefully, the implant could have been larger in comparison to the allowable disc space, resulting in constrained motion. Moreover, even though the design of the implant was similar to the Prodisc-C, it is difficult to say whether the dimensions were the same as that of the original implant.
5.6 Effect of Load versus Motion Control (Prodisc-C)

After converting all of the boundary conditions into the form of moments instead of displacements as specified by the ASTM/ISO standards, the overall motion that was observed visually through the viewport and compared to the displacement test case were reduced significantly. It should be noted that the ASTM standard specifies 2.0, 2.0 and 4.0Nm for flexion/ext, bending and rotation respectively as being equal to ±7.5°, ±6.0° and ±4.0° in displacement control mode. During static test cases, the motion values were calculated with a moment of 1.5 Nm in all modes (lesser than the values suggested by ASTM standard). However, the motion angles were not close enough to the values suggested in the displacement control mode. Nevertheless, as mentioned earlier, the overall motion computed for the ball-on-socket Prodisc-C implant was much smaller in comparison to the values reported in the literature [146, 147]; the size of the implant, though chosen carefully, could have been larger in comparison to the allowable disc space which may have resulted in constrained motion. The ROM for the spinal unit is directly specified in the displacement control mode whereas the ROM is deduced from the equivalent moments in the load control mode. So during the displacement control mode, the spinal unit is made to move through the exact ROM as specified, unlike the load control methodology wherein the equivalent moment is applied to reach a certain ROM.

Lift-off, which was observed during the displacement controlled simulations, was not observed during the moment controlled test case. The maximum von-Mises stress was reduced 5 times and the stress contour was also circumferential. This resulted in a difference in the wear pattern for the load controlled test case. Due to the reduced overall
motion, the slip values were reduced a significant 9.5 times in comparison to the
displacement test case and that led to an overall decrease in the wear rate, both linear and
volumetric. In a real life scenario, it might be difficult to say whether the spine operates
under the load control or displacement control conditions. The load control methodology
is used during cadaver testing of motion segments and is a well accepted procedure
among researchers. However, it might be feasible to use the displacement control mode
for wear studies to ensure exact ROM values during the test. It might be interesting to
simulate lower displacement values to match the equivalent wear rate reported by the
load control mode.

5.7 Disc versus Disc+FSU (Prestige)

The findings from the Prodisc-C (metal on polymer implant) indicate that in vitro
wear simulations represent a harsher environment. The Disc only test case reported a
higher wear rate in comparison to the Disc+FSU model. However, the simulations of
Prestige (metal on metal) implant suggest otherwise. This difference in wear behavior
could be attributed to the differences in the implant design. The lift-off phenomenon was
observed for both devices. It was more pronounced in the case of the Prodisc-C. The ball
on socket (Prodisc) implant separated by 0.06 mm while the ball on trough (Prestige)
implant disengaged by half of that distance. The lift off phenomenon led to stress
concentration and eventually caused one-sided wear for the Prodisc-C.

In comparison to the socket design of the Prestige, the trough feature in the
Prestige disc allows translational motion in addition to the rotational motion between two
components of the artificial disc. This resulted in a reduced lift-off phenomenon. The
maximum von Mises stress for the implanted model was less in comparison to the disc only test case, but the stress distribution was uniformly distributed over a larger contact area. According to Archard’s law, the wear rate is a function of not only the contact stresses but also the slip/sliding distance at the interface. The slip distances were larger by a factor of 5.2 in the case of the Disc+FSU Prestige model in comparison to the standalone test case. The slip distances were larger due to the increased translational motion which was observed in the implanted test case and hence an increase in both volumetric and linear wear rate.

The wear contour for the Disc only as well as the Disc+FSU Prestige model resembles the in vitro and the retrieved implant wear patterns, respectively, as depicted in Figure 5-9 [148]. A study on the same device was performed by Kurtz et al. and the results of this study are presented for comparison in Figure 5-9 adapted from his presentation[148].
Figure 5-9 (a) Depicts the wear pattern observed in an *in vitro* simulation versus a retrieval test case[148] (b) Depicts the wear pattern observed in an in disc alone test case versus Disc + FSU as computed during this study

In another study based on the same implant by Anderson *et al.* the device was tested in a simulator for 315000 cycles. The implant showed a significantly higher wear rate in comparison to a retrieved implant after 39 months. It should be noted that the authors equated 315000 cycles in a simulator to 6 months *in situ*. Nevertheless, it is debatable whether the time frame in a simulator can be directly converted into real time *in situ*. In a highly referenced work by Hedman *et al.* [149] 125000 flexion/extension bends were used to simulate wear for a year, but there was no mention of rotation or bending. If the work of Anderson *et al.* is put on the same time scale as Hedman *et al.*, 315000 cycles of *in vitro* testing would translate to 2.5 yrs or 30 months *in situ*. In another study [20], *in vitro* results for 1 million cycles were compared to 3.3 yrs *in vivo*. The average surface roughness of the retrievals and *in vitro* tested components were computed to be 0.12 µm
and 0.16 µm respectively. This difference was still not substantial enough to argue that standard *in vitro* tests for 1 million cycles replicates an *in vivo* scenario.

Most of these retrievals were conducted within a span of a few years. Additionally, as seen during the computational modeling, the initial wear rates (up to 1 million cycles) for the Disc only and the Disc+FSU were not as significantly different when compared as shown in Figure 5-10. The Disc+FSU reported slightly higher wear rates, but the differences were marginal. The differences exist post 750,000 cycles and hence, comparing short term retrievals to *in vitro* simulations fewer than 1 million cycles might not be correct.

![Figure 5-10 Linear wear depth computed for Disc only (Prestige) and Disc+FSU (Prestige) within 1 million cycles at intervals of 250,000 cycles.](image)

Figure 5-10 Linear wear depth computed for Disc only (Prestige) and Disc+FSU (Prestige) within 1 million cycles at intervals of 250,000 cycles.
Until long term retrieval data for these devices are available, it is difficult to draw a comparison between the *in vitro* and *in vivo* test scenario. Thus FE based predictive wear models might enable us to bridge the gaps until more long term retrieval data is obtained.

### 5.8 Effect of Facets and Ligaments on Wear (Prestige)

The comparison of the Disc versus Disc+FSU test case revealed that contrary to our previous conclusion for Prodisc-C, the ligamentous model led to an increased wear rate, which was attributed to the disc design leading to reduced lift-off. In order to understand the role of each of the spinal ligaments, they were sequentially added or removed from the existing FE model. The addition of the ALL/PLL did not lead to significant increase in wear rates, but the addition of both the ALL+PLL led to a much higher wear rate. This was primarily because of an increase in the contact stresses by 8 MPa.

The addition of the PLL precipitated the appearance of a wear scar at the posterior edge of the trough due to localized stress concentration. This stress concentration could be attributed to the edge loading/impingement caused by the addition of the PLL. On removal of the facets, the lift-off phenomena was reduced but still existed. This led to a decrease in the translational motion and a slight decrease in slip values. The von Mises stress increased by 15 MPa; thus, the insignificant reduction in sliding distance was compensated by an increase in the stresses, leading to a slight increase in linear wear and volumetric wear. On removal of all the ligaments, facet joint and the follower load (replaced by a compressive preload) the wear pattern resembled that of the Disc only test case. The stresses, however, increased by 21 MPa. The lift-off phenomenon was absent, and the sliding reduced two times in comparison to the Disc+FSU test case for the
Prestige device. This could be explained by complete removal of the lift-off phenomenon, which was compensated for by increased stress. Thus, due to the absence of lift-off and reduced translational motion, the wear contour matched that of the Disc only test case. However, increased stress led to a slight increase in the linear wear, while the volumetric wear increased 2.5 times. This again confirmed our previous conclusion that the lift-off phenomenon was due to the follower load which was used to replicate the effect of the muscles *in vivo*. Even though the implanted test case represented a harsher environment for the device, the addition of soft tissues still had a positive impact in terms of mitigation of the wear phenomenon. This could be explained by the further increase in the volumetric wear on removal of all the ligaments and facet joint.

5.9 Effect of Malpositioning of the Device (Prestige)

Dooris *et al.* [75] suggested that anterior placement of the device led to increased facet joint loads in compression and extension. These findings suggest that if the implant is placed posteriorly within the disc, then the spinal stiffness will be restored and facet loads will be maintained at pre-implantation levels.

The motion for the various implanted positions during the static test run (1.5Nm of constant moment and follower load used to simulate flexion, extension, bending and rotation separately) was compared. The ROM values were in line with the values reported in the literature [146, 147]. Anterior/posterior positioning of the implant led to posterior edge wear, which was not seen during the neutral test case run. Additionally, there was no significant difference in the sliding distance amongst different test cases. This could be attributed to the significant increase in extension mode, in comparison to the neutral
position, when the device was moved anteriorly or posteriorly. The increase in extension could have led to edge loading and eventually posterior edge wear. It was found that there were no significant changes in either linear or volumetric wear for anterior/posterior placement of the Prestige device. In summary, despite the lack of a significant difference in wear when the device was moved in A/P direction, posterior edge wear was seen for both positions.

5.10 Effect of Material on Wear

It was concluded that due to the differences in designs, the implanted case of the Prestige device yielded a higher wear rate when matched to the disc only test case. This was not the case in the instance of the Prodisc-C. To further test the hypothesis of the metal-on-metal Prestige device, the material couple was converted to a metal-on-polymeric device. The trough of the original Prestige device was assigned the material properties of UHMWPE, similar to the polymeric core in Prodisc-C (Young’s modulus = 1400 MPa, Poisson’s ratio= 0.46). The Disc and the Disc+FSU test cases were re-run with the new material properties. The findings of these test runs proved the hypothesis that the disc design was the primary reason for the difference in findings of the Prestige and Prodisc device. Additionally, there was no significant difference for the Disc only test cases for both material combinations. Thus the implanted test cases reported a higher linear wear than the stand alone test cases for a different material couple. Interestingly, the polymeric wear for both the implanted and standalone cases were smaller than the metallic wear that was reported.
It has previously been shown by Bushelow et al. [150] that in case of lumbar discs, polymeric wear is 3-4 times less than the metal wear rate, contrary to 10-50 times reduction as shown in THA. Bushelow et al. [150], compared the poly versus metal for a ball on socket versus ball on trough design [Figure 5-11 (a)]. Similarly when the cervical discs used in this study were compared, metal on metal combination led to a decrease in volumetric wear by 85 times as depicted in Figure 5-11 (b).

Figure 5-11 Change in volumetric wear due to shift in material couple (a) Data reported by Bushelow et al. [150] to compare the changes in TDA versus THA (b) Comparison of volumetric wear for Prodisc-C and Prestige (c) Comparison of volumetric wear for Prestige with different material combinations (d) Comparison of volumetric wear for Prodisc, Prestige and polymeric Prestige under implanted condition.
Thus it was difficult to discern whether this difference was due to the material combination or the designs. So this enabled in comparison of the material combination keeping the design constant. It was seen that with the design being constant, metal-on-polymer combination led to a decrease in wear rate by two times [Figure 5-11(c)]. Moreover when the implanted test cases were compared with each other, the difference in wear rate was not substantial enough to draw a conclusion.

Thus it refutes the claim by researchers that metallic wear couples are always superior to a metal-polymeric (MP) combination. Thus, metal on metal (MM) could be a better combination for THA, not for TDA. Superiority of metal on metal could be true during an *in-vitro* test, but might not hold true in an *in-vivo* setting. This could be explained by higher stresses on the contact area for the Disc (MM) +FSU in comparison to the Disc (MP) +FSU. Also ball on trough design could be much better suited for MM than MP. Moreover it is too simplistic to look at just the material couple or just the design. It is important to consider the location of the implant and the impact the surrounding anatomy and physiology will also have on the material couple and design.

5.11 Effect of Load versus Motion Control (Prestige)

On converting the existing displacement boundary conditions to moments, as specified by the ASTM standards, the overall motion was reduced significantly. Lift-off, which was observed during the displacement controlled simulations, was not observed during the moment controlled test case. There was no significant difference in the maximum von Mises stress value but the stress contour was different. The stress was distributed over a larger surface area for the displacement control test case scenario in
comparison to the moment controlled simulation. This resulted in a difference in the wear pattern for both the cases. Due to the reduced overall motion (that was observed visually through the viewport and compared to the displacement test case) and the absence of the lift-off phenomenon, the slip values were significantly reduced by a factor of three which led to an overall decrease in both the linear and volumetric wear rate. The cumulative wear trend increased linearly contrary to the peaks which were observed during the displacement control mode. It should be noted that the ASTM standard specifies 2.0, 2.0 and 4.0Nm for flexion/ext, bending and rotation respectively as being equal to ±7.5°, ±6.0° and ±4.0° in displacement control mode. During static test cases, the motion values were already calculated with a moment of 1.5 Nm in all modes (lesser than the values suggested by ASTM standard). However, the motion angles were not close enough to the values suggested in the displacement control mode. Additionally, the ROM values were in line with the literature reported values[146, 147].

In the displacement control mode, the spinal unit moves through the exact ROM as specified unlike the load control methodology wherein the equivalent moment is applied to reach a certain ROM. Thus the ROM for the spinal unit is directly specified in the displacement control mode whereas the ROM is deduced from the equivalent moments in the load control mode. In an in vivo scenario, it is difficult to determine whether the spine operates under load control or displacement control conditions. The load control methodology is used during cadaver testing of motion segments and is a well accepted procedure among the researchers. However it might be feasible to use the displacement control mode for wear studies to ensure that the exact ROM values are used during the
test. It might be interesting to simulate lower displacement values to match the equivalent wear rate reported by the load control mode.

5.12 Summary

Four different aspects have been addressed separately in this dissertation. The effects of spinal structures implant positioning, input conditions and design/material combinations were tackled separately in each section. This section is an attempt to combine the discussion of the previous sections to present an insightful perspective.

It was observed that the simulations using stand alone devices versus devices implanted in a ligamentous FE model had significant differences. The lift-off phenomenon was observed during extension and bending, which was found to be due to the facets and the follower load which emulated the effect of muscles. The implanted test case for the Prodisc-C generated lower wear rates and an unbalanced wear distribution in comparison to the standalone simulation. On the other hand, the implanted test case for the Prestige device demonstrated a higher wear rate in comparison to the standalone device scenario. It was hypothesized that this difference was due to the facets and the follower load which was further confirmed when the facetectomy and no ligaments + no follower load test case resembled the standalone device scenario.

Furthermore, it was assumed that the differences observed in the case of the Prestige and Prodisc-C devices were due to the differences in design. Keeping the design constant, when the Prestige implant was converted to a metal-on-poly disc, it was observed that the implanted test case still reported higher wear. Thus, it was concluded that ball-on-trough design was the primary reason for this difference as it led to an additional translational
(slip/sliding) motion for the implanted test case. The design of the implant had a greater role to play in comparison to the material couple combination. When the design was held constant, the reduction in the wear rate for the material couple as it was switched from metal-on-metal to metal-on-poly was not as significant as that which was observed in the case of total hip arthroplasty. This was further supported by the findings of Bushelow et al. [106].

Furthermore, the effect of surgical procedures was studied by changing the position of the implant within the disc space. Although there was no significant finding for the Prestige disc, posterior positioning led to a higher wear rate in the case of the Prodisc-C. Additionally, anterior positioning led to a marked reduction in overall motion at the C5-C6 level.

Load displacement testing methodology forms the basis of spine biomechanics evaluation in vitro. This ensures constant loading across the levels and does not constrain the motion of the spinal segment [125]. Displacement controlled methods, on the contrary, enable application of rotational and translational inputs derived from the in vivo calculated motions. Both ASTM and ISO wear testing standards prescribe the displacement control test mode. ASTM standards, however, define an equivalent and alternative load control data set for usage. However, on shifting to the load controlled input, the segmental motion was significantly reduced as well as the overall wear rate. It remains difficult to determine which methodology predicts wear closer to an in-vivo scenario. It is probable that a displacement controlled system might generate a worst case test scenario. The approaches presented in the current work guide us towards the design of a realistic testing methodology that is capable of replicating in vivo wear patterns
comparable to those seen in retrievals. Experimental validation of mathematical models is a crucial step to prove their credibility, and to ensure that they represent the physics of the real world. At present it was not practical to experimentally validate the Disc+FSU wear pattern due to the inherent limitations of the present generation wear simulators. For instance, the limited space at each station precludes specimen placement and testing. Furthermore, our own attempts to undertake such tests revealed that the device endplate separated from the bony endplate of the FSU after a few thousand cycles of testing, forcing thus disrupting the experiment. To achieve this objective one would require redesigning of the wear simulator that would emulate a variable center of rotation, a strengthening of the implant bone interface, etc and such other modifications.

Retrieval analysis of explanted devices from humans is being conducted to understand the performance of these devices and to provide information related to both implant and biomaterial-related failure modes. However, many of these retrievals reflect failure modes that are not observed during bench top simulations and thus point us towards the deficiencies associated with these test systems. Additionally, these experiments are time consuming, expensive and labor-intensive procedures. One million cycles of test simulation takes 12 days at a frequency of 1 Hz and as a result, many groups have resorted to using a frequency of 2 Hz. Both ASTM and ISO standards allow a frequency up to 2 Hz. In the absence of retrievals, it is difficult to choose a frequency that more closely mimics the physiologic state. In a study by Kettler et al. [151], a frequency of 2 Hz led to an increase in the wear rate in comparison to a frequency of 1 Hz for the same number of cycles. Additionally, data variability among different laboratories and testing stations cannot be ruled out. In spite of the fact that experimental data are
indispensable, alternatives need to be explored. These could range from modern day wear simulators to finite element based predictive modeling techniques to simulate clinical scenarios.

Increases in computational speed have led to the development of complex FE packages. Commercially available packages are capable of handling complex geometries and non-linearities with respect to geometry and materials, which are present in physiological structures such as the cervical spine. This allows for more accurate modeling of the spine with fewer modeling assumptions. In such models, the effect of individual variables can be judged independently, leading to an understanding of the role of that each parameter has on the final outcome. Along these lines, the predictive modeling approach based on the finite element technique presented here serves as an excellent design tool for parametric analyses. The wear code that has been implemented requires little or no modification for different geometries or material couples. Thus, it has opened up a new arena such that the same mathematical algorithm can be used to simulate wear in the knee, hip, and shoulder implants as well as the natural synovial joints.

5.13 Future Work

The predictive model in this dissertation incorporates the osteoligamentous components of the lower cervical region with a follower load to emulate the effect of muscles. It was also concluded that muscles have a significant role to play in terms of the wear performance of the implant. Thus, incorporation of muscle forces into the model may be able to better delineate its effect on the wear outcome. The current single
segment model could be extended to include the upper cervical region which would allow for a better understanding of the lift-off phenomenon. As mentioned previously, the current wear model can only incorporate wear at one interface (inherent to the software that was used). Thus, multiple wearing surfaces in a single simulation would be an interesting direction.

Additionally this finite element model is on a macro-scale. A micro level approach to generate/create wear particles through a numerical approach would be interesting. Inclusion of other wear models such as adhesive and fretting wear apart from abrasive wear could be incorporated in the wear subroutine by modifying the governing equation or by introducing newer variables in the existing mathematical model. Another modification could include the effect of creep and combine its effects with the existing wear code. Although there are existing alternative forms of the wear model, Archard’s wear law has been used here because of its simplistic approach and ease of implementation, in spite of its inherent limitations. Thus introducing a time variant factor in the Archard’s equation to capture the non-linearities in the wear phenomenon would be a major breakthrough in the field of mathematical modeling of wear.

As mentioned previously, the experimental standards have inherent limitations. They do not dictate the interpretation of the results and leave it solely on the user to define the acceptance criteria. Despite these standards being flexible enough to enable testing of more than one kind of design, it is not a “one size fits all” kind. Thus, they require modification or adaptation by the user based on the device design and usage. The hip and knee wear standards prescribes motion profiles as per the gait cycle while the spine wear standards describes a more generalized motion pattern which might not
represent an *in vivo* scenario. The number of cycles and the motion patterns for the spinal column during activities of daily living is still unknown. Thus simulation of complex *in-vivo* loading environments during an *in-vitro* test for spinal implants might be near impossible[152].

As clinical experience with newer implants grows in pace with iterative design modifications, it becomes increasingly important to understand the mechanics and long-term wear behavior of the implants. A logical approach would be the design of a more realistic experiment which is capable of emulating the activities of daily living with respect to the spinal column and thus replicate *in vivo* wear.
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158. *Endolab spine wear simulator.*

159. *4-specimen/4-DOF Spinal Disk Fatigue/Wear Simulator.*


Appendix A  Wear Basics

A.1: Types of Wear

Wear can be broadly classified into some categories such as: abrasive, adhesive, fatigue, fretting, erosive and corrosive wear [153]

- Adhesive wear: This results from strong adhesive forces at the interfaces. An asperity of one surface fuses or locks up with the asperities of the opposing surface Figure B-1 (a). Subsequently these asperities are ruptured due to relative motion leading to particle formation. Fragments pulled from one surface adhere to the other [154].

- Abrasive wear: Hard protuberances on one surface are forced to move against another surface Figure B-1 (b). This leads to series of grooves being formed on the surface and eventually particles are loosened or dislodged from the surfaces. Third body particles which are entrapped also acts as an abrasive and leads to further wear [141].

- Fatigue wear: Exists at non-conforming interfaces in form of pitting/rolling wear. Primarily caused due to repeated loading/unloading cycles which led to subsurface cracks or failure Figure B-1 (c). This phenomenon is dominant in brittle materials [154].
- Fretting wear: Primarily caused due to oscillatory or vibratory movement at the contact surface. Cyclic stress at one component leading to fretting wear of the other component is a common phenomenon [154].

- Erosive wear: This is due to impingement of particles on a component or surface which leads to removal of material. This wear phenomenon is observed in components with high velocity flows. The impinging particles lead to denting/fatigue failure of the surfaces [154].

- Corrosive wear: This is a result of chemical reaction at the wearing surface primarily due to the formation of oxides. Sometimes they act as a protective interface, but as they get scraped away, pitting at the interface is observed [154].

Figure A-1 Different kinds of wear phenomenon (a) Adhesive wear (b) Abrasive wear (c) Fatigue wear (d) Third body wear due to entrapment of particulates[155]
A.2: Simulators Utilized for Standard Wear Testing

Pin-on-disc and pin-on-plate machines have been used in biotribological testing for evaluation of material couples under well controlled environmental condition in terms of loading, temperature and lubrication [46]. Further modification of these set-up have given rise to annulus on flat, disc on plate and cylinder in conforming block and tri-pin-on-disc arrangement as shown in the schematic below (Figure B-2 and Figure B-3).

Figure A-2 (a) Reciprocating pin-on-flat (b) pin-on-disc (c) Annulus-on-flat (d) Disc-on-plate (e) Cylinder in conforming block (Used with permission from the publisher) [156]
These devices are called wear screening devices, as they do not represent the specimen geometry of the biomaterials. Simplified specimens are used instead of actual prosthetic joints. However it has become essential to simulate multi-directional motion especially to simulate wear in polymeric implants. In order to conduct performance evaluation of hip, knee or spinal devices joint simulators are required[86]. These simulators are designed to replicate the loading, motion patterns as well as lubrication conditions that are observed \textit{in-vivo}. Thus a wear simulator is a device which causes a prosthetic device to wear in a manner similar to \textit{in-vivo} clinical use under suitable testing environment [153]. These sophisticated machines replicate complex, dynamic conditions to represent physiologic loading conditions. These machines vary in level of sophistication, loading, degree of freedom and number of stations.

Currently there are many equipment options for wear testing, the primary ones which have been used frequently are MTS, Bose and Endolab systems. A comparative description of each of the types of the simulators is listed in Table A.1.
Table A.1 Comparative features of MTS, BOSE and ENDOLAB wear simulator [157-159]

<table>
<thead>
<tr>
<th>FEATURES</th>
<th>MTS</th>
<th>BOSE</th>
<th>ENDOLAB</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of test stations</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>No of soak stations</td>
<td>1 or 2</td>
<td>2</td>
<td>1 or 2</td>
</tr>
<tr>
<td>Source</td>
<td>Hydraulic Pump</td>
<td>Linear Actuator</td>
<td>Hydraulic Pump</td>
</tr>
<tr>
<td>Maximum Flex/Ext ROM</td>
<td>±10°</td>
<td>±10°</td>
<td>+30°/-25°</td>
</tr>
<tr>
<td>Maximum Flex/Ext Torque</td>
<td>15 Nm</td>
<td>±10 Nm</td>
<td>15 Nm</td>
</tr>
<tr>
<td>Lateral Bending ROM</td>
<td>±10°</td>
<td>±8°</td>
<td>+20°/-15°</td>
</tr>
<tr>
<td>Lateral Bending Torque</td>
<td>15 Nm</td>
<td>±12 Nm</td>
<td>15 Nm</td>
</tr>
<tr>
<td>Axial Rotation ROM</td>
<td>±7.5°</td>
<td>±6°</td>
<td>±9°</td>
</tr>
<tr>
<td>Axial Rotation Torque</td>
<td>10Nm</td>
<td>±10 Nm</td>
<td>15Nm</td>
</tr>
<tr>
<td>Axial Loading</td>
<td>4000 N</td>
<td>2000N</td>
<td>5000N</td>
</tr>
<tr>
<td>Axial Displacement</td>
<td>±12.7mm/-3.2mm</td>
<td>±5 mm</td>
<td>50mm</td>
</tr>
<tr>
<td>AP Translation</td>
<td>±4.5mm</td>
<td>±4.0mm</td>
<td>±20 mm</td>
</tr>
<tr>
<td>ML Translation</td>
<td>±4.5mm</td>
<td>±4.0mm</td>
<td>±20 mm</td>
</tr>
</tbody>
</table>

All of these simulators are capable of performing the prescribed wear standards. For Endolab systems however the motions are applied inferiorly while the loads are applied superior to the stations (Figure A-4). In case of MTS (Figure A-5 and Figure A-6) and Bose systems flexion/extension and lateral bending motions are applied superior to the test stations while the axial load and the axial rotation is applied inferior to the station.
Figure A-4 Illustration showing the multi station, multiaxial wear simulator from Endolab, comprises of six test stations and two soak/control station[158]
Figure A-5 Illustration of six station MTS bionix spine wear simulator[157]

Figure A-6 A closer look at the MTS multi station wear simulator, with one soak station and six test stations[157]
Preparation of the test specimens involves extensive cleaning and drying procedure as per the ASTM/ISO standards, Figure A-7. The hydrophobic/hydrophilic nature of the material should first be determined before the test set-up. Hydrophilic samples should be pre-soaked prior to testing and then the initial weights should be recorded accordingly.

Figure A-7 Flowchart depicting the steps during pre and post preparation of a wear study

In addition to the sample preparation, choice of the lubricant (test fluid) plays has an important bearing on the wear outcome. Lubrication conditions are very critical in terms of replicating the wear phenomenon. For instance increased protein precipitation due to an increase in temperature might lead to an effective protection against the wear. So the right lubricant as well as the optimum temperature should be maintained during simulations. Protein concentration, volume as well as temperature play a major role in dictating the lubrication regime for these kinds of tests.

A study by Clarke et al[160] reported that as the protein concentration of the serum was increased from 17-70 mg/ml the wear rates increased by 200%. The albumin/globulin ratio also had a major role to play because increased ratio led to an
increase in wear rate. There was also an increase in wear magnitude of up to 40-100% when the volume of serum was increased by 3 times. Unlike the synovial joints not much is known about the fluid volume in the disc space. It could be just a pseudo capsule or a merely wet environment. Though retrievals suggest presence of protein however the exact protein composition is unknown[18].

Another critical aspect of these tests is the fixturing interface for the device samples to fit into a simulator. The simulator's COR should always match with the sample COR and that is significant for test to be conducted in a right fashion. The fixture design might vary from test to test depending on the design of the implant as well as the measurable test parameter.

These controlled bench top testing however provides us with an insight of a certain aspect of design, material variables associated with the prosthesis. One of the challenging issues to tackle is extrapolation of short term results to long term predictions. Based on the findings of Hedman et al.[149] in a year there are 125000 bends in the sagittal plane which means a 10 million cycle test run corresponds to 8-10 years of device usage. However there are also speculations that it might instead translate to 80 yrs of device usage as these tests are conducted keeping in mind a high factor of safety. Test fluid collection and particulate analysis are the two critical steps during wear analysis.

Test fluid samples are prepared by adding serum digestion solution to the sample collection bottles. The fluid is then filtered through a 0.2 µm polycarbonate membrane using vacuum filtration techniques to collect the wear debris. Using Computer Controlled Scanning Electron Microscopy (CCSEM), particle sizes, morphology and their elemental constituents are identified. In post CCSEM analysis, particles are classified and placed
into various particle type categories based on their elemental constituents and morphologies. Particle mass was calculated by assigning a density value to the particles.

It has been observed in the past that substantial number of wear particulates could pass freely through filter membranes. This led to underestimation of particle number and over estimation of particle size. So in order to assess the efficiency of the test fluid collection and wear debris collection, an isolation and recovery validation study should be conducted[161]. This enables us to determine a calibration factor which can later be applied to all gravimetric measurements to obtain the actual wear debris mass.

A known quantity of artificially generated particulates consisting of a full spectrum of sizes up to a maximum are immersed in diluted bovine calf serum. This is added to the station assemblies and cycled. This is followed by the routine fluid collection procedures, as described previously. The collection efficiency rate was calculated from the difference of the initial and retrieved particulate mass from all validation samples. The measurable variables post wear testing involves computation of linear, volumetric, gravimetric and dimensional wear analysis the details of which are listed below.

A.3: Wear Measurement Parameters

A.3.1 Linear wear

As a result of contact geometry the penetration/displacement of one component to another leads to linear wear. An in-vivo wear measurement involves comparison of initial and post surgery radiographs to compute the displacement of one component with respect to another. Linear wear has long been a sufficient method of providing a “quick and dirty” indication of surface degradation in which a point is located and that point is
tracked to a different location thus indicating wear has occurred. Osteolysis in radiographs is often marked by a focal or an expanding radiolucency at the bone-implant interface.

**A.3.2 Volumetric wear**

It represents the volume of material removed from the articulating surface. It can be directly measured by sampling of the wear debris particulates from the test fluid. A volumetric wear technique also takes into consideration the dimensional changes due to creep as well as wear. Linear wear is converted into volumetric wear by multiplying it with the surface area in consideration. Gravimetric wear is often converted into volumetric wear values by using the density of the material.

**A.3.3 Gravimetric wear**

In bench-top studies wear is measured using gravimetric methods in which the samples are weighed pre and post test simulation. Weight change measurement is a classical approach that is still being used during simulations. These measurements are as per ASTM F2025 and F1714 however human error cannot be ruled out during this process thus pre-calibration or validation should be conducted.

Protein from the test media (bovine serum) gets denatured as the temperature rises due to localized heating effect at the interacting surfaces. This might result in an overall mass gain instead of an expected mass loss. A similar phenomenon was observed for a study during the wear testing of a polymeric pedicle based screw system as shown in Figure A-8 [162]. Because the fixture design prevented disassembling, as it might have caused
damage to the implant, complete protein removal and weighing of individual devices at each million cycle interval was not possible.

Figure A-8 Embedded protein deposits in the polymeric bumper of Percudyn™ post 10 million cycles of wear simulation[163]

This resulted in an overall mass gain instead of an expected mass loss in the analytical mass measurements conducted for this study. Thus due to the protein depositions, physically measured mass loss measurements could not be correlated to those obtained from particulate analysis. This further emphasizes the need for using particulate analysis for computing the gravimetric mass loss since it provides greater accuracy in the wear mass results.
A.3.4 Dimensional measurement of wear

This is another simplistic technique used for determination of dimensional changes post simulation. These measurements might include both wear as well as creep. This has been a proven technique to measure the thickness of acetabular cup and could be extended to other devices. Single point thickness measurements are carried using, and after the device is held in position, a micrometer or a vernier caliper might be used to measure the change in height. An important assumption used here is that direction of wear lies along the direction of application of load. The creep component is usually subtracted using the deformation obtained from the control specimen.

The tools and techniques that are primarily used for the measurement of wear parameters are described in detail in the following section.

A.4 Techniques Utilized for Measurement of Wear

A.4.1 Light microscopy

The samples are usually observed in normal white light and polarized light. In normal light opaque or stained particles, or particles which have their own color is observed while small transparent particles cannot be seen. In polarized light birefringence is the main concept which comes into play which is inherent to anisotropic crystals. Substances showing birefringence properties are sutures, polymers, bone, cartilage etc. In case of dense particles such as metal however crossed polarization filters are used. A high angle of scatter is observed at the edge which leads to the formation of intensity gradient. This in turn appears as yellowish or reddish violet lines at the edges of the large particles and
as a surface light effect for the smaller ones. The particle sizes can also be measured using the eye piece screw micrometer and thus calibration of this eye piece is necessary in which the conversion units are finally converted into units of length. Agglomeration of smaller particles as well as particle orientation in different planes might lead to erroneous data[156].

**A.4.2 Electron microscopy**

For particles smaller than 0.5µm electron microscopy is the preferable method. The magnification factor can go up high as 250,00x and thus it gives us an overview of the arrangement of the particles even at cellular levels. However a very small rather thin section can be analyzed due to the lack of topographical orientation of the tissue in question. Thus this method does not give us reliable information of the tissue from which the particles has originated. It is thus primarily utilized in understanding of submicroscopic changes in the structural properties of the cell. Thus the tissue sections needs to be first analyzed using light microscopy followed by electron microscopy in order to gain the overall information of the tissue structure as well as the particles embedded within them.

**A.4.3 Scanning electron microscope**

In this case the surface of the object is illuminated instead of image formation due to transmitted beam as seen in light and electron microscopy. This not only provides a wide range of magnification from 20-20000, but also a good spatial resolution and depth of focus. The tissue sections are prepared with paraffin method, and they are embedded in a good electrical conductor such as aluminum or gold in order to prevent thermal damage
due to bombardment of electrons. The concept involves a highly accelerated beam of
electrons (100 angstrom diameter) in a linear scanning fashion within a vacuum
environment. The image is produced due to secondary electrons produced from the
surface and are further recorded by means of a scintillating crystal detector in the
recording tube[156]. An electron microprobe can also be connected as an ancillary tool to
undertake non destructive microanalysis of the sample.

An X-ray fluorescent radiation is generated from the surface which can be analyzed
to understand the type of the element (wavelength) and amount of the element (intensity)
present using energy dispersive or wave dispersive detector. In a recent study conducted
[162] the polymeric device wear particulates were separated from the polymeric fixturing
material using EDS. During the wear simulation, both the device as well as the fixture
particulates was generated in the serum. During particulate analysis, the shape and size of
the particulates were computed using SEM, while the elemental spectra from the EDS
enabled separation of fixture particulates from the device particulates, Figure A-9. The
sample preparation is same as that of electron microscopy. The samples are thus studied
first using scanning electron microscopy followed by electron beam probe.
Figure A-9 Elemental Spectra differentiating the polymeric fixture and PCU (device) particulates. (a) Polymeric fixture, (carbon and chlorine spectra) (b) represents PCU (polycarbonate urethane - carbon and oxygen spectra) using EDS

A.4.4 X-Ray diffraction analysis

For non-destructive structural analysis of crystalline foreign material set in the tissue sample X-ray diffraction methods is used. The diffracted X-Ray beams are analyzed based on their angular distribution. These angles are further dependant on the size and shape of the particulates. The diffracted beams are compared with that of known materials and thus unknown substances can be identified using this technique. Thus two alloys of same material will produce a similar diffracted beam and thus the elemental components can be easily identified using this principle.

A.4.5 Spectral analysis and atomic absorption spectrometry

This method is primarily used to determine the concentration of an element in the sample. The main concept applied here is that the electrons of the atoms can be promoted to higher orbitals for an instant by absorbing a set quantity of energy (a quantum). This
amount of energy is specific to a particular electron transition in a particular element. Spectral analysis is carried out using a platinum crucible where the tissue is incinerated. During atomic absorption however the tissue is digested using acids like sulphuric acid or nitric acid. The final values are either expressed in parts per million or percentage weight.

### A.4.6 Holographic interferometry

Dual index holographic contouring (DIHC) is the most commonly used methodology. In this method the sample is immersed in transparent liquids of refractive indices $n_1$ and $n_2$. The exposure of the object (object beam) is made through a slit or window in the tank for each individual liquid. The interference fringes which are then observed on the object surface[156]. A simplistic diagram is shown in Figure A-10.

![Figure A-10 Object set-up for dual index holographic contouring (Used with permission from the publisher)[156]](image-url)
The height difference (Δh) is computed between the fringes such as $\Delta h = \lambda / 2 (n_1 - n_2)$. Thus DIHC method can be used to compute wear at various intervals, as well as measuring the surface roughness during the simulations. A schematic of the DIHC set-up is shown in the following diagram, Figure A-11. This method can also be improved upon by utilization of one refractive index, and two wavelength of light beam.

![Diagram of dual index holographic contouring](image)

Figure A-11 Experimental set up for dual index holographic contouring (Used with permission from the publisher)[156]

In a similar holographic technique image subtraction methodology is used. In this a real time hologram acts as an image subtraction device. During a double exposure hologram, a phase difference of $\pi / 2$ between the object and the reference beam enables subtraction of two identical images. The area of plastic deformation or wear is estimated by using the reconstructed image by measuring the image intensity of the two reconstructions. It should also be noted that holographic technique measures displacement which includes both creep and plastic deformation. Thus it becomes
essential to use a blank or a control specimen under constant load, such that creep can be solely measured and can be subtracted from the actual reading. The holographic method can be further improved by using lasers and usage of computer digitization.

A.4.7 Radioactivity for wear measurement

This has been a successful technique for wear measurement in moving parts of internal combustion engine. During this process either one or both of the interacting surfaces are activated. The non-activated surface can later be examined for wear, once the active surface is rubbed against it. The activity of the radioisotopes can also be measured in the lubricant as a function of time. However this method could taint the simulator and thus special safety measures should be observed. Also shifting towards thin layer activation holds promise for usage in joint simulators. The thickness of the layer could vary from 10µm - 1000µm can be produced over up to 5cm$^2$ of contact area.

Different sliding surfaces can be activated with different kind of radioisotopes such that $\alpha$ particles are emitted from one while $\gamma$ particles being produced by another. The lubricant can later be analyzed for a particular kind of radiation in order to separate the wear rate from one substance to another. The loss or release of radioactive materials can be used to calculate the volume of material removed during the wear interval and the rate at which removal is occurring. A detailed diagram of the set-up is depicted in the Figure A-12.
A.4.8 In Vivo Radiographic Assessment

Radiographic methods have evolved over the past three decades from manual methods to computer assisted techniques which enables us in computation of wear in vivo. Charnley and Cupic were the pioneers of uniradiographic wear measurement. The distance was calculated by finding the difference between the maximum width of the non-weight bearing area and the minimum (narrowest) measurement in the region of weight bearing. This assumption used out here was that wear was occurring in the vertical direction. Later Charnely and Halley came up with the concept of

Figure A-12 Schematic layout for the measurement of wear using radioisotope technique (Used with permission from the publisher)[156]
duoradiographic measurement using post-operative radiographs. This was computed using the difference between the edges of the head to the cup wire by recent radiograph along the same line [164],[165].

Scheier and Sandel [165] further modified the aforementioned technique by locating a center of the head and then a major axis of the elliptical wire was also drawn. The distance was then measured from the edges of the head to the wire and the center of the head to the axis of the wire. Effect of magnification was also accounted for during this technique.

Livermore[164] further improved upon the existing methods by drawing concentric circles to locate the center of the femoral head and calculation of the shortest distance from center of the femoral head to the acetabular cup. These measurements were further corrected for magnification. Dorr and Wan[165] prescribed a uniradiographic method for metal backed acetabular components. This was calculated as half the difference between the measured distance between the superior aspect of femoral head to superior acetabular rim and the distance between inferior head to inferior acetabular rim.

Pollock et al.[164] described another method in which a dual circle principle was used which involved usage of wear templates. This method is supposedly more useful clinically than many other manual methods that are being used. Of all manual methods being practiced Livermore technique is the probably one of the best as it eliminated the need for referencing the wire marker. Digitization of this technique involved determination of center of the head and the acetabular component. Along this line the manchester x-ray image analysis technique was introduced by Hardinge et al. [164] which would enable automatic image analysis for duoradiographic method. This
involved usage of high resolution camera, copy stand and light box and lines were drawn interactively using software. The basic principles of the radiographic technique are depicted in Figure A-13.

Figure A-13 Radiograph demonstrating the basic principles of computer assisted dual circle technique. The femoral head and the acetabular center are determined on the basis of edge detection and motion of the femoral head center (with respect to the acetabular center) is determined with use of vector analysis \( A \rightarrow B \), \( A \) is the original head center, \( B \) is the head center at the time of follow up. (Used with permission from the publisher) [165]

EBRA technique introduced by Ilchmann et al.[164] was one of the most accurate system compared to others. This technique utilized the use of pencil, ruler and a digitizing table with a computer. Edge detection technique was proposed by Shaver et al. in which edges of the acetabular and femoral head was identified using edge detection filter. Dual circle principle was used to compute the head penetration into the acetabular component.

Similarly a three dimensional measurement technique was devised by Devane et al. in which 3D model of the components was created using the radiographic projections. 2D
wear was computed based on serial radiographs and further 3D wear was calculated by including the penetration component in lateral radiographs. This software was also utilized in computation of the volumetric wear component.

Martell and Berdia came up with a semi-automatic computer assisted technique called the dual circle Hip analysis suite. This method used edge based detection and vector analysis of the radiographs and had a very good repeatability and accuracy in comparison to other computer assisted techniques. Further this method was utilized for computation of three dimensional wear data. A schematic of each of these techniques has been depicted in Figure A-14. Based on the understanding of various radiographic methods, it was summarized that these tools should be more qualitative than quantitative. Moreover addition of computer digitization technique actually did not have a major impact on the accuracy of the system.

![Figure A-14 Schematic depictions of different wear measurements (a) Livermore (b) Uniradiographic (c) Duoradiographic (d) Dorr (Used with permission from the publisher) [165]](image)
A.4.9 Radiostereometric Analysis

Apart from radiographic methods radiostereometric analysis is also another common method for computation of three dimensional micromotion. This was method was originally introduced by Goran Selvik in early 1970s[165]. In this method radiopaque tantalum beads are inserted in the skeleton and the prosthesis in order to keep a track of the device. In order to compute the wear of metal backed acetabular components the markers are placed onto the polymeric liner. In case of non-metallic implants the markers are inserted onto the bone or the peripheral edge of the device. Simultaneous radiographs of the patient are taken and the 3d co-ordinates of the implants are determined over time with respect to the beads. Notable feature of this technique is that the patient is placed in a calibrated cage system. Proximal migration/vertical movement as well as total migration or three dimensional wear is reported using radiostereometric technique.

Baldursson et al [164, 165] were the pioneers in usage of radiostereometric technique for computational of device wear. Various other groups have utilized this technique and there have been variabilities in the reported data. However the common feature was the difference in total migration and proximal migration, which made it obvious that “out of plane wear” did exist. Radiostereometric analysis has also been digitized and its accuracy has been proved by Bragdon et al.[165]. The accuracy and precision of radiostereometric technique has been validated by various groups using mathematical analysis, phantom studies etc. The schematic of this technique is shown in Figure A-15.
Figure A-15  Illustration depicting the principles of radiostereometric analysis. The space surrounding the implant is calibrated with use of a calibration cage containing tantalum markers. Analysis of wear is based on two simultaneous radiographs, each made at an angle of 40° relative to each other. Motion of the femoral head in three-dimensional space with respect to markers on the acetabular component is reported as three-dimensional wear. (Used with permission by the publisher) [165]

This technique is perhaps the best method for measurement of small amounts of wear (penetration) and should be applied to low wear couples. Till date there has been no consensus on the standardized method of reporting in vivo wear. The accuracy of both radiographic and radiostereometric data is dependent on image quality and accurate positioning of the patient. There has been debate on whether standing or supine positions are superior from one another. Some researchers claim to have found differences between weight bearing and non-weight bearing positions while others have refuted such a claim. It should also be noted that though radiostereometric techniques are superior in terms of
accuracy and precision, however expense, calibration and adequate expertise have limited their frequent usage.

Accuracy, precision and repeatability are the important aspects in these measurement techniques. However the most crucial aspect however is delineating the wear rates which are below or above the biological threshold level which play an impact on presence of osteolysis.
Appendix B  Subroutines

B.1 Wear Subroutine UMESHMOTION

SUBROUTINE UMESHMOTION(UREF, ULOCAL, NODE, NNDOF,
$     LNODETYPE, ALOCAL, NDIM, TIME, DTIME, PNEWDT,
$     KSTEP, KINC, KMESHSWEP, JMATYP, JGVBLOCK, LSMOOTH)

include 'ABA_PARAM.INC'

C     USER DEFINED DIMENSION STATEMENTS

CHARACTER*80 PARTNAME

C     The dimensions of the variables ARRAY

C     must be set equal to or greater than 15

DIMENSION ARRAY(1000), JPOS(15), TIME(2)

DIMENSION ULOCAL(*)

DIMENSION UGLOBAL(NDIM)

PARAMETER (NELEMMAX=1000)

DIMENSION JELEMLIST(NELEMMAX), JELEMTYPE(NELEMMAX)
integer index

integer nmax,u

parameter (nmax=2798,u=55)

parameter (nstreamlines=5000)

common /linearwear/WEAR(nstreamlines,100),WEARINC(nstreamlines), jslnodes(nstreamlines), WOUT(nstreamlines,100)

c Open the data file

open(u,FILE='/nfs/proj01/PJS0273/moment/sangs.txt',STATUS='OLD', $ FORM='FORMATTED')

$ FORM='FORMATTED')

c Read the number of points

do i=1,nmax

read(u,1000) jslnodes(i)

c write(7,*)'i', i

enddo

1000 format (I4)

c write (7,*) 'jslnodes', jslnodes
c Close the file

close (u)

LOCNUM = 0

JRCD = 0

JTYP = 1

PARTNAME = '

CALL GETPARTINFO(NODE,0,PARTNAME,LOCNUM,JRCD)

NELEMS = NELEMMAX

CALL

GETNODETOELEMCONN(NODE,NELEMS,JELEMLIST,JELEMTYPE,JRCD,

$ JGVBLOCK)

c ldebug=1

c if (ldebug.ne.0) then

c write (7,*) 'UMESHMOTION'

c write (7,*) 'JELEMLIST '  
c do k1 = 1,NELEMS

c write (7,*) JELEMLIST(k1)
end do

write (7,*) 'kstep ',KSTEP

write (7,*) 'kinc ',kinc

write (7,*) 'kmeshsweep ',kmeshsweep

write (7,*) 'Node',NODE

end if

c write (7,*) 'kmeshsweep ',kmeshsweep

CALL GETVRMAVGATNODE(LOCNUM,JTYP,'CDISP',ARRAY,JRCD,
$JELEMLIST,NELEMS,JMATYP,JGVBLOCK)

CSLIP = SQRT(ARRAY(2)**2+ARRAY(3)**2)

c write (7,*) 'cslip is',CSLIP

CALL GETVRMAVGATNODE(LOCNUM,JTYP,'CSTRESS',ARRAY,JRCD,
$JELEMLIST,NELEMS,JMATYP,JGVBLOCK)

CPRESS = ARRAY(1)

CSHEAR = SQRT(ARRAY(2)**2+ARRAY(3)**2)
c write (7,*) 'cshear is', CSHEAR

do i=1, nstreamlines

    if (((LOCNUM-jslnodes(i)).EQ.0) then

        index=i

    end if

end do

c write (7,*) 'Node is: ', NODE, 'LOCNUM is: ', LOCNUM

c write (7,*) 'Index is: ', index

WEAR(index, KSTEP) = WEAR(index, KSTEP) - (1.9D-13 * CSLIP * CPRESS)

WEARINC(index) = WEARINC(index) - (1.9D-13 * CSLIP * CPRESS)

ULOCAL(1) = 0.0D0

ULOCAL(2) = 0.0D0

if (KSTEP.EQ.3) then

    WOUT(index, KSTEP) = WEARINC(index)

else

    WOUT(index, KSTEP) = WEARINC(index)*250000

endif
C    write (7,*)'linear wear is',LWEAR
C    write (7,*)'linear wear2 is',LWEAR2
C    write (7,*)'ULOCAL(1)is',ULOCAL(1)
C    write (7,*)'ULOCAL(2)is',ULOCAL(2)
C    if ( LOCNUM.eq.6976 .and. abs(TIME(1) -1)<1e-12 )then
C        write (7,*)'linear wear is', WEAR
C        write (7,*)'linear wear2 is', WEARINC
C    endif
if (KSTEP==3.and.kmeshsweep.eq.0.and.abs(TIME(1) -1)<1e-12)then
    ULOCAL( 3 )=WEARINC(index)
extif(KSTEP==4.and.kmeshsweep.eq.0.and.abs(TIME(1)-1)<1e-12)then
    ULOCAL( 3 )= WEARINC(index)*250000
elseif(KSTEP==5.and.kmeshsweep.eq.0.and.abs(TIME(1)-1)<1e-12)then
    ULOCAL( 3 )= WEARINC(index)*250000
elseif(KSTEP==6.and.kmeshsweep.eq.0.and.abs(TIME(1)-1)<1e-12)then
    ULOCAL( 3 )= WEARINC(index)*250000
elseif(KSTEP==7.and.kmeshsweep.eq.0.and.abs(TIME(1)-1)<1e-12)then
    ULOCAL( 3 )= WEARINC(index)*250000
elseif(KSTEP==8.and.kmeshsweep.eq.0.and.abs(TIME(1)-1)<1e-12)then
    ULOCAL( 3 )= WEARINC(index)*250000
elseif(KSTEP==9.and.kmeshsweep.eq.0.and.abs(TIME(1)-1)<1e-12)then
    ULOCAL( 3 )= WEARINC(index)*250000

C Continue the same for up to 43 steps (such that each step equals 250,000 cycles)

C 10 million cycles equals 43 steps

ELSE

    ULOCAL( 3 )=0.0D0

c write(7,*),'ulocal3 is', ULOCAL(3)

endif

if (((KSTEP.NE.1).and.(LOCNUM.eq.6976).and.(kmeshsweep.eq.1).and.

$((abs(TIME(1)-1)<1e-12)) then

    do i=1, nstreamlines

        WEARINC(i)= 0.0D0

    end do
endif

C

JRCD = 0

LSMOOTH = 1

B.2  UFIELD Subroutine (user defined field variable for linear wear)

C  USER INPUT FOR ADAPTIVE MESH CONSTRAINT

SUBROUTINE UFIELD(FIELD,KFIELD,NSECPT,KSTEP,KINC,TIME,NODE,
1  COORDS,TEMP,DTEMP,NFIELD)

include 'ABA_PARAM.INC'

CHARACTER*80 PARTNAME

DIMENSION  FIELD(NSECPT,1),TIME(2), COORDS(3),
1 TEMP(NSECPT), DTEMP(NSECPT)

integer index

parameter (nstreamlines=5000)

common /linearwear/WEAR(nstreamlines,100),WEARINC(nstreamlines),
\$ \ jslnodes(nstreamlines), WOUT(nstreamlines, 100) \\

LOCNUM = 0

JRCD = 0

JTYP = 1

PARTNAME = ''

CALL GETPARTINFO(NODE, 0, PARTNAME, LOCNUM, JRCD)

do i=1, nstreamlines

if (((LOCNUM - jslnodes(i)).EQ.0) then

index = i

end if

end do

FIELD(1, 1) = WOUT(index, KSTEP)

c write (7, *) 'FIELD', FIELD

RETURN

END