

Design and characterization of additively manufactured compliant features for spinal implants

by

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Author's Declaration

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Spinal fusion is the most common surgical reconstruction method to treat spinal disorders. In this procedure, the degenerated disc is removed, with an interbody device inserted between two adjacent vertebral bodies to restore disc height. Eventually, bone will grow over the implant providing long-term stabilization and immobilization of the joint. Spinal fusion implants are often metallic to provide the necessary structural support; however, most devices are much stiffer than the underlying bone, which can cause stress shielding and bone failure leading to poor patient outcomes. Furthermore, fusion implants do not reflect the compliant and mobile nature of the spine. An alternative to fusion is total disc replacement which uses an artificial spinal disc as a replacement to the natural disc, however, there are few on the market and most have high revision rates.

Another approach to the current rigid spinal implants is to consider compliant implants, with flexible or energy absorbing features to more naturally respond to spinal loading similar to the intervertebral disc. While these designs are largely unproven to date, the use of additive manufacturing (AM) enables the realization of new metamaterials and compliant mechanisms to evaluate the potential of these features in spinal implants. Therefore, the overall goal of this thesis was to design and manufacture AM compliant features in interbody devices for spinal reconstructive surgeries and characterize them using novel test methods. To achieve this goal, two studies were designed: (1) to explore the design of flexible elements in a cervical interbody device, and (2) to evaluate the performance of a lumbar dynamic surface conforming device to improve vertebral endplate contact area under asymmetric loading.

In the first study, a series of compliant features were developed for cervical interbody devices (CID) using engineered surfaces, optimization simulation, and lattices. The CIDs were manufactured in a polyether-ether ketone (PEEK)-like resin and in a titanium alloy (Ti64) using electron beam melting. The CAD model was compared to both types of print; however, a sub-optimal melt theme was used for the metal parts leading to larger discrepancies and print failures. The successful samples were speckled with paint to measure full-field surface strain using the Aramis 3D motion capture system. The AMTI VIVO joint motion simulator was used to apply compressive loading to the CIDs placed on Sawbones specimens. One set of CIDs was tested until failure resulting in an average ultimate compressive strength of 281 N in resin and 2569 N in Ti64 which varied considerably based on device geometry. Another set of implants was tested in repeated compression (5 cycles at 0.05Hz) to 50N in resin and 500N in Ti64, with three repetitions of each device. The results for Von Mises strain and

load-displacement curves were averaged per device geometry. Each geometry exhibited similar levels of strain in both the resin and titanium devices. The resin devices exhibited non-linear stiffness displaying initial laxity with a steep increase in stiffness while the Ti64 devices were effectively linear. The most compliant device in both materials was an engineered flexible element relying on bending for energy storage.

In the second study, an iterative design process was used to develop a lateral lumbar interbody fusion (LLIF) device with articulating endplates for contact surface optimization, establishing a precedent for designing additively manufactured devices. The developed dynamic surface conforming (DSC) implant and the replicated commercial implants with flat and anatomic endplates were manufactured in PEEK-like resin and in Ti64 using laser powder bed fusion. The design for AM of the DSC implant was successful and printed well in both materials. A custom fixture using machined Sawbones samples was developed to characterize bone-implant contact area in a challenging vertebral endplate geometry associated with partial implant pseudoarthrosis. Compression, flexion-extension, lateral bending, and gait physiological waveforms were derived from the OrthoLoad database and applied in six degrees-of-freedom on the VIVO for 5 cycles at 0.05Hz. Force and displacement data and range of motion data were collected from the VIVO while contact area and pressure were recorded on a Tekscan sensor. Each experiment was repeated three times, and the data was aligned and averaged to one loading cycle. The DSC and anatomically shaped implants had the highest normalized area with the resin implants having an overall higher contact area than the Ti64 implants. The DSC minimized the geometric effect of the challenging scenario while providing as much of a range of motion in other axes as the other implants. Contact pressure was measured to be the lowest for the DSC and anatomically shaped implants, consistent with the contact area measurement. Furthermore, this work has shown differences in the performance of implants in compression and physiologically relevant loading waveforms.

The devices and methods developed in this thesis yields new insights into the strain behavior of engineered and computationally generated flexures and the application of these flexures towards a surgical problem. Despite the preliminary nature, this work demonstrates a functional implant following design for AM principles. Future work is needed to further evaluate the robustness of these devices under fatigue loading and the reliability of these tests compared to established standards.

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Dedication

To my parents, Rado and Andrea, who have always believed in me.

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List of Abbreviations

6DOF – six degree-of-freedom
AM – Additive manufacturing
AP – Anterior-posterior
ASD – Artificial spinal disc
CAD – Computer aided design
CID – Cervical interbody device
DDD – Degenerative disc disorder
DfAM – Design for additive manufacturing
DSC/DSCI – Dynamic surface conforming implant
EBM – Electron beam melting
FE – Flexion-extension
IVD – Intervertebral disc
IE – Interior-exterior rotation
LB – Lateral Bending
LIF – Lumbar intervertebral fusion
LLIF – Lateral lumbar intervertebral fusion
LPBF – Laser powder bed fusion
ML – Medial-lateral
PEEK – polyether-ether ketone
SI – Superior-inferior
Ti64 – Titanium-6Aluminum-4Vanadium alloy
TO – Topology optimization

Chapter 1

Introduction

1.1 Thesis Motivation

The leading cause of years lived with disability is lower back pain, with millions of people suffering from chronic pain worldwide [1]. In Canada alone, tens of thousands of patients receive surgery to treat spinal disorders, easing lower back pain [2]. Diseases relating to the degeneration of the spine are prevalent in the elderly and, with a globally aging population, spinal disorders are of increasing concern and research interest [3]. In particular, disc degeneration disease (DDD) in the lumbar spine accounts for a large portion of spinal disorders requiring surgical intervention [4].

Common surgical interventions for the treatment of DDD are instrumented spinal fusion procedures, where the spinal column is reconstructed and stabilized using implants to promote bone-on-bone fusion [4]. While there are many different types of spinal fusion surgery, it is common for the degenerated intervertebral disc (IVD) to be removed, and a supporting intervertebral body fusion device (“interbody cage”) to be inserted between two adjacent vertebrae. Packed with a bone graft material, bone will grow over time into the implant, fusing the two vertebrae together. This effectively eliminates the disc and restores height and spinal lordosis. Often supporting instrumentation such as rods and screws are used as well for additional stabilization. Spinal implants used in these procedures are generally made of solid blocks of either Polyether-ether-ketone (PEEK) or titanium alloys, which have open voids to contain the bone graft material to promote long-term spinal fusion (Figure 1-1).

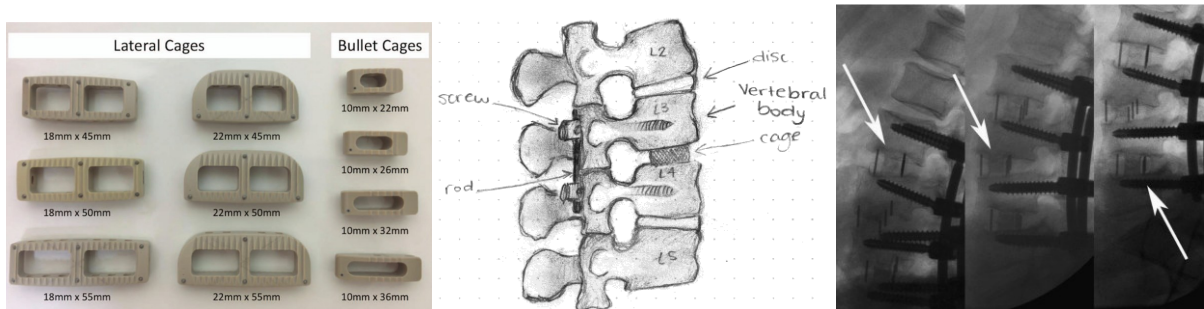


Figure 1-1. Example of PEEK interbody cages on the left, retrieved from [5]. Sagittal illustration of the spine with interbody cage and posterior fixation in the middle. Xray of a spinal reconstruction on the right adapted from [6].

While spinal fusion surgeries have been successfully implemented for decades, it has drawbacks such as diminished patient mobility, material mismatch between the bone and implant, and an elevated risk of disk degeneration in adjacent vertebrae [7]. Artificial spinal discs (ASD) emerge as an alternative strategy by aiming to restore mobility to the affected intervertebral disc [8]. ASD technology attempts to replicate the function of the intervertebral disc. However, there are few commercially available ASDs and approval for surgery remains limited, with numerous studies reporting comparable or inferior patient outcomes compared to spinal fusion procedures [9], [10]. Furthermore, the prevalent issues of implant wear and failure contribute to elevated rates of revision surgery associated with current ASDs [11]. The stability of the intervertebral fusion method thus remains an important solution to DDD despite the drawbacks. Yet, advancements in technologies like additive manufacturing (AM) have created opportunities to address some challenges with fusion devices.

A recognized issue with current fusion devices is a mismatch between the implant stiffness and load distribution with the underlying vertebral bone tissues. These devices are often engineered constructs which do not match the vertebral endplate geometry causing stress concentrations at the vertebral endplate contact points and the potential for implant subsidence (penetration) into the underlying bone [5], [12], [13]. Implants that match the surface area of the vertebral endplates have been shown to decrease the stress on the endplates suggesting a reduction in implant subsidence [14]. Furthermore, due to complex spinal loading, larger implants such as those used in lateral lumbar interbody fusion (LLIF) procedures can experience asymmetrical loading between adjacent vertebrae, where the bone contact and load transfer across the implant is not balanced. In these cases, there are free regions of the implant and bone graft that experience zero load, causing the bone graft in the free end to die from lack of loading. This can result in the vertebral bodies being only partially fused which presents a potential danger to the patient [15]. Thus, there is a need for spinal fusion implants that can more effectively adapt to the endplate for improved load distribution with asymmetrical loading.

Additive manufacturing (AM) has become an important tool for the development of spinal implants, where the design freedom allows for the introduction of architected features that would not be possible through traditional manufacturing techniques. While there has been much interest to date in porous features like latticing to promote osseointegration, there has not been much work to date to explore compliant features to assist with load distribution under asymmetrical spinal loading.

1.2 Thesis Objectives and Approach

The overall goal of this thesis was to explore the design, manufacturing and characterization of compliant features in interbody devices for spine surgeries. To achieve this goal, this thesis used a combination of computational and experimental approaches to evaluate emerging design methodologies and concepts. The specific objectives of this thesis were as follows:

Objective 1: Compare the compliance and deformation response in additively manufactured flexible elements for cervical interbody devices under compressive failure and sub-failure loads.

Seven cervical interbody devices (CID) were designed with compliant features using engineered surfaces, axial and multi-axial loading in a topology optimization simulation, and a gyroid lattice. Dimensions of design samples were 18 mm in diameter by 10 mm in height (based on commercial CIDs). Seven implants were manufactured in Rigid 4000 resin, having similar mechanical properties to PEEK, on a Formlabs Form 3 printer, while six implants (one failure) were printed with electron beam melting (EBM) on an Arcam A2X in Titanium-6Aluminum-4Vanadium (Ti64) alloy. All printed samples were speckled with matte black paint on a matte white paint background for image registration. One set of CIDs in both materials was taken to failure to measure the ultimate compressive strength. Then, compressive, non-destructive loading was applied to the superior endplate of the untested cages using an AMTI VIVO up to 50N in resin and 500N in Ti64. Three repetitions were performed for each CID type. An Aramis 3D motion tracking system was used to measure the full field strain on the surface of the CID flexures. Average Von Mises strain was computed for the strain surfaces and average load displacement curves were computed from the VIVO load cell data.

Objective 2: Evaluate the effect of a lumbar dynamically surface conforming implant on endplate contact area and load distribution.

A lateral lumbar interbody fusion (LLIF) device with articulating endplates was designed using an iterative process. Mock commercially available LLIF implants were recreated with flat and anatomically shaped endplates. A total of five LLIF implant types were manufactured in Rigid 4000 resin on the Formlabs Form 4 printer and with laser powder bed fusion (LPBF) on the Renishaw AM400 in Ti64 alloy. A custom test fixture using 20PCF Sawbones was developed to characterize contact area in a simulated challenging vertebral endplate geometry associated with partial implant pseudoarthrosis. The samples were loaded using the six-degrees-of-freedom (6DOF) dynamic force and motion simulator (AMTI VIVO) in compression, flexion-extension, lateral bending, and gait. The applied

6DOF waveforms were derived from physiological data obtained from the instrumented implant database OrthoLoad. The compression waveform was a modified force-controlled analogue to the ASTM F2077 standard for implant testing and was used as a comparison between the physiological waveforms and established standards. The contact area and contact pressure at the inferior bone-implant interface was measured using a Tekscan pressure sensor. Contact pressure was supplemented with load-displacement curves and range of motion from the load cell data of the VIVO. The contact was compared between sample types and materials over a 3-repetition average of each.

1.3 Thesis Outline

This thesis is structured in five chapters. Chapter 1 introduced the motivation and objectives of the thesis. Chapter 2 details the key background concepts and existing literature on spinal interbody devices and implant test methods. The primary contributions of this work are presented in Chapter 3, which focuses on the characterization of flexible elements in interbody devices (Objective 1), and Chapter 4, which addresses the evaluation surface conforming implants (Objective 2). Finally, Chapter 5 offers conclusions on the present work and recommendations for future study.

Chapter 2

Background

2.1 Anatomical Directions

There are universal anatomical terms that have been established to aid with consistency in the medical field. Figure 2-1 shows three anatomical reference planes and axes used to describe the human body.

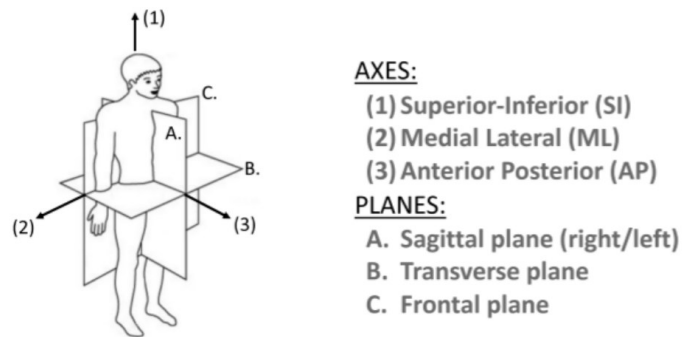


Figure 2-1. Anatomical planes and axes that describe the human body.

The human spine can move in several of these planes and directions. The terms used to describe the anatomical motions of the spine are shown in Figure 2-2.

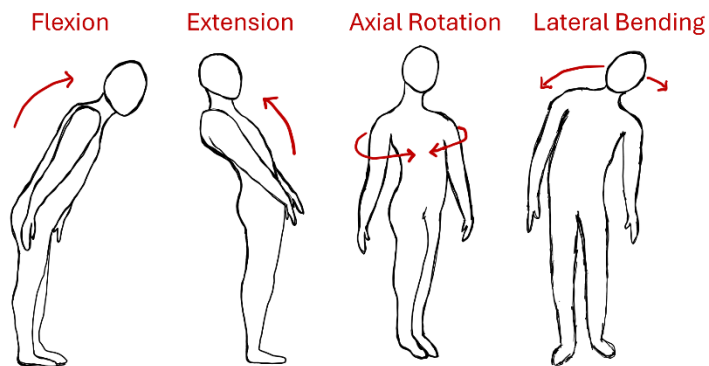


Figure 2-2. Anatomic motions of the spine. Flexion and extension represent bending forward and backward. Axial rotation represents twisting. Lateral bending represents bending to the side.

2.2 Anatomy and Biomechanics of the Spine

The human spine consists of 33 vertebrae connected with the intervertebral discs, ligaments, muscles and other connective tissues. The spine is divided into three spinal regions, the cervical, thoracic, and lumbar spine, followed by the fused sacrum bones and ending with the coccyx. The cervical spine consists of seven vertebrae (C1-C7), and it is located between the base of the head and the top of the shoulders. It is responsible for the rotation of the head in all directions. The vertebral endplates of the cervical spine measure on average 16-24 mm wide by 13-16 mm in length.

The lumbar spine is composed of five vertebrae (L1-L5) in the lower back. These are the largest vertebral bodies in the spine, measuring on average 50 mm by 35 mm in size, with the disc height being 10-12 mm [16]. These vertebrae are the largest because they experience the highest loads of the entire spine, following Wolfe's law [17]. The elevated load in this region causes a high incidence of injuries such as slipped discs, hernias, and degenerative diseases. Such pathologies can affect the entirety of the lower body by impinging on the nerves between vertebrae, known as foraminal stenosis.

2.2.1 Vertebral Anatomy

A functional spinal unit consists of an intervertebral disc between two adjacent vertebrae connected with the anterior, posterior and supporting ligaments, as well as the facet joints as shown in Figure 2-3. A functional spinal unit is capable of shock absorption through viscoelastic behavior [18], [19] and a limited degree of mobility. For example, in the lumbar spine the L4-L5 segment has a range of motion of, on average, 3.7 degrees in flexion, 2.3 degrees in extension, 3.5 degrees in lateral bending, and 1.2 degrees of axial rotation [20] with 2.2% endplate width of translation [21]. The spine, combining these units, has a range of motion of 40-73 degrees in flexion, 7-29 degrees in extension, 15-28 degrees in lateral bending, and 7 degrees in axial rotation illustrating how the chaining of units leads to greater motion [22].

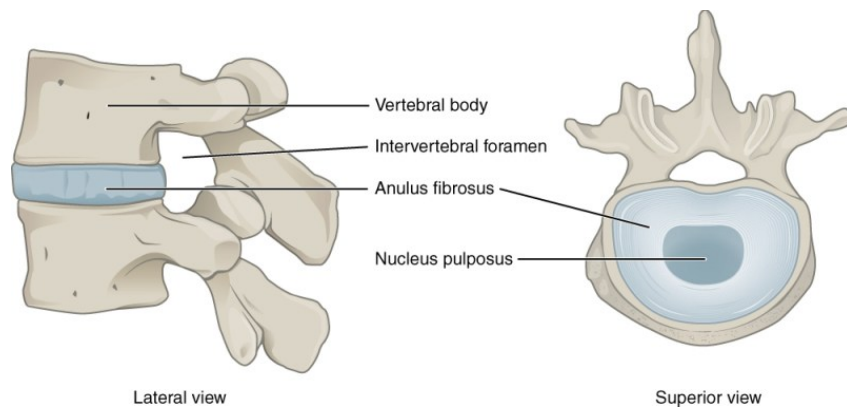


Figure 2-3 Vertebral anatomy. In beige are the bony vertebrae, with the soft intervertebral disc shown in blue. Adapted from [23].

The intervertebral disc is a soft structure between two vertebral bodies. Its function is to restrict the motion of the spine and absorb impacts contributing to the range of motion of the spinal unit. It does this through two main structures, the annulus fibrosus and the nucleus pulposus. The nucleus pulposus is a gelatinous matrix that dissipates impact forces through the movement and compression of fluid within the disc space [19]. The annulus fibrosus is a ligamentous structure surrounding the nucleus that contains the gelatinous matrix and restricts the overextension of the spine [24] [25].

The vertebrae of the spine consist of two different bone tissue materials: cortical bone and trabecular bone. Cortical bone is a dense and hard tissue, having a high strength and elastic modulus, providing mechanical support and serving as a mineral reservoir for the body [26]. This type of bone is found as the outside shell of all bones in the body accounting for 21-39% of total bone mass [27]. In the vertebrae, cortical bone forms a thin layer around the circumference of the vertebral body, being around 0.25-0.4 mm thick [28]. Trabecular bone is a type of bony tissue forming a stochastic lattice of struts and plates encased in cortical bone [29] forming the inner structure of bone such as the vertebral body. The struts and plates, called trabeculae, that form this interconnected lattice are on average 0.16 mm thick [30] and grow preferentially along the direction of loading [31]. Due to its nature as a lattice, it has a lower ultimate compressive strength and elastic modulus than cortical bone. The space between the trabeculae is primarily constituted of bone marrow, blood vessels, and cells that contribute to the function of the bone. The bone marrow along with other intertrabecular fluids create an intraosseous pressure under load, increasing the mechanical stiffness of the bone as a whole [32]. The posterior elements of the vertebral body are also made of trabecular bone wrapped in a cortical shell.

2.2.2 Spinal Disorders

Back pain can be caused by a range of spinal disorders from normal aging, tumors, and trauma to neurological deficits and non-specific pain as described in the book *Spinal Disorders: Fundamentals of Diagnosis and Treatment* by Boos and Aebi (2009) [33]. Prevalence and treatment for spinal disorders has considerable variability. Given the impact of back pain on the population, this is a difficult and controversial field for clinicians and patients [34]. Degenerative diseases account for approximately 90% of all back pain cases [34] and will be the focus of the current work. Specifically, degenerative disc disease is a condition that affects the intervertebral disc and is often a part of the normal aging process, hence its prevalence. It is characterized by the progressive loss of intervertebral disc height, generally due to soft tissue weakening over time. However, degeneration of the disc can result from various factors, including trauma, aging, genetic predisposition, spinal instability, or weakened facet joints [35]. The collapse of the disc space (loss of disc height, sometimes cause by a disc herniation Figure 2-4) can cause the onset of related conditions such as spondylolisthesis (mechanical slipping of the one vertebra anteriorly over the other vertebra) in turn causing foraminal stenosis leading to neural impingement, worsening pain and causing weakness or loss of mobility [36]. It is most common to see disc degeneration in the lumbar and cervical spine and more rarely in the thoracic spine.

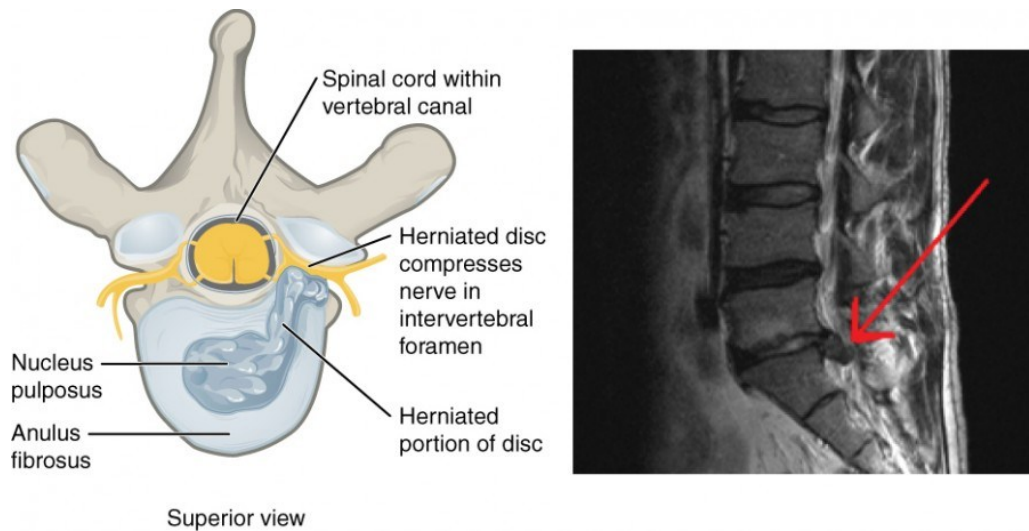


Figure 2-4: Right: Representation of a disc herniation. Left: Radiograph of disc herniation and height loss pointed out by the red arrow [23].

Symptoms of DDD are tingling, numbness, localized pain, and dysfunction in the extremities from the impingement of the spinal cord or nerve roots [36]. Degeneration of the lumbar discs may lead to leg weakness and challenges with walking [36]. The key symptom that impacts an affected person's daily life is debilitating back pain [37]. This pain can be both chronic and acute, intensifying during everyday activities such as sitting, standing, or lifting objects. Methods to assess DDD are already effective at correctly identifying the problem and usually involve palpitation of the region and medical imaging. Treatment strategies for DDD progress from conservative approaches like physical therapy to more interventional options like disc arthroplasty, depending on the severity and progression of the condition. However, surgical interventions are commonly needed to restore disc height and spinal alignment to alleviate nerve root compression and the associated neck or low back pain [34].

2.3 Spinal Surgery

2.3.1 Goals of Spine Surgery

The goal of spinal surgery is primarily to reduce patient pain while restoring as much functionality as possible. This is commonly achieved through instrumented spinal reconstruction procedures, where implants are used to restore intervertebral disc height and spinal curvature. These two factors are important to reduce patient pain which is often associated with nerve pinching.

Spinal fusion is the most common surgical reconstruction method to treat disk degeneration [4]. In this procedure, the intervertebral disc is removed, and spinal implants are used to fuse the vertebrae together. While spinal fusion has been successfully implemented for decades [38], patient mobility is reduced and the risk of accelerating disk degeneration in adjacent vertebrae is increased as a result of the fusion [39].

An alternative to vertebral fusion is total disc replacement (TDR) which can help restore mobility to the affected IVD [40]. Total disc replacement involves the removal of the IVD and the installation of an articulated artificial spinal disc in its place. However, few ASDs are commercially available and fewer are approved for TDR surgery with many reporting equal or worse patient outcomes than spinal fusion procedures [41], [42]. Furthermore, implant wear and failure cause current ASDs to have high revision surgery rates [43].

Advances in spinal fusion procedures include minimally invasive surgery. These procedures and associated implants have gained traction with both patients and surgeons mainly due to the

minimization of tissue trauma, less postoperative pain, and shorter hospital stays. These advantages can also lead to quicker recovery for a faster return to normal. Recently, the lateral lumbar interbody fusion procedure is of interest to surgeons because of the minimally invasive approach to the lumbar spine; gaining access to the intervertebral space via a lateral approach that passes through the retroperitoneal fat and psoas major muscle while avoiding major nerves and vessels. Anterior access to the spine is not necessary for this approach and posterior instrumentation is optional, as such, the surgery can be performed using only two 3-4cm incisions reducing the risks of the procedure [44]. An example of an LLIF procedure can be seen in Figure 2-5. A safe working zone was established for LLIF procedures by Guérin et al. at each level of the lumbar spine. Figure 2-6 shows the safe zone as a third of the endplate depth slightly shifted anteriorly; this zone changes in position and size depending on the position in the lumbar spine due to lordosis and nerve root positions [45].

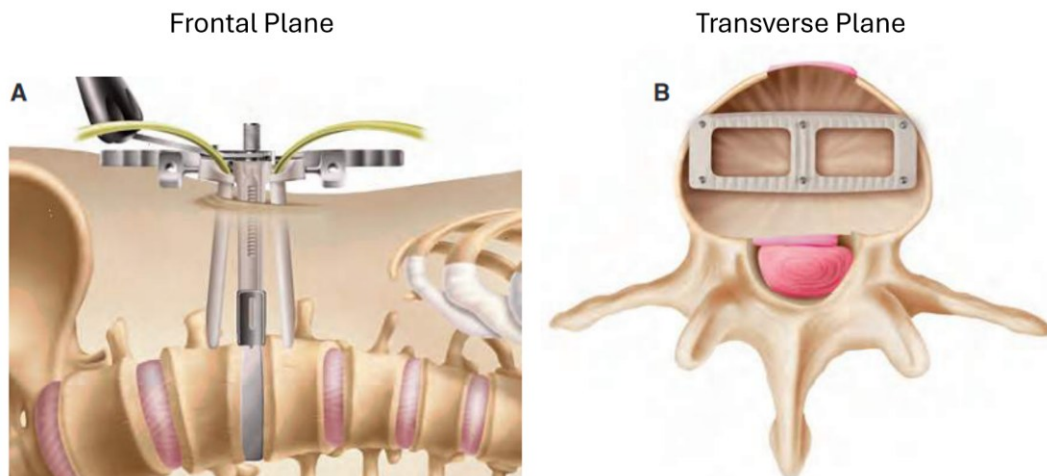


Figure 2-5 A) Extreme lateral intervertebral fusion (XLIF) is a type of LLIF procedure through the lateral side of the body developed by NuVasive®. B) Interbody cage used in XLIF procedures. XLIF implant placement is ideally located between the anterior third and middle third in the anterior/posterior direction and centered in the medial/lateral direction. Adapted from [46].

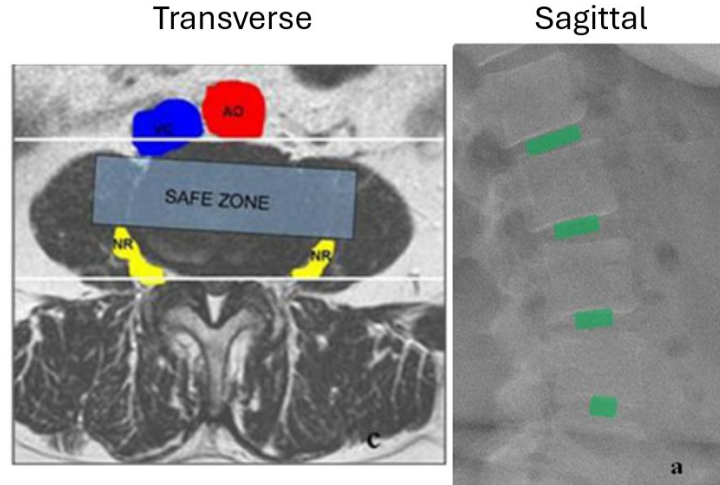


Figure 2-6 Safe working zone for the retroperitoneal approach to lateral lumbar fusion. The safe zone is in the anterior third of the vertebral body as shown in blue on the transverse plane and in green on the sagittal plane. Adapted from [45].

A recognized downside to the LLIF approach is a lack of direct visualization of the spinal reconstruction, making it difficult to correctly position cages in the spine. Expert advice collected from surgeons suggests that current solid or adjustable LLIF cages suffer from vertebral pinching due to their large size. This is a phenomenon when one end of the large cage is pinched between the vertebrae, taking all the load, while the other end floats freely as shown in Figure 2-7. This is highly undesirable as the bone in the free-floating end is not loaded and will thus resorb [17], preventing the fusion of one half of the vertebral body.

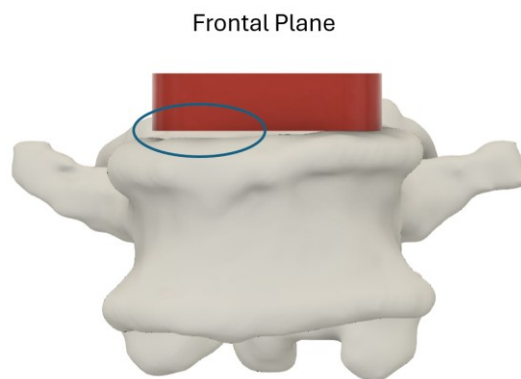


Figure 2-7 Enlarged view of the overhang problem. The gap is circled in blue, the implant is in red.

2.3.2 Spinal Implants for Interbody Reconstruction

There are several types of spinal implants used for different treatments. Anterior spinal reconstruction, for example, often uses interbody spacers with posterior fixation to correct the spine. Historically, spinal implants have had little innovation because the spine is a complex joint and basic spinal fusion with solid constructs works well enough to alleviate pain. Studies have found issues such as implant subsidence [47] and adjacent level degeneration [48] to be a problem with these traditional implants. Recently, the rise of minimally invasive surgery among other factors is driving the innovation of lateral cages. Lateral cages typically have a larger footprint, increasing the surface contact and load distribution across the vertebral endplate. However, these lateral cages can have issues related to increased risk of cage subsidence and loss of surgical correction [49].

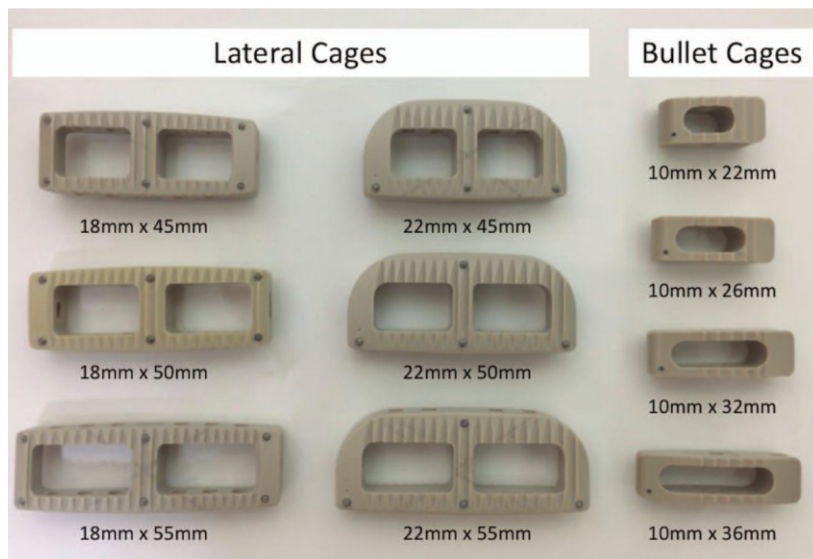


Figure 2-8: Sample of different sizes of LLIF and posterior LIF cages obtained from [5].

A proposed solution to the problem of mismatch between the implant and the vertebral endplate is adjustable or expandable interbody cage implants [50]. There are multiple ways to design such a cage, one of the largest design decisions being to have an expandable or compressible cage. A compressible cage would be designed to be taller than the required height with a low stiffness such that it could be compressed to fit the intervertebral height. The cage would be patient specific as the compliance would have to be tailored to each patient. An expandable cage on the other hand would start smaller than the intervertebral height and would mechanically expand to conform to the endplate

surfaces. This is advantageous because it could allow the surgeon to change the height and shape of the implant during the intervention. Endplate conformance is also advantageous because it is not necessary to have patient specific design as long as the implant has enough adjustability.

Currently, there are several expandable cages on the market as captured in Figure 2-9. There are some for expandable implants for LLIF procedures such as the RISE-L® (Globus Medical, Inc., Audubon, PA) however, most expandable implants have only one expansion platform and one direction. The dual-direction expandable implants are optimized for size and non-invasiveness rather than surface conformance.

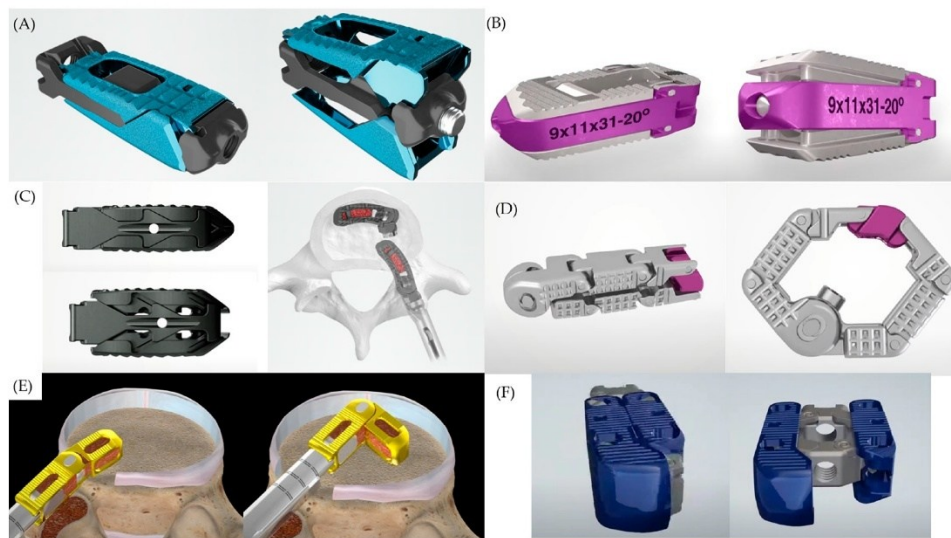


Figure 2-9 Example of expandable cages on the market. Retrieved from [51].

With additive manufacturing and computational tools, it is now possible to create interbody cages tailored to the specific geometries of each patient [52], [53]. Fernandes et al. performed a biomechanical comparison of the subsidence of patient specific versus commercially available posterior LIF (PLIF) implants [54]. The patient specific cages were designed using reconstructed vertebral models from CT scans of cadaveric specimens. The sample size consisted of 18 cadaveric specimens into two sets of 9 experiments. One control and one patient specific implant were randomly assigned a side placed by the surgeon on the vertebrae, each specimen acting as its own control. Results showed that patient specific cages had an implant-bone interface up to 1.6x stiffer and required a 64% increase in the force to subside

over their commercial counterparts. The conclusion was that closely matching the surface of the vertebral body reduces the risk of complications postoperatively.

As this study was performed on PLIF implants, it does not necessarily translate to larger implants like LLIF implants. Another limitation of the study is that the implants were only tested in uniaxial compression rather than under physiologic spinal loading which could change the pressure profile. However, the most relevant aspect of the study is that patient specific implants take expert preoperative planning and precise placement, both of which are difficult to achieve.

In a clinical study, Tartara et al. investigated the use of custom-made ALIF/XLIF titanium implants as treatment for lumbar degenerative discopathy [55]. This study aims to evaluate the safety, feasibility, and preliminary clinical and radiological results of custom minimally invasive LIF interbody cages. A sample of 18 patients both male and female received either ALIF or XLIF implants based on clinical assessment. CT scans were used to customize the implants which were fabricated in titanium using additive manufacturing. The primary endpoints of the study were clinical outcomes measured by the Oswestry disability index and radiologic outcomes including segmental lordosis, sagittal balance, and subsidence occurrence. Researchers were randomly assigned measures and statistical analysis was conducted with a p-value of 0.05. After a one year follow up period, the custom implants were shown to improve the pain index and radiologic measures significantly with no subsidence and no complications. Apart from the small sample size, one major limitation of the study is the absence of a control group which is acknowledged by the authors. Thus, the endplate conformance of the custom ALIF/XLIF implants has not been compared to commercially available implants. However, the study concludes that custom ALIF/XLIF implants are safe and effective thus encouraging the clinical use of such implants and suggesting larger studies.

A paper by Li et al. endeavored to compare adjustable lateral LIF cages to traditional static cages [56]. A total of 66 patients received the adjustable LLIF (RISE-AL®; Globus Medical, Inc., Audubon, PA, USA) and a control group of 27 received static LLIF cages. The study measured VAS and ODI scores, radiologic outcomes (disc height, neuroforaminal height, and segmental lordosis), subsidence, and pseudoarthrosis. The study reported the disability pain scores, the neuroforaminal height, and segmental lordosis to be significantly ($p < 0.05$) improved by the adjustable cage over the control group. Additionally, no subsidence was found in the adjustable cage whereas the control group had 18.5% of cases with subsidence. However, it was found that the control group cage provided the highest disc

height restoration after 24 months. This study shows that adjustable interbody cages are safe and durable in LLIF procedures. It also displays the advantage of restoring the natural lordosis of the spine and matching implant features with spinal features. Some limitations of the study include no randomization or blinding, differences in control and investigated sample sizes, and multiple time frames under study. A drawback of this study is that the adjustable interbody cage did not restore disc height as well as the static cage despite the lack of subsidence. This might be explained by the smaller cage size intended for less invasive surgery. Furthermore, potential conflicts of interest were identified, and therefore the results should be interpreted with caution.

It would thus be beneficial to explore dynamically surface conforming implants without the need for patient specific imagery, reconstruction, and manufacturing. Furthermore, a system to adjust the contact area intraoperatively would allow the surgeon the in-situ control over implant contact area. This system has the potential to reduce the subsidence of LLIF implants and improve surgical ease-of-use while providing a commercially scalable solution. As mentioned, there has been no significant research into a dynamically surface conforming implant. This research would further our understanding of the level of implant surface conformance necessary to mitigate subsidence which ranges from fully surface matching to unidirectionally adjustable. A comparison between dynamic surface conformance and static implants would determine the practical uses of such technologies.

2.4 Design for Additive Manufacturing

Metal additive manufacturing (AM) presents an opportunity to address current shortcomings with ASDs through the ability to produce complex structures and patient specific design frameworks. Several studies have been done in the field of metal additive manufacturing for orthopedics such as the production of customized hip stem prostheses [57], various human subject case studies (clavicular implant, mandibular implant, foot osteotomy, and acetabular cup implants [58]), and veterinary practice [59]. These studies focus on osteointegration, biocompatibility, and stress shielding of the implant manufactured using metal AM technology. The growing literature in the field is promising for traditionally non-innovative fields such as spinal reconstruction.

2.4.1 Topology Optimization

Topology optimization of orthopedic implants has been gaining popularity due to advances in metal AM over the past decade. Most studies aim to minimize the strain energy by a mass fraction constraint as the parameters for the topology optimization of spinal implants [60]. This allows the

vertebral cages to retain their designed stiffness while proving enough mass reduction to insert a bone graft [60]. A similar study used a topology optimization of fixation rods to increase the flexibility of the rod while retaining stiffness [60]. It was found that better patient mobility could be obtained without sacrificing the necessary stiffness for rod fixation.

Kang et al. performed a biomechanical evaluation of a topology optimized multi-segment artificial spinal implant [61]. This interesting study defines a multi-objective optimization methodology based on physiological loading during normal activities. This methodology was then used to design an implant for a multi-vertebral segment reconstruction. A model of the spine in conjunction with a design space for the implant were optimized through the application of complex biological loads. The setup and result can be seen in Figure 2-10. The implant was found to be lightweight, high-strength, high-stability with an overall stress reduction of 41.5%. Furthermore, the artificial vertebral implant was implanted in a patient with observed favorable short-term clinical outcomes.

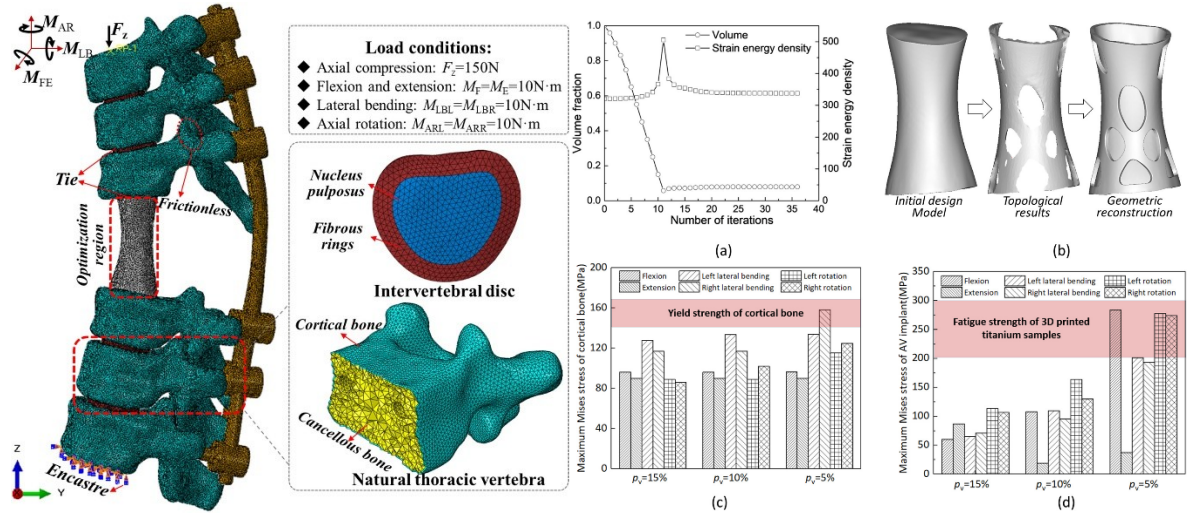


Figure 2-10: Topology optimization of a reconstruction implant [61].

2.5 Spinal Implant Test Methods

There are a multitude of established testing standards for spinal implants, largely focused on specific devices and failure mechanisms (e.g. cyclic fatigue). For example, the ASTM F2267 standard [62] describes implant subsidence testing whereas the ASTM F1717 method [63] describes posterior fixation testing techniques.

Relative to the current work, the ASTM F2077 intervertebral body fusion device [64] test standard describes a set of procedures to characterize the mechanical behavior of interbody cages in compression and shear in a simple and repeatable fashion. The testing apparatus consists of a long pushrod used to eliminate off axis loading, a universal joint, and a truncated sphere bearing surface to eliminate off axis bending. This setup gives as close to unconstrained compression as possible using a regular load frame. In addition, this setup can slightly be altered to achieve a strain configuration. A different setup is described for torsion. The standard also specifies the test methods for static and dynamic testing and the respective medium on which the test is conducted; a block of metal or a block of polyacetal which is proposed to simulate the vertebral body in dynamic loading. The standard suggests using loads based on the users experience and five independent test samples [62], [63].

While these standards are effective at measuring a baseline of safety for intervertebral implants which can serve as a good validation for prototypes [65] [66], they do not measure other factors like surface area, implant strain or range of motion, as such, many groups have developed their own testing methods. Fernandes et al. used a compression testing machine to measure the contact area between the bone-implant interface with a pressure-sensitive measurement film placed between the implant and a denuded and dried vertebral body [53]. The low-pressure Fujifilm ("Ultra super low" Fujifilm, Pressure Metrics, Whitehouse Station, NJ, USA) captures all the pressure on the sensor during the test and is processed after the test. Similarly, Kusins et al. created a custom test fixture to adjust the lordotic angle between two Sawbones (Pacific Research Laboratories Inc., Vashon, Washington, USA) blocks and measured the contact area between the Sawbones-implant surface using a Tekscan sensor [50]. The thin film Tekscan pressure sensor can record the pressure and area on the sensor during a test, adding the measure of pressure over time. A group out of Switzerland was testing ASDs using a six degree-of-freedom (6DOF) testing machine to collect range of motion data [42]. To measure these complex movements, they used an optical tracking system paired with optical markers fixed to the test frame which gave them an accurate recording of three-dimensional motion over time. Other studies use cadaveric testing, like this endplate damage comparison for XLIF cages by Tatsumi et al. [67]. Furthermore, some studies collect data from in-vivo patients. For example, this study by Zaborovskii et al. details 5 patients receiving patient specific 3D vertebral body replacements with a 19-month follow-up [68].

More advanced joint simulators can apply physiologic six degree-of-freedom loading, like the AMTI VIVO joint motion simulator. For example, the VIVO has been used to assess knee joint

biomechanics with virtual ligaments [69]. The validity of using the VIVO as a spine simulator has been demonstrated in the works of McGregor [70], Benais [71], and Carroll [72]. Benais et al. used the VIVO to perform unconstrained load-induced subsidence of cervical vertebral cages and compared the results to the ASTM F2267 subsidence standard. The results showed that the unconstrained force-control system on the VIVO was a more realistic testing method than the ASTM F2267 as the standard would lose energy from friction in its bearing surfaces.

McGregor expanded this work through the use of the VIVO as a physiologic motion segment simulator, multi-axial pedicle screw loosening, and multi-axial implant testing. They found significant differences between traditional evaluation methods and patient case studies while the novel methods presented less differences, indicating a closer match between in-vivo data and VIVO testing methods. In that study, physiologic waveforms were first extracted from the OrthoLoad instrumented implant database, averaged, and modified to fit machine requirements. Then, digitization was used to locate the specimen in space and a transform was used to apply the loads to the specimen using the 6DOF actuators of the VIVO. Finally, results were measured using the VIVO load cell and optical motion tracking with an NDI camera. This demonstrates the ability to obtain complex measurements from physiologically relevant loading scenarios.

2.6 Conclusions

There is currently a need for interbody fusion devices that exhibit more uniform load sharing with bone graft and increased contact area with vertebral endplates than current solutions. Load sharing of the spinal loads between the implant and bone graft is important to promote bone regrowth and hence the successful fusion of the spinal unit, reducing revisions. In addition, bone-implant contact area has been recognized to be an important factor in reducing implant subsidence and increasing load sharing. There exists a gap between ASDs, which are fully compliant, and interbody fusion cages, which are generally stiff, to address these implant factors that can potentially be overcome with novel flexible elements to improve patient outcomes. In this context, additive manufacturing provides opportunities for the development of those flexible elements in geometries that are difficult to manufacture with traditional methods. Furthermore, current spinal implant test methods lack the capabilities to evaluate critical implant characteristics (implant strain, contact area, etc.) and only evaluate implant mechanical properties rather than biomechanically accurate scenarios. As seen in previous studies, significant differences were found in implant behavior in physiologically relevant loading cases as compared to

current standards, potentially skewing results for implant performance. As such, refining the testing methods is on the critical path forward to obtain better performing implants and hence better patient outcomes. With the goal of designing, manufacturing, and characterizing compliant features in interbody fusion devices for spinal reconstructive surgeries the following knowledge gaps were identified:

1. Limited studies have investigated the use of flexible elements to increase load sharing in spinal implants; however, Yu et al. have found promising results [42].
2. The bone-implant contact area has been shown to improve with patient specific implants; however, it is difficult to obtain a precise match from pre-operative imaging which is necessary for a good fit [53] and the cost is prohibitive; standardized implants with intraoperative adjustability remain to be explored.
3. Existing experimental testing methods for assessing spinal implant performance lack the complex loading conditions of the spine, which are potentially misrepresenting the outcomes of implant testing.
4. Few studies have investigated the design for AM in the context of spinal implants. Further investigation of guidelines and techniques would be helpful to expand design opportunities.

Chapter 3

Evaluation of the Strain in Additively Manufactured Flexures for Cervical Interbody Devices

3.1 Background

As discussed in Chapter 2, there is a recognized need for spinal implants that can replace the degenerated IVD to maintain or restore mobility. Ideally, an interbody spinal implant should be able to withstand physiological loading of the spine, while also allowing some small range of motion to promote spinal mobility. However, current interbody implants like metallic cages are not designed to allow for deformation as this would inherently increase the risk of implant failure with cyclic loading. However, there are unexplored opportunities to consider the design of an interbody device using engineered compliant features. Hence, this project will look at using AM flexures and topology optimization (TO) to improve the structural compliance of cervical interbody devices (CID).

In reviewing the literature, a lack of information was noted on the flexibility and manufacturing of metal AM implants, especially for the spine. Furthermore, in a spinal fusion surgery, bone graft ideally needs between 2-10% strain energy [73] to promote bone growth for fusion, with the implant sharing the load with the bone graft. While solid implants do typically fuse successfully [4], fusion implants with a compressive modulus closer to that of the surrounding bone decrease implant failure modes like endplate subsidence and stress shielding [66]. Hence, it is proposed that a more compliant CID would aid in bone formation and load sharing.

The goal of this study was to evaluate the strain performance of engineered compliant elements in a set of CIDs under compressive loading.

3.2 Design Requirements for Cervical Interbody Device

The functional requirements for the CID were defined as follows. The deformation amount was calculated as the reconstruction height multiplied by the desired bone strain.

- Must be a reasonable spinal reconstruction height (~10 mm [13])
- Must not protrude outside of the vertebral endplate (~ø17-23 mm [74])
- Must have space for bone graft
- Must allow for 0.2-1 mm of deformation to increase the compliance of the device
- Must support physiological loads for normal daily activity (~500N [75])
- Stress concentrations cannot exceed the strength of Ti64 (970 MPa [76])

The base geometry is inspired by commercial anterior cervical interbody implant geometries as seen in Figure 3-1. Common dimensions for these cervical implants were approximated to be 12 mm in the anterior-posterior direction, 16 mm in the medial-lateral direction, 10 mm in the superior-inferior direction [71].

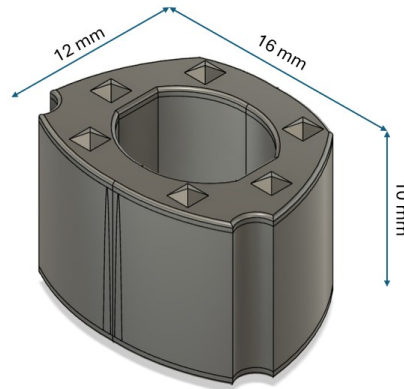


Figure 3-1 Replica of a commercially available cervical interbody implant with annotated dimensions.

3.3 Device Design

Seven different CID geometries were developed with differing levels of theoretical stiffnesses. Three devices were derived directly from the recreated commercially available cervical implant shown in Figure 3-1 while the remaining four were developed from a simplified version of the implant. All devices were 10 mm tall to restore intervertebral height and allow for a bigger design space.

3.3.1 Spindle Designs

The simplified version of the device was created as a cylinder encompassing the dimensions of the commercially available cage. The cylinder has a height of 10mm and a diameter of 18mm which is slightly bigger than the width of the commercial cage. The cylinder was separated into three regions: the top endplate, middle region, and bottom endplate. These endplates are 1mm tall each and the middle region is 8mm tall as seen in Figure 3-2.

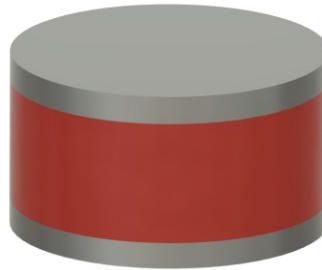


Figure 3-2 The three regions of the simplified CID design space. The top and bottom surfaces (grey) were fixed, and the middle region (maroon) was the available design space.

The three regions were then further refined through several design iterations. The final four cages came from a spindle-like design, where the flexible surfaces are concave with respect to the outer device wall. The flexures bend towards the middle of the device while leaving the central column in the SI axis empty. The flexures curve down to a central diameter of 3 mm with a 2 mm in diameter gap. Two types of spindle surfaces were used. The first was based on elliptical surfaces to get a smooth curve with as low curvature as possible from the top to the bottom of the device. The second was based on a lofted surface which kept the cross section of the flexure constant but created a surface with a higher curvature within the device. The two surfaces can be seen in Figure 3-3. Then, radial slits were added to the spindle geometry to introduce discontinuities in the surface and effectively create separate flexures. The slits were created such that a section in the transverse plane at the midpoint of the device would see approximately 60% solid flexures and 40% gaps. The ellipse design received 1mm wide slits while the lofted design received 2mm wide slits to achieve this.



Figure 3-3 CAD of the device geometries for the spindle like design with a section cut view on the bottom. Left to right: ellipse, ellipse with 1 mm slits, lofted, lofted with 2 mm slits.

3.3.2 Topology Optimized Designs

Two topology optimized devices were developed using the commercial cage design directly. The topology optimization process took multiple iterations, and the design of choice was selected based on the functional requirements of the problem and the manufacturability of the design. Two loading cases were identified: an axial, compressive loading in the SI axis, and a multi-axial load case with patient specific physiological loads as seen in Figure 3-4 . Altair Inspire (Altair Global, Troy, Michigan, USA) was used to perform the topology optimization for both cases. The loads applied to each scenario were obtained from patient data using the OrthoLoad instrumented implant database [75]. The reference activity was chosen to be spinal flexion, as it is an everyday activity whose range of motion is often impacted by spinal fusion surgery [77]. Lumbar vertebral body replacement data for spinal flexion was collected for sample Patient 1 (WP1) from the available data at the time of this study. The dataset for flexion of sample WP1 can be visualized in Figure 3-5. Peak forces and moments were extracted from the recorded movement waveform at the maximum magnitude of the forces resulting in Table 3-1.

Table 3-1: Load case summary for the compressive and patient specific datasets.

Load Case	Fx (N)	Fy (N)	Fz (N)	Mx (Nm)	My (Nm)	Mz (Nm)
1. Compressive	0	0	-600	0	0	0
2. Patient Specific	35	-35	-600	1.5	-27	-1.8

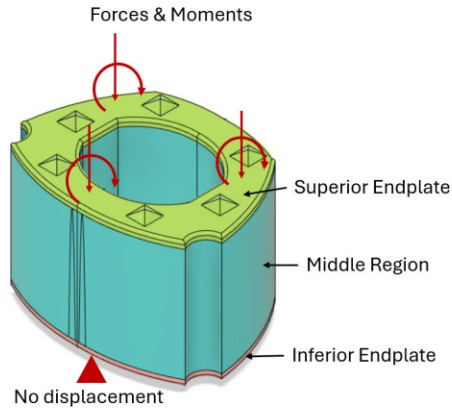


Figure 3-4: Topology optimization setup of the cervical interbody spinal implant with labels. The middle region was the volume to be optimized.

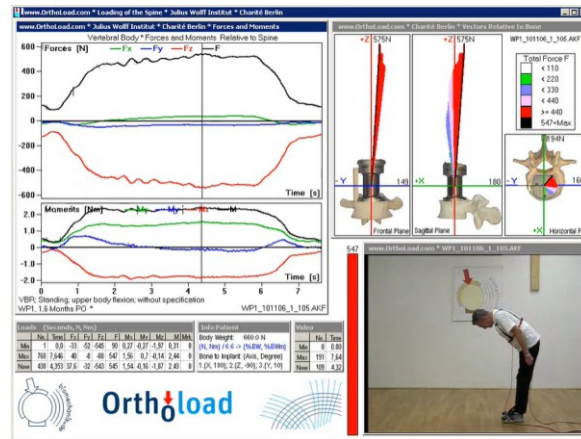


Figure 3-5: OrthoLoad data for patient WP1 sample at peak loading [75].

In the case of axial loading, a compressive force of -600 N was applied to the superior endplate while constraining the inferior endplate to 0 mm of movement in any direction. The middle section of the device was set as the region to be optimized. The optimization was set up with a mass minimization objective and a target safety factor of 1.2. Several results were obtained by changing various parameters as seen in Figure 3-6, more details can be obtained in Appendix A (A.1). Device designs were analyzed in stress and strain as shown in Figure 3-7, and compared based on the previously identified design requirements. The result chosen was the basic optimization as the branched structure provided the most support to the superior endplate hence improving printing outcomes in the SI direction.

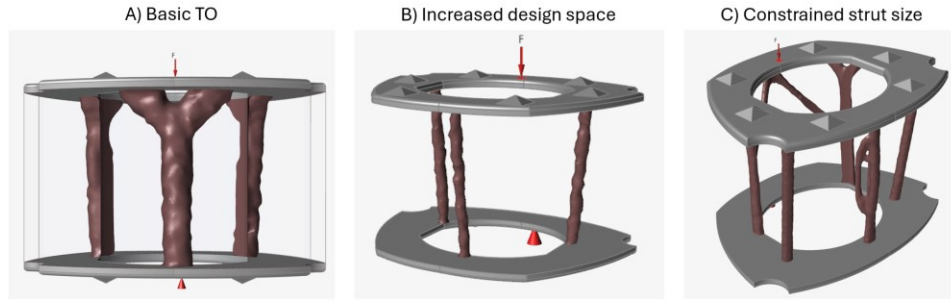


Figure 3-6 Evolution from left to right of the resulting structure over several optimizations. A) basic TO exhibiting wall “sticktion”. B) Increased design space to mitigate “sticktion”. C) Constrained strut size.

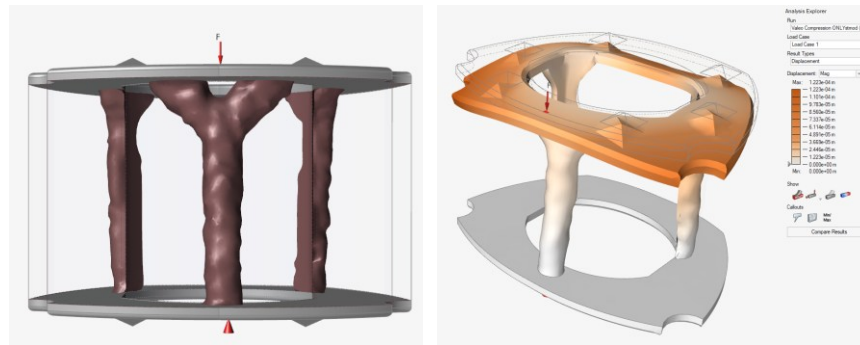


Figure 3-7 Final design for axial compressive loading (left), and the deformation analysis under load, exaggerated (right).

The second load case consists of multi-axial physiological loading during spinal flexion. The forces and moments were evenly applied to the superior endplate while the inferior endplate was held with no displacement. The middle section of the cage was set to be optimized. The optimization was set up with a mass minimization objective and a target safety factor of 1.2. Once again, several results were obtained by tweaking the optimization parameters, and further details can be found in Appendix A (A.2). The result used in this study is shown in Figure 3-8 which resembles the outer structure of the intervertebral disc.

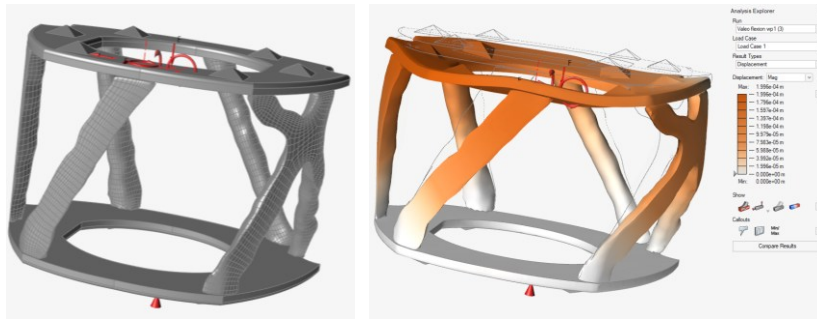


Figure 3-8 Result of the patient specific physiologic load case (right), Deformation under load analysis, exaggerated (left).

3.3.3 Latticed Design

Finally, the last design included a lattice in the middle region of the commercial implant. The lattice was a walled gyroid surface lattice with a unit cell size of 4.85x4.85x4.85 mm and a wall thickness of 0.5 mm. The device had a porosity of 80.1%.

3.3.4 Final Designs

The Figure 3-9 shows the final CID designs. The top row shows the engineered spindle-type devices while the bottom row shows the commercial computational and latticed designs.

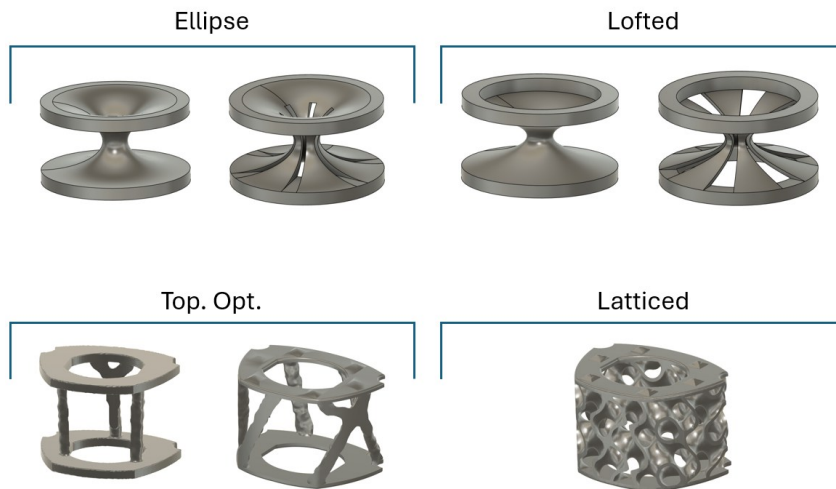


Figure 3-9 The final seven CID designs. Top row: ellipse, ellipse slit, loft, and loft slit. Bottom row: TO axial, TO physiologic, and latticed.

3.4 Implant Manufacturing

The set of seven devices were additively manufactured in Rigid 4000 resin on the Form3 printer from Formlabs (Somerville, Massachusetts, USA). The Rigid 4000 resin was used because it has similar mechanical properties to PEEK, a commonly used material for spinal fusion implants [53]. Print settings included a layer thickness of 50 microns and manually placed supports. The orientation of the parts on the build plate was chosen independently for each part to minimize the supports contacting the flexures with consideration for manufacturing quality. The TO and slitted parts were printed in the SI direction while the others were printed with the SI axis parallel to the build plate as shown in Figure 3-10.

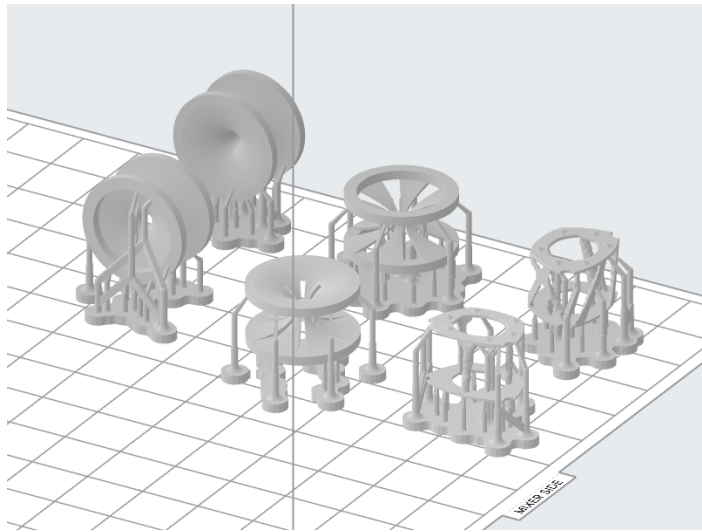


Figure 3-10 Build plate for resin printed cervical interbody devices showing the print orientation and support structures for each device.

Two sets of the seven devices were also printed in the titanium alloy Ti64 using electron beam melting (EBM) on an Arcam A2X (Arcam, Mölndal, Sweden). Implants were printed in partnership with the Multiscale Additive Manufacturing lab at the University of Waterloo using an experimental melt theme. All cages were printed with the SI axis orthogonal to the build plate and without support structures as the EBM process is self-supporting. The powder was removed from the parts using metal AM sandblasting and manual scraping.

Following manufacturing, one set of the Ti64 samples was imaged using the Nikon micro-computed tomography scanner to examine the shape and surface roughness of the as-built design.

3.5 Device Testing

Testing was performed using an AMTI VIVO (AMTI, Watertown, Massachusetts, USA) six degree-of-freedom (6DOF) joint motion simulator. A block of standardized polyurethane (30PCF; Pacific Research Laboratories, Vashon, Washington, USA), selected to simulate vertebral endplate bone [5], was machined into 1.25" x 1.25" x 0.75" rectangular specimens. Custom fixturing was developed to interface between the AMTI VIVO, Sawbones specimen, and device sample consisting of a holder for the Sawbones and an anti-slip pushrod for the device. The Aramis 12M 3D motion tracking system (Zeiss, Germany) with photogrammetry and full field tracking was used to measure flexure strain and to reference end effector movement. Calibration of the Aramis system was performed before each test day using the 55mm volume calibration panel. The camera position was adjusted such that the surface of the flexure facing the camera was at the center of the measuring volume. The setup can be seen in Figure 3-11.

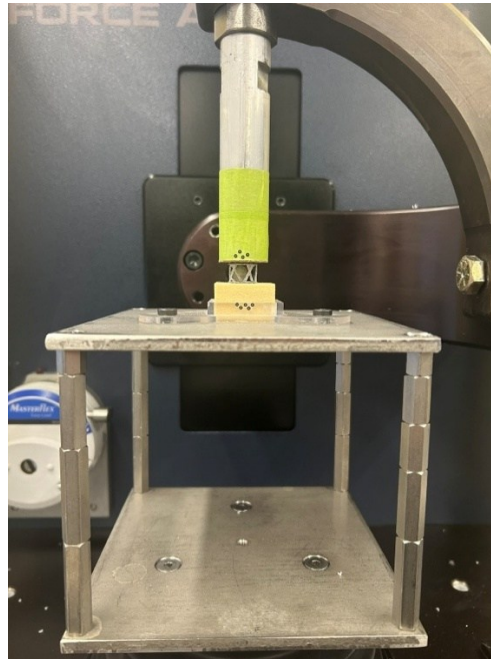


Figure 3-11 Experimental testing setup on the AMTI VIVO with the cervical interbody device and PCF material substrate.

3.5.1 Device Surface Speckling

The device samples were speckled for the use of strain field measurements using matte white and black spray paint. Each CID (Resin and Ti64) was coated with matte white paint. Then, a stiff brush was used to flick matte black paint onto the flexure surfaces in a controlled fashion. This created an even coat of black colored speckles of an appropriate size to use with the Aramis 3D camera system for surface strain measurement using digital image correlation.

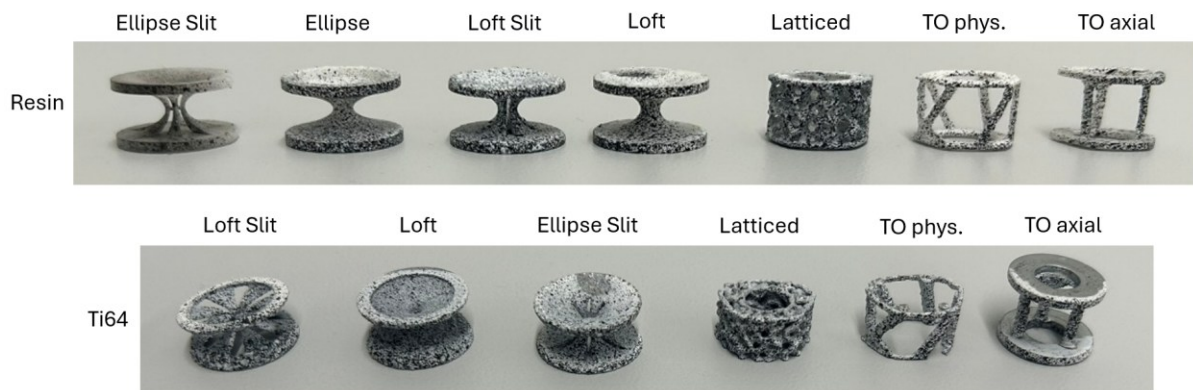


Figure 3-12 Speckling of samples (resin top, titanium bottom) with labels.

3.5.2 Failure Testing Methods

This testing setup was used to perform mechanical failure testing of the devices up to 4000N. The devices were placed between a Sawbones specimen and the pushrod, as shown in Figure 3-11, then the load was increased until failure. One set of seven resin and six Ti64 samples were used for this testing to determine the maximum compressive force to use for each material. The force and displacement were recorded.

3.5.3 Compressive Testing Methods

Compressive testing was used to evaluate the compliance of the device designs. An n=3 Sawbones specimens sample size was collected on which seven resin devices and six Ti64 devices were tested. Devices were randomly chosen using a blind pick method for each specimen. Each device sample was loaded in the SI axis under a compressive loading following a sine wave. Each sample saw 5 loading cycles at a frequency of 0.05 Hz. The compressive loading was obtained from failure loading tests and was determined to be the 50N for the resin devices and 500N for the Ti64 devices.

3.5.4 Data Analysis

Forces, moments, and displacements were recorded on the AMTI VIVO at 100 Hz with a 50 Hz filter (3 dB down). The strain was captured with the Aramis motion capture system recording at 2 Hz. A surface strain component created from the speckle pattern on the devices was used to measure Von Mises strain of the flexure element. An example of the surface can be seen in Figure 3-13. Von Mises strain (Equation 3-1) was chosen because it serves as a scalar representation of the 3D strain tensor. This was useful to reduce the dimensions necessary for the comparison between samples. In this case, the expected strains between the points on the surface were small and most devices did not reach plastic deformation, so the Von Mises equation holds.

$$\varepsilon_{vm} = \sqrt{\frac{2}{3} (\varepsilon_x^2 + \varepsilon_y^2 + \varepsilon_z^2 - \varepsilon_x \varepsilon_y - \varepsilon_y \varepsilon_z - \varepsilon_z \varepsilon_x + 3\gamma_{xy}^2 + 3\gamma_{yz}^2 + 3\gamma_{zx}^2)}$$

Where:

- $\varepsilon_x, \varepsilon_y, \varepsilon_z \rightarrow$ normal strains in the x, y, and z directions
- $\gamma_{xy}, \gamma_{yz}, \gamma_{zx} \rightarrow$ shear strains

Equation 3-1 Von Mises strain of the surface.

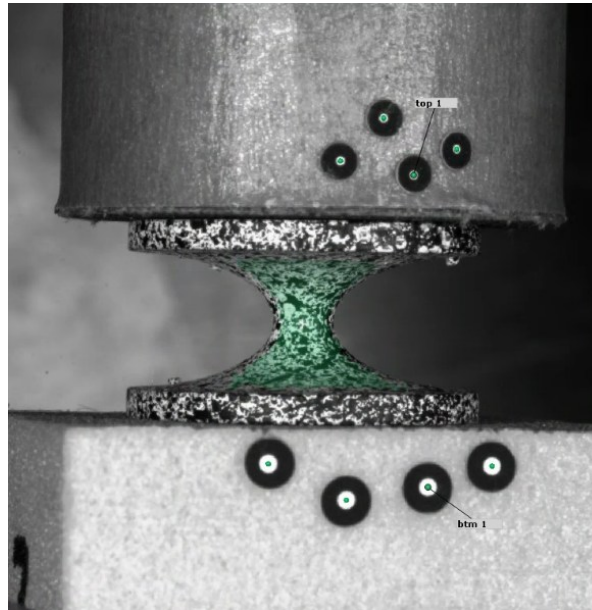


Figure 3-13 Example of the strain surface (in green) on a flexure element.

The Figure 3-14 shows a flowchart representation of the data analysis process for numerical data. First, the data is smoothed using a moving mean with a window of 1 second. Then, for each sample, the first and last cycle must be excluded because the VIVO ramps in and out of the desired forces during those waveforms. The three remaining cycles are then averaged to produce one average measurement cycle per sample. Next, the average cycle for three sample repetitions on different Sawbones specimens are averaged. Plots are produced from this average data.

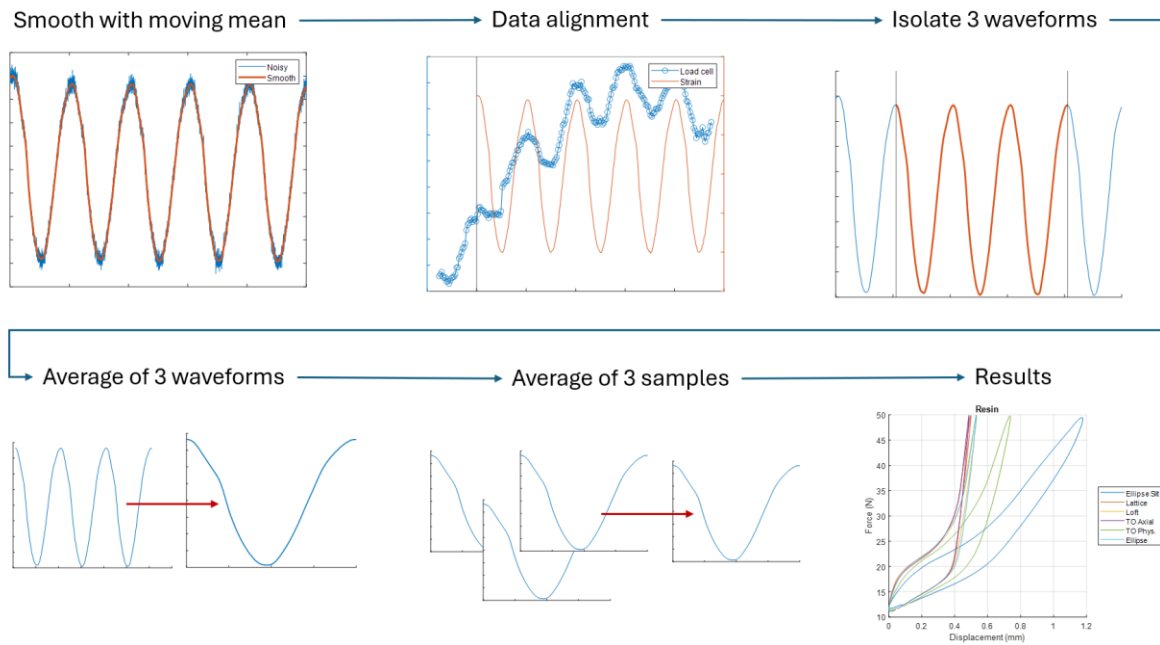


Figure 3-14 Analysis flowchart for data analysis. The signal is first cleaned and aligned, then the data of interest is isolated and averaged between specimens.

3.6 Results

3.6.1 Manufacturing

The manufacturing of the resin devices was successful; however, some difficulties were observed. The support structures created for the resin devices worked well and were able to be removed without difficulty in all designs except the lofted slit and the TO axial. The lofted slit design was the most challenging to print because the fine flexures at the center on the device made it brittle and prone to failure. Supports had to be added in between the flexural elements of the lofted slit design to help during the printing, which then caused difficulties with support removal as the flexures would break. The

design of the loft with slits was not conducive to SLA printing. In addition, it was difficult to remove supports from the topology optimization (axial) design because the endplates would break from the forces applied during removal. Support structures were necessary on this part to preserve the strength of the part with transverse layer lines. As such, the endplates were thickened from 0.5 mm to 1 mm.

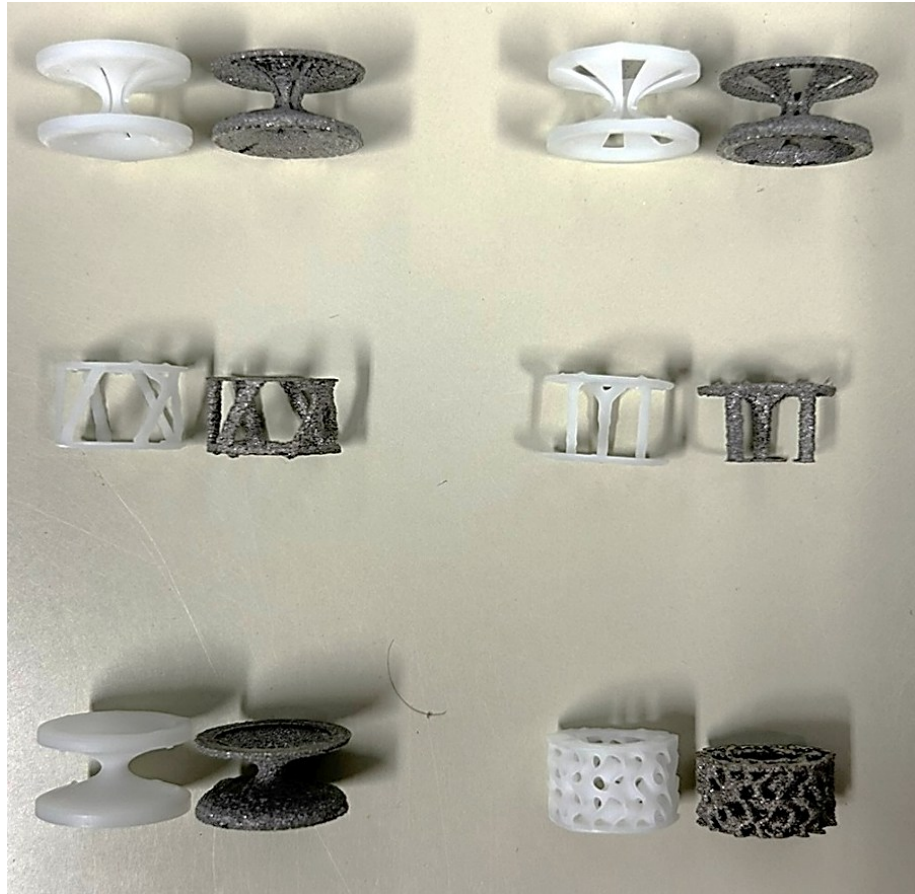


Figure 3-15 The manufactured cervical interbody devices in both resin and titanium materials (white = resin, grey = Ti64). Missing is the ellipse resin device.

The EBM parts were printed in Ti64; however, the quality of the parts was suboptimal. This is due to the use of an experimental melt theme to produce the parts. Figure 3-16 shows some of the parts produced; the parts were over-sintered to the point of melting. This melting caused the part geometry to deform by shortening and thickening the part. This is illustrated in Figure 3-15 where the metal AM parts are compared to the resin parts and CAD. Furthermore, the melt theme caused issues with the depowdering process as the semi-sintered powder cake was over-sintered and difficult to remove.

Mechanical scraping was applied to remove as much powder from the part as possible. The ellipse design failed to print entirely, perhaps due to the curvature of the part causing overhangs as other designs also had trouble with overhangs.



Figure 3-16 Melting of Ti64 devices during the EBM process with experimental melt theme.

The Figure 3-17 shows a comparison of the CAD model to the Resin and Ti64. It can be observed that the resin printing is fairly accurate to the CAD with only minor defects where the support structures attached to the part and some rounding of sharp edges. The Ti64 part has been deformed to be shorter and wider than the original CAD. Additionally, the Ti64 superior endplate is thinner than the CAD while the inferior endplate is thicker than the CAD.

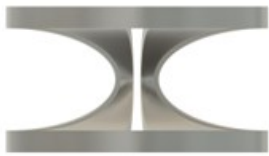
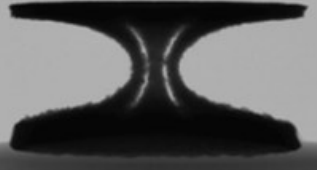
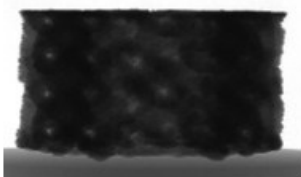
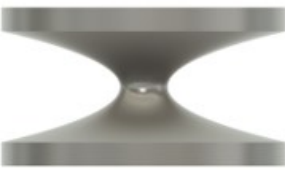
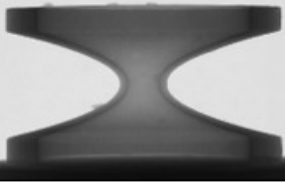
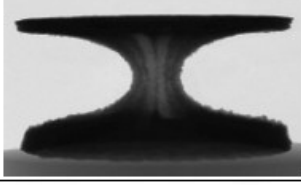
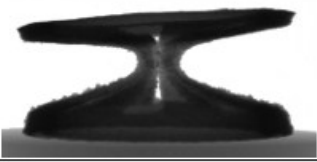
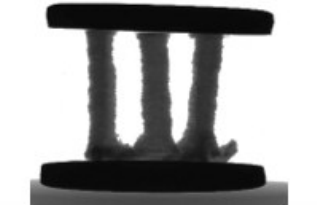
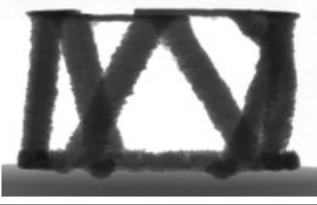
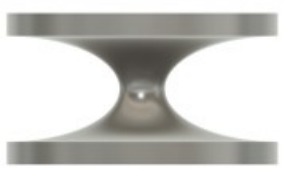
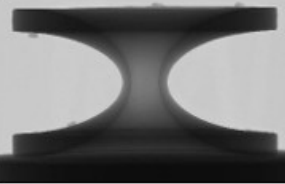
	CAD	Resin	Ti64
Ellipse Slit			
Lattice			
Loft			
Loft Slit			
TO Axial			
TO Phys.			
Ellipse			N/A

Figure 3-17 Comparison of xCT images and CAD. Left: original part CAD. Middle: Resin printed (missing loft slit). Right: Ti64 printed.

3.6.2 Failure Testing

One set of all the devices was successfully tested for failure loading, which included seven resin devices and six Ti64 devices. The resin devices failed on average at 281 ± 231.1 N. The titanium devices failed on average at 2569.3 ± 1368.8 N. The resin devices tended to have approximately 10x lower failure strength than the Ti64 devices; matching geometries performed similarly within their respective material group. The Figure 3-18 shows the boxplot of the failure force for both the resin and titanium devices. The resin devices have a smaller range of failures than the titanium devices. The latticed and topology optimization (axial) titanium devices did not reach failure up to 4000 N. It was noted that the Sawbone started to subside at around 1000N.

The maximum force for non-destructive compressive testing was found by examining the boxplot and failure plots for resin and Ti64 individually. The goal of the compressive testing is to see some elastic deformation but no plastic deformation. Looking at the plots in Figure 3-19, they have a toe in region with a lower slope, the elastic region follows, then the plastic region, and finally failure. For the lower bound of the desired response, the compression load must be greater than the toe-in region, which is above 30 N for resin and above 250 N for Ti64. For the upper bound, the goal is to prevent failure of the devices, so the smallest failure load of all devices could be used. However, the value for resin is 28 N which is below the average toe-in and 400 N for Ti64 which is close to the average toe in. As such, the upper bound can instead be taken as the 25th percentile of failures since most devices haven't failed. The 25th percentile for resin was 94.6 N and the 25th percentile for Ti64 was 1823.8 N. However, in the case of titanium, the Sawbone subsides at about 1000 N which would add undesired compliance to the system, hence the 1000 N is taken as the upper value for Ti64. Finally, adding a safety factor of 2 to further reduce failures and some rounding gives 50 N in compression for resin and 500 N in compression for Ti64.

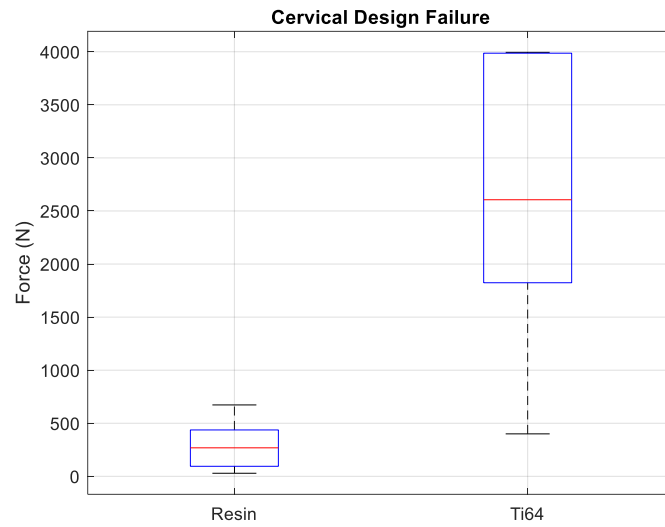


Figure 3-18 Boxplot of the load at failure for the cervical devices. The median for the resin devices was 268.5 N and the 25th percentile was 94.6 N. The median for the titanium devices was 2605.7 N and the 25th percentile was 1823.8 N.

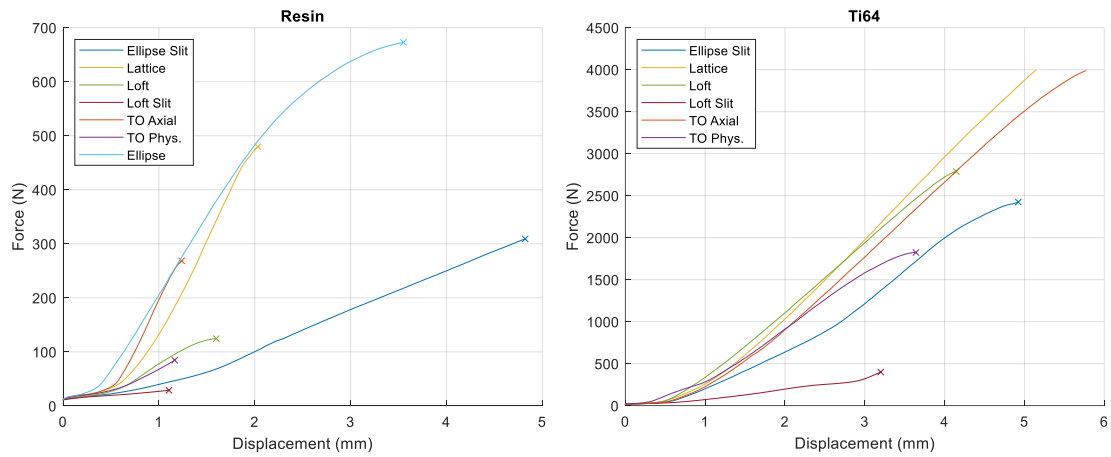


Figure 3-19 Failure plots of the force vs displacement for the resin and Ti64 devices.

3.6.3 Compressive Testing

For the compressive testing, a total of 35 tests were conducted on three Sawbones specimens. Six resin devices and five Ti64 devices were successfully tested on all three Sawbones specimens while the lofted slit design failed in both materials at the first specimen (Figure 3-20). The resin devices had a good tracking surface in general with most of the flexure visible as shown in Figure 3-21 whereas the titanium devices had a poor tracking surface over all samples.

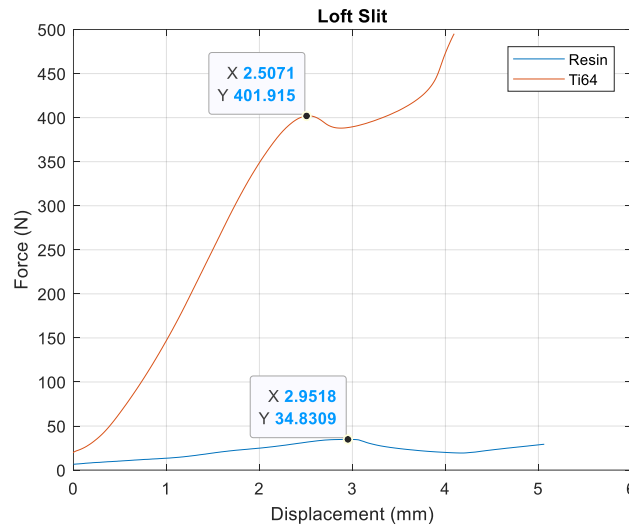


Figure 3-20 Force and displacement plot of the loft slit device which failed on the first specimen. The resin device failed at 34.8 N while the titanium device failed at 401.9 N.

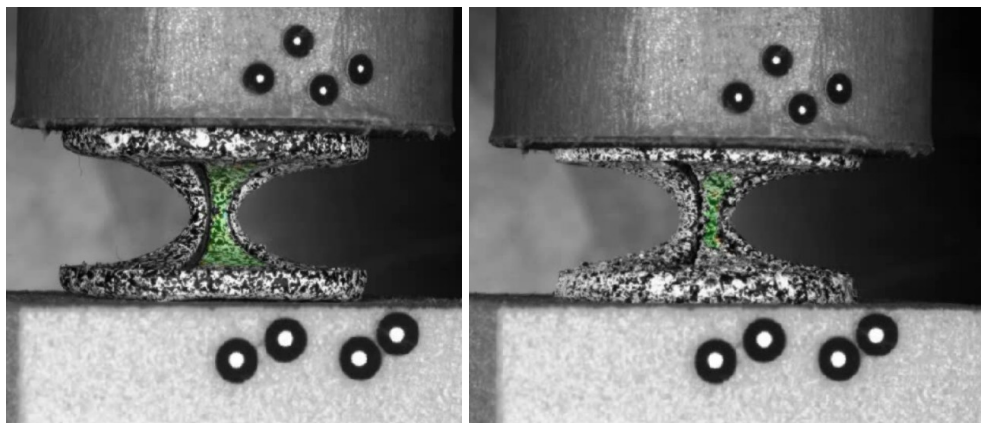


Figure 3-21 Example of the strain surface captured on the device. Left: Resin ellipse slit device. Right: Titanium ellipse slit device.

In general, device geometries with independent flexible elements were more compliant than geometries with a monolithic design and vertically aligned elements. Figure 3-22 shows the maximum von Mises strain for devices of both materials. In resin, the lofted, ellipse, latticed, and TO axial all had similar maximum strains around 0.9% indicating that either they were not tested under high enough loads to differentiate them or, as the slope of the failure plot would suggest, they have similar stiffness under compression. The slitted ellipse had a strain of 3.9% and 5.1% for resin and Ti64 respectively, which is approximately 3% higher than the rest of the devices. The high strain seen in the titanium is most likely due to a poor tracking surface since the device does not show that much compliance on video. It is closer to 2.9% as measured by the displacement of the end effector. Similarly, the lofted device in Ti64 also suffers from poor surface tracking results and only includes one sample (which failed) hence drastically increasing its apparent strain. The TO physiologic device had a strain of 1.6% for the resin and 1.1% for the Ti64, which is the only case where the titanium device had lower strain than the resin one. Otherwise, the standard deviations were within 1.5% of the average.

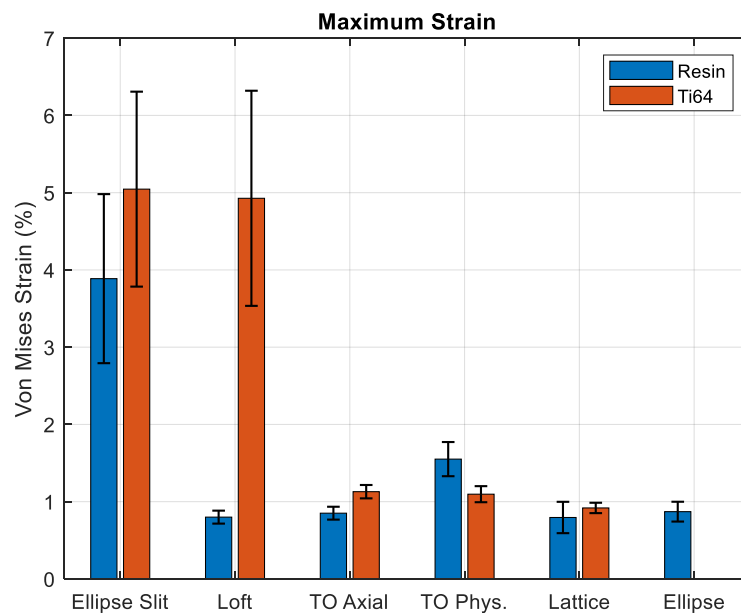


Figure 3-22 Maximum von Mises surface strain for resin and Ti64 cervical devices with standard deviation. The flexure-based devices (Ellipse slit and TO phys.) show more compliance than surface-based devices and strut-based devices (TO axial). The titanium devices show more strain than the resin devices due to poor surface tracking.

The resin devices show an initial compliant region with a stiffening region after about 0.4 mm of displacement as shown in Figure 3-23 and summarized in. The TO axial, latticed, lofted, and ellipse designs have an average stiffness of 47.1 MPa before 0.4 mm which increases to an average of 220.7 MPa after 0.4 mm. The TO physiologic has a stiffness of 31.4 MPa before 0.4 mm and 100.2 MPa after while reaching a peak displacement of 0.73 mm; about 0.4 mm more than the non-flexural devices. The slitted ellipse shows the most compliance with a stiffness of 23.7 MPa and 41.0 MPa while reaching a peak displacement of 1.18 mm which is about 0.65 mm more than the non-flexural devices.

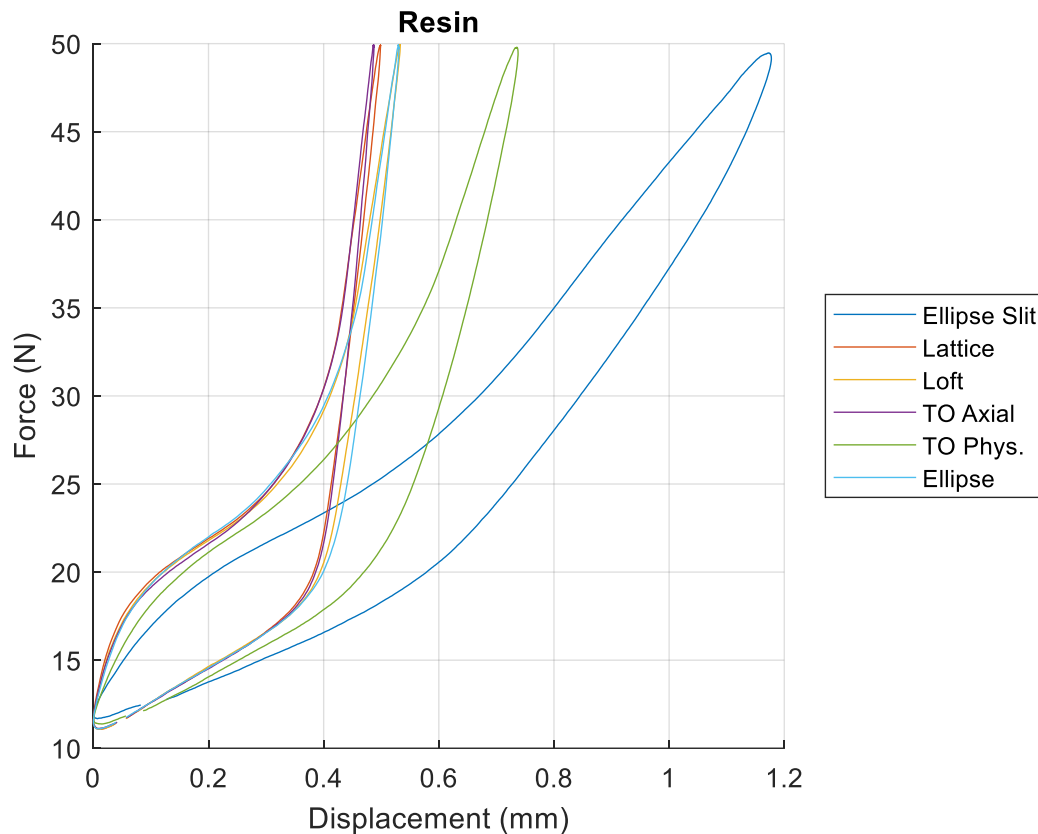


Figure 3-23 Force vs displacement plot for the cervical resin devices. The devices are initially compliant then stiffen around 0.4 mm in displacement. The flexure-based devices (TO phys. And ellipse slit) show less stiffening after 0.4 mm, reaching 0.21 and 0.65 mm more in displacement than other devices respectively.

The titanium devices do not show much change in stiffness during the compression waveform as seen in Figure 3-24 and Table 3-2. This could be due to insufficient loading for the high stiffness of titanium. All the devices except the ellipse slit had a stiffness of, on average, 862.5 MPa and an average displacement of 0.65 mm. The ellipse slit had a stiffness of 503.3 MPa and a maximum displacement of 1.03 mm.

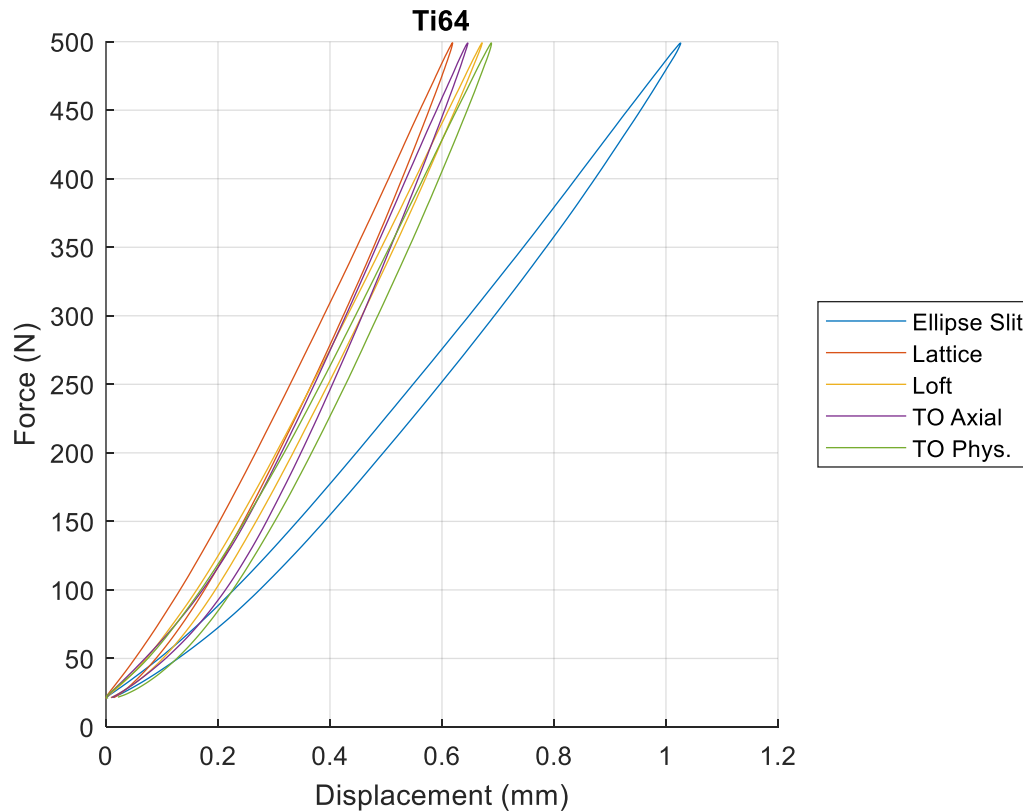


Figure 3-24 Force vs displacement plot for the cervical titanium devices. The titanium devices experience very little change in stiffness during the test, indicating that differences in stiffness are geometry based. The ellipse slit design has a displacement twice as large as the rest of the devices.

The titanium and resin devices show similar distribution of stiffnesses as shown in Table 3-2. The stiffness values were found using a best fit line to each region of the curve; the coefficient of the line representing stiffness. The ellipse slit had the lowest stiffness in both materials. Other devices were all relatively close in stiffness in both materials. The main difference is that the stiffness of the TO physiologic device was closer to the other devices in titanium than it is in the resin.

Table 3-2 Stiffness of the resin and Ti64 cervical devices in the toe-in and linear region. The resin devices had large changes in stiffness between the compliant region and the stiff region, except for the flexure-based devices (TO phys. And ellipse slit). The titanium had very little change in stiffness over the curves. In titanium, the lowest stiffness was the ellipse slit.

	Resin (MPa)		Ti64 (MPa)	
	Non-linear	Linear	Non-linear	Linear
Ellipse Slit	23.7	41.0	-	503.3
Lattice	39.3	234.5	-	879.1
Loft	36.3	198.0	-	829.6
TO Axial	61.8	251.0	-	915.2
TO Phys.	31.4	100.2	-	826.1
Ellipse	51.0	199.2	-	-

3.7 Discussion

In this study, seven devices with different compliant features were designed successfully and printed in Rigid 4000 resin and titanium. The 3D strain fields were examined under compressive loading using a speckled pattern on the devices. Some challenges were encountered during the manufacturing of the Ti64 devices causing the device geometry to be deformed and the ellipse design to fail. On the resin side, the devices proved to have a large overhanging areas and curves below 30 degrees which caused difficulties with supporting the parts adequately. The spindle feature created a deep concave surface around two planes of the device making it impossible to place without internal supports. Some of these supports were very small and difficult to remove or caused the part to break upon removal.

On the speckling side, the highly curved surfaces were difficult to speckle because the paint droplets deformed on angled surfaces, painting more/less than desired. The small geometry of the device made it difficult to get paint into concave surfaces and the parallel endplates prevented the application of paint orthogonally to the surface. Several methods were attempted to create a speckle pattern, for example: spray paint, paint brush, stamps, custom-molded stamps, manually making dots, and flicking paint onto the surface. The most reliable method was the paint flicking method because it dispensed a controlled amount of paint in a constrained direction and region. A stiff toothbrush was found to work best. Despite this, the speckled surface was difficult to capture on the titanium devices. This is probably due to the surface roughness of the titanium devices causing an uneven surface;

scattering light and obfuscating the speckles in each camera's view. This led to poor tracking of the flexure strain in titanium samples and an overestimation of surface strain.

On the design side, topology optimization was used to attempt to make compliant designs. A recognized limitation of this study was the use of lumbar spinal loads for the cervical interbody design space, however, the data for cervical loads was not available. The topology optimization using only a single axial load was unable to create compliant features on its own, resulting in thin vertical structures. The physiologic optimization, however, was capable of producing a more compliant geometry due to the addition of secondary loads shifting the loading pathways to other planes. While the creation of these devices was successful, it was found that current TO algorithms are not built to handle compliance even through the clever combination of optimization objectives and loading pathway negatives. A future direction for this part of the design would be to create custom algorithms to handle compliance optimization, such as Orr et al which design custom algorithms to optimize Ti64 flexures [65].

The experiment showed that the ellipse slit geometry had the most strain in both the resin and the titanium samples, while the lofted slit device failed before reaching the compressive load in both materials. The resin devices displayed initial non-linear behavior in the toe-in region before stiffening into the elastic region. This stiffening was lessened for the ellipse slit and TO physiologic design. The titanium devices did not display a drastic non-linear region, but the stiffness slightly increased during the trial.

Based on the plots for both Ti64 and resin, the high stiffness of the latticed, TO axial, and loft devices is consistent with their structural design. The TO physiologic design exhibits material dependent behavior as it is stiffer in titanium than in resin relative to the other devices. However, it is still the second most compliant device after the ellipse slit design. In both materials, the ellipse slit shows low stiffness and doubles the maximum displacement of the other devices. The slits in the ellipse geometry give this design more compliance by adding controlled defects to increase the bending potential. Hence, engineered flexures are capable of being more compliant than lattices or optimized designs.

There remains much interest in developing spinal implants to match the spinal motion segment where a combination of structures and soft tissues support the spine. A group out of Switzerland has developed a series of studies on the compliance of the intervertebral disc using polymer AM features [78], [79], [42], [80]. Their 2021 study compared five ASD designs manufactured in polymer AM to

the IVD using compression and rotation measurements on a 6DOF custom spine motion simulator [18]. The study showed that ASD designs that more closely mimicked the structure of the IVD had a range of motion and energy dissipation closer to what is seen in a healthy IVD. Furthermore, it was shown that architected materials demonstrated superior matching to the performance of the IVD. Similarly, the current work has shown that architected materials can improve the performance of fusion cages by the ability to tailor the shared strain to the optimal bone growth strain. The current work has also used a similar testing methodology to Yu et al. by using a 6DOF spine motion simulator and 3D optical tracking to measure surface strain. The current study also added a comparison between resin and titanium implants. However, the analysis done by Yu et al. is much more in depth than the one presented here as they looked at rotational stiffness, hysteresis, and sigmoidity in addition to strength, stiffness, and ROM. A limitation identified in the study is the use of quasi-static loading which means that no dynamic effects were able to be measured. The current work also used quasi-static loading and hence suffers from the same limitation.

A 2025 study by Fang et al. investigated chiral metamaterials with large recoverable elastic energy via torsional buckling [81]. The results of this study found that chiral struts can maintain a high stiffness while sustaining elastic strain within an enhanced buckling plateau over non-chiral metamaterials. The results in the current study concur with these findings as torsional buckling was observed in the TO physiologic implants increasing their compliance compared to non-flexural implants. The study by Fang et al. also found similarities between resin and the TC4 titanium alloy corroborating that the geometry controls the stiffness of the metamaterial.

This work is limited in the sample size for the number of features investigated. Ideally, a factorial experiment could be performed to investigate effects and cross effects; however, the power required for statistical significance made it difficult to achieve and the results of this study should be considered exploratory only. While the number of features could have reduced, it was not known which would perform well, and three repetitions were considered enough for design validation. In addition, this study was limited by the topology optimization software available. While nTopology and Altair Inspire were used, they were not designed for the optimization of compliance towards minimizing stiffness. Future work should look at creating algorithms that can optimize flexures and compliant designs to fill the gap in this growing field of meta-materials. Another limitation is that the flexural elements were very small and curved out-of-plane making the calibration of the 3D motion tracking system challenging because of the depth to width ratio of the field of view. This caused the data to be quite poor in some regions

affecting the accuracy of the strain results. The field of view in this study was increased to increase the depth perception, however future work should use a smaller field of view, focusing on different areas of interest and stitching the results together over multiple trials or with some clever mirror placement to increase the accuracy of strain results. On the loading side, the testing was only conducted in compression, which is suitable for preliminary results, but more in-depth testing and analysis is needed.

3.8 Conclusion

This study was an exploration into the viability of using flexural elements in the tailoring of compliant features for spinal devices. As shown in the strain measurement and compression testing results, geometries with engineered flexural elements can achieve a higher compliance than surface-based devices and lattices due to the individual bending of each flexural element. This was seen in both PEEK-like resin and titanium devices, with the resin showing greater non-linear compliance. The limitations posed by the 3D motion tracking system used in this study affected the accuracy of the results but can be overcome by taking extra data collection steps. Future studies should investigate optimization algorithms for compliant features and engineered metamaterials.

Chapter 4

Design and Characterization of a Dynamic Surface Conforming Implant

4.1 Background

A problem space was initially identified through discussions with orthopaedic spinal surgeons partnered with the Orthopaedic Biomechanics and Mechatronics lab at the University of Waterloo. It was suggested that intervertebral cages with large footprints, such as lateral lumbar interbody fusion (LLIF) cages, may not evenly contact the endplate at all locations due to asymmetries across the intervertebral joint and the vertebral endplate surfaces. In this case, the portion of vertebral bone not in contact with the implant may see little to no load as depicted in Figure 4-1, causing either the bone graft or the vertebral bone in that region to resorb due to lack of strain [82] and risk potential failure of the spinal fusion surgery. The loads on the unfused portion of the implant would result in additional stress on the fused portion of the implant, which was determined to be a potential reason for implant failure [54] [47]. Furthermore, the angular mismatch between the vertebral endplate and interbody cage has been shown to increase subsidence in a Sawbones model [12] hence increasing the clinical risks in an asymmetric endplate contact scenario.

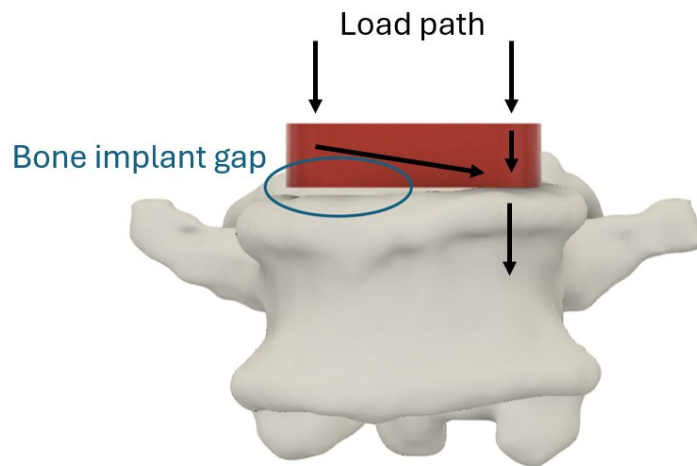


Figure 4-1 Loading pathways for an implant with uneven endplate contact. The bone-implant gap on the left prevents load transfer. Angular mismatch occurs between the vertebrae and implant at the loading surface.

There are several potential solutions to this problem. The most rudimentary would be to remove parts of the vertebral endplates during an anterior approach to level the surfaces. This is not desirable because removing cortical bone from the endplate reduces the overall stiffness of the vertebral body, potentially causing implant subsidence or other complications [67]. Expandable cages are another way to approach this problem, especially for PLIF procedures as shown in Figure 2-9. There are a few expandable large footprint cages like the RISE-L® (Globus Medical Inc., Pennsylvania, United States) on the market. More recently, patient-specific cages have been designed and show promising results for spinal reconstruction [52]. However, these cages require precise positioning to be effective, which is difficult to achieve during surgery [52]. As such, there is space to improve these designs to obtain a cage able to correct spinal disorders while giving the surgeon control over the implant-bone interface.

High surface conformance of the implant with the underlying bone is often critical to the long-term success of spinal surgeries [67] [83]; however, most spinal implants have a limited ability to match the organic surface profile of the vertebral endplate. To address this challenge, the goal of this study was to design and evaluate additively manufactured LLIF cages based on bone contact area and pressure distribution. Within this goal, the capabilities of AM were leveraged to design a large footprint spinal fusion implant as a solution to increase vertebral endplate contact area in challenging spinal environments. Then, the effect of a dynamically surface conforming implant on endplate load distribution was evaluated under physiologically relevant loading scenarios.

4.2 Design Requirements

The following design requirements were identified from the goals of the study. The original problem of a collapsed disc space must be corrected and the cage should maximize contact area. Not all clinical factors are considered as constraints in order to leave an open design space; they are rather included as criteria. Table 4-1 describes the range of adjustments necessary to conform to average lumbar vertebral body measurements. The ML and AP directions are based on the slope formed between the lowest point in the center of the vertebral body to the highest point at its periphery.

The constraints of the design problem are:

- Restore intervertebral height (correcting the original problem)
- Minimally invasive profile
- Maximize contact area between the implant-bone interface

The criteria include:

- Restoring segmental lordosis
- Reduction in implant subsidence
- Maximize the space for bone graft
- Biocompatible materials
- Fatigue resistance
- Material modulus similar to bone

Table 4-1: Vertebral endplate geometry specifications

Anatomical Axis	Range of adjustment	Source
Medial-lateral adjustment	0 to 5 degrees	Height difference in ML vertebral endplate geometry [28]
Anterior-posterior adjustment	0 to 2 degrees	Height difference in AP vertebral endplate geometry [28]
Superior-inferior height	8 to 16 mm	Lumbar vertebral heights [16] [83]

4.3 Design of a Dynamic Surface Conforming Implant (DSCI)

Based on the above requirements, a starting point for what will be called a dynamic surface conformance implant (DSC/DSCI) is to section a solid LLIF cage geometry (see Section 4.4) into components. Those components could then be separately actuated to give the surgeon precise control over surface conformance.

First, the size of the cage must be determined. Figure 4-2 describes LLIF cage sizes used in disc replacement procedures during a study on the radiological and clinical evaluation of the implants. The cadaveric lumbar spine specimens available for this study had endplates that measured on average 46mm by 35mm. Given the safe zone [45], [84] (seen in Figure 2-6) for LLIF implants and the lateral lumbar surgical technique shown in Figure 2-5, the implant size that was determined to be most representative was 40mm x 18 mm with a height of 10 mm.

Characteristic	Levels (n = 223)
Levels treated, n (%)	
T11-T12	1 (0.5)
T12-L1	1 (0.5)
L1-L2	14 (6.3)
L2-L3	39 (17.5)
L3-L4	64 (28.7)
L4-L5	104 (46.6)
Cage length, n (%) (mm)	
40	3 (1.3)
45	17 (7.6)
50	66 (29.6)
55	95 (42.6)
60	36 (16.1)
Cage height, n (%) (mm)	
8	8 (3.6)
10	69 (30.9)
12	115 (51.6)
14	24 (10.8)
16	6 (2.7)
Cage width, n (%) (mm)	
18	117 (52.5)
22	102 (45.7)
Cage angle, n (%) (mm)	
0°	72 (32.3)
10°	150 (67.3)
<i>n indicates number of patients; mm, millimeters.</i>	

Figure 4-2. LLIF cage sizes documented in 223 cases. Adapted from [6].

Next, a mock implant was recreated in Fusion 360 (Autodesk, California, United States) and sectioned into 3 parts as seen in Figure 4-3. This sectioning method was chosen because it would divide the implant along its longest length, thereby reducing the size of the problematic dimension. A single unit of the sectioned implant was isolated to work as an independent functional unit.

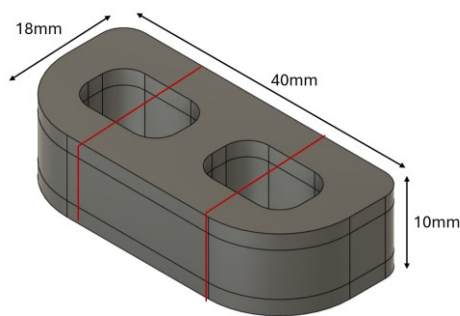


Figure 4-3. Mock LLIF implant with proposed sections.

With the functional unit as a basis for the design, several additional requirements can be identified. The unit must be able to either compress and/or expand in relation to the other units to allow for conformance to the underlying structure. The main difference between the compressible and expandable cage is the stiffness requirement; a compressible cage would need a patient specific non-linear stiffness curve while an expandable cage would need an increased elastic range. A more detailed discussion can be found in Section 2.3.2. An expandable design was settled upon for the preliminary design of the functional unit.

4.3.1 DSC Implant Development & Prototyping

There are several different types of expansion mechanisms such as wedges, screws, wheels, and spacers which can be seen in Figure 2-9. Due to the minimally invasive nature of the surgery for LLIF type implants, it was reasoned that the implant should be able to fully expand from the lateral side facing the incision. This means that the expansion mechanism would need to be accessed by only one port. This would make spacers less effective because it would be difficult to obtain a differential expansion along the different units of the implant. Wedges and screws are generally used for unidirectional expansion which would account for only one degree of bony endplate conformance. This is not ideal as the vertebral endplate can be uneven along multiple planes, and a mechanism for multi-directional expansion would be quite complex with these methods. Reducing the complexity of implants is imperial to improving their performance, as seen in artificial disk replacements [85].

This leaves the option of rotational motion. An ellipse-like shape could expand the implant along its changing radius while providing a central point of contact for the implant to articulate on. This is similar to early total disk replacements such as the Charité Artificial Disc® (DePuy Spine Inc, Raynham, Massachusetts) seen in Figure 4-4 which uses a ball and socket joint to allow for spinal movement.



Figure 4-4 Charite Artificial Disk [86]

Since movement is not a priority for fusion implants, a method of stabilizing the ball and socket joint is necessary. Possible solutions explored include hinges, locking mechanisms, lattices, and flexible members (Flexures). Some lattices were tried for the functional unit, however the size of the struts (e.g. in a BCC lattice) or walls (e.g. in a TPMS lattice) were too thin to obtain the flexibility necessary for surface conformance (Table 4-1). Flexures on the other hand were able to accommodate the range of adaptability necessary for endplate conformance. The first DSC implant prototype design was thus obtained and can be seen in Figure 4-5. The flexures on this prototype follow a polynomial shape with filets to reduce stress at the flexure-implant interface. The wheel is held in place by a central hub mounted to flexures to allow for expansion.

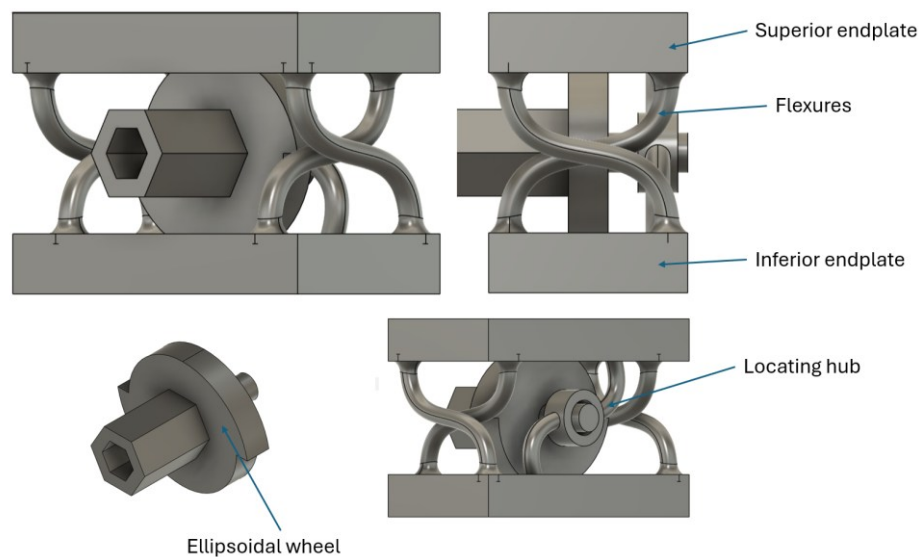


Figure 4-5. The first DSC implant prototype. The concept is that the surgeon can engage the wheel through a hex design which causes the endplates to distract from each other to increase contact area.

The prototypes designs were printed in different resin materials on Formlabs printers. Initial trials were printed in the “Grey Pro” resin due to availability and quality of print. Later prints used the Rigid 4000 resin which has falls within the material properties of polyether-ether ketone (PEEK) [53] [87]. This was done to make the implants similar to bio-safe materials already in use in intervertebral implants to facilitate result comparison. The implants were also printed in the Tough resin due to its exceptional elastic material properties. This was used as a test of material performance versus geometry performance. Grey pro resin and black resins were also tested; however, the elastic performance and material characteristics were not suitable for this research.

After some initial observations, the mating surface between the wheel and the inner implant endplates was optimized over several iterations. It was found that the flat surface of the extruded offset ellipsoidal wheel in Figure 4-5 caused a rocking motion along the long axis of the functional unit due to the contact mechanics of the sharp edges. Additionally, the locating hub was too stiff and would fail under small loads, so it was removed. The wheel was redesigned to an ellipsoidal ball shape and the mating surface was outfitted with a concave curve to fit the ball as seen in Figure 4-6.

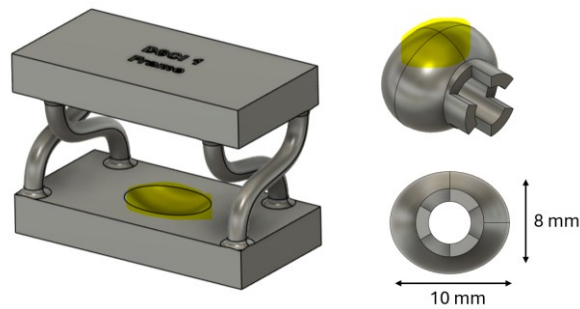


Figure 4-6. Mating surface optimization and 2mm expansion dimensions.

Another major milestone was the combination of the functional units into the overall implant. It was decided that the middle unit would remain solid to increase the rigidity of the overall implant and to provide a connecting structure for the functional units. The result of the combination of the units can be seen in Figure 4-7.

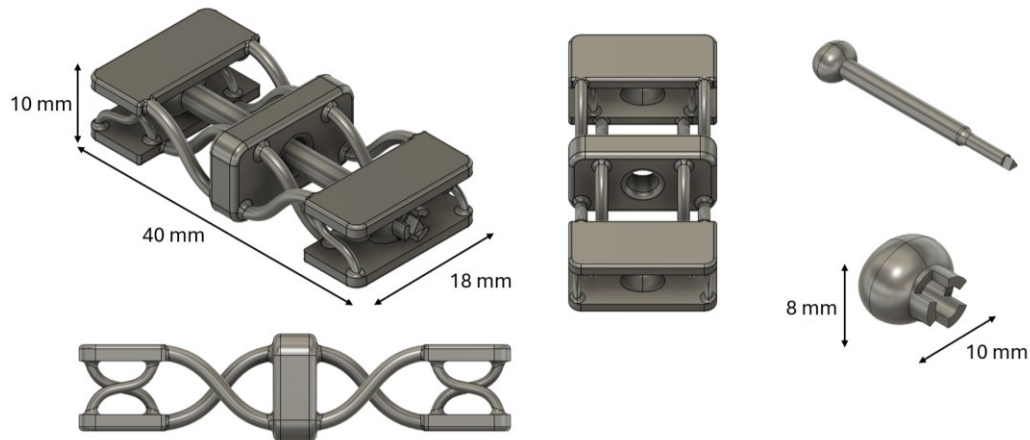


Figure 4-7. Combination of the functional units back into a single LLIF sized device. The expansion mechanism is shown in more detail on the right.

Pilot testing was conducted on the AMTI VIVO (AMTI, Watertown, Massachusetts, USA) six degree of freedom (6DOF) joint motion simulator fitted with custom fixturing. It was observed during the pilot testing that the flexures of the DSC implant would fail destructively around 300N compression for the PEEK-like resin and would fail plastically around 400N for the tough resin. The small flexures in the functional units would fail first during compression while the central connecting flexures would only fail at the maximum loads in flexion. The tough resin version was able to conform to the surface a bit more readily due to the flexibility of the material. It was also observed that the central connecting flexures needed to shorten to accommodate for the expansion of the ellipse hence adding stress. This additional stress is likely the cause of the flexures failing in flexion because the geometry was already in a maximum bending configuration.

In the initial observations, the ellipses and mating surfaces worked well to accommodate the angle of the Sawbones as well as the physiologic movement. The curved surface provided a pivot point for the flat endplates to remain in contact with the Sawbones endplate. In addition, the ellipses held the 500N load with no visible wear or slippage. The friction of the PEEK-like resin was enough to keep the ellipsoids from rotating back to a collapsed state.

The flexures were then redesigned based on these observations. First, it was determined that the flexures being constrained in one plane was affecting the performance of the system, so 3D flexures were designed following a corkscrew/chiral design. This design allows the flexures to accommodate bending in plane and out of plane, hence increasing the possible elastic deformation. This change can be seen in Figure 4-8.

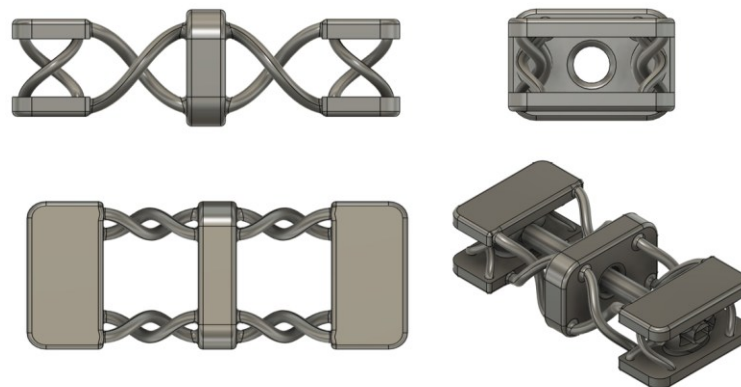


Figure 4-8 Chiral flexure design on the DSC implant.

4.3.2 Final DSCI Design

The flexures within the functional unit were still very brittle after the change. It was found that they were redundant since the central flexures held the implant endplates in place and hence could be removed. The shape of the ellipsoids in the expansion mechanism was improved to add a greater expansion capacity while also allowing for some small compression by making the collapsed state slightly undersized. The final design can be seen in Figure 4-9 with the expansion mechanism in Figure 4-10. The proposed design maximizes the space for bone graft from the void space in the implant, has a minimally invasive profile, and is made from a PEEK-like material suggesting that a bio-safe model is possible. Furthermore, the expansion mechanism of both sides of the implant is actuated from the medial side of the implant.

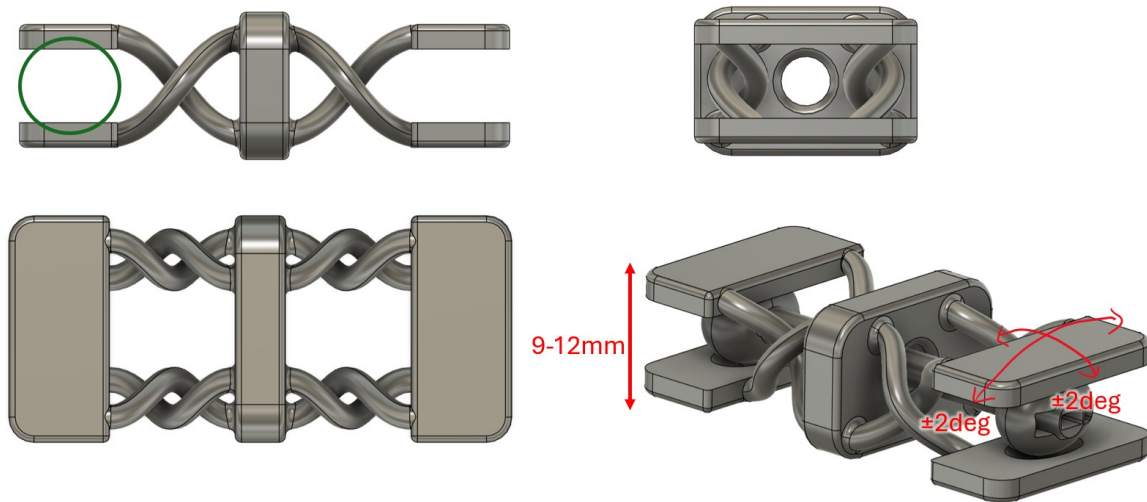


Figure 4-9. Final DSC implant design. Shown in red is the achieved ROM. Circled in green is the removed flexures from the previous design.

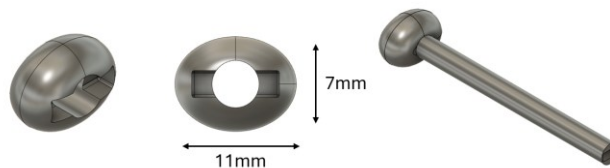


Figure 4-10. Final expansion ellipsoids with an expansion of 4mm.

4.3.2 Design for Additive Manufacturing

The complex shape of the DSC implant lends itself to difficulties with manufacturing. With traditional manufacturing, the flexures, main body, and endplates would be manufactured separately and assembled using biocompatible methods like press fits and screws. The benefit of additive manufacturing is that the structure can be scaled and printed directly and as needed with minimal post processing if done correctly. Hence, there are some guidelines to follow with the AM process to produce viable parts.

For the resin printed implants, the orientation of the part with respect to the print lines, the layer size, and the support structure location all affect the quality of the finished part. The material plane parallel to the layer lines of the print is the weakest in bending due to the delamination of the layers, as such, the main body was printed with the posterior portion facing the print bed so that the flexures were mostly parallel to the print lines. In this orientation, it was possible to place support structures such that all overhangs were mitigated. The expansion wheels were printed on an angle relative to the build plate. The three parts were then assembled post-printing.

For the metal AM part, the laser powder bed fusion process is more complex due to the added complexity of heat mitigation, porosity, and post-processing time. Ti64 support structures require machining to remove, which is complicated with a very three-dimensional part such as the DSC implant. So, necessary supports should be kept to a minimum. Due to the sintering process however, layer lines are not as relevant as part porosity and heat dissipation. The flexures were the main difficulty as the long thin feature with overhangs would be difficult to print. The flexures were adjusted to include a 35-degree chiral slope in the ML direction such that when printing the implant in the ML direction, the flexures would need no supports. This length-wise printing orientation is beneficial because it minimizes the footprint on the print bed hence increasing production quantities. Next, the flat features of the endplates were given a concave shape to allow printing without supports as well. Next, the overhanging portions of the central block was trimmed such that the flexures became the supports for the block. Finally, the expansion wheels were tapered towards the print bed to allow them to be self-supporting as well. The shaft of the expansion wheels would act as a heat sink to the print bed so the print could be printed as one assembly. To do this, the gap between bearing surfaces was adjusted to be over the specification for gap size. Figure 4-11 shows the changes necessary to achieve a print in place implant of complex geometry.

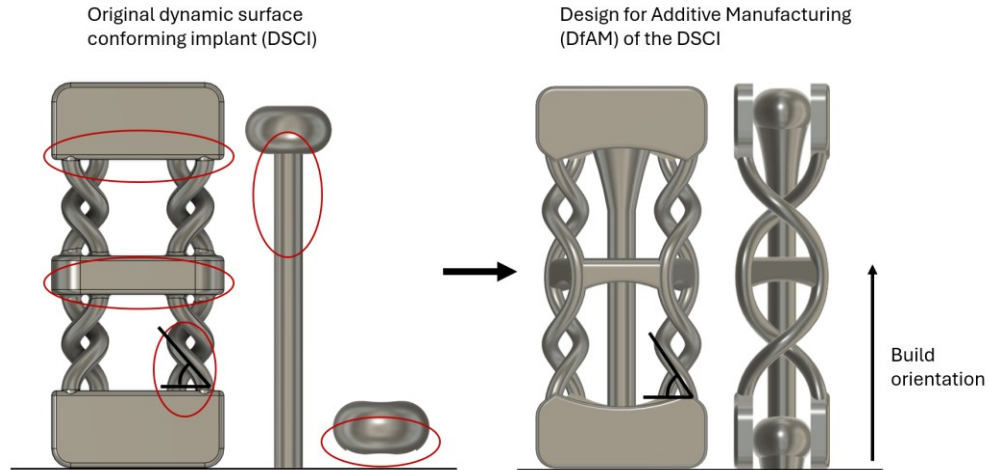


Figure 4-11 The original DSCI design and the DfAM design. Changes are outlined in red, and the angle of the flexure is highlighted by the angle arc.

4.4 Implant Manufacturing

Commercial implants were reverse engineered based on Yuan et al. [5] and other available implants [88], [89]. The result can be seen in Figure 4-12. This base geometry was then modified to produce three other comparison implants. The first modification was to change the endplate of the implant from flat to an anatomically conforming arc. The shape of the arc was based on vertebral endplate concavity measurements performed by Palepu et al. [28], thus shaped to conform to the average lumbar L4/5 endplate. The second modification was to add a lattice to the middle of the flat and anatomic LLIF implants. A thin (2mm) extruded feature was kept on the superior and inferior surfaces of the implant to act as the implant endplate and attach the lattice to a solid structure. The lattice chosen was a triply periodic minimal surface gyroid with a thickness of 0.5mm which was determined through trial and error. This type of lattice structure was chosen because it is a common type of surface lattice. The four commercial style implants can be seen in Figure 4-13. The final DSC implant is shown in Figure 4-14.

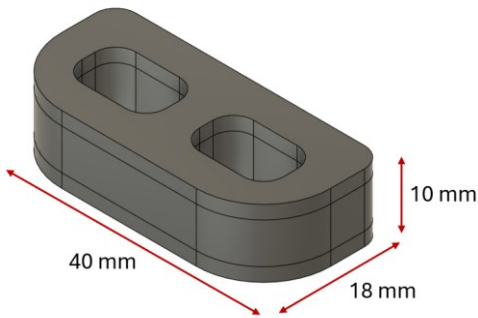


Figure 4-12 Mock commercial LLIF implant with dimensions in red.

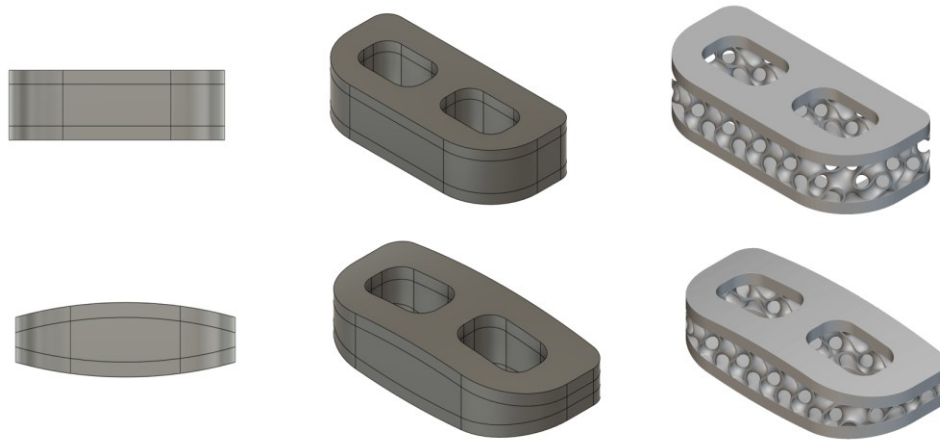


Figure 4-13 The four on-the-market and modified LLIF implants. Top: flat endplate implant with the solid (middle) and latticed (right) versions shown. Bottom: anatomic-shaped endplate implant with the solid (middle) and latticed (right) versions shown.

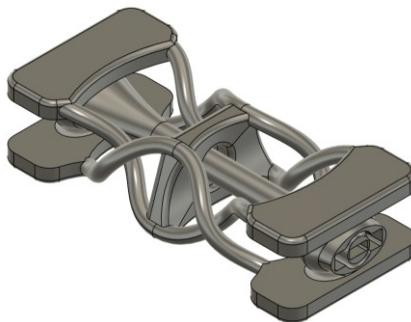


Figure 4-14 Final CAD model of the additively manufactured DSC Implant.

The four modified commercial implants and the DSC implants were manufactured on the Formlabs Form 3+ (Formlabs, Somerville, Massachusetts, USA) printer in the Rigid 4000 resin. This resin was chosen due to the similarity of its material properties to PEEK, as explained in Section 3.4. The DSC implant was additionally printed in tough resin to see if material flexibility would change the results, making a total of 6 resin implants. All cages were the same size: 40x18x10 mm.

In addition, a set of Ti64 implants were printed in LPBF on the Renishaw AM400 (Wotton-under-Edge, England) in partnership with the MSAM laboratory at the University of Waterloo. The four commercial-like implants and one DSC implant were printed. Post-processing consisted of depowdering and machining parts off the print bed.

The printed samples were then spray painted with a thin layer of matte white paint and speckled with matte black spray paint by the instruction of the Aramis 3D motion Tracking team.

4.5 Implant Testing Methods

Testing was conducted on the AMTI VIVO (AMTI, Watertown, Massachusetts, USA) six degree of freedom (6DOF) joint motion simulator fitted with custom fixturing. The custom fixtures were designed to simulate vertebral endplate geometry in a repeatable fashion, similar to the setup used by Kusins et al. [50]. The experimental setup consists of a custom LLIF implant placed on a machined block of standardized polyurethane Sawbones (20 pounds per cubic foot; Pacific Research Laboratories Inc., Vashon, Washington, USA) selected to simulate vertebral endplate bone [5]. Individual sets of Sawbones were machined to induce asymmetric loading in the implant through an angled offset plane geometry causing a floating implant end. The angle of the Sawbones wedge matches the average height difference between the outer edge of a vertebral body and the center of the body, obtained from Palepu et al. [28]. The top end effector of the setup consists of a 3D printed double wedge also matching the angle forming the height of an average vertebral body. This geometry was chosen as a simplification over the actual geometry of the vertebral body to ensure repeatability. An anti-slip strip of sandpaper was glued to the surface of the end effector and trimmed to size. The full assembly can be seen in Figure 4-15.

A Tekscan thin-film pressure sensor (Sensor 5051; Tekscan, Norwood, Massachusetts, USA) was used to measure the contact area and pressure distribution of the experiment. The sensor was placed between the Sawbone sample and the implant as this was the critical measurement surface. To prevent slippage between the sensor and the Sawbones, the sensor was held in place using electrical tape. This

method of measuring the contact area and pressure was previously used by Kusins et al [50] in a similar implant evaluation. The Tekscan sensor was calibrated once at the beginning of the testing after initial preconditioning on a custom designed calibration fixture (Figure 4-16). Calibration was performed using a 2-point calibration curve per the recommendation of Tekscan technical support and collected at 20N and 400N.

The Aramis 3D motion tracking system with photogrammetry and full field tracking on the implant was setup. Data was collected for implant cage migration and to reference end effector movement. (Aramis data was not used in the end.)

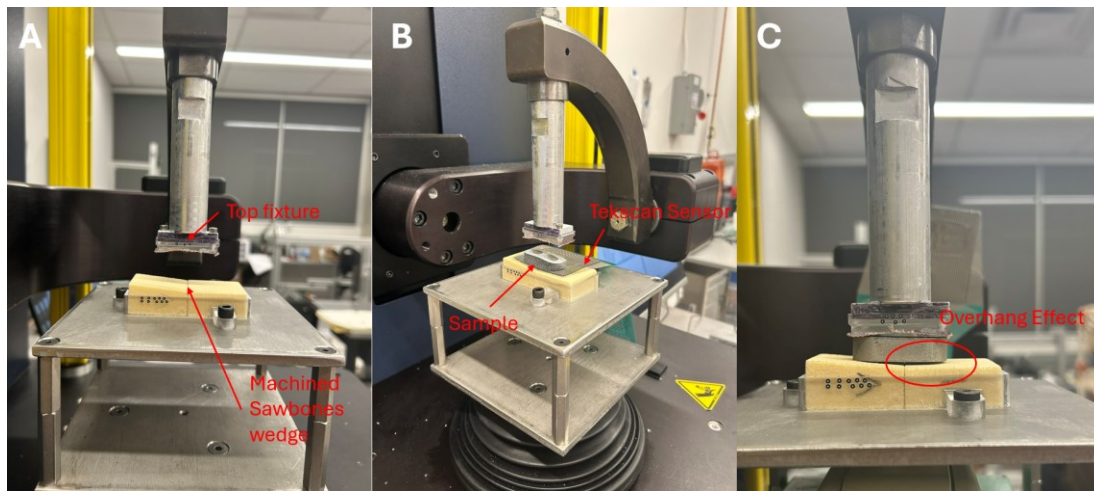


Figure 4-15. Experimental setup. A) Machined Sawbones sample can be seen on the bottom and the anatomically matching printed plate with sandpaper installed can be seen at the top. The structure is fastened to the load frame. B) The Tekscan and mock implant placed on the Sawbones. C) Example of the simulated challenging geometry.

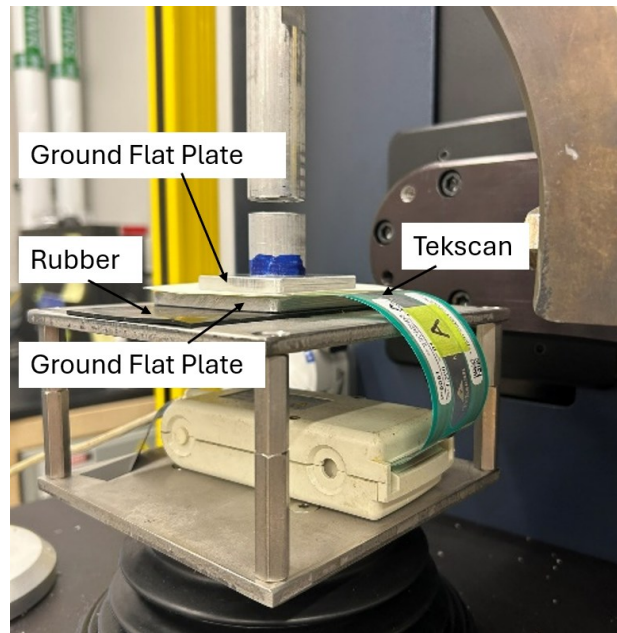


Figure 4-16. Tekscan custom calibration fixture.

Each cage was centered on the top end effector by aligning cage and fixture edges which were designed to have the same footprint. If necessary, expansion of the implant was performed before any load application. The overhanging end of the implant received the maximum expansion while the contacting end received no expansion. The test setup included no lordotic angle.

For pilot testing during initial prototyping, two waveforms were applied sequentially with 5 cycles each at a frequency of 0.05Hz. The first applied waveform was a sinusoidal 500N compressive load with free movement on about all other degrees of freedom simulating the ASTM F2077-22 standard [71]. The second waveform was a simulated 6DOF flexion-extension waveform using a ± 1 Nm moment in FE and a 250 N compression while holding all other forces near 0 N. Load and displacement data was collected using the load cell on the AMTI VIVO while contact area and pressure was collected using the Tekscan sensor. Basic statistics and observational results were used for pilot testing.

More extensive testing was conducted for the full experiment. The spine can perform 3 main isolated movements, namely, flexion-extension (FE), lateral bending (LB), and internal-external (IE) rotation, all while under a compressive load. Everyday activities require a combination of these movements; for example a gait cycle requires all of them. These waveforms were narrowed down based on the pilot testing, and any IE rotation was removed to reduce shear forces on the Tekscan sensor. The

four waveforms used to test the performance of the implants were, in order, FE, LB, gait, and compression. The FE, LB, and compression waveforms were the same as during pilot testing, with the LB being the same as FE except applied about the AP axis. The gait waveform was a simulated 6DOF flexion-extension waveform using a time-warped average of physiologic lumbar spine loads collected from the OrthoLoad instrumented implant database [90] and obtained from McGregor [70]. An example of the gait waveform can be seen in Figure 4-17.

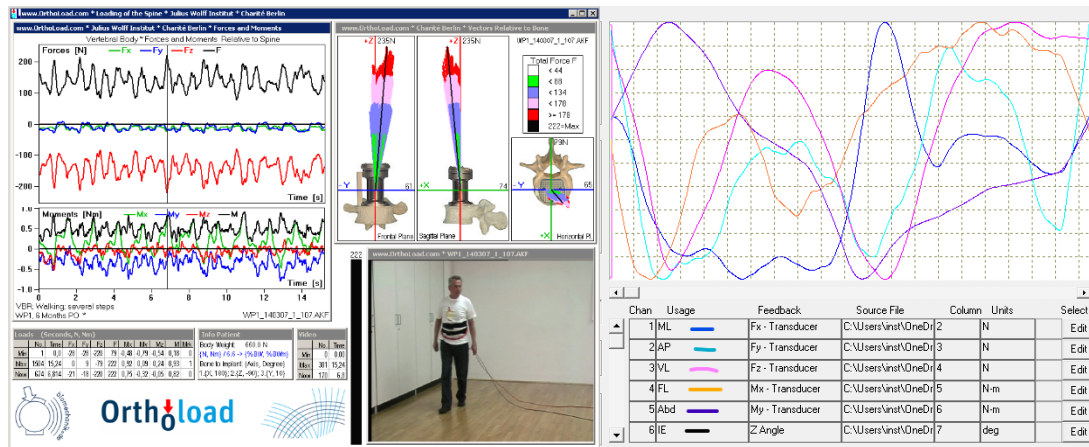


Figure 4-17 Gait waveform. Left: patient WPI gait sample from OrthoLoad. Right: the modified average gait waveform cycle applied in the experiment.

Testing used the protocol shown in Appendix C with each implant type in resin and Ti64 receiving four loading waveforms on three Sawbones specimens. The implants were randomly selected for testing using a blind pick method. Each implant type was tested with all four waveforms performed sequentially in the same order; resetting to its default position between waveform changes. The implants were tested once on the same Sawbones sample and sample integrity was checked visually after each implant. The repeated waveform was run for five cycles on each sample.

4.6 Data Processing

The data was processed by computing the average and standard deviation of the samples following a similar approach to that shown in Figure 3-14. The Tekscan data was recorded by button push, as such it was not aligned between samples or aligned to VIVO data. First, the Tekscan data frames were cleaned of noise which was determined to be five times the cell activation pressure, computed using

Equation 4-1, Equation 4-2, and Equation 4-3 provided by the Tekscan team. The sensor range is determined by the sensor used and the sensitivity factor is based on the calibration information.

Equation 4-1

$$\text{Turn on Pressure} = 3 \times \text{Cell resolution}$$

Equation 4-2

$$\text{Cell resolution} = \frac{\text{Full Scale Range}}{256}$$

Equation 4-3

$$\text{Full Scale Range} = \text{Sensor Range} \times \text{Sensitivity Factor}$$

The area data was extracted from each Tekscan recording by counting the active cells above the noise threshold and multiplying by the cell area. Both the area data and the load cell data were smoothed using a moving average over 1 second. The data for each sample was then aligned to the load cell data from the VIVO. All data was then cut to the middle three cycles of the waveform, which were averaged to one cycle. The reason to cut the data to the central 3 cycles out of the total 5 cycles is because the VIVO takes one cycle to attain the desired forces from the reference pose and then takes one cycle at the end to ramp down from the waveform back to the reference pose. Hence, the first and last cycle are not representative of the actual waveform. Then the data for each implant type was averaged between the three Sawbones specimens.

4.7 Results

4.7.1 Manufacturing

The 3D prints in resin were successful with no defects. It was noted that the Rigid 4000 DSC and flat latticed implants were prone to brittle failure if dropped or handled aggressively. Implants were successfully painted with a speckled pattern. The LPBF implants also printed successfully and were machined off the build plate without any issues. The Ti64 implants were not speckled since the Aramis was not used in the end. The final implants can be seen in Figure 4-18.

Resin



Ti64



Figure 4-18 The five implant specimens. The implants printed in Rigid 4000 are shown on top and are speckled. The bottom implants are the metal AM printed Ti64 implants. The implant types from left to right: flat, flat latticed, anatomic, anatomic latticed, and DSCI. In the resin set the additional DSCI (rightmost) is made from tough resin.

4.7.2 Asymmetric Sawbones Testing

For the resin set, a total of 8 implants of the six implant types (5 types + 1 tough resin) were tested on three separate Sawbones specimens. All six implant types were tested once on each Sawbones specimen. Three implant failures were observed which occurred in the flat latticed implant type under the compression waveform as seen in Figure 4-19. The lattice on the lateral side of the implant contacting the Sawbones wedge failed destructively at approximately 450N. The test was stopped after failure. These failed implants were replaced for subsequent testing necessitating one implant per Sawbones specimen, hence the 3 additional implants. All other implants remained intact throughout testing by visual and data inspection.

For the Ti64 set of implants, all 5 types were tested on 3 Sawbone specimens. No implants failed. Minor subsidence was observed on the wedge side when testing the flat implants, probably due to the sharp edges of the implant. Otherwise, no subsidence was noted for other samples. It is to note that only one specimen was analyzed for the titanium samples due to a lack of time.



Figure 4-19 Flat latticed implant failure of the lattice under compression at around 450N. The edge, circled red in the figure, where the implant contacted the Sawbones, experienced brittle failure. The test was stopped after failure.

The Tekscan was successful in measuring the contact area between the implant and the Sawbone specimens. The data was processed using a noise threshold of 25MPa when the sensor was set to high sensitivity and 0 MPa when the sensor was set to mid sensitivity. The percent area measure used was the measured Tekscan area over the implants endplate surface area computed from the CAD model (Table 4-2). The implant endplate area was computed at the inferior surface of the implant.

Table 4-2 Computed implant surface areas from CAD model in mm²

Type	Flat	Anatomic	Flat latticed	Anatomic latticed	DSCI	Tough DSCI
Area (mm ²)	488.7	491.9	488.7	491.9	360	360

A boxplot of the average contact area of the three Sawbone specimens was plotted for each waveform as seen in Figure 4-20. The anatomic latticed and the DSC implants have the highest percent area of around 60% across all multiaxial waveforms showing good implant-Sawbones surface conformance. They are followed by the flat anatomic and the tough DSC implants with around 50% area coverage. The lowest percentage were the flat implants which obtained below 40% coverage. The range of area coverage during the multi-axial waveforms for the anatomic latticed is smaller than the DSC, indicating more consistent contact area throughout the cycle.

For the compression test, the implants all had similar minimum area values indicating a similar contact surface with the wedge. Both DSC implants had the largest percent area (max 85%) in the compression test compared to the next highest value of 70% indicating better conformance to the Sawbone wedge in a uniaxial simulation. It is to note that the flat latticed implant failed during compression, as such, the value noted in the figure has been blacked out to represent data under failure.

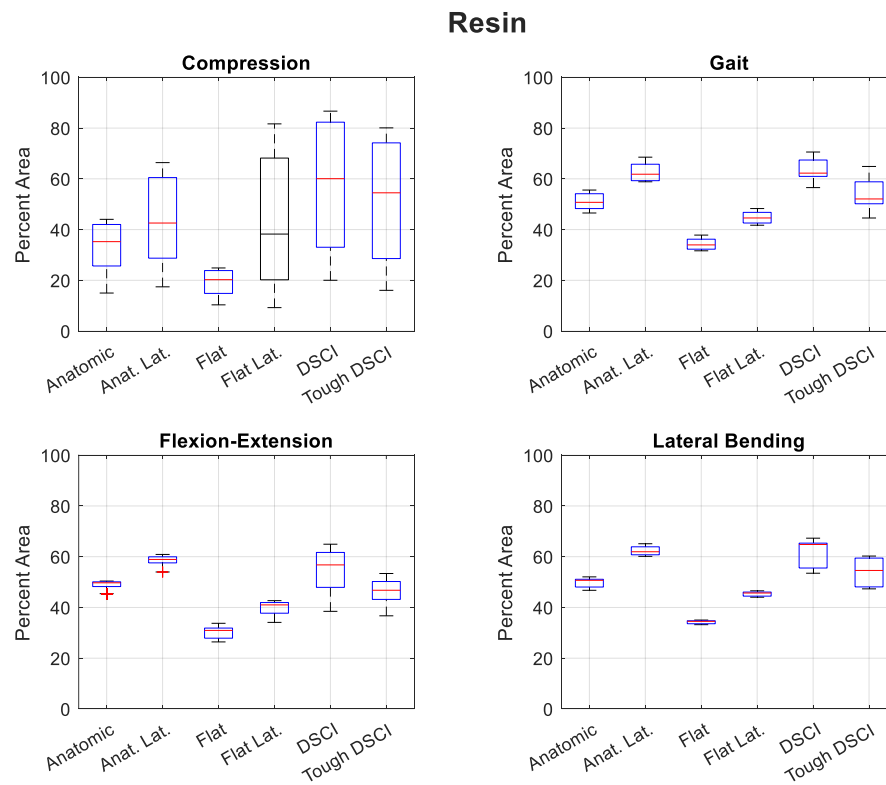


Figure 4-20 Boxplot across all implants over each anatomical movement (Flexion-Extension, Lateral Bending, 5 Step gait, and Uniaxial Compression). The black box in the compression waveform indicates inaccurate results due to implant failure.

The Ti64 implants had an overall 10% lower contact area than the resin implants due to the stiffness difference in the materials. The implant types follow the same trend in the titanium as in the resin where flat implants have the least contact area at 20% and the anatomic and DSC implants have the most at 50 and 40 % in multiaxial cases. The addition of a lattice did not increase the contact area as much as it did for the resin due to the material stiffness of the titanium being much higher than the resin. The flat lattice slightly increases the area range of the flat implant, however, in the anatomic case, the lattice decreases the contact area. This indicates that the test conditions may have been different as the area should be greater or the same. The uniaxial compression test once again shows lower contact area overall, but the anatomic types and DSC have 20% more contact area than the flat implants.

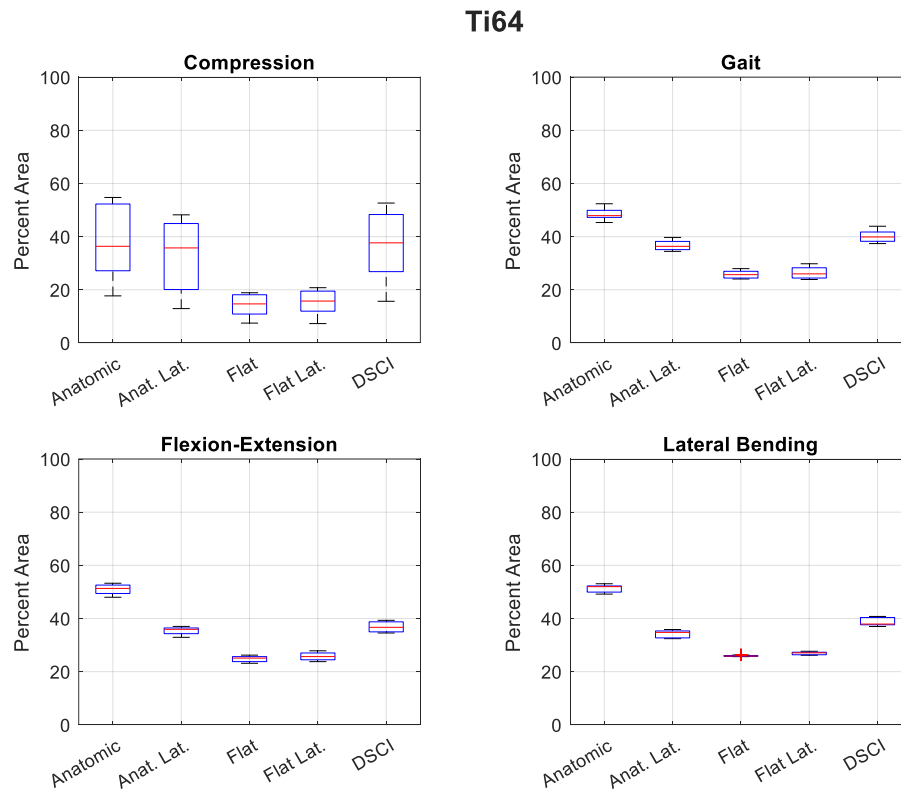


Figure 4-21 Boxplots of the Ti64 implant samples for the four waveforms. The flat implants have a lower contact area than the anatomic and DSCI in all waveforms. Overall, the solid anatomic implant has the highest contact area followed by the DSC implant. The latticed implants do not significantly affect the contact area of their solid counterparts.

The range of motion of the implants can be obtained from the measurements taken from the AMTI VIVO. This again shows that the DSCI conforms better to the asymmetric geometry than the other implants. Table 4-3 describes the maximum measurement of the mean and standard deviation of the three Sawbones repetitions for each anatomical motion. In the case of compression, the motion was restricted in all axes except superior-inferior axis, so all the other axes are 0. The anatomic design and latticed designs had the most displacement in the SI axis in compression. The samples with greater displacement showed some subsidence in the Sawbones, however it was difficult to quantify as the Sawbones display elastic behavior so only a small mark remains visible after the test. As mentioned, motion tracking data was recorded on the Aramis but was not analyzed due to a lack of time.

In all multiaxial cases, the DSC implant reduced lateral bending motion from around 4° to 0.5° compared to the other implants. This shows the effectiveness of expansion at closing the gap between the implant-bone interface. The FE waveform shows that the shape of the implant surface drove the amount of flexion seen, as the anatomic implants had the least FE movement ($\sim 1^{\circ}$) while the DSCI ($\sim 5^{\circ}$) had the most movement. This would make sense as the DSCI has the smallest pivot point (the middle section being small and the ellipses allow rotation) of all implants in the ML axis. Other measurements were similar between implants. In LB, we see the previously described trend where the DSCI has the least amount of lateral motion with all other motions being the same between implants. In the case of gait, SI travel is effectively the same for all implants, except for the tough DSCI. The solid implants seem to reduce the FE motion compared to more compliant implants. As seen previously, the LB in gait is reduced by the DSCI compared to the other implants.

It is to note that all IE rotation was constrained to no displacement in all multi-axial cases to reduce torsional shear on the Tekscan sensor. In the case of the tough DSCI, there is some rotation occurring, but the large standard deviation suggests that the VIVO kinematics are compensating in that axis to achieve the target loads in other axes. Another note is that the peak values reported are the maximum value of the range of motion with the settling motion included. The anatomic and flat implants tended to have at least 2 degrees of settling motion in LB before engaging any waveform, while the DSCI had only about 0.5 degrees of settling motion in LB. This again shows that the DSCI conforms better to the asymmetric geometry than the other implants.

Table 4-3 Peak average motion values of the implants for the resin set. The data represents the maximum of the 3 Sawbone specimens and includes the standard deviation between specimens. The DSC implant reduces the LB in all multi-axial cases. The anatomic cage has the least motion in the FE axis. The compression waveform was constrained to SI motion and hence has no other components.

Resin								
	Compression				Gait			
	SI (mm)	FE (deg)	LB (deg)	IE (deg)	SI (mm)	FE (deg)	LB (deg)	IE (deg)
Anatomic	1.79 ±1.6	-	-	-	1.93 ±1.66	0.12 ±0.37	4.49 ±0.34	0.5 ±1.02
Anat. Lat.	1.37 ±0.14	-	-	-	1.36 ±0.11	1.17 ±0.53	3.99 ±0.71	0.72 ±0.83
Flat	0.63 ±1.5	-	-	-	0.83 ±1.59	0.96 ±0.39	3.45 ±0.28	0.03 ±0.26
Flat Lat.	1.76 ±1.71	-	-	-	1.14 ±1.54	1.72 ±0.57	3.61 ±0.24	0.06 ±0.17
DSCI	1.27 ±1.39	-	-	-	1.05 ±1.37	1.4 ±0.55	0.38 ±0.31	0.18 ±0.45
Tough DSCI	0.77 ±1.58	-	-	-	0.55 ±1.56	1.05 ±0.27	0.39 ±0.43	1.91 ±2.58
	Flexion-Extension				Lateral Bending			
	SI (mm)	FE (deg)	LB (deg)	IE (deg)	SI (mm)	FE (deg)	LB (deg)	IE (deg)
Anatomic	1.85 ±1.66	0.73 ±0.42	4.14 ±0.3	0.26 ±0.33	1.86 ±1.66	0.25 ±0.4	4.71 ±0.36	0.39 ±0.65
Anat. Lat.	1.24 ±0.12	1.31 ±0.49	3.73 ±0.65	0.31 ±0.3	1.26 ±0.11	0.74 ±0.52	4.35 ±0.71	0.48 ±0.52
Flat	0.73 ±1.6	4.65 ±0.38	3.54 ±0.29	0.1 ±0.13	0.75 ±1.59	1.47 ±0.37	3.58 ±0.3	0.06 ±0.19
Flat Lat.	0.99 ±1.53	4.98 ±0.73	3.54 ±0.27	0.1 ±0.12	1.04 ±1.53	2.21 ±0.6	3.71 ±0.23	0.06 ±0.13
DSCI	0.94 ±1.39	5.46 ±1.08	0.21 ±0.23	0.15 ±0.36	0.97 ±1.38	2.23 ±0.6	0.62 ±0.33	0.17 ±0.4
Tough DSCI	0.42 ±1.54	5.64 ±0.72	0.17 ±0.35	1.53 ±1.82	0.47 ±1.56	1.96 ±0.35	0.92 ±0.42	3.17 ±3.74

In the titanium sample, the DSC implant had the least movement in compression over all types, indicating that the expansion effectively filled the gap between the Sawbone wedge and the top fixture. The flat implants had the most SI travel in compression due to the sharp medial edge subsiding into the Sawbone. In all multiaxial cases, the DSC had the least motion in SI and LB with 0.4 mm and 2 degrees less than all others. As with the resin, the anatomic type had the least FE in multiaxial cases; at least 0.5 degrees lower. The LB axis is comparable between the flat and anatomic types. Not much change was observed between the latticed and solid pairs of implants across all waveforms, though the flat lattice was slightly more compliant than the flat solid. All samples had no IE which was the expected outcome.

Table 4-4 Peak of the average motion of the implants for the Ti64 set. The DSC implant shows the least motion over all waveforms suggesting better mitigation of the challenging geometry. The latticed types did not change the motion when compared to their solid counterparts.

Ti64								
	Compression				Gait			
	SI (mm)	FE (deg)	LB (deg)	IE (deg)	SI (mm)	FE (deg)	LB (deg)	IE (deg)
Anatomic	1.47 ±0.01	-	-	-	1.31 ±0	0.2 ±0.01	3.22 ±0.04	0.02 ±0.01
Anat. Lat.	1.44 ±0.01	-	-	-	1.33 ±0	0.14 ±0	3.39 ±0.05	0.02 ±0.01
Flat	1.82 ±0.02	-	-	-	0.87 ±0.01	0.27 ±0.02	2.79 ±0.01	0.02 ±0.01
Flat Lat.	1.76 ±0.02	-	-	-	0.84 ±0	0.64 ±0.01	2.48 ±0.02	0.02 ±0.01
DSCI	0.85 ±0.01	-	-	-	0.4 ±0	1.13 ±0.02	0.46 ±0.02	0.02 ±0
	Flexion-Extension				Lateral Bending			
	SI (mm)	FE (deg)	LB (deg)	IE (deg)	SI (mm)	FE (deg)	LB (deg)	IE (deg)
Anatomic	1.24 ±0	0.82 ±0.01	2.39 ±0.01	0.01 ±0	1.24 ±0	0.36 ±0	2.47 ±0.01	0.01 ±0
Anat. Lat.	1.18 ±0	0.79 ±0.01	2.05 ±0.01	0.01 ±0	1.18 ±0	0.3 ±0.01	2.34 ±0.03	0.01 ±0
Flat	0.81 ±0	2.23 ±0.02	2.84 ±0.02	0.01 ±0	0.8 ±0	0.76 ±0.01	2.91 ±0.01	0 ±0
Flat Lat.	0.82 ±0	1.59 ±0.01	2.52 ±0.01	0.01 ±0	0.79 ±0	1.02 ±0.02	2.67 ±0.01	0.01 ±0
DSCI	0.36 ±0.01	1.57 ±0.04	0.4 ±0.01	0 ±0	0.33 ±0	0.39 ±0.01	0.58 ±0	0.01 ±0

The contact area of the implants in lateral bending shifts from right to left overall as is expected. Figure 4-22 and Figure 4-23 show the contact area in maximum lateral bending when bending into the Sawbone wedge (-LB) and bending towards the flat Sawbone (+LB) for resin and titanium respectively. As shown, the flat implants do not change their contact area much for both resin and Ti64. Only the medial edges of the flat implants contact the Sawbones and the shift in contact area is not substantial. The anatomic implants mostly contact the Sawbone surface in the middle of the implant, which is expected due to the curvature of the implant. These implants rock towards the side where the load is being applied but the lateral edges do not contact the Sawbone surface. The DSCIs also show area transfer between the left and right bending extrema. The lateral endplates on either side of the DSCI carry more load when bending occurs in their respective directions, however, when bending right (towards the Sawbones wedge), the expanded DSCI maintains loading through the left side of the implant in contrast to other implants. This distributes the loading along both sides of the implant when an asymmetric load is applied. This occurs in both resin and titanium; however, it is more apparent in the resin samples. In the resin, the addition of a lattice increases the contact area of the implant to the Sawbone which is shown in Figure 4-22 as an increase in activated cells. It is apparent that the effect of a lattice is negligible in the titanium samples as the charts look the same.

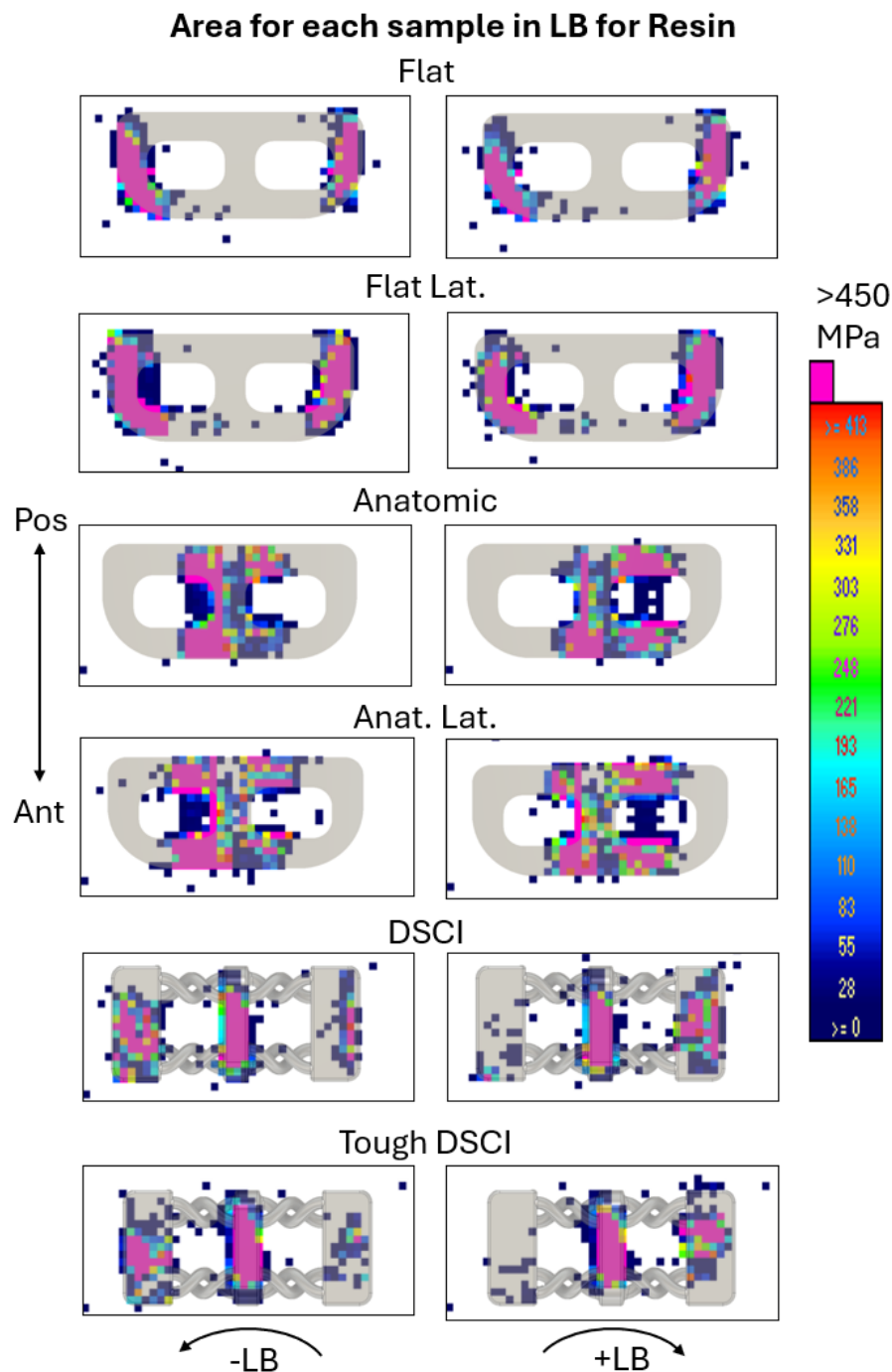


Figure 4-22 Tekscan maps for the contact area during peak LB with overlaid CAD for the resin implants. The expanded DSCI maintains loading through the right side of the implant during -LB in contrast to other implants. The latticed implants show increased contact area over their solid counterparts.

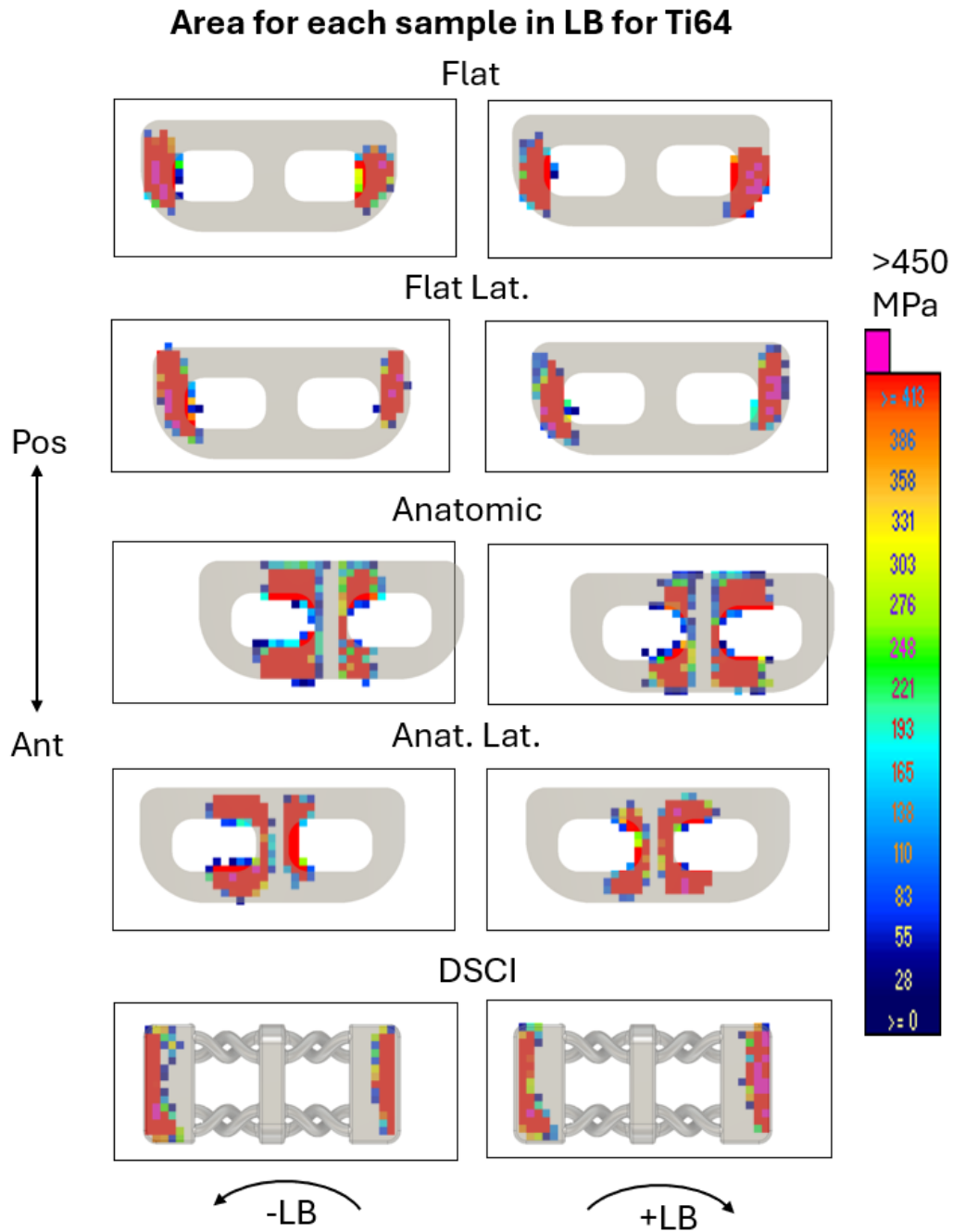


Figure 4-23 Tekscan maps for the contact area during peak LB with overlaid CAD for the titanium implants. The DSCI implant shows maintained loading through both sides of the implant during LB. The latticed and solid implants show very little difference in contact area.

The pressure on the implant was approximated using the force data from the load cell on the VIVO because the Tekscan sensor cells saturated at the calibrated sensitivity. This was achieved by taking the magnitude of the three components of force over the measured area after aligning the data. It was assumed that moments were not significant and did not affect the pressure. Figure 4-24 shows a plot of the pressure data for the resin implant in all four waveforms. General trends can be seen from this figure such as the anatomic latticed and DSC implants having low overall pressure (4-5 MPa) and the flat implant having high overall pressure (10-20 MPa). The DSC and flat solid implants have the largest variations in pressure during all waveforms with about 3-4 MPa in range. The Rigid 4000 DSC has about 2 MPa more pressure variation along the waveforms than the anatomic latticed implant. The latticed implants had lower pressure than the solid implants overall.

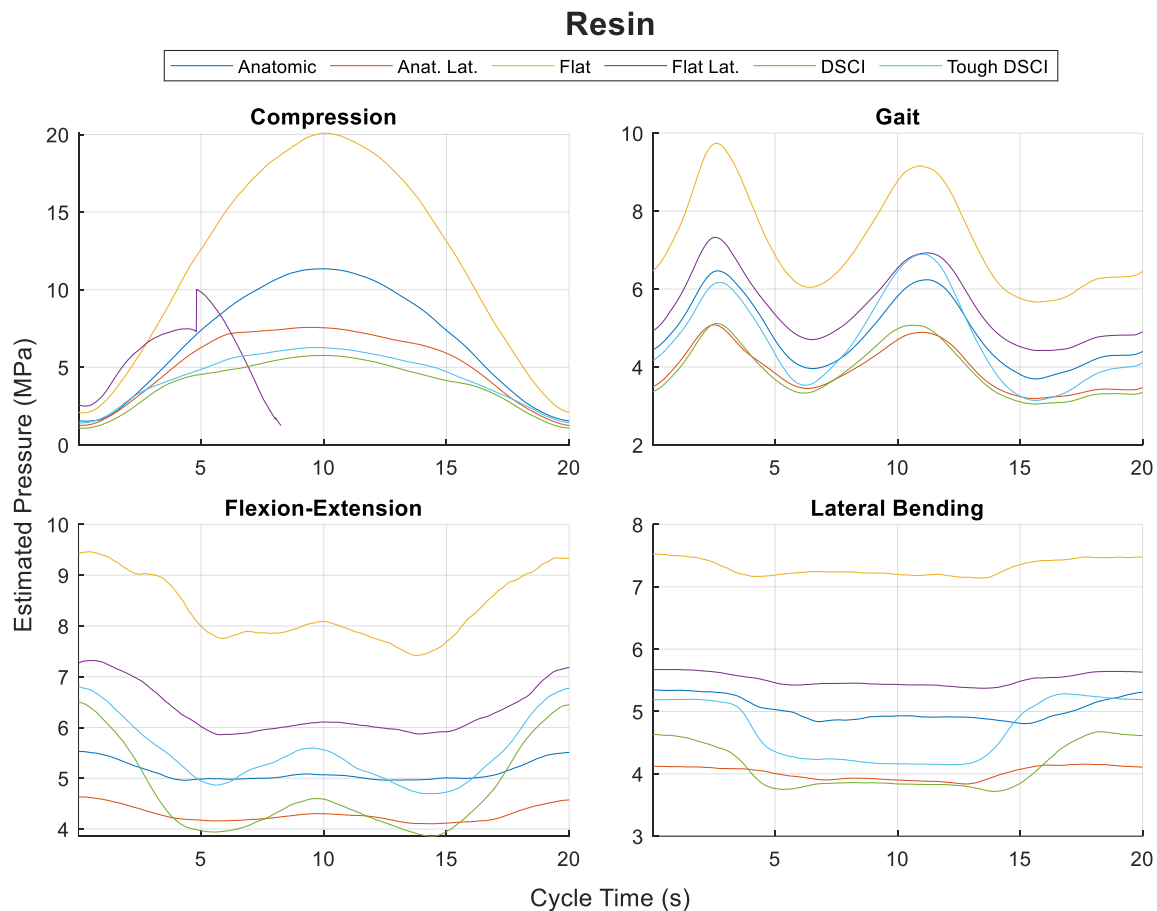


Figure 4-24 Estimated pressure from the force magnitude over the area for one cycle of each waveform. Each implant is represented by a line on the plot and is an average of all Sawbones samples.

The Figure 4-25 shows the estimated pressure of the titanium samples. The shape of the waveforms between the resin and titanium is similar, however the pressure variations are subdued by half the amplitude in the titanium case. The titanium implants show more pressure for the same waveforms as the resin implants, increasing by 1-2 MPa in the multi-axial cases and by a factor of 1.5 in the compression case. The flat latticed and flat solid implants have very similar pressure profiles for all waveforms as opposed to the resin set. This is, once again, due to the increased stiffness of titanium over resin. The anatomic latticed implant sees more pressure than the anatomic solid implant, which is surprising since the lattice did not affect the flat implant. A similar trend to the resin is seen where the anatomic implant has the lowest overall pressure around 5 MPa with the DSC implant having the second lowest pressure at 6 MPa, and finally the flat implant having the highest pressure at 10 MPa.

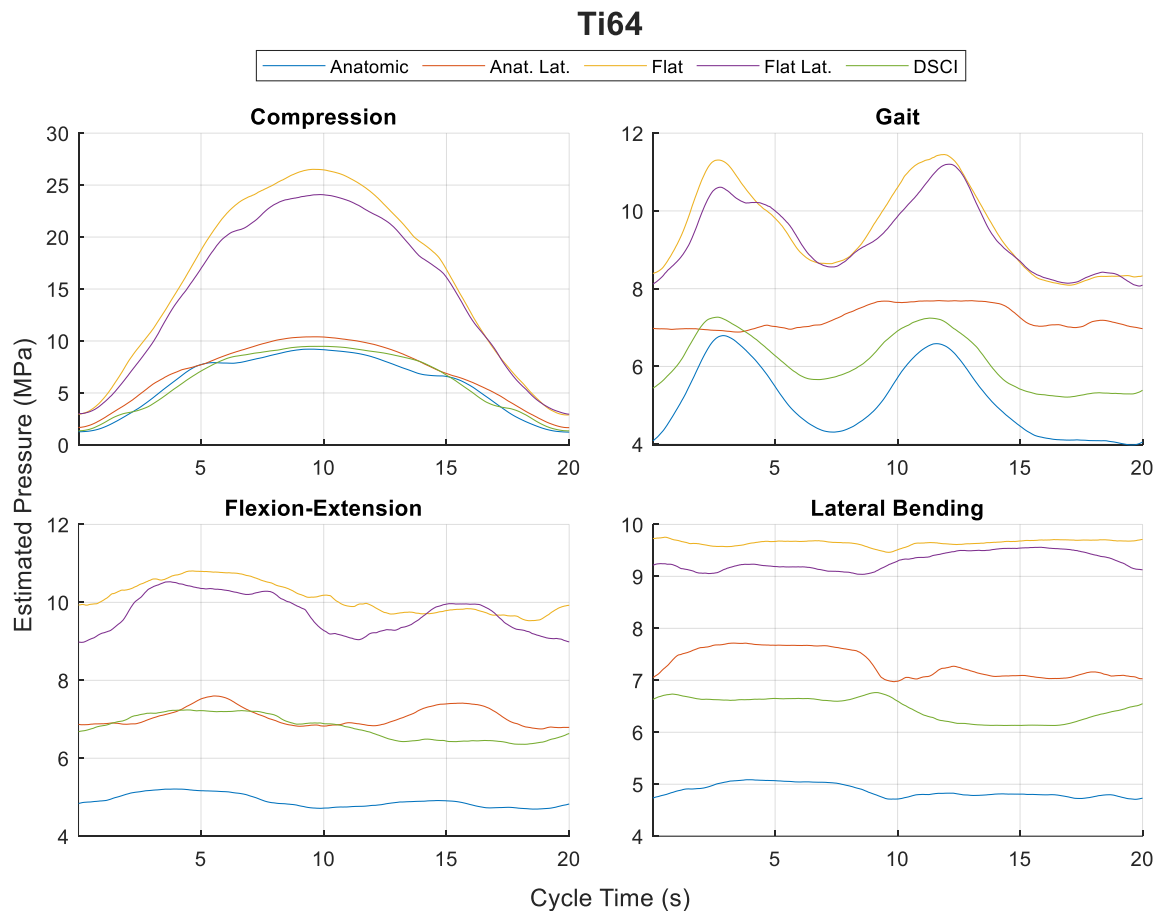


Figure 4-25 Estimated pressure from the force magnitude over the area of the Ti64 implants. Each implant is represented as a line on the plot and represents an average of cycles and specimens.

4.8 Discussion

The goal of this study was to evaluate a surface conforming implant with respect to on the market implant replicas in an asymmetric endplate geometry scenario. This ties into the general goal of addressing shortcomings with current implants for vertebral endplate contact by comparing the performance of these implants in a controlled loading configuration. The results indicate that the latticed anatomically shaped implant and the DSC implant both had contact areas ranging from 55% to 65% of the total implant endplate coverage for the resin and 40 to 50% for Ti64; comparing this to the other implants percent contact area which ranged between 30% to 50% for resin and 20-30% for Ti64, there is an improvement in this metric. Resin implants showed about 10% more compliance as compared to the Ti64 implants which makes sense considering the difference in stiffness from 970 MPa for Ti64 to 69 MPa for Rigid 400 resin. The expanded DSC implant reduced the range of motion in LB compared to the other implants from 4° to 0.5° in both materials which suggests it was successful in leveling the discrepancy in height between the wedge and the flat portion of the Sawbone. The DSC minimized the geometric effect of the challenging scenario while providing as much of a range of motion in other axes as the other implants.

In addition, the DSC implant distributed loading across the implant more evenly than the flat implants in lateral bending, however, it did not have as much contact area as the anatomic implant. Pressure at the contact between the implant and the Sawbone was minimized by the DSCI, with some variation in the pressure along the waveform, compared to other implants, however, the latticed anatomic implant had the lowest pressure. The latticed features only helped achieve more contact area over the solid counterparts when the lattice material had a low stiffness, i.e. in resin, since the loads used are not high enough to deform the titanium lattice. Better utilization of the cages surface area allowed for better load sharing, so increased the contact area lowered the contact pressure.

Based on these results, it does seem like the DSC implant is capable of reducing the effect of an asymmetric endplate geometry and seems to be compliant enough to handle the loading of the lumbar spine while remaining in contact with the vertebral endplate in both resin and Ti64. The latticed anatomic implant in the PEEK-like resin also performed well, showing enhanced compliance from the lattice and minimizing the pressure at the bone-implant interface. The latticed anatomic implant was designed to match the Sawbone wedge and hence is comparable to a patient specific implant type.

The reason for the use of Sawbones was the repeatability and the ability to control conditions to create the specific scenario of asymmetric loading. While this was achieved, the chosen wedge geometry was potentially not the most effective at capturing the overhang of the implant while coupled with the VIVO's unconstrained loading; rather capturing the implants range of motion in adverse geometry. An improvement could be to machine a reconstructed L4-L5 endplate and tilt the inferior vertebrae artificially creating an uneven surface in a more accurate vertebral model.

Two versions of the DSC implant were printed in metal; one was pre-assembled (print-in-place) and the other has its parts printed separately. The design for AM of the pre-assembled DSC implant was noted to improve the print quality in LPBF over the separated parts. In particular, the main body of the separated parts version had printing difficulties in the mid-section due to poor heat dissipation causing part warping. The long cylindrical structures in the pre-assembled version, while not touching the larger part, provided sufficient heat conduction for the overhang regions that were located halfway (and towards the end) of the print. These contact-free support structures in metal AM have been explored by other groups, showing print quality improvement for overhanging regions [91]. This suggests that printing monolithic pre-assembled implants could improve overall print quality.

In a previous study, Fernandes et al. investigated the contact area of 3D printed patient specific posterior lumbar intervertebral fusion (PLIF) cages in comparison to on the market PLIF implants [53]. The patient specific cages were developed by taking a Boolean subtraction of the endplate surface of reconstructed L1-L5 vertebral bodies (CT-Scanned). All implants were 3D printed using Rigid 4000 resin (PEEK-like) on a Formlabs printer such as was done in the current study. Results showed that patient specific cages had a contact footprint of 46.5% which was an improvement over the commercial cages whose contact footprints were 25.5%. These results show a similar increase between commercial and tailored implants as in the current work, indicating that matching existing structures might improve surgical outcomes. Some limitations were that precise implant placement was necessary for the patient specific implants which poses intra-operative challenges. This was one of the reasons for the current study, to design an implant which would not require precision placement but would offer increased contact area. Indeed, the current work shows over 50% endplate contact in a simplified scenario while the study shows 46.5% in a human model. The study used human cadavers to evaluate their implants as opposed to Sawbones used in the current work. This illustrates a future path for the current work, as using cadavers is more physiologically accurate. The study used single degree-of-freedom motion (compression) to evaluate the contact area of implants, however, the intervertebral space experiences

six degrees-of-freedom. The current work used 6 degrees-of-freedom to evaluate the contact surface, and it was observed that multi-axial motion reduces the contact surface compared to compression-only. Additionally, Fernandes et al. used a Fujifilm method of capturing contact area which only shows the sum of all contact that occurred during the test. The current study shows the use of a Tekscan contact area sensor which records real-time data of the contact area, allowing for more in-depth motion analysis.

Another previous study, completed by Kusins et al., investigated the pressure distribution of an expandable and AP adjustable LLIF cage [50]. The study's main finding was that pressure distribution at the bone-implant interface depended significantly on the lordotic angle of the sample test block and less so on the expansion height. The expandable and independent anterior-posterior adjustable endplate hence reduced edge loading pressure at the interface. This study used machined Sawbones in the shape of the implant, which is similar to what was done in the current work, except their samples were machined to the contour of the cages. In addition, they used a Sawbones functional spinal unit to evaluate their implants, which could be another future pathway for the current work. Similarly to this study, they used Tekscan sensors to measure pressure and area of the contact area between the Sawbones-implant interface. Using the Tekscan, they measured maximum pressure and pressure distribution in the AP direction. The current work also measured maximum pressure and observed trends in pressure distribution along any axis. Their findings that a mismatch between the Sawbones surface and the implant causes high edge pressure was further confirmed in the current work where edge pressures were mitigated by a conforming contact surface. As noted with the study by Fernandes et al., this study also only used 1-DOF compression to evaluate the endplate contact while the current work used 6-DOF physiologic motions.

A study by Orr et al. leveraged the compliance of flexures to tailor the compliance of Ti64 in a two-axis expandable posterior lumbar interbody fusion cage (PLIF) [65]. They used a wedge to drive the expansion of four corners connected using a series of flexures, all additively manufactured in Ti64. The study used ASTM F2077 to evaluate their implants, the results showing an average stiffness of 3364 MPa in compression and 1438 MPa in shear. This study demonstrates the viability of flexures in expandable cages as a novel fusion format. The current work expands on this study by gathering experimental data for flexures under physiologic loading, the differences between flexures and other styles of implants, and the effect of materials on implants with flexures.

The current study noted differences in the results between the compression test and the physiological tests. The compression test produced greater variability in contact area compared to the physiological waveforms for both resin and Ti64 materials. Additionally, it revealed a larger disparity between the anatomically shaped and DSC implant areas, whereas the multi-axial loading condition resulted in more comparable contact areas across implant types. Furthermore, the compression test had more SI travel and higher contact pressure for all implants than the other tests in both materials. These results suggest that compressive testing, such as the ASTM F2077 standard, might not reflect the conditions in the spine and could skew the results of testing in comparison to more physiologically relevant methods like the ones developed in this study. A more direct comparison of testing methods and in-vivo loading is necessary to determine the effectiveness of current standards at evaluating implant performance.

4.9 Limitations

There are several recognized limitations to this work. With regards to the DSCI design, limitations include the brittle nature of the flexures, the solid mid-section removing some conformance, and the loose expansion ellipsoids that could shift during implant insertion. The implant is also too stiff in titanium which shows worse performance than the resin design. In addition, the torque required to expand the implant under load was not measured and is important in a clinical setting.

With respect to the testing methodology, one limitation is that Sawbones were used as an analog to determine the vertebral contact surface instead of vertebral body samples. This simplified model allowed control of the environment; however, it does not accurately depict the contact area on a vertebral body. The sample size is also a limitation of this study as many factors are being considered and only three repetitions were performed. This does not have enough power to determine statistically relevant results, but informative trends for future design and manufacturing iterations can be observed from the results nonetheless. Furthermore, the physiologic waveforms were derived from a limited sample size and thus do not represent the general population. Another limitation was that the Tekscan sensor chosen had a large pressure range which meant a high activation pressure. The sensitivity of the sensor hence had to be high to measure the area fully, however this lowered the saturation pressure. As such, the sensor values were saturated at the upper range of pressure and the actual pressure could not be directly measured. Another improvement would be to add a preconditioning waveform or more cycles to the experiment to condition the Tekscan sensor and the sample before testing.

Lastly, the unconstrained implant testing raises questions about the degrees of freedom that can be assumed within the intervertebral disc. In the spine, tissues around the implant would contribute to stability and load sharing. Hence, it's potentially not accurate to use all 6DOF when testing the implant as it might not be receiving the full loading in vivo. However, it was determined that testing to 1Nm in bending shows the implant loading progression in a way that is physiologically realistic based on OrthoLoad data. As previously discussed, shear at the bone-implant interface was actively cancelled by the VIVO because the Tekscan sensor does not allow for shear. It is reasonable to assume the implant surface does not experience too much shear if it is properly seated in the bone.

4.10 Conclusion

This study provides preliminary support for the novel additively manufactured, dynamically surface conforming implant design and incorporates novel spinal implant evaluation methods. With the realities of surgery taken into consideration, monolithic designs fail to meet the unique requirements of each patient, however, patient specific implants are not only expensive, but may present challenges with precision placement in-operation. An LLIF cage was successfully designed that can dynamically conform to the surface of the Sawbones within the required physiological specifications. It functionally restores intervertebral height, maximizes bone graft space, has independent actuation of lateral endplates, and allows independent passive vertebral endplate matching. It is capable of withstanding at least 500N of compressive load and anatomical motions in flexion-extension, lateral bending, and gait. This DSC implant design increased the contact area over commercial implants by 10% as did the latticed LLIF with anatomical endplates. Limitations of this study include using Sawbones as a bone surrogate, saturation of the Tekscan sensor, and validation of the novel test method. Despite the regulatory market making it difficult to innovate in the field of implants, this preliminary design shows promising features to the treatment of spinal disorders. Future work should look to control implant stiffness, test the design in human vertebral bone, and test under fatigue loading conditions.

Chapter 5

Conclusions and Recommendations

5.1 Significance

The recent interest of metamaterials in the field of additive manufacturing has resulted in promising new materials with unique engineered properties. The overall goal of this work was to develop, manufacture, and evaluate flexible elements inspired from these metamaterials in interbody devices for spinal reconstructive surgeries. To effectively characterize these implants, new evaluation methods were developed on the VIVO using 6DOF testing.

The characterization of flexible elements in mock cervical spinal devices using a novel testing method facilitated the understanding of strain behavior in flexures. Access to the Aramis motion tracking system allowed for the flexure mechanics to be captured in full field, permitting 3D evaluation of surface strain. Using this data and the load cell data from the VIVO joint motion simulator, the stiffness and deformation of the implants was analyzed in resin and titanium additively manufactured samples for repeated sub-failure loading. This study established a methodology to evaluate flexible elements in spinal implants, which was not previously clear. In addition, the observations made about flexures give insight into the effectiveness of these engineered elements and the use of optimization software towards compliant design.

An LLIF cage with dynamically surface conforming endplates was designed to restore intervertebral height while allowing for the intraoperative adjustment of lateral endplate distraction and to passively match endplate concavity. Furthermore, the cage was designed following DfAM principles establishing a precedent for translating clinical requirements to manufactured solutions. The DSC implant was designed as a solution to large footprint and patient specific cages reducing the need for precise positioning and malplacement.

Due to the inadequacy of current implant testing standards at capturing implant behavior, a testing methodology was developed to evaluate the contact area at the bone-implant interface using a Tekscan sensor to record real time contact pressure and the VIVO to impart 6DOF physiologic loading. The obtained contact area data and load cell data was used to evaluate the DSC implant, a commercially available implant, and three derivatives of the commercial implant resulting in observations about endplate geometry and vertebral body matching. It was noted that the DSC and anatomically

conforming implants improved contact area in challenging vertebral geometries. The methods established in this study represent a more physiologically relevant implant testing platform which can serve to better understand spinal implant mechanisms and eventually improve patient outcomes.

5.2 Limitations

Some recognized limitations were discussed in earlier Chapters; however, there are some general limitations to address. While the testing methodologies used in this study were novel, they were not directly compared to a similar standard. Although it has been shown in previous studies that the VIVO can be used as an analogue for implant testing standards and that it can augment these methodologies, the testing methodologies used here may not directly translate to implant safety or better patient outcomes. It is still important to consider these standards when testing implants using the methodologies described here.

Due to the prototyping nature of these studies, especially of the DSC implant, it is important to mention that not all patient factors were considered. Many of these factors would be suggested by a clinical team to address the needs of the patients and surgeons. For example, the prototypes have not considered the lordosis of the spine which could be beyond the range of the proposed design, depending on the patient.

Throughout this study, manufacturing challenges were encountered that are native to the additive manufacturing systems. Some parts were over-sintered while others did not print at all or had to be aborted during the print. In resin, some parts would not stick to the build plate or old resin had to be used due to availability. It was not possible to replace some of the parts affected by these challenges and, as such, the study proceeded with these parts. Hence, the results of these studies could be affected by deviations in the parts despite the repeated testing.

5.3 Future work

On the design side, a future direction is to further leverage topology optimization under physiologic loading. As previously explained, developing custom optimization algorithms is necessary to achieve the right balance of implant compliance and structural load sharing. Several groups have made progress towards optimizing flexure size, length, and number to achieve a specific compliance target, which would have been useful in this case to lower the stiffness of the Ti64 flexures in the DSC implant. In addition, several improvements could be made to the DSC implant design. First, the

adjustment ellipses are too loose in the implant and could fall out or shift during insertion and should be stabilized. Second, the adjustment ellipses are held in place by friction once adjusted to the correct height; a safety locking mechanism could be beneficial. Third, the implant expansion mechanism torque should be quantified under load as it affects the intraoperative performance of the implant.

The current work made major strides for design for AM of spinal implants including a print-in-place version of the DSC implant in Ti64. However, some aspects remain to be considered like the surface finish, material porosity, material brittleness, etc. Part of the design included long overhangs which printed ok, however there was a region near the top of each relief arc that printed with a very rough surface. This could be mitigated by increasing the slope to make the arc into a triangle. To identify these print characteristics before printing, software can be developed, similar to the LPBF overhang tools developed by McGregor [70], to check for various implant print factors.

On the testing side, the limitation of comparing the novel test methods to established standards or to *in vivo* data should be addressed. This would solidify the testing methods in data and give a better representation of any deviations that can be expected. As for the equipment used, the Tekscan system is effective and should be used in the future, however the data precision is sensitive to the choice of sensor and should be chosen with tighter ranges to the test protocol. On the Aramis side, it is difficult to speckle small specimens and to gain a view of recessed or concave surfaces. Figuring out these two problems is critical to obtaining better data for the strain performance of implants, especially small Ti64 flexures. The DSC implants should be tested to failure to measure yield strength, according to the standards. The specimens in both studies should be tested in cyclic fatigue to explore the resilience of the design to the repeated stress in the human body.

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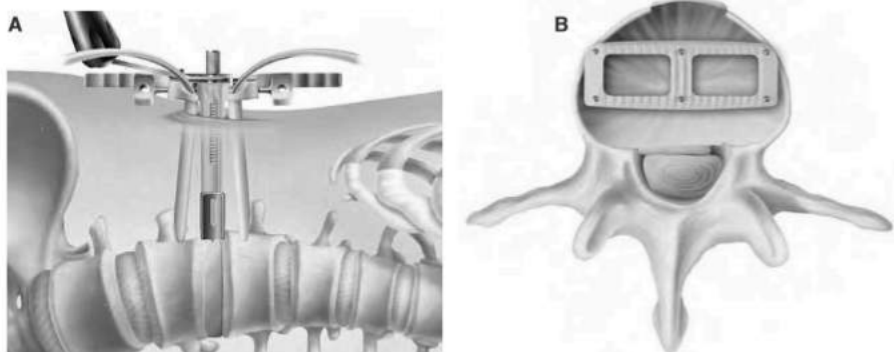


FIG. 8-14 A and B, The implant is ideally centered across the disc space from a medial/lateral perspective and placed between the anterior third and middle third of the disc space from an anterior/posterior perspective.

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Appendix A

Topology Optimization of Cervical Interbody Device

A.1 Compressive Load Case

The topology optimization (TO) was set up with a mass minimization objective and a target safety factor (SF) of 1.2 on the materials (Ti64) ultimate compressive stress. The result is shown in Figure 0-1.

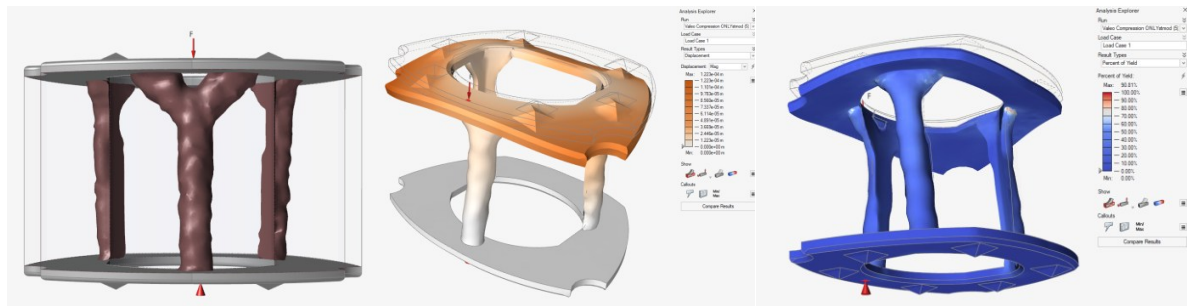


Figure 0-1: TO of Commercial Cage in Compression. Objectives: minimize mass, SF=1.2.
Deformation analysis is in the middle and stress analysis on the right.

This structure is interesting because the optimization chooses 3 points around the design space to place struts. The struts then separate into multiple struts near the top plate to better support the plate giving it this “tree” looking structure. The corners and back area deflect by 0.1 mm under body load. Realistically, this plate would be cemented to a flat piece of bone and the corners would not deflect this drastically. However, there are regions where the stress gets up to 90% the yield strength of the material. This is undesirable as it is close to failure. It can also be seen that there is sticking occurring with the central hole boundary.

Given these observations a new TO can be constructed using a thickened design space. The result is shown in Figure 0-2. The same three strut design is seen, but the size of the struts is significantly reduced due to less sticking on the boundary. This is beneficial because it would improve the displacement of the implant. However, due to the thickened design space the struts overhang into the middle of the cage.

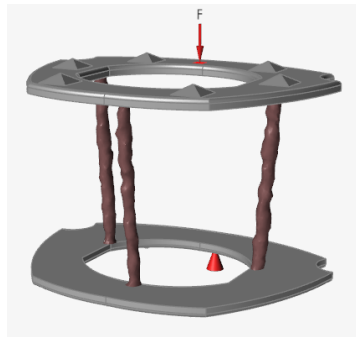


Figure 0-2: Commercial cage TO with an increased design space. Objectives: minimize mass, $SF=1.2$. To fix this, a CAD model is designed in Fusion 360 (Figure 0-3). The TO struts are approximated as cylindrical struts with a diameter of 0.75 mm. They are placed at an offset angle of about 3 degrees with respect to the superior-inferior axis. The struts are placed such that they do not overlap with the central volume of the commercial cage. The CAD model of the three-strut design is then analyzed in Altair Inspire. It can be seen in Figure 0-3 that the maximum displacement is 0.2 mm. Not only that, but the struts bend in a type of flexion motion indicating that deformation of the struts can be achieved under normal loading conditions. Furthermore, the struts experience low percent yield for the most part. At maximum deformation, the struts have some areas that experience about 70% yield strength. This is rather close to the yielding condition, but it is necessary to have a good amount of flexibility. The regions on the top plate which connect with the struts experience stresses over the yield strength of titanium. This is likely due to the small area which connects with the plate at a sharp (90 degree) angle. This could be mitigated by flaring the struts near the top plate as learned from previous TOs.

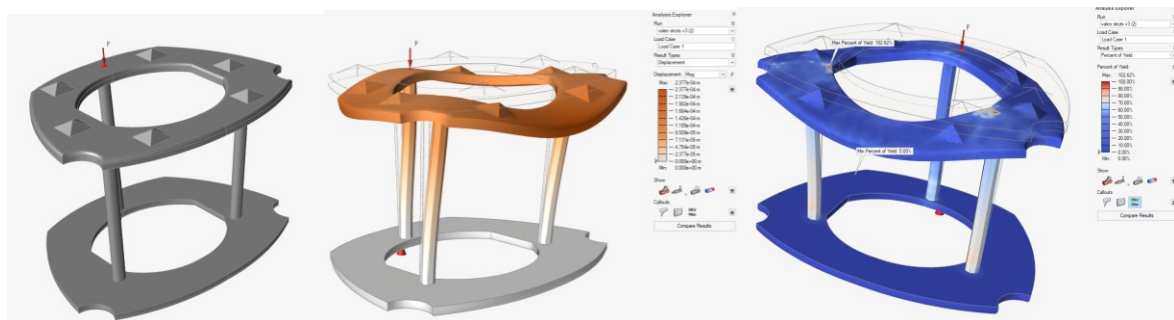


Figure 0-3: Three-strut CAD model with moved struts. Deformation analysis is in the middle and stress analysis on the right.

In order to evaluate the performance under thin strut conditions, a TO is compiled with the objective of minimizing mass to a target of $SF = 1.2$ with the added constraint of strut size between 0.5 mm and 1

mm. As can be seen in Figure 0-4, the tree like structure is even more pronounced with thin struts. This makes sense because now the struts flair near the top providing support to the top plate and reducing the stress below the 1.2 SF threshold. Some strange geometry is seen near the front strut that was added by the TO. It has this thickened section in the middle of the strut. This could be due to sticking of the strut onto the middle of the design space or it could be an artifact of mitigating shear forces generated by compression on the front portion of the Commercial cage.

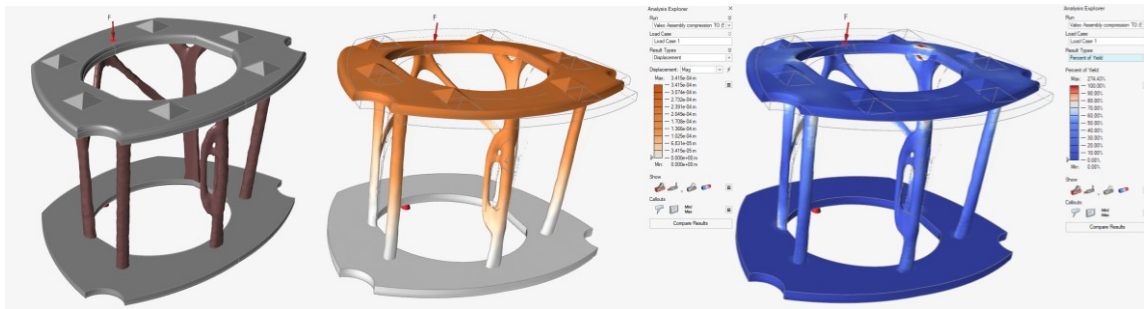


Figure 0-4: TO of commercial cage with strut size constrained to 0.5-1 mm. Objectives: minimize mass, SF=1.2. Deformation analysis is in the middle and stress analysis on the right.

The analysis of the thin strut part reveals a slight posterior flexion of the part. There is a maximum deformation toward the posterior of the plate of 0.34 mm. This is quite a large deformation in the flexion direction. The result is promising as it does include a significant deformation. However, it can be seen that the maximum percent yield on the part is over 100% which means that certain regions will yield under normal body loads. Evidently this is not desirable, but these regions appear to be small and focused at sharp features on the part. With some remodeling, it might be possible to entirely remove these regions. Additionally, there are some struts, notably those that form the long branch in the back of the part, that have thin portions due to sticking on the design space. These struts could be thickened such that they are manufacturable with EBM. Due to complications with exporting the part from Altair, this design was not further pursued although it is the most promising design.

A.2 Patient Specific Load Case

The patient data loading case was applied to the commercial cage. The TO objective was to minimize mass with a target safety factor of 1.2. The result is seen in Figure 0-5. There is a lot of sticking to the design space boundary occurring in this TO. It can be seen however that the loading case adds struts that are angled and struts that cross. The displacement analysis shows that the implant essentially just compresses as a result of the loading on the struts. This is beneficial as having off-axis rotations would

negatively impact the performance of the implant. The lower portions of the struts experience high yield percentage indicating that those sections would break.

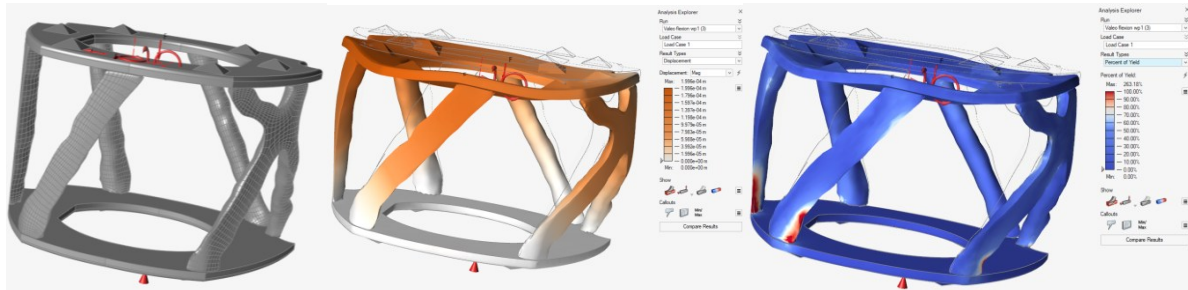


Figure 0-5: Commercial cage TO using patient specific data. Objectives: minimize mass, $SF=1.2$. Deformation analysis is in the middle and stress analysis on the right.

Given that there was sticking to the wall, a second TO was performed with an expanded design space. In this case, some of the struts overhang outside of the Commercial cage. This could be corrected if the design was remade in CAD. As a result of the struts overhanging the cage, some struts were not connected to the bottom plate. This meant that the analysis was not performed properly and the results from the side facing out of the page cannot be trusted. However, the side further into the page seems to display fairly good resistance to the applied loads. Much of the structure appears to be past the yield point though which would indicate the need for larger struts or a better TO.

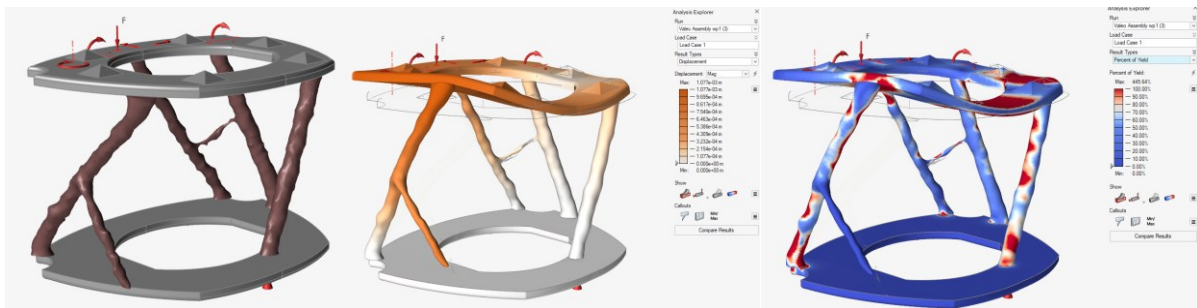
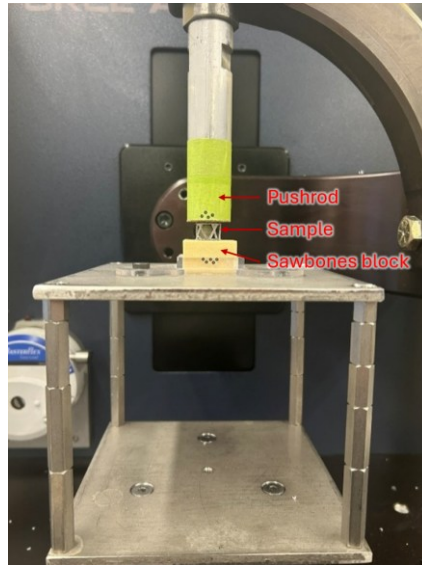


Figure 0-6: Commercial cage TO using patient specific data with an increased design space. Objectives: minimize mass, $SF=1.2$. Deformation analysis is in the middle and stress analysis on the right.

Appendix B

Compressive Testing SOP

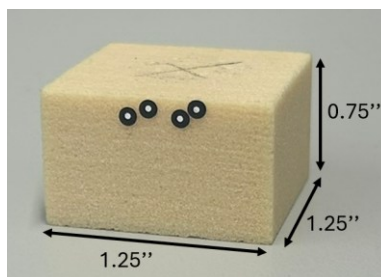


Test apparatus for compressive testing

B.1 Preparation

Cut Sawbones (Sawbones 30PCF) into 1.25" x 1.25" x 0.75" rectangular specimens using a bandsaw.

Use one specimen per set of test implants.



Sawbone specimen dimensions

Prepare the Formlabs printer with rigid 4000 resin. Print a set of implant samples oriented such that layers are on the SI axis to reinforce the implant under compressive loads. Rinse implants in IPA, then cure. Remove supports.

Titanium implants were printed using Ti64 on the Arcam A2X printer at MSAM. The parts were then depowdered using sandblasting and scraping.

B.2 Speckling

Mark one edge of the superior endplate of each implant with a permanent marker to identify the region that will be painted (in the anterior plane)

Use a matte white paint to coat the anterior facing surface of the implant with a thin, even layer. Ensure that the entire face is covered by angling the can towards curved surfaces as needed.

Use a matte black paint to produce the speckled pattern by holding the spray paint can 1-2ft away using sweeping motions to deposit flecks of paint on the surface.

Highly curved surfaces can be difficult to speckle because the paint droplets deform on angled surfaces. Additionally, the small geometry of the implant prevents the application of paint orthogonally to the surface.

B.3 Aramis

Calibrate the camera to a volume of 55mm.

Setup the camera to face the specimen such that the center of the camera's measurement volume is at the center of the VIVO.

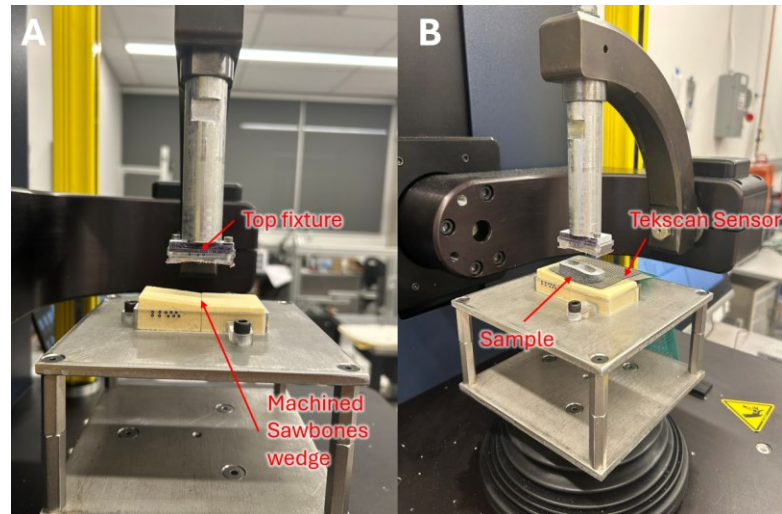
B.4 Instructions

1. Turn on the VIVO
2. Mount the top fixture, consisting of a push rod, and bottom fixture, consisting of a 3D printed specimen holder, to the VIVO
3. Use superglue to adhere new sandpaper to the pushrod of the upper fixture
4. Insert Sawbones specimen into the holder
5. Randomly select an implant
6. Center the implant on the specimen by hand, with the painted side facing the cameras.
7. Adjust the VIVO so that the center of the implant is at the center of the vivo
8. Apply 20N of force in force control, then set to displacement control
9. Set the reference pose
10. Take a capture on the aramis system
11. Analyze the capture for surface quality
 - a. Create a facet point component

- b. Create a surface component based on the facet points
 - c. Check the intersection deviation at a couple locations to be under 0.3
- 12. Adjust the aramis system position then repeat steps 10 and 11 if needed
- 13. Uncheck automatic recalculation on the aramis interface
- 14. VIVO: Set the waveform to the compression waveform with 0 to -50N for PEEK and 0 to -500N for Ti
- 15. Set the cycles to 5, and the frequency to 0.05Hz (about 2 minutes)
- 16. Set the acquisition rate to 100Hz, and a filter of 50db (acquire all data)
- 17. Start the aramis recording
- 18. Start the vivo waveform
- 19. Save the data
- 20. Repeat from step 5 for remaining implants

Appendix C

Contact Area Testing SOP

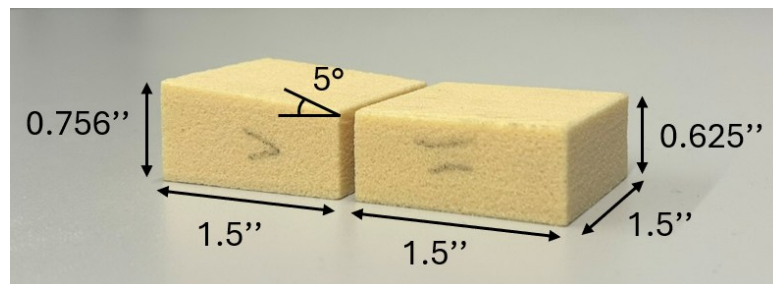


Apparatus for asymmetric testing

C.1 Preparation

Cut Sawbones (Sawbones 20PCF) into 1.5" x 1.5" x 3/8" rectangular specimens using a bandsaw.

Cut another set of Sawbones with a 5-degree slope starting at 3/8" in height to about 3/4".



Sawbone specimen dimensions

Place one flat Sawbone specimen next to an angled specimen with the 3/8" edges touching. Use one specimen per set of test implants.

Prepare the Formlabs printer with rigid 4000 resin. Print a set of implant samples oriented such that layers are on the AP axis to reinforce the implant under bending moments. Rinse implants in IPA, then cure. Remove supports.

Titanium implants were printed using Ti64 in LPBF on the Renishaw AM400 at MSAM. The parts were then depowdered using powder-blasting.

C.2 Speckling

Mark one edge of the superior endplate of each implant with a permanent marker to identify the region that will be painted (in the anterior plane)

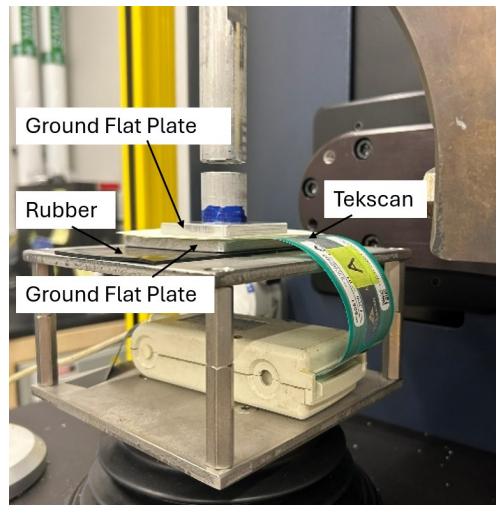
Use a matte white paint to coat the anterior facing surface of the implant with a thin, even layer. Ensure that the entire face is covered by angling the can towards curved surfaces as needed.

Use a matte black paint to produce the speckled pattern by holding the spray paint can 1-2ft away using sweeping motions to deposit flecks of paint on the surface.

C.3 Aramis

Calibrate the camera to a volume of 55mm. Setup the camera to face the specimen such that the center of the camera's measurement volume is at the center of the VIVO.

C.4 Tekscan calibration



Tekscan calibration setup

Set up the Tekscan between two flat plates. Add a piece of paper on either side of the sensor to prevent shear. Load the sensor to your lowest and highest expected loads and capture the two calibration points.

C.5 Instructions

1. Turn on the VIVO
2. Mount the top fixture, consisting of a push rod and angled wedge, and bottom fixture, consisting of a 3D printed specimen holder, to the VIVO
3. Use superglue to adhere new sandpaper to the wedge of the upper fixture
4. Insert Sawbones specimen into the holder (2 pieces as described above)
5. Align the Tekscan sensor with the Sawbone specimens and tape down the sensor
6. Randomly select an implant
7. Center the implant on the specimen by hand, with the painted side facing the cameras.
8. Adjust the VIVO so that the center of the implant is at the center of the vivo
9. Apply 20N of force in force control, then set to displacement control
10. Set the reference pose
11. Take a capture on the Aramis system
12. Analyze the capture for surface quality
 - a. Create a facet point component
 - b. Create a surface component based on the facet points
 - c. Check the intersection deviation at a couple locations to be under 0.3
13. Adjust the Aramis system position then repeat steps 10 and 11 as needed
14. Uncheck automatic recalculation on the Aramis interface
15. VIVO: Set the waveform to the [FE, LB, GAIT, Compression] waveform
16. Set the cycles to 5, and the frequency to 0.05Hz (about 2 minutes)
17. Set the acquisition rate to 100Hz, and a filter of 50db (acquire all data post trigger)
18. Start the Aramis recording
19. Start the vivo waveform
20. Save the data
21. Repeat from step 5 for remaining implants and waveforms