Optimization and biomechanical analysis of cervical ring cage using finite element method

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**OPTIMIZATION AND BIOMECHANICAL ANALYSIS OF
CERVICAL RING CAGE USING FINITE ELEMENT METHOD**

Submitted by

Yang Kai

School of Mechanical & Aerospace Engineering

NANYANG TECHNOLOGICAL UNIVERSITY

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A thesis submitted to Nanyang Technological University
in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

2007

This thesis is dedicated to the memory of my father Yang Shengfu (1937-2001), who gave me life, courage and perseverance. Dad, you are always in my heart!

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SUMMARY

A detailed 3D FE model of the C5-C6 intact segment was created by direct capturing geometrical data on normal human cadaveric specimens. The FE model was validated in flexion, extension, lateral bending, axial rotation, and in internal load distribution of the cancellous core. The results were in agreement with published experimental data.

The optimal combination of cage dimension and material properties was determined using the Taguchi philosophy. The larger width, depth and wall thickness of the cage design produced a higher signal to noise (S/N) ratio and lower von Mises stress. The most significant factors that influenced the endplate stresses were the width of the cage, followed by the depth and the wall thickness. The contribution of the implant materials was minimal.

Obvious changes were found in the distribution and maximum magnitude of the von Mises stresses and compressive displacement at the cage-endplate interface and in the cancellous core when the cervical cage was inserted into the intervertebral space. The influence of osteoporosis on biomechanics of the caged C5-C6 segment was analysed and observations were made.

Bioabsorbable anterior cervical plate was shown to serve a similar function as titanium plate. It greatly reduced the maximum compressive displacement and their vertical components, the maximum von Mises stress on the C6 superior endplate, the maximum von Mises stress in the cortical wall and the cancellous core at the level immediately inferior to the superior screws.

Summary

With the above parameters analysed, the current study can shed more light on the biomechanics of the cervical ring cage and the information extracted is useful for the future design, development and clinical application of the cervical ring cage.

CHAPTER 1 INTRODUCTION

1.1 BACKGROUND

Cervical spondylosis is the most common type of spinal degenerative disease in patients older than 55 years of age (Bohlman *et al.* 1993; Herkowitz *et al.* 1999). It is a progressively degenerative condition of the cervical intervertebral discs and the neighbouring vertebrae, resulting in simultaneous damage to the spinal cord, nerve roots, sympathetic nerve system and cervical blood vessels (Esses *et al.* 1995; Grob 1998). The main symptoms include pain in the neck and shoulder, dysfunction of upper and lower extremities, neurological deficit, dysphasia, dizziness and blurred vision (Bohlman *et al.* 1993; Esses *et al.* 1995), which severely impair the life quality of the patients.

The treatment for cervical spondylosis can be conservative and surgical. The former includes rest, bracing, appropriate exercise and medication. When conservative measures are applied, about 40% of cases improve their conditions within 2 months after symptom onset (Saal *et al.* 1996). Operative intervention is indicated for those patients with intractable pain, progressive neurological deficit, and documented compression of the nerve roots and spinal cord. The surgery consists of decompression of the nerve roots and spinal cord, and removal of the offending posterior osteophytes and protruded discs. Surgery for cervical spondylotic myelopathy is best done within 1 year of the occurrence of symptoms in order to achieve a better long-term result (Majd *et al.* 1999; Saal *et al.* 1996).

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The Smith-Robinson approach for anterior cervical spine fusion has been an established surgical technique for the patients with cervical spondylosis for many decades. This surgical technique offers necessary management for various pathological entities causing multisegmental spondylosis and has more stabilizing effect compared with extensive laminoplasty (Hirabayashi & Satomi 1988). The surgical procedure involves removal of the intervertebral disc and insertion of a tri-cortical iliac crest graft (Smith & Robinson 1958). The graft works as an axial load-bearing strut mechanically and promotes bony ingrowth into the intervertebral space biologically. Although the tri-cortical graft has been the gold standard, complications related to it do exist, for example, donor-site morbidity, graft collapse and extrusion, graft subsidence with endplate fracture, kyphotic deformity, pseudarthrosis, and recurrent symptoms (Natarajan *et al.* 2000).

In order to overcome the side-effects induced by bone graft insertion, cervical fusion cages, a kind of hollow implants filled with cancellous bone and inserted into intervertebral space as adjunction to spondylodesis (Wilke *et al.* 2000a), were then developed. The interbody cage was first designed by Bagby in 1980s to treat equine cervical spine with “wobbler syndrome” to achieve fusion (Bagby 1988; DeBowes *et al.* 1984). The fenestrated hollow cylindrical implant, which was named as the Bagby Bone Basket, was made of stainless steel and inserted into the intervertebral space to allow bone ingrowth. The theory of distraction-compression was proposed by Bagby to describe the basic principle of the stand-alone intervertebral fusion cage (Bagby 1988). The application of the intervertebral cage in the human spine was around 1990, first in the lumbar region with threaded cylindrical titanium cages and rectangular impacted carbon cages (Brantigan & Steffee 1993; Kuslich *et al.* 1998; Ray 1997).

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The use of cages in the cervical spine to manage cervical disorder has become increasingly popular in recent years (Brooke *et al.* 1997; Zdeblick *et al.* 1998; Hacker *et al.* 2000; Hacker 2002; Vavruch *et al.* 2002; Zdeblick & Phillips 2003; Cho *et al.* 2004; Hwang *et al.* 2004; Ryu *et al.* 2006).

Cages are presumed to bring about a series of benefits for the bone healing process when applied in the spinal fusion surgery. They correct the existing mechanical deformation by restoring disc height, creating physiological lordosis, obtaining sagittal balance and enlarging the neuroforaminal space; Cages also provide initial stability to the segment until fusion is achieved; Provision of an optimal biological environment for arthrodesis is the additional merit of cages by incorporating autologous cancellous bone with a possible wide interface with the bony endplates; Further, cages limit morbidity at the donor site due to less demand of cancellous bone (Steffen *et al.* 2000b; Weiner & Fraser 1998).

Cages can be classified into three types as shown in Figures 1 to 3 according to their structural features: horizontal cylinder, vertical ring, open box (Weiner & Fraser 1998). A horizontal cylinder cage of Figure 1, a manufactured equivalent of dowed techniques for interbody fusion, is commonly packed with bone graft and then screwed into position through an anterior laparoscopic approach. A vertical ring cage, similar to a femoral cortical ring of Figure 2 is placed through an open anterior approach and a large annular window. An open box cage is the equivalent of tricortical grafts as shown in Figure 3 and placed through a posterior fusion approach, in which supplemental fixation usually is required.

Figure 1 Schematic View of Horizontal Cylinder Cage

(Weiner & Fraser 1998)

Figure 2 Schematic View of Vertical Ring Cage

(Weiner & Fraser 1998)

Figure 3 Schematic View of Open Box Cage

(Weiner & Fraser 1998)

Among these three types of cervical cages, the vertical ring cage showed a better mechanical and biological function for spinal arthrodesis in *in vitro* and *in vivo* experiments (Kandziora *et al.* 2001; Kandziora *et al.* 2002; Steffen *et al.* 2000b). However, due to the inherent drawback in both *in vitro* and *in vivo* methodologies (Goel & Pope 1995; White & Panjabi 1990; Yoganandan *et al.* 1996a; Yoganandan *et al.* 2001), the optimal design of cages and the information of the internal biomechanical behaviour of the cervical ring cage is still lacking and needs to be further investigated.

1.2 OBJECTIVE

The objectives of this study were:

- To develop and validate a three-dimensional (3D) finite element (FE) model of the lower cervical spine (C5-C6) by direct spatial digitization of an actual human cadaveric specimen for further biomechanical analysis

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- To determine the optimal design of the cervical ring cage with the lowest stress on the vertebral endplate to decrease the risk of cage subsidence into the adjacent vertebral body using the Taguchi philosophy
- To investigate the biomechanical changes in the cervical segment, such as stress distribution and magnitude, contact pressure and compressive displacement at the bone-implant interface, and von Mises stresses in the cancellous core after insertion of a cervical ring cage under normal and osteoporotic vertebral body conditions
- To analyse the stability and biomechanical behaviors of the caged cervical segment when supplemented with anterior cervical plate (ACP) made of titanium and bioabsorbable materials

1.3 SCOPE

The whole study was carried out using a commercialized FE software package Ansys 6.0 (ANSYS, Inc., Southpointe, Canonsburg, PA, USA) for biomechanical analysis of the intact and instrumented spine segment. The interests were focused on the C5-C6 segment region in the lower cervical spine, in which spondylolysis commonly occurs. A high definition 3D contact digitizer FaroArm 2.30 (Bronze Series, FARO Technologies Inc., Lake Mary, FL, USA) was used for capturing the geometric coordinates. The material properties of various structures of the cervical spine were taken from the literature. The Taguchi philosophy was adopted for the cage optimization, since this method provides a simple and effective way for

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fractional factorial design of experiments and for a robust and optimal output. A cervical ring-shaped cage and a constrained anterior cervical plate were modelled in a generic pattern in the current study in order to obtain biomechanical information that can be applied in many of the similar implants used in clinics.

1.4 ORGANIZATION

The report is divided into 8 chapters and a brief description of each chapter is as follows: Chapter 2 gives a literature review on the cage-related studies using clinical, *in vitro*, *in vivo* and finite element method. Topics on the anterior cervical plate and the Taguchi philosophy are also included in this section. Chapter 3 describes the development of a 3D FE model of the intact C5-C6 and the validation with the *in vitro* experimental data. Chapter 4 presents the procedure and results of optimizing a cervical ring cage in terms of producing the lowest von Mises stress on the vertebral endplate using the Taguchi philosophy. This is followed by Chapter 5, in which biomechanical behaviors of the cervical ring cage in normal and osteoporotic vertebral conditions were analysed. Chapter 6 describes the effects of anterior cervical plate made of titanium and Poly-L-Lactic-Acid (PLLA) on biomechanics of the caged C5-C6 segment. Chapter 7 draws a conclusion on the significant results and contributions of the current project. Finally, the limitations and recommendations for future work are stated in Chapter 8.

CHAPTER 2 LITERATURE REVIEW

The use of intervertebral body fusion cages to achieve interbody arthrodesis for treatment of cervical spine disorders has become increasingly popular in recent years. It has been estimated that 60,000 cages are inserted a year in the United States (Togawa *et al.* 2001). A large number of the studies have been performed on the clinical efficacy and biomechanical features of these cages. This section reviews the cage-related studies using clinical, *in vitro*, *in vivo* and finite element method. Topics on the anterior cervical plate and the Taguchi philosophy are also included in this section.

2.1 CLINICAL STUDIES

2.1.1 Basic Concept

Clinical study is a kind of investigation that is conducted in human subjects intended to evaluate an experimental intervention in comparison with a standard or control or to compare two or more existing treatments. The clinical effect, adverse reaction, absorption, distribution metabolism, excretion, safety and efficacy are identified in clinical studies. The aim is to provide evidence for changing policy or standard of care.

2.1.2 Recent Studies

Majd *et al.* (1999) assessed the efficacy and safety of using titanium cage implants and anterior plating in cervical reconstruction. Thirty-four patients were treated by channel corpectomy followed by placement of a titanium cage

packed with autogenous bone graft from the vertebral bodies to reconstruct the anterior column. An anterior cervical plate was added in 30 of 34 cases that involved decompression of two or more levels. The follow-up period ranged from 24 to 56 months averaging 32 months and included examination and radiography. The results showed that there was radiographic evidence of fusion in 97% of the patients six months after surgery. Eighty-eight percent of the patients (30 of 34) did not experience any complications (neither cage dislodgment nor hardware failure). Four patients had complications that included pseudarthrosis, extruded cage, cage in kyphosis, and radiculopathy. They concluded that the titanium cages could provide immediate strong anterior column support with minimum hardware complications and avoid bone graft-site morbidity.

Hacker (2000) conducted a randomized prospective study of an anterior cervical interbody fusion device with a minimum of 2 years of follow-up. Fifty-four patients with radiculopathy with or without mild myelopathy due to one- or two-level cervical degenerative disc disease were randomized in the control group and experimental group. Following microsurgical discectomy, the control group was treated with iliac crest graft fusion; the experimental study group underwent insertion of an interspace cage (BAK-C, Sulzer Spine Tech, Minneapolis MN, USA) and placement of a local autograft. All patients received postoperative follow-up care for at least 2 years. Good or excellent results were found in approximately 97% of the experimental group and 88% of the control group. A solid fusion was achieved in all patients who underwent one-level cage placement, and a solid fusion at one or both levels

was achieved in over 90% of both groups. Chronic donor site pain was reported by 31% of the control group. Hacker RJ concluded that the use of an interbody fusion cage avoided donor site morbidity and placement of autograft achieved a high rate of good or excellent results.

Papavero *et al.* (2002) investigated the clinical efficacy and osseointegration of a rectangular fenestrated titanium cage in cervical spine. The cage was filled with a highly porous hydroxyapatite cylinder soaked with bone marrow aspirated from a vertebra. 102 implants were inserted for anterior cervical fusion. The bone ingrowth was measured in 50 patients by quantitative computed tomography of the implant and the adjacent vertebrae after 1 week, then 6 and 12 months after surgery. The investigation was repeated in 24 randomly selected patients 24 months after surgery. The results showed the surgery benefited 42 of 48 patients with myelopathy, 27 of 28 patients with radiculopathy, and both patients with anterior horn cell syndrome. No graft substitute-related complications were observed, and no revision surgery was performed. Six months after surgery, quantitative computed tomography showed up to a 14% increase in the hydroxyapatite mass in the core of the implant, which was statistically significant ($P < 0.001$). At 1 year, the newly formed hydroxyapatite mass increased to 23%, and in 2 years reached 24%. They concluded that the composite implant was effective as a bone graft substitute, providing immediate load-bearing capacity, an osteoconductive scaffold, and osteoinductive potency.

Matge (2002) evaluated efficiency of cage fusion for surgical treatment of discogenic cervical disorders. This six-year retrospective study analyzed 250 consecutive cases treated by interbody cage fusion with 5 different implants. Indications for fusion concerned degenerative discopathies, disc herniations. Screwed threaded titanium cages (149 cases), impacted squared or anatomically shaped Peek cages (59 cases), and impacted titanium cages (42 cases) were used together with local graft or bone substitute. Additional plating was indicated in 16 unstable cases. Excellent outcome for neck pain (96%) and radiculopathy (97%) was noted, but a less favorable one for myelopathy (60%). All cases were stabilized at 1 year. Complications leading to reoperation included cage migration and subsidence, adjacent level degeneration and stenotic myelopathy. The conclusion was that the cage technology simplified anterior cervical interbody fusion, needed no graft harvesting and saved operating time and hospital stay.

Agrillo *et al.* (2002) reported their preliminary results in performing anterior cervical fusion (ACF) in which carbon fiber cages (CFCs) containing coralline hydroxyapatite (HA) were used as bone substitute. During a 24-month period, anterior microsurgical discectomy was performed in 45 consecutive patients for soft-disc cervical herniation. ACF was performed using a CFC containing a core of granulated coralline HA in all cases. Fifty-seven CFCs were implanted in 33 single-level and 12 two-level procedures. The mean operative time was 83 minutes for one-level and 97 minutes for two-level procedures. The mean hospital stay was 1.51 days, and there were no permanent complications. At a mean follow up of 22.3 months, the pain had decreased or

disappeared in all patients, and the patients' satisfaction rate was very high. Good results were also obtained in patients who smoked cigarettes. Patients underwent radiographic evaluation at Day 1, and 1, 3, 6, and 12 months postoperatively. Implant-related complications were not observed and revision surgeries were not performed. Twelve-month cervical x-ray films demonstrated complete fusion in all cases, without evidence of breakage, collapse, pseudarthrosis, subsidence, angular deformity, or protrusion. Signs of pathological absorption and necrosis were not found in contiguous vertebral bodies, and inflammatory reactions were not seen around cages.

Kandziora *et al.* (2005) performed a prospective cohort study to define indications and analyze the clinical and radiographic results of using interbody cages to surgically treat traumatic cervical spine instability. 53 patients were treated by monosegmental anterior discectomy and interbody fusion using either autologous tricortical iliac crest bone graft and CSLP (cervical spine locking plate) (bone graft group, n=26) or Syncage-C filled with autologous cancellous bone grafts and CSLP (cage group n=27). Intraoperative parameters such as blood loss and operation time were assessed. Prior to surgery and at follow-up (6, 12, and 24 months), radiographic evaluation, including plain x-rays, flexion-extension views, and CT scans was performed. Fusion, segmental mobility, segmental lordosis/kyphosis and disc space height were determined. The results showed that operation time and hospital stay were significantly shorter ($p<0.05$) in the cage group than in the bone graft group. After 6, 12, and 24 months there was no difference between either group in pain, muscle strength, neurological and overall outcome. Although

the cage group showed a trend for prolonged fusion process, there was no statistically significant difference between the groups for all radiographic parameters. They concluded that cages offered a valid alternative to a tricortical iliac crest bone graft in the surgical treatment of monosegmental traumatic cervical spine instability under strict indications. Although there was no significant difference between the cage and the bone graft group in the functional and radiographic outcome, less donor site morbidity, a shorter operating time, and a reduced hospital stay might result in cost-effectiveness of cages

2.2 IN VITRO STUDIES

2.2.1 Basic Concept

The definition of *in vitro* testing in the spine field is the testing of isolated cadaveric human or animal tissue in a laboratory environment when anatomy is important (Smith 1991; Panjabi 1998; Wilke *et al.* 1998). The main purpose of *in vitro* experiment of a new implant is to evaluate their biomechanics in laboratory before they can be accepted into clinical application in order to have a better understanding of the features of the particular instrument and achieve higher clinical success (Wilke *et al.* 1998). In *in vitro* biomechanical studies, a human or an animal cadaveric spine is often the experimental material. The human cadaveric specimens most have perfect vertebral anatomy, physical properties, and facet articulation, which are important biomechanical parameters in representing the living human being (Panjabi 1998).

Classification of biomechanical testing of spinal fixation device generally falls into three categories according to their purposes: strength, fatigue and stability (Panjabi 1998).

Strength testing is usually conducted in a universal testing machine, where the load is applied increasingly until the construct failure occurs. Load-displacement curve such as load-to-failure, energy-absorbed-to-failure and stiffness can be obtained. Information on load-carrying capability of the implant and its failure mechanism can be extracted from this type of testing.

In fatigue testing, a load of fixed magnitude is applied periodically at a certain rate. During each cycle the maximum load applied is much lower than the failure load. The periodical loading is kept on until the construct fails. The fatigue life of the device at that load magnitude is defined as the number of cycles to failure. The fatigue test is usually repeated at several load magnitudes to obtain the fatigue curve, providing valuable information on the longevity of the construct.

Stability testing is designed to evaluate the biomechanical environment at the fusion site of the fracture. The construct is tested in several loading modalities: flexion/extension, lateral bending and axial rotation. The load applied is in the range of physiological values to avoid any destruction to the construct. A more complete picture of the stabilizing capabilities of the instrumentation can be obtained through a large amount of data collected, such as range of motion, neutral zone and elastic zone. Stability parameters form an important index for indicating the potential of the construct for rapid fusion and healing.

2.2.2 Relevant Studies

2.2.2.1 Range of Motion of C5-C6

Panjabi *et al.* (2001) conducted an *in vitro* experiment to measure the range of motion (ROM) of the human lower cervical spine. Sixteen human whole cervical spine specimens were harvested fresh, packed in double plastic bags and stored at -20°C until the testing day. Any specimens with abnormalities beyond the normal age-related degenerative changes were excluded by radiography. Each specimen remained in the study was dissected of all nonligamentous soft tissue. The occiput and the caudal-most vertebra were mounted in polyester resin casts. 1.5 mm-thick Plexiglas markers were attached to the anterior aspects of each vertebral body and the occiput. Each marker contained at least three 0.8 mm-diameter steel balls glued to the Plexiglas surface and distributed noncollinerly. Anteroposterior and lateral roentgenograms were taken of the specimens for the establishment of an anatomic coordinate system in each vertebra and for providing geometric relationships between the coordinate system and the corresponding marker steel balls. The steel balls served as points for stereophotogrammetric motion measurement, but the data were analyzed in the context of spine bony anatomy.

The aim of this test was to determine three-dimensional physical properties of the spine specimen by applying pure moment and measuring the intervertebral motions. A three-dimensional coordinate system was defined for this purpose as shown in Figure 4. The origin was the posterior-inferior corner of

the moving vertebral body. The positive y axis was along the posterior wall of the body of the inferior vertebra directing up, the positive z axis was perpendicular to the y axis pointing forward, and the positive x axis was perpendicular to both y and z axes directing left. Six pure moments were used: flexion (+MX), extension (-MX), left axial rotation (+MY), right axial rotation (-MY), right lateral bending (+MZ), and left lateral bending (-MZ).

Figure 4 Standard 3D Coordinate System (Panjabi *et al.* 2001)

Appropriate equal and opposing forces were applied to the pulleys mounted on the top of the specimen to generate a pure moment as shown in Figure 5. The cephalic and caudal end-vertebrae were mounted in polyester resin mounts. The bottom mount was fixed to the test table while the top mount carried a loading fixture. The loading fixture was designed to apply pure moment to the specimens via three round discs, two vertically oriented and one horizontally oriented. The vertical pulleys were used to apply moments of flexion,

Figure 5 Experimental Setup for Flexibility Test (Panjabi *et al.* 2001)

extension, and lateral bending. The horizontal pulley was used to apply axial torque. The design of the loading arrangement allowed completely unconstrained spinal motions. Each moment was applied in three equal load increments to a maximum value of 1.00 Nm, which was judged to be sufficient to produce physiologic motions but small enough not to injure the specimen. Thirty seconds of creep were allowed at each load step, and three load-unload cycles were applied for preconditioning the specimen and minimizing viscoelastic effects. Stereophotographs were taken of the markers on the specimen, only on the third load cycle. The photographs were digitized, relative three-dimensional motions of each vertebra were calculated and load-displacement curves were plotted. ROM for each level was determined from the measured load-displacement curves from the third load cycle. The ROM

was defined as the rotation from the neutral position to the end position at the maximum load of 1.00 Nm. An upward force of approximate 15 N applied at the center of gravity of the mount balanced the weight of the upper mount.

The accuracy of the motion measurement system was estimated by a rigid body with four vertebral markers, each containing several balls. With the markers fixed in space, the rigid body Euler angles and translations were calculated from 10 stereophotogrammetric images. The precision (the standard deviation of the measurements) was found to be -0.60° for flexion-extension, -0.33° for lateral bending, and -0.17° for axial rotation. For translations, the precisions were as follows: -0.43 mm for axial translation, -0.35 mm for anteroposterior translation, and -0.22 for lateral translation.

The ROMs for C5-C6 segment in the in vitro experiment were $5.5 \pm 2.6^{\circ}$ for flexion, $4.4 \pm 2.8^{\circ}$ for extension, $6.5 \pm 1.5^{\circ}$ for lateral bending, and $5.0 \pm 1.0^{\circ}$ for axial rotation.

2.2.2.2 Lumbar Cage

Tencer *et al.* (1995) used calf and human cadaveric spines to determine motion segment stiffness and laxity after implantation of threaded inserts (the Ray Threaded Fusion Cage, Surgical Dynamics, Inc., Concord, CA) for lumbar and lumbosacral fusion and the factors affecting stability. Mechanical properties were determined by testing lumbar vertebral motion segments in flexion, extension, lateral bending, and torsion combined with axial compressive loading. Stiffness and neutral zone angle or laxity (angular

displacement of the vertebra from no load to 1.0 Nm moment) were determined. Initial tests were performed on calf lumbar vertebrae to determine the effects of placement and number of inserts. Comparisons of bone grafts and inserts with and without supplemental plates were made using human lumbar spines. Cylindrical- and conical-shaped inserts, when placed from anterior, were tested in calf spines. The load-bearing capacity of the insert supported in calf vertebral body bone was determined. The results showed there was no significant effect of placement of inserts in different orientations (lateral, posterolateral, or posterior) on stiffness, except in torsion where posterior placement damaged facets or lamina, reducing stiffness. Placement of two inserts from posterior decreased flexion and lateral bending laxity compared with the intact motion segment. Compared with intact, bone grafts produced more stiffness only in lateral bending and had no effect on laxity. Supplemental posterior plates fixed by pedicle screws across the fusion segment increased flexion and lateral bending stiffness and reduced laxity in flexion, extension, and lateral bending. Conical-shaped inserts placed from anterior into cylindrical holes distracted soft tissue structures, decreasing laxity. Cutting the anterior structures increased laxity by relieving some tissue tension caused by distraction. The mean maximum compressive load that could be supported by the insert was 2998 N (standard deviation = 980 N). Structural failure occurred in the supporting bone.

Brodke *et al.* (1997) performed an *in vitro* biomechanical testing on eight lumbar calf spines to compare the initial stiffness of a standard method of posterior lumbar interbody fusion using structural autograft with the same

procedure using additional posterior instrumentation. These constructs also were compared to a new titanium implant. The eight lumbar calf spines were subjected to axial compression, sagittal moments (flexion-extension), and axial torque while displacement was measured. Stiffness was calculated from the load displacement curves for each construct under each load pattern. The results showed that the posterior lumbar interbody fusion by bone graft alone was the least stiff construct of all modes tested. In two of eight specimens the bone graft dislodged posteriorly into the canal during torsional testing. The titanium interbody implant was similar in stiffness to the bone graft posterior lumbar interbody fusion with posterior instrumentation group in all three modes. They were both significantly stiffer than the normal spine, the destabilized spine, and the posterior lumbar interbody fusion by bone graft alone ($P < 0.05$). The conclusion was that the posterior lumbar interbody fusion with bone graft alone had less initial stiffness than that of the intact spine. The addition of posterior instrumentation or interbody implants can increase initial stiffness significantly

Glazer *et al.* (1997) measured and compared the stiffness of cadaveric lumbar spines stabilized with three anterior spinal instrumentation systems for stabilizing the lumbar spine. Fusion constructs were evaluated in 12 human cadaveric specimens sequentially loaded in axial compression and torsion, flexion and extension, and lateral bending. The fusion constructs used were 1) two anterior bilateral threaded interbody fusion devices, 2) lateral hollow interbody screws (Texas Scottish Rite Hospital-B screws), and 3) femoral allograft and conventional anterior Texas Scottish Rite Hospital

instrumentation. The results showed that the construct with Texas Scottish Rite Hospital-B screws connected by a rod produced stiffness comparable with that produced by conventional Texas Scottish Rite Hospital instrumentation with femoral ring allografts. The threaded interbody fusion device stiffness tested in axial rotation was comparable with that achieved with Texas Scottish Rite Hospital instrumentation. The data demonstrated the effectiveness of threaded interbody fusion device and the Texas Scottish Rite Hospital-B screw in immobilizing the L3-L4 and L4-L5 disc spaces. Rigidity of fixation in the lumbar spine might aid in the maintenance of lordosis.

Goh *et al.* (2000) performed an *in vitro* biomechanical testing on functional spine units with posterior lumbar interbody fusion cage implants to determine the influence of increasing cage size on the restoration of spine stability after total facetectomy. Eight human lumbar functional spine units were obtained and divided into two equal groups; one group underwent bending tests and the other twisting. The functional spinal units were tested intact, after total bilateral facetectomy and with three sets of cages that were progressively larger in size. The results showed, the functional spine unit's stiffness reduced significantly from that of the intact spine in extension (48% of intact), lateral bending (25%), and torsion (39%) after facetectomy. With the posterior insertion of small cages into the facetectomized functional spine units, only extension stiffness was restored to the intact level, whereas flexion stiffness reduced significantly (41% of intact). The medium cages restored the lateral bending stiffness of the facetectomized functional spine units. Only the large cages managed to restore the torsional stiffness. Flexion stiffness of the

facetectomized functional spine units with cages remained significantly less than that of the intact spine, regardless of cage size. They concluded that the cage size influenced lateral bending and torsional stability in the facetectomized lumbar spine unit.

Kanayama *et al.* (2000) used a calf spine model to compare the construct stiffness afforded by 11 differently designed lumbar interbody fusion devices and to quantify their stress-shielding effects by measuring pressure within the devices. Sixty-six lumbar specimens obtained from calves were subjected to anterior interbody reconstruction at L4-5 by using one of the following interbody fusion devices: four different threaded fusion cages (BAK device, BAK Proximity, Ray TFC, and Danek TIBFD), five different nonthreaded fusion devices (oval and circular Harms cages, Brantigan PLIF and ALIF cages, and InFix device); two different types of allograft (femoral ring and bone dowel) were used. Construct stiffness was evaluated in axial compression, torsion, flexion, and lateral bending. Prior to testing, a silicon elastomer was injected into the cages and intracage pressures were measured using pressure needle transducers. The results showed that no statistical differences were observed in construct stiffness among the threaded cages and nonthreaded devices in most of the testing modalities. Threaded fusion cages demonstrated significantly lower intracage pressures compared with nonthreaded cages and structural allografts. Compared with nonthreaded cages and structural allografts, threaded fusion cages afforded equivalent reconstruction stiffness but provided more stress-shielded environment within the devices

2.2.2.3 Cervical Cage

Wilke *et al.* (2000a) investigated the primary stabilizing effect of four different cervical fusion devices. Twenty-four segments from ten human cervical spines were used in their study. After anterior discectomy, fusion was performed either by a Wing cage, a BAK/C cage, an AcroMed cervical I/F cage or bone cement. All specimens were tested in the intact condition and after implantation of one of the four devices. A moment of 2.5 Nm in pure flexion/extension, lateral bending and axial rotation was applied continuously and relative motions in each segment were measured simultaneously. Generally all the implants had a stabilizing effect. In lateral bending, the stabilization was most obvious, with a range of motion between 0.29 in AcroMed cage and 0.62 in BAK/C cage as a fraction of the intact specimen (= 1.0). For all the three testing modalities, flexion/extension, lateral bending and axial rotation, the AcroMed cervical I/F cage had the highest stabilizing effect, followed by bone cement, Wing cages and BAK/C cages. Bone cement showed the most efficiency in stabilization in extension. With regard to the primary stabilizing effect, the AcroMed I/F cage, the Wing cage as well as the BAK cage seemed to be a good candidate to replace bone cement in cervical interbody fusion.

In another paper, Wilke *et al.* (2000b) reported an *in vitro* biomechanical test on subsidence of the 4 aforementioned cervical fusion devices using a new testing protocol that simulated physiological conditions. In this study, 24 human cervical spine segments were tested after stabilization with either a

Wing cage, a BAK/C cage, an AcroMed cervical I/F cage or bone cement. 700 cycles of ± 2.5 Nm pure moment were applied in randomized directions to simulate the patient's neck movements during the first few postoperative days. Measurements of the subsidence depth in combination with flexibility tests were performed before cyclic loading and after 50, 100, 200, 300, 500, and 700 loading cycles. The results showed BAK/C cage had the largest subsidence of 1.63 mm after 700 loading cycles, followed by WING cage (0.90 mm) and the AcroMed (0.82 mm). No statistically significant differences could be found among the three cages designs but all cage types showed a significantly higher subsidence depth than bone cement. Only in the BAK/C group, a moderate correlation between bone mineral density and subsidence depth could be found. A larger increase in the range of motion (ROM) of the constructs in the WING and AcroMed groups was associated with a larger cage subsidence depth after 700 loading cycles. They concluded that postoperative neck movements caused subsidence in all cervical interbody fusion devices. The WING cage and AcroMed cage seemed to have a better resistance against subsidence than the BAK/C cage. All the three cages had a significant higher tendency for subsidence than bone cement.

Kettler *et al.* (2001) studied the influence of simulated postoperative neck movements on the stabilizing effect and subsidence of three different anterior interbody fusion cages and bone cement. Their study was focused on the relation between subsidence and spinal stability. The study sample size and testing protocol was same as the ones done by Wilke *et al.* (2000a; 2000b). Additional flexibility tests in combination with measurements of the

subsidence depth were conducted. In all four groups, the range of motion was increased by the simulated neck movement in all four groups, ranging from 0.4° to 3.1° . The neutral zone was increased from 0.1° to 4.2° . Extension was most distinct in increasing flexibility, followed by flexion, lateral bending and axial rotation. After cyclic loading, range of motion tended to be lower in the groups implanted with AcroMed and bone cement than those fitted with WING and BAK/C cages. The authors pointed out that simulated repeated neck movements led to subsidence of the implants into the adjacent vertebrae as well as an increase of the flexibility. The correlation between flexibility increase and subsidence tended to be dependent on implant design. Subsidence of BAK/C cages partially supported stability whereas WING and AcroMed cage subsidence did not.

Using sheep cervical spine, Kandziora *et al.* (2001) evaluated the biomechanical performance of 10 cervical fusion cages of three different designs: screw, box and cylinder. 80 sheep cervical spines (C2-C5) were tested in flexion, extension, axial rotation and lateral bending with a nondestructive method using a nonconstrained testing apparatus. Three-dimensional displacement was measured using an optical measurement system. Cervical interbody cages were implanted after complete discectomy, with each group consisting of 8 spines. The mean apparent stiffness values were calculated from the corresponding load-displacement curves. In addition, cage volume and volume-related stiffness were determined. The results indicated that design variations in screw and cylinder design groups were of little importance for construct stability. However, cages with a cylinder design

were able to control extension and bending more effectively than cages with a screw design.

2.3 IN VIVO STUDIES

2.3.1 Basic Concept

In vivo studies are an approximation of the performance of spine implants in human by evaluation in animal models, which provide a dynamic biological and mechanical environment for the assessment of implants. By selective incremental sacrifice of the animals, temporal course of healing and adaptation in both host biological tissue and implant can be evaluated (Puttlitz *et al.* 1998). The output of these studies includes flexibility-stiffness and strength of the construct. Additional information is added to biomechanical investigation with the radiographic evaluation, microscopic and electron microscopic examination. These and similar nonbiomechanical examinations provide a more comprehensive understanding of the underlying phenomena and help to elaborate the true biological and biomechanical process involved (Panjabi 1998).

2.3.2 Previous Studies

Zdeblick *et al.* (1998) analyzed the use of the cervical BAK cage, with and without a bone graft substitute to accelerate bone fusion after anterior discectomy. Three level anterior cervical discectomies were performed on 21 mature Alpine goats. 3 treatment groups of 7 goats each were used. In group I, a standard titanium cervical BAK device filled with autogenous bone graft

was used. In group II, a hydroxyapatite-coated BAK device filled with autogenous bone graft was applied. A BAK device filled with recombinant human bone morphogenetic protein-2 was used in group III. The results showed there were no cage displacements on radiographs. Lucencies were observed around 3 of the 21 cages in Group I, 4 cages in Group II, and no in Group III. Fluorochrome analysis revealed that the recombinant human bone morphogenetic protein-2 filled cages had an improved rate of bone growth around and through each cage-vertebral bone interface at 3 weeks. A recombinant human bone morphogenetic protein-2 filled cage seemed to have a more successful arthrodesis than the hydroxyapatite-coated or the standard cage. Biomechanical stiffness testing did not show any statistically significant differences among the three groups. However, successfully arthrodesed interspaces tended to be stiffer than those not arthrodesed segments.

They concluded that the use of a threaded intervertebral fusion cage, with or without hydroxyapatite coating filled with autogenous bone graft offered a fusion rate that is slightly higher than those previously reported using autogenous interbody bone grafts with or without plate stabilization. Recombinant bone morphogenetic protein-2 filled cages resulted in much higher arthrodesis rate compared with either autogenous bone filled BAK devices or autogenous interbody bone grafts with or without plate stabilization.

Kandziora *et al.* (2002) compared the characteristics of interbody fusion achieved by an autologous tricortical iliac crest bone graft with those by a

vertical ring cage and an open box cage in a sheep cervical spine model. The purpose was to determine if there were any differences among three interbody fusion procedures in the ability to preserve postoperative distraction, biomechanical stability and histological characteristics of the intervertebral bone matrix formation.

Twenty-four sheep underwent C3-C4 discectomy and fusion in this study. Radiography was preformed pre- and postoperatively and after 1, 2, 4, 8 and 12 weeks. Disc space height, intervertebral angle and lordosis angle were measured at the same time point. After sacrifice of the sheep at 12 weeks, functional radiographs in flexion and extension were taken at the fusion site. Bone mineral density, bone mineral content and bone callus volume were acquired by quantitative computerized tomography scans. Biomechanical testing was performed in flexion, extension, lateral bending and axial rotation. Stiffness, range of motion, neutral zone and elastic zone were measured. Histomorphological and histomorphometric analyses were performed. The time frame of new bone formation was determined by polychrome sequential labeling.

The result showed that both cages showed significantly better distractive properties compared with tricortical bone graft. The cylindrical cage demonstrated a significantly higher biomechanical stiffness and an accelerated interbody fusion compared with the box-design cage and the tricortical bone graft. The differences in bone matrix formation within both cages were caused

by the significantly lower stress shielding on the bone graft by the cylinder-design cage.

2.4 FE STUDIES

2.4.1 Basic Concept

FE modeling is the modeling of a continuous system, which has an infinite number of degrees of freedom, using a representative geometry of that system made up of a finite number of smaller elements and node points. Once the FE model has been created and the system characteristics have been established in the model, a global stiffness matrix can then be formed for the whole structure. Given the forces and boundary conditions, the unknown displacements at each of the node points can then be used to determine the stresses and strains acting on each element (Kardestuncer 1987).

The FE method was first introduced in 1956 to analyze structure mechanics problems. It was in the early 1970s when the application of this method started in thorax and vertebral column modeling in the area of musculoskeletal biomechanics (Yoganandan *et al.* 1996a). With continuous advancements in numerical techniques and computer technology, the finite element method is able to simulate a variety of clinical situations in a more realistic manner, and has been acting a fully complementary partnership with experimental approaches for spine biomechanics research (Gilbertson *et al.* 1995).

2.4.2 Existing Models

In the early time of spine modeling, the cervical spine was treated as the vertebrae as simple rigid masses connected by spring elements to simulate soft tissue. A realistic response could not be expected due to much simplification of the vertebrae (Yoganandan *et al.* 1996a). It was not until early 1990s that detailed finite element models of the human cervical spine began to emerge.

The earliest detailed cervical spine FE model of Figure 6 was developed from the bases of the skull to T2 by Saito *et al.* (1991) to investigate the effects of postlaminectomy deformities in adolescent and adult patients. The spine was divided into four regions in the midsagittal plane, representing all the elements within that region as a two dimensional structure. The first slice was for the vertebrae and the discs; The second slice included the cortices of the body and the articular facets; The third slice accounted for the transverse processes and the intertransverse ligaments, and the fourth represented the cranium and the cortex of the atlas. Triangular elements were used for bone and disc modeling for a total of 1743 elements in the normal spine model and 1607 elements in the postlaminectomy model. The boundary conditions consisted of fixing the inferior surface of T2 and constraining one point on the cranium to move in the cranial-caudal direction only. The spine model was loaded with 150 N at a point located between the hypophysial fossa and C1-C2. They found that clinically observed postlaminectomy spinal deformity could be produced by the FE model, depending on the load location.

Figure 6 FE Model of C0-T2 (Saito *et al.* 1991)

3D FE models of C5-C6 motion segment of Figure 7 and cervical column with ligaments of Figure 8 were developed by Kleinberger (1993). The complex vertebral anatomy was approximated by a combination of regularly shaped blocks. The superior and inferior surfaces were assumed flat, with no distinctive differences among all vertebrae. The angle between the vertebrae was adjusted to simulate the cervical curvature. Facets were oriented at 45° in

Figure 7 FE Model of Cervical Segment (Kleinberger 1993)

Figure 8 FE Model of Cervical Column (Kleinberger 1993)

the sagittal plane. Supraspinous ligaments replaced the interspinous ligaments.

Contact surfaces between the bodies and the discs were defined as

tight interfaces. Material properties of the disc and the facet joints were the same. T1 was fixed and the occipital condyles were constrained to superior-inferior translation without rotation for compressive loads. The occipital condyles had a free boundary condition for flexion loading. Using linear material properties, Kleinberger compared the results under static and dynamic loadings with those in the literature. The head-neck rotation response from the model was compared with data from human volunteers.

Yoganandan *et al.* (1996b) developed a more anatomically accurate three-dimensional FE model of human cervical spine C4-C6 as shown in Figure 9 based on CT images of an unembalmed cadaveric cervical spine. Material properties of the model were adopted from literature. Eight-noded

Figure 9 FE Model of C4-C6 (Yoganandan *et al.* 1996b)

isoparametric elements were chosen for all the structures of the solid model except cortical wall and endplates, which were simulated by thin shell elements. The three-segment C4-C6 cervical spine FE model consisted of 9178 solid elements and 1193 thin shell elements. The FE model force-displacement response was validated with *in vitro* experiment done by Shea *et al.* (1991). In Shea *et al.*'s experiment, twenty-seven cervical spine specimens consisting of three adjacent vertebrae and their interconnecting ligaments, soft tissue, and disc were harvested for testing. The mechanical tests were conducted using a specially constructed hydraulic, servo-controlled, multi-axial spine testing system, which allowed *in vitro* simulation of the full range of *in vivo* spinal motions. Data were collected for a range of load-displacement conditions at displacement rates up to 5 mms-1 translation or 5⁰s-1 rotation. Curves for loading in anterior-posterior shear, compression-tension and flexion-extension were obtained. The output of Yoganandan's FE model under

the same loading condition showed a good match with results of Shea *et al.*'s experiment. Later, a series of biomechanical studies based on this model were conducted by the same research group (Kumaresan *et al.* 1997; Kumaresan *et al.* 1999; Maiman *et al.* 1999)

Maurel *et al.* (1997) developed a 3D parameterized FE model of the lower cervical spine as shown in Figure 10 to study the influence of the posterior articular facets. A spatial measuring machine was used to measure the three-dimensional coordinates of the points on the surface of the dry lower cervical vertebrae. The model appeared coherent both qualitatively and quantitatively with the published results in flexion, extension and lateral bending. The conclusion showed that the orientation of the facets with regard to the horizontal plane was mechanically important, especially in the axial rotation and the ratio of coupled rotation to the principal rotation.

Figure 10 FE Model of C3-C7 (Maurel *et al.* 1997)

Goel & Clausen (1998) developed a 3D C5-C6 FE model as shown in Figure 11 from serial computed tomographic scans of ligamentous cervical spine segment. The model included nonlinear ligament definition, fully composite intervertebral disc, fluid nucleus, and Luschka's joints. The full model, symmetrical at approximately the midsagittal plane, consisted of 5429 nodes and 5577 elements representing various spinal structures of C5-C6 segments. The model-based displacement predictions were in agreement with the experimental data. The model was used to predict load sharing and other related parameters in spinal elements in response to various loading modalities.

Figure 11 FE Model of C5-C6 (Goel & Clausen 1998)

Heitplatz *et al.* (1998) developed a three-dimensional FE model of C4-C7 using data from the Visible Human Project. The model was used to predict the strain inside the spinal ligaments during whiplash accidents. It consisted of 1702 nodes and 2243 elements. Material properties for the ligaments were

taken from the lumbar spine. The stiffness of C4-C5 under compression was compared well with the result from the *in vitro* test. However, the topological accuracy of the model was compromised and this model was built for predicting the dynamics of the cervical spine in whiplash accident situations rather than for determining stress inside the bony structure and the intervertebral disc.

Natarajan *et al.* (2000) presented a 3D nonlinear FE model of an intact C5-C6 segment using CT scans of a 38-year-old female with a normal spine. The intact FE model results for all moment loads were compared with experimental data from literature. The model was used to analyze the changes in gross response after anterior cervical fusion with loose-fitting and tight-fitting grafts. The maximum compressive stresses under all loading conditions were recorded. The conclusion showed that anterior discectomy and insertion of the loose graft resulted in increased motion and a tight-fitting graft was beneficial in reduction of motion. The maximum compressive stresses within the tight fitting graft were higher than the graft normal stress, which would lead to the risk of graft fracture or collapse. The presence of osteoporosis deteriorated such condition.

Teo & Ng (2001) created a 3D FE model of the human lower cervical spine as shown in Figure 12, consisting of 11,187 nodes and 7,730 elements. The 3D geometric data of the model were obtained by a flexible movement digitizer. The model was validated against the published data under axial compression, flexion and extension. The FE model was further modified to investigate the

role of disc nucleus, facets and ligaments in preserving the stability of the lower cervical spine under different loading conditions. The analysis showed that ligaments, facets and disc nucleus are crucial to maintain the cervical spine stability, in terms of sagittal rotational movement or load distribution.

Figure 12 FE Model of C4-C7 (Teo & Ng 2001)

2.4.3 Cage Studies

There is a paucity of FE studies on the biomechanical performance of the cervical cage in the literature. Kumaresan *et al.* (1997) investigated the external and internal biomechanical response of anterior discectomy coupled with fusion. Five different types of interbody fusion material were used: titanium core, titanium cage, tricortical iliac crest, and tantalum core and tantalum cage. Two different types of surgical procedures were analyzed: Smith-Robinson and Bailey-Badgley. The FE model was exercised in compression, flexion, extension and lateral bending for the intact case and for

the two surgical procedures with five implant materials. The external response in terms of the stiffness and angular rotation, and the internal response in terms of the disc and the vertebral stresses were determined. The Smith-Robinson technique resulted in the highest increase in external response under all modes of loading for all implant materials. In contrast, the Bailey-Badgley technique produced a higher increase in the disc and the vertebral body stresses than the Smith-Robinson technique.

Maiman *et al.* (1999) quantified the biomechanical effects of superior (C4-C5) and inferior (C5-C6) level fusions with different graft materials on the adjacent unaltered components. Smith-Robinson and Bailey-Badgley fusion procedures were analyzed with five different types of interbody fusion materials with varying stiffnesses. The axial and angular stiffnesses and stresses of unaltered intervertebral disc (C5-C6 disc for the superior fusion and C4-C5 disc for the inferior fusion) and C5 vertebral body stresses were determined. The superior level fusion resulted in the highest increase in external response in lateral bending for all implant materials in both surgical procedures. The inferior level fusion produced a higher increase in the C4-C5 disc and C5 vertebral body stresses in compression than the superior level fusion in both surgical procedures. The increased internal stress responses reflecting the changes in the load-sharing following inferior level fusion may explain clinical observations such as enhanced degeneration subsequent to surgery.

2.5 ACP STUDIES

An anterior cervical plate (ACP) for spinal fusion was first developed by Bohler in 1964 (Bohler & Gaudernak 1980), as an attempt to overcome the complications, such as non-union and graft dislodgement, induced by an anterior cervical decompression and fusion. Since then, numerous ACPs have been developed to increase the fusion rate and preserve the physiological lordosis of the cervical spine (Connolly *et al.* 1996; Swank *et al.* 1997; Bose 1998; Caspar *et al.* 1998; Emery *et al.* 1998; Wang *et al.* 2000). The ACPs can be fundamentally divided into 2 categories: nonconstrained and constrained as shown in Figure 13 (McCullen & Garfin 2000; Vaccaro & Balderston 1997).

Figure 13 Classification of Anterior Cervical Plate

(Vaccaro & Balderston 1997)

The nonconstrained plate requires bicortical screw purchase of the cervical vertebral body. Telescoping of the bone-plate constructs may occur to some degree due to slippage and screw angulations in the plate slots in the sagittal

plane. Screw loosening, breakage and plate pullout may happen because of the excessive telescoping. Purchasing the posterior cortical wall may be technically demanding, but is necessitated in this category to minimize the complications (McCullen & Garfin 2000).

The constrained plates have been developed to avoid the need for bicortical screws and have intrinsic stability of the screw-plate interface via a stable angular fixation system. Biomechanical studies showed that the immediate stability of intact and injured stabilized motion segments offered by the constrained, monocortical screws did not differ significantly from those with bicortical screw fixation (Lehmann *et al.* 2004; Lehmann *et al.* 2005; Panjabi 1998; Richter *et al.* 1999). Clinically the constrained plates also showed the same efficacy as the unconstrained fixation in fusion success and functional outcome with no added risk of nerve root and spinal cord injuries (Cabanela & Ebersold 1988; Gardner *et al.* 1994).

The usefulness of ACP has been proven in treating of cervical trauma and degenerative diseases. Anterior plate fixation obviated the need for posterior stabilization in cases of global instability after decompression and fusion in many instances. It is an ideal method of fixation in distraction-extension injuries functioning as an anterior tension band over an applied graft. Anterior plate fixation has decreased the number of fused motion segments in certain instability patterns, such as a traumatic anterolisthesis after a bilateral pedicle fracture; a properly positioned ACP can prevent graft dislodgement and at the same time maintain the sagittal alignment. Lastly, rigid anterior plate fixation

can lessen the need for various bulky and rigid external fixation devices (Tippets & Apfelbaum 1988; Goffin *et al.* 1995; Vaccaro & Balderston 1997; Heidecke *et al.* 1998; Isomi *et al.* 1999; Barnes *et al.* 2002; Bolesta *et al.* 2002; Henriques *et al.* 2004; Yue *et al.* 2005).

Most recently, a kind of absorbable ACP made of Poly-levo-lactide (PLLA) has been developed to meet the new concept of dynamic fixation in anterior plating technology through a collapsing anterior spinal fixation device (Ames *et al.* 2002; Park *et al.* 2004; Vaccaro & Madigan 2002; Vaccaro *et al.* 2002; Vaccaro *et al.* 2003). The benefits of the absorbable ACP include radiolucency for early diagnosis of the fusion with no imaging artefacts and the dynamization during the absorption process allowing stability for approximately 6 to 12 months for the mature bone to develop.

Interbody fusion cages offer an alternative way to stabilize the spine and to promote bony fusion between the adjacent vertebrae by supporting the axial load and reducing the intervertebral mobility (Bagby 1988; Weiner & Fraser 1998; Steffen *et al.* 2000b; Wilke *et al.* 2000a; Zdeblick & Phillips 2003). However, disadvantages do exist in the application of cage fusion. The cage usually does not have a significant effect in extension as it does in flexion and lateral bending (Pflugmacher *et al.* 2004; Schmidt *et al.* 2005), for the anterior surgical approach for discectomy, decompression and insertion of cages destroys the anterior longitudinal ligaments and parts or most of the anterior annulus, causing destabilization partially in extension (Oxland & Lund 2000). Cage settling into the vertebral endplate due to repetitive load (Kettler *et al.*

2000), change of bone density (Jost *et al.* 1998; Lund *et al.* 1998) and loosening of the tension of the annulus fibers because of viscoelastic properties (Kettler *et al.* 2000) contributes the unstable status of the motion segments after the cage implantation. Clinical studies also reported the subsidence of stand-alone cages and loss of disc height after anterior cervical discectomy and cage instrumentation (Gercek *et al.* 2003; Tureyen 2003).

Hence, the application of supplementary anterior cervical plate fixation to augment the stability of the caged segmental construct has been advocated in recent years (Caspar *et al.* 1998; Gercek *et al.* 2003). Clinical studies on the combination of ACP and cervical cages have demonstrated to be a safe and viable alternative technique for cervical trauma and degenerative disease. It can provide immediate strong anterior support, minimize hardware failures, prevent bone-graft recipient and donor site complications, increase intervertebral height and lordosis, and enlarge foraminal diameter. Higher fusion rate, excellent clinical outcome, lower complication occurrence and shorter hospital stay have been achieved with this technique. (Matge 1998; Majd *et al.* 1999; Samandouras *et al.* 2001; Matge 2002; Thalgott *et al.* 2003; Sevki *et al.* 2004; Soderlund *et al.* 2004).

The efficiency of the cervical cage with concomitant use of ACP has been studied in in vitro experiments. Greene *et al.* (2003) evaluated the additional stability provided by adding ACP to the caged construct. Sixteen human cadaveric specimens were tested intact, after discectomy, with graft or cage, with two-level plate and one-level plate. The results showed that adding a one-

or two-level plate significantly reduced the motion in all loading modalities. Pflugmacher *et al.* (2004) compared the biomechanics of several cervical cages. After the range of motion (ROM) of the intact and caged segments was tested, the effect of additional anterior plate stabilization was further measured. The results showed that the additional anterior plate stabilization significantly decreased ROM and increased stiffness in flexion and extension in comparison with the cage implanted alone. Schmidt *et al.* (2005) conducted a study comparing the different effects of the spinal implants on human and porcine cervical spine segments. The results showed that additional anterior plate fixation can lower the median ROM values for both species in lateral bending, flexion-extension and axial rotation, although there are marked differences in distribution of median and range of the data in lateral bending and axial rotation between the two species.

2.6 COMBINATION OF TAGUCHI AND FE METHOD

There are few studies in the literature combining the Taguchi philosophy and the FE method in design optimization in the bioengineering field. The only study found was done by Koh & Fuss (2004) for the design criteria of an artificial hip. In their study, the FE model of an artificial hip joint sandwiched between two bone jigs was developed. Magnitudes of 2188.86 N and 5472.1 N forces were applied on the femoral head of the artificial hip in horizontal and vertical directions respectively. The authors concluded that the most significant factors that influence the stem stress were the stem thickness, followed by the stem length, the neck angle and the distal diameter. The

avoidance of the stress shielding effect might take a higher priority compared to further lowering the stem stresses.

2.7 RESEARCH NECESSITY

Although *in vitro* studies have provided valuable information on cervical cage initial stability, fatigue life and resistance to subsidence into the endplate, they have inherent drawbacks. The *in vitro* implant testing follows loosely standardized testing sequelae and protocol, which is often labour intensive and time consuming; Problems, such as high cost, limited availability and large variability from specimen to specimen in human cadavers, are common in *in vitro* studies (Goel & Pope 1995; Panjabi 1998; Wilke *et al.* 1998) .

In vivo study is suitable for exploring phenomena relating to fusion and osteopenia in response to cage implantation, which is not easily achieved by *in vitro* testing. However, *in vivo* study usually involves quadrupeds which have obvious differences in anatomy, biomechanics and biology from humans. The implant size has often to be scaled according to the anatomy of the animal (Goel & Pope 1995; Panjabi 1998).

FE study, on the other hand, can overcome the difficulties and deficits borne by *in vitro* or *in vivo* study. Internal responses after cage implantation, like stress, strain and load distribution, which are not directly measurable quantities in other means of investigations, can be easily extracted in FE study (Yoganandan *et al.* 1996a). More importantly, FE study can parametrically analyse the optimal design and the sensitivity of the design parameters of any implants even before they are manufactured (Fagan *et al.* 2002; Yoganandan *et al.* 1996a).

Chapter 2 Literature Review

Cage subsidence into the adjacent vertebral endplates is a frequent mode of failure. Subsidence can result in progressive spinal deformity, encroachment of nerves and less likelihood of a successful bony fusion. Further surgery can be necessitated by this worse condition to resect the collapsed vertebral endplates and reconstruct the anterior column (Matge 1998; Majd *et al.* 1999; Matge 2002; Grant *et al.* 2001). Many factors are thought to be involved in the incidence of cage subsidence, including design of the cage, bone status of the neighbouring vertebrae, endplate conditions and supplementary fixation to the construct (Wilke *et al.* 2000a; Wilke *et al.* 2000b; Weiner & Fraser 1998; Oxland & Lund 2000).

However, only sparse FE studies were conducted on the factors contributing cage subsidence into the endplate in the literature. The optimal design of the cervical cage to avoid possible subsidence into the vertebra and the detailed biomechanical performance at the cage-endplate interface has still remained unknown, especially for the ring-shaped cage configuration. Such information is necessary for a better understanding of cervical cage biomechanics and for a more ideal strategy for the treatment of cervical spine disorders.

CHAPTER 3 DEVELOPMENT AND VALIDATION OF LOWER CERVICAL SPINE (C5-C6) FE MODEL

3.1 OVERVIEW

In order to analyse the effect of the ring cage insert and ACP on C5-C6 vertebrae segment, and determine the optimal design of the cervical ring cage and to analyse the biomechanical changes of vertebra-cage construct in various situations, a more realistic cervical spine C5-C6 FE model had to be first built. The following procedures as shown in Figure 14 were carried out for the model construction.

Figure 14 Flowchart for C5-C6 FE Model Development

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Geometric Coordinates Capture

A high definition 3D digitizer was used to obtain the detailed geometrical coordinates from human embalmed cervical specimens.

Raw Data Processing

The 3D coordinate data were then processed to acquire the sequential cross section outlines of each vertebra. The data file was later transferred into a universal graphics format (IGES) and exported into commercially available FE modelling software for solid model development.

Solid Model Generation

The solid models of C5 and C6 were generated individually by surface creation and solid definition. The two solid models were connected by a detailed composite of cervical intervertebral disc and ligamentous tissue to create a solid model of the intact C5-C6 segment.

FE Model Development

An appropriate element type, material properties and contact definition were assigned for the solid C5-C6 model. The discretization was undertaken for the intact FE model development.

FE Model Validation

The developed FE C5-C6 model was loaded according to the boundary condition of the *in vitro* human cadaveric experiments in flexion, extension,

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lateral bending, axial rotation and compression. The results were compared with those obtained in *in vitro* experiments.

3.2 MATERIALS OF EXPERIMENT

For a successful development of an FE model using a contact digitization methodology, the following hardware and software are needed for the procedure: human C5 and C6 specimens for the original geometrical data, FaroArm 2.30 and Surface 7.0 for capturing and processing the data, and Ansys 6.0 for building and validating the cervical spine FE model.

3.2.1 Specimen

The cadaver was obtained from Singapore General Hospital and its details are listed in Table 1. The C5 and C6 cervical vertebrae as shown in Figure 15 & Figure 16 were harvested and embalmed for geometric data capture. Medical record and close examination of the specimen ensured that there was no metastasis, trauma and degeneration. The major dimensions of the two specimens fall within the normal range of those in the quantitative anatomical studies reported by Panjabi *et al.* (1991) and Tan *et al.* (2004).

Table 1 Details of Cadaver

Age	Gender	Race	Weight (N)	Height (m)	Cause of Death
56	Male	Chinese	700	1.72	Ischemic Heart Disease

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Figure 15 Anterior View of C5 Specimen

Figure 16 Lateral View of C6 Specimen

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3.2.2 FaroArm 2.30

FaroArm 2.30 (Bronze Series, FARO Technologies Inc., Lake Mary, FL, USA) is a portable measurement arm designed for engineering, manufacturing and controlling of dimensional quality as shown in Figure 17.

It is a multiple axis articulated arm with a spherical working volume. Each joint has a rotary transducer. FaroArm 2.30 possesses a high definition point/ball probe which is used to create accurate representation of the vertebral geometry. The signals from these transducers are sent through the controller cable which attaches to the port at the back of the Controller Box. A host computer (Pentium 200 MHz, Window NT) is installed for storage and processing of the data. The whole system can deliver a measurement accuracy of ± 0.25 mm.

Figure 17 FaroArm 2.0

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Caliper 3D is the basic operating system of the FaroArm 2.30. This stand-alone 3D measurement program can be used for FaroArm 2.30 certificating, probes changing and communication parameters setting. The accuracy and reliability of the measurement by the FaroArm 2.30 with Caliper 3D have been verified for the measurement of human spine vertebrae, ranging from 0.68% to 1.71% (Tan & Teo 2001; Tan *et al.* 2004).

3.2.3 ANSYS 6.0

ANSYS 6.0 (ANSYS, Inc., Southpointe, Canonsburg, PA, USA) is a commercially available general-purpose FE modeling package that has many FE analysis capabilities, ranging from simple, linear static analyses to complex, nonlinear, transient dynamic. The ANSYS program is organized into two basic levels: Begin level and Processor (or Routine) level.

Begin level acts as a gateway into and out of ANSYS program and is also used for certain global program controls such as changing the jobname, clearing (zeroing out) the database and copying binary files.

At Processor level, several processors are available, with each being a set of functions that perform a specific analysis task. The general preprocessor (PREP7) is applied to build the model. Loads are applied and results are obtained in the solution processor (SOLUTION). The general postprocessor (POST1) is the processor to evaluate the results of a solution. Evaluation of solution results at specific points in the model as a function of time is done in the additional postprocessor (POST26).

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The minimum requirements and available graphics devices for an ANSYS installation and running are:

- Pentium running Microsoft Windows 2000 with Service Pack 2, 128 MB of RAM
- 500 MB free on the hard drive
- Double-speed CD-ROM drive
- Windows 2000, Windows NT, Windows 98, or Windows Me-supported graphics card, capable of supporting 1024 x 768 High Color (16-bit) and a 17-inch monitor compatible with this type of graphics card
- Microsoft Mouse or a mouse compatible with Windows 2000, Windows NT 4.0, Windows 98, or Windows Me

3.2.4 Surfacer 7.0

Surfacer 7.0 (Imageware, Inc., Michigan, USA) is a software for processing, interpreting and analyzing 3D data. The functionalities of Surfacer 7.0 can be divided into three main categories: point processing, curve and surface generation, and entity analysis.

The point processing tools allow the imported data to be performed in a wide variety of operations, including filtering, segmentation, feature extraction, editing, sorting, and scaling.

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The curve and surface generation tools provide a number of different utilities for generating high-quality geometric models directly from various kinds of data sources.

The entity analysis tools provide a complete suite of tools for verifying the quality of surfaces and curves, and for performing a number of operations on point data.

The point processing tools were mainly employed in the development process of FE model in the current project.

3.3 PROCEDURE OF FE MODELING

The reliability of a human spine FE model to simulate various physiological and clinical biomechanical behaviors depends on how accurately anatomical geometry, material properties, boundary and loading conditions are represented. In order to develop a more realistic intact and instrumented C5-C6 FE model, the whole process was divided into the following 5 stages: geometrical data digitization, raw data processing, solid model generation, FE model development and FE model validation.

3.3.1 Geometrical Data Digitization

The 3D geometrical data of C5 and C6 were digitized by FaroArm 2.30 as shown in Figure 18. A rod mounted in a vice was used to secure each vertebra in an upright position, exposing the entire surface of the vertebrae. Any looseness in the fixture had to be prevented to reduce inaccuracies in measurement. The ball probe was connected to the FaroArm 2.30 for surface

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geometric data collection. Calibration and setting of the reference point were conducted prior to the actual digitization. The geometrical coordinates of the outer surface of the whole vertebra were captured at 0.1 mm intervals by moving the ball probe over the various aspects of the vertebra.

Figure 18 Setup for Geometrical Digitization

3.3.2 Raw Data Processing

The coordinate data obtained were then stored in the host computer. Surfacar 7.0 was used to process the vertebral cloud image. Sequential cross section outlines of the vertebra at 1-3 mm intervals were obtained, depending on the complexity of the geometry of the vertebral component. Very irregular structures, like superior and inferior articular facets, were cut into more sections for more accurate geometry capture. The coordinates of the sectional views were saved in universal graphics format (IGES) and exported into a

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commercially available FE modeling software (ANSYS 6.0) for further processing.

3.3.3 Solid Model Generation

3.3.3.1 C5 and C6 Vertebrae

The solid models of the individual C5 and C6 were developed following the procedure provided by ANSYS 6.0. The bottom-up approach was adopted in building the solid model. In ANSYS 6.0, solid model development involves two stages: surface creation and solid definition. The 3D coordinate points imported from FaroArm 7.0 were used as keypoints, the “lowest-order” solid model entities. From these keypoints, a closed curve was generated and further divided into 4 sides to form an enclosed area. With 2 neighboring cross section areas, “skinning” the cross-section through guiding lines generated the side areas of a volume. Volumes bounded by continuous areas were then generated to form the complete solid model of each vertebra as shown in Figure 19. The volumes of C5 and C6 vertebra were built likewise.

3.3.3.2 C5-C6 Segment

The solid models of C5 and C6 were stacked up into a C5-C6 intact segment, according to the normal anatomical alignment. The intervertebral space was reserved for the generation of the disc. The intervertebral disc as shown in Figure 20 was modeled in three layers. The upper and lower layers were the endplates of the vertebral bodies, which were assumed to be 1.0 mm thick to cover the entire contact surface area of the intervertebral disc. An encasing

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middle layer of the intervertebral disc consisted of annulus and nucleus. The anterior height of intervertebral disc was set to 5.4 ± 1.0 mm and posterior height to 3.0 ± 0.9 mm (Gilad & Nissan 1986). After the intervertebral disc had been built, the entire C5-C6 segment solid model was completed as shown in Figure 21.

Figure 19 Solid Model of C6 Vertebra

**Figure 20 Solid Model of Intervertebral Disc
(With Superior Endplate Removed)**

Figure 21 Solid Model of Intact C5-C6 Segment

3.3.4 FE Model Development

In FE modeling, the continuum of a structure is discretized into a finite number of elements that interact at their points of attachment referred to as nodes. Various elements with different geometric forms, e.g., brick, bar, shells, are available to achieve this, rendering it possible to model the complex spine geometry (Gilbertson *et al.* 1995). The outline of the FE modeling procedure is shown in Figure 22.

Figure 22 Outline of C5-C6 FE Modeling

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3.3.4.1 Selecting Element Attributes

Eight-noded isoparametric solid elements, instead of four-noded tetrahedron solid elements, were chosen to model the C5-C6 segment. This element type yields better element behavior in the analysis because the interpolation function of the eight-noded solid elements is an order higher than that of the tetrahedron solid elements (Kleinberger 1993). 3D surface-to-surface contact elements were used to model facet joints, in which friction was assumed to be zero (Natarajan *et al.* 2000; Teo & Ng 2001). The anterior longitudinal ligaments, posterior longitudinal ligaments, ligamentum flavum, capsular ligament, interspinous ligament, and ligamentum nuchae were simulated by 3D tension-only cable elements as shown in Figure 23. The orientation, location and attachment of

Figure 23 Ligaments of FE Model

ligaments were established from detailed descriptions in relevant anatomical literature (Williams *et al.* 1989; Reckling *et al.* 1990; Oliver & Alison 1991).

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Table 2 shows the number and type of the elements used in the intact FE model of C5-C6.

Table 2 Element Type and Number Used in Current Model

Component	Element Type	Number
Cortical Wall		528
Cancellous Core		1152
Endplate	8-noded Brick	560
Posterior Element		2592
Annulus		108
Nucleus		240
Anterior Longitudinal Ligament		55
Posterior Longitudinal Ligament		55
Ligamentum Flavum	3D Cable	6
Capsular Ligament		12
Interspinous Ligament		3
Ligamentum Nuchae		1
Facet Joint	3D Surface to Surface Contact	42
Luschka's Joint		48

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3.3.4.2 Defining Material Properties

The definition of material properties of the individual component is an important feature in FE modeling, for material properties are the key factors determining the performance of the model.

The material properties of the individual spinal component are widely scattered in their values as reported among previous studies in the literature, as shown in Table 3. The wide variation in the material properties used in the previous finite element model is generally due to the inherent biological variability in specimens. Therefore, the most appropriate value for the material properties have to be selected to enable the current model to mimic the gross behavior of the *in vitro* experimental specimens. The following approach was adopted for the material property assignment for the current FE model. A series of parametric analyses on the sensitivity of the outcome to the material properties was conducted under the same loading conditions of flexion, extension, lateral bending and axial rotation as in the *in vitro* experiment (Panjabi *et al.* 2001). Material properties of each component were varied within the range of values reported in the literature until an optimum match of the FE model output and the experimental results under all the loading cases was found. Numerous iterative analyses were performed to obtain the specific set of material properties, as shown in Table 4, which yielded the optimum match to the *in vitro* experimental output done by Panjabi *et al.* (2001).

The material properties of the spinal components were assumed to be homogenous and isotropic with linear elasticity. These assumptions are based

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Table 3 Variation of Material Properties in Previous FE Models

Description	Young' Modulus (MPa)/Poisson's Ratio				
	Yoganandan <i>et al.</i> 1996b	Maurel <i>et al.</i> 1997	Goel & Clausen 1998	Lee <i>et al.</i> 2000	Teo & Ng 2001
Cortical Wall	10000/0.29	12000/0.3	10000/0.3	10000/0.25	10000/0.29
Cancellous Core	100/0.29	100/0.2	450/0.25	100/0.25	100/0.29
Posterior Element	3500/0.29	6000/0.3	3500/0.25	—	3500/0.29
Endplate	500/0.40	300/0.3	2000/0.20	10000/0.25	500/0.4
Annulus	3.4/0.40	2.5/0.45	4.2/0.45	0.8/0.35	3.4/0.40
Nucleus	3.4/0.49	—	—	0.5/0.35	1/0.499
ALL	—	10	15-30	—	54.5
PLL	—	20	10-20	—	20
LF	—	50	5-10	—	1.5
CL	—	20	7-30	—	20
IL	—	3	4-8	—	1.5
LN	—	3	4-8	—	1.5

Note: All--Anterior Longitudinal Ligament; PLL--Posterior Longitudinal Ligament; LF--Ligamentum Flavum; CL--Capsular Ligament; IL--Interspinous Ligament; LN--Ligamentum Nuchae

on the following considerations: the vertebral body has a stiffness many orders of magnitude higher than the intervertebral disc and thus has only a minor influence on the deformation of the motion segments; and the load applied in the current study is in a low magnitude within the physiological range in which failure is not expected to occur. Still, some of the underlying limitations have to be recognized due to these assumptions. Although the vertebral cancellous core

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and cortical shell were treated as distinct regions, the assumptions of homogeneity meant that these regions were not broken down to further into their component parts, e.g., the cancellous core could not be treated a composite of trabecular bone and bone marrow, nor was the cortical shell built up from individual Haversian system. The modeling of the annulus fibrous as a continuum did not recognize the network of fiber layers and the ground substance present in the tissue. Therefore, it should be noted that the current C5-C6 FE model was developed on the basis of a macroscopic scale.

Assigning Anatomical Geometry

Anatomical dimension, surface geometry as well as surrounding soft tissue structure define the motion of the spine and its related biomechanical response. It is therefore important to incorporate, as accurately as possible, the actual geometry of the human cervical spine to obtain results applicable to clinical application (Yoganandan *et al.* 1996a). In the current model, the anatomical geometries, such as the thickness of the cortical wall and the dimensions of the annulus, were adopted according to the detailed quantitative anatomical studies as shown in Table 5.

3.3.4.3 Setting Meshing Control

Two kinds of meshing modes are available in ANSYS 6.0: mapped mesh and free mesh. Mapped mesh means that the mesh density in a model is defined with brick elements for 3D model and rectangular elements for 2D models. It allows for the automatic creation of finite elements, which conform exactly to the

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shape of the defined volume. In free mesh, an internal algorithm of the program determines the size of the element.

Table 4 Material Properties Used in Current Model

Component	Young's modulus (MPa)	Poisson's Ratio	Initial Slackness (%)	Cross-section (mm ²)	Reference
Cortical Wall	10000	0.29	–	–	(Yoganandan <i>et al.</i> 1996b)
Cancellous Core	450	0.25	–	–	(Goel & Clausen 1998)
Posterior Element	3500	0.29	–	–	(Yoganandan <i>et al.</i> 1996b)
Endplate	10000	0.25	–	–	(Lee <i>et al.</i> 2000)
Annulus	4.2	0.45	–	–	(Goel & Clausen 1998)
Nucleus	3.4	0.49	–	–	(Yoganandan <i>et al.</i> 1996b)
ALL	10	–	10	0.5	(Maurel <i>et al.</i> 1997; Teo & Ng 2001)
PLL	20	–	10	0.5	
LF	1.5	–	0	0.3	
CL	20	–	10	0.2	
IL	1.5	–	17	1	
LN	1.5	–	17	1	

Note: All--Anterior Longitudinal Ligament; PLL--Posterior Longitudinal Ligament; LF--Ligamentum Flavum; CL--Capsular Ligament; IL--Interspinous Ligament; LN--Ligamentum Nuchae

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Table 5 Anatomical Geometry Adopted in Current Model

Structure		Dimension (mm)	Reference
Cortical Wall Thickness		1	(Yoganandan <i>et al.</i> 1996b)
Endplate Thickness		1	(Roberts <i>et al.</i> 1989)
Disc	Anterior Height	5.4	(Gilad & Nissan 1986)
	Posterior Height	3.0	
Annulus Anterior Thickness		3	(Mercer & Bogduk 1999)
Annulus Posterior Thickness		1	
Luschka's Joint	Length	8.5	(Yoganandan <i>et al.</i> 2001)
	Width	3.6	
	Height	3.0	

Mapped mesh was adopted for building the intact C5-C6 FE model, because an eight-noded block was to be used and the mesh density could be controlled according to the complexity of the vertebral geometry.

A mesh convergency study was conducted to determine the suitable mesh density for the FE model by considering the maximum von Mises stress on the C6 superior endplate, since the C6 superior endplate is the interest of area in the subsequent analyses. A uniform axial compressive displacement of 0.1 mm was applied on the superior-most nodes of C5. The inferior-most nodes of C6 were

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fully constrained. The maximum von Mises stresses on the C6 superior endplate were extracted and compared. The element number of the C5-C6 intact model was increased from 4476 in Model 1 to 5402 in Model 2 and finally to 6162 in Model 3. The results of the convergency test and the percentage difference between the predicted values were summarized in Table 6 and Table 7 respectively.

Table 6 Effect of Mesh Density on Predicted Results

Model	Element number	Maximum von Mises Stress (MPa)
1	4476	1.165
2	5402	1.126
3	6162	1.094

Table 7 Percentage Difference between Predicted Values

Model	% Difference*
1 and 2	3.34%
2 and 3	2.84%
1 and 3	6.10%

* % difference= (the larger value-the smaller value)÷the larger value×100%

It can be concluded from the convergency test that all the three models can effectively predict the maximum von Mises stress under axial static compression loading; Model 2 can predict the maximum von Mises with a value very close to that of Model 3. The choice of an appropriate mesh density is based on the compromise between the predictive accuracy and computational

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expense. Therefore, the Model 2 with 5402 elements was selected for the subsequent analysis

3.3.5 FE Model Validation

Validation studies are an indispensable link between the development of the FE model and its final intended application. The purpose of validation study is to ensure that the FE model behaves like the real structure under conditions of intended external force application. It is recommended that validation should be conducted under as many loading modes as possible (Yoganandan *et al.* 1996a).

The developed intact C5-C6 FE model was exercised under the boundary conditions according to those in the *in vitro* experiment (Panjabi *et al.* 2001) for validation in range of motion in flexion, extension, lateral bending and axial rotation. The internal load transfer in the cancellous core under axial compression was also analyzed and compared with the results of the *in vitro* experiment in the literature (White & Panjabi 1990).

A 1.00 Nm pure moment was applied uniformly on the top surface of C5 one in a time in flexion, extension, right lateral bending and left axial rotation as shown in Figure 24. The inferior surface of C6 was fully constrained. The predicted angular displacement of C5 with respect to C6 in response to the various loading modalities was calculated as the following:

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Figure 24 Moment Rotations for Intact FE Model

Basic method for ROM calculation for normal C5-C6 segment

The moveable vertebra was assumed to be rigid and non-deformable, since the stiffness of the moveable vertebra was many orders of magnitude larger than that of the intervertebral disc of the C5-C6 segment. To calculate the ROM of C5 with respect to C6, the coordinates of two nodes on the superior surface of C5 along the plane of the applied moment before and after loading were selected and calculated for the ROM in each corresponding plane of applied moment vector.

Figure 25 shows the schematic calculation of ROM under flexion in the sagittal (YZ) plane. Points A_0 and B_0 are the two nodes selected on C5 top surface while

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points A_1 and B_1 are the positions of A_0 and B_0 after flexion. ROM under flexion was calculated as following:

$$ROM_{fl} = \alpha_1 - \alpha_0$$

where α_0 is the angle between the projection of line segment A_0B_0 on the sagittal (YZ) plane and Z-axis

α_1 is the angle between the projection of line segment A_1B_1 on the sagittal (YZ) plane and Z-axis

The calculations of ROM for extension, right lateral bending and left axial rotation follow the same procedure.

Figure 25 Calculation of ROM under Flexion in Sagittal Plane

(A and B are the two nodes selected on C5 top surface, A1 and B1 show the positions of A and B after flexion respectively)

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Calculation of ROM under pure flexion and extension moment of 1.00 Nm

Two nodes $A_0 (X_{a0}, Y_{a0}, Z_{a0})$ and $B_0 (X_{b0}, Y_{b0}, Z_{b0})$ were chosen on the superior surface of C5. After pure flexion or extension moment of 1.00 Nm was applied, the new positions of the two selected nodes became $A_1 (X_{a1}, Y_{a1}, Z_{a1})$ and $B_1 (X_{b1}, Y_{b1}, Z_{b1})$ under flexion, $A_2 (X_{a2}, Y_{a2}, Z_{a2})$ and $B_2 (X_{b2}, Y_{b2}, Z_{b2})$ under extension. The primary motion of the C5-C6 segment is in the sagittal plane (YZ plane) under pure flexion or extension moment. Therefore, only coordinates of Y and Z were used for the calculation of ROM under flexion and extension.

The coordinates of Y and Z for nodes A and B before rotation were:

$$A_0: Y_{a0} = 15.7882 \text{ mm}, Z_{a0} = 0.1627 \text{ mm}$$

$$B_0: Y_{b0} = 16.7478 \text{ mm}, Z_{b0} = 17.3318 \text{ mm}$$

A_0 and B_0 moved to A_1 and B_1 after flexion, and to A_2 and B_2 after extension.

The coordinates of Y and Z for A_1 and B_1 , A_2 and B_2 were as follows:

After flexion:

$$A_1: Y_{a1} = 16.2636 \text{ mm}, Z_{a1} = 0.8132 \text{ mm}$$

$$B_1: Y_{b1} = 16.2226 \text{ mm}, Z_{b1} = 18.0384 \text{ mm}$$

After extension:

$$A_2: Y_{a2} = 15.1732 \text{ mm}, Z_{a2} = -0.8778 \text{ mm}$$

$$B_2: Y_{b2} = 17.3739 \text{ mm}, Z_{b2} = 16.2221 \text{ mm}$$

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The ROM after flexion was calculated in the following manner:

The angle α_0 between the projection of line segment A_0B_0 on the sagittal (YZ) plane and Z axis is:

$$\begin{aligned}\alpha_0 &= \arctan(Y_{b0} - Y_{a0}) / (Z_{b0} - Z_{a0}) \\ &= \arctan(0.0558) \\ &= 3.1994^\circ\end{aligned}$$

The angle α_1 between the projection of line segment A_1B_1 on the sagittal (YZ) plane and Z axis is:

$$\begin{aligned}\alpha_1 &= \arctan(Y_{b1} - Y_{a1}) / (Z_{b1} - Z_{a1}) \\ &= \arctan(-0.0024) \\ &= -0.1363^\circ\end{aligned}$$

The ROM under flexion is

$$ROM_{fl} = \alpha_1 - \alpha_0 = -0.1363^\circ - 3.1994^\circ = -3.3357^\circ$$

The ROM after extension was calculated in the following manner:

The angle α_0 between the projection of line segment A_0B_0 on the sagittal (YZ) plane and Z axis is:

$$\begin{aligned}\alpha_0 &= \arctan(Y_{b0} - Y_{a0}) / (Z_{b0} - Z_{a0}) \\ &= \arctan(0.0558)\end{aligned}$$

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$$= 3.1994^\circ$$

The angle α_2 between the projection of line segment A_2B_2 on the sagittal (YZ) plane and Z axis is:

$$\alpha_2 = \arctan (Y_{b2} - Y_{a2}) / (Z_{b2} - Z_{a2})$$

$$= \arctan (0.1280)$$

$$= 7.3340^\circ$$

The ROM under extension is:

$$ROM_{ex} = \alpha_2 - \alpha_0 = 7.3340^\circ - 3.1994^\circ = 4.1346^\circ$$

Calculation of ROM under pure lateral bending moment of 1.00 Nm

Two nodes $C_0 (X_{c0}, Y_{c0}, Z_{c0})$ and $D_0 (X_{d0}, Y_{d0}, Z_{d0})$ were chosen on the superior surface of C5. After pure right lateral bending moment of 1.00 Nm was applied, the new positions of the two selected nodes became $C_1 (X_{c1}, Y_{c1}, Z_{c1})$ and $D_1 (X_{d1}, Y_{d1}, Z_{d1})$. The primary motion of the C5-C6 segment is in the frontal (XY) plane under pure lateral bending moment. Therefore, only coordinates of X and Y were used for the calculation of ROM under lateral bending.

The coordinates of X and Y for nodes C_0 and D_0 before right lateral bending were:

$$C_0: X_{c0} = 9.5867 \text{ mm}, Y_{c0} = 17.4529 \text{ mm}$$

$$D_0: X_{d0} = -9.6830 \text{ mm}, Y_{d0} = 17.3900 \text{ mm}$$

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C_0 and D_0 moved to C_1 and D_1 after right lateral bending, the coordinates of X and Y for C_1 and D_1 were as follows:

$$C_1: X_{c1} = 8.9092 \text{ mm}, \quad Y_{c1} = 18.0315 \text{ mm},$$

$$D_1: X_{d1} = -10.3519 \text{ mm}, \quad Y_{d1} = 16.7162 \text{ mm},$$

The ROM after right lateral bending was calculated in the following manner:

The angle β_0 between the projection of line segment C_0D_0 on the frontal (XY) plane and X axis is:

$$\beta_0 = \arctan (Y_{d0} - Y_{c0}) / (X_{d0} - X_{c0})$$

$$= \arctan (0.0033)$$

$$= 0.1869^\circ$$

The angle β_1 between the projection of line segment C_1D_1 on the frontal (XY) plane and X axis is:

$$\beta_1 = \arctan (Y_{d1} - Y_{c1}) / (X_{d1} - X_{c1})$$

$$= \arctan (0.0682)$$

$$= 3.9070^\circ$$

The ROM under right lateral bending is:

$$ROM_{rl} = \beta_1 - \beta_0 = 3.9070^\circ - 0.1869^\circ = 3.7201^\circ$$

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Since the right and left lateral bending of spine is assumed to be symmetrical about the sagittal plane, therefore, the total ROM for left and right lateral being is

$$\text{ROM}_{\text{lb}} = \text{ROM}_{\text{rl}} \times 2 = 3.7201^{\circ} \times 2 = 7.4402$$

Calculation of ROM under pure axial rotation moment of 1.00 Nm

Two nodes $E_0 (X_{e0}, Y_{e0}, Z_{e0})$ and $F_0 (X_{f0}, Y_{f0}, Z_{f0})$ were chosen on the superior surface of C5. After pure left axial rotation moment of 1.00 Nm was applied, the new positions of the two selected nodes became $E_1 (X_{e1}, Y_{e1}, Z_{e1})$ and $F_1 (X_{f1}, Y_{f1}, Z_{f1})$. The primary motion of the C5-C6 segment is in the transverse (ZX) plane under pure axial rotation moment. Therefore, only coordinates of Z and X were used for the calculation of ROM under axial rotation.

The coordinates of Z and X for nodes E_0 and F_0 before left axial rotation were:

$$E_0: Z_{e0} = 0.1627 \text{ mm}; X_{e0} = 0.0482 \text{ mm}$$

$$F_0: Z_{f0} = 17.3318 \text{ mm}; X_{f0} = -0.2108 \text{ mm}$$

E_0 and F_0 moved to E_1 and F_1 after left axial rotation, the coordinates of Z and X for E_1 and F_1 were as follows:

$$E_1: Z_{e1} = -0.1619 \text{ mm}; X_{e1} = -0.1892 \text{ mm}$$

$$F_1: Z_{f1} = 16.9897 \text{ mm}; X_{f1} = 0.1502 \text{ mm}$$

The ROM after left axial rotation was calculated in the following manner:

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The angle θ_0 between the projection of line segment E_0F_0 on the transverse (ZX) plane and Z axis is:

$$\begin{aligned}\theta_0 &= \arctan (X_{f0} - X_{e0}) / (Z_{f0} - Z_{e0}) \\ &= \arctan (-0.0151) \\ &= -0.8643^\circ\end{aligned}$$

The angle θ_1 between the projection of line segment E_1F_1 on the transverse (ZX) plane and Z axis is:

$$\begin{aligned}\theta_1 &= \arctan (X_{f1} - X_{e1}) / (Z_{f1} - Z_{e1}) \\ &= \arctan (0.0198) \\ &= 1.1369^\circ\end{aligned}$$

The ROM under left axial rotation is:

$$ROM_{la} = \theta_1 - \theta_0 = 1.1369^\circ - (-0.8643^\circ) = 2.0012^\circ$$

Since the right and left axial rotation of spine is assumed to be symmetrical about the sagittal plane, therefore, the total ROM for left and right axial rotation is

$$ROM_{al} = ROM_{la} \times 2 = 2.0012^\circ \times 2 = 4.0024^\circ$$

In summary, the ROMs of the intact FE model in response to 1.00 Nm pure moment under different loading modalities are as follows: 3.34° for flexion; 4.13° for extension; 7.44° for lateral bending; 4.00° for axial rotation.

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For axial compression, a uniform axial compressive load of 110 N, simulating the physiological load (Lim *et al.* 2001), was applied on the superior-most nodes of C5. The inferior-most nodes of C6 were fully constrained as shown in Figure 26. The load distribution between the cortical shell and cancellous core was extracted for validation purpose.

Figure 26 Boundary and Loading Conditions for Axial Compression

The analyses were carried out on SGI Origin 3400 Servers (32 CPUs, MIPS 64 Bit R12000 400MHz/8MB RISC, 44.8 GB/sec System bandwidth, 2 x 18 GB System Disks, IRIX Operating System, On board memory 32GB, TP 9100 Storage, Silicon Graphics Inc.) using a general FE code, ANSYS 6.0 at the Centre for Advanced Numerical Engineering Simulations (CANES), School of Mechanical and Aerospace Engineering, Nanyang Technological University, Singapore.

3.4 RESULTS AND DISCUSSION

3.4.1 Model Development

An anatomically realistic 3D C5-C6 FE model was finally developed consisting of 5402 elements and 7928 nodes as shown in Figure 27. All the important structures of the cervical segment, including anterior longitudinal ligaments, posterior longitudinal ligaments, ligamentum flavum, capsular ligament, interspinous ligament, and ligamentum nuchae, annulus fibrosus, nucleus pulposus and Luschka's joint, were incorporated in the developed FE model.

Figure 27 Exploded View of Intact C5-C6 FE Model

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There have been a number of lower cervical spine FE models existing in the previous literature (Yoganandan *et al.* 1996b; Maurel *et al.* 1997; Goel & Clausen 1998; Heitplatz *et al.* 1998; Natarajan *et al.* 2000; Teo & Ng 2001). All the cervical models simulated the cervical disc annulus as a ring of fibers. However, a recent study (Mercer & Bogduk 1999) using micro-dissection method on the morphology of lower cervical intervertebral disc showed that the 3D architecture of the cervical annulus fibrosus is more like a crescentic anterior interosseous ligament rather than a ring of fibers surrounding the nucleus pulposus. The current FE model incorporated the new finding of the intervertebral disc structure, the most important component being the biomechanical features of the spinal segment (White & Panjabi 1990). Thus, the simulation of the intervertebral disc was closer to the real structure and a more realistic prediction of the segment biomechanical behavior could be expected.

3.4.2 Model Validation

The angular displacements of the intact FE model in response to 1.00 Nm moment under different loading modalities are as follows: 3.34° for flexion; 4.13 ° for extension; 7.44 ° for lateral bending; 4.00 ° for axial rotation. The results were compared for validation with the experiment done by Panjabi (Panjabi *et al.* 2001) as shown in Figure 28.

For the intact C5-C6 FE model, the cancellous core contributed 36.3% of the strength of the whole C6 vertebra, and the other 63.7% went down through the cortical shell of the vertebral body. Figure 29 shows the FE prediction of load

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transfer in cancellous core of C6 under axial compression and its comparison with the *in vitro* experimental results done by Rockoff *et al.* (1969).

Figure 28 Comparison of FE Prediction and Experimental Results

The purpose of the *in vitro* experiment done by Rockoff *et al.* (1969) was to determine the relative contribution of the cortical shell and of the central trabecular bone to the peak, non-destructive compressive strength of the excised human lumbar vertebrae. Fifty lumbar vertebra “units” were harvested from 32 fresh cadavers. A vertebral unit consisted of the endplate and a minimal amount of the neighboring bone from the vertebrae above and below the vertebra being studied, plus the intervening intervertebral discs. The configuration was chosen in order to utilize the subjects own disc to distribute the compressive forces to the vertebrae.

The units were generally tested within 24 hours after cutting and thawing. Compression testing of the units was conducted using an Istron testing machine

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(type TT-C-L). A uniform crosshead speed of 0.02 in/min was used. Each intact unit was placed in the vertical position on a steel platform on the calibrated load-recording cell. All compressive tests were performed three times on each specimen on each occasion, with all calculations being taken from the third trial. Compressive loading of each unit was steadily and slowly applied until the first appearance of departure from the linearity of the steepest slope. This point was regarded as the non-destructive peak load borne by the unit. The absence of destructive alterations in the unit during testing was proved by the fact that there was no decrease in the peak strength by the repeated loading. As soon as the first sign of failure of linearity of the steepest slope, the cross head direction was immediately reversed and the specimen was unloaded with the same speed as for loading.

After the intact unit was tested, one of the two secondary configurations was applied for study from each of the units. One configuration was to remove the cortex of the central vertebra of the unit by a high speed circular hand saw with fine teeth. The other one was to make a central horizontal cut through the trabecular bone by means of a narrow probe into the posterior vascular foramen of the central vertebra. The cortex remained totally in the latter preparation. The purpose of determining the loss of the strength due to removal of the cortex was to provide a measure of the importance of the cortex to the strength of the unit. Also, the strength of the unit without the cortex was a measure of the absolute strength of the trabecular bone alone. The loss of strength of the unit with a central trabecular removal measured the importance of the central core to the

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vertical force transmission. The result showed that average contribution of the trabecular core for the normal adult is 25-55%, averaging 35%.

Figure 29 Load Transfer in C6 Cancellous Core

Biomechanical analyses of the complicated structures like cervical spine require several assumptions and simplifications which might have a strong influence on the results. Even though all the material properties of the involved tissues are in the physiological range, there is no guarantee for the normal behavior of the whole model. In order to achieve a normal behavior of the globe structure, modification of certain material properties within their physiological range is sometime necessary. Validation of the developed C5-C5 FE model was therefore mandatory.

The validation tests were conducted for the verification of the C5-C6 FE against experimental results. The gross external response of the FE model to the pure moments replicating the loading and boundary conditions used in the published experimental studies were extracted first. Then, the internal load transfer within the lower vertebra (C6) under the physiological load was analyzed.

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The angular displacements of the intact FE model in flexion, extension, lateral bending and axial rotation under 1.00 Nm is in agreement with the mean experimental data. This is a general criterion for an FE model of a spine segment to be accepted as being in agreement with that of the real spine, which means that the developed FE model's gross mechanical response to a defined external load would be similar to that of the real spine under the similar situation (Yoganandan *et al.* 1996a; Yoganandan *et al.* 1996b; Goel & Clausen 1998; Panjabi 1998; Teo & Ng 2001).

It may be noticed that the difference between the predicted angular displacements and mean experimental values under different loading configurations does exist. This is because the FE model is not built from the same dimensions as the specimens used in the *in vitro* experiments. It is a procedure of approximate simulation of a living structure rather than an exact duplication of a concrete spine segment. The material properties used in the model are adopted from the literature, and represent the average normal structures. In this view, the disparity of the current FE model with the actual experimental results would be acceptable.

The results of the FE model under axial compression of 110 N showed a 36.6% of compressive load shared by cancellous bone, which is coherent with the result of a 25-55% concluded from the *in vitro* experimental result (White & Panjabi 1990). In most physiological situations, the compressive load is transmitted from the superior endplate of a vertebra to the inferior endplate by way of two paths, the cortical shell and cancellous core (White & Panjabi 1990).

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The close agreement with the experimental results in load transfer is a further validation of internal biomechanical behavior of the current model.

Moreover, this is the only lower cervical spine FE model that underwent validation not only in gross response under three different loading modalities, but also in the internal reaction under axial compressive load. With the validation showing adequate comparability between the predicted and *in vitro* experimental results, the current intact C5-C6 FE model could be used with more confidence for further application in both fundamental and clinical scenarios.

3.5 SUMMARY

The objective of this section was to develop and validate a three-dimensional FE model of the lower cervical spine (C5-C6) for further biomechanical analysis by direct spatial digitization. The embalmed human C5-C6 cervical vertebrae were used for FE model generation. A 3-D coordinates capturing system was adopted for obtaining the detailed spatial features of the cervical specimens. After the stages of raw data processing and solid model generating, the anatomical realistic FE model of C5-C6 was developed. All the important structures of a cervical spine segment were represented in the C5-C6 intact FE model and the new features of the anatomical finding of cervical intervertebral disc was also incorporated. The FE model was then validated with *in vitro* experiments in external kinematic response to pure moments and internal load transfer to axial compressive load. Both the overall kinematic response and

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intrinsic load distribution showed a good accordance with the *in vitro* experimental results.

After the completeness of the initial validation of the C5-C6 FE model, the model can be treated with confidence as an analytical tool with repeatability and reproducibility characteristics that is ideal for future biomechanical studies.

CHAPTER 4 OPTIMIZATION OF CERVICAL RING CAGE USING TAGUCHI PHILOSOPHY

4.1 INTRODUCTION

As described in Chapter 1, interbody cages have been widely used in the treatment of cervical spondylosis in recent years (Brooke *et al.* 1997; Zdeblick *et al.* 1998; Hacker *et al.* 2000; Hacker 2002; Vavruch *et al.* 2002; Zdeblick & Phillips 2003; Cho *et al.* 2004; Hwang *et al.* 2004; Ryu *et al.* 2006). Among the current cage designs, the cervical ring-shape cage has shown biomechanical advantages over the other types: minimal destruction of the endplate integrity is needed for the cervical ring cage implantation and better distraction on segments can be achieved; the available volume for the bone graft provided by the vertical ring cage is usually larger; the cervical ring cage is featured with an inverse shape of the endplate concave contour for an ideal surface fit (Weiner & Fraser 1998; Steffen *et al.* 2000b; Kandziora *et al.* 2001; Kandziora *et al.* 2002).

However, subsidence into the vertebral body after insertion is also a major complication for a cervical ring cage, which can lead to kyphotic deformity, pseudoarthrosis and recurrence of symptoms (Grant *et al.* 2001). The subsidence may result from osteoporosis, excessive removal of the endplate or vigorous postoperative activity. Although all these factors should be carefully considered to prevent such side effects, the design of the cage is of critical importance in preventing subsidence while achieving fusion. Cage implantation affects the stress distribution on the supporting endplate and ultimately influences the stability at the cage-endplate interface.

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Therefore, the purpose of this section was to determine an optimal design of the cervical ring cage to produce the lowest stress on the endplate under different fusion environments and to decrease the risk of subsidence. The Taguchi philosophy was adopted as the method of optimization through a series of analyses of cervical cage implanted FE models.

4.2 TAGUCHI PHILOSOPHY

4.2.1 Basic Concept

The Taguchi Philosophy was first introduced by Dr. Genichi Taguchi to improve the product design and quality control in late 1940s. There are three stages being considered in a product development: system design, parameter design and tolerance design (Roy 1990; Taguchi 1993; Taguchi *et al.* 2000).

The focus of the system design is to use scientific and engineering principles and experience to create a prototype of the product that will meet the functional requirement and also to formulate process that will build it. System design helps to identify the working levels of the design factors, while parameter design seeks to determine the factor levels that produce the best performance of the product or process under study. The optimum condition is selected so that the influence of the uncontrollable factors causes minimum variation of system performance. The tolerance design is a step to fine-tune the results of parameter design by tightening the tolerance of factors with significant influence on the product.

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Taguchi methodology emphasizes the importance of the parameter design stage in the whole design process - a stage that is often neglected in industrial design practice. The methodology involves identification of controllable and uncontrollable parameters and the establishment of a series of experiments to find out the optimum combination of the parameters which has the greatest influence on the performance and least variation from the target of the design.

4.2.2 Loss Function

The loss function is employed in Taguchi philosophy to define the quality of a product. The loss function maintains that there is an increasing loss which is a function of the deviation from the target value of any design parameter. The greater the deviation from target, the greater is the loss. Variability inevitably means a kind of waste. The conventional response has been to set not only a target level for performance but also a range of tolerance about that target which represents acceptable performance. Thus, if performance falls anywhere within the range, it is regarded as acceptable, while if it falls outside that range it is not acceptable.

Instead of applying the traditional function of acceptability, Taguchi methodology suggests that a more realistic function is used based on the square of the deviation from the ideal target.

This function, the quality loss function (Roy 1990), is given by the expression:

$$L(y) = k(y-T)^2$$

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$L(y)$ is the loss to society of a unit of output at measured value y ; T is the ideal state target value; k is the loss coefficient. The quality of loss function can also be illustrated in Figure 30, where LSL stands for lower specification limit and USL means upper specification limit. The function will penalize even a small deviation of y from the target T . It is different from the traditional view towards loss, which usually imposes penalties only to the situation where y is outside the lower and upper allowable limit.

Figure 30 Taguchi's Loss Function (Roy 1990)

In summary, Taguchi philosophy constitutes three main concepts:

- Products and processes should be designed so that they are robust to uncontrollable factors
- Experimental design methods are important tools to help accomplish this objective
- Operation on-target is more important than conformance to specification.

4.2.3 Advantages and Application

Although conventional design of experiment (DOE) utilizes fractional factorial experiments investigating a fraction of all the possible combinations in order to save considerable time and cost, DOE requires rigorous mathematical treatments and may have different designs for the same experiments, which in turn yield different results. The Taguchi method can avoid these drawbacks by simplifying and standardizing the fractional factorial design in such a manner that the design and results for the same experiments can be formatted (Roy 1990).

In the design of engineering products and processes, analytical simulation plays an important role in transforming a concept into the final product design. The Taguchi approach can be applied to arrive at the best parameters for the optimum design configuration with the least number of analytical investigations. Although there are several methods available for optimization using such analytical simulations when factors are continuous, frequently the Taguchi method can significantly reduce computing time by means of treating factors at discrete levels (Roy 1990; Taguchi 1993; Montgomery 1997; Taguchi *et al.* 2000).

4.3 METHODOLOGY

4.3.1 Generation of Caged Model

The Smith-Robinson approach for treatment of cervical spondylosis was first simulated in the C5-C6 intact FE model as shown in Figure 31. The detailed

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procedure was as follows: the elements for the anterior and posterior longitudinal ligaments were removed from the intact C5-C6 FE model; the elements for the disc from anterior edge to the posterior edge were deleted; the elements for the inferior endplate of the C5 vertebral body and the superior endplate of the C6 vertebral body were kept intact.

Figure 31 Discectomy of C5-C6 Segment

A generic cervical ring cage was incorporated centrally into the discectomised intervertebral space to mimic the cage implantation as shown in Figure 32 and Figure 33. The cage-endplate interface was modeled by surface-to-surface contact elements. There are two surfaces in the contact pair: contact surface and target surface. Since the cage surfaces had stiffer surface than the endplates, the cage surfaces were designated as the target surfaces while the endplates were designated as the contact surfaces according to the contact definition in Ansys

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6.0. The augmented Lagrangian method was specified as the contact algorithm. The real constant FTOLN for an allowable maximum penetration for the augmented Lagrangian method was set to 0.1. The normal penalty stiffness (FKN) was set to 1 to specify the amount of penetration between the two surfaces. The initial perfect contacting surface was assumed by setting KEYOPT (9) =1 and KEYOPT (12) = 4 to ignore the initial penetration from both surfaces and the initial forces acting across the contact interface.

Since most cages have small teeth or serrations on the contact surface that are supposed to prevent motion of the implant, the contact between the cage and the endplate was simulated to be an interface with a very high friction. The exact friction coefficient between the cage and endplate is not available. The reported friction coefficients for the implant and bone ranged from 0.3 to 0.8 in previous FE studies in the literature (Adam *et al.* 2003; Kim 2001; Villarraga *et al.* 1999, Polikeit *et al.* 2003a). Therefore, a higher friction coefficient of 0.8 (Polikiet *et al.* 2003a) was assigned for the cage-endplate contact in the current model.

Figure 32 Cervical Ring Cage on C6 Superior Endplate

Figure 33 C5-C6 FE Model with Cage inside

The dimensions of the cage were assigned according to different runs in the design of the experiment in the Taguchi method as shown in Table 8 and Table 9. In order to work efficiently, the creation of the cage with different dimensions was achieved by running a batch file, in which the cage dimension was parametrically set. Thus, the results would be generated by repeated FE simulation and analyses with different sets of levels of factors in the Taguchi layout.

With the inferior-most nodes of C6 being fully constrained, a uniform axial compressive force of 110 N was applied on the superior-most nodes of C5 as shown in Figure 34. The von Mises stress on the C6 superior endplate exerted by the cage was extracted to compare the effects of the different cage designs.

Figure 34 Boundary Condition and Load of Analysis

4.3.2 Design of Taguchi Strategy

4.3.2.1 Overview of the analysis

The whole analysis was conducted using the flowchart shown in Figure 35 in order to find the optimum design insensitive to the influence of the noise factors according to the Taguchi theory. The optimum design is Taguchi's robust conditions that control the yield close to the target value despite the uncontrollable factors during the production process. To incorporate noise factors into the design of the experiment, the factors and their levels were treated in a manner similar to the controllable factors. The conditions of the uncontrollable factors dictated the number of repetitions for the trial runs.

Signal to noise ratio (S/N) was used as a criterion for the optimal condition. Then, the analysis of variance (ANOVA) was done to estimate the percentage

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contribution of the individual factors and to determine the most robust set of conditions from variation within the results. Lastly a confirmation run was done on the optimum design identified in the analysis to verify that the best performance setting was chosen and that it closely matched the performance predicted by analysis.

Figure 35 Flowchart of Taguchi Method

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4.3.2.2 Strategy of Experiment Design

The objective of cervical ring cage optimization was to determine the best set of the parameters that ensure the cage to exert the lowest von Mises stresses on the vertebral endplate under physiological load compression subject to various in situ biological environments.

There were four major controllable parameters of the cage design being considered: cage materials, depth, width and wall thickness. Young's modulus of the cage materials were 1300 MPa, 6500 MPa, 115000 MPa to represent Polyetheretherketone (PEEK), carbon reinforced polymer, and titanium/vanadium alloy respectively; the Poisson's ratio was 0.2 for each of them (Adam *et al.* 2003). The levels of cage dimensions were extracted from a range of commercial cage designs. The relative dimensions of the ring cage are illustrated in Figure 36. These factors and their levels are shown in Table 8.

Figure 36 Sketch of Relative Dimensions of Ring Cage

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Table 8 Controllable Factors and Levels for Cage Optimization

Factors	Level 1	Level 2	Level 3
A: Cage Materials (MPa)	1,300	6,500	115,000
B: Width (mm)	12	15	18
C: Depth (mm)	12	14	16
D: Wall Thickness (mm)	2	3	4

Note: for cage materials, 1300 MPa, 6500 MPa, 115000 MPa represent Polyetheretherketone (PEEK), carbon reinforced polymer, and titanium/vanadium alloy respectively

It can be seen from Table 8 that there are four factors, each with 3 levels. Therefore, the L9 orthogonal array as shown in Table 9 was selected for the test according to Taguchi philosophy (Roy 1990; Taguchi 1993; Montgomery 1997; Taguchi *et al.* 2000).

In Taguchi method, Table 9 is defined as orthogonal array (OA) and designated as L9 which is derived from full factorial design of 3^4 (81 runs) by a series of very sophisticated mathematical algorithms including combinatorics, finite fields, geometry and error-correcting codes. The algorithms ensure that the OA to be constructed in a statistically independent manner that each level has an equal number of occurrences within each column, and for each level within one column, each level within any other column will occur an equal number of times as well. Then, the columns are orthogonal to each other.

Orthogonal arrays are available with a variety of levels, prepared by statisticians. Since each column is orthogonal to the others, if the results

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associated with one level of a specific factor are much different at another level, it is because changing that factor from one level to the next has a strong impact on the quality characteristic being measured. Since the levels of the other factors are occurring an equal number of times for each level of the strong factor, any effect by these other factors will be ruled out. Therefore, an estimation of the effect of any one particular factor will tend to be accurate and reproducible because the estimated effect does not include the influence of the other factors.

Table 9 L₉ Orthogonal Array

Run No.	Factor A	Factor B	Factor C	Factor D
1	1	1	1	1
2	1	2	2	2
3	1	3	3	3
4	2	1	2	3
5	2	2	3	1
6	2	3	1	2
7	3	1	3	2
8	3	2	1	3
9	3	3	2	1

The fundamental function of the cage insertion into the intervertebral disc is to provide axial support to facilitate the bone healing process. On the other hand, the cage behavior may not be the same when it is used in patients with a normal and osteoporotic spine. Therefore, the phases of bone healing within the intervertebral space and the status of the patient's vertebra were selected as the uncontrollable factors. Two levels of the healing bones were defined to

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represent the haematoma stage immediately after cage implantation and the cortical fusion bone stage 1 year after the implantation. Since there is no bone formation in haematoma stage, graft bone was assumed not to transfer axial load and was not modeled in the FE model. Young's Modulus of fusion bone was set to be 10,000 MPa for the cortical fusion bone stage.

For the patient vertebra status, there are also 2 levels to represent the normal and osteoporotic vertebrae. The material properties of normal and osteoporotic vertebrae were respectively 450 MPa and 150 MPa with the Poisson's ratio of 0.2 (Natarajan *et al.* 2000). Table 10 shows the uncontrollable factors and their levels. The combination of the two 2-level factors of Table 10, as shown in Table 11, determined the repetition of running for different settings of cage parameters.

Table 10 Uncontrollable Factors and Levels

Factors	Level 1	Level 2
E: Fusion Bone	Graft Bone	Cortical Bone
F: Vertebra Bone	Normal	Osteoporosis

Table 11 Number of Runs Determined by Uncontrollable Factors

Run No.	Factor E	Factor F
1	1	1
2	1	2
3	2	1
4	2	2

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According to the Taguchi methodology, there are two OAs in the complete parameter design layout. One OA containing the controllable factors is called the inner array; and the other containing the uncontrollable factors is called the outer array. Each run from the inner array is tested across each run from the outer array. Table 11 is the outer array in the current study while Table 9 is the inner array. They together form the complete parameter design layout.

Therefore, a crossed array parameter design layout is shown in Table 12. Executions of the analyses based on the 36 FE models were conducted and the von Mises stress on the C6 superior endplate of each model were extracted and compared to determine the optimal cage design.

4.4 RESULTS AND DISCUSSION

The results of all the runs according to Taguchi crossed array parameter design layout of Table 12 are presented in Table 13. The results are then analysed in terms of mean square deviation (MSD), signal to noise ratio (S/N), average performance and ANOVA. The purpose of these result analyses was to seek what the optimum condition was, which factors contributed to the results or by how much, and what the expected result at the optimum condition would be.

4.4.1 Signal to Noise Ratio

The concept of S/N ratio has been applied in the fields of acoustics, electrical and mechanical vibrations, and other engineering disciplines for many years. The change in the quality characteristics of a product under investigation, in response to a factor introduced in the experimental design is the “signal” of the

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Table 12 Taguchi Crossed Array Parameter Design Layout

					Run					
					Outer Array					
					E					
					F					
Inner Array										
Run	A	B	C	D					$\tilde{y}$	S/N_i
1	1	1	1	1	y_{11}	y_{12}	y_{13}	y_{14}	$\tilde{y}_1$	S/N_1
2	1	2	2	2	y_{21}	y_{22}	y_{23}	y_{24}	$\tilde{y}_2$	S/N_2
3	1	3	3	3	y_{31}	y_{32}	y_{33}	y_{34}	$\tilde{y}_3$	S/N_3
4	2	1	2	3	y_{41}	y_{42}	y_{43}	y_{44}	$\tilde{y}_4$	S/N_4
5	2	2	3	1	y_{51}	y_{52}	y_{53}	y_{54}	$\tilde{y}_5$	S/N_5
6	2	3	1	2	y_{61}	y_{62}	y_{63}	y_{64}	$\tilde{y}_6$	S/N_6
7	3	1	3	2	y_{71}	y_{72}	y_{73}	y_{74}	$\tilde{y}_7$	S/N_7
8	3	2	1	3	y_{81}	y_{82}	y_{83}	y_{84}	$\tilde{y}_8$	S/N_8
9	3	3	2	1	y_{91}	y_{92}	y_{93}	y_{94}	$\tilde{y}_9$	S/N_9

Note: Y_{ij} , where, $i=1, 2, 3, \dots, 9$ and $j=1, 2, 3, 4$, is the response of the i th run in the inner array and the corresponding j th run. $\tilde{y}_i$ is the mean response of Y_{ij} in the i th run in the inner array. S/N_i stands for signal to noise ratio.

desired effect. The “noise” is the external factors which are not designed into the experiment but do have their effect on the outcome of the quality characteristic under test. S/N ratio measures the sensitivity of the quality characteristic being investigated in a controlled manner, to those external influencing factors not under control (Roy 1990).

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The S/N ratio expresses the scatter around a target value. The larger the ratio, the smaller the scatter is. Taguchi's loss function can be expressed in terms of mean square deviation (MSD), and thus S/N ratio. The goal of the Taguchi method is to determine the highest possible S/N ratio for the result. A high value of S/N implies that the signal is much higher than the random effects of the noise factors. Product design or process operation consistent with highest S/N always yields the optimum quality with minimum variance (Roy 1990; Taguchi 1993; Taguchi *et al.* 2000).

From the quality point of view, there are three possible categories of the quality characteristics. They are: (1) Smaller is better; (2) Nominal is better; (3) Bigger is better (Montgomery 1997). In this cage design situation, the maximum stress on the endplate is the type of "Smaller is better". Hence, the S/N ratio is given by

$$S/N = -10\log_{10}(MSD) \quad (4.1)$$

where $MSD = \sum_{j=1}^4 (Y_{ij})^2 \quad (i = 1, 2, 3, \dots, 9) \quad (4.2)$

Therefore, the values of all MSDs and S/Ns are given in Table 13. S/N is conventionally expressed in a decibel scale in Taguchi method.

Table 13 Results of Taguchi Crossed Array Parameter Design

Outer Array		Run		1	2	3	4				
		Fusion	Hameto- ma	Hameto- ma	Cortical	Cortical					
			Vertebra	Normal	Osteop- orosis	Normal	Osteop- orosis				
Inner Array											
Run	Cage	Width (mm)	Depth (mm)	Wall (mm)	y_{11} (MPa)	y_{12} (MPa)	y_{13} (MPa)	y_{14} (MPa)	$\bar{y}$ (MPa)	MSD (MPa ²)	SN (db)
1	PEEK	12	12	2	2.499	4.842	1.279	1.483	2.526	8.381	-9.233
2	PEEK	15	14	3	1.756	3.121	1.400	1.641	1.980	4.369	-6.404
3	PEEK	18	16	4	1.279	2.348	1.285	1.530	1.610	2.784	-4.447
4	Carbon	12	14	4	2.147	3.860	1.304	1.503	2.204	5.867	-7.684
5	Carbon	15	16	2	1.757	3.481	1.298	1.505	2.010	4.789	-6.803
6	Carbon	18	12	3	1.868	3.244	1.294	1.499	1.976	4.483	-6.516
7	Titanium	12	16	3	1.959	4.143	1.309	1.507	2.230	6.248	-7.957
8	Titanium	15	12	4	1.797	3.457	1.297	1.495	2.011	4.774	-6.788
9	Titanium	18	14	2	1.423	2.791	1.292	1.492	1.749	3.427	-5.349

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4.4.2 Computation of Average Performance

To compute the average performance of the factor A at level 1 (_A1), add the results for trials including factor A1, and then divide by the number of such trials.

$$\begin{aligned} _A1 &= (SN_1 + SN_2 + SN_3)/3 \\ &= [(-9.233) + (-6.404) + (-4.447)]/3 \\ &= -6.695 \end{aligned} \quad (4.3)$$

The average performance of all the factors at different levels can be calculated in a similar manner and the results are presented in Table 14.

Table 14 Average Performance of Factors at Different Levels

_A1	_A2	_A3	_B1	_B2	_B3	_C1	_C2	_C3	_D1	_D2	_D3
-6.695	-7.001	-6.698	-8.292	-6.665	-5.437	-7.512	-6.479	-6.402	-7.128	-6.959	-6.307

4.4.3 ANOVA of Results

4.4.3.1 Sum of Squares

$$SS_T = \sum_{i=1}^9 SN_i^2 - C.F. \quad (4.4)$$

$$\text{where } C.F. = \frac{\left(\sum_{i=1}^9 SN_i \right)^2}{N} \quad (4.5)$$

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$$\begin{aligned}
 CF &= (SN_1 + SN_2 + SN_3 + \dots + SN_9)^2/9 \\
 &= [(-9.233) + (-6.404) + (-4.447) + \dots + (-5.349)]^2/9 \\
 &= 831.827
 \end{aligned}$$

$$\begin{aligned}
 SS_T &= SN_1^2 + SN_2^2 + SN_3^2 + \dots + SN_9^2 - C.F. \\
 &= (-9.233)^2 + (-6.404)^2 + (-4.447)^2 + \dots + (-5.349)^2 - 831.827 \\
 &= 31.838
 \end{aligned}$$

$$\begin{aligned}
 SS_A &= A_1^2/N_{A1} + A_2^2/N_{A2} + A_3^2/N_{A3} - C.F. \\
 &= (-40.169)^2/6 + (-42.005)^2/6 + (-40.189)^2/6 - 831.827 \\
 &= 0.371
 \end{aligned}$$

$$\begin{aligned}
 SS_B &= B_1^2/N_{B1} + B_2^2/N_{B2} + B_3^2/N_{B3} - C.F. \\
 &= (-49.749)^2/6 + (-39.991)^2/6 + (-32.624)^2/6 - 831.827 \\
 &= 24.598
 \end{aligned}$$

$$\begin{aligned}
 SS_C &= C_1^2/N_{C1} + C_2^2/N_{C2} + C_3^2/N_{C3} - C.F. \\
 &= (-45.074)^2/6 + (-38.875)^2/6 + (-38.414)^2/6 - 831.827 \\
 &= 4.611
 \end{aligned}$$

$$\begin{aligned}
 SS_D &= D_1^2/N_{D1} + D_2^2/N_{D2} + D_3^2/N_{D3} - C.F. \\
 &= (-42.770)^2/6 + (-41.754)^2/6 + (-37.840)^2/6 - 831.827 \\
 &= 2.258
 \end{aligned}$$

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$$\begin{aligned}
 SS_E &= SS_T - SS_A - SS_B - SS_C - SS_D \\
 &= 31.838 - 0.371 - 24.598 - 4.611 - 2.258 \\
 &= 0
 \end{aligned}$$

4.4.3.2 Degree of Freedom

From the table of F-ratio at 99% confidence, the degree of freedom (DOF) for the numerator is the DOF of each factor. The DOF for the denominator is the DOF of the error (Appendix F-ratio table). From equation 4.6, 4.7, 4.8, the DOF of each factor for this experiment is 2. The number of replicates in each run condition in the crossed array design is 2. The total number of data used in the whole experiment is 18 and the total DOF in this experiment is 17.

$$\text{DOF of each factor} = \text{Number of levels} - 1 \quad (4.6)$$

$$\text{Total DOF} = \text{DOF of error} + \text{DOF of factors} \quad (4.7)$$

$$\text{Total number of data} > \text{Total DOF} + 1 \quad (4.8)$$

$$\text{Degree of freedom of } SS_T: f_T = 18 - 1 = 17$$

$$\text{Degree of freedom of } SS_A: f_A = 3 - 1 = 2$$

$$\text{Degree of freedom of } SS_B: f_B = 3 - 1 = 2$$

$$\text{Degree of freedom of } SS_C: f_C = 3 - 1 = 2$$

$$\text{Degree of freedom of } SS_D: f_D = 3 - 1 = 2$$

$$\text{Degree of freedom of } SS_E: f_E = 17 - f_A - f_B - f_C - f_D = 17 - 2 - 2 - 2 - 2 = 9$$

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4.4.3.3 Variance

$$\begin{aligned}V_A &= SS_A/f_A \\ &= 0.371/2 = 0.185\end{aligned}$$

$$\begin{aligned}V_B &= SS_B/f_B \\ &= 24.598/2 \\ &= 12.299\end{aligned}$$

$$\begin{aligned}V_C &= SS_C/f_C \\ &= 4.611/2 \\ &= 2.306\end{aligned}$$

$$\begin{aligned}V_D &= SS_D/f_D \\ &= 2.258/2 \\ &= 1.129\end{aligned}$$

$$\begin{aligned}V_E &= SS_E/f_E \\ &= 0/9 \\ &= 0\end{aligned}$$

4.4.3.4 F-Ratio

$$F_A = V_A/V_E$$

$$F_B = V_B/V_E$$

$$F_C = V_C/V_E$$

$$F_D = V_D/V_E$$

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F_A is indeterminate because of the zero value of V_E . Similarly F_B , F_C and F_D are indeterminate. In this kind of situation, pooling is used, which is a process of disregarding an individual factor's contribution and then subsequently adjusting the contributions of other factors. Therefore, V_E can be combined with variance V_A .

$$\text{The new } SS_E' = SS_A + SS_E;$$

$$\text{The new } f_E' = f_A + f_E$$

Then the new error variance is computed as

$$\begin{aligned} V_E' &= (SS_A + SS_E) / (f_A + f_E) \\ &= (0.371+0) / (2+9) \\ &= 0.034 \end{aligned}$$

Thus, F_B , F_C , F_D can be determined. Knowing the degree of freedom of the factors and error, the significance of each factor can be determined by the F-ratio table.

$$\begin{aligned} F_B &= V_B / V_E \\ &= 12.299 / 0.034 \\ &= 365.053 \end{aligned}$$

$$\begin{aligned} F_C &= V_C / V_E \\ &= 2.306 / 0.034 \\ &= 1 \ 36.870 \end{aligned}$$

$$F_D = V_D / V_E$$

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$$= 1.129 / 0.034$$

$$= 33.516$$

4.4.3.5 Percent Contribution

The percent contribution of each factor is the ratio of the factor sum to the total, expressed in percent.

$$P_B = (SS_B' / SS_T) \times 100$$

$$P_C = (SS_C' / SS_T) \times 100$$

$$P_D = (SS_D' / SS_T) \times 100$$

$$P_E = (SS_E' / SS_T) \times 100$$

Where, SS_B' , SS_C' , SS_E' , SS_D' are the pure sum of squares of the factors, which is the sum of squares minus the degree of freedom times the error variance.

$$SS_B' = SS_B - f_B \times V_E'$$

$$= 0.371 - 2 \times 0.034$$

$$= 24.531$$

$$SS_C' = SS_C - f_C \times V_E'$$

$$= 4.611 - 2 \times 0.034$$

$$= 4.544$$

$$SS_D' = SS_D - f_D \times V_E'$$

$$= 2.258 - 2 \times 0.034$$

$$= 2.191$$

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$$\begin{aligned} SS_{E''} &= SS_E' + (f_A + f_B + f_C) \times V_E' \\ &= 0.371 + (2+2+2) \times 0.034 \\ &= 0.573 \end{aligned}$$

Therefore, the percent contribution of each factor is as the following.

$$\begin{aligned} P_B &= (SS_B' / SS_T) \times 100\% \\ &= (24.531 / 31.838) \times 100\% \\ &= 77.0 \% \end{aligned}$$

$$\begin{aligned} P_C &= (SS_C' / SS_T) \times 100\% \\ &= (4.544 / 31.838) \times 100\% \\ &= 14.3\% \end{aligned}$$

$$\begin{aligned} P_D &= (SS_D' / SS_T) \times 100\% \\ &= (2.191 / 31.838) \times 100\% \\ &= 6.9\% \end{aligned}$$

$$\begin{aligned} P_E &= (SS_E' / SS_T) \times 100\% \\ &= (0.573 / 31.838) \times 100\% \\ &= 1.8\% \end{aligned}$$

The final results can be shown in Table 15 with the effect of the factor A pooled.

The pooled effects are shown as the error term in the ANOVA table.

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Table 15 Pooled ANOVA for Cervical Cage Design

Source	SS	Pure SS	DOF	Variance	F-Ratio	Percent
A	Pooled					
B	24.598	24.531	2	12.299	365.053	77.0 %
C	4.611	4.544	2	2.306	136.870	14.3%
D	2.258	2.191	2	1.129	33.516	6.9%
Error	0.371	0.573	11	0.034		1.8%
Totals	31.838	31.838	17			100%

4.4.4 Graph of Response

The response graph as shown in Figure 37 provides information on the trend of each factor with respect to different levels.

Figure 37 Response Graph for Significant Factors

4.4.5 Determination of Optimal Run

The analysis of average performance showed that the optimum condition is B₃C₃D₃. Because factor A is found not significant, it can be set at any level. But the average $\bar{A}_1$ tends to produce a highest SN (-6.695) among the three levels of factor A. Therefore, the full recommendation for optimization will be A₁B₃C₃D₃. This happened to be Run 3. The testing results also showed this combination produced the highest SN and lowest compressive stress on the C6 superior endplate.

4.4.6 Discussion

The objective of the Taguchi method seeks to determine the factor levels that produce the best performance of the product or process under study (Roy 1990; Montgomery 1997; Taguchi *et al.* 2000). The optimum condition is selected so that the influence of the uncontrollable factors causes minimum variation of system performance. This implies that the combination of a cage with larger width, depth and wall thickness can produce the lower von Mises stress under various conditions, whether it is in a normal patient or a patient with osteoporosis, or whether is in the early stage of cage insertion or the final stage of bone fusion. Thus, the risk of cage subsidence due to high stress on the cage-endplate interface could be minimized.

In the current study, the choice of exclusively axial compression on the construct was based on two facts. One is the result of an FE analysis done by Polikeit *et al.* (2003). In their study, the factors influencing stresses within vertebrae after insertion of intervertebral cages were analyzed in pure

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compression, flexion, extension and lateral bending. The result showed that the loading conditions had a minor influence on the stress distribution compared to a cage insertion. The stress distribution remained relatively consistent among different loading conditions. The other fact is that the neck of the patient after the cage insertion surgery is usually immobilized by external brace so that any movements of the head and neck are restricted. Therefore, only uniform compressive load was considered in the current FE study.

The Taguchi method was applied in this study to determine the optimal design parameters of the cervical ring cage. The Taguchi approach can be utilized to arrive at the best parameters for the optimum design configuration with the least number of analytical investigations. Although there are several methods available for optimization, using such simulations when factors are continuous, frequently the Taguchi method can significantly reduce computing time by means of treating factors at discrete levels.

The advantage of the FE method in the design stage of an implant lies in its easy modification of certain parameters in the developed FE model and subsequent analysis of the corresponding results. As the number of spinal implants increases and the standards of the design become more complex, the biological testing of the new implant *in vitro* and *in vivo* is more time-consuming and labor-intensive. The FE approach provides a suitable start point for analysis of the implant for design optimization, material properties, and clinical related events. In this way, the number of experiments could be decreased and the cost for product development would finally be minimized.

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So far in the human spine field, the combination of the Taguchi philosophy and the FE method has not been applied in any other studies yet. The results of the current study showed the combination of A₁B₃C₃D₃ in the cage design produced the highest S/N ratio and lowest von Mises stress on the C6 superior endplate. In general, the larger width, depth and wall thickness of the cage design produces a higher S/N ratio and lower von Mises stress. From the percentage of contribution of each factor, it can be seen that the most influential factors on the endplate stresses are the width of the cage, then followed by depth and wall thickness. The contribution of the implant materials is quite trivial.

Von Mises stress, σ_v , is a scalar function of the components of the stress tensor that gives an appreciation of the overall magnitude of the tensor.

Von Mises stress in three dimensions is

$$\sigma_v = \sqrt{\frac{(\sigma_1 - \sigma_2)^2 + (\sigma_2 - \sigma_3)^2 + (\sigma_3 - \sigma_1)^2}{2}}$$

where $\sigma_1, \sigma_2, \sigma_3$ are the principal stresses

Since it is always possible to locate two orthogonal planes for a certain point for the applied load, the shear stress can vanish in one plane. These planes are called the principal planes while the normal stresses on these planes are the principal stresses (Alexander, 1981). In the cage optimization study, the spinal

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operative condition rather than bone failure status was modeled, where the stress on the endplate is quite below its failure stress of 4.0 MPa (Lim *et al.* 2001). Therefore, the von Mises stress was used as a performance indicator for comparing the optimization results.

In the aforementioned compressive loading case, the vertical component is the major portion of the applied load. Force is an invariable in this case. Therefore, the principal stress is mainly determined by the size on the contact area between the cage and endplate. Since the extent increased in width is larger than in depth and wall thickness, therefore, more change in contact area would be produced by the change in cage width, which in turn lowers the von Mises stresses.

The trivial contribution of implant materials to the endplate von Mises stresses found in the current analysis was supported by the previous studies. Adam (Adam *et al.* 2003) performed a sensitivity analysis for a lumbar hollow rectangular cage to investigate the change of maximum stresses on the endplate with the implant elastic modulus over the range from 1.3 GPa to 200 GPa. The maximum von Mises stress on the superior endplate of the lower vertebra only increased by 8.9 MPa. The paper concluded that although the elastic modulus of the implants affects stress level, the variation is much less than would be expected, especially when the implant material properties were above 5 GPa. Palm et al (Palm *et al.* 2002) built a planar finite element model to describe the frontal plane bone-implant interfaces stresses acting on a generic cylindrical interbody cage on a lower lumbar motion segment. The effect of implant material properties on these stresses was evaluated and the associated load

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transfer mechanisms were determined by changing the implant materials from cortical bone to metal. The results showed only 11% variation of the maximum von Mises stress at the interface with the implant Young's modulus over the range of 17 GPa to 200 GPa. They concluded that interface stresses were largely independent of implant materials.

The current results have some implications in the biomechanical study and clinical setting. The fact that experimental studies showed no significant differences in construct failure strength among cages with different materials (Brantigan *et al.* 1991; Hoshijima *et al.* 1997; Jost *et al.* 1998) may be truly due to no appreciable difference existing, rather than the lack of statistical power, the drawback of which the *in vitro* studies commonly have. On the other hand, the larger cage is always a better option whenever it is possible in clinics for the patients with cervical disorder for avoiding the possible risk of cage subsidence in the vertebral endplates.

4.5 SUMMARY

The aim of this section was to determine the optimal design of the cervical ring cage to minimize the risk of subsidence into the endplate. The Smith-Robinson approach for treatment of cervical spondylosis was first simulated. Then a generic cervical ring cage was inserted into the operated intervertebral space to mimic cage implantation. A uniform axial compressive force of 110 N was applied on the superior-most nodes of C5 to simulate the physiological load. The von Mises stress on C6 superior endplate induced by the cage was extracted to compare the effects of different cage designs. The Taguchi philosophy was

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used in the design of the experiment for determining the optimal combination of various factors. ANOVA was adopted for the analysis of the contribution of each factor. The results showed the larger width, depth and wall thickness of the cage design produces a higher S/N ratio and lower von Mises stress. The most significant factors that influence the endplate stresses are the width of the cage, and then followed by depth and wall thickness. The contribution of the implant materials is minimal.

The combination of the Taguchi philosophy and the FE method provide a new way of determining design optimization for a spinal implant. The results of the current analysis suggested that in order to achieve a robust result for lower endplate stresses after cervical cage insertion, a cage with larger width, depth and wall thickness would be a better option.

CHAPTER 5 BIOMECHANICS OF CERVICAL RING CAGE ON NORMAL AND OSTEOPOROTIC VERTEBRAE

5.1 INTRODUCTION

The primary function of the cervical cage insertion to the spine segment is to work as a load-carrying entity to provide stability to the segment for three to six months for biological formation of the new bone within the intervertebral space. At the same time, cages also provide a favourable milieu for bone formation by accommodating a sufficient amount of fresh autologous bone graft by means of osteoinduction (Steffen *et al.* 2000b; Weiner & Fraser 1998; Zdeblick & Phillips 2003). The success of a cage insertion is regarded as the fusion and thereby the stabilization of the spine. Apart from the biological factors, there are numerous factors influencing the prognosis of spine fusion, such as interface between the bone and the cage, material properties of the cancellous cores and geometry of the implants, etc (McAfee *et al.* 1999; Mulholland 2000; Steffen *et al.* 2000b; Tsantrizos *et al.* 2000).

The FE method has more advantages in addressing the above mentioned mechanical problems over the *in vitro* experiments. It can provide complementary information especially in term of internal stress distribution and load transfer mechanism (Goel & Pope 1995; Yoganandan *et al.* 1996a). However, only a few FE studies on the biomechanics of the cage-segment construct have been conducted in literature. Kim (2001) investigated the effect of mechanical parameters at the bone-implant interface of the lumbar spine segment under various combined loading

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conditions. A FE model of L3-L4 lumbar segment with two titanium interbody cages was constructed. The model was used to study the mechanical behaviour at the bone-cage interface. Relative micromotion, posterior axial displacement and stress were predicted for different friction coefficients, loading conditions and cage-related material-geometric properties of the spinal segments. The study concluded that relative micromotion is sensitive to the friction coefficient of the interfaces, the bone density and the loading conditions. A reduction in age-related bone density is less likely to allow bone growth into surfaces of the cages.

Palm *et al.* (2002) used a planar finite element model to study parametrically the load transfer characteristics of the lower lumbar motion segment implanted with dual anteroposterior cylindrical interbody cages. A uniform compressive loading was simulated on the implanted segment model. Material properties of the interbody cages were varied to simulate cortical bone, titanium, and stainless steel implants. Normal and shear interface stresses were output along the length of the interface. The results showed that magnitudes of both the normal and shear interface stresses were substantially higher at the medial and lateral side of the interface than in the centre. The cylindrical interbody implants had inherent limitations including the stress concentration at the bone-implant interfaces and possible stress shielding to the graft.

Polikeit *et al.* (2003b) evaluated the effects of the cage insertion on a lumbar functional spinal unit. A three-dimensional finite element model of L2-L3 was developed and an anterior approach for a monobloc, box-shaped cage was modelled. The results showed that inserting a cage increased the maximum von Mises stress and changed the load transfer in the adjacent structures. Varying the cage materials or the

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loading conditions had a much smaller influence than varying the cancellous bone density.

Polikeit *et al.* (2003a), in another paper, studied the effects of the endplate properties and their distribution on stresses in a lumbar functional spinal unit by modification of a previously developed L2-L3 FE model. The endplate was modelled thicker adjacent to the annulus than in the central region. The endplate material properties varied to represent a wide spectrum of bone qualities ranging from the stiffness of the cancellous bone to that of the cortical bone. Two non-homogeneous distributions of endplate properties were modelled. A rough distribution had four different moduli defined across the surfaces, and a fine distribution had the outer periphery of the endplate further divided. The results showed that a harder endplate led to increased concentration of the stress peaks and high stresses were propagated further into the vertebral body. Stress distributions were similar for the two endplate preparation techniques of the complete preservation and partial endplate removal from the centre.

Adam *et al.* (2003) investigated biomechanics of a rectangular cage by developing an anatomically simplified lumbar vertebral body, which used separate element mesh regions for cancellous core and cortical shell with the meshes tied together at the core/shell interface. The results predicted that endplate stress of approximately 12 times the nominal contact pressure due to the differing deformation stiffness of the implant and endplate structures. Reduction of the cancellous core elastic modulus to simulate severely osteoporotic bone resulted in endplate stresses up to three times than the values for the intact cancellous core.

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These FE studies provide a better understanding on the biomechanics of a cage in the lumbar spinal segment; however, no studies have been focused on the cervical cage and region, especially on the internal biomechanics of the construct. It has long been known that there is drastic variation in the structure and functions between the lumbar spine and cervical spine. The lumbar vertebrae are larger and stronger for the task of upholding the upper body weight and allowing motion in the sagittal plane; while the cervical ones are smaller and irregular, allowing easy movement of the head (Martini 2001; Anderson 1983; Williams *et al.* 1989; White & Panjabi 1990). Furthermore, the designs of the cervical cages are greatly different from those of the lumbar cages. Hence, the cervical and lumbar cages would behave biomechanically differently from each other.

The motivation for work presented in this chapter is therefore to investigate the biomechanical changes of the cervical segment (C5-C6) after insertion of a ring shape cage using the FE method. The stress distribution and magnitude at the bone-implant interface and in the cancellous core of the C6, as well as the compressive displacement of the C6 superior endplate were analysed. In addition, the effect of osteoporosis on the abovementioned parameters was analysed. Knowledge on the biomechanics of caged cervical segments would provide more information on factors influencing the fate of spinal fusion and on strategies for increasing fusion rate and avoiding subsidence of the cage.

5.2 MATERIALS AND METHODS

The FE model of the C5-C6 segment with the optimized cervical ring cage inserted into the intervertebral disc space as shown in Figure 38 was used for the analysis. The details of the caged FE model construction have been described in Chapter 3 and Chapter 4.

Figure 38 Caged C5-C6 FE model

Young's modulus of the cage material was set to be 1300 MPa and Poisson's ratio was to be 0.2 to simulate that of Polyetheretherketone (PEEK) (Adam *et al.* 2003). The dimensions of the cage were 18mm, 16mm and 4mm respectively for width, depth and wall thickness. In order to analyse the different behaviour of the cervical ring cage under normal and osteoporotic conditions, Young's modulus of the cancellous core of both C5 and C6 was changed from 450 MPa to 150 MPa (Natarajan *et al.* 2000), on the basis of the decrease in bone mineral density due to age from 4 g/cm³ for a normal vertebra to 3 g/cm³ for an osteoporotic bone (White & Panjabi 1990). The graft bone

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within the cervical cage was not simulated due to its inability to transmit any load in the initial stage of the implantation.

Same loading and boundary condition was applied same as in Chapter 4, with 110 N compressive load on the C5 top surfaces and full constriction on the C6 bottom as shown in Figure 34. For the caged cervical segment FE model, the following parameters for a normal vertebral body were extracted: the stress distribution and magnitude on the C6 superior endplate, stress profile in C6 cancellous core, compressive displacement along the midsagittal on C6 superior endplate. Subsequently, effect of the osteoporosis on these parameters was investigated.

5.3 RESULTS AND DISCUSSION

5.3.1 Cage Biomechanics of Normal Vertebrae

Figure 39 shows the predicted von Mises stresses distribution on C6 superior endplates of caged C5-C6 FE model with normal vertebral body under 110 N physiological axial compressive load. It is noticeable that there is uneven distribution of the stress on the C6 superior endplate. The cervical ring cage seems to tend to concentrate von Mises stresses on the posterior portion of superior endplate, rather than evenly distributing the applied load. The cage deforms the endplate in such a way that the cage is mainly supported by the posterior 1/3 portion of the endplate, resulting in a maximum von Mises stress of 1.28 MPa located in this area on the superior endplate, while most of anterior part of the superior endplate is less loaded. The minimum von Mises stresses appeared mostly in anterior 1/3 of the endplate.

Figure 39 Stress Distribution on C6 Superior Endplate in Normal Vertebra

The compressive stress in the C6 cancellous core of the normal vertebral body is shown in Figure 40. For a better illustration, the entire cortical shell and superior and inferior endplate of C6 vertebra are removed, and a midsagittal cut is made through the cancellous core. The maximum stress occurs in the middle portion of the posterior edge between the superior surface and posterior wall of the cancellous core with a peak value reaching 1.11 MPa. Then the magnitude gradually decreased in all directions along the cancellous core.

The compressive displacement of C6 superior endplate of the normal vertebrae is presented by the deformed profile on the entire endplate Figure 41 and along the midsagittal plane on C6 superior endplate as shown in Figures 42-44.

It can be seen in Figure 41 that the maximum compressive displacement occurs at the central part of the posterior region of the superior endplate, forming a kidney shaped compression on the endplate surface bulging towards the cancellous core. A narrow spindle-shaped area that slightly moves upwards is

along the posterior edge of C6 superior endplate and centered by the midsagittal plane.

Figure 40 Compressive Stress in Normal Cancellous Core

Figure 43 demonstrates the geometrical profile of the compressive displacement along the midsagittal plane. The graphical illustration of the compressive displacement is shown in Figure 44 with the transverse axis as the distance away from the posterior edge of the C6 superior endplate and the vertical axis as the magnitude of the compressive displacement. The maximum compressive displacement occurs from 6.10 mm away from the posterior edge of the superior endplate with a maximum magnitude of 11.44 μm , then smoothly decreases to the minimum compressed part around anterior 1/6 portion along the midsagittal plane. There is noticeable an upward displacement at the posterior edge of the superior endplate, reaching a peak value at 3.72 μm .

Figure 41 Endplate Compressive Displacement in Normal Vertebra

Figure 42 Nodes Selected for Compressive Displacement Analysis

Figure 43 Endplate Compressive Displacement of Normal Vertebra (Geometry)

Figure 44 Endplate Compressive Displacement of Normal Vertebra (Graph)

For the normal intervertebral disc structure, the nucleus pulposus is located in the central part of the intervertebral space, rich in various proteoglycans. The water content is about 70-90%. The nucleus pulposus fills about 30-50% of the total disc areas in the cross-section in the cervical region. The annulus fibrosus composed of collagen fibers surrounds the nucleus pulposus. They attach the

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endplate in the more peripheral zone directly to the osseous tissue of the vertebral body (Antoniou *et al.* 1996; Roughley 2004).

When a normal spinal segment is subjected to a compressive load, the load is transferred from upper vertebral body to the lower one by way of the nucleus pulposus and the annulus fibrosus. The normal discs with their sufficient water content act like a gelatinous mass. As the axial compressive load is applied, there is a build-up of pressure within the nucleus, pushing the surrounding structures in all the directions away from the center of the nucleus. The endplates are pushed away from the nucleus and towards the center of the vertebral body. Therefore, the stress distribution on the endplates is more centered and gradually decreases towards the peripheral area of the endplate in a physiological spine segment (White & Panjabi 1990).

The above situation would be changed greatly if the intervertebral disc is removed and a cervical cage is inserted. The compressive load is mostly transferred directly from the superior vertebra to the inferior via the cage, which contacts the peripheral portion of the endplate. The validated C5-C6 FE model has been developed in a more realistic way so that the physiological lordosis of the normal cervical spine is included with anterior disc height at 5.4 mm and the posterior disc height at 3.0 mm. The C6 superior endplate and C5 inferior endplate are not parallel to each other, and so are the top and bottom surfaces of the wedged cervical cage. When the axial compressive load is applied on the caged construct, more stress is experienced on the endplate contacting the posterior portion of the cage as shown in Figure 45.

Figure 45 Load Transfer in Caged Cervical Segment

The current result of stress distribution on the superior endplate is somehow different from that in the FE stress analysis of the lumbar box-shaped interbody implant (Adam *et al.* 2003). The previous study showed that the von Mises stress was concentrated along all the contacting parts between the hollow implant and the lumbar superior endplate. The following reasons may contribute the major difference between the current finding and the previous one. The FE model used in Adam's study had only one geometrically simplified vertebral body simulating L5 with a flat superior endplate and no posterior elements and ligaments. No physiological lordotic angle was simulated in one en bloc vertebra model. The compressive load would go through the entire cage wall evenly, rather than shifting towards the posterior part of the construct.

The pattern in which the von Mises stress is concentrated in the posterior portion of the superior endplate would result in a lack of load transfer in the central area of the endplate. This finding partially supports the results of Steffen *et al.* (2000a) and Hollowell *et al.* (1996), in which the central endplate removal

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method produced no reduction of the cage-vertebrae construct compared with the non central endplate removal method. This is because, on one hand, the endplate is structurally stiffer in the peripheral part; on the other hand, most of the load is borne by the peripheral region for the ring shaped cages.

In the lumbar region, the *in vivo* compressive loads induced by the upper body weight have the potential of overlapping with the failure strength of the cage-vertebral construct (Jost *et al.* 1998). There is also risk of cage subsidence into the endplate during routine activities. On the contrary, in the cervical region, the maximum von Mises stress on the C6 superior endplate in the caged FE model is 1.28 MPa and the failure stress of the cervical endplate is 4 MPa (Lim *et al.* 2001). Therefore, the application of the cage in the cervical region is theoretically the safer compared with its use in the lumbar region.

5.3.2 Cage Biomechanics of Osteoporotic Vertebrae

The distribution and magnitude of von Mises stress on the C6 superior endplate subjected to 110 N physiological axial compressive load is appreciably changed when Young's modulus values of the normal vertebral bodies are replaced by those of osteoporotic ones as shown in Figure 46. Compared to the stresses on the superior endplate of the normal vertebra, the region of stress concentration still falls in the area around the junction of the middle and posterior 1/3 on the superior endplate. However, two new locations of stress concentration on the posterior edge between the superior endplate and posterior cortical wall

Figure 46 Stress Distribution on C6 Superior Endplate in Osteoporotic Vertebra

at about 5.58 mm on both sides of the midsagittal line. The magnitude of the von Mises stress on the C6 superior endplate is 2.35 MPa, an increase of 83.59 % compared with that in the normal vertebral body. The minimum stressed region was in anterior portion of the superior endplate but had a smaller area compared with that in a normal vertebra.

The compressive stress in the cancellous core with the osteoporotic vertebra is shown in Figure 47. The less and minimum stressed area seems to be larger than that in the normal cancellous core, mostly in the anterior and inferior portion of the cancellous core. The stress value is 1.08 MPa of the junction among superior surface, posterior wall and mid-sagittal plane of the cancellous core. The magnitude of the maximum stress decreases 2.7 % from that in the normal cancellous core.

Figure 47 Compressive Stress in Osteoporotic Cancellous Core

The compressive displacement of the entire endplate for caged FE C5-C6 model with the osteoporotic vertebrae is shown in Figure 48 while Figure 49 and Figure 50 depict the geographical and graphical changes of the compressive displacement along the midsagittal line on the C6 superior endplate.

Figure 48 Endplate Compressive Displacement in Osteoporotic Vertebra

Figure 49 Endplate Compressive Displacement of Osteoporotic Vertebra (Geometry)

Figure 50 Endplate Compressive Displacement of Osteoporotic Vertebra (Graph)

The contour of the compressive displacement of the entire C6 superior endplate with the osteoporotic vertebrae resembles that of the normal vertebra, but the maximum magnitude of the compressive displacement reaches 26.55 μm , increasing 131.99% compared with the normal vertebra. For the compressive

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displacement along the midsagittal plane on the C6 superior endplate with the osteoporotic vertebrae, the posterior edge of the C6 superior endplate experienced an upward displacement reaching a maximum as much as 13.95 μm . The upward displacement gradually decreased to zero at the 1.06 mm away from the posterior wall where the downward compressive displacement starts to increase from zero to its peak value at the point 4.23 mm away from the posterior edge. Then the compressive displacement decreased gradually back to the original level at the anterior part of the superior endplate.

Finally, a summary of results of the normal and osteoporotic vertebra under the 110 N compressive load was shown in Table 16.

Table 16 Comparison of Results between Normal and Osteoporotic Vertebra

Vertebra	Maximum von Mises Stress on Endplate (MPa)	Maximum Compressive Stress in Cancellous Core (MPa)	Maximum Compressive Displacement of Endplate (μm)
Normal	1.28	1.11	11.44
Osteoporotic	2.35	1.08	26.55

Osteoporosis is an aging process that leads to unfavorable changes in architecture and material properties in bone (Keaveny & Yeh 2002). Age-related osteoporotic fractures of the spine have a prevalence of 500,000 cases a year and are more common in females (Jensen *et al.* 1982; Melton *et al.* 1989). More than 80% of observed fractures are attributed to anterior wedge fractures

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(Jensen *et al.* 1982; Melton *et al.* 1989). One of the major important pathogenic changes in osteoporosis is the reduction in the quantity of solid bone tissue in a given volume, which can be monitored by means of area bone mineral density (BMD) using dual energy X-ray absorptiometry and volumetric BMD by quantitative computed tomography (QCT).

The structure of a vertebral body can be represented mechanically by a stiff box (cortical shell) containing a relatively flexible core (cancellous core). When the caged C5-C6 segment is subjected to compressive loading, the compressive force experienced by the lower vertebral body is shared by both the cortical shell (F_2 , F_3) and cancellous core (F_1) as shown in Figure 51. When osteoporosis occurs, the material properties of the cancellous core reduce drastically to one third of the normal ones. More load will be taken by the cortical shell ($F_2' + F_3'$) and less load taken by the cancellous core (F_1') (White & Panjabi 1990). The following relations shall exist when the vertebral body becomes osteoporotic:

$$F_1' < F_1;$$

$$F_2' + F_3' > F_2 + F_3$$

Therefore, the endplate would experience a higher von Mises stress compared to the normal vertebral body.

A similar effect of osteoporosis on the stress distribution and peak on the superior endplate was found in a previous FE analysis on the lumbar spine (Mizrahi *et al.* 1993). An isolated human L3 vertebral body FE model was

Figure 51 Load Sharing Between Cortical Shell and Cancellous Core

developed for the study on how material properties and loading conditions influence endplate and cortical shell displacement and stress. A 50% reduction in trabecular bone modulus alone increases the peak stresses on the endplate by

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74%. Although the detailed structures of the cervical and lumbar spine are apparently different, the basic structures of vertebral bodies consisting of the cortical shells and cancellous cores are quite similar. The box-frame analogy could be also applied to explain the effect of the reduction in the material properties in the cancellous core in the lumbar spine on stress variations.

The results from the biomechanical change in the osteoporotic vertebra have certain clinical implications. The drastic increase in the maximum von Mises stress and compressive displacement in the posterior region on the superior endplate when the vertebrae becomes osteoporotic suggests that the endplate at this region would be at a higher risk of failure compared to the normal cervical spine. Since an osteoporotic vertebra has changed its mechanical features and the endplates are prone to be fractured, the physician should be more cautious on whether cage insertion is the preferred option for the treatment of cervical disorder in patients with osteoporosis in order to avoid the risk of cage subsidence and endplate fracture. At the same time, the unstressed anterior portion of the endplate in the osteoporotic vertebra would experience a stress shielding effect. Long term of unloading of the vertebral bone would aggravate the existing osteoporosis, resulting on further disturbance of load transfer and bone metabolism.

The simulation of osteoporosis in a vertebra by a reduction of the Young's modulus in the cancellous core is a simplification of the real osteoporotic scenario and has its own limitation. Osteoporosis is a global degenerative change the skeletal system. The age-related change affects the geometric and

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material properties of the vertebral body and the ligamentous tissues. Increase in endplate curvature, thinning of the cortical shell and endplate, stiffening of the intervertebral disc and relevant ligaments have been reported (Margulies *et al.* 1996; Buckwalter 1995; Keller *et al.* 1990; Keaveny & Yeh 2002). Incorporating all these changes to simulate a more realistic situation of the osteoporosis might be more idealistic. However, the exact changes in material properties and geometric changes of these structures and materials have not been well documented. Bold introduction of these not-well-defined parameters would introduce a further source of uncertainty for the results. More over, the major changes in osteoporosis in the spine are still in the cancellous core, whose formation is greatly reduced with aging (Keaveny & Yeh 2002). Therefore, it seems acceptable to use the definition of the changes in material properties to represent an osteoporotic situation in a vertebral body to evaluate the clinical intervention on an osteoporotic vertebra until well-defined parameters for the endplate curvature, the cortical shell thickness and material properties of the relevant ligamentous structures in the osteoporotic spine become available.

5.4 SUMMARY

There is paucity in literature on intrinsic biomechanics of cervical ring cage inserted in a cervical segment. The aim of the section was to analyse the influence of cervical ring cage insertion on the biomechanical behavior of the C5-C6 segment with normal and osteoporotic vertebrae. An instrumented C5-C6 FE model with a generic cervical ring cage inside was simulated and subjective to an axial compressive load of 110 N. The stress profiles and compressive displacement at the cage-endplate interface,

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the compressive stress in cancellous core was extracted. The influence of the osteoporosis on these parameters was analysed by changing Young's Modulus of the cancellous core from 450 MPa to 150 MPa.

The results showed insertion of the cervical ring cage to the C5-C6 segment remarkably changed overall biomechanics of the construct. The cervical ring cage shifted the maximum von Mises stress towards the posterior 1/3 of the C6 superior endplate, leaving most of the anterior portion less stressed. The maximum von Mises stress produced by cervical cage insertion was 1.28 MPa, which is below the endplate failure stress. Similarly, the peak value of displacement also occurred at the posterior 1/3 of the superior endplate when the cage was instrumented.

The cervical ring cage had an apparently different effect on the caged segment when the vertebrae became osteoporotic. The maximum von Mises stress on the C6 superior endplate increased by 83.59%. The compressive stress in cancellous core decreased by 2.7%, showing the stress shielding effect of the endplate on the cancellous core. The maximum compressive displacement on the superior endplate due to the cage insertion increased by 131.99%.

The results imply that the application of cervical ring cage under a physiological load is relatively safer for a patient with normal vertebrae, compared with the use in the lumbar region where much of the body weight is applied. However, there still is a considerable interference in the mechanical behavior to the cervical segment when the cages are inserted in the intervertebral space. A long term closer examination of the stress concentration and load shielding effect of the cage on the cervical spine biomechanics should be given. When osteoporosis occurs, the endplate under the

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cervical ring cage is at a higher risk of failure compared to the normal cervical spine. Also attention should be paid to aggravation of the existing osteoporosis because of the long term stress shielding effect of the cage on the endplate and cancellous core. Therefore, clinicians should be cautious when deciding on cage insertion surgery as an option for cervical disorder treatment in patients with an osteoporotic condition.

CHAPTER 6 BIOMECHANICAL EFFECTS OF ANTERIOR CERVICAL PLATE ON CAGED C5-C6 CONSTRUCT

6.1 INTRODUCTION

Various techniques have been reported for the anterior decompression and fusion for the cervical spine since the pioneering work of Smith and Robinson (1958), Cloward (1958; 1961) and Bailey and Badgley (1960) in the late 1950s. As decompression and fusion for the cervical spine disorder has become a popular practice in the past decades, difficulties and complications in its application seem apparent. A consistent rate of non-union was reported to be 10% to 12% for single level fusion, 20% to 27% for 2-level fusions and approximately 30% for 3-level fusions (Bohlman *et al.* 1993; Vaccaro & Balderston 1997). Graft dislodgement has been cited to be 2.1% to 4.6% in single level fusions and as high as 10% to 29% in multilevel fusions (Gore & Sepic 1984; Kalff *et al.* 1992; Slone *et al.* 1993).

The supplementation of anterior cervical plate (ACP) to interbody cage implantation has been proposed for a stronger fixation and lesser complication (Caspar *et al.* 1998; Gercek *et al.* 2003). Although this efficiency of this combination of ACP and cage has been reported by many clinical studies and biomechanical experiments, no studies have been found investigating the internal mechanical changes with the supplementary fixation of ACP to the caged cervical segments has not been studied, possibly due to the inherent limitation in these research methods. Therefore, the purpose of the current section is to analyse biomechanical effects of ACP on the caged

segment, especially in the variation of stability, stress distribution and load transfer, using a 3D finite element cervical spine construct. In addition, the effect of the absorbable ACP was also studied to analyse its immediate postoperative biomechanical influence on the spine construct. The purpose of the study is to acquire more comprehensive information on the cervical spine-cage-ACP construct to allow clinicians to choose the appropriate therapeutic regimen for cervical spine disorders.

6.2 METHODS AND MATERIALS

In order to investigate the influence of ACP on the caged C5-C6 segment, supplementation of a constrained ACP was simulated on the 3D caged C5-C6, which was built in Chapter 5 as shown in Figure 52.

Figure 52 Caged Cervical Segment with ACP Supplement

The generic one-level constrained ACP system consists of a precontoured plate to fit C5-C6 lordosis, and 4 screws with a diameter of 4mm. The screws were anchored in the vertebral cortex unicortically, reaching three-fourths of the anterior-posterior depth of the vertebral body. Each component of the ACP system was modeled using 8-nodes

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brick elements. The Young's modulus and Poisson's ratio were set to be 110 GPa and 0.2 to simulate the titanium material used for the plate and screw system. The screw-plate interface at the holes on the plate was modeled as surface to surface contact definitions with a tight bonded mode. The screw and the plate surfaces were assigned as contact and target surface respectively. These were used to mimic the rigid fixation of the screw on the plate by the titanium expansion screw to reduce the screw backout (McCullen & Garfin 2000; Vaccaro & Balderston 1997). The model of the anterior cervical plate fixation was assumed to be rigidly bonded where the ACP screws and the surrounding bone shared the common nodes to simulate the tight anchorage of the screw on the vertebral bone (Goel *et al.* 1988; Goel *et al.* 1991; Puttlitz *et al.* 2001). For the purpose of studying the influence of ACPs with different materials on the biomechanics of the caged construct, the Young's modulus of ACP was then changed to 5 GPa to represent the PLLA material.

The load and boundary conditions were the same as in previous chapters: the inferior surface for the inferior-most vertebral body was not allowed to deform in any direction and an axial compressive load of 110 N was applied on the nodes of the top surface of C5 superior endplate. The caged models with supplementary fixation of ACP with different material properties representing the titanium and absorbable PLLA were executed in the Ansys 6.0 (ANSYS, Inc., Southpointe, Canonsburg, PA, USA). The primary results were further processed to yield the maximum compressive displacements, von Mises stresses on the C6 superior endplate, the maximum von Mises stress in cortical wall and cancellous core at the level immediately inferior to the superior screws, contact stress at the interface between the cage and C6 superior

endplate. The results were also compared with those in the C5-C6 model implanted solely with the cervical ring cage.

6.3 RESULTS AND DISCUSSION

The maximum displacements of the construct instrumented with titanium and PLLA ACP under 110 N compressive load are presented in Figure 53 and also compared with that in the C5-C6 construct with the cervical ring cage alone. The locations of the maximum displacements of the three models are all at the apex of C5 posterior process as shown in Figure 54. The purpose of examining the maximum displacement of the different models is to compare the overall stiffness of the C5-C6 segment with different instrumentations, since the higher initial stiffness of the whole construct (spinal segment and implant) is the clinical indicator for a more successful future bone fusion (Steffen et al., 2000b; Stokes 1998).

Figure 53 Maximum Displacement of C5-C6 Construct with Different Implants

Figure 54 Location of Maximum Displacement of C5-C6 Construct

The C5-C6 model with cervical cage alone exhibits the highest maximum displacement with a value of 103.29 μm among the three different constructs. The supplementation with titanium ACP greatly decreases the maximum displacement to a magnitude of 3.528 μm . The PLLA ACP shows a comparable stabilizing effect to the titanium ACP with a value of 4.232 μm .

In order to have a better understanding of the deflection trend crossing the C6 superior endplate, the compressive displacement profiles of the endplate from posterior to anterior along the midsagittal plane of the three models are extracted. Figure 55 shows the nodes selected on C6 superior endplate along the midsagittal plane for the analysis and Figure 56 shows the comparison of the compressive displacement profiles of the three models. It can be seen that the cage only model has the largest displacement at the posterior portion of the superior endplate. After the supplementation of the ACPs, the displacement in the posterior portion is sharply reduced. The endplates of the ACP

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models exhibited the displacements in a shallow and smooth manner. The effect of PLLA ACP was quite comparable to that of titanium ACP in decreasing the compressive displacement of the endplate.

Figure 55 Nodes Selected on C6 Superior Endplate for Analysis

Figure 56 Compressive Displacement of Endplate along Midsagittal Plane

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Figure 57 shows the predicted von Mises stress distribution on the C6 superior endplate in caged C5-C6 segment supplemented with titanium ACP under compressive loads. The overall distribution of von Mises stress on the C6 superior endplate is similar to that in the C5-C6 model with cervical cage alone. The von Mises stresses are more concentrated in the posterior 1/3 portion of the superior endplate. However, the magnitude of the von Mises stress is drastically decreased to 0.062 MPa compared the value of the 1.279 MPa in C5-C6 model with cervical ring cage alone.

Figure 57 Endplate Stress Distribution in Titanium ACP Construct

Von Mises stress distribution on the C6 superior endplate in the caged C5-C6 segment with PLLA ACP instrumentation presents a similar pattern to that in the titanium ACP instrumented model as shown in Figure 58. The magnitude of the maximum von Mises stress is close to that for the titanium ACP model with a value of 0.065 MPa.

Figure 58 Endplate Stress Distribution in PLLA ACP Construct

The maximum von Mises stress in the cortical wall and the cancellous core at the level immediately inferior to the superior screws is shown in Table 17 for the caged C5-C6 FE model with titanium and PLLA ACP, and compared with the cervical cage alone C5-C6 model. A comparison of the maximum von Mises stresses on the C6 superior endplate is also included in Table 17. The magnitudes of the maximum von Mises stresses in both titanium and PLLA models are very compatible, with a slightly higher value in the cancellous core in the PLLA ACP model. Compared to the cage alone model, stresses in the cortical wall and cancellous core are remarkably reduced in the ACP model, regardless of the plate materials.

The maximum contact pressures at the interface between the cage and the C6 superior endplate for models with cage alone, titanium ACP and PLLA ACP are given in Figure 59. The supplementation of titanium ACP to the caged C5-C6 construct greatly reduced contact pressure at the cage-endplate interface by 82.29%, when compared with the C5-C6 segment implanted with cage alone. When the material

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properties of the ACP is changed from titanium to PLLA, the PLLA plate shows nearly the same effect on reducing the interface contact pressure by 80.12%, with a value of 0.459 MPa in comparison with 0.409 MPa in the titanium ACP model.

Table 17 Maximum Stresses in C5-C6 with Different Instrumentations (MPa)

Models	Superior Endplate	Cortical Wall*	Cancellous core*
Cage alone	1.279	2.471	1.178
Cage with Titanium ACP	0.062	0.112	0.046
Cage with PLLA ACP	0.065	0.115	0.051

*Maximum von Mises stress in the cortical wall and cancellous core at the level immediately inferior to the superior screws.

Figure 59 Maximum Contact Pressures in Different Constructs

The initial objective of the ACP supplementation to the cervical segment implanted with cage insertion is to increase its stability, which is necessary for a

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successful bone fusion between vertebrae. Figure 53 and Figure 56 suggest that the addition of titanium ACP has greatly decreased the flexibility of caged C5-C6 segments. The ACP system simulated in the current study is a constrained plate, in which the screws are rigidly fixed by the plate expansion screws and have a predetermined trajectory. The constrained ACP system works as rigid frame bridging the discectomied and caged C5-C6 segment with a Young's modulus of 110 GPa as titanium material. At the same time, the screw-bone interfaces are modelled as in the case of a secured anchorage of the screws in the cancellous bone (Goel *et al.* 1988; Goel *et al.* 1991). All these factors work together to contribute to the high stabilizing efficiency of the ACP supplementation to the caged segment.

Previous experimental studies supported the hypothesis that the increased spinal implant rigidity would enhance the possibility of spinal fusion and a stiffer implant would result in stiffer fusions (Johnston *et al.* 1990; McAfee *et al.* 1991). The results of this FE analysis imply that the addition of titanium ACP to the caged segments has increased the stability of the targeted segments, which in turn would promise a high rate of successful fusion. Clinical studies showed that the supplementation of ACP after discectomy and cage implantation increased the spinal fusion and decreased symptomatic morbidity, and thus further proved the above conclusion (Majd *et al.* 1999; Samandouras *et al.* 2001; Thalgott *et al.* 2003; Sevki *et al.* 2004; Soderlund *et al.* 2004). However, the optimal stability of the spine construct for a successful solid fusion is still not known. Future works of the FE study could be directed to the optimization of the construct stability with regard to the solid fusion.

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The stress magnitudes on the C6 superior endplate, cortical wall and cancellous core decreased after the instrumentation with the titanium ACP, compared with the cage alone construct. The mechanism of the change in stress can be illustrated in the schematic diagram of the stress shielding effect as shown in Figure 60. The axial compressive load applied on the top surface of C5 vertebra is F_0 . When there is only the cage inserted in the intervertebral space after discectomy, the majority of the F_0 will go through vertebra-cage-vertebra pathway as F_1 . In the case of ACP supplemented, ACP forms a strong rigid frame that spans the caged segment. As the majority of the load will go through by the pathway of screw-plate-screw as F_2 , leaving the bypassed

A. Cervical Segment with Cage

B. Caged Cervical Segment with ACP

Figure 60 Stress Shielding Effect of ACP Supplementation

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vertebra-cage-vertebra section less loaded ($F_1 < F'_1$). As stress is defined as the force per unit area upon which the force is applied, the stress within the ACP bypassed region will decrease.

The stress-shielding effect of the titanium ACP augmentation has significant clinical relevance. According to the Wolf's law which states that bone will degenerate as it is less stressed (White & Panjabi 1990), the titanium ACP bypassed bone region will develop implant-induced osteoporosis. As a result of osteoporosis, decrease of bone mineral density, loosening of screw fixation and even fracture of vertebrae would occur, leading to the need of revision surgery to fix the deformities. The symptom is even worse in the already osteoporotic patients and malignant loop of osteoporosis progress might happen. Therefore, clinicians have to be more cautious when applying a titanium ACP to a patient who is already osteoporotic.

PLLA is a member of the alpha-polyester family, which has gained more attention as a promising candidate of bioabsorbable material used for spinal implants recently (Vaccaro & Madigan 2002; Vaccaro *et al.* 2003). PLLA, based on the lactic acid monomer, has been shown to degrade uniformly with bone tissue, with its breakdown products incorporated in normal cellular, physiological and biochemical procedures. These end products have been proved to be biocompatible and tolerated with the host, with no immunogenic and mutagenic tendencies. As a stereoisomer of polylactides (PLA), PLLA possesses a half-life of 6 months, the slowest rate of degeneration among the alpha-polyester family (Vaccaro & Madigan 2002; Vaccaro *et al.* 2003).

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The comparable stabilizing effect of the PLLA ACP addition to the caged construct with that of the titanium ACP implies that the PLLA ACP could provide a similar role in maintaining the stability and function as load supporting device as the titanium ACP does. The rigid initial construct for the segment is necessitated for a successful fusion for a cervical spine. Although the PLLA ACP has almost the same stress-shielding effects immediately after the implantation as titanium ACP, PLLA has a unique bioabsorbable material property, which the metallic titanium ACP does not possess. In the long run, it could be predictable that the axial load would gradually shift the vertebra column as the PLLA implant steadily degrades into to carbon dioxide and water in the following 6 months, which will give sufficient time to allow activation of the bone formation process, including inflammation, chondrocyte, and calcification and remodeling (Vaccaro & Madigan 2002; Vaccaro *et al.* 2003). The change in load transfer again can be illustrated in Figure 60. As the plate screw system has been changed to PLLA, degradation of the system takes place, F'_1 would become larger and F_2 get smaller. Dynamization of the axial load to the vertebra column would aid the fusion maturation and ensure a high quality bone between the two vertebrae. A clinical study done by Vaccaro *et al.* (2002) on use of PLLA ACP in the treatment of cervical degenerative and traumatic disc disruption supported the current prediction. The results showed that 77% of the patients were found to have radiographically solid fusion. No significant complication was clinically or radiographically noted in any of the patients.

The application of PLLA ACP in spinal fusion is promising because of its various advantages that the metal implant does not possess. However, as detailed variation of the axial load among the vertebral column and the degradation of the PLLA implant during the fusion maturation is not known, the temporal course of the load

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transition and stress change within the spinal construct could be a focus as the future study with an attempt to shed new light on the bioabsorbable implant augmented spinal construct.

6.4 SUMMARY

The objective of this chapter was to analyse the internal biomechanical influences of the titanium and PLLA ACP augmentation on the caged C5-C6 segment. A 3D FE model of caged C5-C6 with a constrained ACP supplementary fixation was simulated. Internal parameters of the titanium and PLLA ACP, such as the maximum compressive displacement and its component displacements in three directions in global Cartesian system, the maximum von Mises stress on the C6 superior endplate, the maximum von Mises stress in the cortical wall and the cancellous core at the level immediately inferior to the superior screws, contact stress at the interface between the cage and the C6 superior endplate were analysed and compared with those in the C5-C6 model implanted with cage alone.

The results showed that the titanium and PLLA ACPs greatly reduced the maximum compressive displacement and their vertical component; the maximum von Mises stress on the C6 superior endplate, the maximum von Mises stress in the cortical wall and cancellous core at the level immediately inferior to the superior screws were also greatly decreased. The maximum contact pressures at the interfaces between the cage and the C6 superior endplate for titanium and PLLA plate were respectively reduced by 82.29% and 80.12% of the magnitude in the cage alone segment.

The clinical relevance of the study is that both the titanium and PLLA ACPs can provide sufficient initial rigidity which is needed for the fusion maturation. More

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caution has to be paid to the complication induced by the stress shielding effect of the titanium implant due to its high rigidity compared to the bone material. On the other hand, the PLLA absorbable ACP can have a stabilizing ability at the initial stage of implantation comparable to the titanium ACP. With the consideration of its unique bioabsorbability, the PLLA ACP would introduce the dynamization of the axial load to the vertebral column in the later stage and promise a more successful fusion rate and low clinical complication.

CHAPTER 7 CONCLUSIONS

The current project was initiated to optimize and analyze the cervical ring cage using finite element method with the attempt to provide useful information for clinical practice in spine field. As a first step, an anatomically detailed finite element model of the lower cervical spine segment was developed and validated to lay the ground work for further biomechanical analysis. Then, the optimal design and material of the cervical ring cage with the lowest risk of subsidence into the vertebral endplate were determined using Taguchi method. The biomechanical changes of the cervical segment after cage implantation were subsequently investigated under normal and osteoporotic vertebral condition. Lastly, the stiffnesses and biomechanical behaviors of the caged segment supplemented with anterior cervical plates were predicted.

The development of the anatomically detailed C5-C6 FE model began with the acquisition of 3D coordinates of the embalmed human cervical vertebrae using high-definition digitizer. The developed C5-C6 FE model was then validated with in vitro experiment done by Panjabi *et al.* (2001). The predicted range of motion of the FE model was 3.34° for flexion; 4.13° for extension; 7.44° for lateral bending; 4.00° for axial rotation, which were in a good agreement with the results of the *in vitro* experiment. Thus, the developed C5-C6 FE model can be regarded as a good approximation of a real human cervical spine and used with confidence for further biomechanical analyses.

The adoption of the Taguchi philosophy as the method for cage optimization has greatly enhanced the efficiency of the analysis with a limited number of runs. The optimal set of the cage design configuration and material to have the lowest risk of

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subsidence into the endplate is Polyetheretherketone for cage material, 18 mm for cage width, 16 mm for cage depth and 4 mm for cage thickness. The most influential factors on the endplate stresses are the width of the cage (77.0%), followed by depth (14.3%) and wall thickness (6.9%). The contribution of the implant materials is minimal. The cage optimization result provides a guideline for decision-making on which factors of the cage to be considered with priority in clinics.

The analyses of biomechanical behavior of the C5-C6 segment with normal vertebrae after cervical ring cage insertion have shown that the cervical ring cage concentrated stresses at the posterior 1/3 of the C6 superior endplate, leaving most of the anterior portion less stressed. The maximum von Mises stress produced by cervical cage insertion was 1.28 MPa. Similarly, the peak value of compressive displacement of C6 superior endplate also occurred at the posterior 1/3 of the superior endplate with a magnitude of 11.44 μm . When the vertebrae became osteoporotic, the cervical ring cage exhibited a different effect on the caged segment compared with normal vertebrae. The maximum von Mises stress on the C6 superior endplate increased by 83.59%, while the maximum compressive displacement on the superior endplate increased by 131.99%. The results imply that cage implantation is at a higher risk of subsidence into the endplate in the osteoporotic vertebrae than in the normal cervical spine, and clinicians should pay more attention to the aggravation of the existing osteoporosis due to the long term stress shielding effect of the cage on the vertebrae.

The biomechanical effects of anterior cervical plates (ACP) of titanium and PLLA materials on the caged segments were investigated in terms of construct stiffness and stress distribution. The locations of maximum displacements in the cage only

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model, cage with titanium ACP model and cage with PLLA ACP model are all at the apex of C5 posterior process. The ACP supplementation greatly decreased the value of maximum displacement from 103.29 μm in cage only model to 3.528 μm in cage with titanium ACP model and 4.232 μm in cage with PLLA ACP model. The addition of ACP also greatly reduced the compressive displacement of the C6 superior endplate along the midsagittal plane. The maximum von Mises stress on C6 superior endplate were reduced from 1.279 MPa in cage only model to 0.062 MPa in cage with titanium ACP model and 0.065 MPa in cage with PLLA ACP model. The maximum von Mises stresses in the cortical wall and cancellous core at the level immediately inferior to the superior screws were also reduced from 2.471 MPa and 1.178 MPa in cage only model to 0.112 MPa and 0.046 MPa in cage with titanium ACP model, and to 0.115 MPa and 0.051 MPa in cage with PLLA ACP model, respectively. The clinical relevance of the results is that ACP supplementation can provide sufficient initial rigidity which is needed for the fusion maturation but their stress shielding effect can not be neglected. The absorbable PLLA ACP has a comparable stabilizing effect to that of the titanium ACP, thus provides a similar role in maintaining the construct stiffness and function as load supporting device. PLLA ACP is more recommended for spinal fixation in clinics due to its unique bioabsorbable property without any complications from the stress shielding effect.

In conclusion, the research objectives of the current project are well met with the above detailed analysis. More light is shed on the biomechanics of the cervical ring cage as an implant for cervical spine disorders and useful information is extracted for the future design, development and clinical application of the cervical ring cage.

CHAPTER 8 LIMITATIONS AND RECOMMENDATIONS

8.1 LIMITATIONS OF CURRENT STUDY

Although the current FE study has extracted various useful facts on the biomechanics of cervical spine constructs, there are some limitations and restrictions in the results presented.

8.1.1 Validation of FE Model

Although the range of the FE model validation included the external response and internal changes of the segment, the data for the comparison were previous *in vitro* experiments in the literature. The age, material properties, and volume of the specimen would be different from the one on which the current FE model was developed. So differences in the FE prediction and experimental tests inevitably exist. The ideal case would be to use a cadaveric segment to determine the material properties of bony and ligamentous structures. Then use the same cadaveric specimen to get geometry data of the FE model. This would produce an advantage of a greater anatomical and mechanical resemblance of the generated FE model with the original spinal segment. However, more accurate predictions would not be produced because of the variability of biological tissues. And the material properties of the specific specimen would have to be determined through *in vitro* experiment, which would require specialized equipment and additional time to measure the material properties of cortical bone, cancellous, discs and all the ligaments. This would be much beyond the scope of the current study.

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8.1.2 Assignment of Material Properties

The assignment of linear, isotropic and homogeneous material properties to various structures in C5-C6 segment is an apparent limitation in the current FE model. It is well known that material nonlinearities, anisotropy and inhomogeneity are prevalent in spine structures. The discrepancy in materials between the FE model and a real specimen could produce some bias to the results. The introduction of slackness of the ligaments and nonlinear contact elements for the articulation, together with the geometrical nonlinearity, were adopted in the current model for the purpose of minimizing the bias as much as possible. Inclusion of more nonlinear, inhomogeneous and anisotropic materials for future FE models could be done when more data on these parameters becomes available.

8.1.3 Simulation of Soft Tissue

In the current model, only ligaments were simulated in the intact C5-C6 segment while various muscles were not taken into account due to the small amount of information available on muscle force magnitudes for most cervical activities. In addition, the pretension caused by the cage insertion was not included in the current model. It has been known that muscle forces have an important influence on the mechanical behavior of the human spine (Panjabi 1998; Quint *et al.* 1998; Zander *et al.* 2001) and the tensioning of the ligament and muscles will be caused by cage insertion in the intervertebral space according to the “distraction-compression” concept (Bagby 1988). So these drawbacks constitute additional limitations in the current study.

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Therefore, the current cervical spine FE model is best treated as a simple approximation of the *in vivo* human cervical spine rather than its exact copy due to the complexity and variability of the biological issues. In light of this, the predicted results obtained from the current FE model are best interpreted as a trend rather than absolute mathematical values. The FE method would be better regarded as a complementary investigating tool to extract information that other experimental methods can not easily accomplish, instead of as a complete replacement of *in vivo* and *in vitro* biomechanical testing.

8.2 RECOMMENDATIONS FOR FUTURE WORK

Plenty of research areas in cervical spine biomechanics including the physiological behaviours, pathological changes, iatrogenic disorders and therapeutic regimes have not been well documented yet (Goel & Pope 1995; Yoganandan *et al.* 1996a; Panjabi 1998; Weiner & Fraser 1998; Wilke *et al.* 1998; Steffen *et al.* 2000b; Vaccaro *et al.* 2003; Zdeblick & Phillips 2003). Since the FE method has its unique strength in spine biomechanics, future studies could be conducted based on the current model.

8.2.1 Improvement of Material Properties

Because nonlinearity, anisotropy and inhomogeneity is prevalent in biological tissue, the current model is somehow limited by its inclusion of linear, isotropic and homogeneous materials. To make the current model represent a more realistic situation of the cervical spine, the detailed material properties could be assigned to intervertebral disc, ligaments, endplate, cancellous core and cortical wall.

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Simulation of the osteoporosis in vertebrae can be further detailed. Osteoporosis is a systemic change in musculoskeletal tissue, including cancellous core, cortical wall, intervertebral disc and ligaments (Margulies *et al.* 1996; Buckwalter 1995; Keller *et al.* 1990; Keaveny & Yeh 2002). The material and structural changes could be incorporated in the future FE model in order to delineate the complex effects of these variations in material and structures.

8.2.2 Simulation of Temporal Course

Bone as a living tissue is under constant remodeling process to adapt to the mechanical stress loaded on it during daily activity. The addition of implants apparently interferes with the physiological bone metabolism. The effects of the augmentation with the implant on intersegmental fusion are likely to change over time after surgery. Therefore, the influence of the instrumentation on the biomechanics of the cervical spine along the temporal course could be further studied by incorporating the time-dependent material properties into the vertebrae and the connective tissues of the current model.

8.2.3 Inclusion of Paraspinal Muscles

The skeletal muscles in the spine are classified into two types: the local and the global system. The local system consists of muscles with insertion or origin (or both) at cervical vertebrae, whereas the global system consists of muscles with origin on other parts of the body bony structures (Williams *et al.* 1989; Marieb & Mallatt 1997). From the mechanical point of view, paraspinal muscles comprise the active components in the highly complex spinal system (Bergmark 1989). They have a significant influence on the biomechanical behavior of the

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spine in maintaining posture and responding to the applied loads and even shield parts of the spinal implant from the loads (Zander et al. 2001). Therefore, inclusion of local muscles (multifidus muscles) and global muscles (erector spinae muscles) in the future model could provide a more accurate analysis of the biomechanics of the cervical spine and implant instrumentation.

8.2.4 Development of C3-C7 Model

Although the current C5-C6 FE model based on spinal segments representing regional characteristics of the spine can provide much information on the intrinsic biomechanics of the cervical spine and its instrumentation, the influence of the implants on the adjacent upper and lower intervertebral discs and vertebrae can not be investigated using the current single segment model.

Further, the fusion with the cage and ACP for two or more segments is often used in clinics (Bose 1998; Hwang *et al.* 2004; Majd *et al.* 1999; Sevki *et al.* 2004). The clinical fusion rate is far lower for the multi-segmental fusion than one segmental fusion due to the difference in fusion procedures for multi-segments and one segment. The biomechanics of the ACP spanning more than one segment should be studied in the future with an attempt to investigate the mechanical cause for the lower fusion rate and achieve a better long term clinical result.

Hence, a logical extension of the current study is to develop a multi-segment model including C3 and C7 constituting a whole lower cervical spine for a complete picture of the biomechanics in the intact and instrumented lower cervical spine. The project of building a C3-C7 multi-segment model and

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analyzing its relevant clinical issue in the lower cervical spine is now being undertaken.

With the aforementioned advances in the depth and scope for the current study, it is hoped that the biomechanical milieu of the lower cervical spine and its interplay with the implant during the fusion processes could be more clearly delineated, and the knowledge gained could serve as guidelines for the clinical work to ensure an effective and safe treatment for the patients with spinal disorder.

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Appendix A

APPENDIX A F-TABLE FOR ANOVA TEST

The lower percentage points of the distribution may be obtained from the relation:-

$$F_{1-\alpha; \nu_1, \nu_2} = 1/F_{\alpha; \nu_2, \nu_1}$$

e.g. $F_{.95; 12, 8} = 1/F_{.05; 8, 12} = 1/2.85 = 0.351$

$\nu_2 \backslash \nu_1$	1	2	3	4	5	6	7	8	10	12	24	∞
1	161.4 (648) 4052 4053*	199.5 (800) 5000 5000*	215.7 (864) 5403 5404*	224.6 (900) 5625 5625*	230.2 (922) 5764 5764*	234.0 (937) 5859 5859*	236.8 (948) 5928 5929*	238.9 (957) 5981 5981*	241.9 (969) 6056 6056*	243.9 (977) 6106 6107*	249.0 (997) 6235 6235*	254.3 (1018) 6366 6366*
2	18.5 (38.5) 98.5 998.5	19.0 (39.0) 99.0 999.0	19.2 (39.2) 99.2 999.2	19.2 (39.2) 99.2 999.2	19.3 (39.3) 99.3 999.3	19.3 (39.3) 99.3 999.3	19.4 (39.4) 99.4 999.4	19.4 (39.4) 99.4 999.4	19.4 (39.4) 99.4 999.4	19.4 (39.4) 99.4 999.4	19.5 (39.5) 99.5 999.5	19.5 (39.5) 99.5 999.5
3	10.13 (17.4) 34.1 167.0	9.55 (16.0) 30.8 148.5	9.28 (15.4) 29.5 141.1	9.12 (15.1) 28.7 137.1	9.01 (14.9) 28.2 134.6	8.94 (14.7) 27.9 132.8	8.89 (14.6) 27.7 131.5	8.85 (14.5) 27.5 130.6	8.79 (14.4) 27.2 129.2	8.74 (14.3) 27.1 128.3	8.64 (14.1) 26.6 125.9	8.53 (13.9) 26.1 123.5
4	7.71 (12.22) 21.2 74.14	6.94 (10.65) 18.0 61.25	6.59 (9.98) 16.7 56.18	6.39 (9.60) 16.0 53.44	6.26 (9.36) 15.5 51.71	6.16 (9.20) 15.2 50.53	6.09 (9.07) 15.0 49.66	6.04 (8.98) 14.8 49.00	5.96 (8.84) 14.5 48.05	5.91 (8.75) 14.4 47.41	5.77 (8.51) 13.9 45.77	5.63 (8.26) 13.5 44.05
5	6.61 (10.01) 16.26 47.18	5.79 (8.43) 13.27 37.12	5.41 (7.76) 12.06 33.20	5.19 (7.39) 11.39 31.09	5.05 (7.15) 10.97 29.75	4.95 (6.98) 10.67 28.83	4.88 (6.85) 10.46 28.16	4.82 (6.76) 10.29 27.65	4.74 (6.62) 10.05 26.92	4.68 (6.52) 9.89 26.42	4.53 (6.28) 9.47 25.14	4.36 (6.02) 9.02 23.79
6	5.99 (8.81) 13.74 35.51	5.14 (7.26) 10.92 27.00	4.76 (6.60) 9.78 23.70	4.53 (6.23) 9.15 21.92	4.39 (5.99) 8.75 20.80	4.28 (5.82) 8.47 20.03	4.21 (5.70) 8.26 19.46	4.15 (5.60) 8.10 19.03	4.06 (5.46) 7.87 18.41	4.00 (5.37) 7.72 17.99	3.84 (5.12) 7.31 16.90	3.67 (4.85) 6.88 15.75
7	5.59 (8.07) 12.25 29.25	4.74 (6.54) 9.55 21.69	4.35 (5.89) 8.45 18.77	4.12 (5.52) 7.85 17.20	3.97 (5.29) 7.46 16.21	3.87 (5.12) 7.19 15.52	3.79 (4.99) 6.99 15.02	3.73 (4.90) 6.84 14.63	3.64 (4.76) 6.62 14.08	3.57 (4.67) 6.47 13.71	3.41 (4.42) 6.07 12.73	3.23 (4.14) 5.65 11.70
8	5.32 (7.57) 11.26 25.42	4.46 (6.06) 8.65 18.49	4.07 (5.42) 7.59 15.83	3.84 (5.05) 7.01 14.39	3.69 (4.82) 6.63 13.48	3.58 (4.65) 6.37 12.86	3.50 (4.53) 6.18 12.40	3.44 (4.43) 6.03 12.05	3.35 (4.30) 5.81 11.54	3.28 (4.20) 5.67 11.19	3.12 (3.95) 5.28 10.30	2.93 (3.67) 4.86 9.34
9	5.12 (7.21) 10.56 22.86	4.26 (5.71) 8.02 16.39	3.86 (5.08) 6.99 13.90	3.63 (4.72) 6.42 12.56	3.48 (4.48) 6.06 11.71	3.37 (4.32) 5.80 11.13	3.29 (4.20) 5.61 10.69	3.23 (4.10) 5.47 10.37	3.14 (3.96) 5.26 9.87	3.07 (3.87) 5.11 9.57	2.90 (3.61) 4.73 8.72	2.71 (3.33) 4.31 7.81
10	4.96 (6.94) 10.04 21.04	4.10 (5.46) 7.56 14.91	3.71 (4.83) 6.55 12.55	3.48 (4.47) 5.99 11.28	3.33 (4.24) 5.64 10.48	3.22 (4.07) 5.39 9.93	3.14 (3.95) 5.20 9.52	3.07 (3.85) 5.06 9.20	2.98 (3.72) 4.85 8.74	2.91 (3.62) 4.71 8.44	2.74 (3.37) 4.33 7.64	2.54 (3.08) 3.91 6.76
11	4.84 (6.72) 9.65 19.69	3.98 (5.26) 7.21 13.81	3.59 (4.63) 6.22 11.56	3.36 (4.28) 5.67 10.35	3.20 (4.04) 5.32 9.58	3.09 (3.88) 5.07 9.05	3.01 (3.76) 4.89 8.66	2.95 (3.66) 4.74 8.35	2.85 (3.53) 4.54 7.92	2.79 (3.43) 4.40 7.63	2.61 (3.17) 4.02 6.85	2.40 (2.88) 3.60 6.00
12	4.75 (6.55) 9.33 18.64	3.89 (5.10) 6.93 12.97	3.49 (4.47) 5.95 10.80	3.26 (4.12) 5.41 9.63	3.11 (3.89) 5.06 8.89	3.00 (3.73) 4.82 8.38	2.91 (3.61) 4.64 8.00	2.85 (3.51) 4.50 7.71	2.75 (3.37) 4.30 7.29	2.69 (3.28) 4.16 7.00	2.51 (3.02) 3.78 6.25	2.30 (2.72) 3.36 5.42
13	4.67 (6.41) 9.07 17.82	3.81 (4.97) 6.70 12.31	3.41 (4.35) 5.74 10.21	3.18 (4.00) 5.21 9.07	3.03 (3.77) 4.86 8.35	2.92 (3.60) 4.62 7.86	2.83 (3.48) 4.44 7.49	2.77 (3.39) 4.30 7.21	2.67 (3.25) 4.10 6.80	2.60 (3.15) 3.96 6.52	2.42 (2.89) 3.59 5.78	2.21 (2.60) 3.17 4.97