TOPOLOGY OPTIMIZATION OF SPINAL INTERBODY CAGE FOR REDUCING STRESS SHIELDING EFFECT

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FE	:	Finite Element
FEA	:	Finite Element Analysis
CT	:	Computer Tomography
MRI	:	Magnetic Resonance Imaging
PLIF	:	Posterior Lumbar Interbody Fusion
ALIF	:	Aosterior Lumbar Interbody Fusion
BMD	:	Bone Mineral Density
DXA	:	Dual-energy X-ray absorptionmetric
Ti	:	Titanium
PEEK	:	Polyetheretherketone
IGES	:	Initial Graphics Exchange Specification (file format)
SIMP	:	Soid Isotropid Material with Penalization
PLLA	:	Poly L-Lactic Acid

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GLOSSARY

Osteoporosis	: Bone mircroarchitecture is disrupted and it reduces the bone mineral density
Spinal fusion	: Formation of bridging vertebrae
L4	: The forth short bone of Lumbar segment
L5	: The fifth short bone of Lumbar segment
Dissect	: Disassemble the organ or component inside body or structure
Physiology	: The normal function of living organism
Lordotic	: The inward curve pattern of spine segment
Proteoglcan	: A compound consist of protein which normally encouterred in spinal disc.
Neurapraxia	: The nerve injury where the sensory is weaken or lost.

PENGOPTIMUMAN TOPOLOGI SANGKAR ANTARA SPINA UNTUK MENGURANGKAN KESAN PEMERISAIAN TEGASAN

ABSTRAK

Kemerosotan atau kerosakan ceper antara vertebra yang disebabkan daripada kecederaan secara akut atau kronik akan menghasilkan ketidakstabilan struktur spina. Ketidakstabilan struktur spina ini boleh diselesaikan melalui rawatan pembedahan, penyambungan spina di mana sangkar implan dipasangkan ke dalam ruang kerosakan ceper intervertebra untuk menggalakkan pertumbuhan tulang dan seterusnya, membentukkan penyambungan vertebra. Seterusnya, konfigurasi penyambungan antara vertebra bersebelahan dapat menstabilkan struktur spina.

Kemajuan pertumbuhan tulang amat bergantung kepada magnitud tegasan yang terhasil pada tulang. Dengan sedemikian, sebahagian daya yang tersimpan oleh implan itu patut diminimumkan dan seterusnya mengurangkan kesan pemerisaian tegasan pada tulang. Dengan memanipulasikan teori komposit, faktor isipadu dan modulus Young implan memberikan kesan terhadap hadangan tegasan pada tulang. Untuk menilai kesan faktor-faktor tersebut terhadap hadangan tegasan, segmen separuh spina yang terdiri daripada dua vertebra yang sama dipasangkan dengan satu implan yang berbentuk segi empat telah dihasilkan. Dengan mengurangkan isipadu implan, tegasan pada verterbra atas dan vertebra bawah telah bertambah sepadan dengan pengkukuhan segmen di bawah daya mampatan 0.31 MPa. Sebaliknya, penukaran bahan implan (modulus Young) menghasilkan hadangan tegasan yang hampir sama.

Satu L4-L5 segmen model telah dihasilkan dan ia dibandingkan dengan keputusan yang telah diterbit (Shirazi, 1994, Panjabi, 1977) untuk pengesahan. Segmen spina yang disah itu dipasang dengan sepasang implan sangkar dan segmen tersebut dikenakan dengan lima pasang daya otot-otot spina. Kaedah pengoptimuman topologi digunakan untuk mengoptimumkan implan sangkar supaya mengurangkan kesan pemerisaian. Tujuan pengoptimuman adalah memaksimakan ketegaran implan sementara isipadu implan dikurang sebanyak 30% hingga 80% daripada isipadu implan asal. Rekabentuk baru telah dihasilkan berdasarkan kepada penyelesaian isipadu yang berkurangan sebanyak 70%. Perbandingan rekabentuk baru dengan sangkar Saber cage menunjukkan pengaruh dalam pengurangan hadangan tegasan dengan menghasilkan tegasan yang lebih tinggi dengan nilai tegasan minimum masing-masing 17.10%, 18.11% dan 18.43% pada badan vertebra bagi pergerakan bengkok hadapan-belakang, bengkok sisi dan putaran paksi. Tiga rekabentuk yang bergeometri sama dengan bahan PEEK, Titanium dan cortical menghasilkan magnitud tegasan yang hampir sama di dalam vertebra dalam semua pergerakkan badan walaupun modulus Young Titanium (110 000 MPa) adalah jauh lebih besar daripada PEEK (20 000 MPa) dan Cortical (17 000 MPa). Rekabentuk optimum yang berisipadu kurang daripada rekabentuk asal menunjukkan potensi untuk mengurangkan kesan pemerisaian tegasan.

TOPOLOGY OPTIMIZATION OF SPINAL INTERBODY CAGE FOR REDUCING STRESS SHIELDING EFFECT

ABSTRACT

Intervertebral disc degeneration or damage resulting from acute and chronic spinal injury induces the spine structure instability. The spinal structure instability can be resolved by surgical treatment, spinal fusion where the defected disc column is inserted with spinal cage implant to provoke the bony growth and thus, form the bridging vertebrae. Subsequently, the adjacent vertebrae fused configuration successfully stabilizes the structure of functional spine unit.

The bony growth progress is strongly base on the stress magnitude formed on the bone. Therefore, the partial load retained by the implant should be minimized and thus reduces the stress shielding effect to bone. By manipulating the composite theory, the factor of volume and Young Modulus of implant were encountered have influence to the stress shielding effect to the bone. For investigating the influence of the factors to stress shielding effect, a half two identical vertebrae segment model instrumented with a block shaped implant was developed. By reducing the implant volume, the stress of the superior and inferior vertebrae increased corresponding to the reducing segment stiffness under 301 MPa compression force. In contrast, the change of material (Young Modulus) produced the similar stress shielding effect.

A L4-L5 intact segment was developed and validated by comparing to the published result (Shirazi, 1994, Panjabi, 1977). The validated segment was instrumented with a pair of cage implant and it was imposed with five pairs of spinal muscles force. The topology optimization method was employed to optimize the cage for reducing the stress shielding effect. The optimization objective was to maximize the implant stiffness while constraining the volume

reduction from 30% to 80% from the initial implant volume. The new design base on 70% volume reduction solution has reduced the stress shielding effect by generating minimum 17.10%, 18.11% and 18.43% higher stress value in vertebrae body compared to Saber cage model in flexion-extension, lateral bending and axial rotation respectively. Three identical geometry new designs with PEEK, Titanium and cortical materials produced the similar stress magnitude in vertebrae in three phases of trunk movements even the Young Modulus of Titanium (110000 MPa) is larger than PEEK (20000 MPa) and cortical (17000 MPa). The optimized design with less volume compared with initial design showed the potential to reduce the stress shielding effect.

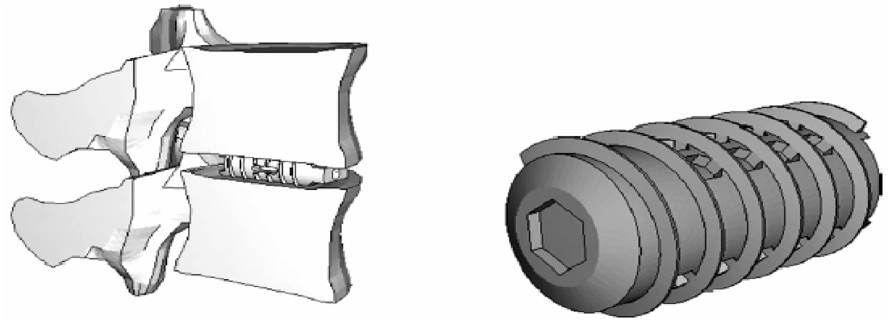
CHAPTER ONE
INTRODUCTION

1.0 Research Background

As human life progressing in period, human tissues experience the inevitable ageing and deforming process. The severe defected organ resulting from ageing and deforming process might need medical treatment or organ replacement by bionic artificial implant. The serious defection on skeletal joints especially at spinal disc, elbow joint and foot ankle joint are the common disease which the patient must receives the surgical operation. It is due to the lubricated medium in the skeletal joint is irreplaceable naturally after it wear out.

For investigating the bio-mechanical effect of implant on bone, three major research methods which are clinical approach, Finite Element Analysis (FEA) and experimental work are manipulated to observe and predict the performance of implant. Among these methods, FEA tool with numerical formulation poses advancement in predicting the long term bio-mechanic response in shorter period such as tissue remodeling process. In general, the application of FEA on human organ analysis could be done by importing the particular organ geometry point after the conversion of CT scan data by various graphic convertible softwares (CT scan data containing the image of the interest organ). It is followed by instituting the organ surfaces according to the geometry points and developing the solid model in FEA. Then, the solid model is discretized into small elements for simulation.

With the benefit of mathematical formulation offered by FEA, it becomes the preference tool for bio-mechanical researcher and surgeon to investigate the unknown medical treatment response. For spine disordered treatment, three dimensional medical diagnostic assessment tool embedded in advance FEA software provides better diagnostic view compared with the two dimension MRI image (Magnetic Resonance Imaging) at pre-operation and post-operation stages. Natural organ replacement by medical implant reveals a new dimension for solving human orthopedic diseases. The design of the implant strongly affects its role and performance in human body. For instance, the implantation of spinal disc



a) b)

Figure 1.1 a) Human vertebrae segment implanted with b) spinal implant (Fantigrossi et al., 2006).

allows trunk movement for the surgical vertebrae segment while interbody cage plays prominent role to stabilize the spine segment (Figure 1.1) by fusing the adjacent vertebrae with cancellous bone. The efficiency of spinal cage playing its role could be predicted by using FEA tool.

The motive of spinal cage implantation between vertebrae is to encourage the bony growth for occupying the dissected disc space and thus, stabilize the spinal segment structure in fusing configuration. The progressive level in promoting the new grafting bone between vertebrae is crucial for determining the length of compete arthrodesis period. Thus, the factors that contribute to the progress of bony growth should be defined and the progressive level could be enhanced mechanically by decreasing the stress shielding effect to vertebrae where higher stress generated at spinal bone body. In other words, serious stress shielding occurrence yields a condition where the applied load is retained and filtered by the implant and thus, less load quantity is transferred to bone. At the spinal post-operation period, the majority load resulted from the body weight, muscle forces and external force which are supposed to be transferred to the inferior vertebrae are shielded if poor designed interbody cage is inserted between intervertebral column. Thereby, the insufficiency of loading on bone induces the lost of bone tissue mass and vice versa.

For minimizing the stress shielding effect by the interbody cage, the softer cage design generates higher stress in vertebrae body and it induces better bony growth in the vertebrae disc space. The stiffness of interbody cage that influenced by the factors of the geometry and the assigned material are the primary considerations in reducing the risk of stress shielding effect. Even these two factors were known as stiffness dependent variables, some researches (Fantigrossi et al., 2006, Van Dijk et al., 2002) only advocated the stress shielding effect for individual factor rather than considering both factors in the researches.

Various implant geometries exhibit different stiffness for spine segment at the surgical post operation. The hollow spinal implant structure could produce the better stability and increase the bonny growth stimulus sufficiency (Lin et al., 2004). In contrast, the risk of stress shielding was predicted increased as the spinal segment was being instrumented with solid design. Nevertheless, the volume factor was never been considered and evaluated in spinal research.

The interbody cage which is able to contribute successful bony growth by generating the higher stress in the adjacent vertebrae should be the preference in cage selection for spinal fusion. The researches regarding the bony growth stimulus (Kim, 2001, Epari et al., 2005, Polikeit et al., 2002) in stress shielding issue also carried the same weight as important as the spine stability (Fantigrossi et al., 2006, Sengupta et al., 2002). The cage stiffness is affected by material property, the influence of different materials on the stress on human vertebrae body was rarely encountered in the published studies.

In numerous clinical follow up studies for interbody implant, several spinal cages fracture failures were exposed under MRI inspection. The interbody structures destruction needed surgery revision for removing the damaged implant from spine and implantation of new spinal cages were performed simultaneously in the same surgical operation. The cost consumed for surgery revision associated with this spinal disordered disease is enormous as the spinal fusion operation cases showed rapid increase from 148000 to 250000 in a decade from 1981 to 1990 (Rasmussen et al., 2001).

For vitro experimental spinal research (Smit et al., 2006), the MRI observation on the bony growth aggressive level is needed and it may take at least three years to reach the complete arthrodesis process. Therefore, the FE simulation work should be performed to predict the practical result such as cage failure and bony growth response in order to avoid the valuable research time wasted due to the incorrect practical research hypothesis. Furthermore, the finite element analysis incorporated with optimization procedure provides the enhancement of cage performance by generating the new optimized design from the existing interbody cage geometry.

By regarding the factors discussed above, neither the optimization on the spinal cage structure geometry nor the material are necessary to be carried out for improving stress quantity in the vertebrae while minimizing or maintaining the deformation severity on the interbody cage. Topology optimization could be utilized for generating an alternative cage the design as the solution to achieve the required improvements.

1.2 Objectives

An optimized interbody cage implant should serve as the buttressing structure while possessing the nature that enables better bony growth stimulation in the vacant space between surgical spinal segment after implantation. Thus, present research objectives are established as below:

1) To identify the factors contribute to the stress shielding problem.
2) To develop and validate a three dimension FE L4-L5 segment with intradiscal disc model.

3) To generate a new cage design by topology optimization with spinal muscle forces load and investigate the stress shielding effect of the optimized geometry by assigning three different medical materials to the new design for pre-implantation and post-implantation condition.

1.3 Thesis Scope

The presented thesis is served in six primary chapters which commenced with the introduction and follows by literature review, methodology and validation, topology optimization and result evaluation and conclusion. The first chapter has introduced briefly on the implant and stress shielding problem. The objective and the thesis outline are also included in this chapter.

In chapter two, the brief literature on basic structure of functional spinal unit and vertebrae are reviewed. The human natural degeneration issue and application of cage implant as surgical solution also had been discussed. Beyond the failure of spinal cage, the factors that influence the bony growth in dissected lumbar vacant space were evaluated in this chapter.

For chapter three, analytical analysis was performed to define the influenced factors of stress shielding effect and a simple three dimension half vertebrae segment was modeled to predict the observed the spinal segment stiffness and stress in L5 vertebrea.

In the chapter four, the modeling of 3D L4-L5 intact segment solid model and L4-L5 segment model instrumented with interbody cage model were constructed. The intact model was validated with published results while the segment instrumented with interbody model was simulated for obtaining the stress on the implant. The topology method was applied on the spinal cage in obtaining an optimized solution. Then, the optimization solution from ANSYS was taken as reference for modeling a new design. The new design was simulated under six body movements of flexion, extension, right-left lateral bending and right-left axial rotation.

In the fifth chapter, the outcomes from the simulations were plotted and the plotted results were evaluated corresponding to the prescribed objectives.

At the end of thesis, chapter six provides the conclusion and future works for the present study.

CHAPTER TWO
LITERATURE REVIEW

2.0 Overview

In this chapter, the introduction on the basic structure of functional spinal unit and vertebrae were review and it was followed by the coverage on the low back pain problem resulting from intervertebral disc degeneration. The surgical solution by the introduction of spinal cage implanted between spinal vertebrae was discussed. Beyond the review on the existing spinal implant failure, the factors of geometry features and the material that impinge spinal fusion healing or bone remodeling also presented in the following topic. The optimizations or enhancements on the spinal cage performance by previous researches were briefly evaluated at the end of this chapter.

2.1 Spine structure

Basically, a spinal structure is instituted by a series of spinal segments and spinal muscles which attached along the structure.

2.1.1 Functional spine unit

The human body physiology movement is facilitated by a functional spinal unit which consists of five primary segments where spinal muscles and nerves are attached on it. The first segment of the spine, Cervical is located at the posterior region of the human scull and it is connected by Thoracic, Lumbar, Sacrum and Coccyx segment. From the lateral plane of view (Figure 2.1), the spine forms convexity of Thoracic segment and concave curve at Lumbar segment. This curvature configuration is called lordotic curve.

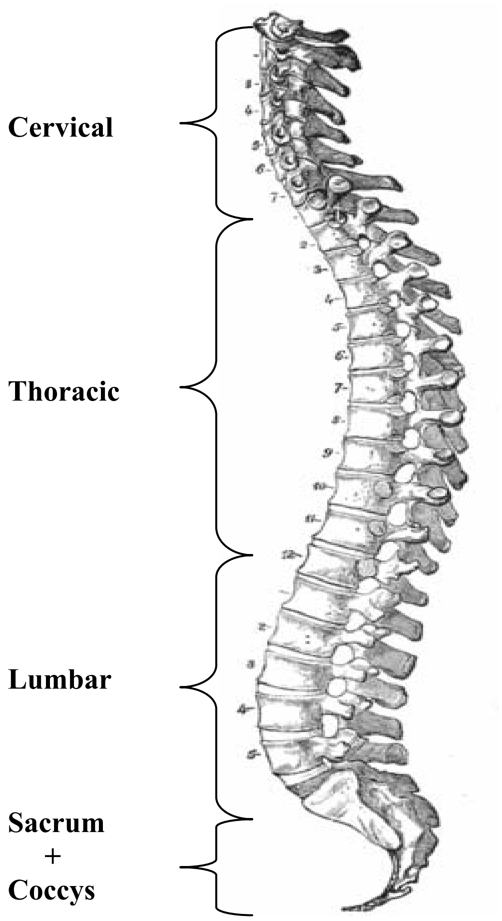


Figure 2.1 Functional Spine Unit (Wikipedia (a)).

These five segments are constituted by a series of 34 pieces of short bones called vertebrae. The female thoracic verterbrae dimensions are significantly smaller compared with the male short bone in thoracic segment (Liau et al., 2006).

2.1.2 Spinal muscle

A functional spine unit is supported by various muscles to stabilize the spinal structure and it is noted that muscle forces are utter important in influencing the loading on the spine. In Palm, 2002 and Polikeit, 2002 works, a pair of equal and opposite axial forces was applied on the L4 vertebrae to facilitate the trunk bending movement but these researchers disregarded the muscle forces which acting on the lumbar segment to counterbalance the unwanted vertebrae overbending and overflexing motion due to the activation of muscle force corresponding to the external load in the boundary condition (White and Panjabi, 1990). Figure 2.2 shows the back muscles of the spine.

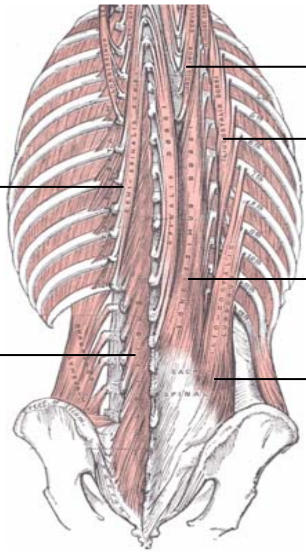


Figure 2.2 Back muscle of spine (Wikipedia (b)) .

Definition of two major groups of muscles force for flexion-extension was done by Rohlmann et al., 2005. With the validated lumbar segment FE model, erector muscle force showed linear increased in magnitude value from neutral position to 30 ˚ of flexing angle. Contrary to flexion, erectus muscle force decreased in extension phase. This research work failed to demonstrate the activation of erectus and rectus detail muscles such as Iliocostalisis and Longisismus muscles in the flexion and extension movements.

The research worked by Wilke et al., 1996, investigated the influence of five detail muscles on the intradiscal pressure. The lumbar segment was imposed with 3.75 Nm moment by a rotary motor and S1 was fixed in all degree of freedom. Ten cables represent five pairs of muscle were fixed at respective locations at L4 vertebrae while the other end of the cables were connected to pneumatic cylinder to facilitate the muscle force. The outcome from the experiment work inferred that multifidus muscle individually generated highest intradiscal pressure among all simulated muscles and the highest pressure, 0.39 MPa was created in all muscle activation condition. The static forces applied on the vertebrae was the limitation for this work as the physiology muscle force magnitude and direction should varying corresponding to the actual human body movement.

2.1.3 Vertebrae structure

Basically, an intact lumbar vertebrae structure (Figure 2.3) is constructed by vertebrae body, pedicle, lamina, process transverses, spinal process and facet. Figure 2.3(b) shows the cross section of the vertebrae body where the cancellous bone is surrounded by cortical. A pairs of pedicle and lamina components form an arch where the spinal nerves pass through the hollow vertebral canal. Besides, it serves as support for all the vertebrae processes that attach to it. On the other hand, superior and inferior facets play a role in restricting overbending and overflexing of spine by interbolocking with adjacent intervertebrae facet and thus, stabilize human body balance.

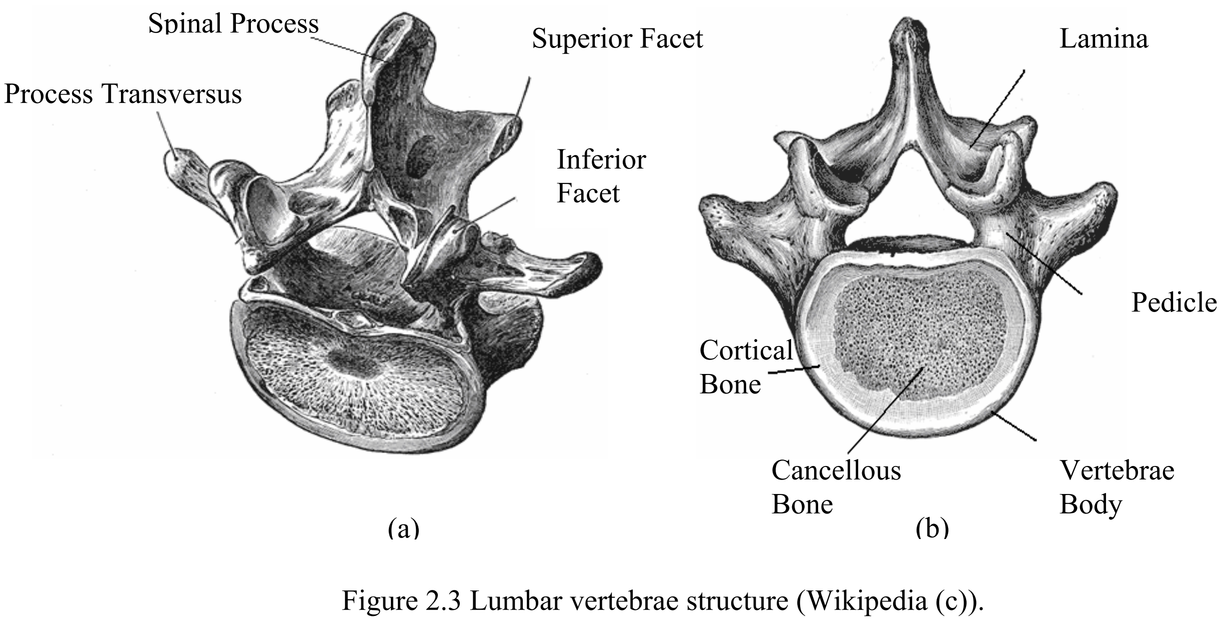


Figure 2.3 Lumbar vertebrae structure (Wikipedia (c)).

A thin layer of cartilaginous endplates is encountered attached on top and bottom surface of vertebrae body. Its perforated network configuration allows solution to return into disc without flowing into adjacent disc.

2.1.4 Spinal structure FE model development

As voluntary donation of spinal segment for research purpose is sparse, computer model instead of actual spine segment is utilized to predict the bio-response in simulation work. The spinal segment modeling technique could be developed in computer Finite Element Analysis (FEA). Nabhani and Wake, 2002, constructed a three dimensional L4-L5 segment FE model and analyzed the mechanical deformation on verterbrae. The geometry coordinates were collected by using probe where the data were registered according to vertebrae outer surface in slices configuration. After the conversion of coordinate data into FE software package, spline lines were build up to form vertebrae external surface. Then, the volume model was developed and discretized into smaller element. With the developed L4-L5 spinal FE simulation, the maximum stress was encountered occurred at pedicle region for vertebrae model with hollow shell, cancellous bone in core center and fully solid cortical bone. The value of stress at pedicle shows proportional relationship to the load imposed at superior facet.

For minimizing the three dimensional modeling time, Ochia et al., 2006, investigated spinal segment motion in six body movements by using advance software, Mimic Materialise which provides the interface between medical data between FEA. The Computer Tomography data (CT data) slices were imported and interpreted into solid spinal model. Extensive to FEA level, the software (Smartlouge, 2008) enables the better meshing assessment and it allows the assignment of material properties on the solid model.

2.1.5 Intervertebral Disc

In human natural spine, an intervertebral disc provides linkage between two vertebrae as showed in Figure 2.4. The presents of water content, Proteoglcans in invertebral disc enables the spine to absorb the shock from the external loading on the body.

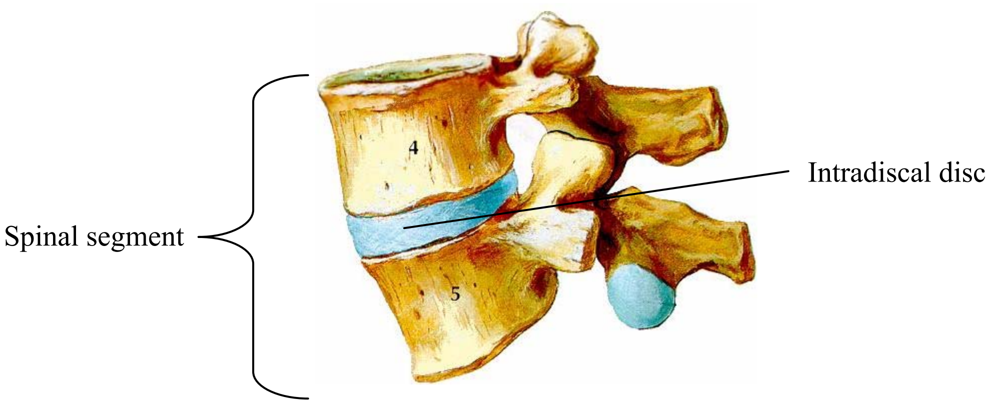


Figure 2.4 The intradiscal disc for lumbar segment (SpineService).

As the spine is being loaded, the highly hydrated disc performs its stress distribution nature on adjacent intervertebrae (Adams et al., 2000). As the load is being applied on interverrtebral disc, the water content is forced to flow out through endplate. In contrast, the Proteoglcans is attracted and pumped into the disc due to the lower pressure inside the disc boundary when load is being released (Joshi, 2004).

2.2 Disc degeneration

Major disc degeneration disease is resulted from the aging problem as the intervertebral disc experiencing the loss of water in nucleus (White and Panjabi, 1990). Ordinary, nucleus possesses 90% of water substance inside the disc and it gradually decreases to 70% or even less as age progressing in human life. Figure 2.5 illustrates the water contain in the discs of seventeen years old and fifty five year old persons.

Figure 2.5 a) Seventeen years old healthy spinal disc b) degenerated disc resulting from losing water content (Euro Spine, 2007).

The occupational mechanical loading on the lumbar segment also provokes the disc degeneration disease. The endplate failure due to the frequent posterior shear loading promotes several cartilage endplate fracture configurations (Gallagher et al, 2005) which might induce Proteoglcans leakage from disc component. Besides, superfluous body movement beyond the physiology angle limit increases the disc pressure leading to disc injury. The earlier researches encountered that the higher intradical pressure value approximate 1.00-1.04 MPa in spinal disc during performing sitting and and standing posture but these two movements were found not associated with low back pain problem where the lower pressure of 0.5-0.6 MPa in the spinal disc were recovered in later research (Claus et al., 2006). It was because of the apparatus sensitivity limitation in measuring the dynamic intradical pressure in the earlier researches.

Reduction in disc height associated with serious damaged of intervertebral disc decreases the feramona opening space. Subsequently, the compression on extended nerve roots from spinal canal occurs and the improper contact between adjacent facets generates the occurance of low back pain diseases .Therefore, restoration of disc height by inserting medical prosthetic between verterbrae paved the way in solving low back pain problem in 1980s.

2.3 Intervertebral disc replacement

Low back pain was reported as the common spinal disease in United Stated where 80 % of the citizen suffering from the musculoskeletal pain (America Academy of Physical Medicine and Rehabilitation). From year 1979-1981 to 1988-1990, the medical lumbar surgery treatment (fusion surgery) cases were boosted up more than 200% (from 18000 cases to 38000 cases) (Lee and Langrana , 2004) for solving the low back pain problem.

In the preliminary stage, a surgery alternative was introduced to overcome the low back pain problem by substituting the damaged disc with a natural human bone for sustaining the approximate original disc height. Posterior Lumbar Interbody Fusion (PLIF) and Anterior Lumbar Interbody Fusion (ALIF) are the two common surgical techniques for disc replacement operations.

For PLIF technique (Scoliosis Associate), the defected disc is approached by incision size of three to six inches long at the patient back. It is followed by retracting the muscle in order to access the surgical area. Lamina and facet are removed, defected disc is dissected and implant is inserted between the vertebrae. Contrary to PLIF, ALIF are performed at the lower abdomen where incision sized three to five inches cutting either at center or side region (Tsuji and Dawnson, 1991). Muscles and blood vessels are retracted and the surgeon able to approach and remove the disc. After the implant insertion in the vacated space, the fusion between adjacent vertebrae is facilitated.

In order to terminate the risk of neurapraxia in harvesting the allograft, the application of stainless interbody fusion medium was pioneered and popularized by Badgy, GW in 1988 (Steffen et al., 2000) to restore the disc height and compression on spinal nerve root could be avoided by the cage insertion. The insertion of the artificial interbody cage generated the successful fusion between adjacent vertebrae segment and it was reported and published the follow up work where fusions were developed in 91% of the operated patient after 24 months (Kuslich et al., 1998). In Kulich research work, he inferred that Anterior Lumbar Interbody Fusion (ALIF) procedure had the better fusion level than Posterior Lumbar Interbody Fusion (PLIF) procedure (Figure 2.6) in the two years follow up result.

Figure 2.6 Posterior Lumbar Interbody Fusion (PLIF) (American Academy of Physical Medicine and rehabilitation)

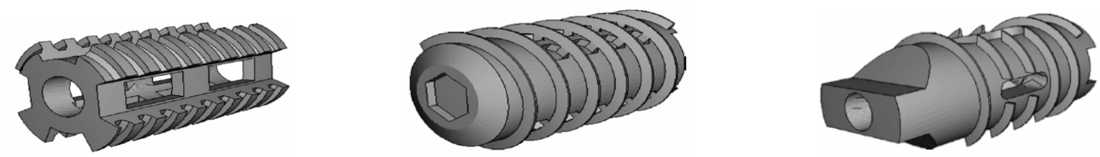
Generally, the cage is classified into two major categories according to its external geometry (Steffen et al., 2000). Cylinder cage and rectangular cage are the two common geometries for cage design.

2.3.1 Cylinder Cage

Cylinder cage is classified into two categories corresponding to its insertion configuration of horizon and vertical placement.

Figure 2.7 Harms cage (Vadapalli, 2004)

Harms cage (Figure 2.7), also called as Surgical Titanium cage, was designed in 1986. The vertical perforated cage design is to maximize the load transferred to graft material and maintaining the stability at thoracic and lumbar segment. This cage insertion is approached by using PLIF method and the installment of PLIF fixation device consist of screws, plates and angle ring which are required for mounting the surgical vertebrae. Seventy percent of the surgical vertebral body with Harm cage insertion was reported complete fusion at 2 years follow up (Wiesel et al., 2004).



a) BAK™ cage b) Interfix™ c)Interfix FLY™

Figure 2.8 Various cylinder cage designs (Fantigrossi et al., 2006).

BAK, Interfix and Interfix Fly (Figure 2.8 (a), (b) and (c)) are inserted parallel in pair in horizontal configuration in the lumbar region. The threaded configuration is designed around the external surface of its solid body. This configuration is designed to engage the implant with the superior and inferior surface of adjacent vertebrae for minimizing the migrant of spinal cage after implantation. Cylinder cage placement surgical procedure by milling on the endplate is required in order to serve good matching contact surface for implant and vertebrae. Verdict from Fantigrossi et al., 2006, FEA simulation work inferred that Interfly cylinder cage with less contact area of 185mm^2 compared BAK cage, 442.6 mm^2 produced high peak stress at several area on bone while BAK cage generated more uniform stress distribution.

2.3.2 Rectangular Cage

Rectangular cage could be designed in neither singular nor in pair configuration. Figure 2.9 illustrates few rectangular cages in the market. The lying bed preparation needs endplate removal to create the interface between bleed bone and grafting material inside the cage (Steffen et al., 2000). The larger space inside rectangular allows more occupancy of grafting material where it increases the chance of fusion. Thus, Zhong et al., 2006 tended to improve the cage design by removing the material and maximizing the inner space of LS-RF cage.

(a) LS-RF cage (b) Corin cage (b) Jaguar cage

Figure 2.9 Typical rectangular cage (a) LS-RF cage (Zhong et al., 2006)
(b) Corin cage (Sengupta et al., 2002) (c) Jaguar cage (Depuy Spine, Johnson-Johnson)

The tapered configuration of Corin cage is designed to maintain the lordosis angle at the surgical lumbar segment. Its large central open space enables more cancellous bone occupation in the cage. For both PLIF and ALIF procedures, the cage is inserted horizontally and it is being rotated by 90° to create the anchorage for the cage and bone.

Jaguar cage is the PEEK implant which its large perforated structure allows more cancellous bone filled inside the cage. The insertion of Jaguar cage by PLIF approach could be accessed at one or two level from L2-S1 with PLIF fixation devices. The teeth design on the top and the bottom cage surface provides the engagement function in order to avoid the cage migration.

2.4 Modeling of cancellous bone

According to the Culmann discovery on the change of bones structures (Wolff, 1986), the alteration on bone external shape modifies the stress quantity on bone resulted from the change of compression and tension acting direction on bone structure. Thus, the sudden change of structure provokes the new cancellous growth for the altered bone in order to adapt to the new environment. Therefore, no bony production at the region where no load is transferred meanwhile progression of initial new bone modeling occurs at the stress concentration area. It should be noted that the insufficient loading might induce disease of osteoporosis. Figure 2.10 visualizes the bony growth bridging L4-L5 vertebrae resulting from the increase of stress on bone after implantation (Kuslish et al., 1998). Due to the retention of disc, the stress at vertebrae is low and thus, no bone formation was encountered between L3-L4 segment.

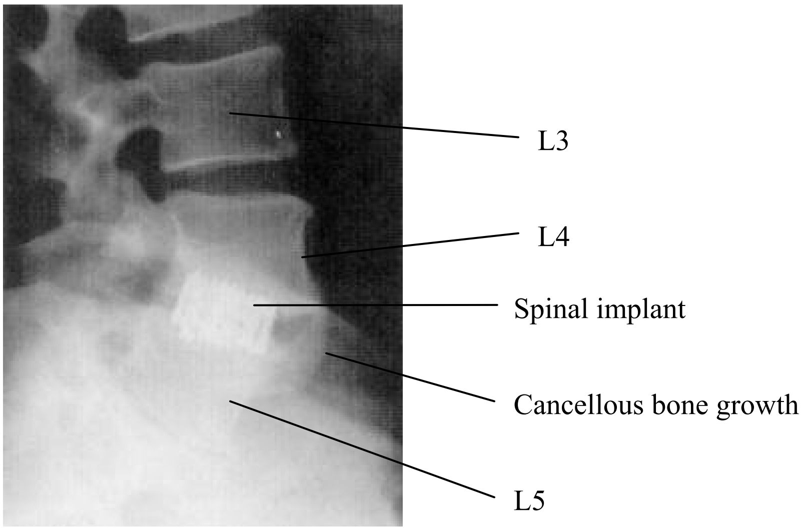


Figure 2.10 Cancellous bone formation between L4-L5 (Kulish et al., 1998).

The new bone formation process is impinged by the deformed displacement of fibrocartilage tissue around the cage implant. Bone modeling process is initialized as the deformed displacement achieved 40μm (Lin et al., 2004). In contrast, the maximum motion, 150 μm of cage migration which proposed by Kim, leads to cease of bone promotion. The rate of lumbar fusion is strongly depending on the implanted cage stiffness. Spinal cage with lower stiffness value provides the better fusion rate for the operated spine segment (van Dijk et al., 2002).

The determination on bone remodeling level could be measured by in vivo Bone Mineral Density (BMD) value during therapy period. Generally, the patient BMD value is obtained by dual-energy X-ray absorptionmetric (DXA) in order to observe the bone promotion progress. Thereby, the decision making on surgery revision is strongly depend on BMD value but the reliability of DXA has been questioned and concerned recently (Bolotin,

2007) due to its methodology erroneous by scanning the additional substances such as fat and soft tissue in the region of interest.

2.5 Stress shielding

At post operation stage, the implant body lay closely and interface with the bone where load sharing situation exist (Epari et al., 2005) certain quantity amount of load is taken and retained in the implant. Thus, the initial load is being shared and reduced by the implant. Subsequently, lower stress is encountered in the bone. This load transfer scenario is called as stress shielding. Stress shielding occurs in composite which contains of different stiffness level of materials. Van Dijk et al., 2002, advocated that the softer implant stimulated the bony growth or interbody fusion in shorter period. Geometry and material are the key factors that influence the stiffness of implant.

2.5.1 Biomechanical analysis study on implant geometry

For analyzing the biomechanical behavior on vertebrae, Fantigrossi et al., 2006, utilized L4-L5 segment with two identical vertebrae to simulate the influence of implant geometry at vertebrae. Three different geometry titanium implants which are BAK, Interfix and Interfix Fly cage were instrumented into the spinal segment. Although BAK and Interfix Fly cage are cylinder cages, the softer implant, BAK cage showed lower potential in stress shielding effect by producing broader and higher stress in vertebrae body compared to the segment with Interfix Fly in neutral position as illustrated in Figure 2.11.

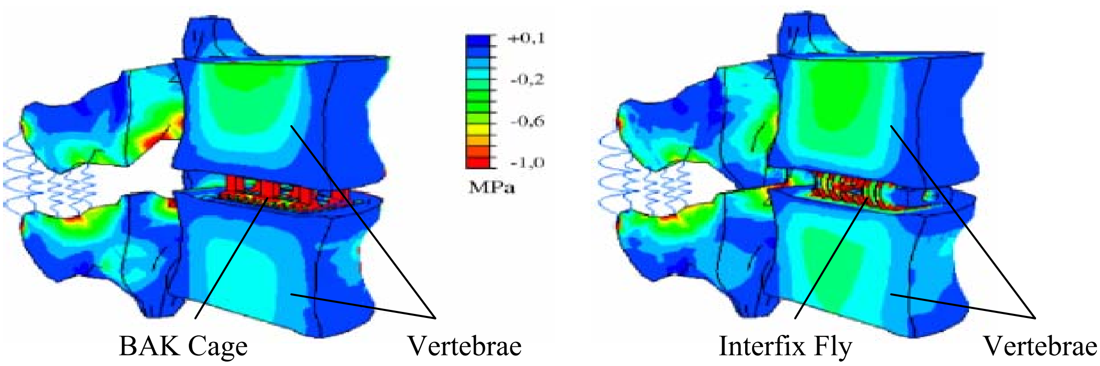


Figure 2.11 The higher stress in adjacent spinal segment instrumented with Interfix Fly compare with BAK cage (Fantigrossi et al., 2006).

Extensive work to investigate the spinal cage geometry effect in various trunk movements was carried out, Polikeit et al., 2002, constructed a two vertebrae segment FE model from slice data and it was inserted with a singular rectangular cage, Syncage (Mathys Medical Ltd. Bettlach, Switzerland). Differ from the cylinder cage (Interfix and Fly cage), this rectangular cage generated the lowest stress at central region of inferior vertebrae body. It is probably due to the lack of compression resulting from the larger inner space of singular rectangular design. In this work, the highest stress was found in flexion phase where it was 307% higher than intact condition.

Similar to Polikeit et al., 2002, work, Zhong et al., 2005 developed L1-L3 segment FE model and simulated the segment in four phases of body movements but the author inserted a pair configuration of rectangular cage, LS-RF cage into the spinal segment. The verdict from the result inferred that the maximum stress approximate to 1.25 MPa was generated at adjacent disc in lateral bending but it was only slightly higher than the stress in intact condition.

From the researches' discussions above, the workers tended to investigated the stress in spinal segment instrumented with either cylinder cage or rectangular cage. Owing to the lack of concurrent comparison for these two type of cages, Epari et al., 2005 performed the stress shielding analysis on bone graft by inserting the cylinder cage (Harm cage, Depuy-Acromed) and rectangular cage (Syn Cage-C, Synthes) into two dimensional spinal segment FE model. The strain of bone graft inside the cylinder cage is 0.066% higher than the rectangular cage. Thus, the cylinder cage with less rigidity decreases the stress shielding effect compared to the rectangular cage (Epari et al., 2005).

For both types of spinal cages, the teeth or thread configuration is design on the top-bottom or external surface of implant to anchor the interfaced bone. Kim, 2001 anticipated that the friction coefficient of the contact surface between the implant and the bone significantly effect the bone growth. The implant external surface design that induced high friction could lead to lower micromotion and stress magnitude on bone. It was concluded that friction coefficient has inverse relationship with stress generated on bone.

2.5.2 Biomechanical analysis study on implant material

Application of material on the interbody implant is crucial in determining the bone promotion progress during healing period. Due to the realization of material effect on bony growth, researchers focused on this study with FEA and clinical research.

As Palm et al., 2002, notified that the research concern on load transferred for spinal cage is sparse, the writer created a two dimensional cylinder cage-implant interface finite element model in order to observe the response of material effect of stress on bone under compression loading. The implant was assigned with material properties of stainless steel, titanium and cortical bone. The stress response along the circular cage-bone fully bounded interfaced line was observed. The difference of Young Modulus value for cortical bone (E = 17000 MPa) and stainless steel (E = 110 000 MPa) generated the similar stress magnitude at the bone-implant interface line. It inferred that the Young Modulus had not influence the stress shielding effect.

In order to understand the effect of material on bony growth in practical work, van Dijk et al., 2002, implanted three identical geometry spinal cages with Poly L-Lactic Acid (PLLA) and titanium material into Dutch milk goat. The clinical research outcome indicated that PLLA cage specimen has advancement in bony growth at the third month while the segment inserted with titanium showed slower cancellous bone growth at six month. The writer advocated that the softer cage accelerate the rate of lumbar fusion. Similar to van Dijk work, Smit et al., 2006, encountered that the PLLA prevailed over titanium material in fusion by using goat as specimen in the experiment work.

2.6 Failure of interfusion body after implantation

Undeniable, the stress quantity carried by the adjacent vertebrae body and the new bone construction progress are the primary concerns after the instrumentation of spinal cage but detail observation and attention also should be given to the deformation condition of the implant. For instance, Harm cage was reported to provide good initial stability for spine segment and excellent bony promotion during healing period (Epari et al., 2005), nevertheless, X-ray demonstrated the fracture sign at the middle section of Harm cage and decrease in intervertebral disc height in the clinical follow up (Zdenek et al., 2007).

BAK cage widely used as interfusion implant in lumbar segment and a lot of studies (Kuslish et al., 1998, Kuslish et al., 2000, Zhao et al., 2002) implied that the cage has high rates of radiograpgic fusion and low surgery revision rate at 1 % but the 4 years clinical follow up were done by the BAK cage designer, Kuslish S. between 1998 and 2000. For long term BAK observation, further clinical follow up (Button et al., 2004) was performed on the patient with BAK cage implantation after six years. In contrast, the research outcome reported the worst surgery revision figure as high as 22 % of the patient population. Thus, it strongly reflected that short term follow up on new cancellous promotion rate is not essential for BAK cage.

Since the 100% fusion rate between vertebrae by using Brantigan carbon fiber implant (AcroMed Cleveland, OH) to 28 patients were reported in clinical follow up in 1993, this material was widely used as interbody fusion prosthetic for lumbar segment. Even the success of the carbon fiber implant highlighted by Brantigan JW and Steffee AD in 1993, a scarce implant non-union failure case (Tycho, 1998) reported that a 44 years old man experienced the back pain and leg pain resulting from the breakage of the cage structure. Nevertheless, the author operated on approximate 100 patients and found no cage broken.

From the aspect of stress shielding effect and interbody implant deformation researches review, it was realized that the lack of bony growth at implanted segment and cage breakage led to cage failure. For solving these cage failure scenarios, various engineering optimization method were manipulated to enhance the performance of medical implant.

2.7 Structure Optimization

Following the stream of demanding a better performance on mechanical structure, various optimization methods were manipulated on the structure for fulfilling the consumer satisfactions. For instance, medical product especially implant prosthetic were highly concerned on enhancement of its bio mechanical performance in human body.

2.7.1 Structure optimization approaches

Sigmund, 2000, classified structure optimization into four major categories, sizing optimization, material optimization, shape optimization and topology optimization. Different beam structure problem as illustrated in Figure 2.12 was given as an example by the author for clarifying the optimization criteria for each method.

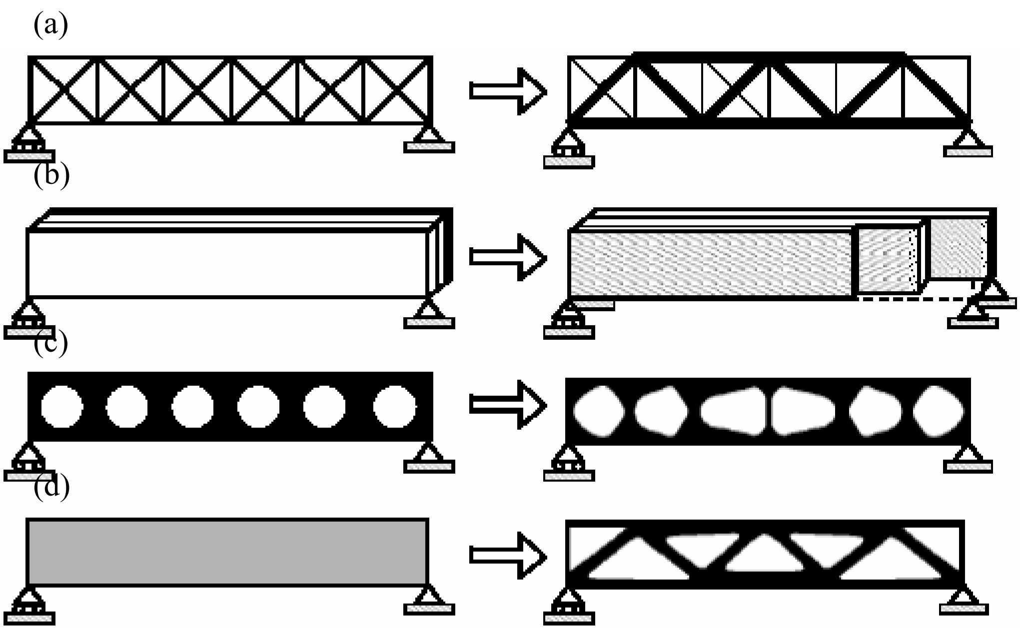


Figure 2.12 Four optimization methods (a) sizing optimization (b)material optimization (c) shape optimization (d) topology optimization (Sigmund, 2000).

In sizing optimization, the objective was to maximize structure stiffness by constraining on its weight while the cross section of the each beam was the design variable. This method solution in Figure 2.12 (a) provided eleven larger cross-section beams to form an optimized design with the prescribed optimizing condition. The optimized design of the structure could also be obtained by material optimization where the thickness of each compostite layer and the material orientation arrangement are the design variable. The structure with maximum stiffness generated the design as in Figure 2.12 (b). Generally, shape optimization is applied on the high concentration structure. The solution on the structure as in Figure 2.12 (c) by shape optimization generated the change of hole parameters where the circular holes were modified to three different shape of holes in the structure. Topology optimization is the efficient method to reduce the volume of the structure design with desired objective, constrain and design variable. The insufficient material inside the solid beam was removed and the final design is illustrated in Figure 2.12 (d).

2.7.2 Review of implant optimization

Shape optimization on implant prosthetic is common (Kayabasi and Ekici, 2007) for medical device but it is rarely found in the published work for spinal cage even the cage failures and stress shielding effect yielded the serious healthy consequence to patient after the interbody implantation.

By using topology optimization method, Zhong et al., 2006 reduced the cage volume as high as 36% from reference design while the optimized implant allows more bone graft constructed inside the cage. The new design not only saves the fabricating material but it also able to perform the similar biomechanical characteristic as reference cage. However, the author only focused on stress analysis on adjacent disc and no evaluation on load transfer between bone and implant.