

Biomechanical analysis of osteoporotic spines with diseases using CT-based finite element method

(CT 画像を利用した有限要素法による疾患を有する骨粗鬆症脊椎の生体力学解析)

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ABSTRACT

The eventuality of recurrent fractures on the adjacent level of fractured vertebra is becoming prevalent in this era. To date, the underlying cause of this phenomena is either due to low bone quality or adverse geometrical changes of the vertebral body, as a result of osteoporosis and vertebral compression fractures (VCFs). To further investigate the determinant factor of this phenomenon, an image based finite element analysis (FEA) was used to scrutinize the biomechanical response of spines that have been afflicted by different types of spinal deformities, namely; wedge-shaped, fish-shaped and plana-shaped vertebrae. The evaluation was made based on its structural integrity in accordance to stress and strain distributions, and fracture risks prediction. These findings were then further corroborated by evaluating other associating factors such as kyphotic deformity angle and bone density distribution in order to find the underlying cause of this symptom. The results showed that the low bone density due to osteoporosis has become the dominant factor in inciting the risks of subsequent fractures on the adjacent vertebrae. This is based on the contradictory relation between the number of the failure elements distributions and the degree of the kyphotic deformity angle, as described by the wedge-shaped vertebral fracture model. Obviously, the most highly structural deformed vertebra still could withstand any kinds of high input loads, provided that its structural formation is still intact and has not severely affected by osteoporosis.

The high incidence of subsequent fractures following Balloon Kyphoplasty (BKP) in both the augmented and adjacent vertebrae is quickly becoming a clinically unresolvable complication. The underlying cause of this phenomenon is still unknown and to date medical

practitioners are still unable to explain the fundamental cause of this phenomenon. To verify this claim, an image-based finite element analysis was used to investigate the effectiveness of BKP treatment of pre-operative and post-operative osteoporotic spine models. The three-dimensional (3D) non-linear finite element (FE) models of the thoracolumbar spine (T11-L3) were developed from CT-scan images. The biomechanical responses were evaluated based on the models' load sharing mechanisms, load transfer mechanisms, stiffness recovery, stability, and kyphotic deformity restoration. The margin of safety for each of the models was evaluated under incrementally increased loads (1-10kN). This margin would be determined based on the fracture risk evaluation in accordance to the associated onset fracture load. The results showed that the BKP procedures play a significant role in enhancing the structural integrity of the treated spine by lowering the effect of the bone fracturing and optimizing the biomechanical alterations up to its pre-fracture level. However, the phenomenon of high incidence of vertebral bone failures on the augmented and its neighboring vertebrae indicates that the osteoporosis severity is the most influential factor in determining the sufficiency of the BKP treatment.

Cage subsidence, pedicle screw loosening and instability are the most prevalent posterior lumbar interbody fusion (PLIF)-related complications. These may be attributed to interrelated mechanical, biomechanical and environmental factors. Current advancement in medical treatment has paved the way for the implementation of unilateral cages in an oblique position to overcome unintended mechanical and clinical shortcomings. To verify this claim, an image-based finite element analysis (FEA) was used to evaluate several factors; cage subsidence, screw loosening and PLIF construct stability via stress profiles, fracture risk prediction and range of motion (ROM) evaluations in the different type of cage materials and cage orientations. Obviously, obliquely-placed unilateral fusion cage constructs with PI exhibited the most reliable

biomechanical constructs by showing the smallest ROM and producing the minimal distortion stress at the cage-endplate and pedicle screw-bone interfaces. Moreover, these results also showed good agreement with the results obtained using fracture risks assessments by showing the lower numbers of deformation elements at the both contact interfaces in normal and traumatic events. In conclusion, biocompatible cage materials and structural symmetry are the most important criteria in achieving biomechanical advantage in PLIF surgery.

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CHAPTER I

Introduction

1.1. Background of study

Osteoporosis is a disease characterized by low bone mass and micro-architectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture [1]. Osteoporosis affects over 200 million people worldwide [2], with an estimated 10 million osteoporotic patients in Japan alone [3]. This kind of bone-related pathology is the most common disease affecting both men and women, and it is becoming increasingly prevalent in an aging society. Basically, osteoporosis could affect the entire skeleton; however, the most prevalent fracture site occurs in the spine [4]. In the United States, about 1.5 million fractures due to osteoporosis are reported annually including over 700,000 vertebral fractures [5]. Fracture resulting from osteoporosis leads to significant pain, deformity, disability, morbidity, mortality and economic burden. Moreover, the survival rate of the patient afflicted by osteoporosis fracture is totally dependent on how early the symptom could be detected. It was reported that if the symptom is detected within a year from its initial state, the survival rate would be as large as 72%. However, if the symptom is spotted after five years from its initial condition, the survival

rate would drop significantly to only 28% [6]. Therefore, with the prediction that life expectancy is continuously on the rise, the understanding on the specific treatment for osteoporosis is extremely important in order to improve the quality of life so that proper preventive and precautionary measures could be established in advance.

1.2. Spine

Human spine (**Figure 1(a)**) is made up of 33 individual bones called vertebrae. The primary function of the vertebrae is to provide body's upright support and to protect the spinal cord from injury. The vertebrae are stacked on top of one another in a flexible curved structure and they are divided into four segments namely; cervical (neck), thoracic (chest/trunk), lumbar (low back) and sacrum (pelvic). The cervical spine, thoracic spine, lumbar spine and sacrum spine is made up of seven cervical vertebrae, twelve thoracic vertebrae, five lumbar vertebrae and five sacral vertebrae, respectively. First lumbar vertebra has been identified as the weakest region in the spine because it is located at the most critical inflection point of the spine, in which the combination of bending forward and downward pressure will generate excessive pressure on the vertebral body [4]. The spine is also surrounded by muscles and ligaments to provide support and stability to the spine and the upper body (**Figure 1(b)**). Strong ligaments connect the vertebrae and help keep the spinal column in position.

Intervertebral disc (**Figure 1(c)**) lies in between the vertebrae. In total there are twenty four intervertebral discs in the human spine. They are round and flat, and about a half inch thick. Its primary function is to act as a shock absorber between each of the vertebrae in the spinal column by keeping an appropriate distance between the vertebrae when there is an impact from

activity. Besides, they also serve to protect the spinal cord and its branches (nerve roots) from injury. Intervertebral disc is made up of two components. The outer part of the disc is known as annulus fibrosus and the inner part of the disc is called nucleus pulposus. The annulus fibrosus is composed of a ring of strong ligament fibers (collagen type II) and its primary function is to hold the nucleus pulposus in place. The nucleus pulposus is fabricated from a jelly-like substance (collagen type I) and it serves to provide disk flexibility and strength. The combination of these two elements allow the spine movements to take place as well as maintaining the strength of the spine.

Facet joints are a small joints act as a hinge that provide flexible movement and stability to the spinal column. There are two set of facet joints for each vertebra that link vertebrae together. One pair which is facing upward is known as superior articular facet, while the other pair which is facing downward is called inferior articular facet. Facet joints are composed of fluids that protects and lubricates the joints, and they are encapsulated in facet joint capsules. These characteristics is significant in allowing the vertebrae to move smoothly without crashing to each other.

Generally, vertebra can be divided into two important segments namely; anterior (vertebral body) and posterior column (vertebral arch). The anterior and posterior column of the vertebra carries 75% and 25% of the compression load across the spine, respectively [6]. In general, vertebral bone is made up of a complex network of trabeculae encapsulated in a thin cortex made of cortical bone. Even though both the anterior and posterior column are having the similar bone compositions, the vertebral arch has relatively thicker coverings of cortex as compared to the vertebral body. The vertebral endplates which are located at the superior and inferior surface of a vertebral body play an essential role in preventing vertebral failures,

especially in a condition when a surgical intervention is believed could technically alter the load transfer mechanisms of the affected and its neighbouring vertebrae [6]. The endplate is covered with a layer of fibrocartilage linked to intervertebral discs.

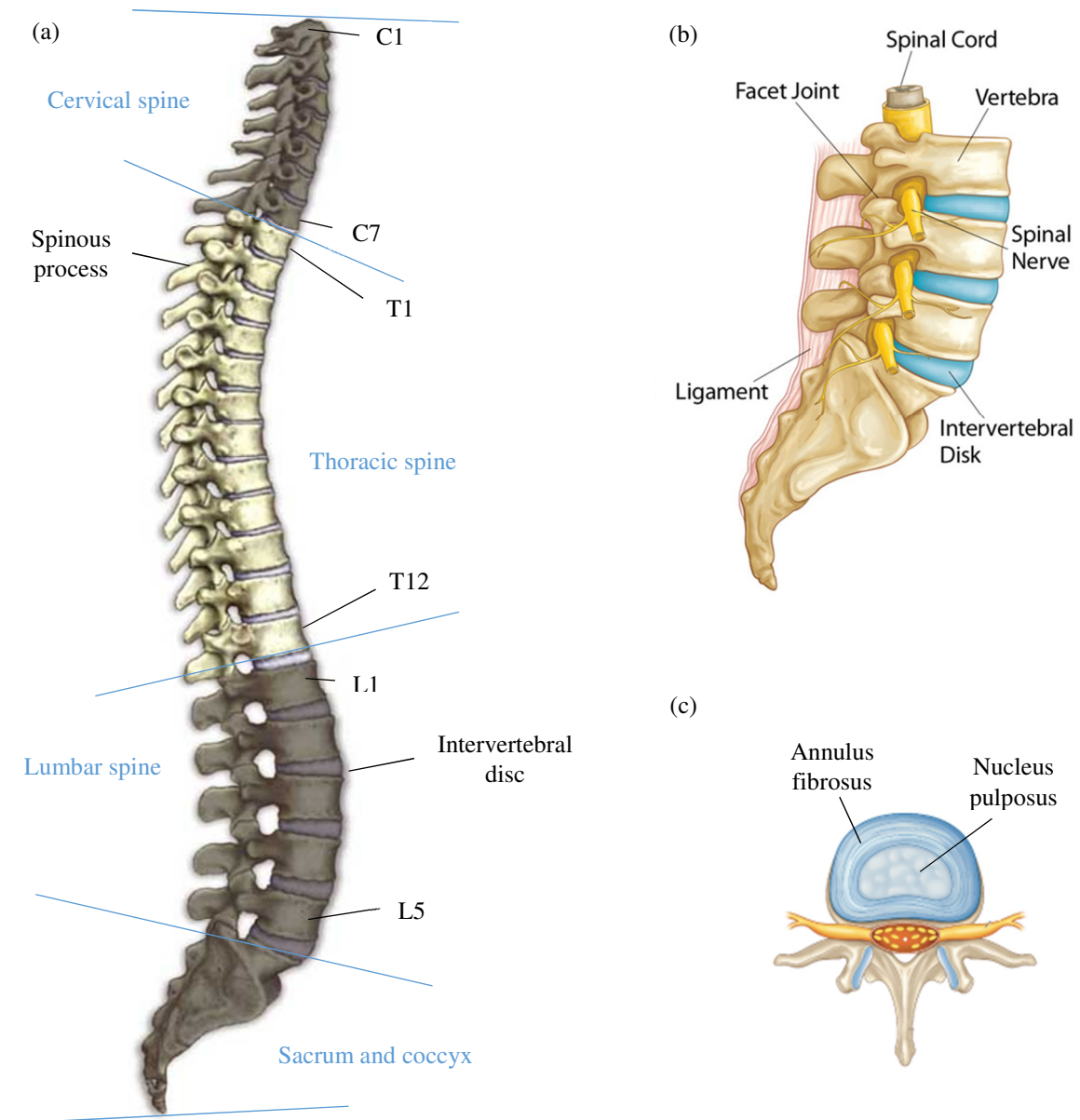


Figure 1: Anatomical compositions of human spine: (a) Spinal column [7], (b) vertebral muscle and ligament [8] and (c) intervertebral disc composition [9].

1.3. Osteoporosis

Osteoporosis is a disease characterized by reduced bone mass due to imbalance between bone formation and bone resorption [10], resulting in a loss of bone density and a change in trabecular bone micro-structure (refer to **Figure 2(a)**), with a consequent increase in bone fragility and susceptibility to fracture. This condition is due to altered bone remodeling cycle (**Figure 2(b)**) that increase in the length of the remodeling cycle and reduced capacity to lay down a new mineralized bone matrix [11].

In a normal condition, the trabecular bone is made up of densely packed, highly connected, thick, and plate-like trabeculae structures (**Figure 3(a)**). With the progression of osteoporosis, the trabecular bone micro-structure transforms into a poorly connected, thin, and rod-like trabeculae architectures (**Figure 3(b)**) [10, 12-13]. The transformation occurs through the progressively thinning of the individual trabeculae, perforation of the transverse trabeculae micro-structure, growing space between trabeculae, and increasing structural anisotropy in the direction of loading. In addition, due to higher remodeling rates of trabecular bone as compared to cortical bone, osteoporosis is presumed to affect trabecular bone to a larger extent than cortical bone [14]. Even though osteoporosis is always attributed to trabecular bone, studies have also found that osteoporosis could also cause a vast depreciating on cortical bone that subsequently ends in bone fracturing [15,16].

Osteoporosis is remarkably known as a ‘silent disease’ due to its asymptomatic nature, and for that reason it is frequently undiagnosed and improperly treated until fracture occurs. Basically, the use of drug therapies to treat osteoporosis is futile once the trabecular bone structure has been badly degraded. In other words, the efficacy of any related treatments would

be diminished as osteoporosis progresses, making early diagnosis critical for the management of the disease [17].

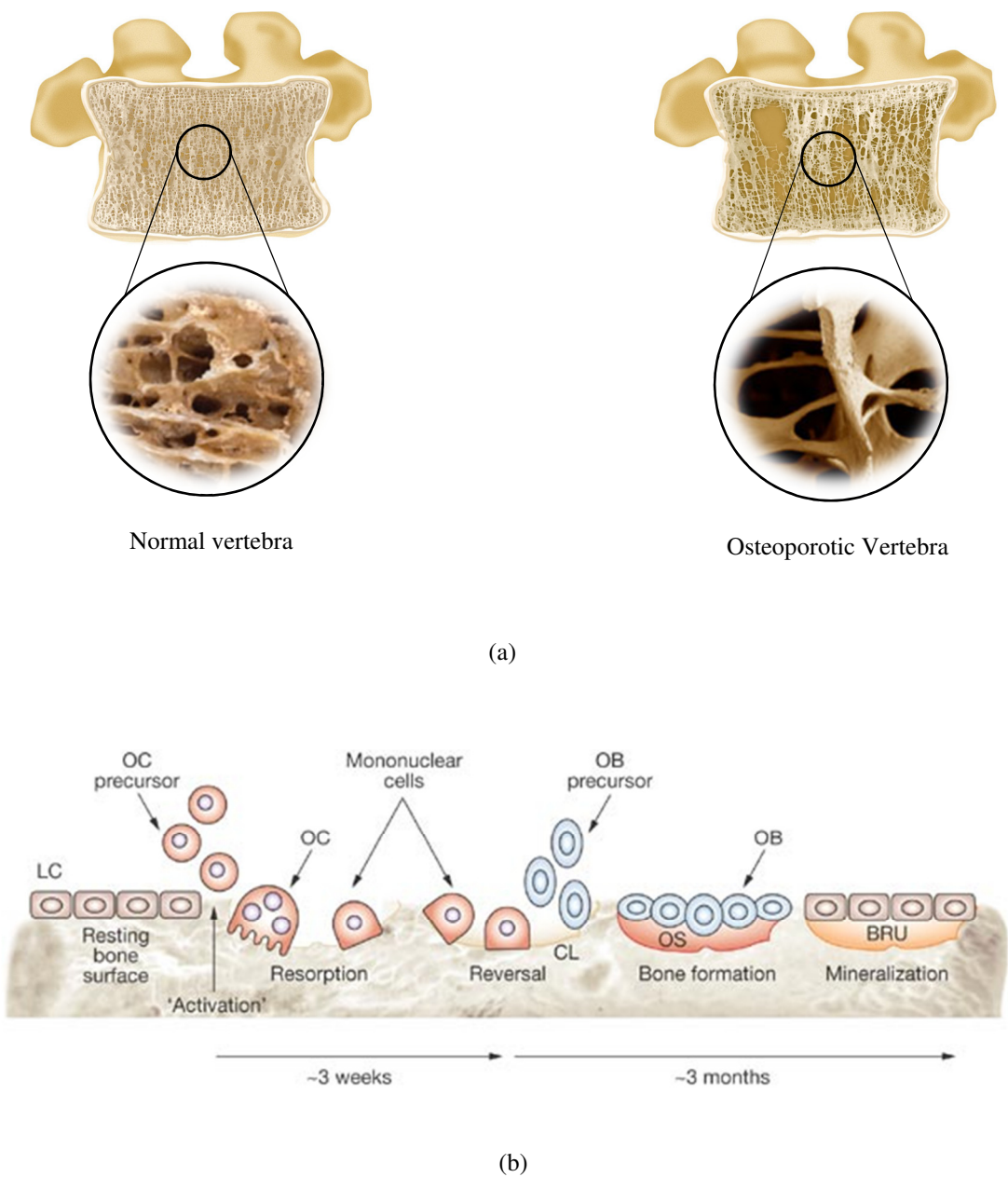
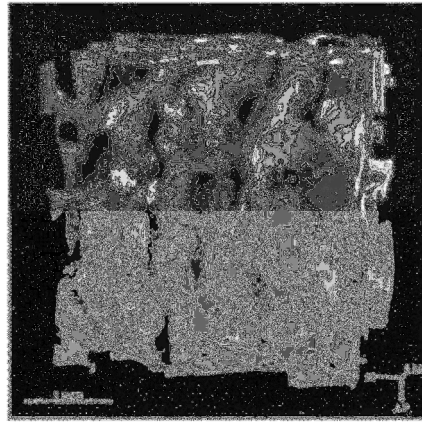
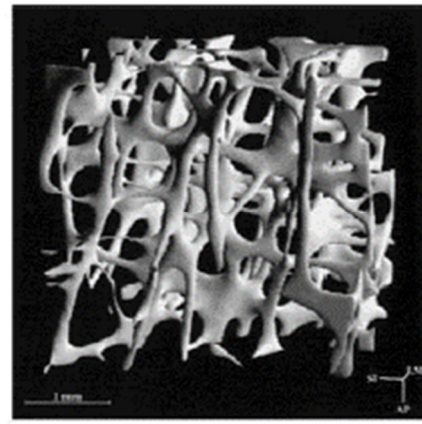


Figure 2: (a) Normal and osteoporotic vertebra [18], and (b) healthy bone remodeling cycle [11].



(a)



(b)

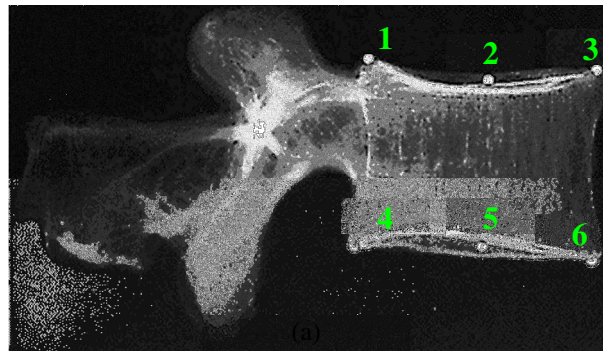
Figure 3: Micro-CT images of calcaneus trabecular bone samples for (a) healthy – plate-like structure and (b) osteoporosis – rod-like structure [16].

1.4. Vertebral Compression Fractures (VCFs)

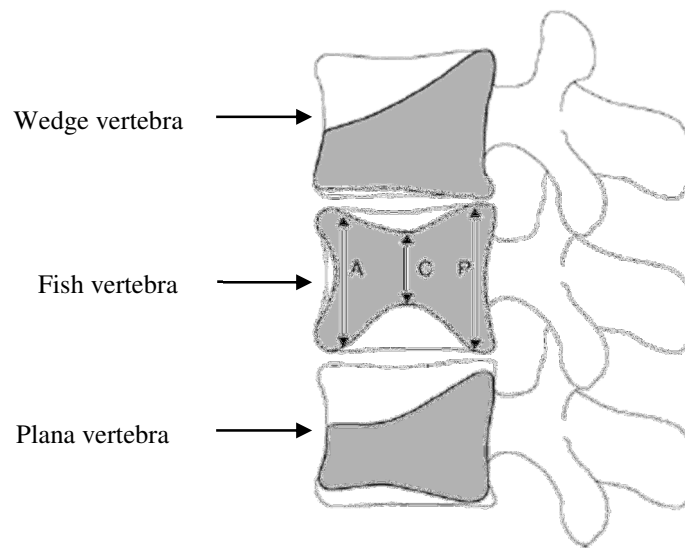
The structural changes occurring upon osteoporotic bone have resulted in a formation of low energy fracture that may lead to increased risk of fractures, with the most prevalently reported fracture sites occurring in the spine. Generally, osteoporosis-related vertebral fractures are common in men and women, and this condition indicates a greater tendency of recurrent and new fractures occurring either in the spine or hip [19]. Moreover, it has been reported that only one third of the osteoporosis-related vertebral fractures could be detected, as a large portion were thought to be asymptomatic [20-21]. VCF was reported to be the most common osteoporotic fractures that can occur in the most severe cases of osteoporosis [22]. It is associated with chronic back pain, increased risks of hip fractures and cardiopulmonary complications, reduced individual's mobility, and severed physical debilitation [23]. VCF can be easily recognized by a partially collapse of the vertebral bodies, which is radiographically represented by a reduction of 15% to 20% of the vertebral height as compared to its adjacent vertebrae. The need to prevent or detect fractures is very crucial as the occurrence of VCF increases the chance of additional fractures by 500% [24].

In clinical practice vertebral fractures can be determined by quantitatively analyse a thoracolumbar region in a lateral view via conventional radiograph instrumentations. Commonly vertebral fractures can cause alteration in geometrical appearance of a vertebra, however fractures are not the only contributor of all vertebral deformities. To further investigate this matter, the anatomical changes of the vertebrae must be thoroughly investigated through additional radiographic projections or by complimentary examinations such as CT or MRI scans. Basically, vertebral fractures can be classified into wedge-shaped, plana-shaped and fish-shaped vertebral fractures according to the standard six-point morphometry method [25-26]. The

classification is made based on the vertebral body height reduction at the anterior, central and posterior of the superior and inferior endplates of vertebra (refer to **Figure 4**). Based on this method, the wedge-shaped vertebral fracture is defined when the anterior body height decreases with the ratio of A/P less than 0.75, the fish-shaped vertebral fracture is defined when the central of the vertebral body decreases with the ratio of C/A less than 0.8 or C/P less than 0.8, and the plana-shaped vertebral fracture is defined when the whole vertebral body height decreases by more than 20% of its initial height.



(a)



(b)

Figure 4: Classification of vertebral compression fractures, (a) six-point morphometry and (b) it corresponding vertebral fractures [25-26].

In recent years, a more comprehensive method has been put in place to evaluate and diagnose the occurrences of vertebral fractures called semi-quantitative (SQ) assessment method (refer to **Figure 5**) as proposed by Genant et al. [27]. This method is superior than the six-point morphometry method due to the fracture classification that is not only focused on the vertebral height reduction, but also careful attention is given to alterations in the shape and configuration of the vertebrae relative to adjacent vertebrae and expected normal appearances.

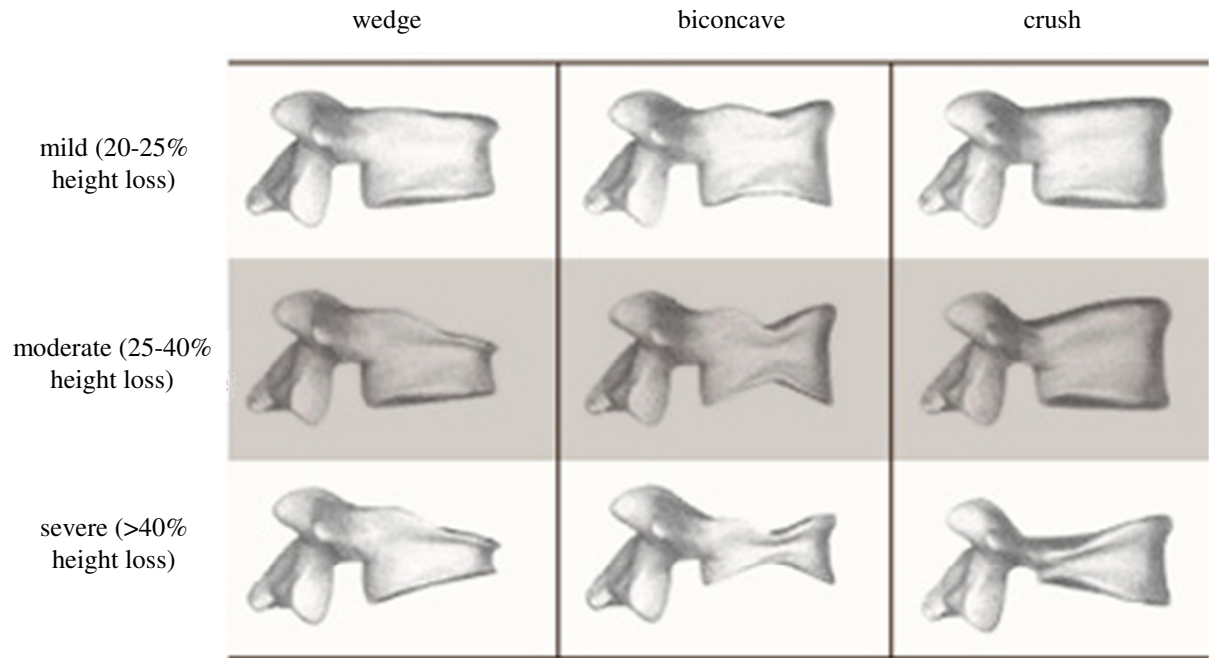


Figure 5: Semi-quantitative (SQ) assessment method [27].

1.5. Vertebroplasty and Kyphoplasty

Vertebroplasty and kyphoplasty are minimally invasive treatments performed to repair spinal fractures. These treatments are used to replace conservative treatments such as bed rest, pain medications, and braces, which are considered practically slow to relieve pain and to gain full recovery. By injecting bone cement into the fractured vertebral body, the possibility of recurrent fractures can be significantly reduced. This is because the rectification elements of such procedures are intended to improve the vertebral body's structural strength and height to the point that is closer to its pre-fracture level. Biomechanical studies have also shown that the inclusion of bone cement into the fractured areas can significantly reduce endplate deformation, as well as time-dependent creep deformation [28].

Vertebroplasty and kyphoplasty are almost similar procedures (refer to **Figure 6**). Both are performed through a hollow needle insertion to the fractured vertebra. In vertebroplasty, bone cement such as polymethylmethacrylate is injected through the hollow needle into the fractured bone. In kyphoplasty, a balloon is first inserted and inflated to expand the compressed vertebra to its normal height before filling the space with bone cement. Naturally, without treatment, the fractures will eventually heal, but in a collapsed position. At this point, kyphoplasty procedure appears to surpass the capability of the vertebroplasty procedure by allowing the vertebral body height return to its normal position before the bone hardens. Patients who have undergone kyphoplasty procedure reported to have experienced significantly less pain post-operatively as compared to vertebroplasty procedure [29]. However, it has to bear in mind that those procedures require that the vertebral body height reduction should not exceed more than 65% of its initial height [30]. Apparently, beyond this limit more complex surgical procedures are necessary to overcome this problem. Therefore, high-end medical instrumentations are required to perform

surgical intervention, which is associated with greater risks of medical complications especially in elderly patients [31]. A systemic review and meta-analysis comparing complications following kyphoplasty and vertebroplasty procedures have also found that vertebroplasty possess higher rates of complications, new vertebral fractures, and cement leakage compared to kyphoplasty procedure [32].

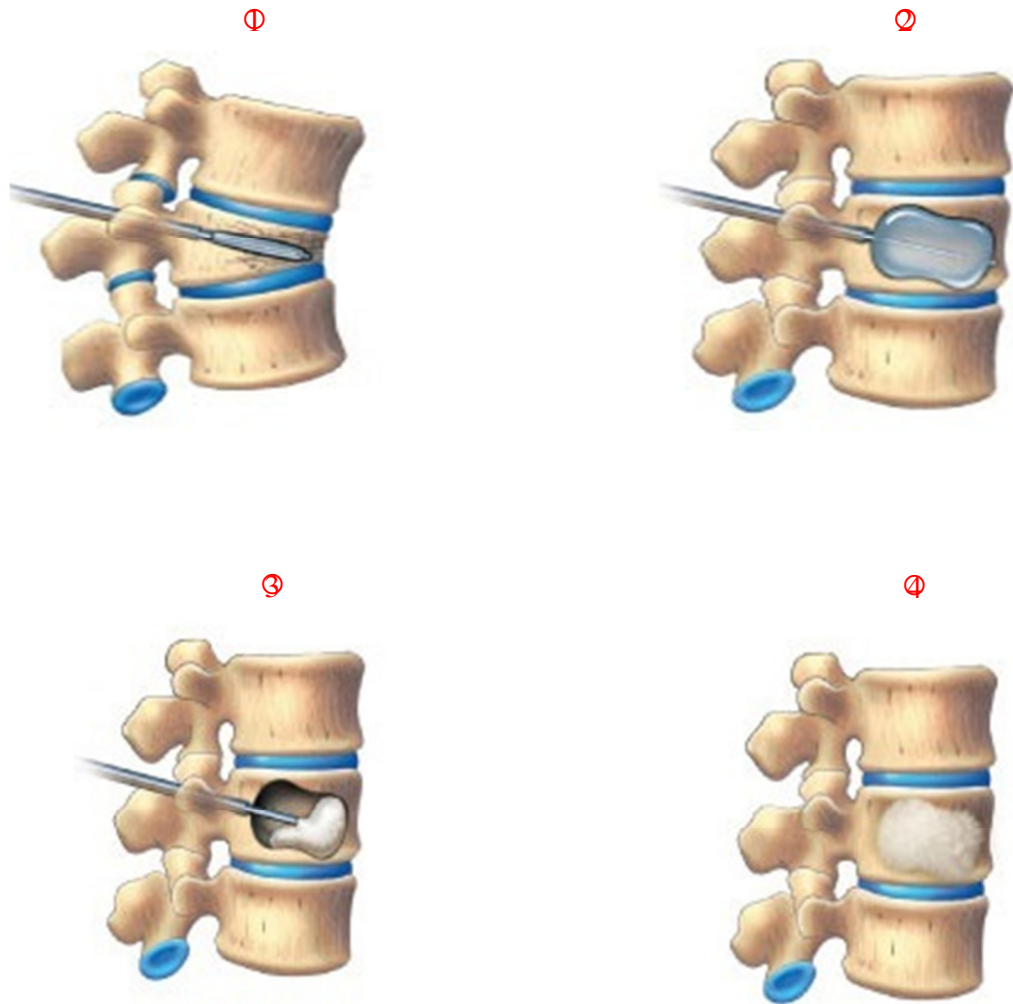
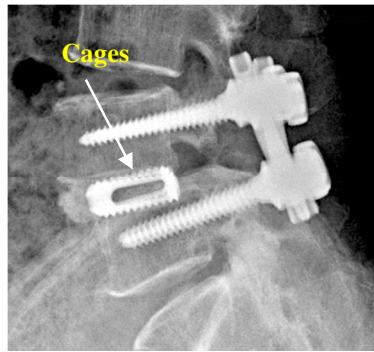


Figure 6: Kyphoplasty (step ①-④) and vertebroplasty (step ③ and ④) procedures; ① Balloon

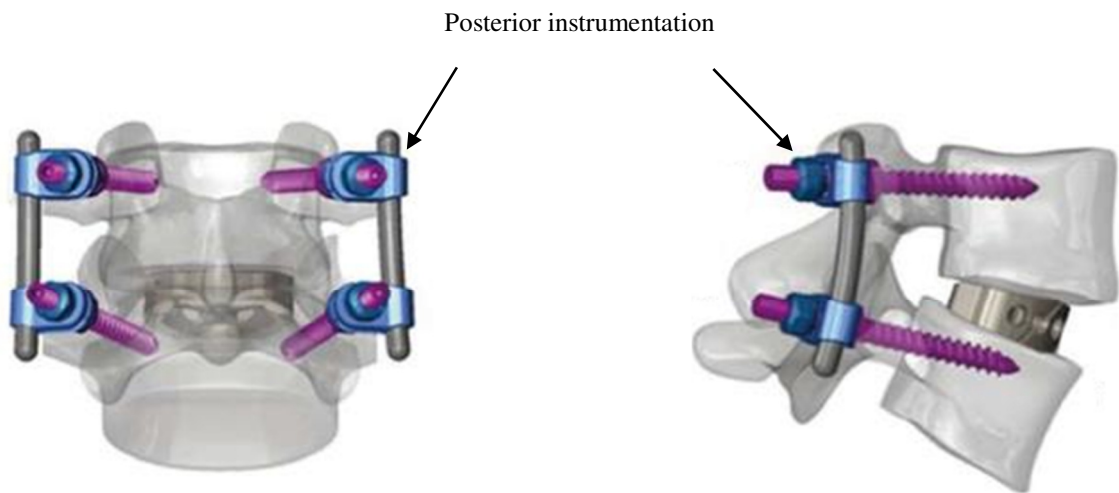
insertion, ② Balloon inflation, ③ cement injection, and ④ internal cast formation [33].

1.6. Spinal fusion

Spinal fusion is a surgical procedure to stop the motion at a painful vertebral segment, which in turn should decrease pain generated from the joint (refer to **Figure 7**). This surgical procedure is used to treat lumbar degenerative disc disease, lumbar spondylolisthesis, vertebral fractures, scoliosis, and other conditions including a weak or unstable spine (caused by infections or tumors). The primary purpose of this treatment is to relieve pain and stabilize the symptomatic spinal segment by fusing two adjacent vertebrae. The spinal segment is fused together through a solid bridge of bone substitute formation in the intervertebral disc space, which originates from an implanted bone graft. The bone graft provides the basis and atmosphere to allow the body to grow new bone and fuse two vertebral segments together via cage instrumentation. Posterior instrumentation typically consisting of rods and screws systems is deployed to form a solid construct and provide stability to the affected segment for the first few months after surgery, in which the bone graft does not form a fusion at the time of the surgery.



(a)



(b)

Figure 7: Interbody fusion surgery: (a) lateral view of CT-scan image of posterior lumbar interbody fusion and (b) graphical representations in posterior and lateral views of combined anterior/posterior arthrodesis using anterior lumbar interbody fusion [34].

The interbody graft material can be obtained either through autograft or allograft. The use of autograft is advantageous due to its complete biocompatibility, in which tissue or bone replacements are taken from a part of the person's own body. However, patients who undergo this procedure have to bear increased post-operative pain coming from the donor and treated sites. Moreover, this procedure is unsuitable for patients who have been diagnosed with osteoporosis, where they are not able to provide good or sufficient graft materials. For that reason, allograft seems to be the best alternative solutions. With allograft the recovery time may be slower and it poses a greater likelihood of bone graft failures. However, there is no second procedure required to remove and transfer a portion of the patient's native bone or tissue. Therefore, surgical time may be minimized, postoperative discomfort reduced, and patients may be back to normal activities more quickly. This proved that the clinical significance between both of these procedures is still elusive. Hence, further corroboration of their usability is needed in order to further optimize the clinical outcome of the treatments.

Basically, bone graft substitutes are not structural and therefore a complimentary assistive device is required to hold it in place while the bone graft substitute heals. Typically, spinal implants/cages/spacers are either manufactured out of a metal product (e.g. titanium), plastic (e.g. polyetheretherketone (PEEK)), or carbon fiber. To date, PEEK-based cage is the most reliable tool of interbody fusion surgery due to its Young's modulus (3.6 GPa) that is much closer to that of cortical bone (12 GPa) [35]. Apparently, by having low stiffness mismatch the stress shielding effect can be reduced as well as improved the load sharing mechanisms between the cage and the vertebral bone that leads to achieving higher fusion rates eventually. Cages are mainly used to achieve the required mechanical support which is not given by either allograft or autograft until a

fusion occurs between the vertebrae. They are also used to spread the two vertebrae apart, which allow more room for nerve roots, as well as decreasing pinching and irritation on the nerves.

Obviously, there are several types of complications associated with the usage of the cage interbody fusions. The most prevalent complications are cage migration, cage subsidence, injury to spine and nerves, and infection. To date there are many types of interbody fusion devices (**Figure 8**) available in the market with some of them having been approved for use by the United States Food and Drug Administration (FDA). Just to name a few such as horizontal cylinders, vertical rings and open boxes or rectangular cages.



Figure 8: Different types of cages (titanium coated PEEK disk cages) [36].

Posterior instrumentation (refer to **figure 9**) consists of pedicle screws and rods system. The primary function of this construct is to prevent motion at the segments that are being fused. The pedicle screw provides a means of gripping a spinal segment. The screws themselves do not fixate the spinal segment, but act as a firm anchor point that can then be connected with a rod. Many surgeons believe that pedicle screws enhance patient recovery because they provide immediate stability for the spine and early mobilization for the patient. The rod is used to connect the screws and this structure is important in terms of supporting and transferring loads between vertebrae and pedicle screws.

There are many types of spinal fusion surgery options. The most commonly utilized method includes:

- Posterior lumbar interbody fusion (PLIF)
- Anterior lumbar interbody fusion (ALIF)
- Transforaminal lumbar interbody fusion (TLIF)
- Posterolateral gutter fusion
- Extreme lateral interbody fusion (XLIF)
- Anterior/posterior spinal fusion

It is important to note that with any types of spine fusion, there are a risks of clinical failure despite achieving a successful fusion.



Figure 9: Posterior instrumentation (rods and screws system) [37].

1.7. Aims and Objectives

The aims of this study were to corroborate the biomechanical behaviors of vertebral compression fractures (VCFs), and identify variables that influence the compatibility of its associated surgical interventions of kyphoplasty and interbody fusion surgeries, so that the risks of subsequent fractures could be avoided and surgical management could be optimized in the future. For that purpose, an image-based three dimensional (3D) finite element analysis (FEA) models of normal and osteoporotic thoracolumbar spines were obtained and developed in Finite Element (FE) platform to closely imitate the real mechanical behavior of human spine. The aims of this study were attained through the following objectives:

- To quantitatively analyze the structural integrity and fracture risks assessment of thoracolumbar spine with different types of VCFs namely; wedge-shaped, plana-shaped and wedge-shaped VCFs.
- To quantitatively analyze the load transfer mechanism, load sharing mechanism, stiffness recovery, stability and kyphotic deformity restoration of pre-operative and post-operative vertebrae that have undergone Balloon Kyphoplasty (BKP) treatments.
- To quantitatively investigate the phenomenon of cage subsidence, PLIF construct stability and pedicle screw loosening phenomena in four different sets of PLIF constructs and to identify the most effective surgical intervention modalities.

The originality of this study lies on the development of inhomogeneous FE models of intact vertebrae with real BKP and simulated PLIF cage constructs based on the bone strength assessments and failure risks prediction patterns. Apparently, this study was an enhancement of the previous studies, which were lack of biomechanical considerations and spine features that can hinder the imitation of the real spine environment.

CHAPTER II

Research Methodology

2.1. Finite element modelling

The FE models were constructed in MECHANICAL FINDERTM software (Research Center of Computational Mechanics Co. Ltd. Japan). Written informed consent, permission and cooperation of the subjects involved in this research were obtained prior to participation in the study. To create the FE models, CT scan images of the subjects were taken and transferred to the FE software. The FE models were constructed based on the extracted bone edges of the region of interests (ROIs) around the outer region of the cortical bone to obtain the anatomical structure of the spinal bone (refer to **Figure 9**). The vertebral bodies were defined as cancellous bone core surrounded by a 0.4 mm thick cortical shell. The cancellous bone, intervertebral discs and facet joint cartilages were modelled with 1.0 mm solid tetrahedral elements while the cortical bone was modelled with 1.0 mm linear shell triangular elements (refer to **Figure 10**).

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