แบบจำลองหมอนรองกระดูกสันหลังระดับคอของคนไทย

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THE CERVICAL DISC DEMENSIONS OF THAI POPULATION

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อรรถพล วันดี : **แบบจำลองหมอนรองกระดูกสันหลังระดับคอในคนไทย** (THE CERVICAL DISC DIMENSIONS OF THAI POPULATION) อ.ที่ปรึกษา: ศ.นพ. พิบูลย์ อิทธิระวิวงศ์, อ. ที่ปรึกษาร่วม: รศ.นพ.ทวีชัย เตชะพงศ์วรชัย และ อ.ดร. ไพรัช ตั้งพรประเสริฐ, 56 หน้า.

การรักษาหมอนรองกระดูกคอเสื่อมร่วมกับมีอาการทางคลินิก ซึ่งส่วนใหญ่พบในผู้ป่วยอายุ 40 ปีขึ้นไป อุบัติการณ์เพิ่มขึ้นเป็น 2 เท่าเมื่อเทียบกับอายุน้อยกว่า 40 ปี การผ่าตัด Anterior cervical discectomy and fusion (ACDF) ให้ผลการรักษาที่ดีมาก ในระยะยาวพบว่าคนไข้มีอาการของหมอนรองกระดูกใกล้เคียงเสื่อมเร็วขึ้น Adjacent segment disease (ASD) จากรายงานพบว่าอุบัติการณ์ 3-11% ต่อปี ใน 10 ปีแรก ด้วยเหตุนี้จึงมีการพัฒนาการรักษาด้วยการผ่าตัดโดยการรักษาการเคลื่อนไหวของหมอนรองกระดูก การพัฒนาหมอนรองกระดูกเทียมขึ้นเพื่อลดภาวะแทรกซ้อน ASD ในปัจจุบันได้มีการนำหมอนรองกระดูกเทียมมาใช้ในเมืองไทยเพิ่มมากขึ้น หมอนรองกระดูกเทียมต่างๆ ที่มีในท้องตลาดที่ไม่มีความเหมาะสมกับลักษณะทางกายวิภาคของหมอนรองกระดูกที่ใช้ในกลุ่มประชากรต่างๆ ได้ ซึ่งทำให้เกิดปัญหาที่กล่าวมาได้ ซึ่งพบได้ในการเกิด Subsidence และ migration ได้ การลดปัญหาต่างๆ เหล่านี้ในคนไทยสามารถทำได้โดยพยายามทดสอบหา prosthesis ที่มีอยู่ในท้องตลาดที่มีความเหมาะสมกับลักษณะทางกายวิภาคของรูปร่างคนไทยมากที่สุด หรือ ออกแบบ prosthesis ใหม่ที่สร้างมาจากพื้นฐานของลักษณะทางกายวิภาคของคนไทยได้

ผลของการวัดระยะคือค่าเฉลี่ยความสูงของหมอนรองกระดูกในคนไทยค่าเฉลี่ยรวมทั้งหมดเป็นดังนี้ C3-4 6.44 mm , C4-5 5.90 mm , C5-6 5.79 mm, C6-7 6.28 mm และ C7-T1 6.21 mm. มีความแตกต่างระหว่างระยะในเพศชายและเพศหญิงอย่างมีนัยสำคัญ ค่าความสูงที่สุดและต่ำที่สุดจาก sample ทั้งหมดคือ 6.63 mm และ 5.47 mm ตามลำดับ ส่วนค่าเฉลี่ยความกว้างในแนวกลางของหมอนรองกระดูกในคนไทยค่าเฉลี่ยรวมทั้งหมดเป็นดังนี้ $C3_1$ 14.77 mm , $C4_2$ 14.77 mm , $C4_1$ 15.23 mm, $C5_2$ 15.13 mm, $C5_1$ 15.74 mm, $C6_2$ 15.62 mm, $C6_1$ 15.72 mm,$C7_2$ 15.69 mm, $C7_1$ 15.79 mm และ $T1_2$ 16.00 mm. มีความแตกต่างระหว่างระยะในเพศชายและเพศหญิงอย่างมีนัยสำคัญ ค่าความสูงที่สุดและต่ำที่สุดจาก sample ทั้งหมดคือ 16.47 mm และ 13.33 mm ตามลำดับ ส่วนค่าเฉลี่ยความกว้างในแนวขวางของหมอนรองกระดูกในคนไทยค่าเฉลี่ยรวมทั้งหมดเป็นดังนี้ $C3_1$ 21.77 mm , $C4_2$ 22.15 mm , $C4_1$ 22.15 mm, $C5_2$ 22.95 mm, $C5_1$ 23.44 mm, $C6_2$ 24.23 mm, $C6_1$ 25.36 mm,$C7_2$ 26.28 mm, $C7_1$ 26.92 mm และ $T1_2$ 26.95 mm. มีความแตกต่างระหว่างระยะในเพศชายและเพศหญิงอย่างมีนัยสำคัญ ค่าความสูงที่สุดและต่ำที่สุดจาก sample ทั้งหมดคือ 27.73 mm และ 20.80 mm ตามลำดับ แบบจำลองหมอนรองกระดูกสันหลังที่วัดได้ทำให้รู้กรอบคร่าวๆของขนาดอุปกรณ์ในการวางแผนการรักษาและทำการผลิตในกรณีจะผลิตออกใช้จริง

สาขาวิชา วิศวกรรมชีวเวช ลายมือชื่อนิสิต.....

ปีการศึกษา 2551 ลายมือชื่ออาจารย์ที่ปรึกษาวิทยานิพนธ์หลัก.....

ลายมือชื่ออาจารย์ที่ปรึกษาวิทยานิพนธ์ร่วม.....

ลายมือชื่ออาจารย์ที่ปรึกษาวิทยานิพนธ์ร่วม.....

5087234320 : BIOMEDICAL ENGINEERING
KEYWORD : CERVICAL DISC DIMENSIONS, CERVICAL SPONDYLOSIS, CERVICAL DISC PROSTHESIS

UDTHAPON WANDEE: THE CERVICAL DISC DIMENSIONS OF THAI POPULATION. THESIS ADVISOR: PROFESSOR PIBUL ITIRAVIVONG, M.D., THESIS CO-ADVISOR: TAWEECHAI TEJAPONGWORACHAI, M.D., PAIRAT TANGPORNPRASERT, PH.D., 56 pp.

The incidence of complications with cervical disc arthroplasty was 6.2% per treat level. The perioperative kyphosis, heterotopic ossification and migration may be occurred due to undersized prosthesis. Measurement of dimensions cervical disc of Thai population aim to be a pilot study to know the estimation dimensions cervical disc that refers to size of disc prosthesis device. Objectives of this research are measure dimensions cervical disc in Thai patients from MRI cervical spine and to prepare data for preoperative planning and cervical disc prosthesis design.

Total mean maximum disc height in Thai population are C3-4 6.44 mm , C4-5 5.90 mm , C5-6 5.79 mm, C6-7 6.28 mm and C7-T1 6.21 mm The maximum and minimum distances from all samples are 6.63 mm and 5.47 mm respectively. Total mean sagittal diameter in Thai population are C3i 14.77 mm , C4s 14.77 mm , C4i 15.23 mm, C5s 15.13 mm, C5i 15.74 mm, C6s 15.62 mm, C6i 15.72 mm,C7s 15.69 mm, C7i 15.79 mm and T1s 16.00 mm. The maximum and minimum distances from all samples are 16.47 mm and 13.33 mm respectively. Total mean transverse diameter in Thai population are C3i 21.77 mm , C4s 22.15 mm , C4i 22.15 mm, C5s 22.95 mm, C5i 23.44 mm, C6s 24.23 mm, C6i 25.36 mm,C7s 26.28 mm, C7i 26.92 mm and T1s 26.95 mm. The maximum and minimum distances from all samples are 27.73 mm and 20.80 mm respectively. The differences in maximum disc height, sagittal diameter, and transverse diameter between males and females were significant.

Disc dimensions measurement can refer to range of size to manufacturer for the device to cover the use in Thai patients. The data fulfill the goal describe for cervical disc dimension for Thai population. The results of the project could provide design and data for the manufacturer and next step experiment for cervical disc prosthesis suitable for Thai population.

Field of Study : .Biomedical Engineering.. Student's Signature : Udthapon Wandee
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CHAPTER I

INTRODUCTION

1.1 Background

The precise events of intervertebral disc degeneration have been widely studies but not completely understood. However, it is known that when disc tissues become damaged or degenerated, pathologic joint mechanics as well as pathologic changes in innervations and nociception cause back pain, which is usually exacerbated by movement. [1]When this pain is persistent despite conservative treatment, operative management can be considered. Operative intervention for back pain such as a spinal fusion is itself fraught with complications and often has poor outcomes. [2]

One core principle of orthopaedic approach to degenerative joint disease is that pathologic motion causes pain, and if that motion can be arrested, the patient will benefit. This concept of knee and hip for many years and continues to be the mainstay of spine surgery. The evolution toward arthroplasty to treat painful knee and hips has raised the important question of whether degenerative joint diseases of the spine might be better treated by arthroplasty than by arthrodesis. Considering that fusion of a single lumbar motion segment of degenerative disease of the spine may result in pain relief in some patients, artificial disc replacement technology should at least replicate that or do better. Total revolutionized the field of orthopaedic surgery. Both primary total hip and knee replacement have resulted in high rates of patient satisfaction, and surgeons and patients have become accustomed to excellent long-term results. Surgeons hope to achieve similar benefits with disc arthroplasty.

By mid-20th century, spinal problems were well recognized. Discectomy was frequently follows by disc pace collapse, loss of mobility, recurrent protrusions, canal and foramenal stenosis, scarring with root entrapment, instability, and facet arthritis. Decompression, although seldom advocated or performed, could lead to recurrent stenosis, instability,

perineural fibrosis, dural tears, failure of pain relief, and neurologic sequelae. Fusion was often attended by perioperative morbidity, pseudarthroses, stenosis, scaroiliitis, fixation failure, and adjacent level instability. Spinal fusion, with its shortcomings, becomes the gold standard of care for the failed spine. Stabilization of the spine after discectomy by Lucite pegs (Gardner, 1950s) and methyl acrylic (Cleveland, 1955; Hamby, 1957) had met with cool or no enthusiasm. Arthroplasty of the spine was considered to be a nasty phrase, as per the history of the specialists demonstrates. Paul Harmon, from 1959 to 1961, used vitallium balls through an anterior approach to stabilizers (the first disc arthroplasty) but had his California license suspended and spent 2 years in South America before his restoration. Ulf Fernstrom, form 1962 to 1792, favored steel ball arthroplasty of the spine over Hirsch's spinal wires to prevent and treat spinal instability. In 1966, he reported treating 105 patients by steel ball arthroplasty from a posterior approach with few complications, safe fixation, slow subsidence, retained stability, absence of spurring, and assisted mobility.[3] By 1972, he report 195 total 13 patients treated by anterior cervical approach, with excellent results in 65% of patients. Although 85% had return to work after his surgery.[3] It was said by his detractors, "15% of his patients never worked again!" For his efforts, he was removed from his seat at the University of Udevalla to the village of Hudiksvaal, north of the Arctic Circle, with suppression of further opportunity to publish. Reitz and Joubert, (1964) had carried out steel ball, hemispherical, and Silastic top arthroplasties at 32 cervical and nine lumbar levels in South Africa before having their surgery suspened.[4]Al McKenzie, in 1971, reported short-term results if 40 steel ball arthroplasties carried out during 1969 and 1970.[5] 25 years later, in 1995, the author was finally able to have published his report of 10 to 20 years (17-year average) result of re-examining 67 of 103 patients treated at 155 levels, suspended the procedures in 1974, the author reported excellent and good long-term results for 83% of patients in the discectomy and prosthesis group and 75% excellent and good results of the spondylosis and prosthesis group, with 95% of all patients having returned to work. One prosthesis became displaced and was exchanged,

whereas another was removed for discitis. Disc space preservation had been excellent and good in 55% fair in 28%, and poor in 17%. Anterior cervical discectomy and fusion (ACDF) of one or two levels for spondylotic myelopathy or radiculopathy has proven to be an extremely effective procedure in terms of clinical and radiographic outcomes.[6,7,8] The rate of adjacent segment degeneration has been reported to be as high as 3% to 11% per year for the first decade after fusion, with up to two thirds of patients requiring reoperation.[9,10] Hypermobility of segments adjacent to a fused segment is also often observed.[11] Advantages of cervical disc arthroplasty over anterior cervical discectomy and fusion.[12] Recently cervical arthroplasty trends to be used more than ACDF, The incidence of complications with cervical disc arthroplasty were 6.2% per treat level. The perioperative kyphosis may be occurred after removed anchoring pin and dual-track milling guide because mismatched size of prosthesis.[14] The heterotopic ossification may be occurred by limited motion of prosthesis due to undersized prosthesis.[13]Delay prosthesis migration have been found in patients who were immediate kyphosis after operation.[14]

However, results from clinical study are still lacking the dimensions cervical disc of Thai population.[15] We, therefore, conducted study of dimensions cervical disc of Thai population to prepare data for preoperative planning and cervical disc design.

Objective

1) To collect parameters data of disc dimensions of cervical spine in Thailand for the future researches (pilot study).

2) To provide data cervical disc dimensions that be used in Thailand for preoperative planning and design cervical disc prosthesis

3) To understand size relation disc dimensions between levels of cervical spine in Thailand people.

CHAPTER II

LITERATURES REVIEW

The prevalence of abnormalities in individuals who were older than 40 years (28%) was twice the prevalence of abnormalities in individuals less than 40 years old (14%), indicating that these abnormal changes become more prevalence with increasing age, even in asymptomatic individuals.[16,17] Symptoms suggestive of cervical and lumbar stenosis are relatively common among this cohort of older men, and generalized spinal stenosis may occur in as many as 4%.[18] The most common age group of Thai population 30-60 years.[19]

Anterior cervical discectomy and fusion (ACDF) of one or two levels for spondylotic myelopathy or radiculopathy has proven to be an extremely effective procedure in terms of clinical and radiographic outcomes. [6,7,8] The rate of adjacent segment degeneration has been reported to be as high as 3% to 11% per year for the first decade after fusion, with up to two thirds of patients requiring reoperation.[9,10] Hypermobility of segments adjacent to a fused segment is also often observed.[11] Advantages of cervical disc arthroplasty over anterior cervical discectomy and fusion.[12] Recently cervical arthroplasty trends to be used more than ACDF, The incidence of complications with cervical disc arthroplasty were 6.2% per treat level.[13] The complications were

1. retropharyngeal hematoma
2. neurological worsening
3. intraoperative and delay migration
4. postoperative segmental kyphosis
5. heterotopic ossification and spontaneous fusion
6. partial dislocation of the prosthesis in extension
7. neck and shoulder pain

Some complications from arthroplasty such as subsidence may be occurred after prosthesis replacements.[20] There are 3 factors had been studied in cervical cage.[20]

1. Distance from anterior vertebral rim.
2. Spacer versus end-plate surface ratio.
3. Ratio of pre- and immediate postoperative height of the intervertebral space.

The perioperative kyphosis may be occurred after removed anchoring pin and dual-track milling guide because mismatched size of prosthesis.[13] The heterotopic ossification may be occurred by limited motion of prosthesis due to undersized prosthesis.[13]Delay prosthesis migration have been found in patients who were immediate kyphosis after operation.[13] In a 2-year follow up period, a reoparative of 2.05% appears to be acceptable rate considering the investigative nature of this study.[21]

In order to design the cervical disc prosthesis, we had reviewed the knowledge about anatomy[15] and biomechanics[22, 23] of cervical spine. The biomechanics parameters that influence to design cervical disc prosthesis are

1. Disc space area[20]
2. Disc height[20]
3. Rank of motion (ROM) [23, 24]
4. Instantaneous axis of rotation (IAR)[24, 25, 26,27]

There are many prosthesis have been used today. The cervical disc replacements that are undergoing FDA approval study in the United States include the Charite`, the Prodisc, the Bryan Disc, and the Prestige Disc, respectively but no cervical prosthesis that manufacture base on disc dimensions for Thai population. These data may useful to preoperative planning and design cervical disc in Thailand.

The cervical prosthesis that be used in Thailand today are Prodic-C, Prestige, and Mobi-C. Details of other groups of devices are presented in full version of review of literature attached with this study.

The cervical intervertebral disc device

1. ProDisc-C Total Cervical Disc Replacement[28]

The ProDisc-C prosthesis (Synthes, West Chester, PA) shares many of the physical characteristics of the ProDisc-L (Synthes, West Chester, PA) lumbar prosthesis. The device is essentially a ball and socket joint (as figure 1): the end plates are constructed of a cobalt-chrome alloy, and articulating convex insert is made of ultra-high-molecular-weight polyethylene (UHMWPE). Both of these are proven materials with an extensive track record in hip and knee arthroplasty. Both upper and lower end plates have slotted keels and titanium plasma spray coating. These design characteristics allow for immediate fixation onto the vertebral end plates, as well as long-term fixation via bony ingrowth.

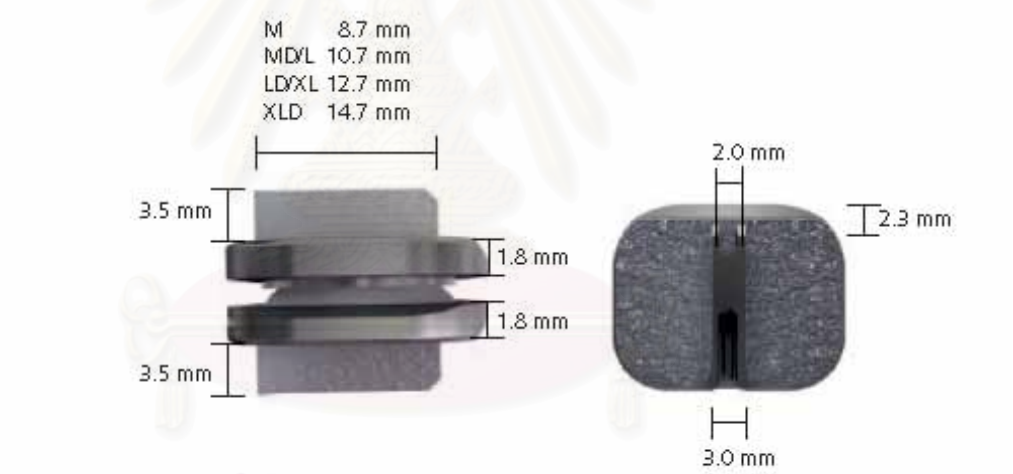


Figure 1 ProDisc-C.

The UHMWPE insert is fixed onto the lower end plate. The kinematic philosophy of the ProDisc-C prosthesis again parallels that of the ProDisc-L. This is a semiconstrained device with fix axis of rotation. Rotation is allowed along all three axes. Translation is constrained. However, because the axis of rotation for the device actually lies inferior to the disc space, translation is not eliminated. Minute (1mm) anterior and disc space, anterior and posterior translational shift is allowed during flexion and extension, as is seen

physiologically. However, excessive translation is not allowed, protecting the facet joints from undue loading in the absence of the native disc. It is hoped that this method will prevent accelerated degeneration of the facet joints, which would otherwise ear the majority of the shear stabilization load in the presence a nonconstrain artificial disc. However, the semiconstrained dynamics dose shift shear load from the facets to the prosthesis-bone interface, highlighting the importance of the prosthesis fixation feature mention earlier. Base on human anatomic studies, four different prosthetic disc heights are available, range from 5-8 mm. Disc height restoration is key in maintaining cervical lordosis and foramonal height. Similarly, six different footprint sizes are available. The largest allowable footprint is necessary to optimize load distribution and to decrease risk of subsidence. Angular motion in the sagittal, coronal, and axial planes is also matched to physiologic intervertebral motion, which is important if abnormal loading or motion is to be avoided in the remaining unaffected segments. Again, based on human anatomic studies, the ProDisc-C device allows a maximum of 20 degrees of flexion-extension, 20 degrees of side-to-side bending, and 12 degrees of axial rotation. Standard design implant are still available with the following articular numbers height 5, 6, 7 mm. Footprint are depth 12, 14, 16, 18 and width 15, 17, 19 mm. (as figure 2)

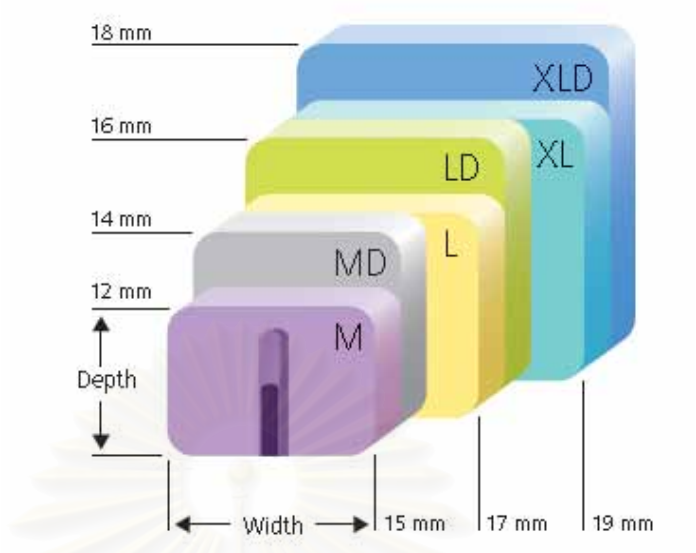


Figure 2 Footprint ProDisc-C

2. Mobi-C[29]

The Mobi-C represents a metal-on-polyethylene device. It is composed of two soinal plate consisting of cobalt, chromium, 29 molybdenum ISO 5832-12 alloy, and an ultra-high-molecular-weight polyethylene mobile insert.(figure 3)

Figure 3 Mobi-C

The inner contact surfaces of the superior and inferior plates are spherical and flat, respectively. The mobile insert is self-centering on the inferior end plate. Each movement of the superior plate induces the mobile surface of superior plate is spherical, allowing a fully congruent contact surface with the convex spherical dome of the mobile insert. The inner contact surface of the inferior plate is flat and contains two lateral stops that limit the mobility of the mobile

insert reduce the potential for migration of the mobile insert. Both the superior and inferior spinal plates contain two teeth rows that are located laterally on each plate to ensure the primary fixation. A titanium and hydroxyapatite plasma spray coating is allied to the bony interface surfaces of the superior and inferior plates. Different plate size are available (13x15, 13x17, 15x17, and 15x20, depth by length in mm. (as figure 4), to restore the physiologic height of the disc. The device allows for various degree of mobility that include five independent degrees of freedom, two translational and three rotational.

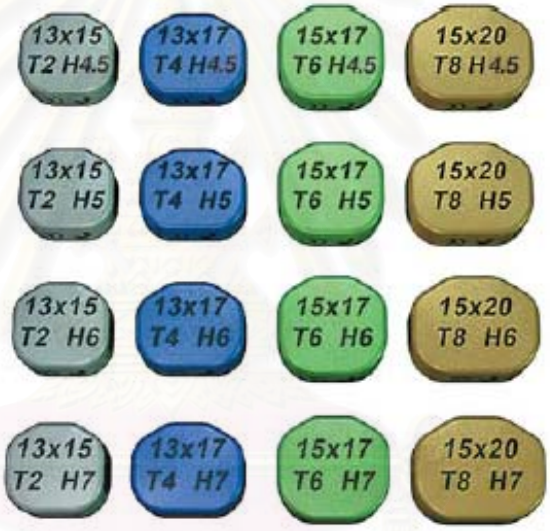


Figure 4 footprints Modi-C

3. Prestige Cervical Disc[30]

The Prestige ST is construct is constructed of stainless steel and consists of two articulating components attached to the cervical vertebrae with locking screws. (As figure 5)

Figure 5 Prestige ST

The ball-and-trough design of the Prestige ST allows relatively unconstrain motion, which is comparable to that of a normal cervical spinal segment, including antero-posterior (AP) translation which is physiologically coupled with sagittal plane rotation. The 2.5 mm anterior face is comparable to the thickness of the majority of anterior cervical plates. The surfaces that contact the vertebral end plates are grit-blasted to promote osteointegration. The Prestige LP has a ball-and-trough articulation that is identical to that of the Prestige ST. (as figure 6) The Prestige LP is manufactured from a unique titanium ceramic composite material which is highly durable and imaging scans. Initial fixation is achieved by the vertebral bodies. A porous titanium plasma spray coating on the end plate contacting surfaces facilitates bone ingrowth and long-term fixation. Both the Prestige ST and LP are available in a number of sizes, and specialized

instrumentation for implantation has been developed for each. Different plate sizes are available (6x12, 6x14 mm, 7x12, 7x14, 7x16, 7x18 mm, 8x14, 8x16, 8x18 mm)

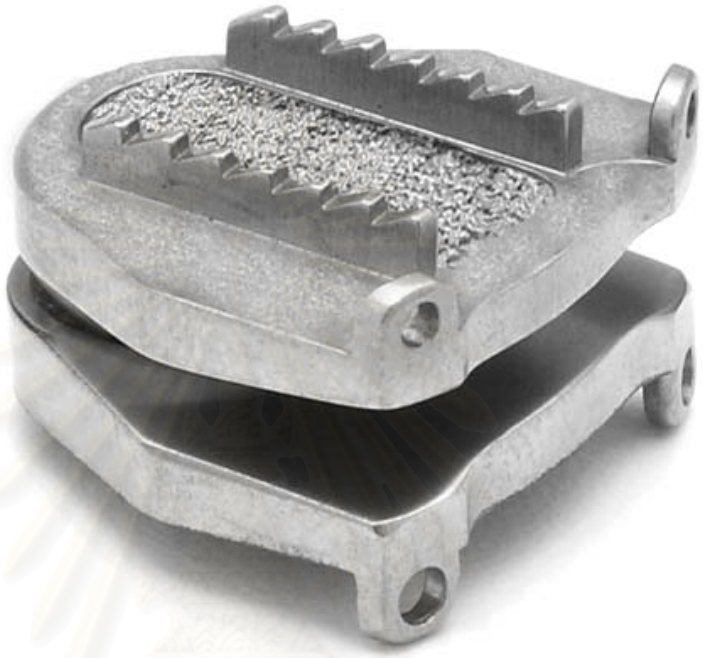


Figure 6 Prestige LP

However, a result from clinical study is still lacking the dimensions cervical disc of Thai population.[16] We, therefore, conducted study of dimensions cervical disc of Thai population to prepare data for preoperative planning and cervical disc design.

CHAPTER III

MATERIALS AND METHODS

Patients Selection

Between January 2008 and December 2008, 60 consecutive C-spine magnetic resonance imaging studies were performed in Thai subjects. The selection criteria of each subject included 22 to 76 years of age, no congenital deformity, no scoliosis, no traumatic injury to spine, no previous spine surgery 30 were males and 30 were females. The demographic data is shown in Table 1.

Sex	Total	Male	Female
Subjects Number	60	30	30
Age (year)	51.00 ± 12 (22-76)	52.47 ± 11.01 (30-72)	50.33 ± 13.13 (22-76)
Weight (Kg.)	60.75 ± 11.80 (40-100)	66.90 ± 10.00 (50-100)	54.60 ± 10.24 (40-88)
Height (cm.)	162.75 ± 6.53 (149-175)	165.70 ± 5.71 (150-175)	159.00 ± 5.57 (149-173)

Table1. The basic information of the subjects*

**Represented as mean ± standard deviation, median (range)*

MRI Measurements

MRI was performed using a 1.5 Tesla whole body MR imaging system (Siemens 1.5 Tesla, Avanto, Germany) with an extremity coil. Pulse sequences were T2-weighted images. The direction of axial slice imaging placed the slice perpendicular to the spinal mechanical axis in the coronal plane and perpendicular to the long axis of spine in the sagittal plane. All 60 images were reconstructed at 3-mm intervals. These images had been obtained from patients attending clinics for neck pain. Patient below the age below 20 year-old, congenital cervical spine anomaly, past surgery cervical spine, pregnancy, or with an abnormal disc, not according to the Woodend classification I (as figure 7), were excluded. The Woodend classification grades disc on a scale of 1-4, where grade 1 is normal disc with a white nucleus, normal shape, and no annular tears.[31]

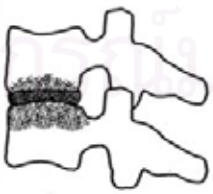
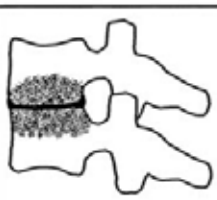
Grade	Disc Changes			Disc Height (H)
	Axial Sections	Saggittal view	Description	
Normal (DC-1)	White (Hypertensive) 		Flat or slightly convex, posterior anulus, nuclear cleft, on sagittl views. Anular margins well defined (bean shaped or rounded), no tears in axial views.	Normal (H1)
Mild (DC-2)	White or speckled 		Flat or bulge of posterior anulus on sagittal views. Distortion of the bean shape, or a rounded appearance of the anulus. Small radial tears not reaching the PLL on the axial views.	Reduced by 10% (H2)
Moderate (DC-3)	Speckled or dark 		Bulge or Prolapse of the posterior annulus on the sagittal views. Ill defined appearance of the annulus in axial views. Radial tears extending upto torn PLL on the sagittal/axial views, +/- prolapse or end plate changes.	Reduced by 10% - 50% (H3)
Severe (DC-4)	Dark (Hypointense) 		No difference between the appearance of annulus and nucleus, +/- complex tears, +/- Prolapse with or without end plate changes.	Reduced by 50% or more (H4)

Figure 7 Woodend classification

Measurement of the disc dimensions counted on 3-plane slice imaging at the most midline cut of MRI in T2 weighted image. Considering lordosis of the cervical spine, we measure the height of vertebral body at anteriorly, posteriorly, and maximum disc height. (as figure 8). The data concerning the endplates were obtained from the caudal surfaces. On each surface we measured three diameters. The median sagittal diameter (SD) goes through the middle of the transverse diameter. (as Figure 9) The transverse diameter (TD) is maximum breadth across the vertebral body (as Figure 10) .As "diagonal diameter" (DD), we considered the longest diameter running through the intersection of the two others and forming and angle between 30^{o} and 60^{o} with the sagittal (as Figure 10). If we suspected a slight asymmetry, we compared the diameter from right anterior to left posterior with the one from left anterior in right posterior (as Figure 11). But never found a significant difference. Grossly asymmetrical cases would have been considered pathological and therefore exclude. Data were obtained by a computerized coordinate system from MRI images. All data were analyzed by Student's t test, ANOVA, and correlation between levels. The validation of data has been done by intraobserver method and analyzed by Student pair t-test. A total of 300 measured cervical spine levels were done.

Figure 8 Anterior disc height, maximum disc height and posterior disc height

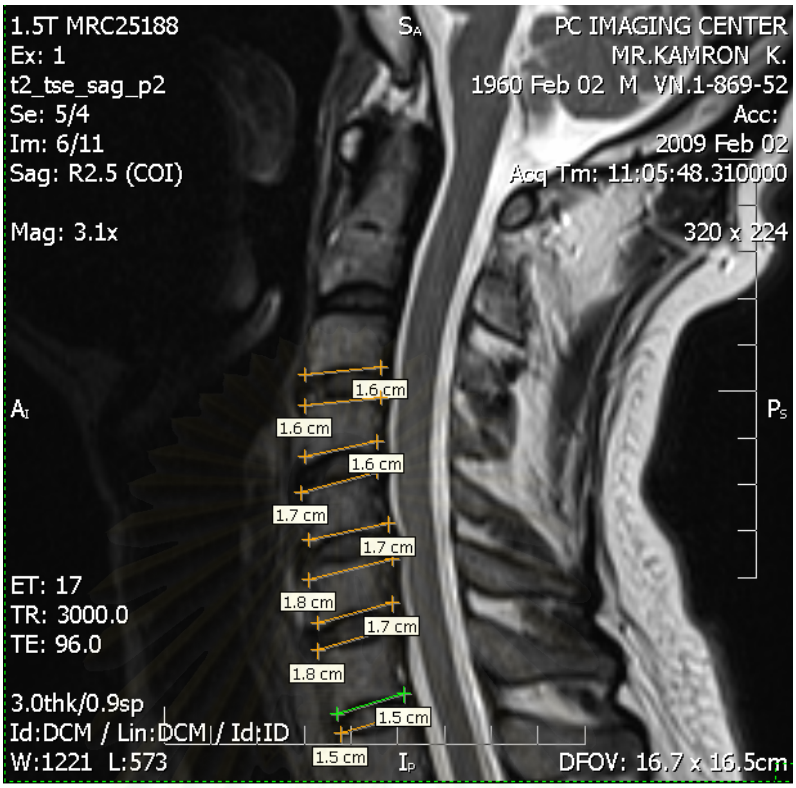


Figure 9 Sagittal diameters (SD)

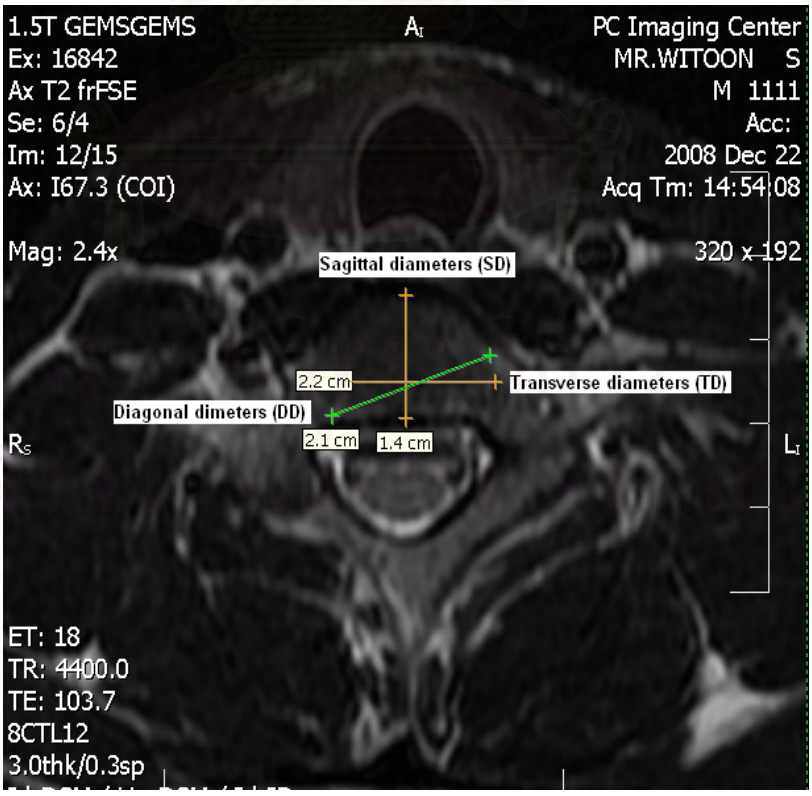


Figure 10 Transverse diameters (TD) and Diagonal diameters (DD)

Sample size

Population size depends on previous study.[32] The calculation of population size was demonstrated as table 2.

TABLE 1. Summary list of all data (all measurements are in millimeters)

			Cervical
Transverse diameter	Extreme values	Macerated	17–29
		CT	12–28
	Mean values	Macerated	21.1 ± 2.4
		CT	18.1 ± 4.8
		Total	21.2 ± 3.7
Diagonal diameter	Extreme values	Macerated	16–24
		CT	12–28
	Mean values	Macerated	19.8 ± 1.9
		CT	19.3 ± 5.1
		Total	19.6 ± 3.0
Sagittal diameter	Extreme values	Macerated	12–24
		CT	13–19
	Mean values	Macerated	16.1 ± 2.2
		CT	16.6 ± 1.8
		Total	16.2 ± 2.1

Table 2 previous study[34]

Population size

- $N = Z^2_{a/2}SD^2/d^2$
- $SD = 3.7$
- $Z_{a/2} = 1.96$
- $d^2 = 1^2$ mm
- $N = 52$

However, there's no pilot study in cervical disc dimension of Thai population. We conduct the size of cervical prosthesis to analyze the appropriated size for Thai cervical disc size. In order to prepare data for preoperative planning and cervical disc design in the future.

Conceptual frameworks

- ❖ Device used by anterior surgical approach.
- ❖ The device would have proper dimension to compensate for dimensions loss in early disc degenerative to near normal.
- ❖ To decrease complications from improper disc dimensions
- ❖ To compare prosthesis that be used in Thailand.

From the conceptual frameworks as already maintained, the model would be compared by cluster analysis.

CHAPTER IV

RESULTS AND DISCUSSION

Disc dimensions

Measurement was done in 60 samples (30 male 30 female) and result as seen below.

Table 3 Average anterior cervical disc height

subject	Subject number	Average anterior cervical disc height (mm)				
		C3-4	C4-5	C5-6	C6-7	C7-T1
male	30	3.40	3.40	3.17	3.50	3.63
female	30	3.03	2.77	2.47	3.03	2.93
Total	60	3.41	3.23	3.05	3.44	3.51

Maximum anterior cervical disc height in male was 3.63 mm at C3-4 level and minimum 2.47 mm at C5-6 level in female. There are statistical significantly difference between male and female with test by ANOVA. (P-value <0.05) The mean difference had been shown between male and female as figure 11 and 12. Considering lordosis of the cervical spine, we measure the height of vertebral body at anteriorly, posteriorly, and maximum disc height. The lordosis of cervical spine had been shown in anterior disc height as figure 13.

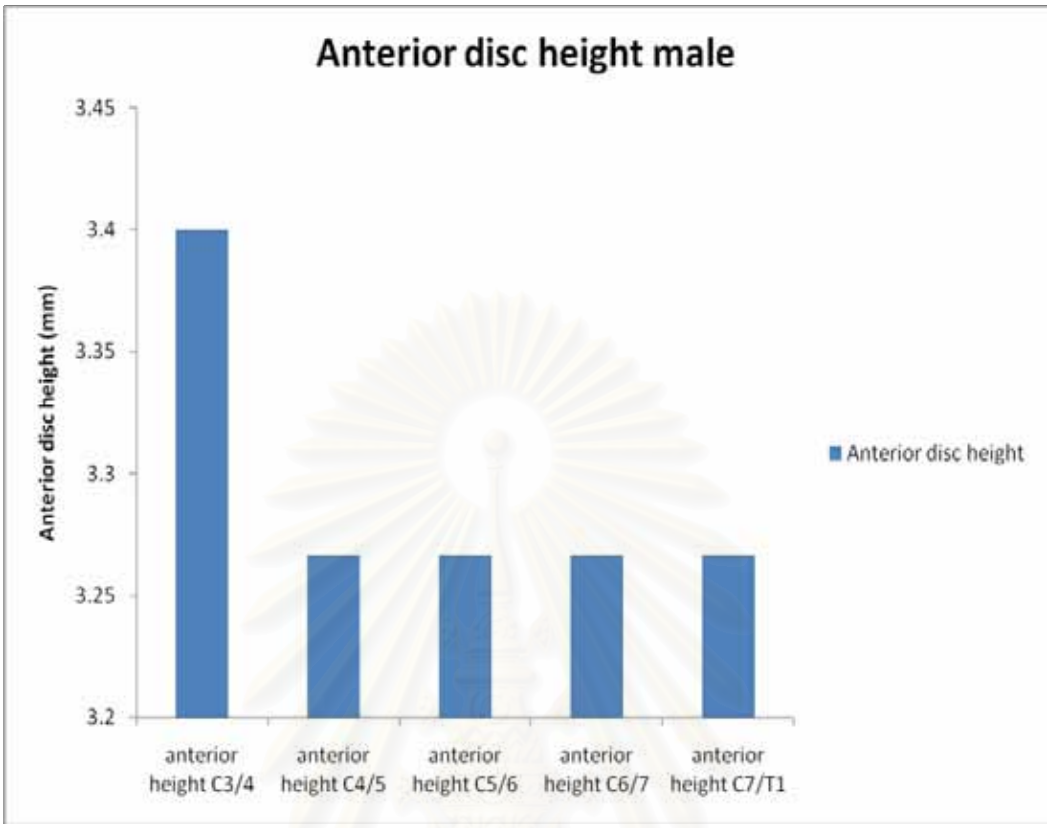


Figure 11.Anterior disc height male

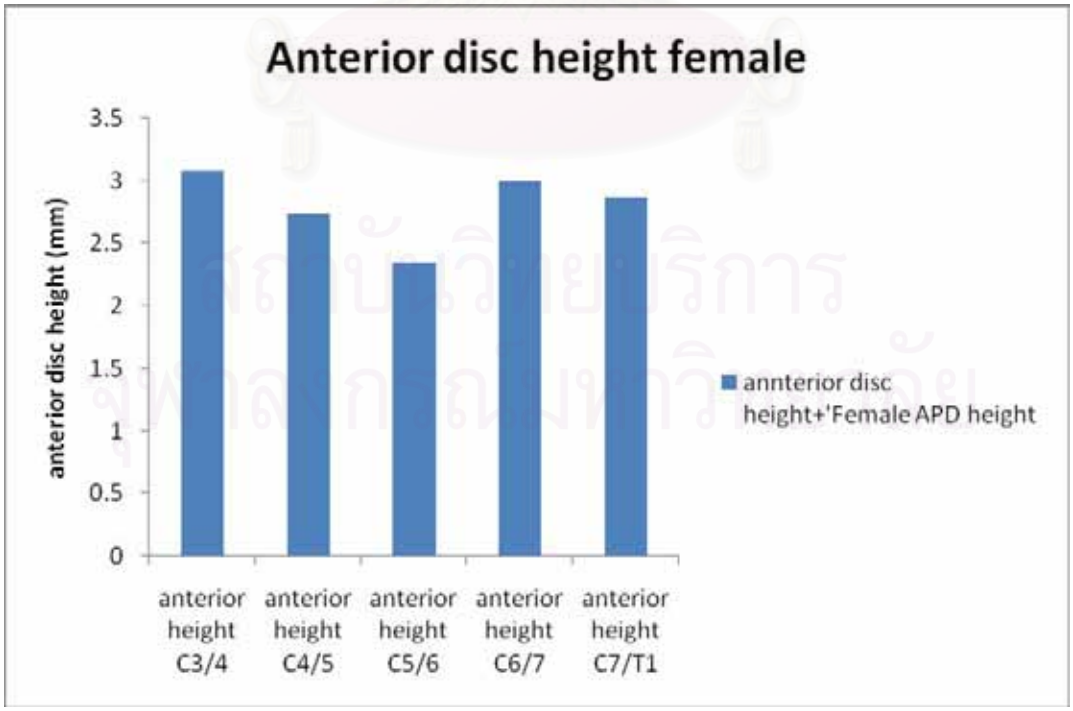


Figure 12.Anterior disc height female

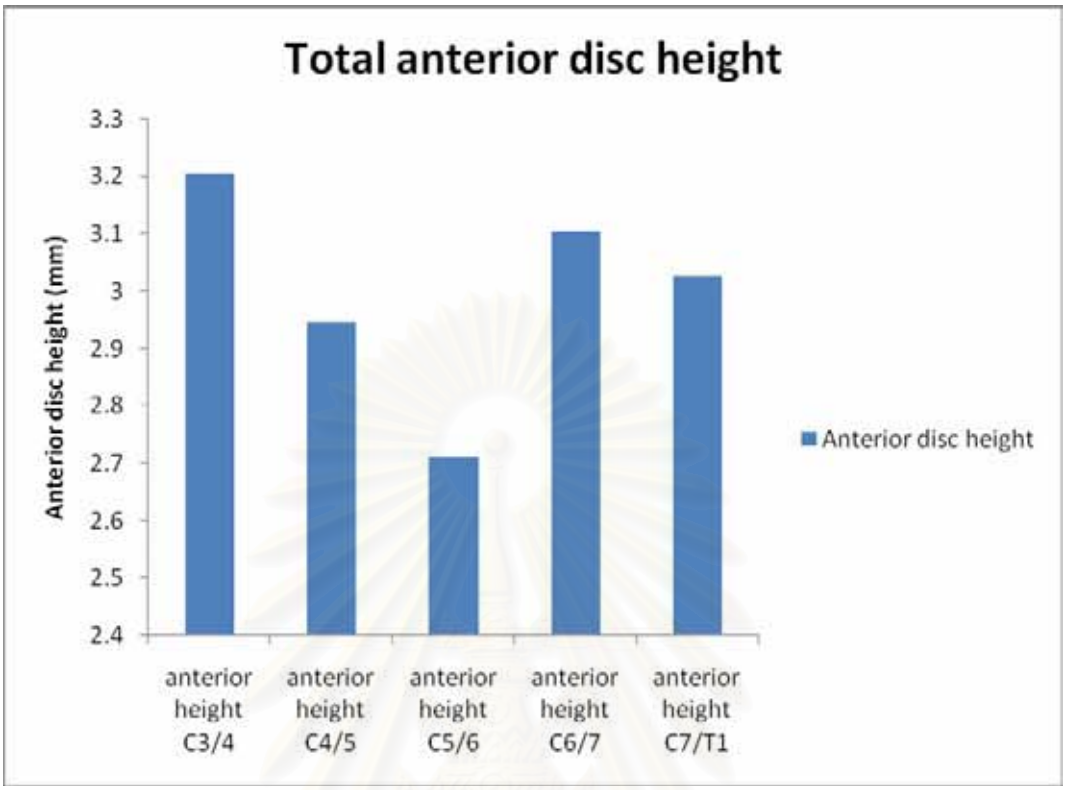


Figure 13.Total anterior disc height

Table 4 Maximum cervical disc height

subject	Subject number	Average maximum cervical disc height (mm)				
		C3-4	C4-5	C5-6	C6-7	C7-T1
male	30	6.63	6.07	5.87	6.37	6.20
female	30	5.83	5.53	5.47	5.87	6.10
Total	60	6.44	5.90	5.79	6.28	6.21

Maximum cervical disc height in male was 6.63 mm at C3-4 level and minimum 5.47 mm at C5-6 level in female. There are statistical significantly difference between male and female with test by ANOVA. (P-value <0.05) The mean difference had been shown between male and female as figure 14 and 15. Considering lordosis of the cervical spine, we measure the height of vertebral body at anteriorly, posteriorly, and maximum disc height. The lordosis of cervical spine had been shown in maximum disc height as figure 16.

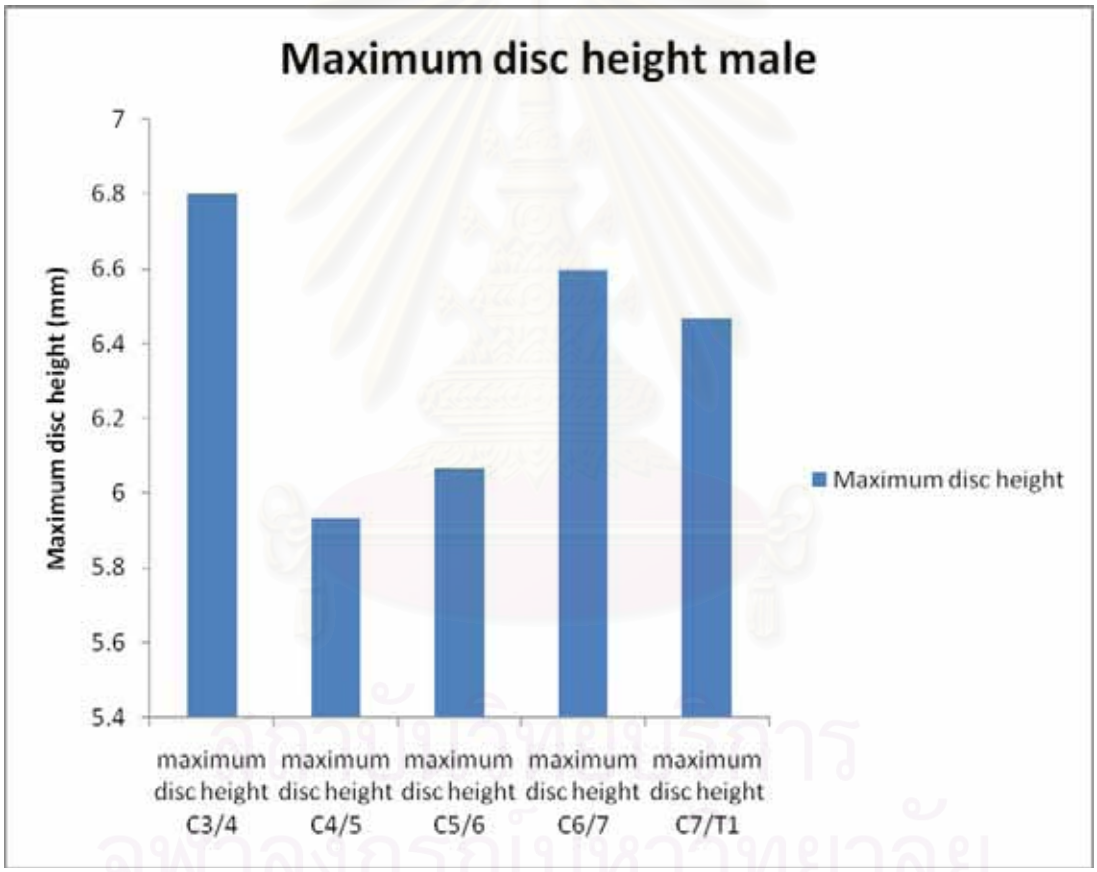


Figure 14.Maximum disc height male

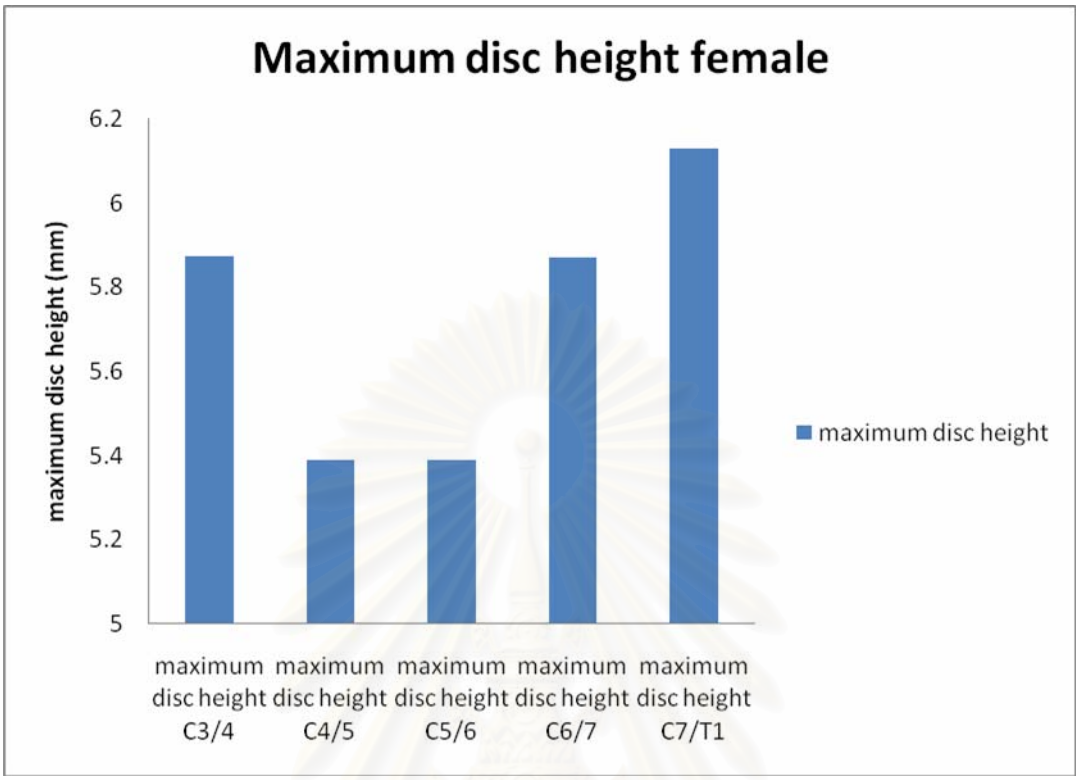


Figure 15.Maximum disc height female

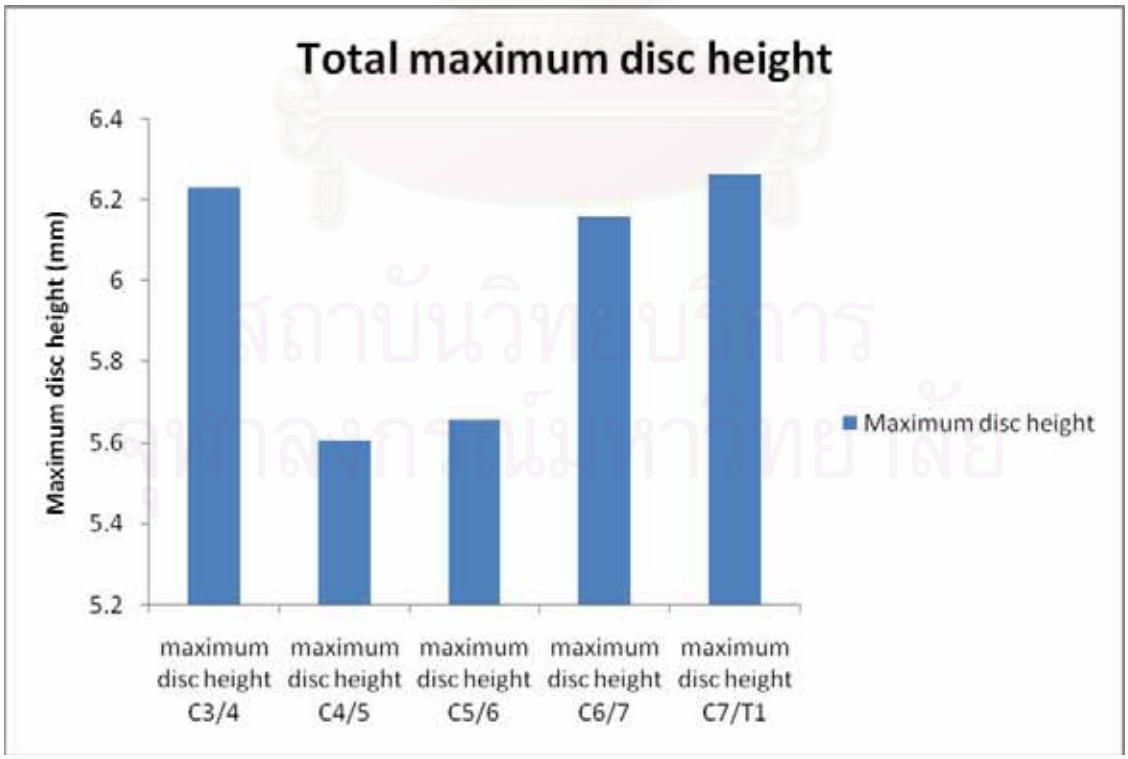


Figure 16.Total maximum disc height

Table 5 Posterior cervical disc height

subject	Subject number	Average posterior cervical disc height (mm)				
		C3-4	C4-5	C5-6	C6-7	C7-T1
male	30	3.30	2.97	2.97	3.03	3.03
female	30	2.80	2.63	2.37	2.53	2.67
Total	60	3.23	2.87	2.90	3.00	2.95

Maximum posterior cervical disc height in male was 3.30 mm at C3-4 level and minimum 2.37 mm at C5-6 level in female. There are statistical significantly difference between male and female with test by ANOVA. (P-value <0.05) The mean difference had been shown between male and female as figure 17 and 18. Considering lordosis of the cervical spine, we measure the height of vertebral body at anteriorly, posteriorly, and maximum disc height. The lordosis of cervical spine had been shown in posterior disc height as figure 19.

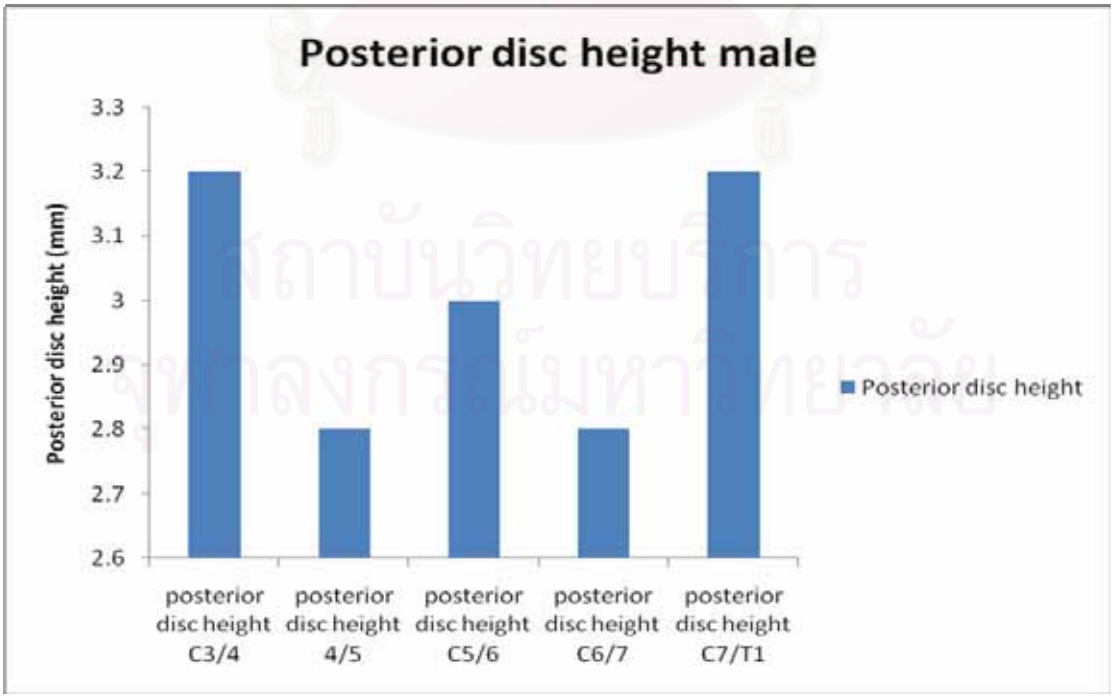


Figure 17.Posterior disc height male

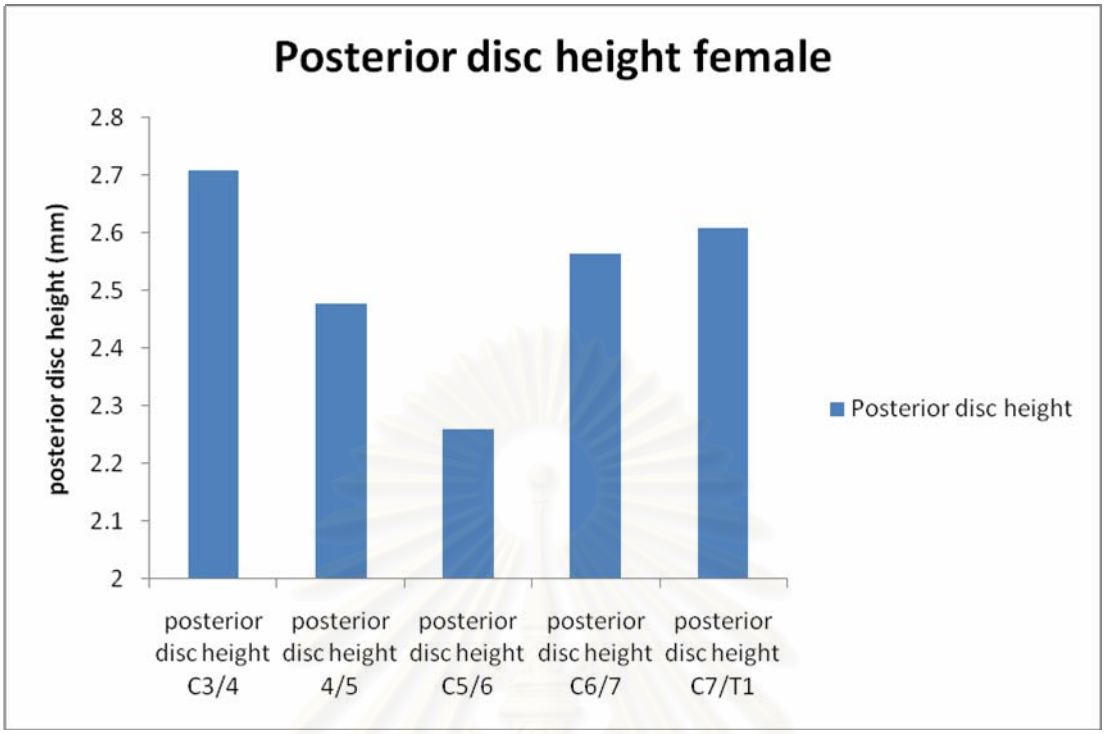


Figure 18.Posterior disc height female

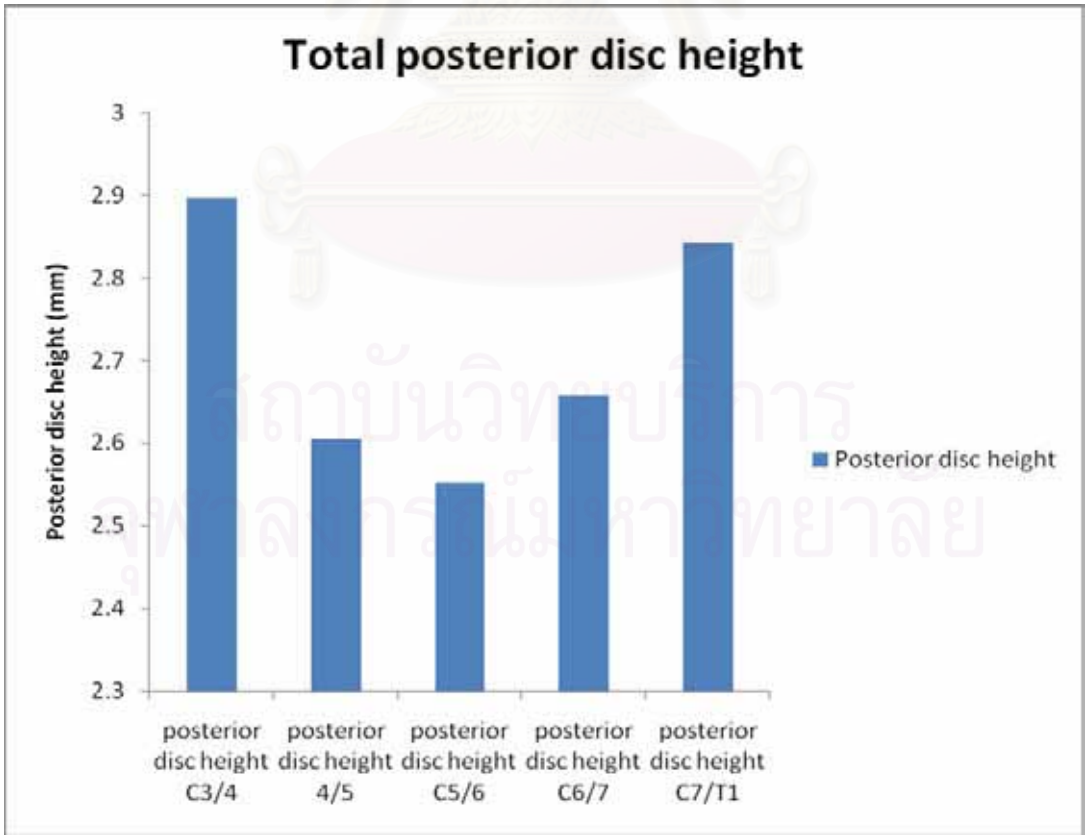


Figure 19.Total posterior disc height

Table 6 Sagittal diameters

Subject		Male	Female	Total
Subject number		30	30	60
Average sagittal diameter (mm)	**$C3_i$**	15.17	13.33	14.77
	$C4_s$	15.10	13.37	14.77
	$C4_i$	15.67	13.77	15.23
	$C5_s$	15.63	13.37	15.13
	$C5_i$	16.17	13.93	15.74
	$C6_s$	15.90	13.97	15.62
	$C6_i$	16.20	14.03	15.72
	$C7_s$	16.07	14.13	15.69
	$C7_i$	16.33	13.67	15.79
	$T1_s$	16.47	14.22	16.00

Maximum sagittal diameter in male was 16.47 mm at T1 level and minimum 13.33 mm at $C3_i$ level in female. There are statistical significantly difference between male and female with test by ANOVA. (P-value <0.05) The mean difference had been shown between male and female as figure 20 and 21. The size of cervical spine had been shown in sagittal diameters as figure 22.

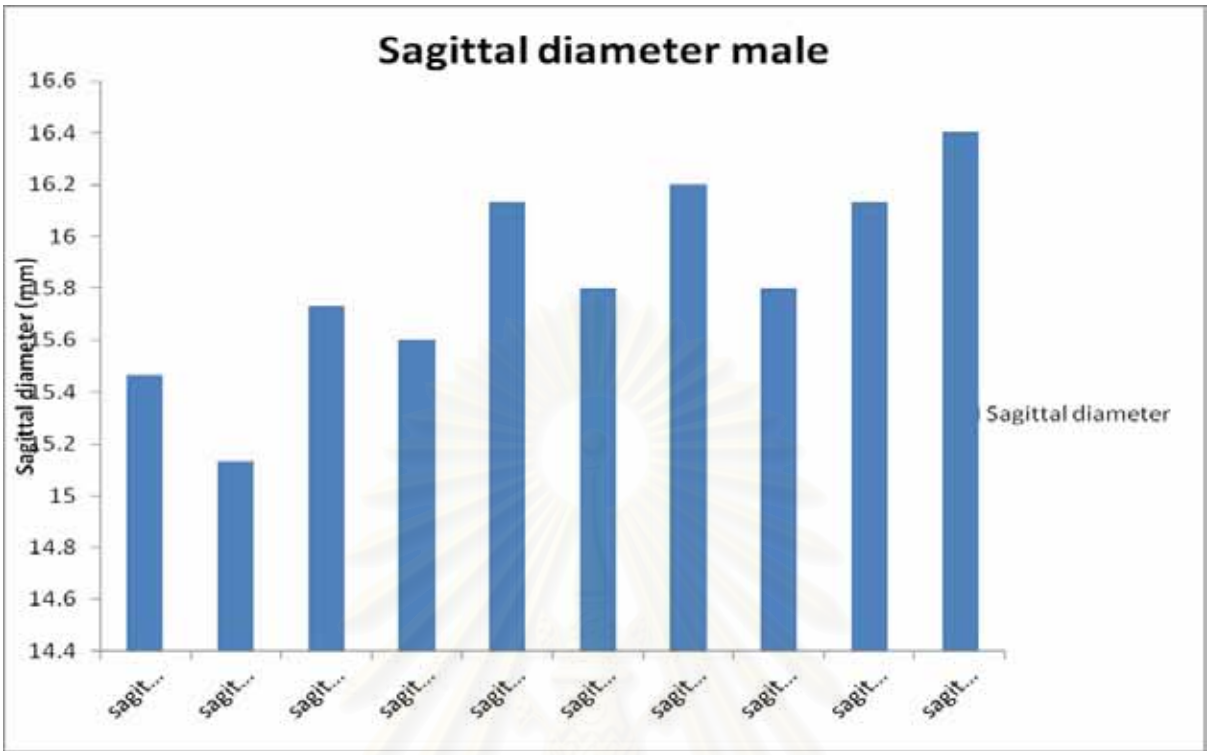


Figure 20.Sagittal diameter male

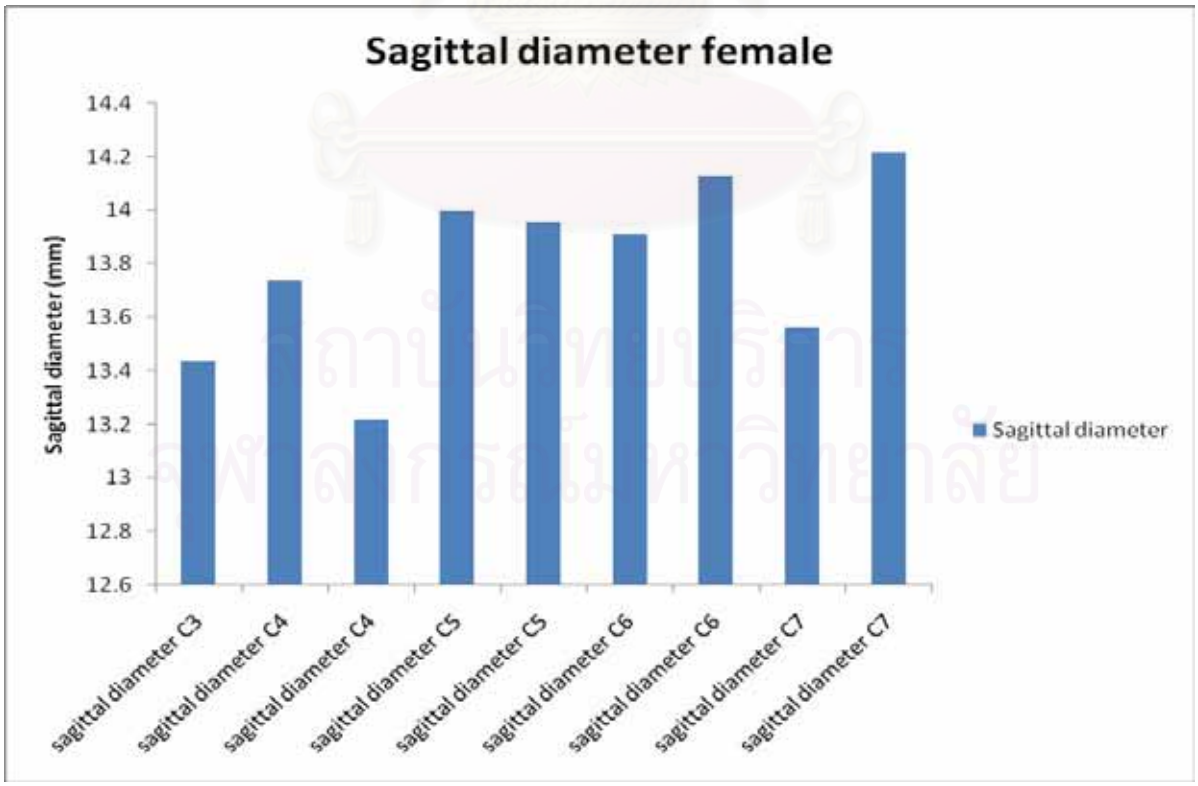


Figure 21.Sagittal diameter female

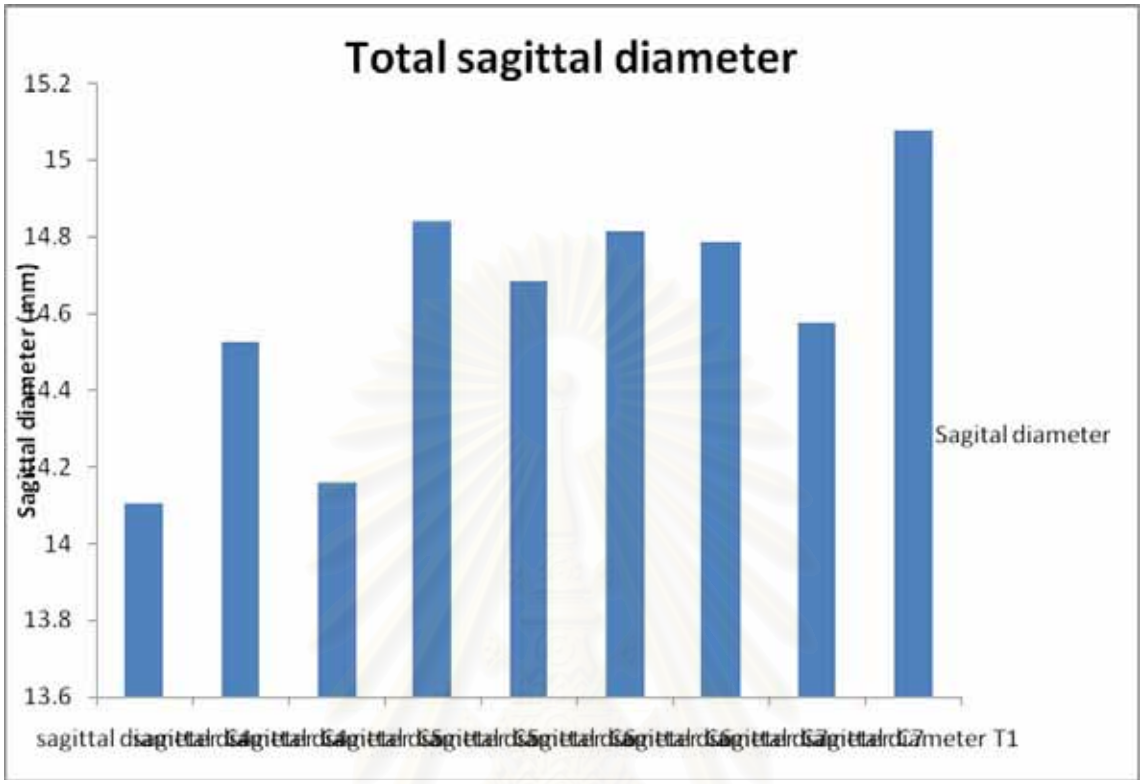


Figure 22.Total sagittal diameter

Table 7 Transverse diameters

Subject		Male	Female	Total
Subject number		30	30	60
Average transverse diameter (mm)	**$C3_i$**	22.10	20.80	21.77
	$C4_s$	22.30	21.50	22.15
	$C4_i$	22.40	21.70	22.15
	$C5_s$	23.20	22.20	22.95
	$C5_i$	23.73	22.83	23.44
	$C6_s$	24.57	23.40	24.23
	$C6_i$	25.83	24.13	25.36
	$C7_s$	26.60	25.43	26.28
	$C7_i$	27.47	25.57	26.92
	$T1_s$	27.73	24.80	26.95

Maximum transverse diameter in male was 27.73 mm at T1 level and minimum 20.80 mm at $C3_i$ level in female. There are statistical significantly difference between male and female with test by ANOVA. (P-value <0.05) The mean difference had been shown between male and female as figure 23 and 24. The size of cervical spine had been shown in transverse diameters as figure 25.

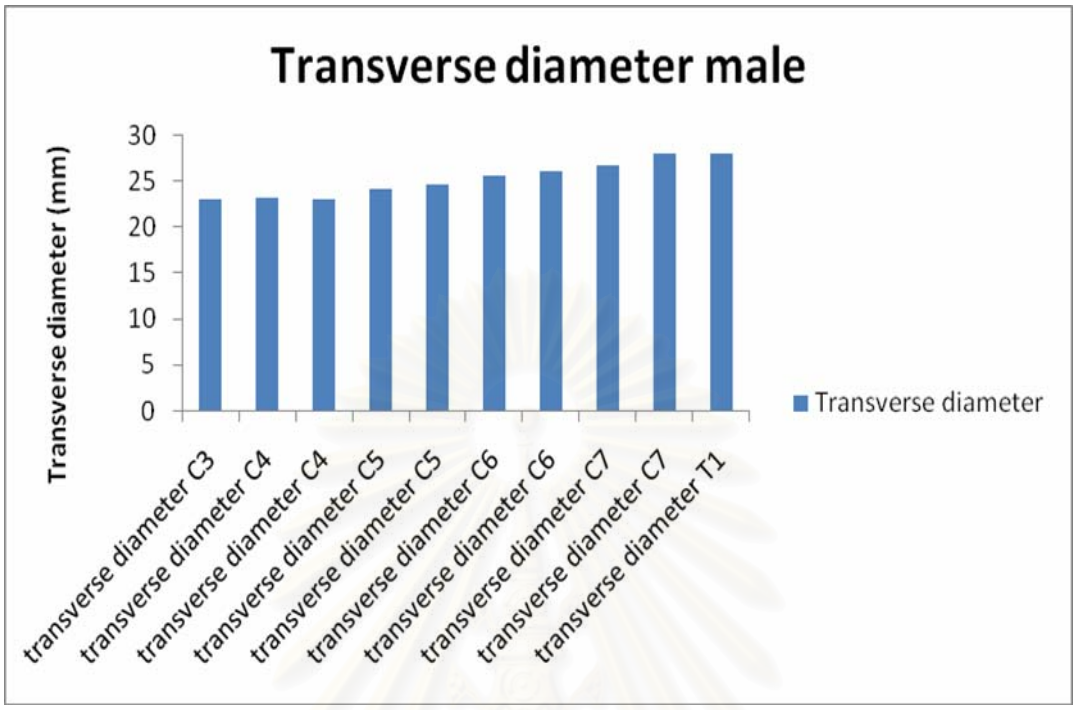


Figure 23.Transverse diameter male

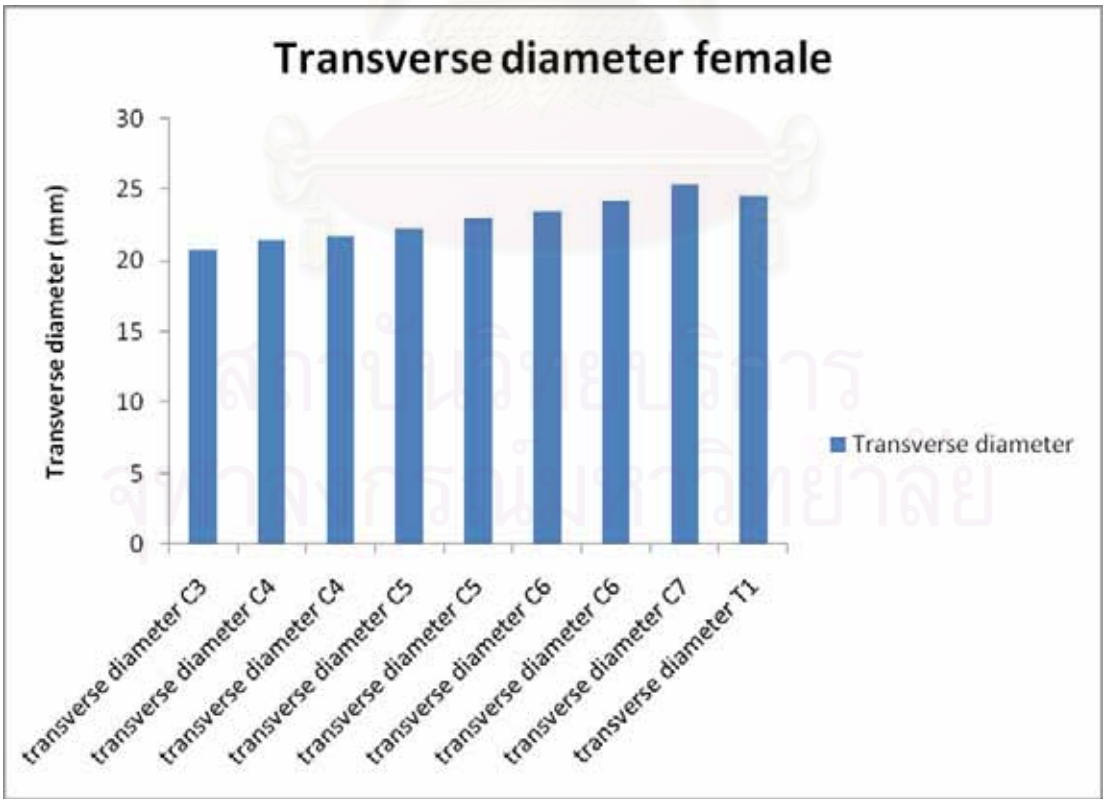


Figure 24.Transverse diameter female

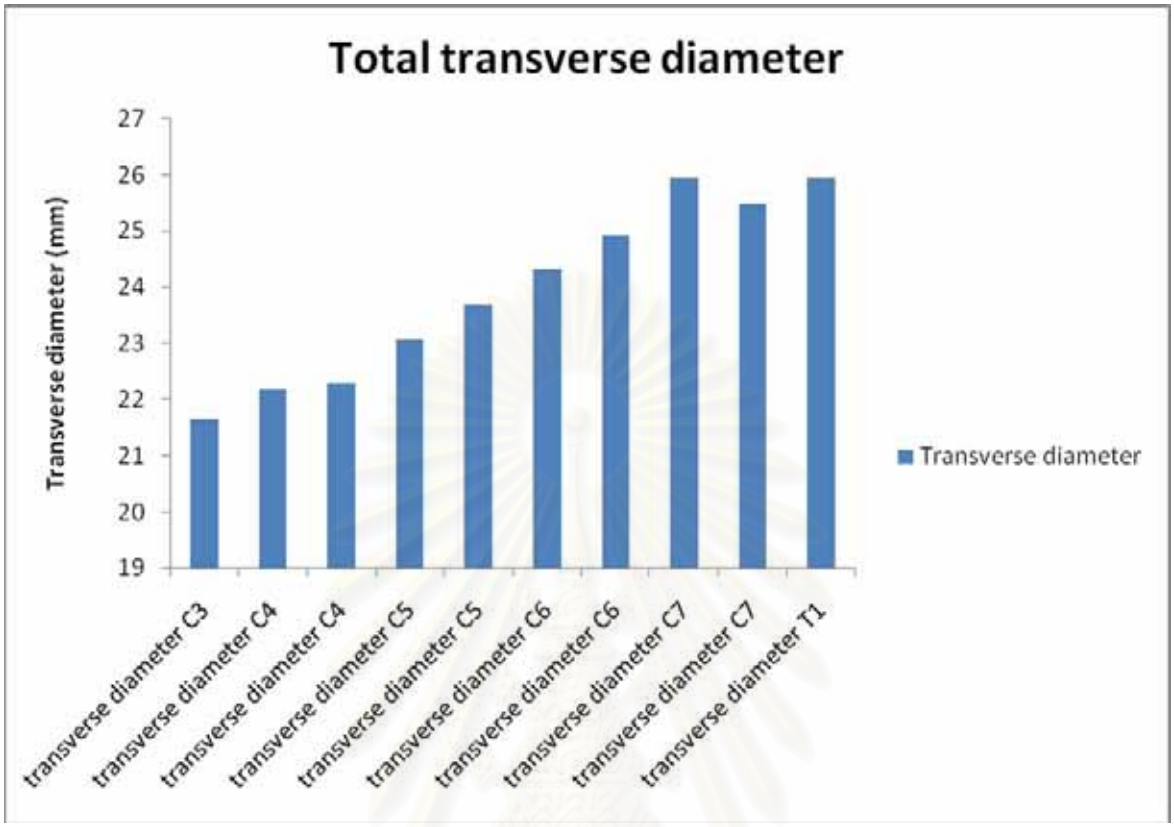


Figure 25.Total transverse diameter

Table 8 Diagonal diameters

Subject		Male	Female	Total
Subject number		30	30	60
Average diagonal diameter (mm)	**$C3_i$**	21.90	21.37	21.77
	$C4_s$	22.73	22.40	22.87
	$C4_i$	22.00	21.57	21.92
	$C5_s$	23.13	22.47	23.18
	$C5_i$	23.20	22.30	22.75
	$C6_s$	23.93	23.17	23.55
	$C6_i$	24.83	23.83	24.33
	$C7_s$	25.57	24.50	25.03
	$C7_i$	25.13	24.43	24.78
	$T1_s$	25.53	23.80	24.67

Maximum diagonal diameter in male was 25.57 mm at $C7_s$ level and minimum 21.37 mm at $C3_i$ level in female. There are statistical significantly difference between male and female with test by ANOVA. (P-value <0.05) The mean difference had been shown between male and female as figure 26 and 27. The size of cervical spine had been shown in transverse diameters as figure 28.

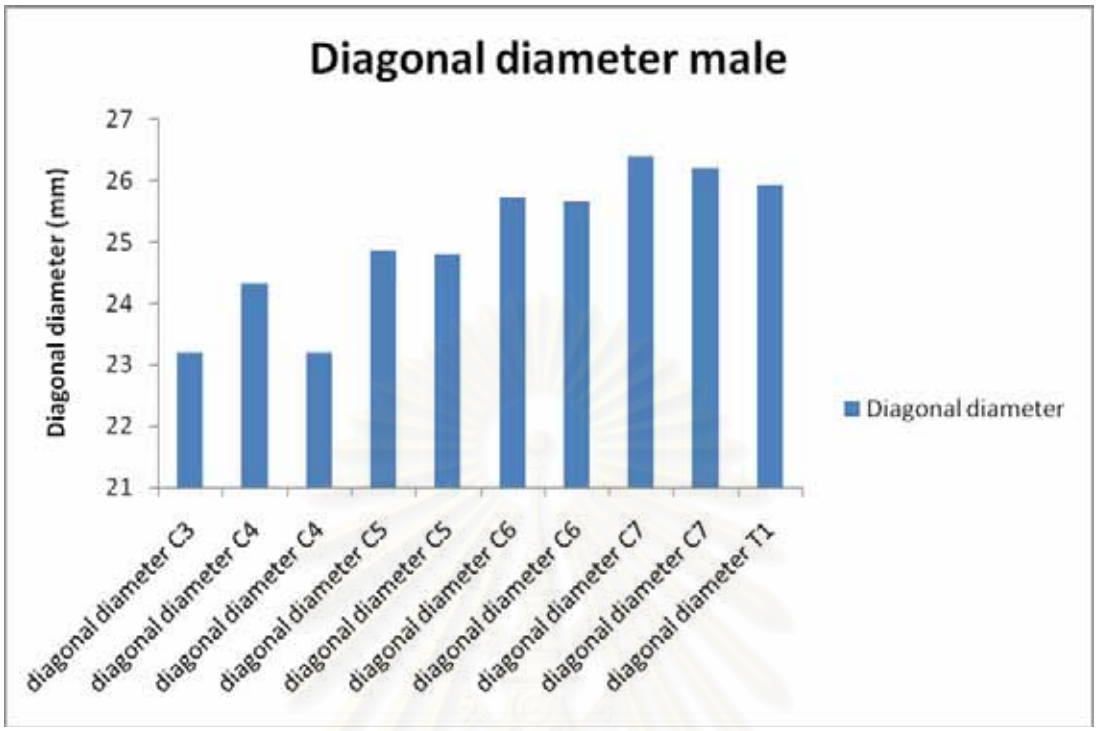


Figure 26.Diagonal diameter male

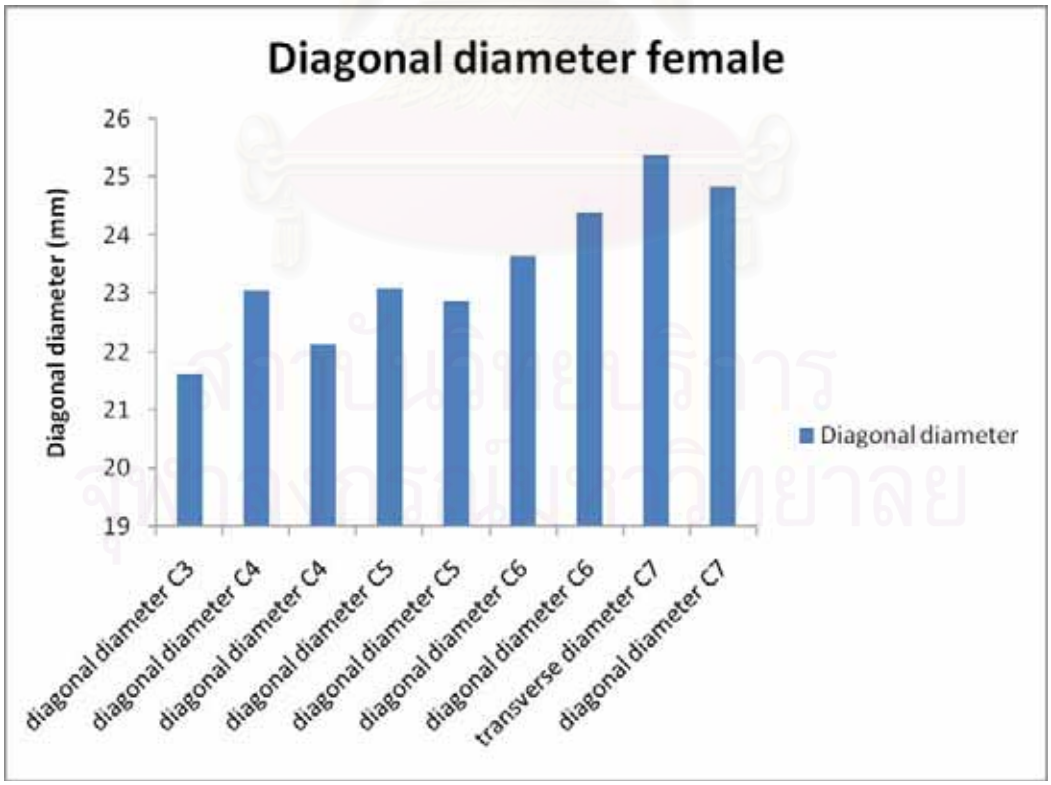


Figure 27.Diagonal diameter female

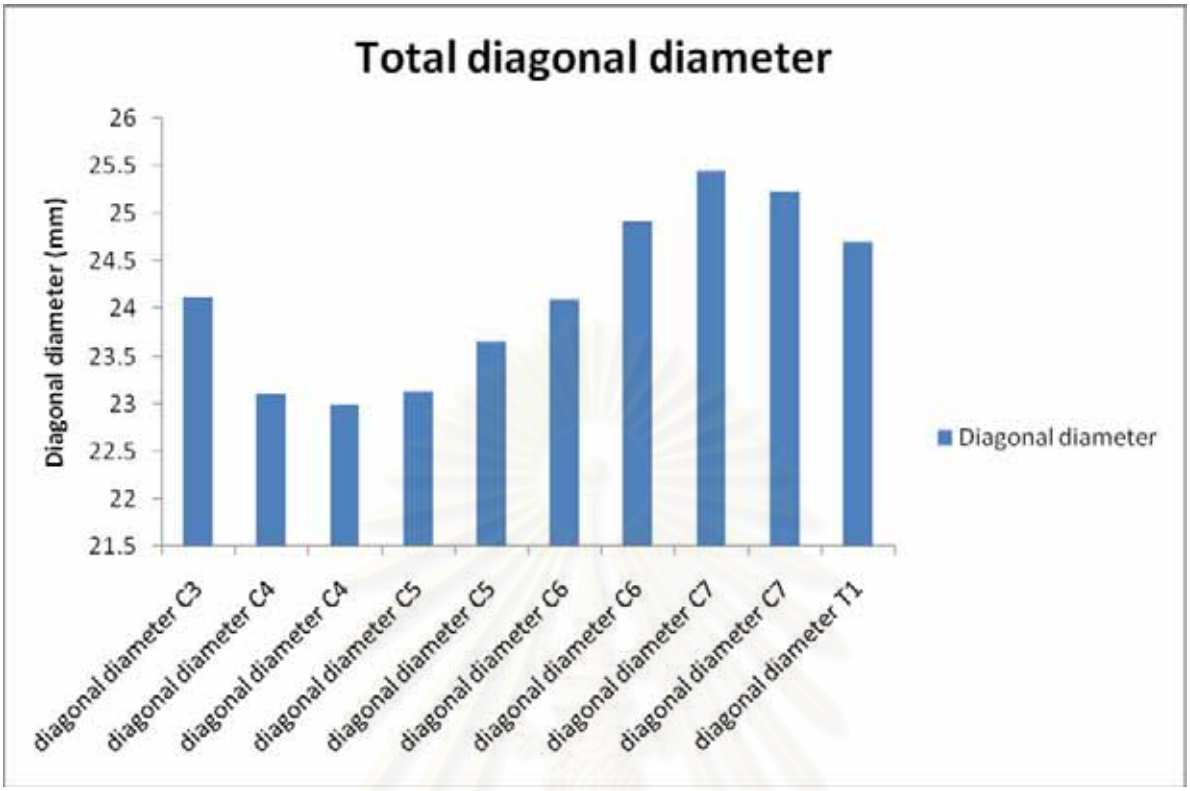


Figure 28.Total diagonal diameter

The validation of data has been done by intraobserver method and analyzed by Student pair t-test. The result has been shown table below.

Subject	Mean of 1st measurement (mm)	Mean 2nd measurement (mm)	P-value
Sagittal diameter	14.47	14.46	0.1
Transverse diameter	25.52	25.14	0.2
Diagonal diameter	22.49	21.73	0.00001
Disc height	5.79	5.95	0.08

Table 9 Validation of intraobserver measurement

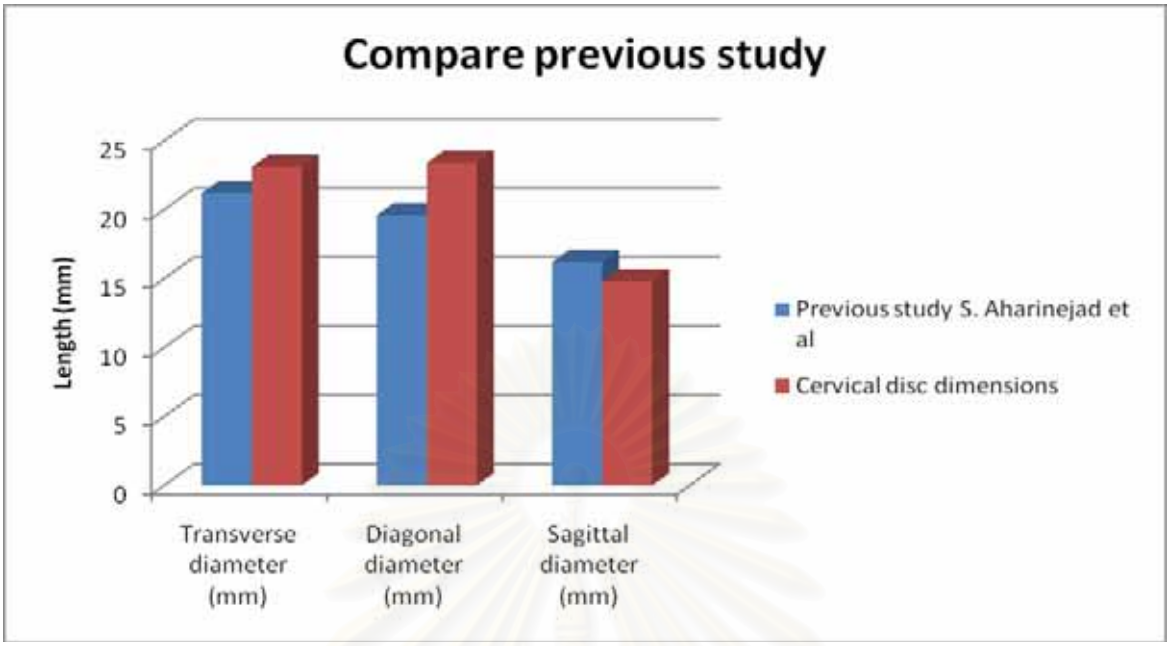


Figure 29.Compare the previous study

From previous study of cervical disc dimension (as table 2), we compared cervical dics dimensions data between sagittal diameter, trasnverse diameter, and diagonal diameter by using Student's t-test. The results has been shown as table 10 and figure 9.

Subject	Previous study S. Aharinejad et al.	Cervical disc dimensions	P-value
Transverse diameter (mm)	21.2 $\pm$ 3.7	23.1 $\pm$ 3.6	<0.001
Diagonal diameter (mm)	19.6 $\pm$ 3.0	23.4 $\pm$ 2.3	<0.001
Sagittal diameter (mm)	16.2 $\pm$ 2.1	14.8 $\pm$ 1.9	<0.001

Table 10 compare previous study

The cervical disc dimensions of Thai population is different from previous study that the sample data were collected from Austria (caucasian). This different dimensions of the cervical dics from caucasion may be inappropriated cervical dics prosthesis that be used in Thailand.

Before compare the size between cervical disc prosthesis, we had evalulated the correlation between sagittal diameter and cervical disc height, sagittal diameter and transverse diameter. The results have been shown in figure 28,29.

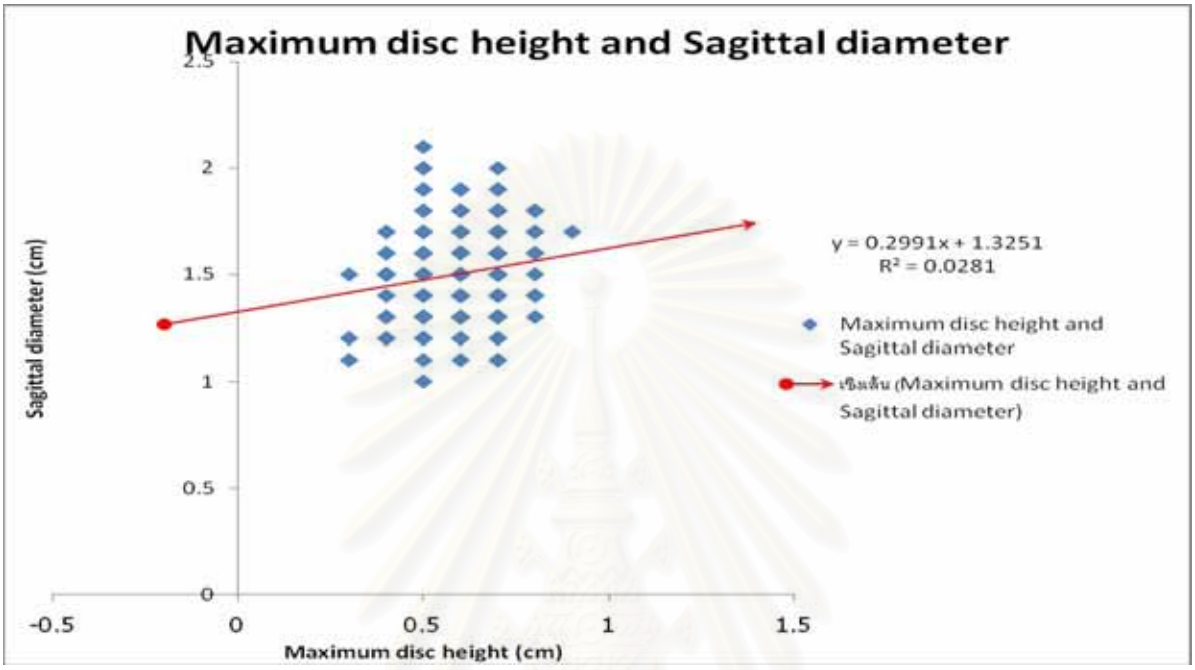


Figure 30.Compare correlation between maximum disc height and sagittal diameter

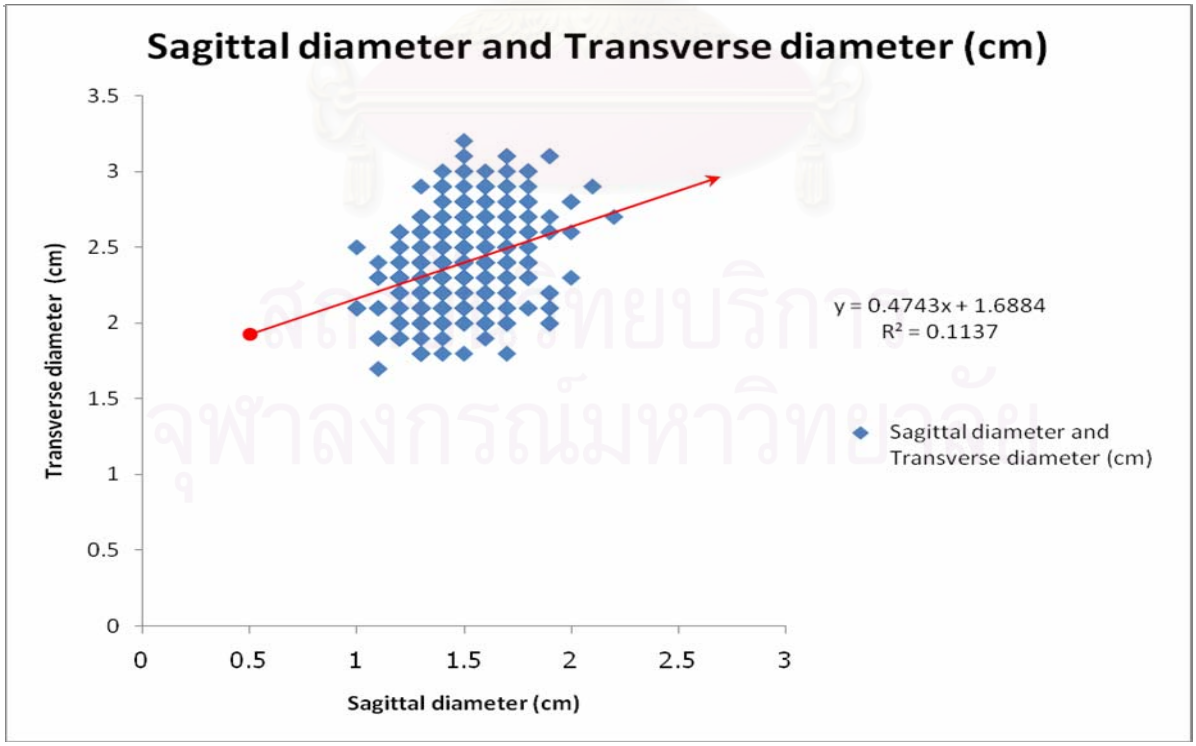


Figure 31.Compare correlation between sagittal diameter and transverse diameter

In order to compare between cervical disc dimensions and cervical disc prosthesis that be used in Thailand, We had collected data of the cervical disc prosthesis that be used in Thailand were Prodisc-C, Mobi-C, and Prestige LP. There are many footprints for theses prosthesis that show in table 11 below.

Subject	Height (mm)	Sagittal diameters (mm)	Transverse diameters (mm)
Prodisc-C	5, 6, 7, 8	12, 14, 16, 18	15, 17, 19
Mobi-C	4.5, 5, 6, 7	13, 15	15, 17, 20
Prestige LP	6, 7, 8	12, 14, 16, 18	NA

Table 11.Footprints of prosthesis

We compared disc dimensions from MRI with cervical disc prosthesis, (as figure) the graph had shown the cervical disc dimensions from MRI may be smaller height than the cervical disc prosthesis that be used in Thailand.

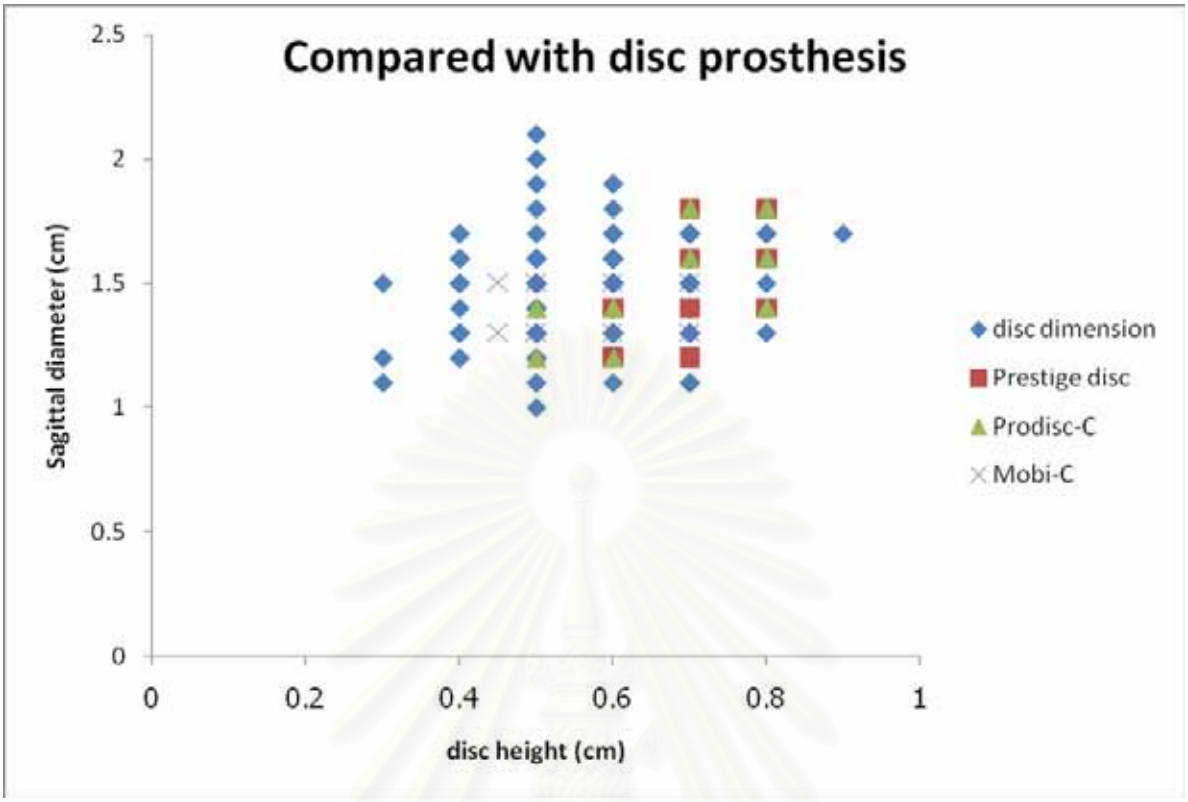


Figure 32.Compare with disc prosthesis between sagittal diameter and disc height

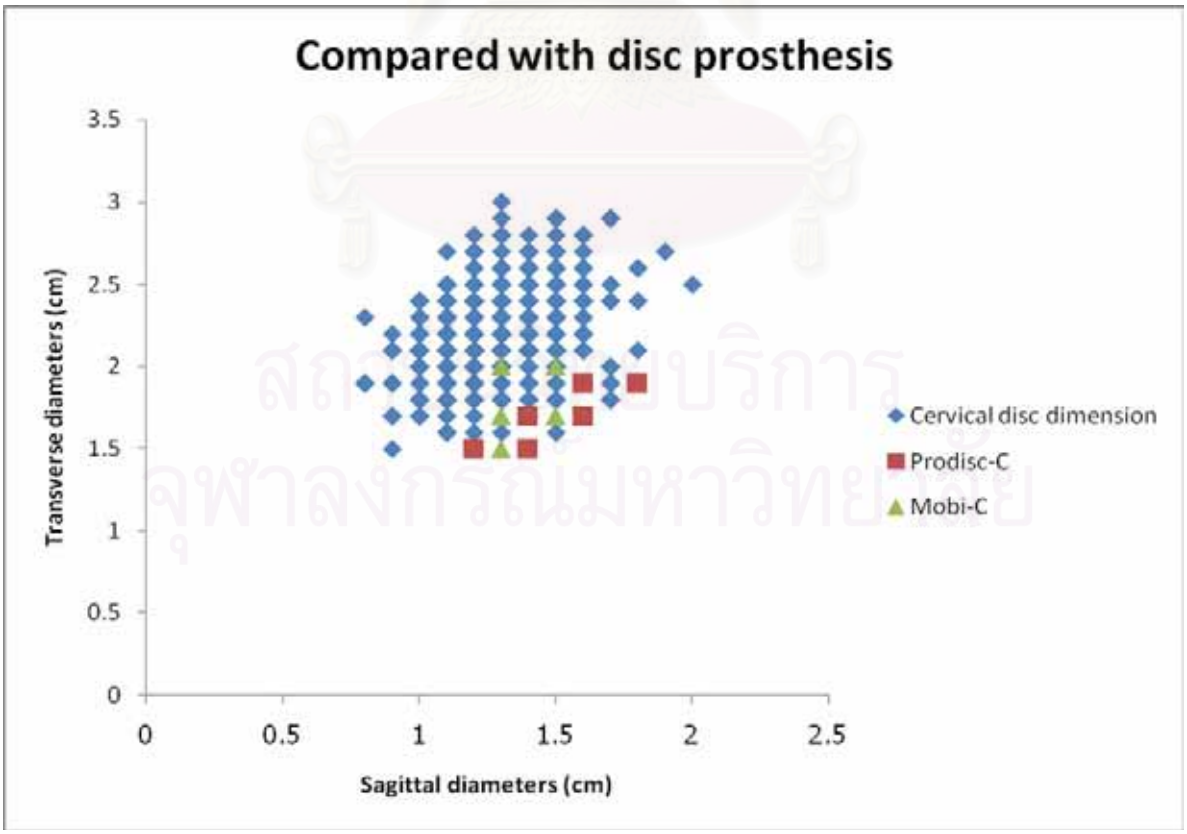


Figure 33.Compare with disc prosthesis between sagittal diameter and transverse diameter

From measurement disc height result, number of size of cervical disc height we should manufacture is 7 sizes of disc height (from 3 mm to 9 mm). We use cluster analysis for disc height by K-mean cluster analysis, the result as table 12 and figure 32.

Table 12.Final Cluster Centers Disc Height

	Cluster						
	1	2	3	4	5	6	7
DH	.80	.70	.60	.50	.40	.90	.30

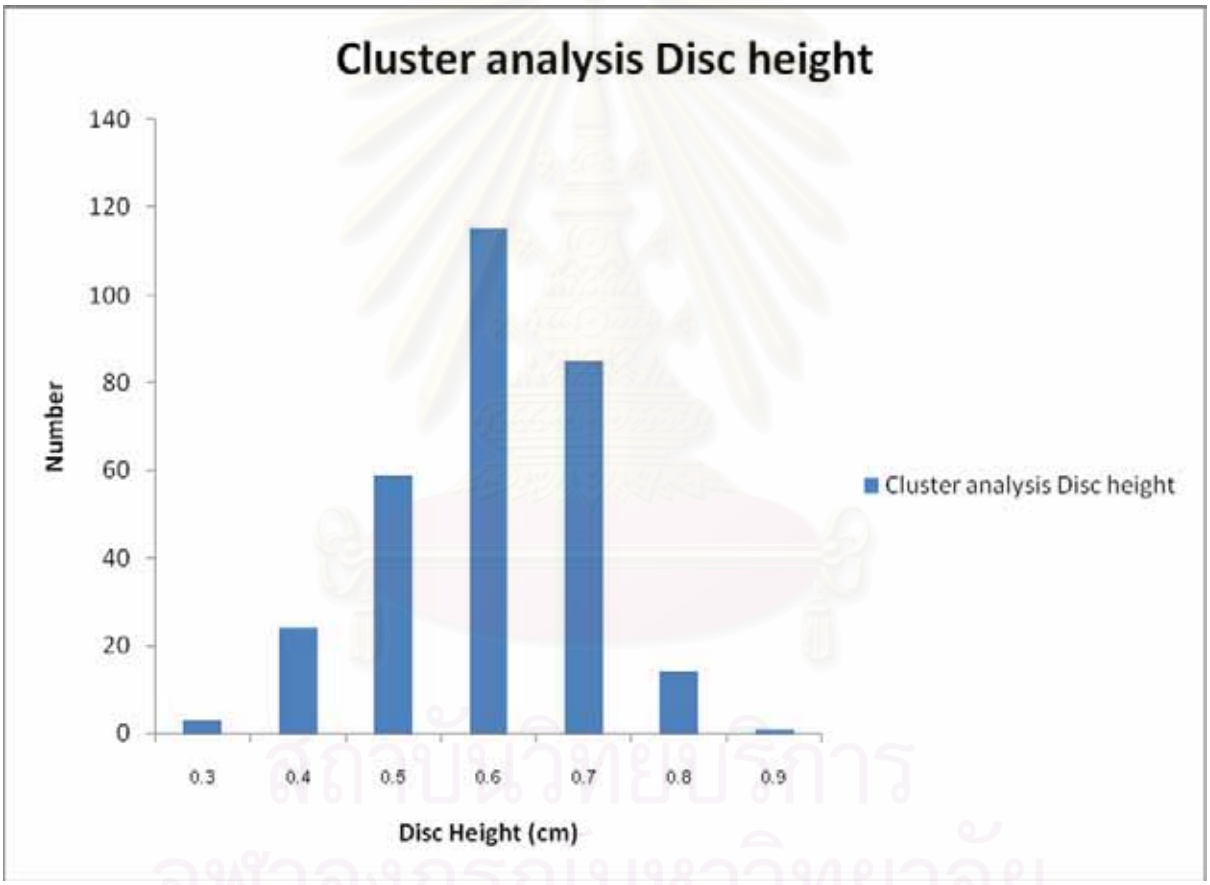


Figure 34.Cluster analysis disc height

From measurement sagittal diameter result, number of size of cervical sagittal diameter we should manufacture is 6 sizes of sagittal diameter (from 10 mm to 22 mm). We use cluster analysis for sagittal diameter by K-mean cluster analysis, the result as table 13 and figure 33.

Table 13.Final Cluster Centers Sagittal Diameter

	Cluster					
	1	2	3	4	5	6
SD	1.00	2.05	1.18	1.58	1.35	1.83

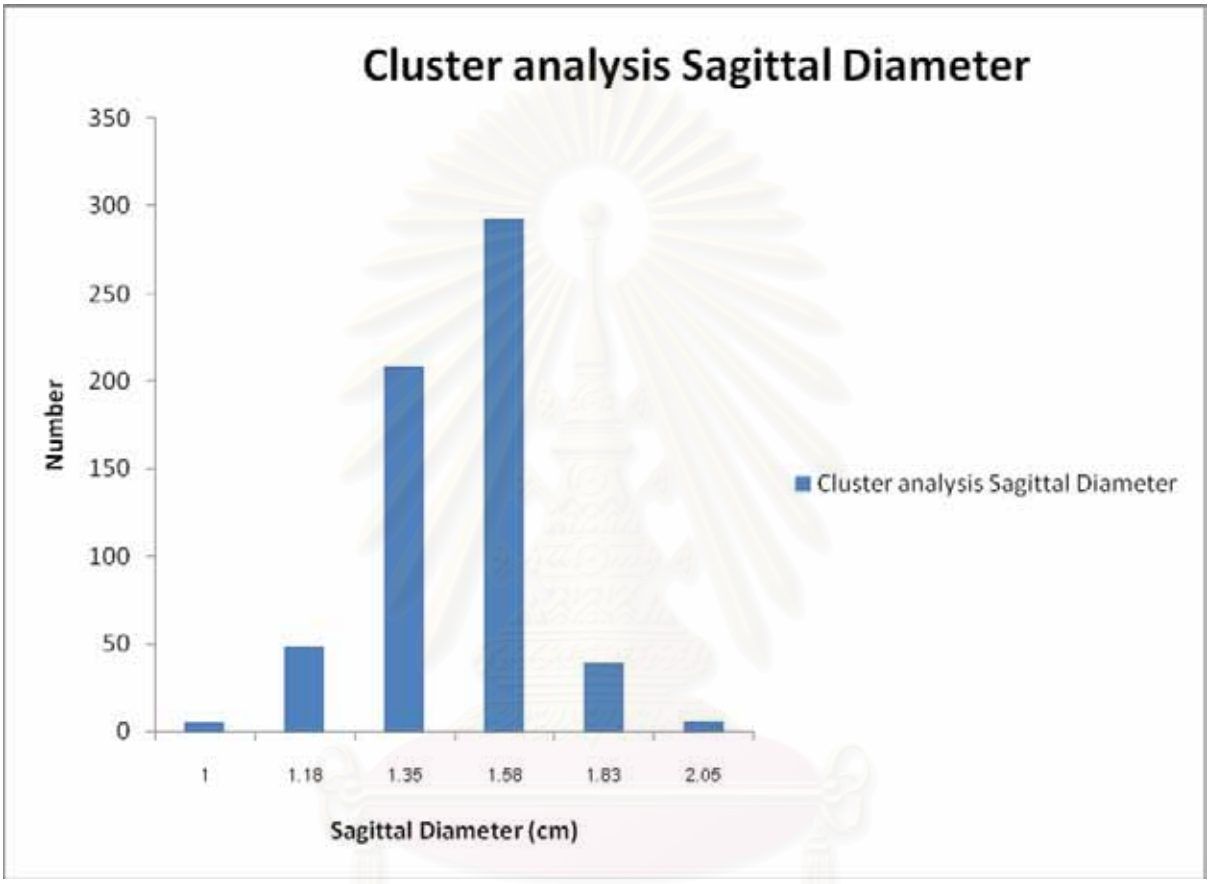


Figure 35.Cluster analysis sagittal diameter

From measurement transverse diameter result, number of size of cervical transverse diameter we should manufacture is 9 sizes of transverse diameter (from 17 mm to 32 mm). We use cluster analysis for transverse diameter by K-mean cluster analysis, the result as table 14 and figure 34.

Table 14.Final Cluster Centers Transverse Diameter

	Cluster							
	1	2	3	4	5	6	7	8
TD	2.49	2.06	2.26	2.74	3.12	1.70	1.86	2.93

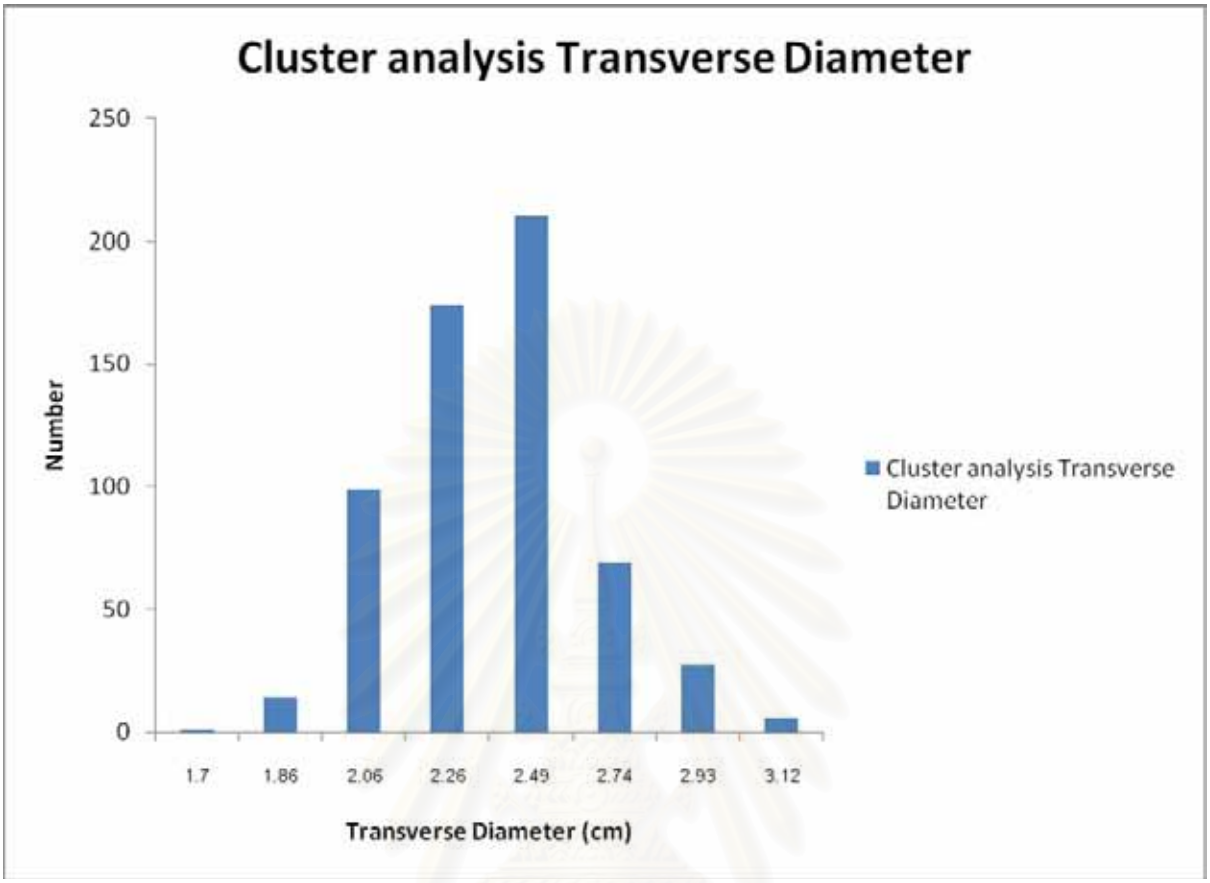


Figure 36.Cluster analysis transverse diameter

CHAPTER V

CONCLUSION

1. Conclusion

This project aimed to know the cervical disc dimensions of Thai population and to compare with cervical disc prosthesis that be used in Thailand. As the cervical disc dimensions to use in cervical spine measurement of the cervical disc dimensions was done only in cervical segment. From the measurement result, it was recommended that the cervical disc prosthesis should cover 7 varies sizes (from 3 mm to 9 mm) for disc height, 6 sizes (from 10 mm to 20.50 mm) for sagittal diameter, and 8 sizes (from 17 mm to 31.20 mm) for transverse diameter.

The cervical disc dimensions in this research had been measured by MRI method that it could replace disc morphology in early degenerative motion segment and correct it to near normal. It allowed motion segment to move in flexion and extension.

There are different demographic data between male and female, may be limited to compare between male and female. More size disc may be available in Thailand. To compare the cervical disc dimension with previous study was significantly different in sagittal diameter, transverse diameter, and diagonal diameter. The differences have been shown that cervical disc dimensions of Thai population seem to be smaller in disc height and transverse diameter than previous study.

Some complications from arthroplasty such as subsidence and migration may be occurred after prosthesis replacements.[20] Although, Failure of an intact cervical endplate occurs with an axial load of 634-745 N.[33,34] The cervical disc prosthesis subsidence likely stem from multiple causes including osteoporosis, aggressive endplate preparation, postoperative exogenous forces, and bracing.[35,36] The improperly prosthesis disc height, the compressive force increase higher when increasing disc height.[37]

If we have a proper size of disc dimension, it may decrease incidence of subsidence or migration. The results of cervical disc dimensions may be useful for preoperative planning and data for cervical disc prosthesis design in the future.

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