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MEASUREMENT OF INTERSPINOUS DISTANCE OF THAI POPULATION IN MRI AND NEW DESIGN INTERSPINOUS DYNAMIC STABILIZATION SYSTEM OF THE LUMBAR SPINE

Mr. Saran Tantavisut

A Thesis Submitted in Partial Fulfillment of the Requirements
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Thesis Title:	MEASUREMENT OF INTERSPINOUS DISTANCE OF THAI POPULATION IN MRI AND NEW DESIGN INTERSPINOUS DYNAMIC STABILIZATION SYSTEM OF THE LUMBAR SPINE
By	Mr. Saran Tantavisut
Field of study	Biomedical Engineering
Thesis Principal Advisor	Professor Pibul Itiravivong, M.D.
Thesis Co-advisor	Associate Professor Tawechai Tejapongvorachai,M.D.
	Pairat Tangpornprasert, PhD

Accepted by the Graduated School, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

.... Vice President
Acting Dean of the Graduate School
(Assistant Professor Dr.M.R.Kalaya Tingsabadh)

THESIS COMMITTEE

....Chairman
(Associate Professor Prakit Tienboon, M.D.)

....Thesis Principal advisor
(Professor Pibul Itiravivong, M.D.)

.... Thesis Co – advisor
(Associate Professor Tawechai Tejapongvorachai, M.D.)

.... Thesis Co – advisor
(Pairat Tangpornprasert , PhD)

.... External Member
(Associate Professor Viroj Kawinwonggowit, M.D.)

ศรัณย์ ตันติ์ทวิสุทธิ์ : การวัดระยะระหว่างสันกระดูกสันหลังส่วนเอวและออกแบบอุปกรณ์ยึดเชื่อมกระดูกสันหลังชนิดพลวัตรของคนไทย (MEASUREMENT OF INTERSPINOUS DISTANCE OF THAI POPULATION IN MRI AND NEW DESIGN INTERSPINOUS DYNAMIC STABILIZATION SYSTEM OF THE LUMBAR SPINE THESIS) อ.ที่ปรึกษา: ศ.นพ.พิบูลย์ อิทธิระวิวงศ์, อ. ที่ปรึกษาร่วม: รศ.นพ. ทวีชัย เตชะพงศ์วรชัย, อ.ดร. ไพรัช ตั้งพรประเสริฐ และ อ.ดร. ชัญญาพันธ์ วิรุฬห์ศรี, 56 หน้า.

อุปกรณ์ยึดเชื่อมกระดูกสันหลังชนิดพลวัตรเป็นอุปกรณ์ที่มีประโยชน์และมีการใช้อย่างกว้างขวาง แต่ยังมีราคาแพงและมีจุดบกพร่องอยู่บ้าง โดยการวัดระยะระหว่างสันกระดูกสันหลังส่วนเอวใน คนไทยจากภาพMRIจะช่วยทำให้รู้ขนาดโดยประมาณของอุปกรณ์ได้ เพื่อให้เหมาะกับการผลิตใช้ในคนไทยวัตถุประสงค์ของงานวิจัยนี้คือเพื่อวัดระยะระหว่างสันกระดูกสันหลังส่วนเอวในคนไทยจากภาพMRI และออกแบบอุปกรณ์ยึดเชื่อมกระดูกสันหลังชนิดพลวัตรแบบใหม่โดยออกแบบและทดสอบโดยวิธีFinite element การวัดระยะนั้นทำในผู้ป่วยอายุ20-50ปี ในระดับL1-2, L2-3, L3-4 และL4-5 รวมทั้งหมดเป็น240ระดับ ที่มีอาการปวดหลังจากกระดูกสันหลังเสื่อมระยะต้นหรือหมอนรองกระดูกกด ทับเส้นประสาทระยะต้น และไปรับการทำMRIที่ศูนย์MRIประชาชื่นในปี2007 ไม่มีการผ่าตัด หรืออุบัติเหตุหรือความพิการแต่กำเนิดใดๆของกระดูกสันหลัง ส่วนการออกแบบอุปกรณ์ยึดเชื่อมกระดูกสันหลังชนิดพลวัตรแบบใหม่นั้น ทำโดยออกแบบและวาดรูปด้วยCATIA program เก็บและเปลี่ยนรูปแบบของข้อมูลเป็นUGNX และ parasolid model ตามลำดับ นำข้อมูลที่ได้เข้าโปรแกรมANSYSและใส่ค่าของอุปกรณ์และกระดูกต่างๆให้ถูกต้อง แล้วจึงทำการทดลองด้วยวิธีFinite element ปรับรูปแบบและค่าต่างๆจนได้อุปกรณ์ที่มีสมบัติตามต้องการ

ผลของการวัดระยะคือค่าเฉลี่ยในผู้หญิงเป็นดังนี้ L1-2 12.51 mm , L2-3 11.78 mm , L3-4 10.95 mm และ L4-5 10.57 mm ค่าเฉลี่ยในผู้ชาย L1-2 12.20 mm , L2-3 11.63 mm , L3-4 10.74 mm และ L4-5 10.15 mm ค่าเฉลี่ยรวมทั้งหมด L1-2 12.36 mm , L2-3 11.71 mm , L3-4 10.84 mm และ L4-5 10.36 mm ไม่มีความแตกต่างระหว่างระยะในเพศชายและเพศหญิงอย่างมีนัยสำคัญ ค่าระยะที่กว้างที่สุดและแคบที่สุดจาก sample ทั้งหมดคือ 14.2 mm และ 8 mm ตามลำดับ ส่วนผลการออกแบบนั้นได้อุปกรณ์เป็นรูป U shape ซึ่งสามารถทดแทนค่า stiffness ที่ลดลงจนใกล้เคียงปกติได้ (4.0Nm/degree) โดยตัวอุปกรณ์ออกแบบขึ้นเพื่อใช้ในposterior approach, มีชิ้นส่วนน้อยเพื่อง่ายในการผลิตใช้จริงในขั้นตอนต่อไป, ไม่จำเป็นต้องตัดหรือเจาะกระดูกเพื่อวางอุปกรณ์ ระยะระหว่างสันกระดูกสันหลังที่วัดได้ทำให้รู้กรอบคร่าวๆของขนาดอุปกรณ์ที่จะต้องทำการผลิตในกรณีจะผลิตออกใช้จริง ส่วนการออกแบบที่พิสูจน์ว่าใช้ได้ผลจริงในทางFinite element นั้นจะเป็นจุดเริ่มต้นของการศึกษาขั้นต่อๆไป

สาขาวิชา : วิศวกรรมชีวเวช
ปีการศึกษา : 2550

ลายมือนิสิต : ....
ลายมือชื่ออาจารย์ที่ปรึกษา : ....
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม : ....
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม : Paisarn Tangpornprasert

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SARAN TANTAVISUT: MEASUREMENT OF INTERSPINOUS DISTANCE OF THAI POPULATION IN MRI AND NEW DESIGN INTERSPINOUS DYNAMIC STABILIZATION SYSTEM OF THE LUMBAR SPINE. THESIS ADVISOR: PROFESSOR PIBUL ITIRAVIVONG, M.D., THESIS COADVISOR:, TAWEECHAI TEJAPONGWORACHAI, M.D., PAIRAT TANGPORNPRASERT, PH.D., CHANYAPHAN VIRULSI, PH.D., 56 pp.

Dynamic stabilization device aim to use in neurogenic intermittent claudication and early degenerative lumbar spinal stenosis not response to conservative treatment.Measurement of lumbar interspinous distance in this study aim to be a pilot study to know the estimation of interspious distance that refers to size of interspinous device. Objectives of this research are measure interspinous distance in Thai patients from sagittal view of MRI lumbar spine and to design and test new design dynamic stabilization system in Finite element method.

Mean distance in female are L1-2 12.51 mm, L2-3 11.78 mm, L3-4 10.95 mm and L4-5 10.57 mm. Mean distance in male are L1-2 12.20 mm, L2-3 11.63 mm, L3-4 10.74 mm and L4-5 10.15 mm. Total mean distance from all sample are L1-2 12.36 mm, L2-3 11.71 mm, L3-4 10.84 mm and L4-5 10.36 mm. The differences in interspinous distance between males and females were not significant. The maximum and minimum distances from all samples are 14.2 mm and 8 mm respectively. New design device is U shape with cable to sling around adjacent spinous process. The device design to use by posterior approach, simple and less modularity, easy to manufacturer, can insert without any cut or destroy bony structure and can correct stiffness loss in early degenerative lumbar spine to near normal.

Interspinous distance measurement can refer to range of size to manufacturer for the device to cover the use in Thai patients. New design device fulfill all goal describe above under finite element testing. The results of the project could provide design and data for the manufacturer and next step experiment for dynamic stabilization device suitable for Thai population.

Field of Study : Biomedical Engineering
Academic Year : 2007

Student's Signature : ....
Principal Advisor's Signature : ....
Co-advisor's Signature : ....
Co-advisor's Signature : Pairat Tangpornprasert

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CHAPTER I

INTRODUCTION

1.1 Background

Neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis has been described and proved to be a posture dependent condition in which symptoms such as lower limb tingling, pain and numbness are typically exacerbated in extension and relieved in flexion [1,2]. It was described 20 years later by Verbiest.

The posture dependent nature of NIC is well understood, and the mechanism has been describe in a number of biomechanical and clinical studies. The current treatment of patient with NIC include both nonoperative and surgery.Studies suggest that conservative care may be more appropriate for patients with mild symptoms , while surgery may be more suitable for patients with severe symptoms and physical limitation. There is little conconsensus on the appropriate treatment for moderate symptoms, although the literature seems to suggest that surgery may be more effective than nonoperative therapy.

Decompressive surgery typically involves excision of the ligamentum flavum and partial removal of the laminae. Medial facetactomies and foraminotomies are often performed as well, depending on the source of the stenosis, and fusion with or without instrument may be necessary for concomitant segmental instability. The goal for decompressive surgery is to remove the source of neurologic compression.

Spinal fusion with or without instrumentation always add in the case of instability or iatrogenic instability. Following spinal fusion, the load transmission across motion segment become direct from bone to bone. Fusion has increased the successful fusion rate to close to 98% but fail to improved the overall clinical success rate. Reasonable to conclude that stopping affected vertebral movement is not the factor in achieving relief of back pain.

Following successful fusion, the pattern of load distribution to adjacent vertebral segment has changed. Changes at adjacent level disc had been observed radiologically in 50% of the patient who were followed for long period of time. Some patient would develop new canal stenosis, the occurrence of these change may develop to the new radiculopathy or radiculopathy [4,5] . In previous reports, the incidence for symptomatic adjacent segment disease has range from 7% to15%.

Dynamic stabilization [3,6] of the lumbar spine may be define as a system that would alter favorably the movement and load transmission of the spinal motion segment, without the intention of fusion of the segment. Hypothesis behind dynamic stabilization is that control of abnormal motion and more physiologic load transmission would relieve pain and prevent adjacent segment degeneration. A remote expectation is that, once normal motion and load transmission is achieved, the damaged disc may repair itself unless the degeneration is too advance.

Most of dynamic stabilization implants in the market nowadays have been reported with satisfactory clinical result, but reference still remained some problems to be solved in most instruments. This defect should be analyze and adjust to make the instrument most effective and safe. Finite element model is a good tool to predict the biomechanical behaviour of the lumbar segment, provided that a suitable material modeling for soft tissue is included. Moreover, this computational model allows the biomechanical property (ie. From the static and kinematic standpoint) of the device used for the “dynamic stabilization” of a disease lumbar motion segment.

The aim of this research is to measure interspinous distance of healthy Thai population and would be use as reference to design the proper dynamic stabilization device suitable for Thai patients.

Objective

1) To measure interspinous distance of Thai population in MRI (pilot study).

2) To design new dynamic stabilization device that once implant can compensate for stiffness loss in early disc degenerative disease to near normal, improve abnormal motion in flexion and extension of degenerative motion segment to near normal motion

3) This device should be simple in design and manufacturer, can insert easily without any drilling or destroy bony structure

CHAPTER II

LITERATURES REVIEW

Spinal fusion in many cases successfully relieves back pain. Following spinal fusion, the load transmission across the motion segment becomes direct from bone to bone. Fusion have increase the successful rate to close to 98% but fail to improve the overall clinical success rate. The debate continues and fusion remains the seriously challenged standard surgical treatment of back pain. Most studies reported suggest 50-70% excellent to good clinical outcome but 30% failure of improvement of back pain and found to have no correlation between fusion success and references clinical outcome. It's reasonable to conclude that stopping movement is not the factor in achieving relief of back pain. Creating a normal loading pattern is more important for clinical success. This lead to the era of a new looks into the problem of mechanical low back pain which is "stabilize but do not fuse"

Dynamic stabilization system of the spine aims to permit motion and while at the same time also share load. The load sharing should be more or less uniform during the entire range of motion. There is various dynamic stabilization systems are different and can be group as shown in Table1

Table 1: The different dynamic stabilization systems, that have been used clinically may be classified into four categories
Inter-spinous distraction devices
Minns silicone distraction device
Wallis system
X-stop
Inter-spinous ligament devices
Elastic ligament (Bronsard's Ligament across the spinous processes)
Loop system
Ligaments across pedicle screws
Graf ligament
Dynesis device
Semi rigid metallic devices across the pedicle screws
FASS system
DSS system

This study would concentrate on details and clinical trial results of interspinous distraction device. It's the deviced group of great interested and needed further study for designing new model that suitable for Thai population. Details of other groups of devices [10,11,12,13,14,15,16,17,18] are presented in full version of review of literature attached with this study.

The interspinous distraction device

1) **Minns silicone distraction device**[7]

The device is made from silicone in dumbbell shape, covering several sizes between 8-15 mm. it aims to protect the spinous process from approximation when spinal column bears axial load, off load at the facet and to decrease intradiscal pressure.

2) **Interspinous U device**[7]

In U shape as shown in figure 1 and 2.it's made from titanium

Fig. 1 Interspinous U device

Fig. 2 Interspinous U in L3-4, L4-5

The device would share load from intervertebral disc in flexion and extension position. When implanting this device, spinous process drilled and screwed that might fracture spinous process and not suitable in osteoporosis patient

3) The Diam device[8]

The device is made from silicone coated with polyethyleneas a spacer and attatched hook made from titanium as shown in figure 3 and 4.DIAM(Intervertebral Assisted Motion) is a silicone interspinous process ‘‘bumper’’, designed to provide facet distraction, to decrease intradiscal pressure,and to reduce abnormal segmental motion and to adjust alignment.

Fig. 3 DIAM device

Fig. 4 DIAM inserted at interspinous space

4) The Wallis Implant

The device is a Interspinous blocker made from PEEK(polyetheretherketone), was placed between 2 adjacent interspinous processes with 2 woven Dacron ligaments under tension,as shown in figure 5 ,6 and 7

Fig. 5 Wallis device

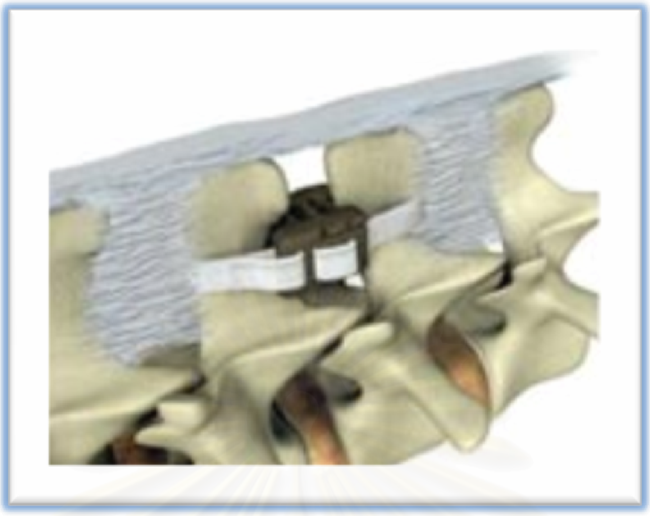

Fig. 6 Wallis device inserted in interspinous space

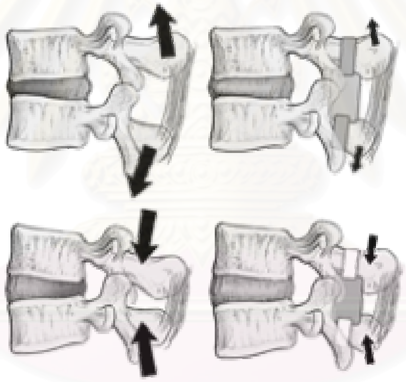

Fig. 7 Wallis device can limit range of movement in flexion and extension

5) X-stop device

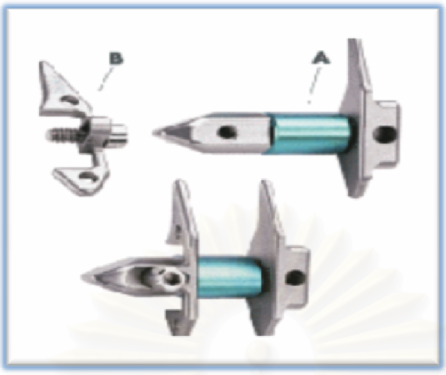

Fig. 8 X-stop device

Fig. 9 X stop device inserted in interspinous space

It is a titanium interspinous device that keeps spinal segment in flexion position. The device is designed for use with minimal invasive technique. Cadaveric study revealed that X-stop device could increase canal area, canal diameter, foraminal area and foraminal width up to 18%, 10%, 10% and 41% respectively.

X stop device could permit limited extension, no control a flexion, lateral bending and would not assist in axial load sharing.

Regarding literature reviews reference, the interspinous devices appeared to have a satisfactory clinical result and many advantage. the device would improve neurogenic intermittent claudication by fixing levels of disease motion segment in slight flexion and acting as extension block, thus relatively widening neutral foramen and spinal canal.The device could be operated under local anesthetic thus lessened operative time and is suitable in case with moderate symptom, old age, poor medical condition and not interfere with standard decompressive operative method. The advantage of the interspinous device is that it has been approved for not disturbing or changing pattern in adjacent intradiscal pressure [21,22] or motion segment movement and has high safety margin.

However current interspinous device have been reported with problems ,such as Unmatch of Young modulus elasticity between device and bone leading to arthritic change of bone or in some case, fracture of spinous process and displacement of device.All interspinous devices now design based on anatomical parameters of the European patients that may not perfectly suitable to use in Asian or Thai patients and cost of device are very expensive.

PRODUCT	DISADVANTAGE
X-Stop	Not function in flexion position, reported of device displacement , very has very high stiffness.
Wallis	Hard to applied , report of device loosening
Coflex Interspinous U	Defect in spinous process from drilling to insert device, report of spinous process fracture.
Dynesys	Report of screw loosening.

This research was developed base on hypothesis that a new design interspinous device would relieve neurogenic intermittent claudication, compensate for stiffness loss in early disc degenerative to near normal, and improve abnormal motion in flexion and extension of degenerative motion segment to near normal motion.

This research would employ finite element method. Finite element model is a good tool to predict the biomechanical behavior of the lumbar segment, provided that a suitable material modeling for soft tissue was included [24,25,26,27]. Moreover, this computational model allows the analysis of biomechanical property (ie. from the static and kinematic standpoint) of the device used for the "dynamic stabilization" of a disease lumbar motion segment.

This paper would also measure interspinous distance of healthy and mild degenerate or mild disc herniated Thai population and will use the range for the size of instrument that suitable to use in Thai population

CHAPTER III

MATERIALS AND METHODS

Patients Selection

Between January 2007 and December 2007, 60 consecutive L-S spine magnetic resonance imaging studies were performed in Thai subjects. The selection criteria of each subject included 20 to 50 years of age, no congenital deformity, no scoliosis, no traumatic injury to spine, no previous spine surgery 30 were males and 30were females. The demographic data is shown in Table 2.

Table2. The basic information of the subjects*

Sex	Subjects Number	Age (year)	Weight (Kg.)
Total	60	37.78 ± 8.82 (20-50)	64.36 ± 12.58 (37.7-104)
Male	30	35.67 ± 8.64 (20-50)	70.42 ± 12.24 (46-104)
Female	30	39.9 ± 8.62 (20-50)	58.29 ± 9.8 (37.7-80)

**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 T1-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.

Measurement of the interspinous process distance counted on at the most midline cut of MRI in T2 weighted image. Length of spinous process of L1 to L5 was measure then divided in half. Line was draw between those points then interspinous distance was measured on this line as seen in picture below. A total of 240 measured lumbar levels were done.

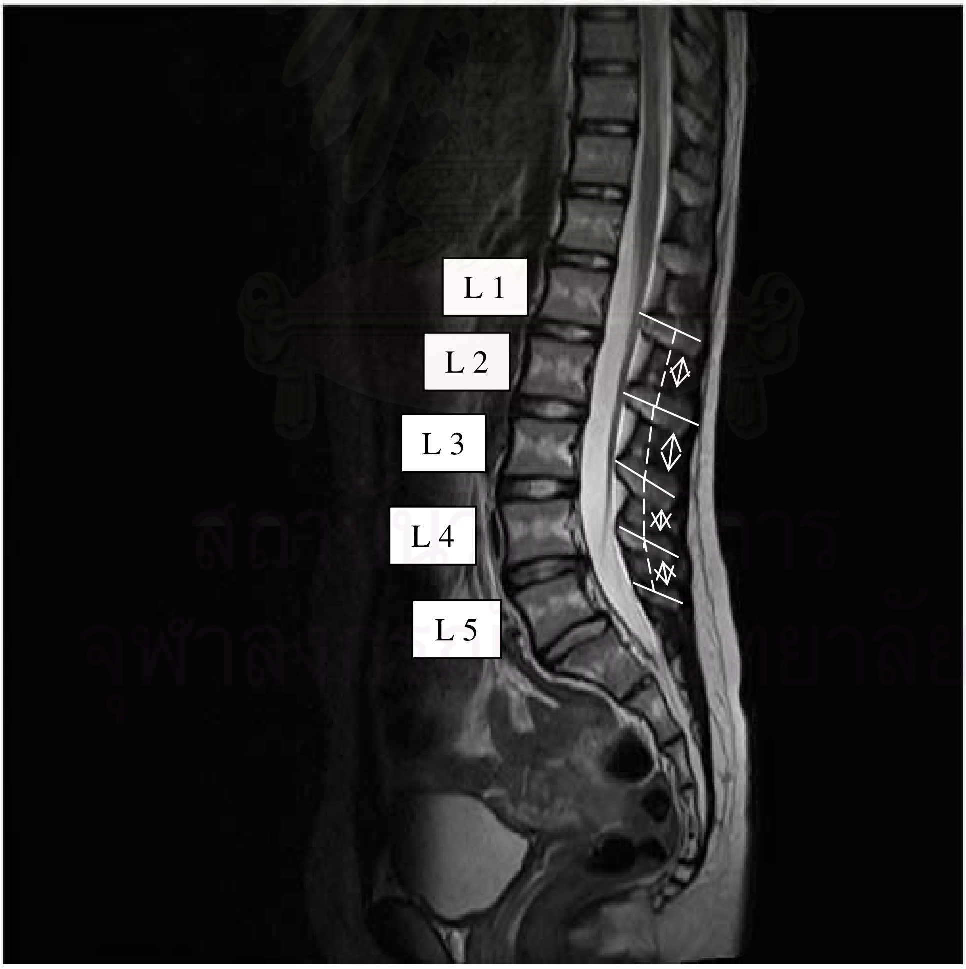

Fig. 10 Method of MRI measurement

Conceptual design (Design Constrain and Design Criteria)

- Device used by posterior surgical approach.
- The device would have proper stiffness to compensate for stiffness loss in early disc degenerative to near normal.
- To improve abnormal motion in flexion and extension of degenerative motion segment to near normal motion.
- The device would have simple design and less modularity.
- Require no drilling or damaging any bony component

From the conceptual design as already maintained, the model would be tested by finite element program to calculate stiffness. Referring to standard biomechanical data it was founded that normal vertebral motion segment stiffness in flexion was equal to 1.8 Nm/degree and in extension was 2.8 Nm/degree. In this research Titanium material was chosen for prototyped design as to its mechanical property (table 3).

Method and materials to calculation of Finite Element by ANSYS

Step 1 : Design of the device

a) Drawing new design dynamic stabilization system in CAD model by CATIA Program.

b) Transfering the drawing file to be read by UGNX program.

c) Converting CAD Model to Parasolid Model.

d) Importing file model Parasolid into program ANSYS for further mechanical calculation.

Table 3 Mechanical properties of Ti-9Al-4V

Mechanical Properties	
Elastic Modulus	120 GPa
Poisson Ratio	0.3
0.2% Yield Strength	950 MPa
Tensile Strength	1075 MPa
Fatigue Strength 10^7Cycle	580MPa

Step 2 : Mechanical testing of the designed device

e) Divided model into small element, choose size of element as smart size, size 3-4. 10 node Tetrahedral (SOLID 92) as seen in fig 11

Fig. 11 10 nodes Tetrahedral SOLID92

f) Calculate stiffness by torque and angle that change after applied force then graph was plotted to find a slope that represent stiffness of the device fig 12.

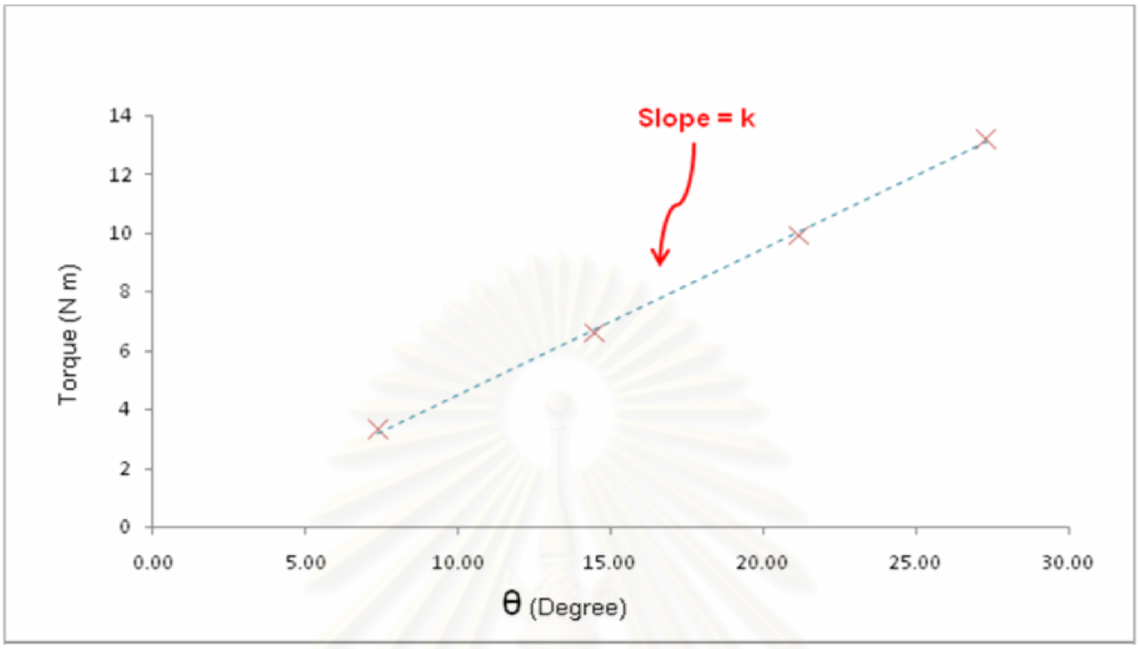

Fig 12 Estimated Stiffness of the device

g) Thickness adjusting by calculating stiffness of system(degenerate motion segment + device) as described above then adjusting the thickness of device until system reached proper stiffness (equal or near normal motion segment stiffness)

Step 3 : Calculate finite element calculation for stiffness of the vertebral bone (motion segment)

a) Add property of bone into motion segment model

b) Set lower surface of bone to have ux=uy=uz=0

c) Choose 2 reference point at most outer surface of superior border of vertebral body model by, point (A) at center , most posterior of body,point (B) at center , most anterior of body as shown in figure 13

d) Before starting the calculation and analysis , measure angle between line drawed from point A and B and axis Y (can measure angle from $\theta_1 = Arc\tan\left[\frac{\Delta z_1}{\Delta y_1}\right]$)

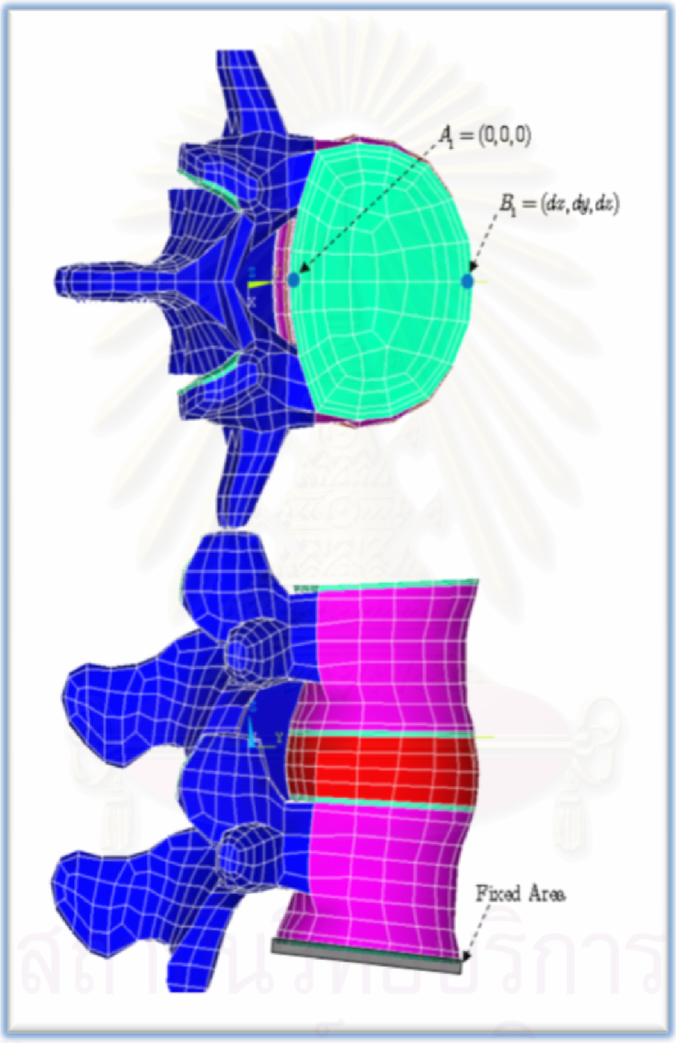

Fig .13 Two referent point to apply load

e) Couple forces [F] acting on model at point A,B were 200N, 400N, 600N, 800N, 1000N respectively , direction of force was for flexion , force at point A $[F_A]$ had direction–Z : force at point B $[F_B]$ had direction +Z, for extension , force at point A $[F_A]$ had direction +Z ; force at point B $[F_B]$ had direction –Z .

f) If applied force was centered at only one point(either point A or B) significant error would be created, to solve this problem by the applied force would be stressed on area around point A,B instead(figure 14).

- ❖ Area around point A 138 mm2 $P_A = \dfrac{F_A}{(138\ mm^2\ \ 10^{-6})}$
- ❖ Area around point 105 mm2 $P_B = \dfrac{F_B}{(105\ mm^2\ \ 10^{-6})}$

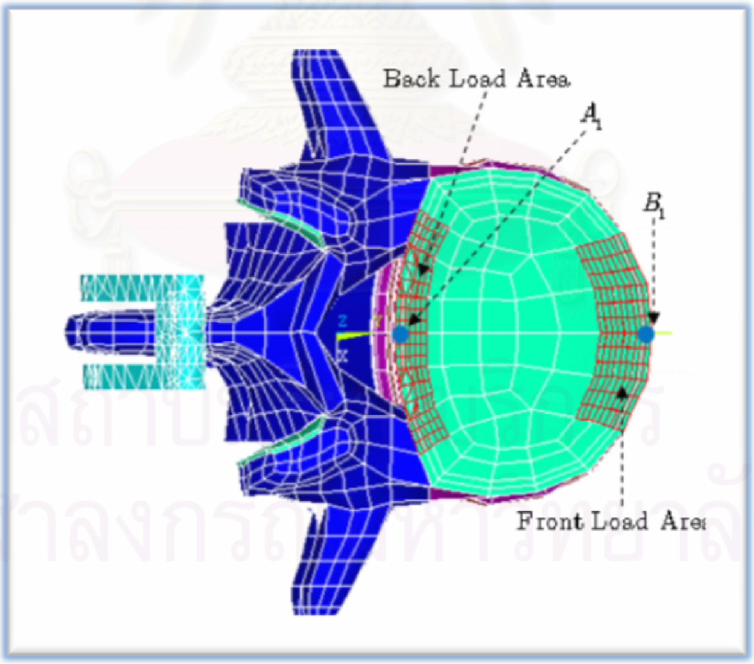

Fig. 14 Area to apply load

g) By analyzing and measuring the different distance of point A,B , the applied force , calculate angle between 2 lines (before and after applied load) was analyzed with Z axis $\theta_2 = Arc\tan\left[\frac{\Delta z_2}{\Delta y_2}\right]$ then $\Delta\theta = (\theta_2 - \theta_1)$.

h) Estimated Torque that act to bone by $M = F(\Delta y_1)$.

i) Change F from 200 to 400, 600, 800, 1000 respectively (repeating same procedure).

j) $T = k(\Delta\theta)$, then k (Torsional Stiffness) of the model could be calculated by plotting graph between torque and $\Delta\theta = (\theta_2 - \theta_1)$ and then estimating the slope of the graph.

Step 4 : The analysis of Modulus of Elasticity of degenerative intervertebral disc by Finite element method

Because there were no known data of modulus of elasticity of degenerative intervertebral disc, this paper suggested alternative calculation to obtain such data.

First by removing nucleus pulposus property from normal or intact model to represent degenerative disc model. Second by creating model of motion segment with degenerative intervertebral disc by referenced research paper about stage of degenerate intervertebral disc related with torsional stiffness(k).Early degenerate intervertebral disc showed decreased stiffness while late degenerative showed increased stiffness.However there were no reported document about Modulus of elasticity (E) of degenerate intervertebral disc. In order to calculate this modulus of elasticity of intact model was randomly numbered till torsional stiffness equalled to degenerate stiffness as mentioned in referenced paper.Then modulus of elasticity of intervertebral disc at that point was utilized for further calculation and analysis.

a) Method of analyzation by ANSYS program

1) Load motion segment model and give a mechanical properties to model as table 4

Table 4 Mechanical property of model

Section	Modulus of Elasticity (MPa)	Poisson's Ratio
Cortical Bone	12000	0.30
Cancellous Bone	25	0.20
End Plate	12000	0.25
Posterior Element	3500	0.25
Nucleus	1	0.499

2) Up and down changing the property of annulus fibrosus (trial and error until the stiffness was decreased to required level)
3) Set lower surface of bone to have ux=uy=uz=0
4) Choose 2 reference point at most outer surface of superior border of vertebral body model by, point (A) at center , most posterior of body,point (B) at center , most anterior of body as shwn in figure 15

5) Before starting the calculation and analysis , measure angle between line drawed from point A and B and axis Y (can measure angle from $\theta_1 = Arc\tan\left[\frac{\Delta z_1}{\Delta y_1}\right]$)

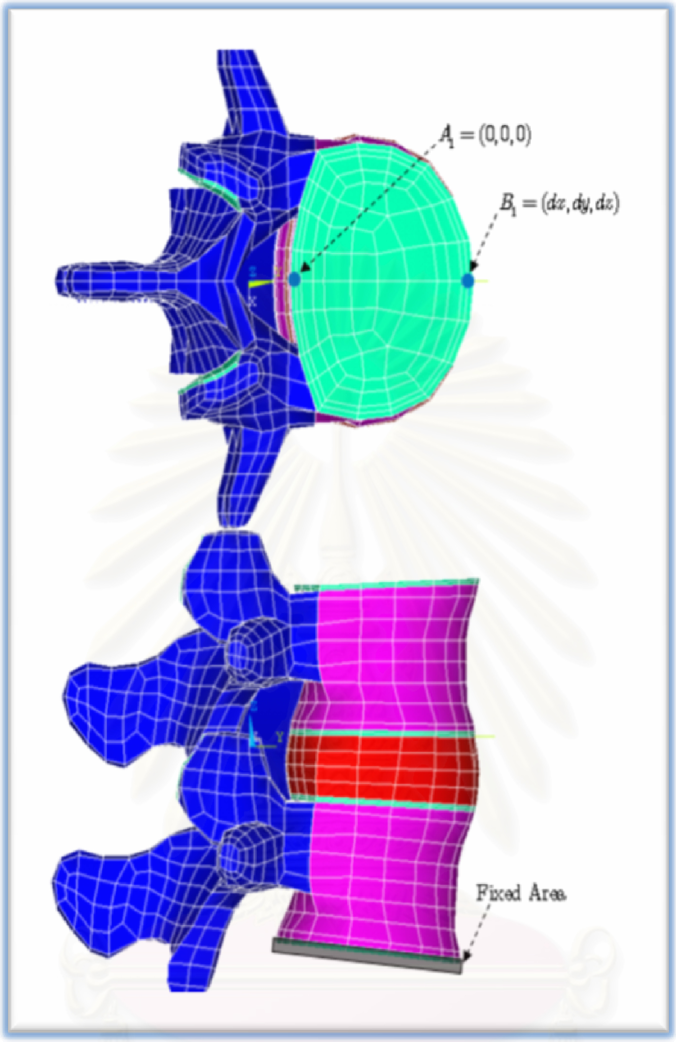

Fig. 15 Two referent point to apply load

6) Couple forces [F] acting on model at point A,B were 200N, 400N, 600N, 800N, 1000N respectively , direction of force was for flexion , force at point A $[F_A]$ had direction–Z : force at point B $[F_B]$ had direction +Z, for extension , force at point A $[F_A]$ had direction +Z ; force at point B $[F_B]$ had direction –Z .

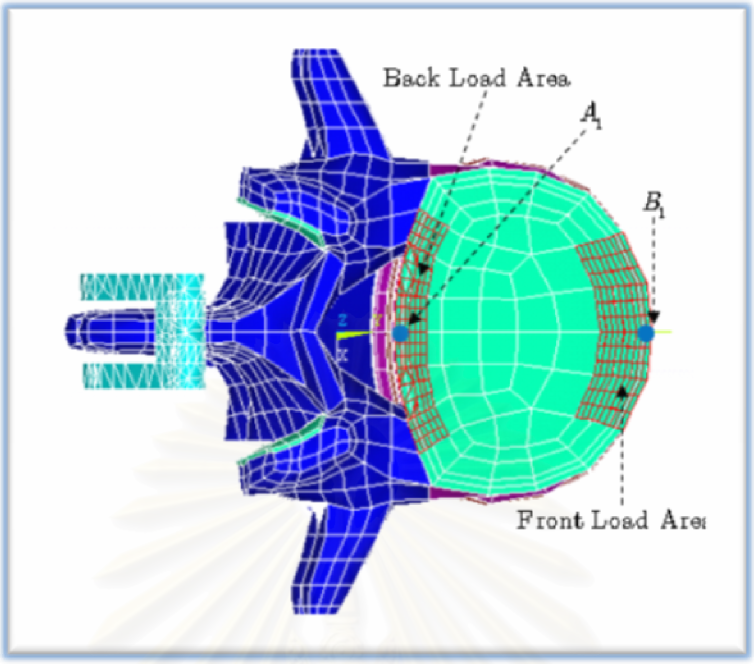

Fig. 16 Area to apply load

7) If applied force was centered at only one point(either point A or B) significant error would be created, to solve this problem by the applied force would be stressed on area around point A,B instead(figure 16).

- Area around point A 138 mm2 $P_A = \dfrac{F_A}{(138\ mm^2\ 10^{-6})}$
- Area around point 105 mm2 $P_B = \dfrac{F_B}{(105\ mm^2\ 10^{-6})}$

8) By analyzing and measuring the different distance of point A,B , the applied force , calculate angle between 2 lines (before and after applied load) was analyzed with Z axis $\theta_2 = Arc\tan\left[\dfrac{\Delta z_2}{\Delta y_2}\right]$ then $\Delta\theta = (\theta_2 - \theta_1)$.

9) Estimated Torque that act to bone by $M = F(\Delta y_1)$.

10) Change F from 200 to 400, 600, 800, 1000 respectively (repeating same procedure). $T = k(\Delta\theta)$, then k (Torsional Stiffness) of the model could be calculated by plotting graph between torque and $\Delta\theta = (\theta_2 - \theta_1)$ and then estimating the slope of the graph

11) $T = k(\Delta\theta)$ then we can find k (Torsional Stiffness) of the model by plot graph between torque and $\Delta\theta = (\theta_2 - \theta_1)$ then estimated the slope of graph

b) Calculation of the stiffness of degenerative annulus fibrosus model

1) Remove nucleus pluposus property

Stiffness in extension of disc in intact model when applied extension force is 1.18. when we remove property of disc out of the model and test it for stiffness just describe above. The stiffness of model without nucleus pulposus is 1.19. No significant change between both models. We conclude that this method is not proper to simulate degenerative model.

2) From reference research, stiffness of degenerate intervertebral disc is 0.69 $^{N\,m}$ / Degree in flexion and 1.13 $^{N\,m}$ / Degree in extension. We try to change property of annulus fibrosus with trial and error technique and load with force 200,400,600,800 and 1000 same as just describe above. Torque and degree of change was plot and stiffness of disc was found as a slope of the graph. We change elastic modulus of annulus fibrosus and test until the stiffness reach reference point as seen in table 5.

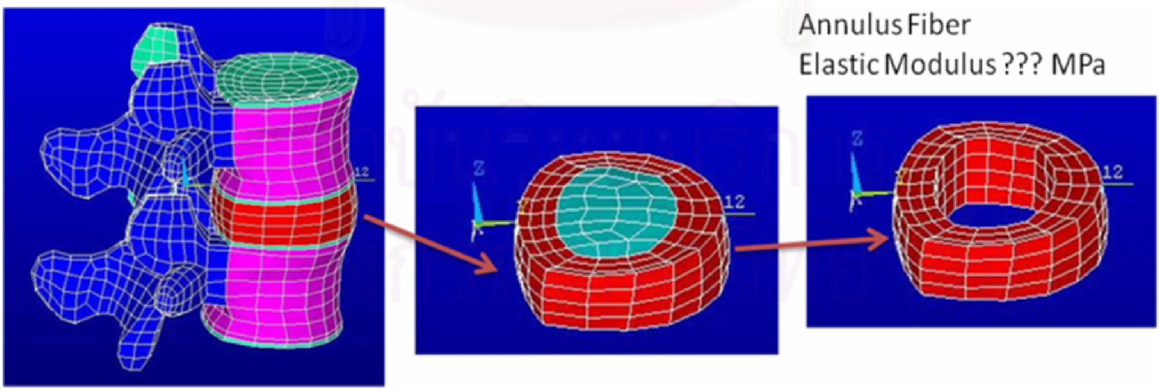

Fig 17. Annulus Fiber

Table 5 Stiffness of intervertebral disc correlation with Elastic Modulus

Flexion		Extension	
Elastic Modulus (MPa)	Stiffness (Nm/degree)	Elastic Modulus (MPa)	Stiffness (Nm/degree)
2.8	1.47	3.8	1.23
1	0.69	3.5	1.15

From simulation, when stiffness of intervertebral disc equal to degenerative intervertebral disc in reference paper, Modulus of elasticity of annulus fibrosus in different direction will be as below.

Flexion : Elastic Modulus = 1 MPa

Extension : Elastic Modulus = 3.5 MPa

We use this Modulus of Elasticity to represent degenerative annulus fibrosus and motion segment.

Step 5 : Simulation of device attach with degenerate motion segment model

rational of analysis

Test on device alone can't estimate torsional stiffness (k) in real situation. We decide to create degenerative intervertebral disc model as describe above and attach with new design device then calculate and analyze it together again.

a) Testing of torsional stiffness in flexion of degenerate disc model attach with device

After analyze Modulus of Elasticity (E) of degenerated intervertebral disc. Modulus of Elasticity (E) of degenerated Annulus Fiber is 1.0 MPa (Torsional Stiffness of flexion is 0.69 $^{N\,m}$ / Degree). Mechanical property of degenerate intervertebral disc in flexion and other are in table 6.

Table 6 Mechanical property of motion segment that have Stiffness equal to degenerative disc in Flexion

Section	Modulus of Elasticity (MPa)	Poisson's Ratio
Cortical Bone	12000	0.30
Cancellous Bone	25	0.20
End Plate	12000	0.25
Posterior Element	3500	0.25
Annulus Fiber	1.0	0.45
Nucleus	1	0.499
Titanium	120,000	0.3

1) Load motion segment model and import new design device

2) Give mechanical properties to model as table 6.

3) Divide motion segment model and device to Elements by

- ❖ Motion segment model use Elements Solid95 type
- ❖ New design device use Elements Solid92 type

4) Set contact at surface between cable and upper, lower spinous process as

- Volume Contact
- Static friction 0.37 (from reference paper)
- Set contact as Bonded and Close Gap because it may have a tiny space between device and bony contact surface. Set cable not to slide on bone

5) Set contact surface between Spacer and bone by

- Volume Contact
- Static friction 0.37 (from reference paper)
- Set contact as Bonded and Close Gap because it may have a tiny space between device and bony contact surface

6) Set the lower surface of vertebra fix and no movement ux=uy=uz=0

7) We have to measure angle and add couple force to create torque, flexion and extension.Choose 2 reference point at most outer superior surface of vertebra.

- Point (A) at center , most posterior of body (0,0,0)
- Point (B) at center , most anterior of body (dx,dy,dz)

8) Before starting calculation and analysis, measure angle between line drawed from point A and B and axis Y (can measure angle from $\theta_1 = Arc\tan\left[\frac{\Delta z_1}{\Delta y_1}\right]$)

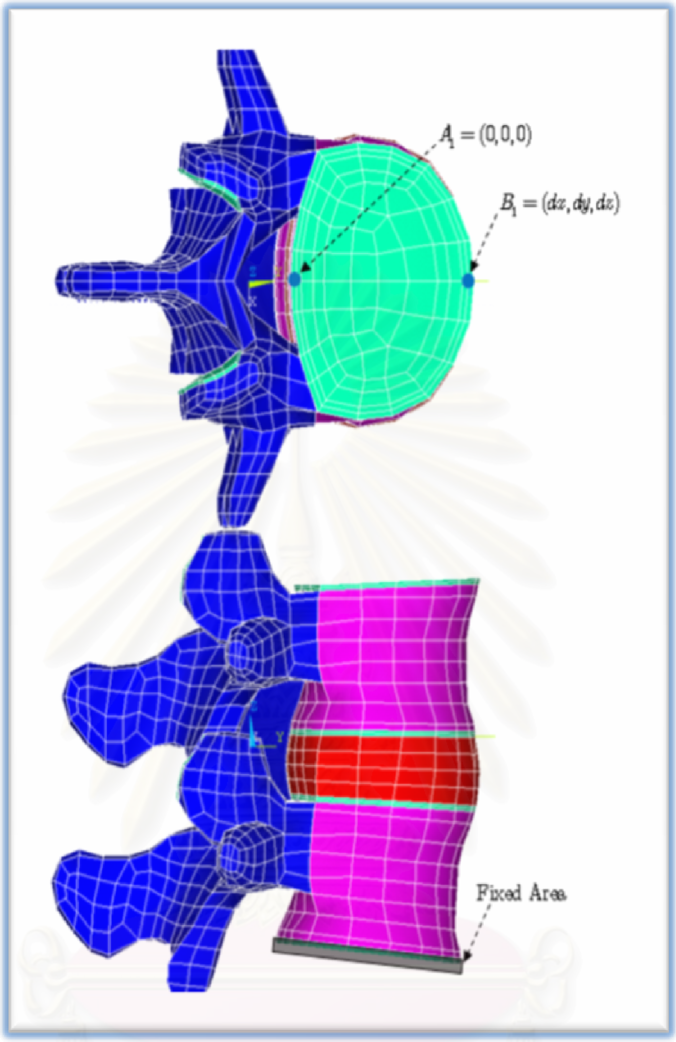

Fig. 18 Two referent point to apply load

9) Couple forces [F] acting on model at point A,B were 200N, 400N, 600N, 800N, 1000N respectively , direction of force was for flexion , force at point A $[F_A]$ had direction–Z : force at point B $[F_B]$ had direction +Z, for extension , force at point A $[F_A]$ had direction +Z ; force at point B $[F_B]$ had direction –Z .

10) If applied force was centered at only one point(either point A or B) significant error would be created, to solve this problem by the applied force would be stressed on area around point A,B instead(figure 19).

- ❖ Area around point A 138 mm^2 $\quad P_A = \dfrac{F_A}{(138\ mm^2\ 10^{-6})}$
- ❖ Area around point 105 mm^2 $\quad P_B = \dfrac{F_B}{(138\ mm^2\ 10^{-6})}$

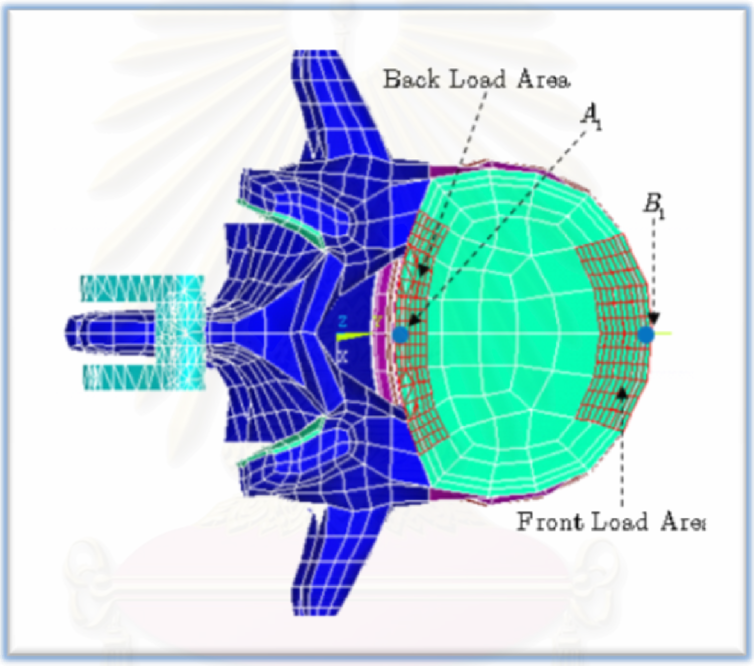

Fig 19. Area to apply load

12) By analyzing and measuring the different distance of point A, B, the applied force , calculate angle between 2 lines (before and after applied load) was analyzed with Z axis $\theta_2 = Arc\tan\left[\dfrac{\Delta z_2}{\Delta y_2}\right]$ then $\Delta\theta = (\theta_2 - \theta_1)$.

13) Estimated Torque that act to bone by $M = F(\Delta y_1)$.

14) Change F from 200 to 400, 600, 800, 1000 respectively (repeating same procedure).

15) $T = k(\Delta\theta)$, then k (Torsional Stiffness) of the model could be calculated by plotting graph between torque and $\Delta\theta = (\theta_2 - \theta_1)$ and then estimating the slope of the graph

b) Testing of torsional stiffness in extension of degenerate disc model attach with device

After analyze Modulus of Elasticity (E) of degenerated intervertebral disc. Modulus of Elasticity (E) of degenerated Annulus Fiber is 3.5 MPa (Torsional Stiffness of flexion is $1.13^{N\ m}$ / Degree. Mechanical property of degenerate intervertebral disc in flexion and other are in table 7

Table7 Mechanical property of motion segment that have Stiffness Equal to degenerative disc in extension

Section	Modulus of Elasticity (MPa)	Poisson's Ratio
Cortical Bone	12000	0.30
Cancellous Bone	25	0.20
End Plate	12000	0.25
Posterior Element	3500	0.25
Annulus Fiber	3.5	0.45
Nucleus	1	0.499
Titanium	120,000	0.3

1) Load motion segment model and import new design device

2) Give mechanical properties to model as table 7

3) Divide motion segment model and device to Elements by

- Motion segment model use Elements Solid95 type
- New design device use Elements Solid92 type

4) Set contact at surface between cable and upper, lower spinous process as

   i. Volume Contact

   ii. Static friction 0.37 (from reference paper)

   iii. Set contact as Bonded and Close Gap because it may have a tiny space between device and bony contact surface. Set cable not to slide on bone

5) Set contact surface between Spacer and bone by

   - Volume Contact
   - Static friction 0.37 (from reference paper)
   - Set contact as Bonded and Close Gap because it may have a tiny space between device and bony contact surface

6) set the lower surface of vertebra fix and no movement ux=uy=uz=0

7) We have to measure angle and add couple force to create torque, flexion and extension.So we choose 2 reference point at most outer superior surface of vertebra.

   - Point (A) at center , most posterior of body (0,0,0)
   - Point (B) at center , most anterior of body (dx,dy,dz)

8) Before start calculation and analyze , measure angle between line drawed from point A and B and axis Y (can measure angle from $\theta_1 = Arc\tan\left[\frac{\Delta z_1}{\Delta y_1}\right]$)

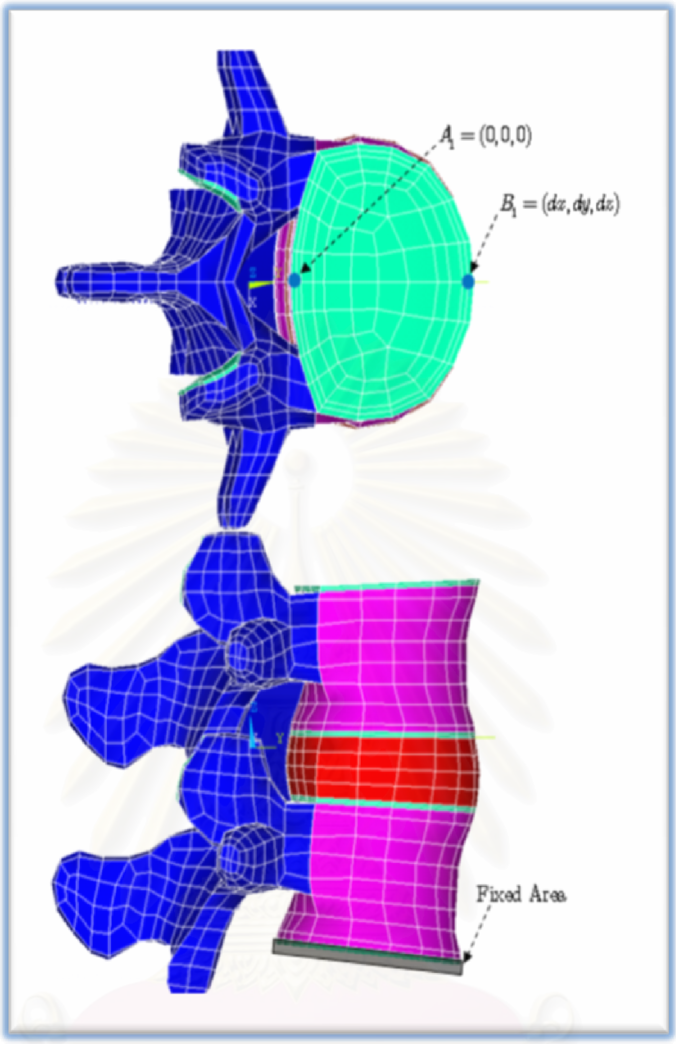

Fig. 20 Two referent point to apply load

11) Couple force [F] act to model at point A,B 200N, 400N, 600N, 800N, 1000N respectively , direction of force as below

- For flexion , force at point A $[F_A]$ have direction–Z : force at point B $[F_B]$ have direction +Z
- For extension , force at point A $[F_A]$ have direction +Z ; force at point B $[F_B]$ have direction –Z

12) If applied force to only one point(point A,B) can made much more error , we solve this problem by applied force as pressure act on area around point A,B instead.

- ❖ Area around point A 138 mm2 $P_A = \dfrac{F_A}{(138\ \text{mm}^2\ 10^{-6})}$

- ❖ Area around point 105 mm2 $P_B = \dfrac{F_B}{(105\ \text{mm}^2\ 10^{-6})}$

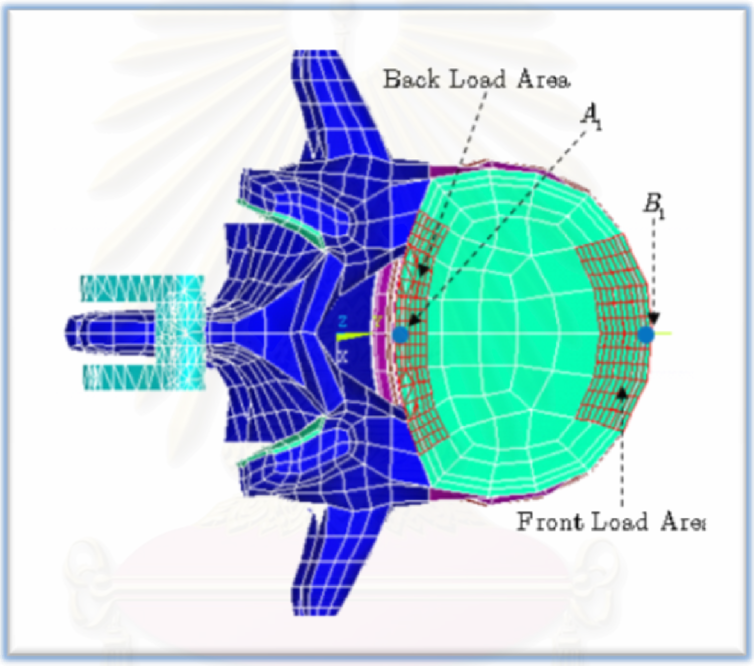

Fig 21. Area to apply load

13) After analyze and measure distance different of point A,B after applied force , calculate angle between 2 lines (before and after applied load) after analyze with Z axis $\theta_2 = Arc\tan\left[\dfrac{\Delta z_2}{\Delta y_2}\right]$ then $\Delta\theta = (\theta_2 - \theta_1)$

14) Estimated Torque that act to bone by $M = F(\Delta y_1)$

15) Change F from 200 to 400,600,800,1000 respectively (repeat same method)

16) $T = k(\Delta\theta)$ then we can find k (Torsional Stiffness) of the model by plot graph between torque and $\Delta\theta = (\theta_2 - \theta_1)$ then estimated the slope of graph

CHAPTER IV

RESULTS AND DISCUSSION

A) Interspinous distance

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

Table 8 Average interspinous distance

subject	Subject number	Average interspinous distance			
		L1-2	L2-3	L3-4	L4-5
male	30	12.51	11.78	10.95	10.57
female	30	12.20	11.63	10.74	10.15
Total	60	12.36	11.71	10.84	10.36

Maximum distance in male was 14.1 mm at L 1-2 level and minimum 8.00 mm at L4-5 level in female .

Table 9 Maximum interspinous distance

subject	Subject number	Maximum distance (mm)			
		L1-2	L2-3	L3-4	L4-5
male	30	14.1	14.1	14.0	13.0
female	30	12.2	11.63	10.74	10.15

Table 10 Minimum interspinous distance

subject	Subject number	Minimum distance (mm)			
		L1-2	**L2-3**	**L3-4**	**L4-5**
male	30	10.2	8.40	9.0	8.40
female	30	10.0	9.15	9.10	8.00

From measurement result, number of size of interspinous device we should manufacture is 6 size (from 8 mm to 14 mm)

B) Design and mechanical properties of the construct

We try to make balance between stiffness of device to let it can compensate degenerative model to stiffness of 2.6 and make the device strength enough to restrain force and not fail under load (maximum stress must less than yield point of titanium at 1200 Gpa, the safe maximum stress should be around 700-800 Gpa at any point of device after test with load).

1) **Flat U design**

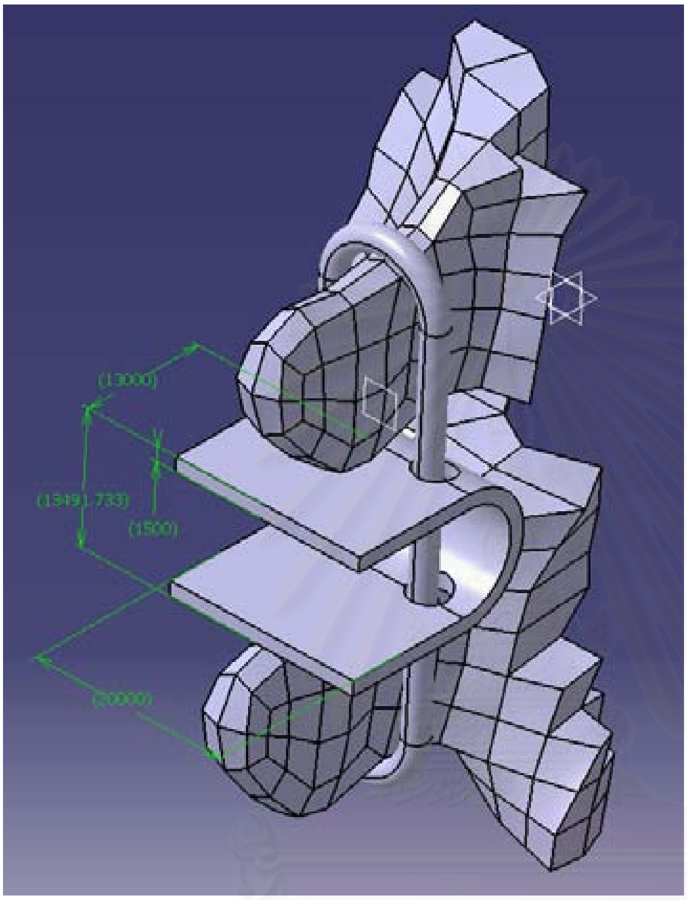

Fig. 22 Flat U device

This design can divide to 2 parts.First the U spacer, is a titanium spacer with 2 holes at side as seen in picture.This part intends to restore height of intervertebral foramen and compensate stiffness loss in extension posture. Second part is titanium sling around spinous process. This part intend to limit abnormal motion and compensate stiffness loss in flexion posture.

Advantage

- simple manufacturing
- less modularity
- can set tension as needed when applied to patient

Disadvantage

Slipped forward when test with finite element method. When it slipped,spinous process and leg of device are not contact to each other ,so it can't calculate in finite element and not achieve goal as described above. After trying to increase size and extend leg of device for more contact but it always slipped.

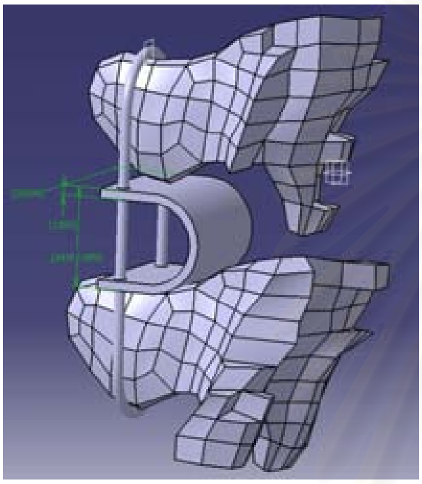

Fig.23 Flat U device with thickness 1.3 mm

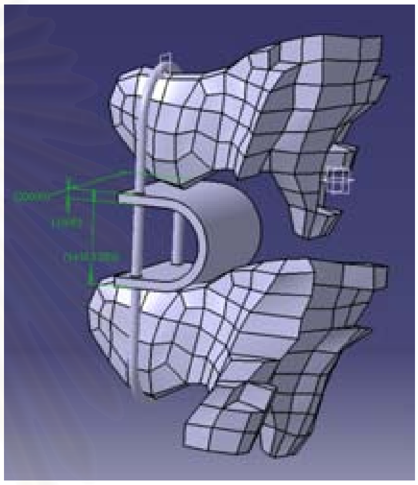

Fig. 24 Flat U device with thickness 1.5 mm

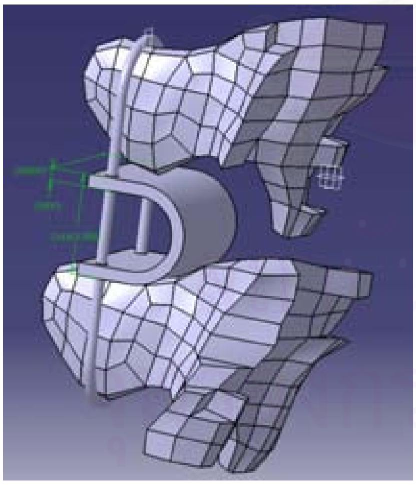

Fig. 25 Flat U device with thickness 1.8 mm

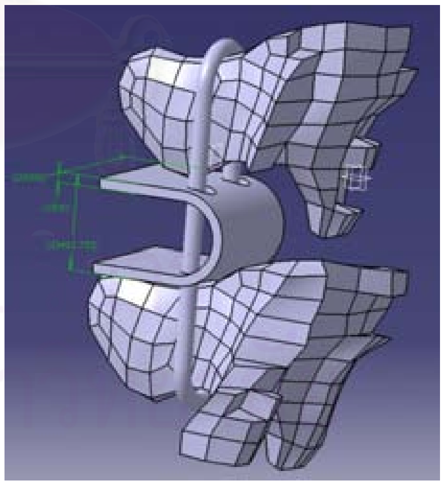

Fig. 26 Flat U device with thickness 1.5 and extended legs of U spacer

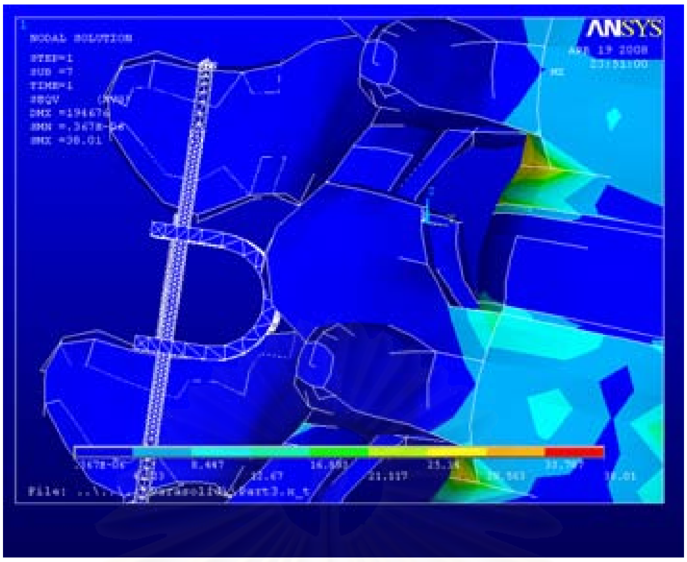

Fig. 27 Slipped forward caused no contact between bone and spacer (calculate by finite element)

2) Narrow U (narrow width spacer) design

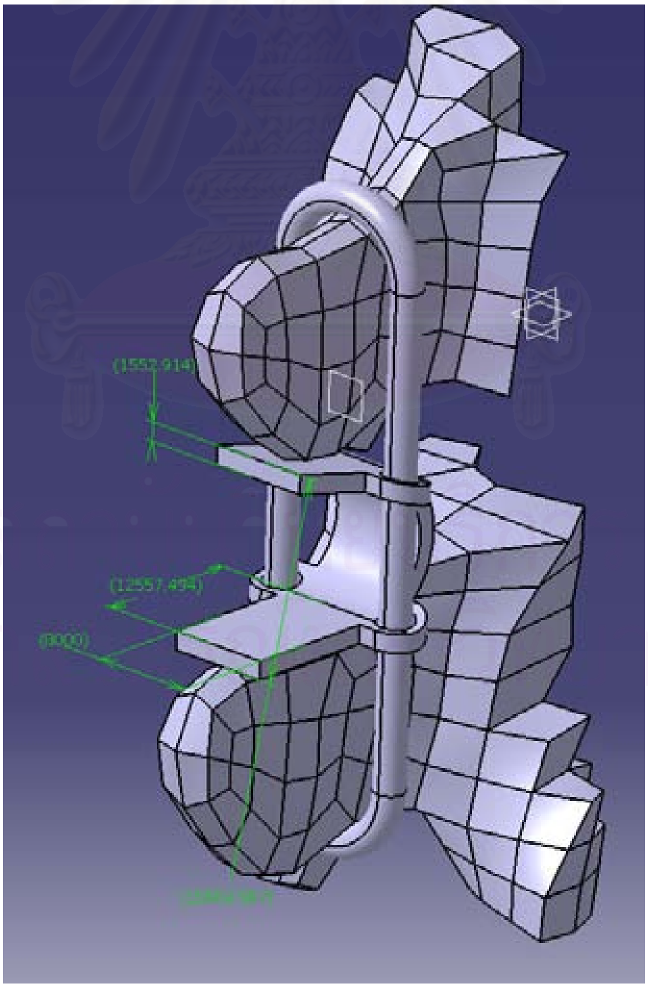

Fig. 28 Narrow U (narrow width spacer) design

To solve the problem of slipped device modified spacer from flat U with parallel legs to modified U with both legs wide spread from each other was created. Another change in this model is that flat U design may have too wide spacer that make stiffness of device can't decrease to required level even when it's very thin. We narrowed it from 20 mm to 8 mm.

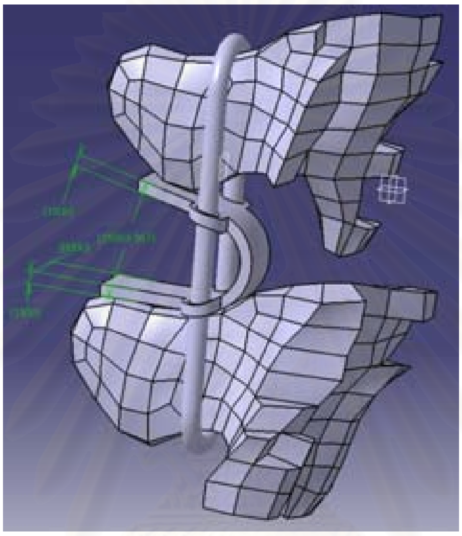

Fig. 29 Narrow U with thickness 1.5 mm

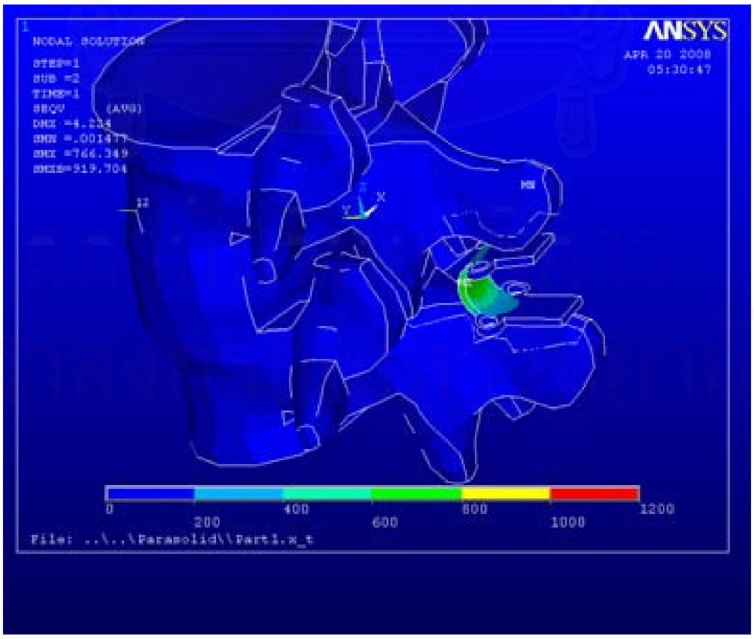

Fig. 30 Stress on narrow U device in finite element test

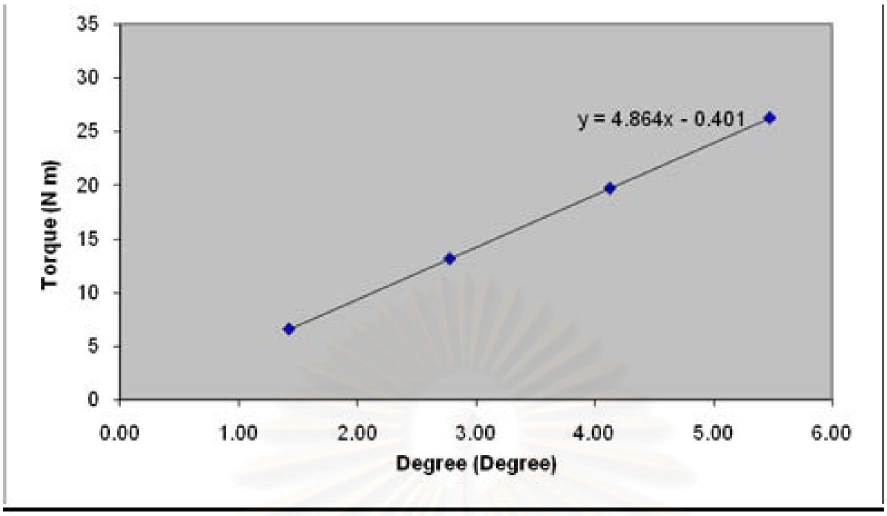

Fig. 31 Torque-degree graph for narrow U design

Fig 31 show slope of graph as stiffness of motion segment+device.It's 4.86 that's mean it's more stiffness than normal (2.6Nm/ degree). Trying to change thickness of spacer from 1.5 mm to o.8 mm was done and the results are as table 11

Table 11 Compare thickness and stiffness of narrow U design

Thickness(mm)	**Stiffness(Nm/degree)**	**Remark**
1.5	5.2	not break device
1.0	4.8	not break device
0.8	3.8	device break under load 600 N

3) <u>Curved U design</u>

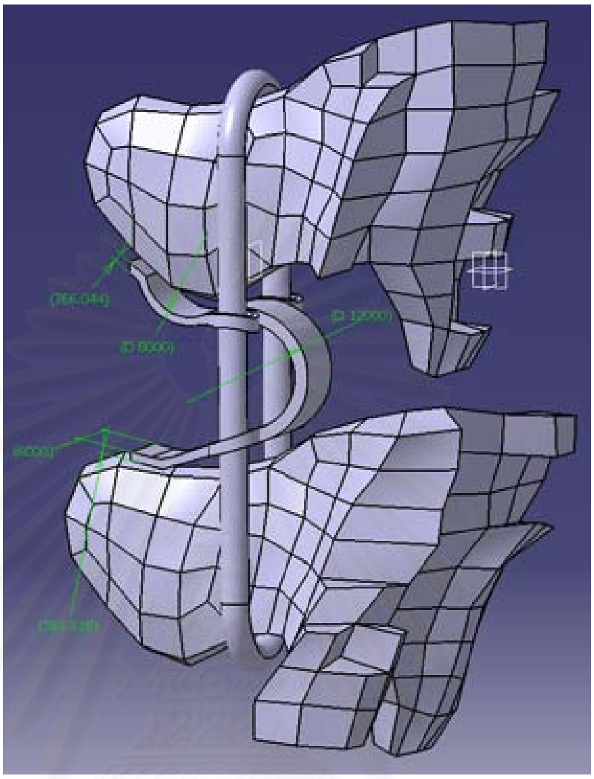

Fig. 32 Curved U design

From analysis of narrow U design, the design has 2 problems.

1) Contact point is too proximal that make increase stiffness of the device.

2) Side hole make legs of U spacer too strong then the stress is not flow on to the legs but pooled at turning point of U spacer. These make the turning point bearing too much load and tend to break. So in the narrow U design, we can't thinner the turning point of U spacer to decrease stiffness because the device will fail easily.

From the reason above, we move contact point more distally, the increase of moment arm will decrease stiffness of device, then we can increase thickness of device to protect it from broken and lessen stiffness of system at the same time. Second, we change design of side hole by let it attach to spacer from just a little contact surface instead of full contact in the former design.

This design can lessen stiffness of the system to satisfied level (3Nm/degree) with thickness of device at 0.8 mm. But at this thickness the device was failed at most proximal part (at turning point of U device).We can't increase thickness of device because if we increase it, it will increase stiffness also

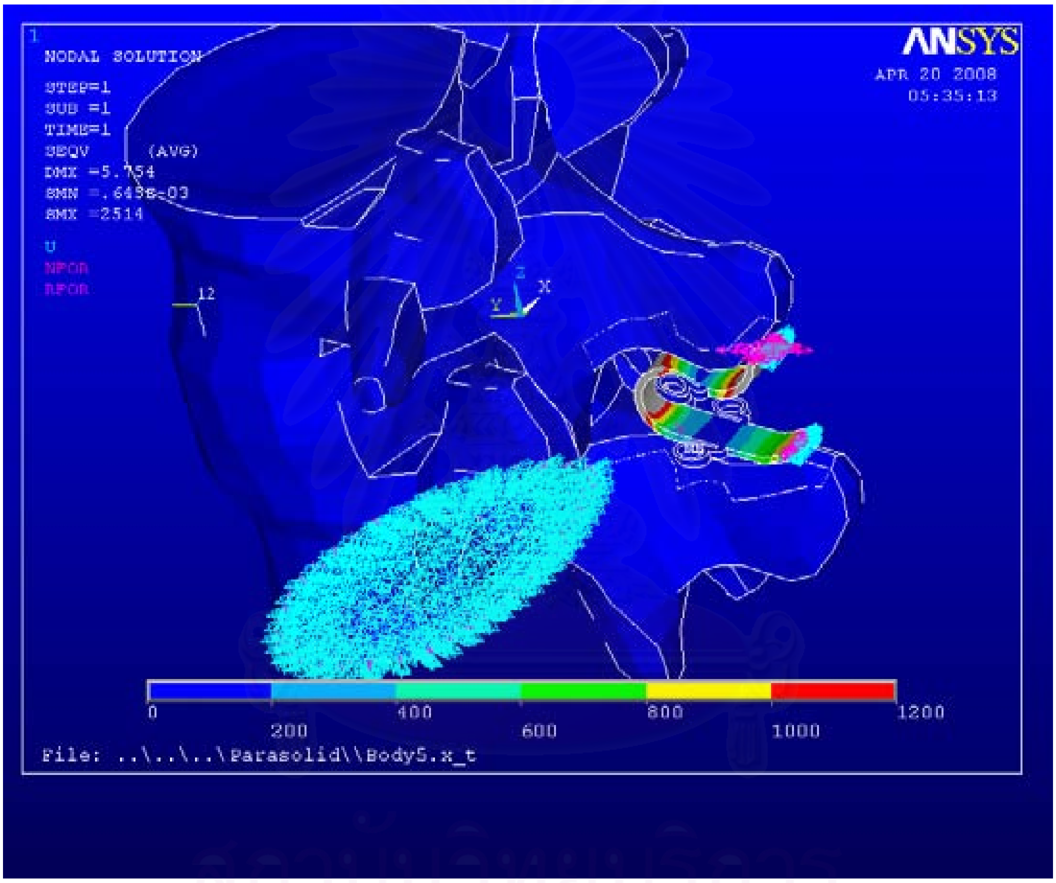

Fig. 33 Stress on curved U device in finite element test

<u>Table 12</u> Compare thickness and stiffness of curved U design

Thickness(mm)	**Stiffness(Nm/degree)**	**Remark**
1.5	6.15	not break device
0.8	3.8	device break under load 600 N

4) Curved U with 2 proximal side arms

4.1 Curved U with 2 proximal side arm (Titanium)

From curved U design, the stress still not flow on the U spacer's legs as we wish even after we decrease contact surface of cable's hole.

In this design we change position of cable's hole from side of spacer to make it arise from turning point of U spacer. This change would make the turning point of U spacer (most common failure point) have more material and more width. We wish it strengthen the turning point of spacer and protect it from failure. Another benefit is to make the stress flew into the area of the former cable's hole because it has less material and width.

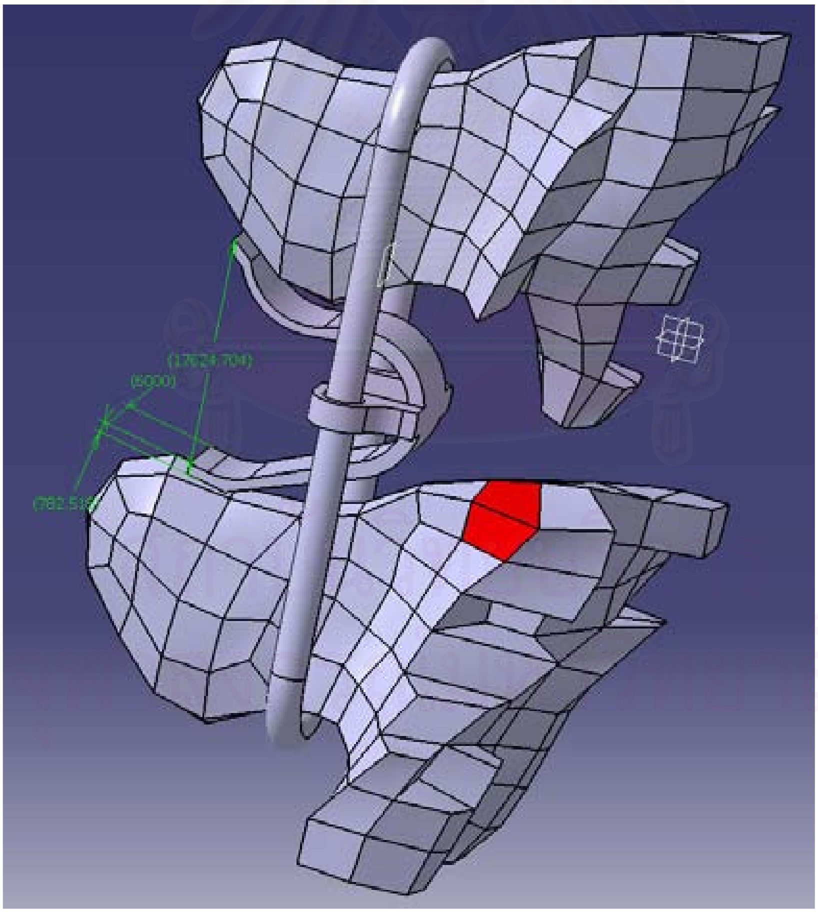

Fig. 34 Curved U with 2 proximal side arm (Titanium)

This design also fails from same reason as curved U device even if we use any thickness. But it can reduce some stress at the turning point and can move the stress flew to the former place of cable's hole.

Table 13 Compare thickness and stiffness of curved U with proximal side arm design (Titanium)

Thickness(mm)	Stiffness(Nm/degree)	Remark	Thickness character
1.5	4.1	device break under load 600 N	Simultaneous thickness
1.8 at central Tr0.8 at most lateral	3.2	device break under load 600 N	Thick at central Thinner laterally

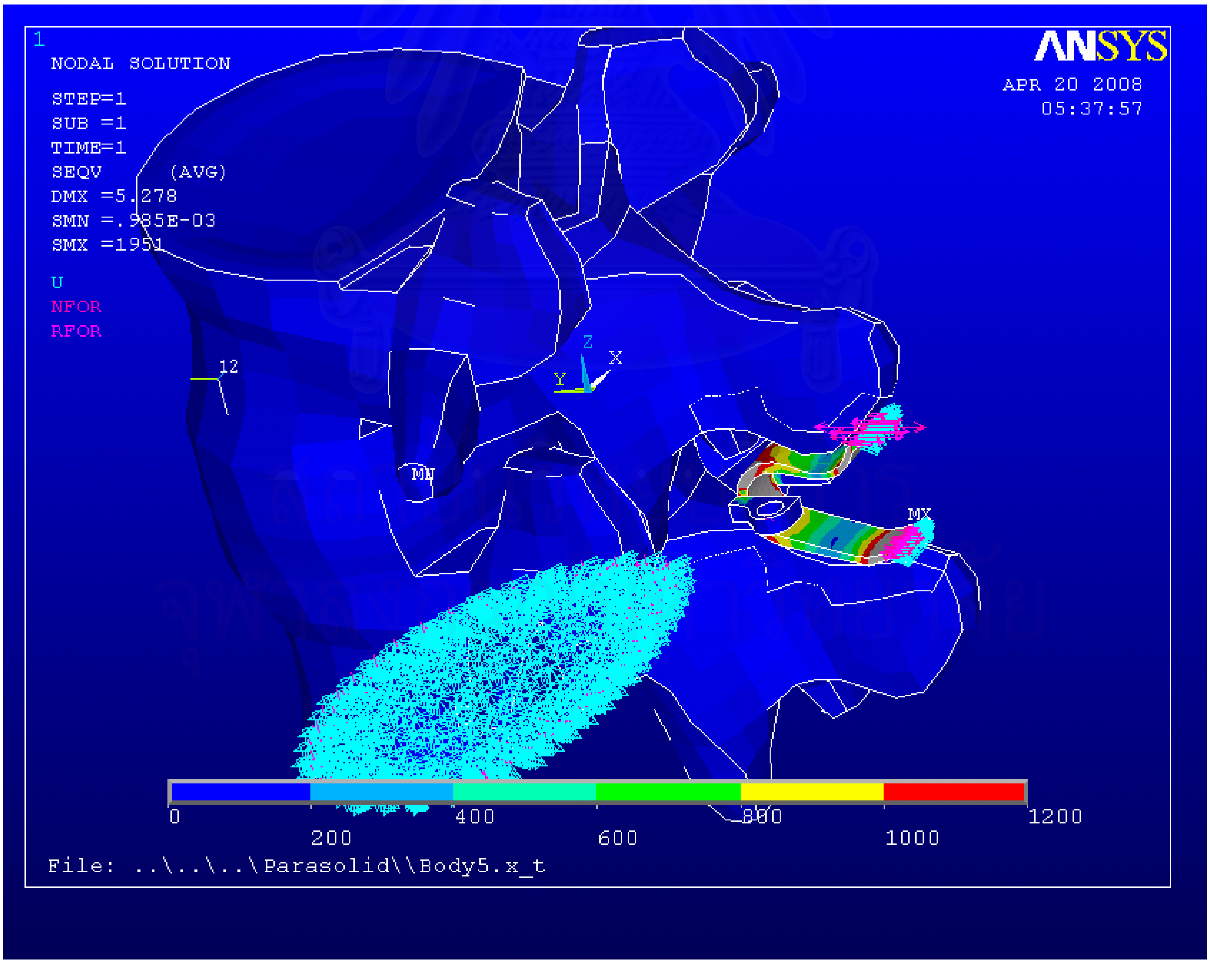

Fig. 35 Stress on curved U device with proximal side arms (Titanium) in finite element test

4.2 Curved U with 2 proximal side arms (Ni-Ti)

From former experiment explained. We can't make the U shape device made of Ti4AlV6 to have stiffness nearly to the normal motion segment and make it survive from failure instrument in the same time. So we try to change the material to Ni-Ti that has more elastic property. We use it in the Curved U with 2 side arms model because it has the best experimental result by our finite element testing.

Table 14 Mechanical property of Ni-Ti

Mechanical property	
Young Modulus	43 GPa
Maximum strain	4% MPa
Yield stress	485 MPa
Poisson ratio	0.3

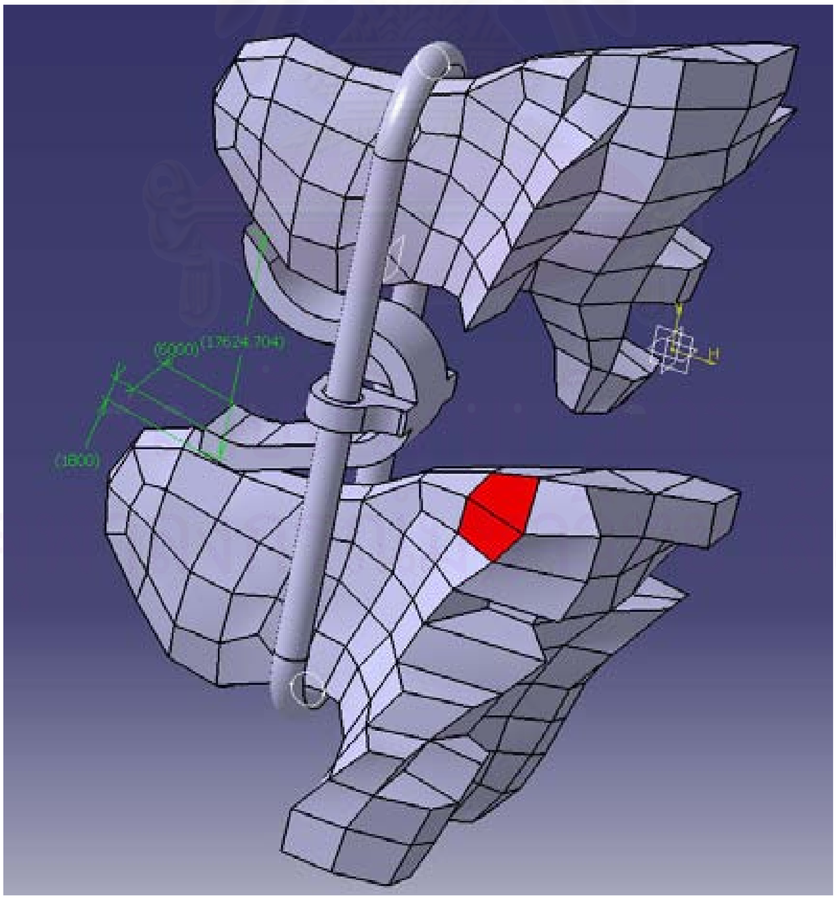

Fig. 36 Curved U with 2 proximal side arm (Ni-Ti)

This material has super elastic property so when we check the failure of device we have to look at the strain percentage. If material elongate less than 4% we'll assume that the device is not failure.

Table 15 Compare thickness and stiffness of curved U with proximal side arm design (Ni-Ti)

Thickness(mm)	Percentage of elongation	Remark	Thickness character
1.8	> 4 %	device break under load 600 N	Simultaneous Thickness
1.8 at central Tr0.8 at most lateral	> 4 %	device break under load 600 N	Thick at central Thinner laterally

5) Modified U device

Model curved U with 2 proximal side arm was failed in both kind of material and its shape makes it hard to manufacturer. After trial we conclude that Ni-Ti not proper to use in interspinous device because the yield stress is too low and material itself is expensive.

We go back to simple model that compose of spacer made of titanium in both legs wide spread from each other. Cable's hole made by drill directly on spacer.

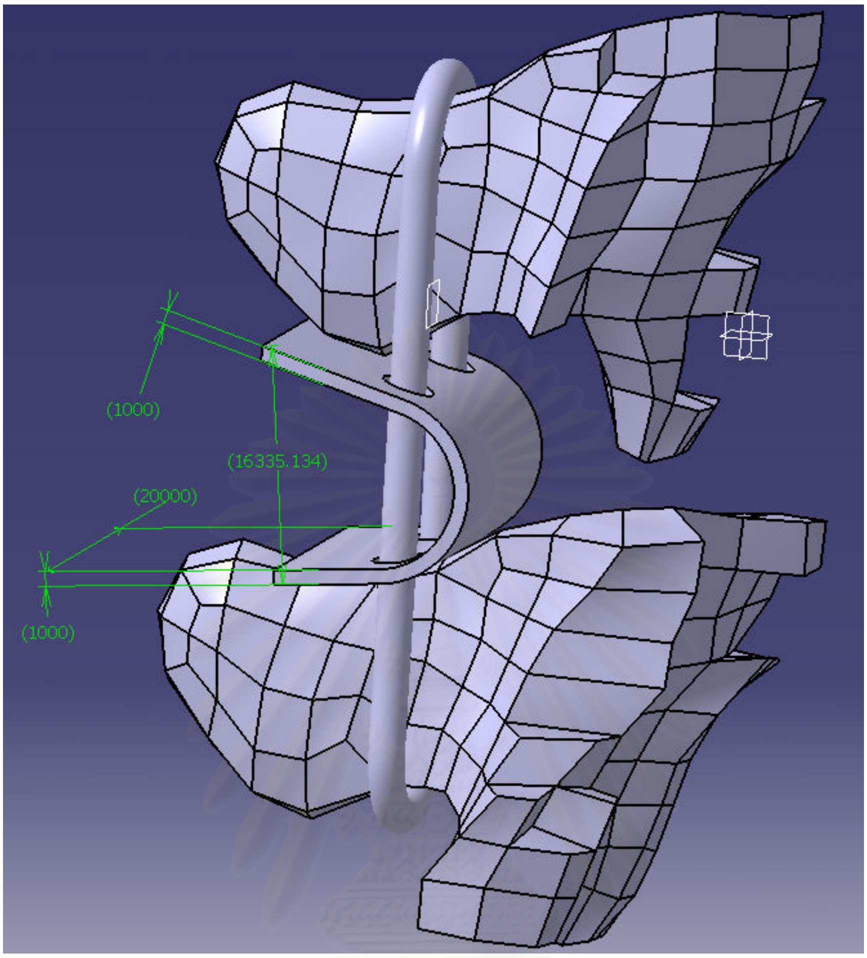

Fig. 37 Modified U design

Advantage

- fit in place under extension load
- made of titanium that cheaper than Ni-Ti
- simple in design so it make easy to manufacturer

<u>**Table 16**</u> Compare thickness and stiffness of Modified U design

Thickness(mm)	Stiffness(Nm/degree)	Remark
1.5	5.1	not break device
1.2	5.03	not break device
1.0	4.058	not break device

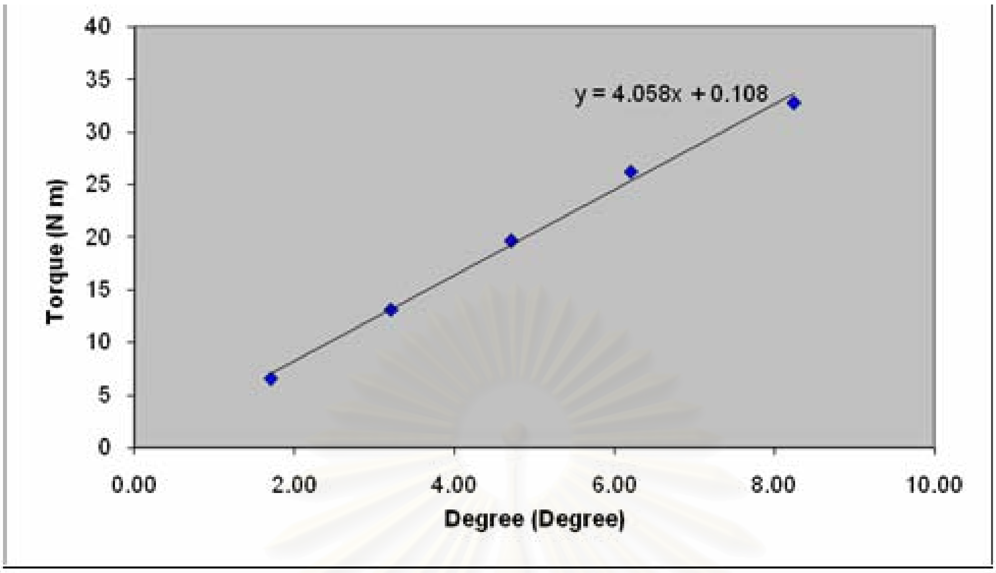

Fig. 38 Torque-degree graph for modified U design

Table 17 Load appied and degree change in modified U design

NO.	F (extension)	ABS T(N m)	ABS d(Zeta)
1	200	6.556173	1.7094
2	400	13.112346	3.2124
3	600	19.668519	4.7146
4	800	26.224692	6.2126
5	1000	32.780865	8.2513
		k=	4.058156615
หน่วย	N	N m	Degree

We choose modified U design as our final design. It not failure device in load applied at 200,400,600,800 and 1000 N. We accept that we can't use our device to compensate stiffness to normal (2.6 Nm/degree) but we can make it to near normal (4.05 Nm/degree). Limitation of material property has a lot effect to result of the design.

Titanium cable

We determine thickness of titanium cable by simulate it on Finite element. We use same mechanical property as titanium (from reference paper said it close to each other) and use trial and error technique to find a proper stiffness that can resist flexion load and have stress 600-700

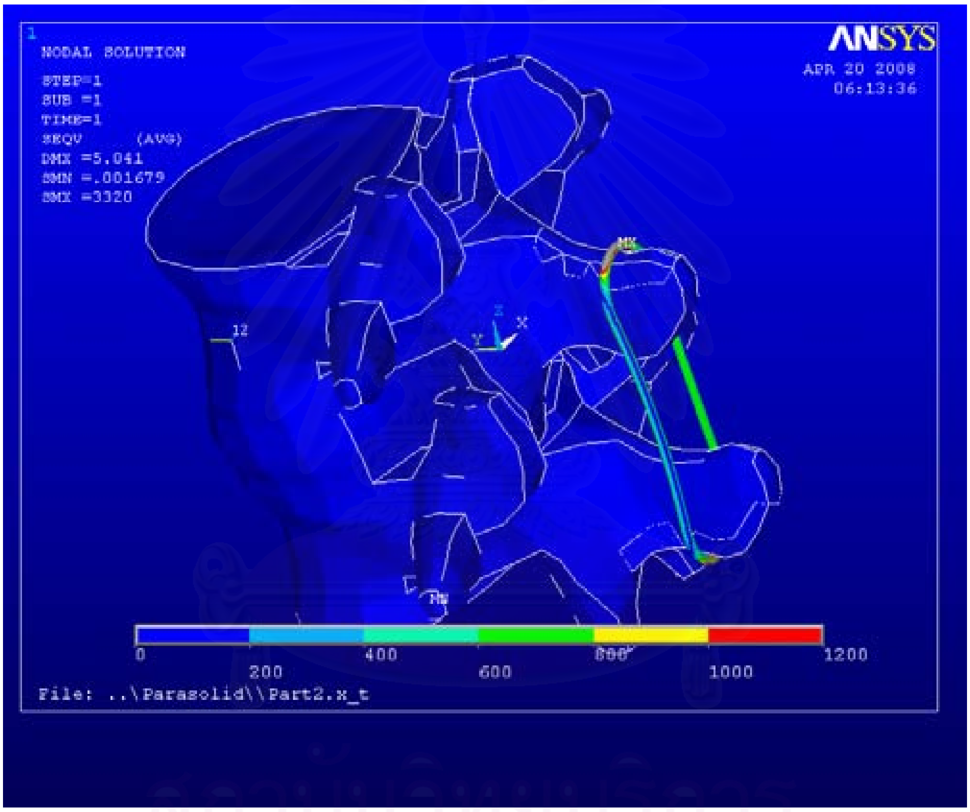

Fig. 39 Simulation of titanium cable on finite element (thickness 1.5mm)

As seen in figure 39, if we use titanium cable size 1.5 mm in diameter, it will fail under flexion force 600 N. Size was change to 2.5 mm and the result was satisfied figure 40 then we choose titanium cable size 2.5 mm in our device

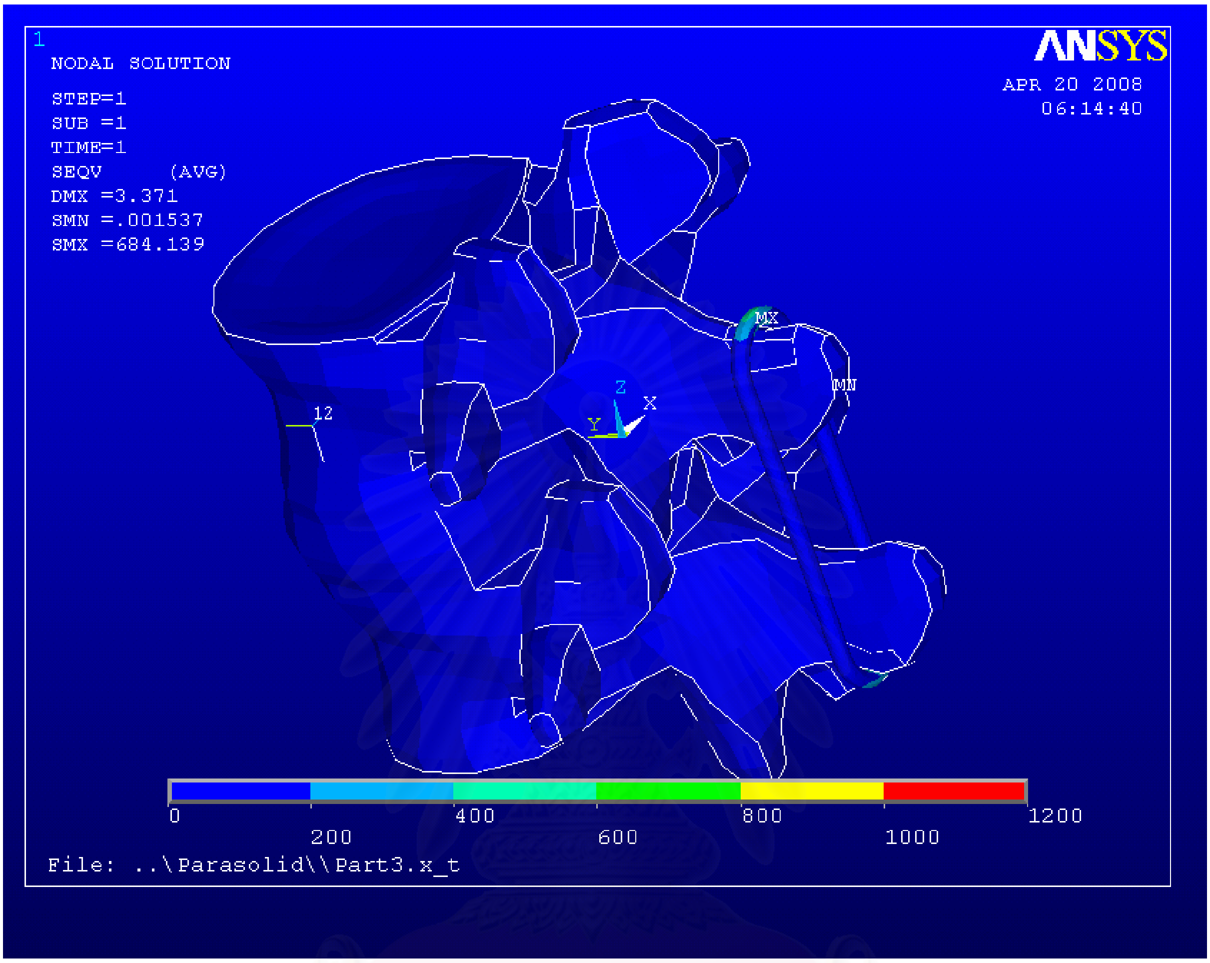

Fig. 40 Simulation of titanium cable on finite element (thickness 2.5mm)

CHAPTER V

CONCLUSION

1. Conclusion

This project aimed to design new dynamic stabilization system and to measure of interspinous distance of Thai population. As the device designed to use in lumbar spine measurement of the distance of interspinous was done only in lumbar segment. From the measurement result, it was recommended that the interspinous device should cover 6 varies sizes (from 8 mm to 14 mm).

The new device designed in this research had been proved by finite element method that it could compensate stiffness loss in early degenerative motion segment and correct it to near normal. It allowed motion segment to move in flexion and extension. The device is minimal modularity. It could inserted from posterior surgical approach and would not have to damage any bony structure.

Once the device was installed in motion segment model (modified U device) and simulated, torsional stiffness in flexion is 1.9251 and 4.068 Nm/degree in extension. It could be interpreted that device can correct degenerate condition to near normal.

2. Recommendation

1) This research has intended to use computer program to design and test. The main program was CATIA (for drawing CAD of new design device) and ANSYS (for analyze torsional stiffness, stress and displacement of device). These two programs ware complicated to use and time consuming. The user required a lot of training and long learning curve.

2. The force that was used to simulate in ANSYS program for Finite element calculation was not real natural force. For future study, it's suggested to learn more about force on spine column, simulation of motion and movement in ADAMS – LifeMOD program.

3. Stiffness used in calculation from only one reference. In real situation, stiffness varies from many factors.

4. Simulation by finite element analysis had limitation.

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Biography

NAME Saran Tntavisut, M.D.

NATIONALITY Thai

POSITION Resident 3rd year

DATE OF BIRTH November 1, 1979

AFFILIATION Department of Orthopaedics, Chulalongkorn Hospital

Faculty of Medicine

Chulalongkorn University

EDUCATION

Medical School

- Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand (2003)

Residency Training

- Department of Orthopaedics, Chulalongkorn Hospital, Bangkok, Thailand (2006)

Qualifications

Doctor of Medicine, Thai Medical License No. 27840 (2003)