Original Article

A biomechanical evaluation of posterior spinal instrumentation applied for osteoporotic bone

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ABSTRACT

In the osteoporotic spine, it is difficult to ensure posterior fixation using a pedicle screw system., and unscrewing pedicle is a serious problem. A solution must include a posterior column- shortening procedure that can change the spinal alignment in the sagittal plane. However, no biomechanical study has examined the relationship between the stability of a pedicle screw system and alignment after a shortening procedure.

The purpose of this study is to clarify the relationships among the strength of a pedicle screw system, the degree of osteoporosis, and spinal alignment after a column-shortening procedure.

An experimental model was created simulate the spine in which of kyphosis developed after a compression fracture of a vertebral body. Biomechanical tests were performed using a universal testing machine. We used 13 cadaveric spines for the study. In each,we created amodel of a kypotic spine by removing wedge-shaped bones of various sizes from anterior part of the spinal body of T12, we created the model of kyphotic spine. We attached pedicles screws to T10, L1 and L2, then, connected the screws with rods to complete the model of the posterior fixation in a kyphotic patients in clinical conditions. Then, we measured the yield strength by applying an axial load to the model. We also measured the pull-out strength of the pedicle screws, and we used D X A to measure bone density. Yield strength of the pedicle screw system showed negative correlation with angle of kyphosis,and positive correlation with bone density.

From this study, we calculated the regression formula : Yielding strength (N) = −20.42x [angle of kyphosis (degree)] + 1048x [bone density (g/cm^2)] + 1014 Although this formula was calculated in vitro study, it might be helpful to consider the relationship among the yielding strength, the degree of kyphosis and the bone density.

Key Word : biomechanical evaluation, pedicle screw system,osteoporotic bone,

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pull-out strength

I. Introduction

Compression fractures in elderly people, especially which are classified as unstable types are difficult to be managed conservatively[1]. Protrusion of the collapsed posterior wall into spinal canal can cause the spinal cord compression and injury[2]. To treat these condition, anterior approach had been a common procedure, because the causative deformity existed mainly in anterior part of spine[3,4,5]. In general, the anterior procedure needed thoracotomy or laparotomy, both operations were severely invasive for aged people[6]. And also, these anterior approach were not familiar to most of orthopedic surgeons except experts of spine surgery.

In contrast, posterior approach to the spine is less invasive compared to the anterior procedure[6]. Furthermore, posterior approach to the spine is a common procedure for many orthopedic surgeons[7,8]. Through the posterior approach, we use pedicular screw system for posterior spinal fixation. By the improvement of the pedicular screw system, the strength at the rod-screw junction had been enhanced. However, the biggest problem is the weakness of the holding strength of the screw against the osteoporotic bone[9].

Especially in elderly people with marked kyphosis, pull-out phenomena of the screw were common complication[10].

To overcome this problem, column shortening procedure of the spine had been developed, and favorable results have been reported[6]. In this operation, posterior part of the spine including the pedicles of the collapsed body is removed[6]. By compressing adjacent vertebral body, the kyphotic deformity can be corrected[6]. And this reduction of kyphotic deformity could enhance the fixation strength with pedicular screw system. However, it could be difficult to acquire the complete reduction of the deformity, we have to accept a certain degree of residual kyphosis in some cases.

No biomechanical testing had been done to clarify the relationship among the fixation strength of pedicular screw system, the degree of kyphosis, and the severity of osteopenia. We performed the following experiment in order to unveil the relationship among these factors.

II. Material and methods

Thoracolumabar spine from T10 to L2 were removed at autopsy from 13 patients (11 males, 2 females, 48-84 years-old, mean 65.7 years-old with no history of metastatic disease or metabolic bone desease). They were harvested according to the routine methods of autopsy. All soft tissue except for the intervertebral disk, anterior and posterior longitudinal ligament were removed.

Then, the bone density was measured from the side to side direction of the vertebral body using DXA (BMD-1X®, Hitachi-Medico Inc, Tokyo, Japan).

In order to simulate the kyphotic deformed spine after compression fracture, the experimental model was created as follows. Various degree of anterior-based wedge shaped bones were removed from the vertebral body of T12, then the osteotomized surfaces of remaining T12 were firmly contacted applied with axial compression load. Degrees of kyphosis were randomly created with no relation to the bone density. Mirage Spinal System ® (Alphatech Inc, CA, USA) was used for the pedicular screw system. Two screws were inserted into each of the T10, and L1 and L2 vertebral bodies. First, a hole of 30mm in depth and 4.5mm in diameter was made at the center of pedicle, then tapped with tapping device of 5.5mm in diameter. Pedicular screw of 5.5mm in diameter was inserted into the hole to the depth of 30mm. A pair of rods for both sides were attached to the pedicular screws to complete the pedicular screw system. Lateral X-ray were taken to measure the degree of kyphosis (40kV, 30mA, 3minutes and 40cm of distance between bulb-tube and film).

A universal testing machine (AGS-H ®, Shimazu Inc, Kyoto, Japan) was used for biomechanical testings. Stress-strain curves were calculated by the analyzing program (SHIKIBU for Windows 95®, Shimazu Inc, Kyoto, Japan) with PC (Compaq Deskpro ®, Hewlet Packard Inc, CA, USA)

A. Measurement of the fixation strength in the kyphosis model.

The bottom of the kyphosis model were fixed to the aluminum base with dental resin (Quick Resin B ®, Shofu Inc, Kyoto, Japan). When the human bend forward at standing position, thoracic spine inclines forward. On the contrary, lumbar spine relatively remains perpendicular to the ground. To reproduce this phenomenon in the testing, "rollers" were put under the base as shown in the Fig. 1, so that it can move to both anterior and posterior direction. On the top of the model, a metal plate was fixed with the resin. Compression load was applied onto this metal plate with the universal testing machine at the speed of 50mm/min according to the method by Kaneda et al[11]. As the increase of the applying loads, the base moves to rearward of the spine (to the right in the figure) on the rollers keeping lower part of the model perpendicular to the base. This rearward movement of the model resulted in the anterior bending of the upper part of the model which was similar phenomenon observed in human at standing position.

Compressive loads were applied until the pedicular screw was pulled out from the spines.

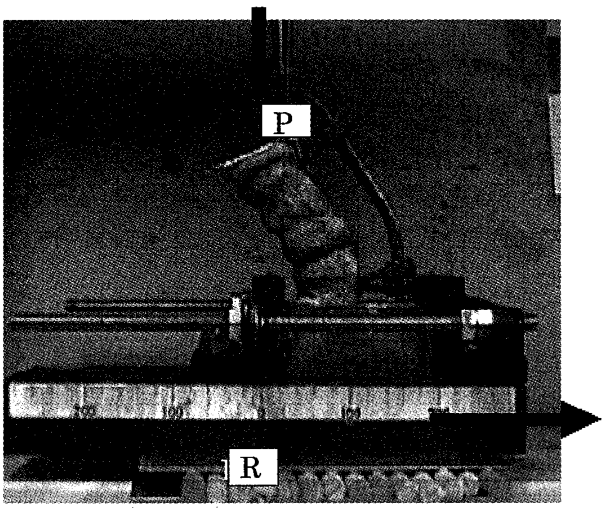

Fig 1 : measurement of the fixation strength in the kyphosis model.
P : compression point by tensile machine.
R : rollers.

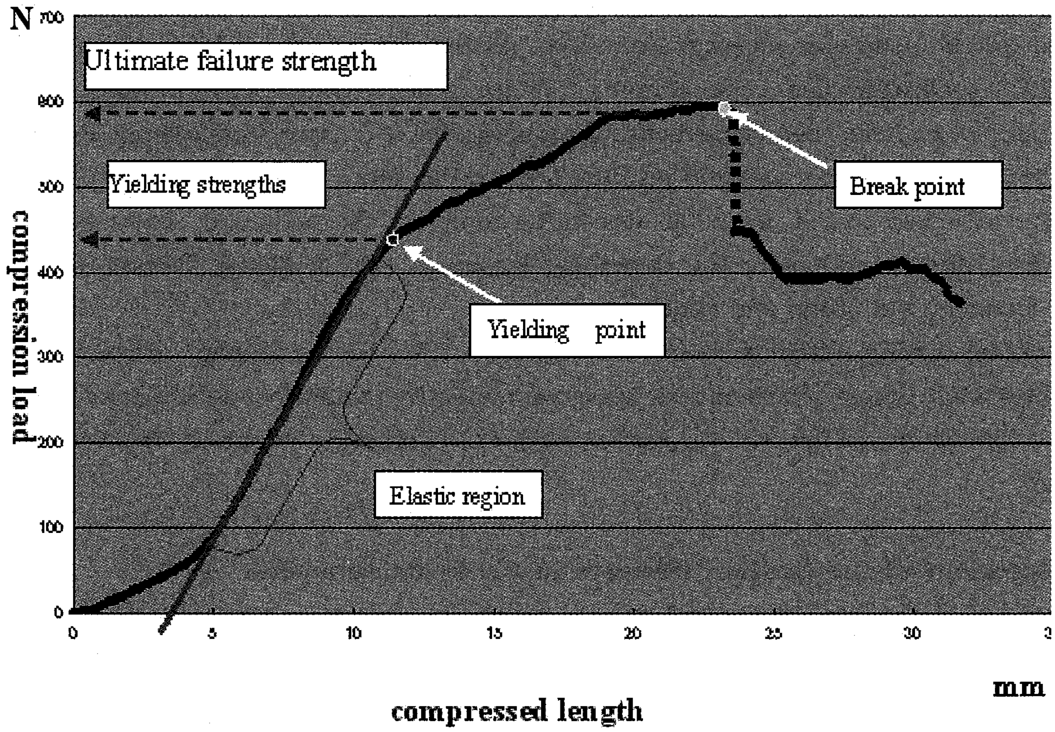

Fig 2 : Stress-Strain curve.

From stress-strain curve shown in Fig. 2, ultimate failure strength and yielding strength were measured. Since over the yielding point the model started plastic deformation, we defined the yielding strength as the fixation strength of this model. The testing procedure was monitored with a video camera (Handycam ® DCR-PC120, Sony Inc, Tokyo, Japan) to clarify the relationship between stress-strain curve and actual phenomenon occurred at the model.

B. Measurement of pull-out strength of pedicular screw from the vertebral body

After the measurement of the fixation strength,T11 body was removed. A pedicular screw was inserted into the pedicle of T11 in the same manner as installation of the pedicular screw system.

As shown in Fig. 3, the vertebral body was hold by a metal plate with holes to avoid being lifted up, pull-out strength was applied with the tensile stress machine at the speed of 50mm/min. The speed of pull-out was referred to the experiment of Amy (1996)[12]. In the stress-strain curve of pull-out testing, it was difficult to identify the yielding point. We defined the ultimate tensile strength as the pull-out strength in this testing.

Statistical analyzing software (Statcel ®, OMS Publication Inc, Saitama, Japan) was used for statistical analysis.

We examined four parameters of bone density, angle of kyphosis, pull-out strength, and fixation strength whether these parameters had the normal distribution or not using with chi-square test. Furthermore, correlations among each parameters were tested using Pearson's correlation test to measure the level of significance ($p<0.05$).

Fig 3 : measurement of the pull-out strength of pedicular screw from the vertebral body.
P : A metal Plate for hold the vertebral body.
S : A pedicular screw pulled out by tensile stress machine.
T11 : 11^{th} vartebra.

To study different factors affecting the fixation strength, we used stepwise regression analysis ($p<0.05$). Explanatory variable in this test was bone density and angle of kyphosis, which could be measured in clinical condition.

III. Results

Mean bone density was $0.547 \pm 0.105 g/cm^2$ (0.395 to $0.719 g/cm^2$), and mean angles of kyphosis was $37.1 \pm 8.55°$ (26 to 53°). Normal distributions were confirmed at angles of kyphosis and bone density in the model. Values of fixation stress was 803.9 ± 276N (260 to 1150N), and the values of pull-out strength was 290.5 ± 151N (89.75 to 554.25N).

Measured single correlation coefficient between the parameters is shown in Table. 1.

Pull-out strength and bone density showed positive correlation ($p=0.012$, $r=0.672$). Fixation strength and bone density showed positive correlation ($p=0.007$, $r=0.714$). And also, highly negative correlation was observed between fixation strength and angle of kyphosis ($p=0.008$, $r=-0.830$). No correlation was found between fixation strength and pull-out strength, and between angle of kyphosis and pull-out strength.

Table 1 : Correlation coefficient matrix.
NS : not significant

	Bone density	Angle of kyphosis	Yielding strength	Pull-out strength
Bone density	1	−0.513 (NS)	0.714 (p=0.007)	0.672 (p=0.012)
Angle of kyphosis	—	1	−0.830 (p=0.008)	−0.319 (NS)
Yielding strength	—	—	1	0.614 (NS)
Pull-out strength	—	—	—	1

In the stepwise regression analysis, both of angle of kyphosis and bone density were selected as factors which affected the fixation strength, and the following regression formula was obtained.

Fixation strength = −20.41 × angle of kyphosis + 1048 × bone density + 1014 (r = 0.895)

IV. Discussion

We focused on yielding strength to represent the strength of the kyphosis model in this study. As shown in Fig. 2 deformation of the model exhibited the linear change in the stress-strain curve. This linear change is so called elastic deformity in biomechanical term. This model show the elastic deformity first and plastic deformation over the yielding point. By motion analysis with the video camera, the yielding point was just the timing of first pull-out of the screw from vertebral body.

Since the system seemed to be failure over the yielding point, we defined the yielding strength as fixation strength in this study. But this study has some limitation. As fatigue fracture in the athletes, repetitive stress with small amount of load causes permanent deformation, which can not be occurred with single small loading. Therefore, fixation strength should be regarded as one of the indicators which reflect the strength of the system.

We measured the bone density from lateral projection. The value of bone density measured from lateral projection differs from one measured from the anteroposterior projection, which is often used in the clinical situation. Takebayashi et al[13] reported that the bone density measured from lateral projection is approximately 80% of the value measured from anteroposterior projection. We used this ratio to convert the value into standardized value of anteroposterior projection adovocated by the Japanese Society for Bone Metabolism[14].

It is impossible to change the bone density in clinical condition. Therefore, in order to obtain sufficient fixation that prevent the failure, reduction of the kyphotic deformity into acceptable alignment is mandatory. To determine the acceptable alignment, it is worthwhile to create the formula from the parameters such as fixation strength and the bone density. We classified severity of osteoporosis with bone density into severe (bone density 0.3g/cm^2), moderate (0.5), and mild (0.7), and attempted to calculate the fixation strength from regression formula obtained from multiple linear regression analysis. Regression formula obtained from the experiment : 【Fixation strength】= −20.42 × [angle of kyphosis] + 1048 × [bone density] + 1014

Fixation strength calculated with the formula is shown in Table 2.

Nachemson et al[15] reported that load at intervertebral disc of L3/4 was 250N in supine position, 500N in the sitting or standing position, 600N and 1000N in 20° or 40° anterior bending respectively in a person with 70kg of body weight.

If we attempt to reduce 10% from the data by Nachemson[15] based on the average body size of elder people in Japan, the value of load on the lumbar disc could be 900N in a daily living.

Assuming that this 900N is the load that required for the fixation strength, we can estimate the acceptable angle of kyphosis depends on the bone density (Table. 2). From the Table. 2 we could speculate that 40° of kyphosis is acceptable angle at the bone density of 0.7g/cm^2, whereas 30, 20° in case of 0.5, 0.3g/cm^2 respectively.

Table 2 : Fixation strength with the pedicular screw system calculated with regression formula.

Angle of kyphosis	Bone density (g/cm²)		
	0.3	0.5	0.7
0°	1328.4	1538.0	1747.6
10°	1124.2	1333.8	1543.4
20°	920.0	1129.6	1339.2
30°	715.8	925.4	1135.0
40°	511.6	721.2	930.8
50°	307.4	517.0	726.6

N

However, since this experiment uses samples without muscles, ligaments, and intervertebral joints had been removed, it should be erroneous to directly apply the clinical cases. But, following two appreciable results would be of value for clinical knowledge. First, we could confirm that the smaller the angle of kyphosis, the stronger the fixation strength of pedicular screw system got. This result suggested that maximal correction of kyphosis should be aimed by shortening column procedure whenever possible. Second, we could obtain the regression formula to calculate fixation strength of the pedicular screw system from the bone density and angle of kyphosis. In cases, the fixation strength calculated by the bone density and the angle of kyphosis are not sufficient enough, postoperative treatment including duration of bed rest and additional support such as cane or walker should be carefully considered.

V. Conclusion

Using fresh cadaveric spines, we created models of osteoporotic spine with kyphosis simulating the unstable spinal fracture treated by posterior spinal instrumentation. Then, we studied the relationship among the fixation strength, the bone density, and the degree of kyphosis.

1. Fixation strength with the pedicular screws showed positive correlation with bone density, and it showed negative correlation with the angle of kyphosis.
2. The regression formula was obtained to estimate the fixation strength of the pedicular screw system from the angle of kyphosis and the bone density. Using this formula, acceptable angle of kyphosis might be calculated. Estimation of the acceptable angle should be meaningful indicator when one considers the postoperative rehabilitation.

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粗鬆骨における脊椎後方固定手術の力学的強度に関する研究

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要　約

椎弓根スクリューシステムは，脊椎圧迫骨折に対する治療法であるが，骨粗鬆や脊椎後彎が著しい例では，固定性に問題がある。脊椎短縮術は後彎を矯正するため，従来は困難な症例にも適応可能な術式だが，力学的検討がなされていない。システムの固定強度に影響を与えると考えられる後彎角度，骨密度との関係を明らかにするために力学的試験をおこなった。新鮮屍体脊椎１３例を用いて後彎した粗鬆骨脊椎モデルを作製し，椎弓根スクリューシステムを設置し，その固定強度を検討した。また，脊椎の骨密度と後彎角度，椎弓根スクリューの引き抜き強度も測定した。システムの固定強度は骨密度と正の，後彎角度とは負の相関があった。後彎角度と骨密度からシステムの固定強度を推定する回帰式固定強度（N）＝－20.42×後彎角度（度）＋1048×骨密度(g/cm^2)＋1014を得た。直接，臨床に適用するには限界があるが，各要素の関係を理解し，手術時の許容後彎角を推定する上で有用と考えた。

Key Word：力学試験，椎弓根スクリューシステム，粗鬆骨，引き抜き強度

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