# Preparation of a gear distraction plate device for spinal reduction and fixation*☆

Cui Xue-wen, Tian Jin, Ding Liang, Lü Shu-hong

**Abstract**

**BACKGROUND:** The most commonly used rod-screw posterior spinal fixation system has some biomechanical drawbacks. The screw-plate system is more preferred for patients.

**OBJECTIVE:** To prepare a new posterior spinal fixation system based on imaging results of distance between two pedicles, radian of spine flexion, extension and the height of intervertebral space of Chinese population.

**METHODS:** The thoracolumbar data of 129 normal people were measured. According to the imaging measurements and relative documents, a device of gear-distraction plate (GDP) for spine reduction and fixation was designed. Eighteen fresh calf lumbar specimens were randomly divided into 3 groups, the test group was fixed by GDP and the other groups were fixed by CD and Steffee plate, respectively. The results of the displacement, strain, strength, stiffness and ultimate strength were measured under the states of vertical compression, flexion, extension and lateral bending respectively, and the results were statistically analyzed.

**RESULTS AND CONCLUSION:** GDP could meet the need of strength and stiffness of human bodies. It showed superior to the CD and Steffee plate groups in strength and stiffness ($P < 0.05$), with 13% or 14% torsion intensity greater than that of the CD or Steffee plate groups. The ultimate mechanical performance test showed that, the load bearing of the GDP group was greater than that of the CD and Steffee plate groups ($P < 0.05$). The findings demonstrated that GDP for Chinese human presented with good biomechanical stability, which can promote vertebrae fracture union and prevent kyphosis relapses or vertebral height loses.

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## INTRODUCTION

At present, the most commonly used posterior spinal fixation system is the rod-screw system. The application of plate system is being used less and less because of the poor distraction and reduction. Based on reviewing the literatures, this paper aimed to design a new posterior gear distraction plate (GDP) device, which can distract and reduce the fracture vertebrae, and to understand the biomechanical properties and provide a basis for clinical application through *in vitro* comparative biomechanical tests.

## MATERIALS AND METHODS

### Design

A basic research.

### Time and setting

The study was performed in Affiliated Hospital of Jiangsu University from October 2004 to October 2009.

### Subjects

A total of 129 healthy volunteers were selected from Outpatient Department in Affiliated Hospital of Jiangsu University from October 2004 to October 2009, including 87 males and 42 females, aged 18–67 years, mean aged 48.4 years, with body height of 160–186 cm, mean height of 170.5 cm.

### Animals

Eighteen fresh calf lumbar specimens (3 months old) were randomly selected, and the pathological specimens were weed out. X-ray film showed the specimen was normal.

### Methods

***Radiological imaging and measurements***

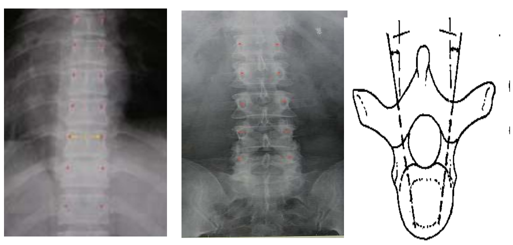
In order to meet the requirements of the normal spinal anatomy of the population, we started designing of the GDP with a study of more than 129 normal radiographs of normal population.

The thoracic and lumbar lateral distance between the pedicles, the normal curvature for the spine, and height of the vertebral body, as well as intervertebral spaces were determined (CR shooting, with zoom ratio of 1∶1). Keeping all the measurements as the reference the GDP was made which is more acceptable.

All the films were taken using UMAX Astra 1200S X-Ray and then scanned then saved to the computer. Pedicle distance, curvature of spine, thoracic and lumbar vertebral body and intervertebral heights were calculated using Sigma Scan Pro 5 software (SYSTAT Company) measurements.

***Vertebral pedicle distance measurement***

The width of lumbar vertebrae was increased from above to below due to minimal variation of “e” angles (“e” angle in thoraco lumbar area was 5°–10°; which was 10°–15° from lumbar spine $L_{2-5}$, Figure 1, Table 1).



a: Interpedicular distance　　b: “e” angle

Figure 1　Measurement of vertebral pedicle distance

Table 1 Bone mineral density in the lumbar spine in different age groups at 6 centers ($\bar{x}\pm s$, g/cm$^2$)

| Gender | Upper thoracic vertebrae | Upper thoracic vertebrae | Lumbar vertebrae |
|---|---|---|---|
| Male | 27.65±2.48 | 28.47±2.84 | 44.43±2.56 |
| Female | 32.7±2.13 | 25.82±2.58 | 41.84±2.68 |

***Spinal curvature measurement***

The spinal curvature of healthy people was measured, and the new implant was designed based on these data to maintain normal anatomy of the spinal column (Figure 2). DGP vertical plate was fixed to three vertebral bodies rather than the whole thoracic or lumber vertebral spine. According to calculations, the curvature of the thoracic spine was fixed down to (−6.32±0.87)° and the lumbar spine was fixed down to (12.26±1.74)°. Since the curvature of the spine was not uniform, the surgical plan should be made considering the mean average curvatures and the clinical situation.

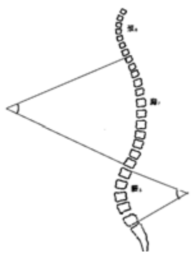
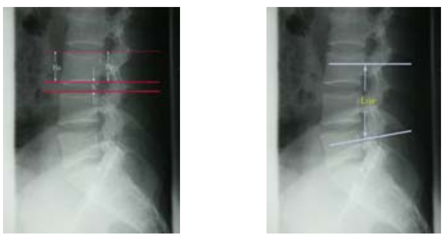


Figure 2 Spinal curvature measurement

***Meticulous measurements of vertebral body and intervertebral space*** (Figure 3)



a: Vertebral body and intervertebral space measurement b: Length of GDP

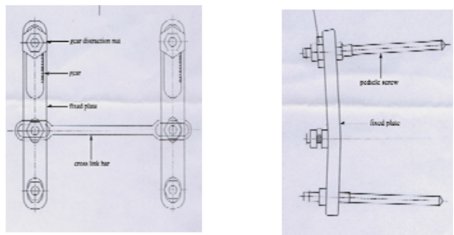
Figure 3 Measurements of a gear-distraction plate (GDP)

Based on the requirement and the meticulous studies, we designed the length of the vertical plate of GDP. Due to the short segment fixation strategy, a GDP vertical plate needs approximately equal to the length of two vertebrae together with two intervertebral space heights. This was attained by measuring the volunteers from X-rays since clinical measurement methods are not uniform and standard.

The results showed that the marginal height of the thoracic vertebrae of adults was (19.52±1.38) mm, lumbar posterior marginal height was (28.74±1.69) mm, intervertebral space in thoracic area was (6.23±0.53) mm, and in lumbar area was (9.68±0.83) mm. Thus, the design of the GDP vertical plate was concluded with vertical plate height of thoracic spine at (52.45±2.03) mm and in the lumbar spine was about (78.64±2.56) mm.

***GDP design***

GDP consists of fixed plate, pedicle screw, fixation nut, gear distraction nut, and horizontal connecting rod (Figure 4). ①Fixed plate: for the need of different segment of spine, the length of plate was designed 55−85 mm, the curvature was −6.5° to 20°, the thickness of the plate was 5 mm, and the width was 14 mm. ②Gear distraction nut: it is the key part for distraction, which gear coincided with the fixed plate with 6 mm hollow diameter, 1 mm wall thickness, and 1 mm gear height and width, respectively. ③Pedicle screw: diameter was 35−70 mm and the length was 20−55 mm. ④Cross link bar: the width was 4 mm, thickness was 2 mm and the length was 25−45 mm.



a: Anterior posterior position b: Lateral position

Figure 4 Design of a gear-distraction plate

***Biomechanical test***

Specimen preparation: Fresh calf lumbar was screened by X-ray to select normal specimens. The interception of specimens carefully removed after leaving the attachment of local muscles, ligaments and articular process of reserved segments, and then sealed in a −20 ℃ freezer and gradually thawed before testing.

Grouping: The samples were divided into GDP, CD control and Steffee plate fixation groups.

Lumbar spine compression-type fracture models were prepared with reference to Panjabi[1] methods. After the X-ray films showed spinal instability, the gear-type open reduction and internal GDP device was fixed[2]. The control and Steffee groups were also fixed in the same way (All the devices were produced by the Affiliated Hospital of Jiangsu University with same length).

Experimental test method: Experimental samples were allowed to thaw before 24 hours of the experiment. The experimental stress analysis was in accordance with the strict requirements of films. Wiring and temperature compensation techniques were done with a sound preparation.

Specimens were installed on the testing machine with a special fixture and the location of the stable center of gravity was identified, and force and displacement measurement sensors arranged in the corresponding position, and then imposed by pre-load to remove bone relaxation, creep and other time the effectiveness of impact, and formal testing (Figure 5). Four kinds of specimens in their physiological conditions, according to loading rate 1.4 mm/min were loaded, and the data were collected at each 30 seconds after loading, and the procedures were repeated until obtained satisfied accuracy.

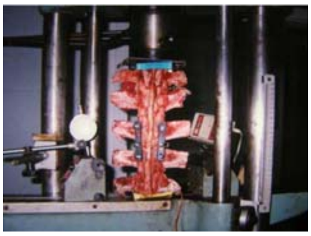


Figure 5 Fresh calf lumbar specimens fixed with a gear-distraction plate for biomechanical test

**Main outcome measures**

The changes of strain, displacement, strength, stress, torsion intensity and torsion angle under different physiological states.

**Statistical analysis**

Biomechanical study were carried out on the aspects of lumbar strain, displacement, stress, torque, torsion angle before mechanical quantity, such as data processing, which was estimated to be a satisfactory range of values and home spaces. Followed by linear regression, analysis of variance was done by the least square method. According to a survey of mathematical statistics to calculate the relevant parameters, *t*-tests, the accuracy of analysis and calculation was done using standard SPSS 10.0 statistical analysis software. A level of $P < 0.05$ was considered statistically significant.

## RESULTS

**Spinal load-strain changes**

Load-strain test showed a basically linear change of strain as the load increases, which reconversion after load removal. The contingency test showed that, compared with the control group, the GDP group could fixed equipment firmly and decreased spine deformation. The average strain force showed that the GDP group was 13% than the CD group and 22% less than the Steffee plate fixation group. Therefore, GDP showed superiority in fixation to other groups under the same load ($P < 0.05$). GDP was basically similar to the posterior spine as that of the pedicle under compression, flexion, extension and lateral flexion, which was coincided with the normal movement of the human body.

**Spine load-displacement relationship**

In all three circumstances, the fixation devices were fixed firmly and caused displacement was relatively little. The average displacement of the GDP group was 12% less than the CD group and 23% less than the Steffee plate group ($P < 0.05$). Under the similar load force, the horizontal displacement and compression factor of the GDP group was less than the CD and Steffee plate systems. The vertical compression displacement was about 4.2%, which was very less and can be negligible. The findings demonstrated that GDP fixation on the spine cause relatively less displacement and relatively strong load bearing capacity. This proves that it is indeed a good fixation for spinal fractures.

**Strength changes of vertebral body**

If the strength of vertebral body changed greater, it can lead to stress concentration in the spinal vertebrae, result in failure of the implant, recurrence of anterior column fracture, poor stability of the spine, as well as vertebral height loss, ultimately, lead to the failure of the procedure. The GDP had a smallest stress (average of 7.19 MPa) with a solid fixation. The CD group (8.22 MPa) and the Steffee plate group (9.25 MPa) were having 13% and 22% greater stress compared to GDP group. Therefore, GDP has a good level of overall strength and it is safe for spinal fixation.

**Spinal axial stiffness and rigidity**

The axial stiffness of the GDP group was greatest in three groups, which was 15% greater than the CD group. There was also a 23% difference between the GDP group and Steffee group ($P < 0.05$). GDP fixation devices showed strong resistance capacity in spinal axial deformation. The size of the axial stiffness of the spine was also reflected in the quality of spinal stability. GDP has certain advantages over other fixations.

**Spinal torsion property**

The torsion angle of GDP fixation was minimum under the same amount of torque, its torsion angle was 10% less than the CD group and 17% less than Steffee group ($P < 0.05$). Similarly, under the same torsion angle deformation, GDP fixation could achieve the greatest torsional strength of 3.06 N•m, but the CD group only could reach 2.66 N•m, the difference was 13%. The torsional strength of the Steffee plate group was only 2.23 N•m, which was 7% difference between the GDP group ($P < 0.05$).

**Ultimate mechanical properties**

The results showed that ultimate load of GDP group was 3 750 N, followed by the CD group was 3 050 N and the last Steffee group was 2 250 N (40% smaller than the GDP group). There were obviously differences among the three groups ($P < 0.05$). This showed that GDP can carry more capacity and has good stability.

## DISCUSSION

**Structural characteristics of GDP**

It resolves the distraction problems of plate structure. There was a rack on the sidewall in the plate hole, dentate distraction nut roll in the rack and drive the pedicle screw move, hence the GDP can distraction. According to the measurement of the height of vertebral body and intervertebral space, the length of rack was designed 3 cm, which is equal to the distraction distance. This ensures sufficient space distraction and would fully restore the height of compressed vertebrae. The radian of GDP made different angles between pedicle screw and plate called “screw plate angle”, it plays an important role in restoring the height of anterior and middle column. The structure of gear and “screw plate angle" not only compensate the lack of distraction of plate structure, but also decompose of the compression load of the head of pedicle screw, this is important to reduce bending and broken nails postoperatively[3].

**Biomechanical characteristics of GDP**

①The GDP has radian and this makes the stress transfer uniformity. The connection between the fixed plate and screws applies embedded structure which make the connection firmly and low profile, so that the fixed plate close to spinal column is conductive the power transmission. Experimental results show the load-strain and load-displacement was smaller than the control group but its axial or level rigidity higher than the control group ($P$ < 0.05). The fixed spine is hard to distortion under physiological loads; this will help bone fusion and maintain vertebral body height rather than stress concentration, plate and screw broken. ②GDP has plate structure, in theory, this structure has strong anti-torsion properties. The experimental results showed the performance of its torsion is better than the control group ($P$ < 0.05). ③The GDP consists of four pedicle screws, two fixed plates, a horizontal rod, dentate distraction nuts and lock nut. The plate has a certain degree of curvature and the curvature match the spine, so the surgeon use the curvature to restore the anterior column of the spine and then distraction to restore the height of vertebrae and intervertebrae space. The fixed plate tightly affixed to the back of the spine structure because of the match curvature and such fixation has strong power, good stability and also restoring the normal physiological curvature of spine. All these are benefit to fracture healing and maintain the balance of the body. ④This experiment does not involve biomechanical muscle and the coordination roleof living body[4]. However, the muscle system influence the fixation device load great[4], so there is still a great challenge to accurately simulate the mechanical situation of internal fixation in the physiological conditions. The principle of reduction for GDP and the current clinical application of screw-rod system are difference, it belongs to short segment fixation device and does not require bending and rolling rod. It fixes less segment and retained most of the function of spinal activities.

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# 齿轮撑开式脊柱复位固定板装置的研制*☆

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崔学文☆，1968 年生，博士，副主任医师，主要从事脊柱外科方面的研究。

**摘要**

**背景**：目前临床应用的脊柱后路复位固定的钉棒系统存在一定程度的生物力学的缺陷，钉板系统更适合在患者中广泛使用。

**目的**：依据中国人脊柱的椎弓根间距、弧度、椎体及椎间隙高度的影像学测量结果，研制一种新型的脊柱后路复位内固定板装置。

**方法**：测量 129 例门诊查体的正常者的胸腰椎数据。依据影像学测量的结果，并在复习文献的基础上，对新型脊柱复位内固定器进行图纸设计及形状设计。取 18 具新鲜小牛腰椎标本随机分为实验组给予行齿轮撑开式脊柱复位内固定板装置固定，CD 及 Steffee 组分别用 CD 及 Steffee 钢板固定，测量标本在受到轴向压缩、前屈、后伸及侧屈载荷状态下的位移、应变、刚度和破坏性能等测试，结果进行统计学处理。

**结果与结论**：齿轮撑开式脊柱复位内固定装置(GDP)能较好地满足人体强、刚度的要求。GDP 组测得椎体固定的强度和刚度均比对照组 CD 和 Steffee 钢板系统优越($P$ < 0.05)，腰椎的扭转力学性能比 CD，Steffee 钢板内固定分别高出 13%和 14%，腰椎的极限力学性能测试结果显示 GDP 能承载载荷，比 CD,Steffee 钢板更大($P$ < 0.05)。说明齿轮撑开式脊柱复位固定板装置的设计符合中国人脊柱的解剖规格，生物力学稳定性良好，可以显著促进椎骨骨折的愈合，防止脊椎后凸的复发和高度的丧失。

**关键词**：齿轮撑开式脊柱复位固定板；后路；复位；内固定；生物力学；医学植入物
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