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行政院國家科學委員會補助專題研究計畫成果報告

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※　夾具設計對脊椎內固定器之生物力學測試的影響　※

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計畫主持人：陳博光

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計畫參與人員：

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Abstract: This study discusses the suitability of these four jig assemblies for flexion stability testing of the short- and long-segmental spinal implants. This study might provide insight what jig-related factors are associated with physiologically reliable outcomes of the flexion stability test for the lumbar implants.

Keywords: spinal implant, jig design

Introduction

At present, spinal stabilization using spinal implants has been a widely used technique to treat with various kinds of spinal diseases. For the implant designers and the clinicians, the new implants after designed and manufactured as the prototypes are often evaluated biomechanically, either in isolation or in conjunction with artificial or cadaveric components. Biomechanical evaluation of spinal implants can generally be divided into three types: stiffness, fatigue, and stability tests. Among these tests, the stability of the spinal construct is clinically important as the results indicate information about the implant's performance *in vivo* in stabilizing the spine. However, the stability test in contrast to the other two tests has not yet had the standard experimental protocols because of the sensitivity of its results to many factors, such as specimen type, loading/boundary conditions, and testing procedure etc [1].

Compared with stiffness and fatigue tests, the stability test is structurally nondestructive, and the loading types and magnitudes applied on the spinal construct are in physiologic range for revelation of the clinical performance. For the daily activities, besides the compression and twisting loading types, flexion and extension are the most common motion types for the lumbar spine. When performing the stability tests for the lumbar implants, therefore, the flexion test is the inevitably used one.

For the general material-testing machine used in the spinal stability tests, load or motion control in the axial compressive and twisting tests can be directly achieved by the jigs attached to the platform and actuator of the testing machine. However, because of a common material-testing machine can not apply pure bending moment, the flexion moment on the spinal construct will be simulated by applying axial compression eccentrically or shear force laterally. These must be done with the structurally more complex jig assemblies than those used in the compressive or twining stability tests.

A variety of jig assemblies have been used to investigate the flexion/extension behaviors of spine-fixator complex [2-15]. Little consensus has been drawn for jig-related influences on the performance of different fixators [1,16,17,18]. Because of different jigs used, quantitative comparisons between studies are difficult. It is now recognized that a more biomechanically suitable jig assembly must produce a physiologically reasonable loading condition on the spinal construct and thus facilitate the evaluation of spinal fixators.

The purposes of this technical study are divided into two parts. **1)** Based on the column theory of elasticity, the spinal construct is considered as a homogeneous and isotropic straight Euler column. Then the distribution mode of the bending moment and lateral deflection of the spinal construct between four types of jig assembly in Figure 2 are compared. **2)** Correlating the results predicted by this study with the spinal biomechanics, this study would discuss the suitability of these four jig assemblies for flexion stability testing of the short- and long-segmental spinal implants. This study might provide insight what jig-related factors are associated with physiologically reliable outcomes of the flexion stability test for the lumbar implants.

Materials and Methods

Although the majority of the deformation of the instrumented lumbar is concentrated on the unfused discs and the implant is stiffer than the lordotic spine, this study assumes the spinal construct to be a homogeneous and isotropic straight Euler column that the load-deflection behavior is linearly elastic. This assumption on the spinal construct would be discussed later. In a general case, there are two ways to flex the spinal construct: **1)** exerting a lateral shear force or **2)** applying a bending moment on the upper end of the spinal construct as shown in Figure 1.

Four basic jig assemblies can achieve these two types of applying flexion moment on the spinal construct. These jig assemblies are schematically shown in Figure 2.

As shown in Figure 2 (A), the jig assembly, Type I, can apply a horizontal lateral force on the upper end of the spinal construct without axial compression. Therefore, the spinal construct can be simulated as a cantilever column with lower end fixed and subjected to a lateral concentrated load (P_1) at the upper free end as shown in Figure 2 (E). For mechanical analysis, the lower end of the spinal construct is defined as the origin of the x-y coordinate system for all four constructs. The x-y plane is the coronal plane of the spinal column and the orientation of the x and y-axes is shown in Figure 2 (E). Two guide plates of Type II jig assembly will constrain the motion of the upper end of the spinal construct only in the x direction. The bending rod will flex the spinal construct with a moment arm (eccentricity) when the actuator of the testing machine moves downward. Type II spinal construct will be simulated as a column with the lower end fixed and the upper end constrained in the x direction as shown in Figure 2 (F). The bending rod will apply a bending moment (M_2) and a compressive force (C_2) on the upper end of the spinal column. Type III jig assembly allows the upper end of the spinal construct free move in the x-y plane and the bending rod will also compress and flex the spinal construct while testing. The spinal construct will be simulated as a column with lower end fixed and upper end free in the x-y plane. As the actuator moves downward, the bending rod will apply a flexion moment (M_3) and a compressive force (C_3) on the upper end of this spinal construct. For Type IV jig assembly, the two springs with equal stiffness on the opposite side of the bending rod will produce a couple while actuator moving downward. Thus, the bending rod applies a net bending moment (M_4) with no axial compression on the upper end of the spinal column as shown in Figure 2 (H).

From the classical elasticity, the distribution functions of the bending moment and lateral deflection along the x direction for the four jig assemblies are as follows:

Bending Moment

Type I : $M_1(x)=P_1(L-x)$

Type II : $M_2(x)=C_2\ e[Tan(k_2\ L/2)Sin(k_2\ x)+Cos(k_2 x)]$

Type III : $M_3(x)=C_3\,e[Sec(k_3 L)Cos(k_3 x)]$

Type IV : $M_4(x)= M_4$

Lateral Deflection

Type I : $v_1(x)=k_1^2\,x^2\,(3L-x)/6$

Type II : $v_2(x)=e\ [Tan(k_2\ L\ /2)Sin(k_2\ x)+Cos(k_2 x)-1]$

Type III : $v_3(x)=e\,[Sec(k_3 L)][1-Cos(k_3 x)]$

Type IV : $v_4(x)=M_4 x^2/(2EI)$

where $M_i\ (x)\ (i=1,2,3,4)$ is the bending moment on the i^{th} spinal construct at a distance x from the base of the spinal construct. $v_i(x)$ is the lateral deflection of the i^{th} spinal construct in the y direction. The notation k_i is defined as $(P_1/EI)^{0.5}$ for Type I and $(C_i/EI)^{0.5}$ for Type II and III jig assembly. The eccentricity e is the horizontal distance from the centroid of the cross section of the spinal construct to the line of action of the axial compression as shown in Figure 2 (C). E, I, and L are the *Young's* modulus, moment of inertia, and the length of the spinal construct.

The axial compression on the spinal construct in Type Ⅱ or Ⅲ jig assembly is applies in the range much less than the critical buckling compression P_{cr} $(=\pi^2 EI/L^2)$. If the material constant (E) and the geometric parameters (L, I, and e) known, the distribution functions of bending moment (M_i) and lateral deflection (v_i) can be calculated.

was Mathematica, Ed. 3 (Wolfram Research, Champaign, IL). The short- and long-segmental fixation is assumed applied on 0.3- and 0.6-mm construct, respectively. The value of EI is determined as the 5-cm diameter of the spinal column and 0.5-Mpa of effective *Young's* modulus. Following values are assumed for these parameters in this study: L = 0.3 and 0.6 m, $EI \approx 0.5$ N-m^2, and e = 0.1m.

In order to produce the identical flexion moment on the tested implants, this study further postulates the flexion moment on the spinal fixator, instrumented at the middle level of the spinal construct, is the same in each construct. Under such assumptions, the flexion moment distribution and lateral deflection functions along the length of the four spinal constructs can be computed from the aforementioned equations. In this study the assessments between the four jig assemblies were identified with four indices: 1) lateral deflection of the spinal construct, 2) loading condition on the spinal construct, and 3) implant failures at the bone-screw interfaces.

Results

Figures 3 (A) and (B) are the lateral deflection of the spinal construct for the short-and long-segmental instrumentation, respectively. The lateral deflection of the spinal construct at the upper end is the largest for Type I and the smallest (= 0) for Type Ⅱ in both short- and long-segmental cases. In both fixation cases, the constrained motion in the x direction for upper end of Type Ⅱ construct is not physiologically reasonable for natural spinal motion. For short-segmental case, Types Ⅲ and Ⅳ have the approximately equal lateral deflection at upper end. However, in the long-segmental case, the lateral deflection of Type Ⅲ at upper end is close to that of Type I.

Figures 3 (C) and (D) are the bending moment distribution along the spinal construct for the short-and long-segmental instrumentation, respectively. In both fixation cases, Type I has the linearly increasing bending moment distribution from cephalic to caudal end, and Type Ⅳ has the uniform bending moment distribution along the spinal construct. The maximal bending moment of Type Ⅱ and Type Ⅲ occurs respectively at the middle and the upper end. If the flexion moment at the center of spine construct is assumed the same, below the spinal middle, the bending moment of Type I is greater than the others. However, above the spinal middle, the result is reverse.

As described above, implant failure, especially for pedicle, can be divided into two types: loosening and breakage. The loosening of the pedicle screw from the vertebral body is related to the deflection-gradient of the spinal construct. From Figures 2.15 (A) and (B), Type I jig assembly results in the steeper deflection-gradient of the flexed spine than the others in both fixation cases. For short-segmental case, Types Ⅲ and Ⅳ have the approximately equal deflection-gradient. The deflection-gradient of Type Ⅱ at the spinal middle is zero in two cases.

From Figures 2.15 (C) and (D),

However, above the spinal middle, the result is reverse. Types Ⅱ and Ⅳ produce the equal bending moment on the caudal and cephalic screw pairs. Type Ⅲ predicts the higher failure possibility of caudal screw pair that cephalic due to greater bending moment at caudal portion.

Discussion

For revelation of clinical performance of spinal fixator, the loading condition of stability test on the spinal construct is set in the physiological range. The stability test using cadaveric or animal model can be further divided into two types: short- and long-term test. The short-period temporal responses (*i.e.*, viscoelastic behaviors) of the spinal construct under physiological loading range are identified with stiffness of spinal construct, fixed and justa-fixed disc deformation, and stress-shielding effect of spinal fixator *etc*. Nevertheless, the failure characteristics of the spine-fixator complex are also of clinical and design importance and can be investigated in long-term stability tests. Because of the much less strength of bone than fixator and the stability loss of the spinal construct due to muscles dissection, the failure sites of the long-term stability test usually occur at the bone-fixator interface rather than at the fixator itself, as in the stiffness and fatigue tests using UHMWPE model. Therefore, as compared with stiffness and fatigue tests, the purposes of stability test are to find the temporal or failure behaviors of the spine-fixator complex but not the structural or mechanical defects of fixator (i.e., strength or fracture mechanism). Hence, the suitability of four jig assemblies for the stability test of short- and long-segmental fixation is discussed in terms of the short- and long-term response of the spine-fixator complex.

In the short-segmental case, the deflection-gradient of Types I, Ⅲ, and Ⅳ were nearly the same as shown Figure 3 (A). However, in the long-segmental case, the deflection-gradient of Type I and Ⅲ were greater than the other two as shown Figure 3 (A). In Figures 3 (A) and (B), fixing both ends of spinal construct in the *x-y* plane, Type Ⅱ jig makes symmetric deflection and the greatest lateral deflection occurs at the center of the specimen. However, this deflection pattern is inconsistent with the physiological condition that the cephalic end has the greater deflection. For both fixation cases, the probability of both cephalad and caudal screw loosening may be equal.
During testing, if the cephalic portion of spinal construct deforms larger than the physiological condition, the cephalic screws will be prone to be withdrawn from the bone (Figure 4). Hence, in terms of lateral deflection, Type I, Ⅲ, and Ⅳ jig assemblies were all suitable to use in the short-segmental test. However, the larger deflection-gradient of Type I and Ⅲ will make the loosening at the screw-bone interfaces easier, especially at long-term test with higher cyclic loading rate. That is, with reasonable lateral deformation at cephalic end as shown in Figure 3 (A), Type Ⅳ jig seems to be more suitable for long-segmental testing than the other three types.

During testing, the majority of deflection may concentrate on the unfixed discs due to rigidity-raising effect of fixator on the instrumented level. Then the measured deformation of entire construct or instrumented level may be influenced by the rigidity-raising effect. Such raising rigidity will decrease over a long testing period because of the loosening at the screw-bone interfaces, especially in the long-segmental cases with Type Ⅲ or I jig. In this study, however, the relationship between the excessive deflection by jig-factor and the concentration deformation of the justa-fixed discs is unknown. Therefore, such a relationship can be well investigated in the future works to understand the effect of jig-factor on the raising rigidity due to the fixator. In terms of the deflection, rigidity-raising effect, and loosening, hence, Type Ⅳ jig is more suitable in the long-segmental case.

From the biomechanical viewpoints, while performing a flexion motion, both caudally increasing bending moment and vertical compression exist along spinal column, resulting from a progressively cephalad-caudal increase in bodyweight. Therefore, the more suitable jig should simultaneously produce a set of both caudally increasing compression and flexion moment on the spinal construct. From Figures 3 (C) and (D), Type IV jig assembly produces the uniform moment distribution along the construct length. In both fixation cases, Type I has the linearly increasing bending moment distribution from cephalic to caudal end. Both Type I and IV jigs produce no net axial compression on the spinal construct.

While performing a flexion motion with Type I jig assembly, a posteroanterior shear force (P) applies on the spinal column. Such a lateral shear is non-physiologically reasonable and makes the cephalic screw pair prone to be withdrawn from the bone as illustrated in Figure 5 (C). The schematic illustration for effects of steeper deflection-gradient on the flexed spinal construct is shown in Figure 2.16. Within the instrumented region, loosening of the upper screw will easily occur for the long-term testing if the upper end of the spinal construct flexes more. Moreover, too larger lateral deflection may make the measurement of disc deformation with extensometers more difficult. Also, from Figure 5 (B), the axial compression C transmitted from the upper vertebra to the cephalic screw pair increases the bonding strength at screw-bone interfaces and thus hinders the withdrawal of screw from bone. From such an inference, in the short-segmental case, the risk sequence of the cephalic screw pair to be withdrawn from the bone is Type I, Type IV, and Type II (or III). However, as described above, the lateral deflection rather than the axial compression C is the determinant in the loosening of pedicle screw from the vertebral pedicle.

The breakage of the pedicle screw is related to the load on instrumented region. Type IV produces the uniform bending moment along the spinal construct. Thus the cephalic and caudal screws theoretically have the equal failure risk. This is the viewpoint of White III et al. [1] to load a complex construct uniformly so that failure will occur at the weakest point rather than at some point where there is excessive load due to the method of load application. This is also the situation for Type II for its symmetric loading condition as shown in Figures 5 (C) and (D). The caudal screws are predicted with higher potential for failure than the cephalic ones in Type I in response to the greater bending moment at the caudal portion. However, the direct sharing in the axial compression C by Type III, the cephalic screws with less bending moment are almost at the same failure risk with the caudal ones as shown in Figure 5 (B). Among four jigs, Type I has the highest and least failure potential at the caudal and cephalic portion in comparison with the others.

In conclusion, this study appraises the boundary and loading conditions, enforcing by four possible jigs, on the spinal construct while performing the biomechanical flexion test of spinal construct. The physiologically unreasonable deflection at the upper portion of the spinal construct makes the screw likely to be withdrawn and thus loose the integration at the bone-screw interface, especially for the long-term test. This is the major defect for the Type I jig in short-and long-segmental fixation. With the caudally increasing flexion moment and reasonable deflection, Type III jig is suitable for the shore-segmental fixation. Type IV jig seems to be more appropriate for the long-segmentation case with reasonable deflection.

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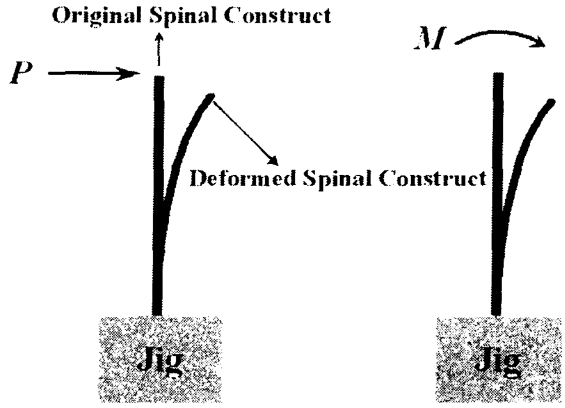


Figure 1: Two ways to flex the spinal construct. P is the anteroposterior shear force, and M is the flexion moment.

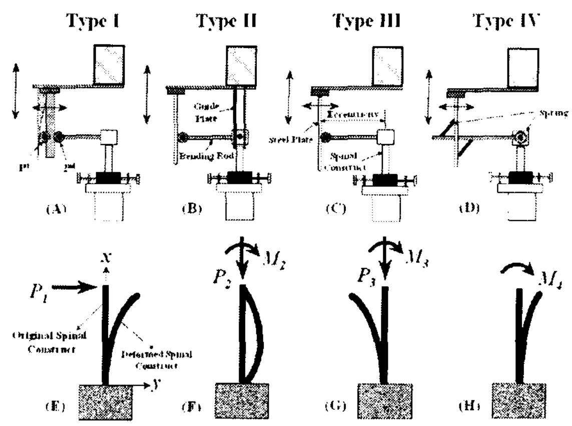
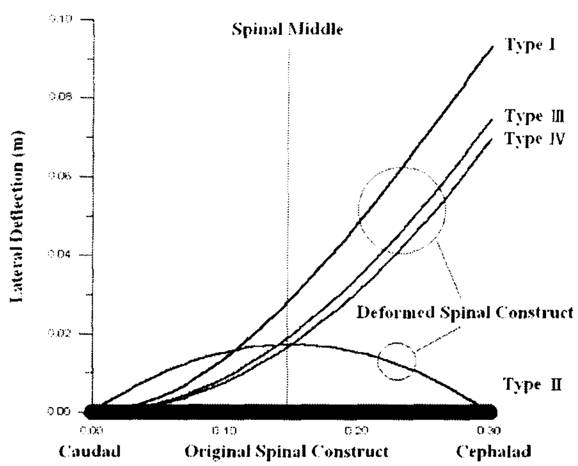
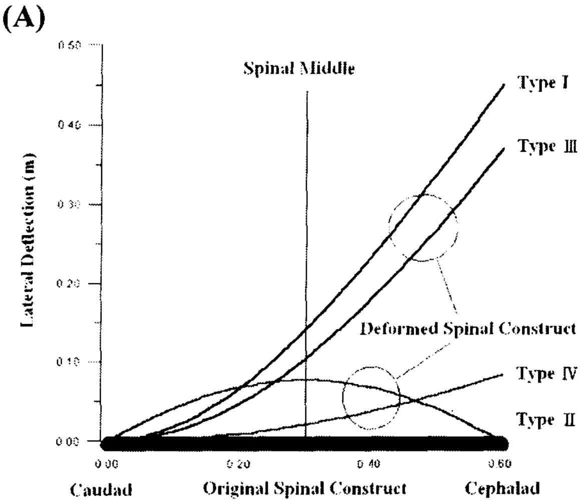


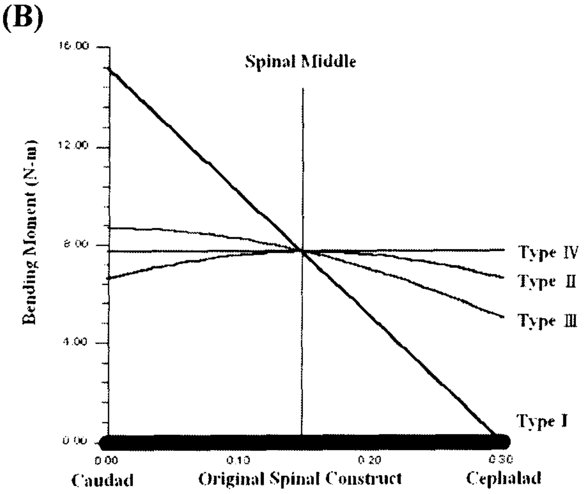
Figure 2: Four jig assemblies for producing flexion moment on the spinal construct in biomechanical testing of the spinal implants. The curve-edged steel plate in Type I jig can push the 1st roller slide to right. The symbol ↔ means the rectangular steel plate can move horizontally with the push of the 1st roller and eliminate nonhorizontal force transmitted from the 1st roller. Therefore, the 2nd roller can be pushed to exert an anteroposterior shear force to the upper end of the spinal construct.



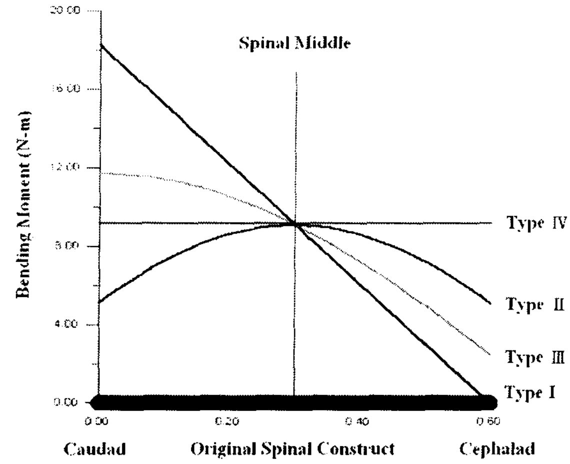
(A)



(B)



(C)



(D)

Figure 3: The lateral deflection and the flexion moment along the length of the spinal construct. The length of the spinal specimen is 0.3 m for (A) & (B) and 0.6 m for (C) & (D). The flexion moment at the center of the spinal construct is assumed the same for four jigs.

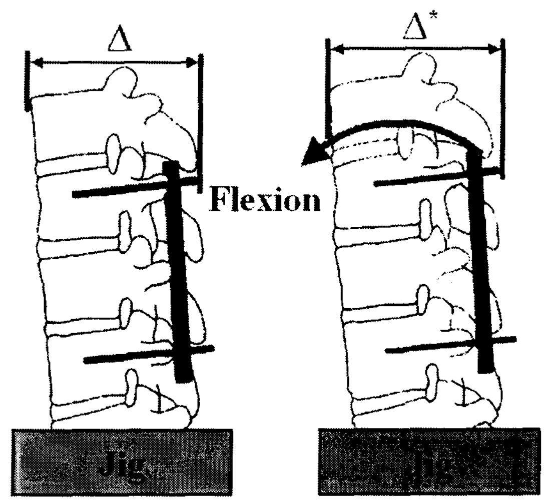


Figure 4: The schematic diagram for illustrating the effects of deflection-gradient on the flexed spinal construct. The upper end of the right spinal construct flexes more than that of the left one. Loosening of the upper screw will easily occur for the long-period testing if the upper end of the spinal construct flexes more (*i.e.*, $\Delta^* > \Delta$). Consequently, the rigidity loss at bone-implant interface will be prone to reduce the measured stability of the spinal construct after long-term cycles.

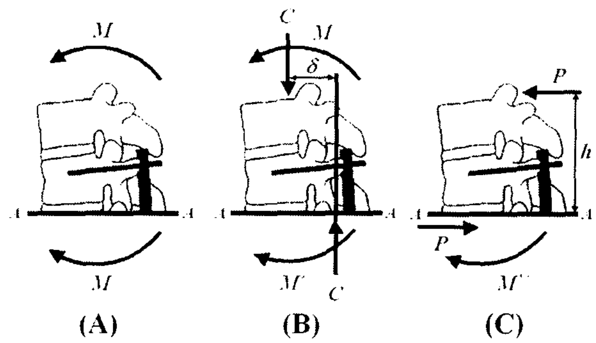


Figure 2-5: The free body diagrams for upper spinal construct sectioned at *A-A* plane and subjected to 3 boundary loads. Diagram (A), (B), and (C) is for the case of Type IV, II (or III), and I jig, respectively.