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The Effects of Cord Pretension and Spacer Length in Dynamic Neutralization Stabilization System (Dynesys): *In Vitro* Experiment

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Abstract:-

Purpose

The purposes of this in vitro study are that to investigate if the cord pretension and spacer in posterior dynamic stabilization affects the flexibility in sheep lumbar spine.

Methods

Eight sheep lumbar spine in the intact state, Dynesys with neutral spacer and 300N cord pretension, Dynesys with neutral spacer and no cord pretension, Dynesys with 300N without spacer, and rigid rod fixation were evaluated. The range of motion (ROM) and neutral zone (NZ) of flexion-extension, lateral bending and axial rotation were measured calculated to evaluate the flexibility of sheep lumbar spine.

Results

There were significant decrease the ROM and NZ in flexion -extension, in lateral bending (ROM, $p<0.001$; NZ, $p<0.001$) after implantation of Dynesys or rigid fixator. On comparing the effect of the cord pretension, the ROM and NZ in flexion-extension was significant difference between the instrumentation of Dynesys with 300N pretension and Dynesys without pretension was found (ROM, $p=0.013$; NZ, $p=0.037$). On comparing the effect of the spacer, there was no significant difference in ROM and NZ between the instrumentation of Dynesys with spacer and Dynesys without spacer in all principal motion direction. Dynesys assembly without spacer showed more stiffness than rigid fixator.

Conclusions

On the basis of this *in vitro* study, the kinematic behavior of Dynesys is similar to the rigid rod fixation. The flexibility of Dynesys was reduced when assembly with 300 N cord pretension. The cord pretension and spacer plays important role in flexibility of Dynesys.

***Keywords**:- Dynamic Neutralization Stabilization System, In Vitro, Sheep, Lumbar Vertebrae*

I. INTRODUCTION

Dynamic neutralization stabilization system (Dynesys) is designed to preserve intersegmental kinematics, to reduce loading of the facet joints and to avoid adjacent segment degeneration[1-3]. Although Dynesys system provides clinical improvement in patient with degenerative lumbar disc disease with or without instability [4-7], it showed similar results as compared to the lumbar fusion surgery *in vitro* or *in vivo* study [8-11]. Less protective effect of Dynesys on the adjacent segment owing to the rigidity of Dynesys have been documented also [9, 11-14]. The effect of cord pretension and spacer length in flexibility of Dynesys has been reported in finite element analysis[15-18]. However, the relationship between the magnitude of cord pretension and the flexibility of Dynesys remains unclear.

The purposes of this *in vitro* study are that to investigate if the cord pretension and spacer in posterior dynamic stabilization affects the flexibility in sheep lumbar spine.

II. MATERIAL AND METHODS

A. Specimen Preparation

For this in-vitro trial, eight motion segments of L4/5 from sheep lumbar spines were studied. Following preparation, the specimens were stored at -30°C. Before testing, the specimens were thawed at room temperature for 24 hours. Muscle tissue was removed away from the specimens, but all the stabilizing ligamentous structures and joints capsules of each specimen were persevered carefully. In order to fix the specimens firmly in the testing apparatus, the upper vertebrae of L4 and lower vertebrae of L5 were fixed with three stainless-steel screws and embedded with custom-designed metal fixtures using a two-component polyurethane casting resin. During the testing period, the specimens were wrapped in a saline soaked cloth to prevent parched (Figure 1).

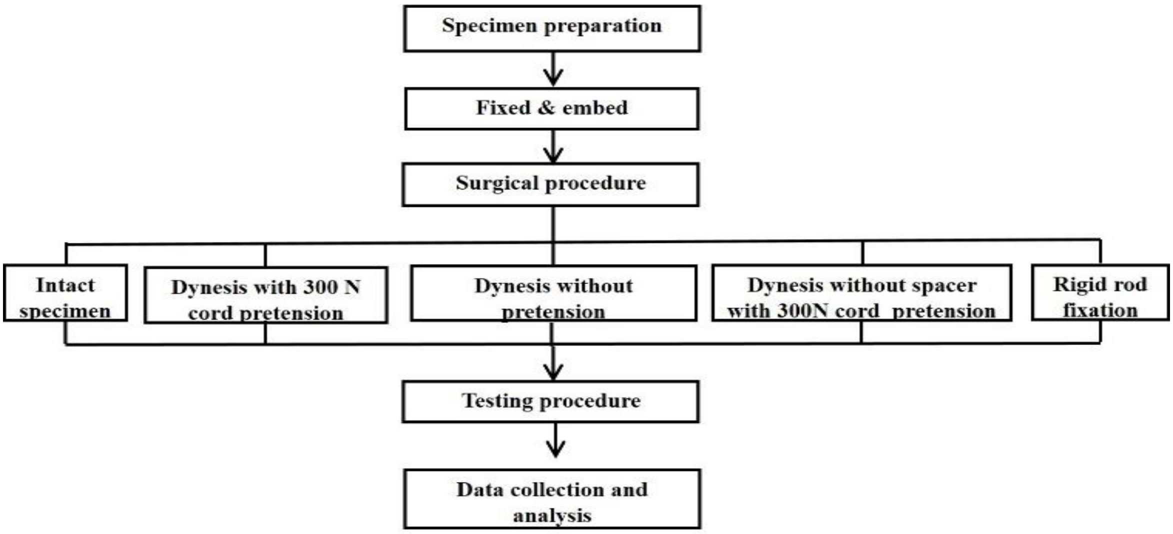

Fig 1: Illustration the flow chart of the *in vitro* study.

B. *Surgical procedures*

All procedures were performed by a single experienced spinal surgeon. First, the intact specimens were tested (Figure 2A, Figure 3A). Secondary, bilateral transpedicular screws were implanted in the motion segment of L4 and L5. After screw implanted, the spacer and cord was assembled with different cord pretension and length of spacer. The spacer and cord was set up following the standard procedure. The cord and spacer were assembled with neutral length of spacer and with 300N cord pretension (Figure 2B, Figure 3B).

Third, the cord and spacer were assembled with neutral of spacer and without the cord pretension (Figure 2C, Figure 3C). Fourth, the cords were assembled with 300N cord pretension without spacer (Figure 2D, Figure 3D). Finally, the rigid rod fixation replaces the Dynesys and the tests were subsequently repeated (Figure 2E, Figure 3E).

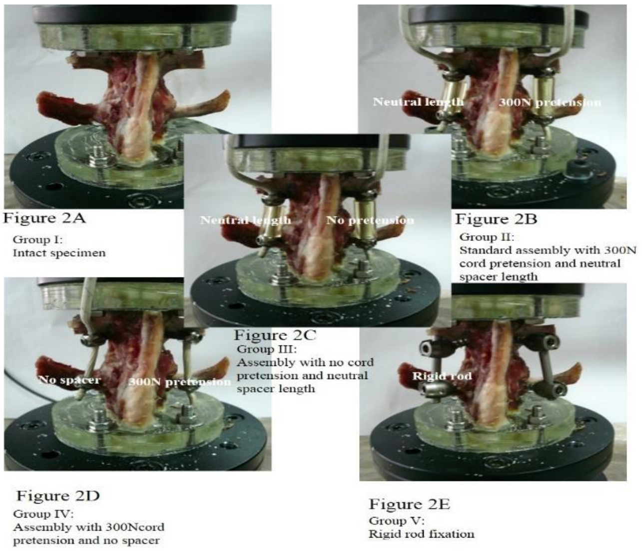

Fig 2: Demonstration of different surgical procedure including the intact specimens (Figure 2A), Dynesys with neutral length spacer and 300N cord pretension (Figure 2B), Dynesys with neutral length spacer and no cord pretension (Figure 2C), and Dynesys with 300N without spacer (Figure 2D), and rigid rod fixation (Figure 2E).

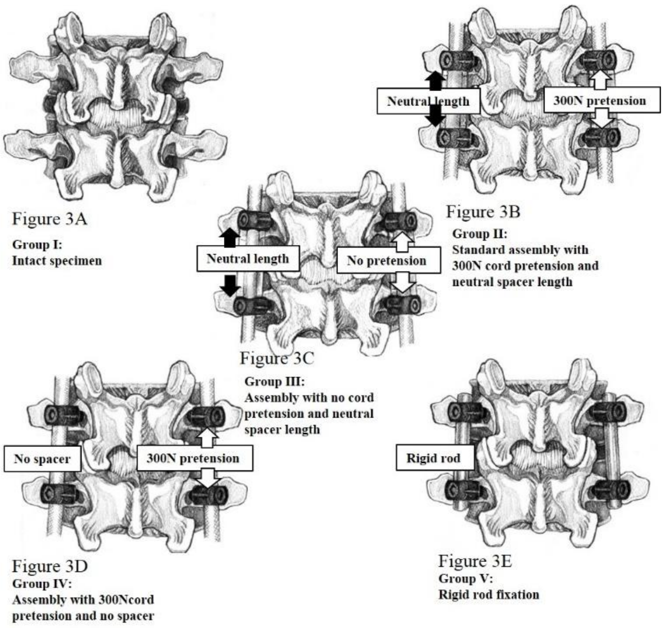

Fig 3: This figure simulate the different Dynesys assembly such as the intact specimens (Figure 3A), Dynesys with neutral length spacer and 300N cord pretension (Figure 3B), Dynesys with neutral length spacer and no cord pretension (Figure 3C), Dynesys with 300N without spacer (Figure 3D), and rigid rod fixation (Figure 3E).

C. *Testing procedures*

Each specimen in the intact state, Dynesys with neutral spacer and 300N cord pretension, Dynesys with neutral spacer and no cord pretension, Dynesys with 300N without spacer, and rigid rod fixation were evaluated in sequence. The lower vertebrae were centered over the load cell and maintained in neutral position [19]. After the specimen was mounted on the spinal tester (Figure 3), left-right lateral bending, flexion-extension and left-right axial rotation of the specimen were conducted at a constant speed of 1°/sec in sequence before and after different surgical procedures. Three loading cycles in all principal motion direction were applied. The first cycle was used for precondition and last two cycles was used for data collection and analysis. A compressive preload of 50 N was applied. The direction was reversed until the moment detected by the load cell applied 4Nm in all specimens. The load cell provided a feedback signal to the computer through RS-232 interface with 40 Hz sampling rate. The load and displacement data were collected and recorded during testing. A real-time graphical display of servo motor angle and applied moment was available during the test. See reference[12] for details

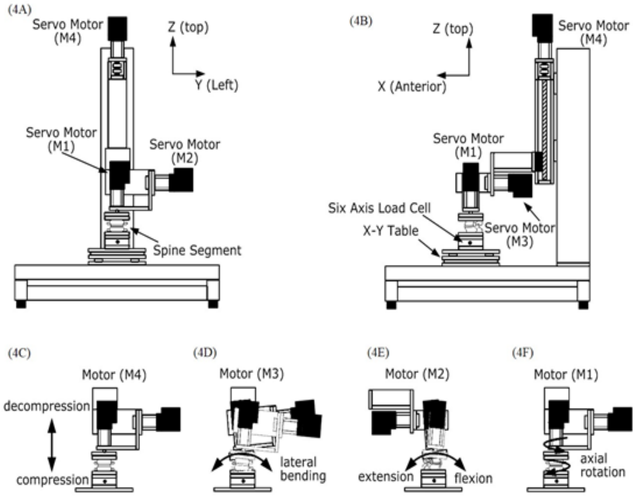

Fig 4: The figure illustrated the appearance of the spinal tester (4A, 4B). A compressive preload of 50 N was applied (4C). The three principal motion were conducted at a constant speed of 1°/sec in sequence (4D, 4E, 4F)

D. *Data Analysis*

The range of motion (ROM) and neutral zone (NZ) of flexion-extension, lateral bending and axial rotation were measured calculated to evaluate the flexibility of sheep lumbar spine in different surgical conditions. The range of motion (ROM) is the total range of deformation between maximal (+4 Nm) and minimal loading (-4 Nm). Neutral zone (NZ) defined as the displacement at the zeroload or minimal load measured from the neutral position [20, 21].

E. *Statistics Analysis*

Comparisons of the range of motion (ROM), and neutral zone (NZ) in different surgical conditions were made by using ANOVA. All statistical results were established significant if p< 0.05. The analysis was performed with the SPSS 17.0 package software.

III. RESULTS

Range of motion (ROM) and neutral zone (NZ) in all principal motion directions under different surgical procedures has been showed in Table 1 and Figure 5.

Table1: Range of motion (ROM) and neutral zone (NZ) in all principal motion axis under different surgical procedures

	Flexion-Extension		**Lateral bending**		**Axial Rotation**	
	ROM(°)	**NZ(°)**	**ROM(°)**	**NZ(°)**	**ROM(°)**	**NZ(°)**
Intact specimen	**15.29±0.97**	**0.73±0.39**	**18.83±2.03**	**0.7±0.20**	**3.07±0.35**	**0.19±0.04**
Dynesys with pretension	**7.72±0.71**	**0.49±0.27**	**4.73±1.58**	**0.42±0.20**	**3.19±0.40**	**0.37±0.18**
Dynesys without pretension	**5.59±1.17**	**0.36±0.11**	**3.88±1.07**	**0.34±0.14**	**2.56±0.35**	**0.29±0.06**
Dynesys without spacer	**4.45±1.62**	**0.54±0.16**	**4.49±1.95**	**0.52±0.23**	**2.60±0.61**	**0.37±0.20**
Rigid rod fixation	**6.92±0.89**	**0.68±0.39**	**4.29±1.76**	**0.39±0.16**	**3.19±0.48**	**0.49±0.23**

- *Implantation of Dynesys led to a reduction in segmental ROM, the kinematics behavior is similar to rigid fixator.*

After standard assembly of Dynesys (Dynesys with neutral length spacer and 300 N cord pretension), the segmental range of motion (ROM) and neutral zone (NZ) in intact specimen was observed to be 15.29±0.97° and 0.73±0.39° in flexion–extension, 18.83±2.03° and 0.7±0.20° in lateral bending, 3.07±0.35° and 0.19±0.04° in axial rotation, respectively. There were significant decrease the ROM and NZ in flexion -extension, in lateral bending was observed (ROM, $p<0.001$; NZ, $p<0.001$) compare to intact specimen and there was no significant difference in the ROM and NZ compared to rigid fixator. Therefore, implantation of Dynesys led to a reduction in segmental ROM, the kinematics behavior is similar to rigid fixator.

- *Dynesys assembly with 300N cord pretension and neutral length spacer demonstrated more stiffness than Dynesys without cord pretension*

On comparing the effect of the tension of cord, the ROM and NZ in flexion-extension was significant difference between the instrumentation of Dynesys with 300N pretension and Dynesys without pretension was found (ROM, $p=0.013$; NZ, $p=0.037$). There was no significant differences were found in lateral bending (ROM, $p=0.909$; NZ, $p=0.955$) and axial rotation (ROM, $p=0.106$; NZ, $p=0.920$). The ROM and NZ in flexion-extension were significantly reduced when increased the pretension of cord.

- *Dynesys assembly without spacer and with 300N pretension demonstrated more stiffness not only than intact specimen but also than rigid fixator.*

On comparing the effect of the spacer, although there was no significant difference in ROM and NZ between the instrumentation of Dynesys with spacer and Dynesys without spacer in all principal motion direction (ROM in flexion-extension, $p=0.422$; in lateral bending, $p=0.975$; in axial rotation, $p=1.000$ and NZ in flexion-extension, $p=0.953$; in lateral bending, $p=0.951$; in axial rotation, $p=0.790$), but there was significant difference in ROM compared between the instrumentation of Dynesys without spacer and intact specimen, rigid fixator. Therefore, Dynesys assembly without spacer and with 300N pretension demonstrated more stiffness not only than intact specimen but also than rigid fixator.

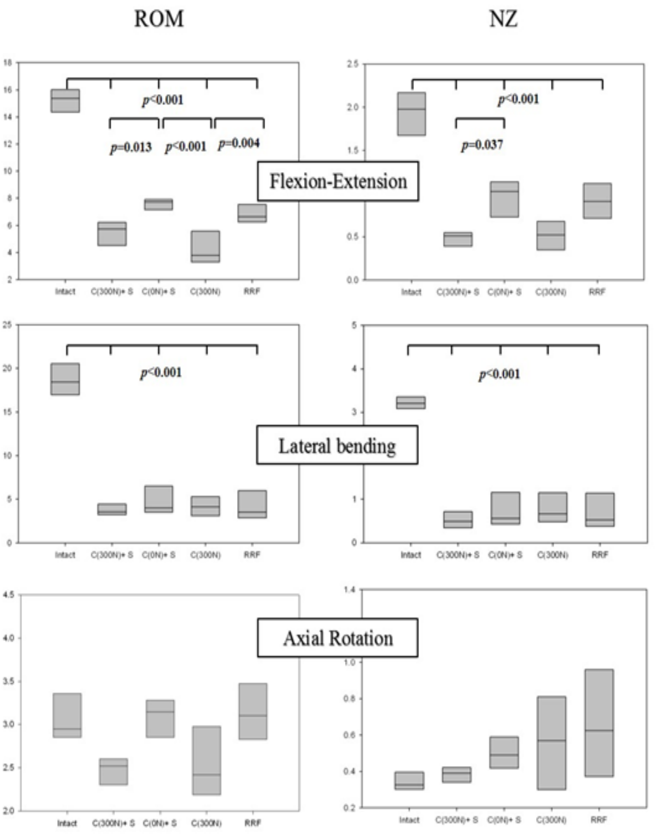

Fig 5: Range of motion (ROM) and neutral zone (NZ) in all principal motion directions under different surgical procedures.

IV. DISCUSSIONS

- *Dynesys with the similar kinematics behavior to the rigid fixator*

A restriction of segmental range of motion after implantation of Dynesys was investigated comparing with the intact specimen [22-26]. Gedet et al [22] demonstrated Dynesys offers a substantial stabilization of lumbar spine due to significantly reduce the segmental range of motion. Schulte et al [23]demonstrated implantation of the devices leads to a restriction of ROM in all motion planes. In our study, the range of motion (ROM) and neutral zone (NZ) of flexion-extension and lateral bending were significantly reduced following both different instrumentation with dynamic stabilization implants comparing to the intact specimen, which is consistent with the results of these literatures [22-26]. Furthermore, the intersemental motion was reduced after implantation of Dynesys with similar rigid fixator kinematics behavior. Our results demonstrated the range of motion (ROM) and neutral zone (NZ) in all principal motions directions were not significantly differences following both different instrumentation with dynamic stabilization implants comparing to the rigid rod fixator, which is consistent with the results of these literatures [27-30].

- *The Dynesys cord pretension*

Although some authors try to clarify the relationship between the magnitude of cord pretension and the stiffness of the Dynesys system using finite element analysis[15-17], the relationship between the magnitude of cord pretension and the flexibility of Dynesys remains unclear. To sum up, alteration of cord pretension affects the range of motion, facet contact force, annulus stress within the construct[15], screw-spacer force and bone-screw stress[17]. Dynesys assembly with a 300 N cord pretension causes a much higher stiffness at the implanted level .We try to investigate how the cord pretension affects the flexibility of Dynesys. As we known, the cords of Dynesys stabilize the spine by a tensile preload that provides uniform system rigidity ; and act against tensile forces as well as flexion moments [29].In this study, the ROM and NZ in flexion-extension was significant difference between the instrumentation of Dynesys with 300N pretension and Dynesys without pretension was found. On the basis of results, alternation of cord pretension affects the flexibility of Dynesys and higher cord pretension with higher stiffness at the implanted level. The cord of Dynesys can stabilize the spine, but over cord pretension may reduce the flexibility and increase the stiffness of spine.

- *The Dynesys spacer*

The spacer provides support for the posterior elements of lumbar spine as the spine bends backwards; it determines the segmental position such as disc height, facet joint position, and tension of the ligaments. Niosi et al try to clarify the effect of Dynesys spacer on the kinematics behavior and facet contact forces at the implanted level and suggest that the length of the Dynesys spacer had a significant effect on the kinematics behavior, with a range of motion and a motion pattern that was closer to that seen in an intact specimen[31] ;and on facet loads, with the long spacer resulting in lower facet loads than the short spacer[24]. In addition, Shih et al reported that changing the diameter of the spacers will alter the stiffness of the Dynesys construct[18]. We also try to determine if the shorter or no spacer contributes to difference in the kinematics behavior. There was no significant difference in ROM and NZ between the instrumentation of Dynesys with spacer and Dynesys without spacer in this study, but there was a significant difference comparing to intact species and rigid fixator. These results demonstrate that no spacer or shorter than neutral length spacer showed more rigidity than not only intact specimen but also rigid fixator, because the shorter spacer than neutral length spacer could not provide support for the posterior elements of lumbar spine.

- *Assembly strategies of Dynesys*

Based on the results, determining the cord pretension and length of spacer are curial surgical options for using the Dynesys. However, the appropriate length of spacers and the cord pretension are still controversial. Adjusting the length of spacer and cord pretension are important strategies and parameters that influence the rigidity of segment[24, 31]. Little evidence proves the appropriate spacer length and cord pretension in this study, but the flexibility of Dynesys may be increased following longer spacer and lower cord pretension. We propose the strategies of Dynesys assembly as follow (Figure 6): First, The standard Dynesys assembly with 300N cord pretension and neutral length of spacer provide the good stability of lumbar spine. Second, assembly with longer spacer than neutral length and lower cord pretension than 300N cord pretension will increase the flexibility of intersegment at implanted level. Finally, assembly with shorter spacer than neutral length of spacer and higher 300N cord pretension will increase the rigidity of intersegment at the implanted level.

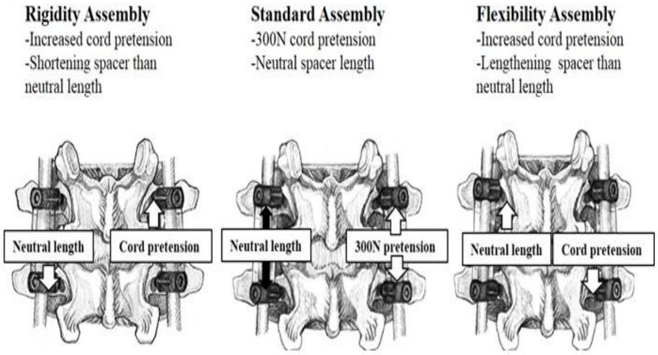

Fig 6: This figure illustrates the Dynesys assembly strategies. **Standard assembly** is 300N cord pretension in the neutral spacer length (Fig 6 B). **Rigidity assembly** is higher cord pretension in the shorter spacer (Fig 6A). **Flexibility assembly** is lower cord pretension in longer spacer (Fig 6C).

V. CONCLUSIONS

On the basis of this *in vitro* study, the kinematics behavior of Dynesys is similar to the rigid rod fixation. The flexibility of Dynesys was reduced when assembly with 300 N cord pretension. The cord pretension and spacer plays important role in flexibility of Dynesys. Although determining the cord pretension and spacer length are the curial surgical options, the relationship between the cord pretension, spacer length and the stiffness of Dynesys system is need further study.

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