Biomechanical Analysis of A Turkish-Made Posterior Spinal Instrumentation System

Part II. Evaluation of the Stability And Strength Provided By the Transpedicular Screw Fixation Device

Türk Malı Bir Posterior Spinal Enstrumantasyon Sisteminin Biyomekanik Analizi

Bölüm II. Transpediküler Vida Fiksasyon Cihazı Tarafından Sağlanan Stabilite ve Dayanıklılığın Değerlendirilmesi

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ABSTRACT

OBJECTIVE: To determine the construct stability and strength provided by a Turkish-made transpedicular fixation device (TIPSAN Posterior Instrumentation System, Tıpsan Tıbbi Aletler, İzmir, Turkey) compared to another well known system (Moss-Miami System, DePuy AcroMed, Raynham, MA, USA) in lumbar calf spine.

METHODS: Six L3-L5 levels were used for each device. A posterior and middle column injury was created on L4-L5 interspace on each specimen. Pedicle screws were placed to bilateral L3, L4, and L5 levels along with rods and one cross-link. In stability testing, specimens were non-destructively tested intact, after injury, and after instrumentation at the physiologic loads using a materials testing machine. Overall stiffnesses of the specimens were calculated. In strength testing, specimens were loaded in flexion mode until failure occurred. Stability and strength performances of both devices were compared using statistical analysis.

RESULTS: The Tıpsan system showed greater stiffness in flexion. Stability performances of the two devices in extension and lateral bending were similar. Both devices showed no breakage or bending in the strength test.

CONCLUSION: The Tıpsan Posterior instrumentation system was found to have at least similar construct stability and strength performance in comparison to a well-known system and proved to have equal worth as a spinal implant.

KEY WORDS: Animal model, biomechanics, bone screws, compressive strength, lumbar vertebrae, spinal fractures, spinal fusion.

ÖZ

AMAÇ: Türk malı bir transpediküler fiksasyon sisteminin (Tıpsan Posterior Enstrümentasyon Sistemi, Tıpsan Tıbbi Aletler, İzmir, Türkiye) gösterdiği stabilite ve dayanıklılığı iyi bilinen bir yabancı sistemle (Moss-Miami Sistemi, DePuy AcroMed, Raynham, MA, ABD) karşılaştırarak değerlendirmek.

YÖNTEM: Her bir implant tipi için L3-L5 düzeylerini içeren altı lomber dana omurgası kullanıldı. Omurlara L4-L5 disk seviyesi hizasında orta ve arka kolon hasarı uygulandı. L3, L4 ve L5 omurlarına iki yanlı olarak konulan pedikül vidalarını takiben ikişer rod ve bir adet çapraz bağlantı uygulandı. Stabilite testinde rod sistemi bir malzeme test cihazıyla fizyolojik yükler altında non-destrüktif olarak sağlam, hasar sonrası ve enstrumantasyon sonrası modlarda test edildi ve direngenlikleri hesaplandı. Dayanıklılık testinde rod sistemi yetmezliğe uğrayana dek fleksiyonda yüklendi. İmplantların stabilite ve dayanıklılık performasları istatistik analizle karşılaştırıldı.

BULGULAR: Tıpsan sistemi fleksiyonda daha yüksek direngenlik gösterdi. Her iki implantın ekstansiyon ve yana eğilmedeki stabilite performansları ise benzerdi. Dayanıklılık testinde iki implantta da kırılma ya da eğilme gözlenmedi.

SONUÇ: Tıpsan posterior enstrumentasyon sistemi iyi bilinen başka bir sistemle karşılaştırıldığında en az diğer sistem ölçüsünde stabilite ve dayanıklılık performansı göstererek bir spinal implant olarak eşit değerde olduğunu düşündürtmüştür.

ANAHTAR SÖZCÜKLER: Hayvan modeli, biyomekanik, kemik vidaları, kompressif kuvvet, lomber vertebralar, spinal kırıklar, spinal füzyon.

INTRODUCTION

Spinal instrumentation improves fusion rates, allows early mobilization, and lessens or eliminates the need for postoperative braces. Berthold Earnest Hadra was the first surgeon to use metallic materials to establish stabilization in the spine in 1891. He used silver wire in a cervical dislocation(13). Fritz Lange started to use steel wires attached to the spinal processes by silk to prevent deformity of spondylitis in 1908(1, 18). Don King was the first to use a screw for spinal stabilization. He introduced the facet screw for lumbosacral fusion in 1944(15).

Transpedicular fixation devices are useful tools to accomplish stabilization of the lumbosacral spine and the most popular method of dorsal instrumentation. Boucher pioneered pedicle screw fixation in 1959, using long facet screws obliquely passing through the pedicle (5, 6). Harrington and Tullos were the first to use "pure" pedicle screw fixation in 1969 (14). Successful series were reported in the 1970s and 1980s by Cotrel and Dubousset (7), Dick (9), Roy-Camille et al (23) and Louis(19).

Today, there are numerous different designs of pedicle screw fixation systems sharing similar principles. The biomechanical properties and advantages or disadvantages of these systems have been extensively studied (3, 8, 12, 16, 17, 22, 24, 26).

The reliability and performance of a particular spinal instrumentation system depends on numerous factors. It is expected that a fixation system should achieve enough motion restriction at the levels it has been applied (this is called the stability or stiffness of the device) and handle applied load without submitting excess load to the unstable spine at the physiologic limits of the range of the motion (this is called the strength of the device). The instrumentation system is also expected to be easy to apply, not to interfere with radiological investigations, and be affordable.

Biomechanical testing of a new spinal instrument can be achieved in two ways: it can be tested part by part (component-component interfaces and bone-implant interfaces) or as a whole device, either in isolation or attached to a specimen (artificial model, animal or cadaveric specimen). Testing of the whole spinal device is usually of three types: strength, fatigue, and stability (20). In the strength test, a gradually increasing load is applied to the device until the construct fails. This type of test gives information about the load-carrying capability of the device, its failure mechanism, and weak points. In the fatigue test, the device is subjected to cyclic loading until failure occurs. The applied loads are in physiologic ranges and fairly low compared to the failure load. This test provides information about the longevity of the construct. In the stability test, the device is tested in several loading modes in the range of physiologic loads. Unlike the first two, the stability test is nondestructive. The device can therefore be tested in all loading modes (compression, flexion, extension, lateral bending, and torsion) and a large amount of data can be collected on its stabilizing capability.

This is the second part of a two-part study in which we evaluated a Turkish-made spinal instrumentation system (Tıpsan Posterior Instrumentation System, Tıpsan Tıbbi Aletler, İzmir, Turkey). In the first part of the study, we tested the pullout strength of screws. The aim of the present study was to test the construct stability and strength provided by this device in comparison to another well known system in a middle and posterior column injury model in lumbar calf spine.

MATERIALS AND METHODS

Instrument characteristics

The Tıpsan Posterior instrumentation system and DePuy AcroMed Moss-Miami System (DePuy AcroMed, Raynham, MA) were compared in this study. The 5.5x40 mm screw of the Tıpsan system has a top-loading head and three pieces in its screw-rod connection: inner nut, ring, and contra-nut. The diameter of the screw head is 14.8 mm. The system has a knurled surface, 6 mm-diameter rods, and three-piece cross-links (Figure 1).

The DePuy AcroMed Moss-Miami system is a well-known device for spinal stabilization. The 5.0x40 mm screw of the system has a top-loading head, an inner nut, and an outer nut piece at its screw-rod connection. The diameter of the screw head is 10.9 mm. The system has smooth-surface rods 5 mm in diameter, and three-piece cross-links (Figure 2).

Study design

We performed a series of tests using lumbar calf specimens. The testing procedure consisted of two steps: I. Stability test, II. Strength test.

In the stability test, the specimens were non-destructively tested for the applied loads and the resulting vertebral motion to determine construct

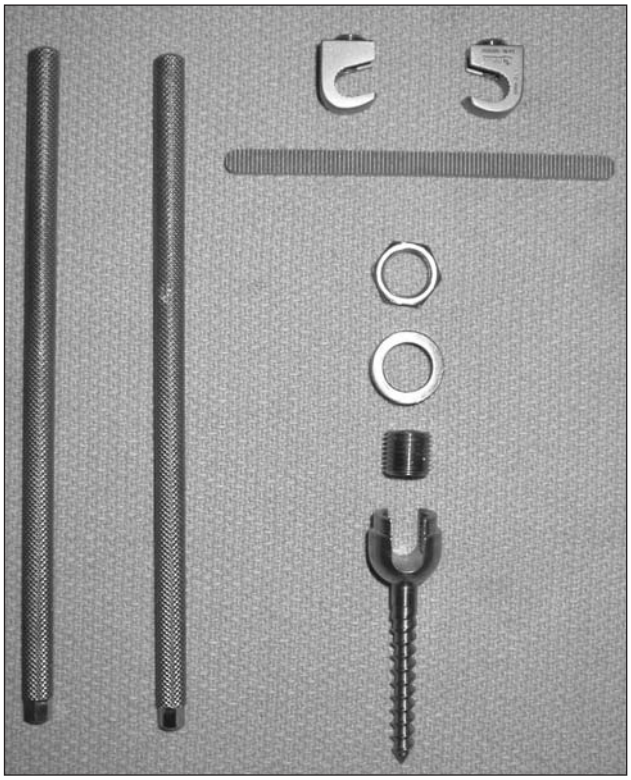

Figure 1: Components of TIPSAN device

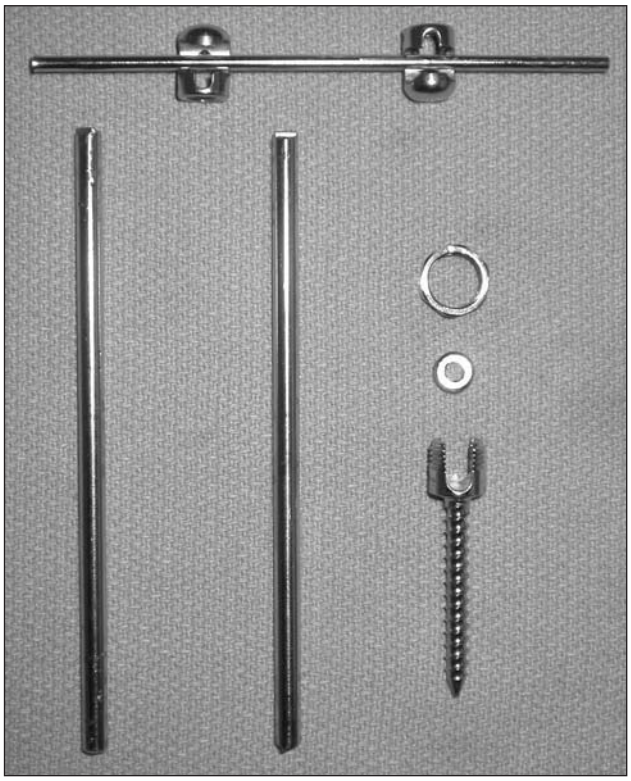

Figure 2: Components of MM device

stiffness. The specimens were tested under three conditions: intact, post-injury (destabilized), and instrumented status. The intact testing allowed for each specimen to serve as its own control. Testing after destabilization provided data to quantify how injury changed the stiffness. Testing after instrumentation provided data regarding the stabilization effect of both devices.

After completion of stability testing, each specimen was tested destructively to determine its maximum load bearing capacity (=strength test). A sample size of 6 devices per test group (Tıpsan and Moss-Miami) was used to test construct stability and strength.

Specimen preparation

For this study 12 fresh lumbar calf spines were obtained for biomechanical testing. All specimens were approximately 14 weeks old. All soft tissue was dissected, leaving only the ligamentous and osseous structures intact, and divided in a fashion that produced the L3-L5 segment to be used.

The specimens were embedded into polyester resin (Bondo body filler, Atlanta, GA) up to the mid-body on the superior end of L3 and the inferior end of the L5, leaving their pedicle entering points visible. Each specimen was wrapped in moistened gauze and plastic bag, labeled, and kept frozen until the test day.

Destabilization procedure

A surgical destabilization process was performed after the intact testing of each specimen. The process included a posterior and middle column injury at the level of L4-L5. It consisted of the sectioning of all posterior structures and the posterior half of the disc, leaving only the anterior half of the disc and the anterior longitudinal ligament intact as described by Panjabi et al (21) (Figure 3). All posterior ligaments, bilateral articular processes, the posterior longitudinal ligament and the posterior half of the disc were cut linearly but not resected.

Instrumentation

After intact testing, destabilization process and testing post-destabilization, each specimen was randomly instrumented with either the Tıpsan or the Moss-Miami transpedicular system. Three-level (L3, L4, and L5) bilateral pedicle screws, two rods and a cross-link at the level of L3-L4 were used for each specimen (Figure 4A, 4B).

All destabilization and instrumentation procedures were conducted by the same surgeon (CK) to maintain consistency.

Figure 3: Testing of a destabilized specimen at the flexion mode

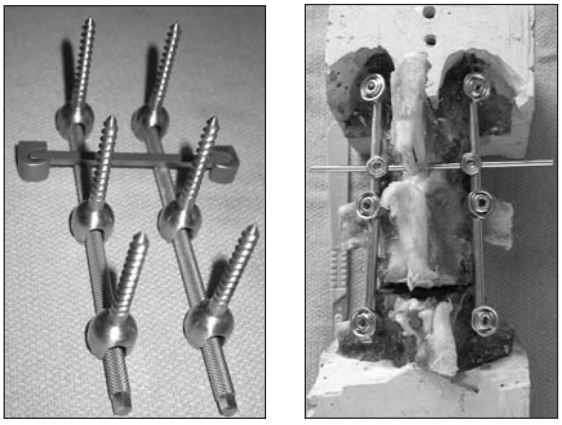

Figure 4A, B: Instrumentation desing

Biomechanical testing

I. Stability test

The specimens were secured into an electromechanical universal materials testing machine (MTS Alliance RT/10, MTS Corp., Eden Prairie, MN), and tested for flexion, extension, and left lateral bending conditions (Figure 5). The specimens were subjected to a constant compressive axial load of 700 N for compression, and 250 N compressive loads with 5 Nm bending moment for flexion, extension, and left lateral bending. The bending moment was obtained by shifting the specimen 2 cms from the instantaneous axis of rotation (IAR) using a lever arm connected to the upper gripping fixture. As an exception, 50 N of compressive load was used instead of 250 N for the destabilized specimens at flexion mode as these specimens could not tolerate higher loads (Figure 3). The loads were applied at a rate of 25 mm/min, and the load-displacement and the load-angular displacement data was recorded at a sampling rate of 20 Hz. Each specimen was cycled 6 times and the data from the last cycle were sampled. Overall stiffnesses of the specimens were calculated by using the angular motion data collected by a rotational potentiometer attached to the top and the bottom gripping fixtures, as well as the load and displacement data acquired by the testing apparatus.

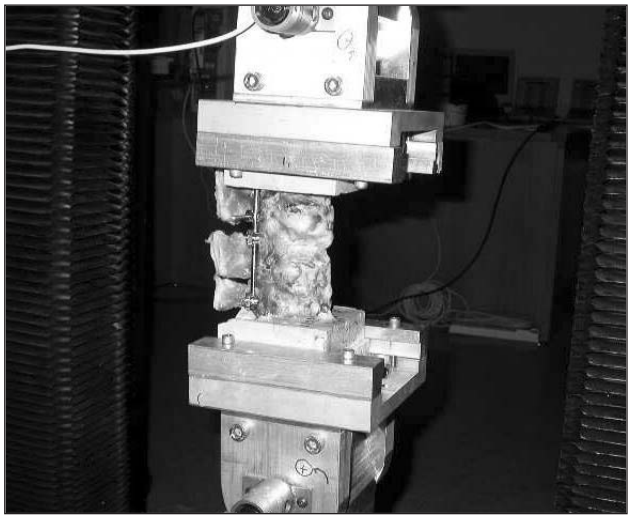

Figure 5: Testing Procedure in MTS machine

II. Strength test

After the stability tests were completed, each specimen was tested for construct strength by steadily increasing the load at a displacement rate of 25 mm/min in flexion mode until failure occurred. During this process, the peak load (refers to the highest load sustained by the device), displacement, angular motion and stiffness values were obtained. Failure was defined as a gross fracture of the bone or implant component, or separation of bone from the potting material.

After testing was complete, all the instrument components were checked for signs of loosening or damage and the screws were manually checked for loosening in the bone.

Analysis of data

Descriptive statistics and an analysis of variance were employed to detect any differences between groups: the stiffnesses at intact, destabilized, and instrumented conditions. The stiffness values of instrumented specimens were compared for the two

devices. Graphpad Prism 3.02 (Graphpad Software Inc., San Diego, CA) was used for statistical analysis.

RESULTS

Stability test

The results for the mean stiffness values for both devices are shown in Table I. The destabilization process decreased specimen stiffness at the flexion mode only. The specimens did not show stiffness changes at the extension and lateral bending modes. Both instruments significantly increased specimen stiffness at flexion, extension, and lateral bending modes (Figures 6-8).

Table I. Mean values and standard deviations of stiffness for both instrument types (n=6 for each instrument).

MODE	Instrument	Stiffness (Mean ± SD) (Nm/deg)		
		Intact	Destabilized	Stabilized
Flexion	Tıpsan	0.71 ± 0.12	0.24 ± 0.04	5.25 ± 0.99
	Moss-Miami	0.73 ± 0.08	0.20 ± 0.03	3.53 ± 1.48
Extension	Tıpsan	1.02 ± 0.13	0.98 ± 0.35	5.72 ± 0.62
	Moss-Miami	1.04 ± 0.21	0.94 ± 0.28	5.72 ± 0.62
Lateral bending	Tıpsan	0.70 ± 0.13	0.65 ± 0.10	5.48 ± 0.87
	Moss-Miami	0.76 ± 0.11	0.61 ± 0.06	5.06 ± 0.70

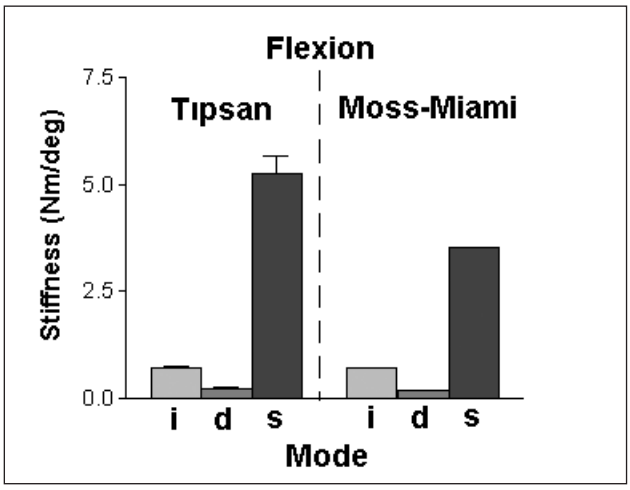

Figure 6: Stiffnesses at intact, destabilized and instrumented modes at flexion for Tıpsan and Moss-Miami instrumentations. The destabilization process significantly lowered specimen stiffness, and stabilization (i.e., instrumentation) significantly increased the stiffness ($p<0.0001$) for both of the instruments (i=intact, d=destabilized, s=stabilized)

Figure 9 shows the comparison of mean stiffnesses of the TIPSAN and Moss-Miami systems. While the two systems have similar stabilizing capability in extension and lateral bending modes, the Tıpsan system was found to be significantly stiffer than Moss-Miami in flexion mode.

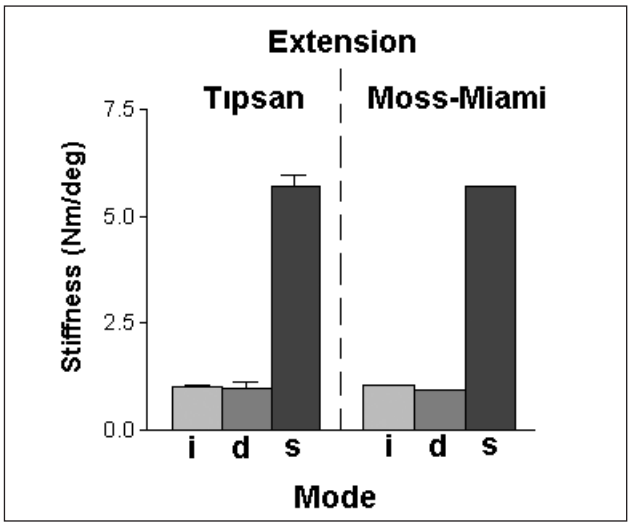

Figure 7: Stiffnesses at intact, destabilized and instrumented modes at extension for both devices. While the destabilization process did not affect specimen stiffness, stabilization significantly increased the stiffness ($p<0.0001$) for both of the instruments (i=intact, d=destabilized, s=stabilized).

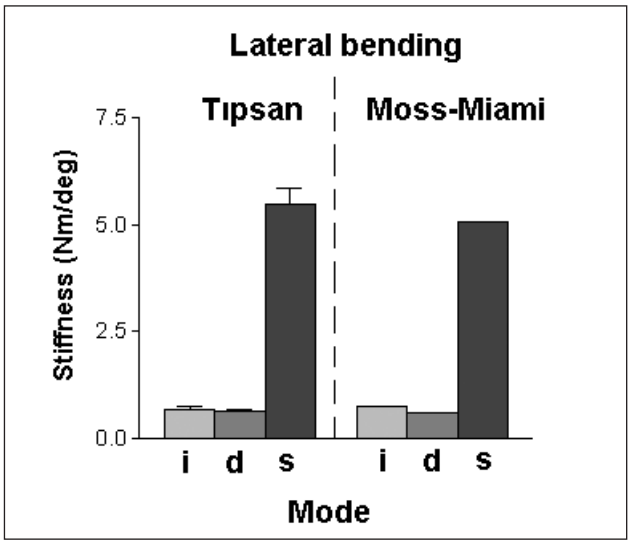

Figure 8: Stiffnesses at intact, destabilized and instrumented modes at lateral bending for Tıpsan and Moss-Miami instrumentations. While the destabilization process did not affect specimen stiffness, stabilization significantly increased the stiffness ($p<0.0001$) for both of the devices (i=intact, d=destabilized, s=stabilized).

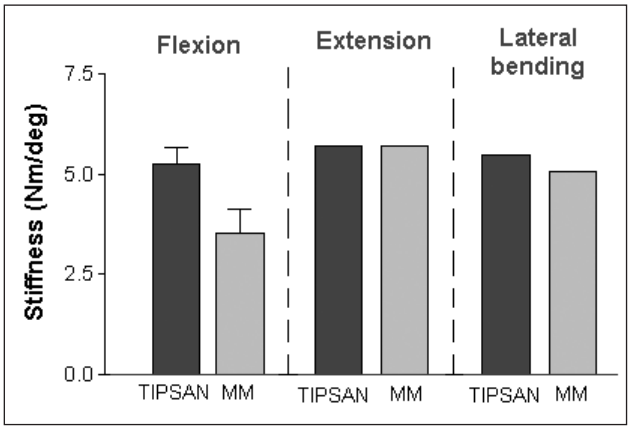

Figure 9: Comparison of TIPSAN and Moss-Miami stiffnesses at flexion, extension, and lateral bending modes. The TIPSAN system was stiffer than Moss-Miami (p=0.039) at flexion mode. There were no statistically significant difference at extension and lateral bending modes.

Strength test

Figure 10 shows the results of the strength (=crush) test. Specimen failure occurred via partial loosening of bottom screws and separation of L3 vertebra from the top embedding material between 2500 and 3000 N in all specimens. There was no significant difference between the peak loads of the Tıpsan and Moss-Miami instruments.

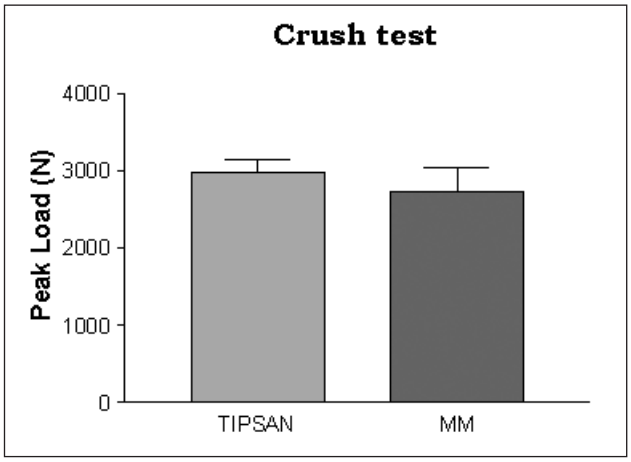

Figure 10: Comparison of TIPSAN and Moss-Miami peak loads in the strength (=crush) test. The results are similar.

DISCUSSION

In the present study we chose a posterior and middle colon injury model as the injury model was able to simulate a situation which is a posterior fixation system's proposed application(20). This procedure created a clear instability and was constantly reproducable in all the specimens. Although destabilized specimens showed lower levels of stiffness than the intact state, the destabilizing effect of the injury was found to be significant only in the flexion mode. This finding may stem from features of the destabilization process as well as anatomic characteristics of calf specimens. Calf vertebrae have large articular processes. They are therefore still strong after sectioning the spines and very large bone-to-bone surfaces prevent excess movement during extension and lateral bending.

Different moment values are used in stability testing in the literature, ranging from 3 Nm to 15 Nm (10, -12, 21). It has been reported that the relative stabilities of each implant does not very much using different load magnitudes(2, 21). Using a similar specimen (lumbar calf spine, one level longer than the one used in this study) we observed in our laboratory that the specimens had been broken at lateral bending mode with a moment of 7.5 Nm. In the present study, we used 5 Nm moment, similar to the value we generally use in our laboratory.

The most important consideration in evaluating a spinal instrument is its ability to provide stability to the spine at the injury or fusion site. This determination is clinically important as it affects healing speed and fusion rate. There are many spinal systems using different designs. Design changes are primarily seen at the component-component (especially screw-rod) interface and have some effect on stabilizing strength. The Moss-Miami system was chosen for comparison since it mainly uses the same implant design and is similar to the Tıpsan system morphologically. In the present study, the Tıpsan and Moss-Miami systems were found to provide similar stability at all movement directions but flexion. It should be noted that the constructs could not be tested at axial rotation, since the testing machine was not capable of performing this movement. This is the main limitation of the current study.

The Tıpsan system was found to be stiffer than the Moss-Miami system at flexion mode. This difference may have clinical importance as the specimens showed clear instability only at the flexion mode in the posterior and middle column injury model. As the two systems have similar design features and neither showed loosening or failure at the rod-screw interface, the reason of the stiffness difference at flexion mode may result from

the difference of the systems' profiles, such as the rod and screw sizes. The Tıpsan system has 1 mm thicker rods and screws 0.5 mm bigger in diameter than those of the Moss-Miami system. Although the main task of a spinal implant is rigid fixation and stability at the spine level it is applied to, stress shielding caused by the instrument may lead to osteopenia and degeneration of adjacent segments. The optimal stiffness of a spinal instrument is unknown.

One of the differences between two devices was their rods. The Tıpsan system has thicker and knurled surface rods, while the Moss-Miami system has smooth-surface rods. Knurled surface rods may enhance maximal torsional or axial push strength adding more friction between the components (4). We found that mean peak loads in the crush test were similar for the Tıpsan and Moss-Miami devices. All specimens first showed slight loosening of bilateral L5 screws, but separation of bone from upper embedding material followed. Failure therefore occurred at the embedding interface, not at bone or the implant.

In conclusion, the Tıpsan Posterior instrumentation system was found to have construct stability and strength performance at least similar to a well-known system, and proved to have equal worth as a spinal implant.

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