

# BIOMECHANICAL EVALUATION OF INTERSPINOUS DEVICE, MIDFIX IN DESTABILIZED SPINE

© Ertuğrul Şahin<sup>1</sup>, © Fatih Ertem<sup>2</sup>, © Ahmet Karakaşlı<sup>3</sup>, © Sang-Ho Lee<sup>4</sup>, © Sang-Ha Shin<sup>4</sup>, © Junseok Bae<sup>4</sup>

<sup>1</sup>Kafkas University Faculty of Medicine, Department of Orthopaedics and Traumatology, Kars, Turkey

<sup>2</sup>Dokuz Eylül University Institute of Health Sciences, Department of Biomechanics, İzmir, Turkey

<sup>3</sup>Dokuz Eylül University Faculty of Medicine, Department of Orthopaedics and Traumatology, İzmir, Turkey

<sup>4</sup>Wooridul Spine Hospital, Clinic of Neurosurgery, Seoul, South Korea

## ABSTRACT

**Objective:** The purpose of this study was to evaluate the stability and loosening of the Midfix device under complex cyclic loading with the resection of interspinous and supraspinous ligaments.

**Materials and Methods:** A biomechanical study of motion analysis and cyclic loading on six fresh-frozen lamb spines was conducted. Specimens were divided into three groups: control, destabilized, and midfix groups. The excision of interspinous and supraspinous ligaments was performed in the destabilized and Midfix groups. Axial loads of 400 N were applied to the spine, and an increased moment of up to 8400 N-mm was generated through the axial movement to achieve the flexion-extension (FE) and right-left bending (LB) motions. During testing, the extensometer recorded the intervertebral displacement at decompression levels L4-5. According to the analysis, the value for which  $p < 0.05$  was considered statistically significant.

**Results:** Implantation of the ISD (Interspinous Device) to strengthen segment stabilization resulted in a significant decrease in the range of motion of 43.2% in extension, 57.8% in flexion, and 25.6% in LB, yet an increase in right bending by 25.6%. A comparison between the intact spine and Midfix groups revealed significant differences in the range of motion in FE and LB. However, there were no statistically significant differences in right bending.

**Conclusion:** The Midfix device stabilized the segments after resecting the interspinous and supraspinous ligaments. In addition, Midfix was more effective in flexion and extension than the other loading modes. Therefore, the lack of a stabilizing effect in bending should be carefully considered.

**Keywords:** Biomechanics, lumbar spine, interspinous device, lamb

## INTRODUCTION

Low back pain (LBP) stands as one of the most prevalent global health issues concerning musculoskeletal problems, presenting a considerable challenge to clinicians tasked with its management<sup>(1)</sup>. Based on the severity of the pain and the patient's condition, the treatment of LBP ranges from conservative to surgical<sup>(2)</sup>. Surgery is the treatment option that is employed following conservative treatment failure in LBP. Depending on the condition causing the LBP, there are different surgical procedures, including decompression with or without arthrodesis, decompression arthrodesis with or without instrumentation, fusion with or without instrumentation, and non-fusion dynamic stabilization devices to treat spinal pathologies<sup>(3)</sup>. However, among these procedures, spinal fusion is the gold standard in treating degenerative spine diseases. Moreover, fusion without instrumentation often leads to the

non-union of bone, which is called pseudoarthrosis. Many spinal implants, including cages, plates, screws, pedicle screws, rods, and wires, were designed to overcome this complication and to stabilize the fused spine.

Non-fusion procedures, such as dynamic stabilization, total disc arthroplasty, interspinous devices (ISDs), and less invasive systems have been developed as alternative treatment options for spine stabilization<sup>(2,4,5)</sup>.

Minimally invasive spine surgery (MISS) involves performing small incisions. These procedures have advantages compared with conventional surgeries, including reduced blood loss, less damage to surrounding muscles, and reduced surgery time<sup>(6,7)</sup>. Technological improvements have led to the development of new MISS instruments that increase the stability of spine with less invasive surgical exposure. ISDs are dynamic stabilization systems that are implanted between spinous processes using minimally invasive techniques. The primary mechanism of

**Address for Correspondence:** Ertuğrul Şahin, Kafkas University Faculty of Medicine, Department of Orthopaedics and Traumatology, Kars, Turkey

**Phone:** +90 506 808 22 69 **E-mail:** ertugrulsahinn@hotmail.com **Received:** 19.05.2024 **Accepted:** 09.10.2024

**ORCID ID:** orcid.org/0000-0002-8509-3570

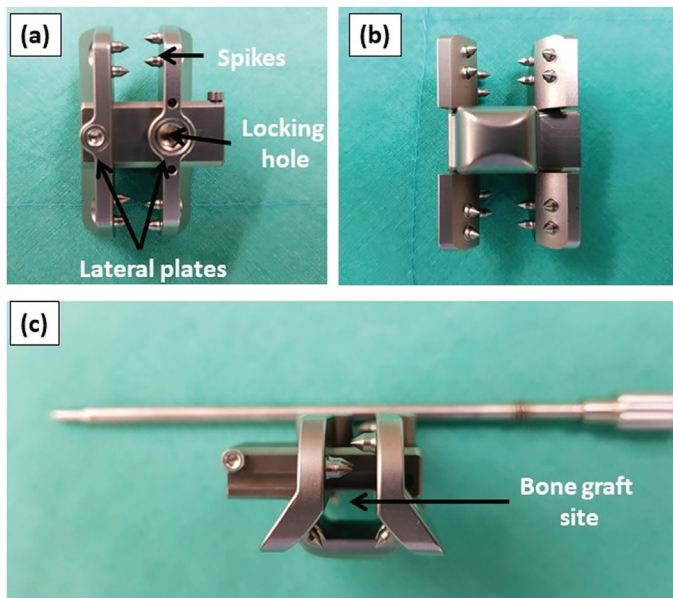


ISDs is to decrease the load of facet joints and the distraction between adjacent spinous processes to block intervertebral extension at the level of application. They allow movement of the spine while providing stability<sup>(8,9)</sup>. Indications for the use of ISDs encompass various conditions including spinal stenosis, degenerative spondylolisthesis (grade 1), discogenic pain in low back, facet joint pathologies, lumbar disc herniation, and non-traumatic instability<sup>(9)</sup>. Different designs of ISDs are tailored to address specific needs, such as solely limiting extension or restricting both flexion and extension.

ISD use has only recently become widespread; therefore, few biomechanical and clinical studies have reported on the effectiveness of these devices<sup>(10,11)</sup>. Karahalios et al.<sup>(5)</sup> conducted a comparative analysis of the Aspen device alongside alternative devices, including its application when used alongside anterior lumbar interbody fusion (ALIF). Kaibara et al.<sup>(12)</sup> undertook a biomechanical investigation utilizing the Aspen system in conjunction with transforaminal lumbar interbody fusion. Wang et al.<sup>(4)</sup> performed a biomechanical assessment of the CD-HORIZON-SPIRE fixation system, evaluating the stability of SPIRE with both uni-bilateral inserted pedicle screws in a destabilized spinal.

The Midfix (Huvexel, South Korea) ISD was designed to provide supplemental fixation and to support a minimally invasive surgical technique. Midfix is an all-in-one device consisting of two lateral plates with spikes and one vertical plate with a locking hole (Figure 1).

The Midfix device is implanted between the vertebral spinous processes and provides a fixation site toward the lamina and spinous processes coexisting with a bone grafting site (Figure 2). This device is made up of titanium that is biocompatible in the human body. Midfix is indicated in patients with degenerative spondylolisthesis, spinal instability, and recurrent



**Figure 1.** Midfix interspinous fusion device (a) posterior view (b) anterior view (c) superior view

disc herniation. In addition, it can be used with the adjunct of an upperinstrumented vertebra to pedicle screw fixation, especially in deformity correction.

The aim of this study is to evaluate the stability provided by the Midfix device under cyclic loading during flexion-extension (FE) and lateral bending in six fresh-frozen lamb lumbar segments without the posterior ligaments. We hypothesized that resection of the interspinous and supraspinous ligaments would not reduce the stability of the lumbar spinal segments instrumented with a Midfix ISD.

## MATERIALS AND METHODS

This study was approved by the Dokuz Eylül University Non-Interventional Research Ethics (approval number: 2021/28-03, date: 13.10.2021), and was performed using standardized loading protocols<sup>(13)</sup>. As this study involved animal specimens, no patient informed consent was obtained.

### Specimen Preparation

The number of specimens was determined based on a previously conducted study that analyzed the suitability of different animal specimens for pre-clinical implants<sup>(14,15)</sup>. Six fresh-frozen lamb spines (including L1 to L5 vertebrae) were used in this study. Each specimen was thawed 12 hours before



**Figure 2.** Midfix interspinous fusion device placed in between spinous processes

testing to return it to normal condition at room temperature. The paraspinal muscles of each specimen were removed, keeping the interspinous ligaments, supraspinous ligaments and intervertebral disc intact.

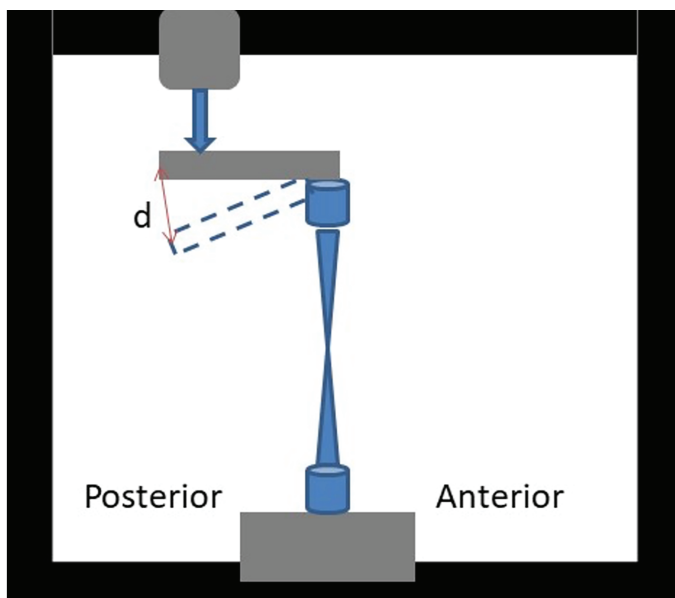
The caudal and cranial ends of the motion segment were potted using polyester putty, and an accelerator was added to shorten the hardening process. Potting was employed to ensure that the intervertebral disc plane was horizontal in all specimens. Following specimen preparation, they were divided into three groups: a control group consisting of intact specimens, a destabilized group, and a Midfix group. The destabilized group and the Midfix group underwent a surgical procedure that involved cutting the interspinous and supraspinous ligaments. Lastly, biomechanical tests were conducted.

### Biomechanical Tests

Biomechanical testing was performed utilizing the axial-compression system (AG-I 10-KN, Shimadzu, Japan). This system incorporates TRAPEZIUM 2 and CCD camera-extensometers (non-contact video extensometer DVE-101/201, Shimadzu, Japan) to obtain measurements without direct contact with the specimen. Figure 3 depicts an illustration of the specially designed fixture used in the experiments.

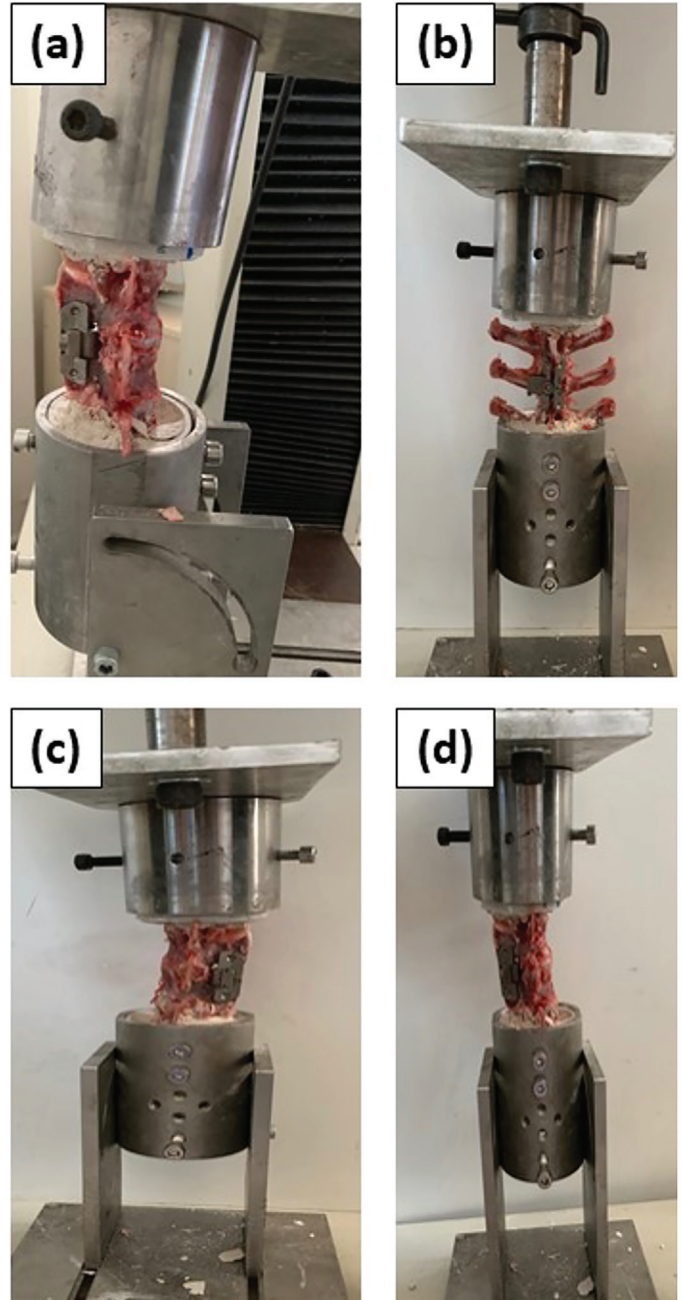
The potted intact motion segment was fixed on the testing frame. Axial loads were applied to the anterior, posterior, right, and left sides of the center of motion, producing bending forces for FE movements and right-left bending (RB-LB), respectively (Figure 4).

In a neutral position, 400 Newton (N) axial loads were applied to the spine and were increased up to 8400 N-mm generated through the axial movement to achieve the FE and right-LB motions<sup>(46)</sup>. During testing, the extensometer recorded the



**Figure 3.** Illustration demonstrates the biomechanical setup. Value of "d" represented the displacement (mm) of intervertebral distance while applying axial force

intervertebral displacement at decompression levels L4-5. Gauge marks were inserted into the specimen with pins to measure the superior-inferior and anterior-posterior displacement. The two non-contact cameras captured images of the gauge marks. The displacement of gauge marks on the CCD screen was converted into actual displacement. This conversion process involved recording displacement values via two non-contact cameras connected to a personal computer linked to the test machine.



**Figure 4.** Motion segment implanted with Midfix interspinous fusion device with various positions in Biomechanical test (a) Flexion test (b) Extension test (c) RB test (d) LB test  
RB: Right bending, LB: Left bending



## Statistical Analysis

The distribution of the data was evaluated using the Shapiro-Wilk test. Continuous variables are presented as mean and standard deviation (SD). The differences in mean values for the specimens were evaluated using the paired samples t-test. All statistical analyses were conducted using SPSS for Windows (version 22.0; IBM Corp., Armonk, NY, USA). A significance level of  $p < 0.05$  was deemed statistically significant.

## RESULTS

The mean and SD displacement distances for the vertebrae in FE and right-LB motions are presented in Table 1.

The motion of the destabilized spine increased significantly in extension by 32.4%. However, placement of the Midfix device decreased the extension by 43.2% compared with the intact spine.

Destabilization of the spine increased the flexion range by 57.8%. After implantation of the Midfix device, a 59.4% decrease in the range of motion was observed compared with the control specimen ( $p < 0.05$ ).

The RB range increased by 67% in the destabilized spine specimen. Implantation of the Midfix device resulted in a 22.2% decrease in RB range compared with the destabilized spine. However, the Midfix device did not produce an improvement in RB stiffness, and a 30.2% increase was observed in the range of motion compared with the intact spine.

The range of motion for LB was 46% in specimens with ligaments removed compared with the control specimens. Unlike RB, the Midfix device improved LB stiffness and decreased the range of motion by 25.6% in the destabilized spine compared with the intact spine.

A significant reduction in the degree of displacement between the control and Midfix groups was observed for flexion ( $6.4 \pm 0.5$  vs.  $2.6 \pm 0.8$ ,  $p = 0.015$ ), extension ( $3.7 \pm 1$  vs.  $2.1 \pm 0.5$ ,  $p = 0.048$ ), and LB ( $3.9 \pm 0.7$  vs.  $2.9 \pm 0.6$ ,  $p = 0.021$ ). Nonetheless, no statistically significant difference was noted in the degree of RB between the control and Midfix groups ( $4.3 \pm 0.7$  vs.  $5.6 \pm 1.1$ ,  $p = 0.06$ ).

## DISCUSSION

In our study, the Midfix device produced improvements in FE and LD stiffness compared with both intact and destabilized spines. However, no significant improvement was observed in RB range in specimens implanted with the Midfix device. These results suggest that Midfix may be clinically useful in the restabilization of the destabilized spine regarding FE and LB motion. The device allowed less motion on FE and right-LB than the destabilized spine alone. Comparison of the results of intact and Midfix-implanted specimens revealed more rigid fixation in the sagittal plane and non-rigid fixation in the coronal plane with the Midfix device.

Techy et al.<sup>(16)</sup> reported a 74% decrease in FE motion, 5% decrease in LB, and 0.4% decrease in RB in ISD-instrumented spines. ISDs provided as much FE stability as bilateral pedicle screw instrumentation; however, ISDs produced minimal rigidity in bending motions when used alone. These results are consistent with our findings. Lindsey et al.<sup>(17)</sup> performed a biomechanical study on interspinous spacers (X Stop; SFMT, Concord, CA, USA) and found a decrease in FE range and no significant change in AR or LB. Wilke et al.<sup>(18)</sup> reported a reduction in only FE motion in a biomechanical study of four different ISDs. Karahalios et al.<sup>(5)</sup> implanted an ISD to support an L4-L5 ALIF procedure and observed more stiffness stability in FE and less in AR or LB, which is in line with previous studies. Tsai et al.<sup>(19)</sup> performed a biomechanical study on the Coflex™ interspinous fixation device in human cadaver spines.

The Coflex device ensures non-rigid fixation and can return a partially destabilized spine to the intact state regarding flexion, extension, and axial rotation.

Extensometers have been widely used in the literature. Shono et al.<sup>(20)</sup> used an extensometer to compare the stiffness and unit motion of a calf spine with anterior instability. Chen et al.<sup>(21,22)</sup> performed a biomechanical study on porcine spines with three different sagittal alignment patterns: normal, kyphotic, and lordotic. The intervertebral displacement of adjacent segments was measured using an anterior extensometer. Gurr et al.<sup>(23)</sup> measured intervertebral displacement through a corpectomy site using an extensometer to compare the stability of different types of posterior instrumentation on a calf spine model. In our study, we used an extensometer to compare the differences in intervertebral displacement between intact, destabilized, and Midfix-implanted spines.

We chose a moment of 8400 N-mm because recent studies reported that the maximal moment was reached at 8400 N-mm, which stopped the flexion or extension motion. During the extension of the spine, the facet joints lock and prevent more posterior vertebral displacement, and the moment increases quickly to the endpoint of 8400 N-mm<sup>(24)</sup>.

In our study, we conducted excision of the interspinous ligaments while leaving the disc intact. Notably, the displacement values observed in our study remained unaffected by disc height.

**Table 1.** Mean and SD values for extension-flexion and RB-LBs

	Control group (n=6) Mean ± SD (mm)	Destabilized group (n=6) Mean ± SD (mm)	Midfix group (n=6) Mean ± SD (mm)
Flexion	6.4±0.5	10.1±2.7	2.6±0.8
Extension	3.7±0.1	4.9±0.5	2.1±0.5
Right bending	4.3±0.7	7.2±1.2	5.6±1.1
LB	3.9±0.7	5.7±0.9	2.9±0.6

SD: Standard deviation, Mm: Millimeter, RB: Right bending, LB: Left bending

However, there were variations in intradiscal pressure (IDP) across different implants. Specifically, the pedicle screw system exhibited the lowest IDP at the surgical level across all motion modes, albeit with a significant increase in IDP at adjacent levels. Shen et al.<sup>(25)</sup> conducted a finite element study and reported that the DIAM™ device demonstrated similar IDP to the intact model, particularly in lateral bending and rotation. Conversely, other devices such as Coflex-F and Wallis exhibited higher IDP at the surgical level, albeit with minor increases at adjacent levels. This observation suggests that ISDs may not significantly affect IDP at adjacent levels, potentially offering benefits in preventing adjacent segment degeneration over the long term. Further clinical investigations focusing on the effects of Midfix on IDP are warranted to provide additional insights into its impact. The results for FE were expected and relevant as Midfix is located at the midline, between the spinous processes. However, the decline in LB motion was surprising considering the position of the ISD. Moreover, we observed an increase in RB motion in the destabilized spines implanted with Midfix compared with the intact spines. One explanation may be that the locking hole was positioned at the right side, leading to less torque, so it could not resist the torque of the system as the distance of the force arm was minimal. The left side had a longer force arm distance, so the ISD could resist the force on the system during LB motion. Moreover, the differences between human and lamb spinal structures could influence these results, and this issue must be considered. An updated design of the ISD in which the locking part is located more medially would balance the range of motions in RB and LB. The impact of implant size, placement, and fixation on both the implanted segment and adjacent segments is paramount. The current body of literature offers various recommendations to address these factors, including measuring the distance between spinous processes or employing device templates to facilitate precise implantation and mitigate the risk of overestimating device size. However, consensus regarding the most suitable implant size remains elusive. Anasetti et al.<sup>(26)</sup> noted that device size and positioning significantly affect the neutral position's displacement. While small devices offer limited spinal stabilization, larger devices may increase the risk of disc overload due to a kyphotic position. Zheng et al.<sup>(27)</sup> conducted a biomechanical study assessing various sizes of the same device. Their findings suggested that employing a larger device may be advantageous in treating patients with lumbar spinal stenosis. For patients with degenerative disc disease, implant placement with a spacer height matching the distance between interspinous processes proves effective. Therefore, selecting the appropriate implant size hinges on the patient's clinical scenario. In our study, we maintained consistency by employing identical-sized devices across all specimens. Nevertheless, future research endeavors should explore the utilization of varying device sizes to provide a comprehensive assessment of their impact. Fusion devices offer rigid stabilization at the level of the spacer body and promote fusion through biomechanical means. These devices can be used in isolation, in conjunction

with cages, or alongside other spinal devices to induce fusion, akin to more invasive fusion techniques.

From a biomechanical perspective, it's crucial to acknowledge that ISDs may induce segmental kyphosis in the spine, which typically exhibits lordosis. This discrepancy could potentially lead to anterior disc overload if ISDs are employed independently. However, when ISDs are combined with cages, this focal kyphosis may adversely affect interbody fusion and graft integration. Our study focused solely on evaluating ISD use in isolation; hence, future investigations should be designed to address these concerns.

Conversely, biomechanical studies suggest that ISDs may yield comparable outcomes to pedicle screw rod application in limiting FE motion, with potential advantages in limiting axial rotation and lateral bending. However, our analysis only accounted for motion in the sagittal and coronal planes (FE, lateral bending, and axial rotation). Therefore, it is imperative to conduct further investigations to assess the effects of ISDs under different loading conditions, including axial rotation.

There are some limitations to our study. First, this study was conducted on lamb lumbar spine specimens, which did not have physiological structures including, spinal alignment, and the number of lumbar segments in lamb spines differ from those in human cadaveric spines. However, in the literature, numerous studies report that animal spines are often the preferred choice for conducting such experiments due to their convenience and suitability for biomechanical research<sup>(28,29)</sup>.

Rigid fixation can cause hypermobility in the adjacent segment, which leads to acceleration of degenerative conditions<sup>(20,30)</sup>. The range of motion of adjacent segments was not evaluated with the insertion of the Midfix. In our study, we observed a 43.2% decrease in extension and a 59.4% decrease in a flexion. Although this finding indicates the theoretical disadvantage of Midfix, clinical results might not be in line with these results. In the testing methodology employed in this study, the application of load was dynamically optimized, aiming to minimize off-axis loads. This approach ensured unconstrained pure moment loading conditions throughout the test. Consequently, future analysis of long-term clinical results will be essential for a comprehensive understanding of the findings.

The primary goal of ISD is stabilization of the unstable spine. The secondary goal is a reduction in the pressure on the disc by distracting the interspinous space and unloading the facet joints. In our study, confirmation of whether these goals were biomechanically achieved was not performed. Therefore, other biomechanical studies should be conducted to verify the treatment goals of the Midfix.

## CONCLUSION

Destruction of the supraspinous and interspinous ligaments can lead to the development of instability. The Midfix device provided the required stability in the absence of the interspinous and supraspinous ligaments. The Midfix device had a more pronounced effect on FE than other loading modes. Therefore, surgeons should take care when using Midfix for the

stabilization of bending and rotational movements because of the lack of information about its stabilizing effect.

#### Footnote

**Ethics Committee Approval:** This study was approved by the Dokuz Eylül University Non-Interventional Research Ethics (approval number: 2021/28-03, date: 13.10.2021).

**Informed Consent:** As this study involved animal specimens, no patient informed consent was obtained.

#### Authorship Contributions

Surgical and Medical Practices: E.Ş., F.E., A.K., J.B., Concept: E.Ş., F.E., S-H.L., S-H.S., J.B., Design: E.Ş., F.E., A.K., Data Collection or Processing: E.Ş., S-H.L., S-H.S., J.B., Analysis or Interpretation: E.Ş., Literature Search: E.Ş., Writing: E.Ş., F.E.

**Conflict of Interest:** The authors have no conflicts of interest to declare.

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