A Biomechanical Study Of The Lumbar Spine After Insertion And Removal Of An Interspinous Process Distraction Device:

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Citation

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Abstract

ObjectiveTo determine whether insertion and subsequent removal of this interspinous process distraction device decreases the stability of the lumbar spine. MethodsSix cadaveric fresh frozen L1-L5 spine segments, free from any gross pathology, were harvested. The specimens were tested in rotation, lateral bending and flexion-extension using the following sequence:1) Intact2) With the X STOP implanted at the L3-4 level3) After removal of the X STOPWe compared the stiffness of the spine after removal of the X STOP vs. the stiffness of the intact specimenResultsThe paired t-test analysis of the stiffness of the specimen after the X STOP was removed vs. the stiffness of the intact specimen showed that the post-instrumented spine had significantly lower stiffness in rotation, lateral bending and flexion/extension.ConclusionInsertion and removal of an interspinous distraction device significantly decreases the stiffness of the lumbar spine in all ranges of motion. This may have implications in terms of stability in those patients in whom the implant is tried as a first line of surgical therapy and unsatisfactory results are obtained.

INTRODUCTION

Neurogenic intermittent claudication (NIC) is a clinical entity where thickened ligamentum flavum causes symptoms of lower limb numbness, tingling and pain. These symptoms are posture-dependent and are exacerbated in extension but relieved in flexion [2]. Treatment for this condition has been traditionally been conservative therapy versus surgical decompression (laminectomy or foraminotomies). Recently, an interspinous process distraction device (X STOP, St. Francis Medical Technologies, Concord, CA) has been developed as an alternative treatment for NIC. In the current study, we explore the biomechanical properties of lumbar spinal segments after insertion and removal of the X STOP and how these compare to the intact spine.

MATERIALS & METHODS

Six cadaveric fresh frozen L1-L5 spine segments were harvested and cleaned of soft tissues. The spines were then mounted in our custom built testing fixtures using 5/16 inch screws through levels L1 (proximally) and L5 (distally). The specimens were tested in rotation, lateral bending and as follows:

1. Axial rotation at 0.25Hertz, +/- 3 degrees, for 5 cycles.
2. Lateral Bending at 0.25Hertz, +/- 4mm for 5 cycles
3. at 0.25Hertz, +/- 4mm for 5 cycles

An axial compressive preload of 100-Newtons (25-pounds) was applied to each specimen before rotational testing. No compressive loading was applied to the specimens before or lateral bending. In axial rotation, the specimens were constrained in vices both proximally and distally. As for the and lateral bending testing, only the distal portion was constrained and the proximal end of the specimen was displaced. We measured the stiffness by a displacement controlled system and the corresponding load was measured by either linear or rotational actuators. No angular movement was measured.

The testing sequence used was:

1. Intact specimen
2. With the XSTOP implanted at L3-4
3. After the XSTOP was removed at L3-4

The testing frame used was an Instron 8874 biaxial servohydraulic testing frame (Instron Corporation, Norwood, MA). The testing frame was controlled with the Fast Track Console (Ver 5.8.2) software and the data was acquired using Instron's MAX (Ver 6.7). Plotting and analysis was conducted using Microsoft Excel (Microsoft Corp, Redmond, WA). These controls and software were all performed on a Dell Dimension 4100 (Dell, Corp, Round Rock, TX (Figure 1 & Figure 2). Five testing cycles were used on each step to improve reproducibility. The biomechanical properties of the specimens before and after implantation and removal of the X STOP were compared.

RESULTS

The stiffness values for all six specimens in rotation, lateral bending and are shown in table 1 with their respective average values and standard deviations (Table 1). The average stiffness values of the intact specimen in rotation, lateral bending and flexion/extension were 1.06 N-m/degree, 17.03 N-m/mm and 10.61 N-m/mm, respectively. With the X STOP implanted at L3-4, the stiffness values in rotation, lateral bending and flexion/extension were 1.06 N-m/degree, 14.97 N-m/mm and 10.76 N-m/mm respectively. After the X STOP was removed, stiffness values in rotation, lateral bending and flexion/extension were 0.92 N-m/degree, 14.20 N-m/mm and 9.32 N-m/mm respectively. The paired t-test analysis of the intact specimen vs. X STOP removed showed that after removing the X STOP each specimen had lesser stiffness than that of the intact specimen (Table 2-4).

Figure 1

Table 1. Absolute stiffness values of the specimens after tested intact, after implantation of the X STOP at L3-4 and after removal of the X STOP in rotation, lateral bending and flexion / extension. Average values and standard deviations are also sh

	ROTATION (N-m/deg)			LATERAL BENDING (N/mm)			FLEXION /EXTENSION (N/mm)		
Specimen	Intact	X STOP L3-4	X STOP removed	Intact	X STOP L3-4	X STOP removed	Intact	X STOP L3-4	X STOP removed
1	0.80	0.86	0.68	15.59	16.19	15.41	11.13	12.65	9.37
2	1.27	1.38	1.20	18.58	14.74	15.59	7.93	7.94	7.20
3	1.99	1.89	1.82	18.84	18.13	18.11	11.62	12.61	11.41
4	0.60	0.58	0.45	11.82	8.18	8.50	10.77	8.91	7.24
5	0.65	0.55	0.51	19.87	15.84	13.95	13.28	13.56	12.90
6	1.09	1.11	0.85	17.47	16.76	13.66	8.92	8.91	7.82
Average	1.06	1.06	0.92	17.03	14.97	14.20	10.61	10.76	9.32
SD	0.52	0.51	0.52	2.94	3.51	3.21	1.92	2.43	2.38

Figure 2

Table 2. Paired t-test analysis of the average stiffness of the specimen after X STOP has been removed from the L3-4 level vs. intact in axial rotation.

Intact (N-m/deg)	*Standard Deviation*	*X STOP Removed*	*Standard Deviation*	*P value*	*Power*	*Significant*
1.06	±0.52	0.92	±0.52	0.001	0.99	Yes

Figure 3

Table 3. Paired t-test analysis of the average stiffness of the specimen after X STOP has been removed from the L3-4 level vs. intact in lateral bending.

Intact (N-m/deg)	*Standard Deviation*	*X STOP Removed*	*Standard Deviation*	*P value*	*Power*	*Significant*
17.03	±2.94	14.20	±3.21	0.02	0.71	Yes

Figure 4

Table 4. Paired t-test analysis of the average stiffness of the specimen after X STOP has been removed from the L3-4 level vs. intact in flexion / extension.

Intact (N-m/deg)	*Standard Deviation*	*X STOP Removed*	*Standard Deviation*	*P value*	*Power*	*Significant*
10.61	**±1.92**	**9.32**	**±2.38**	**0.05**	**0.47**	**Yes**

Figure 5

Figure 1. The speciment being tested on the Instron 8874 (Instron Corporation, Norwood, MA)

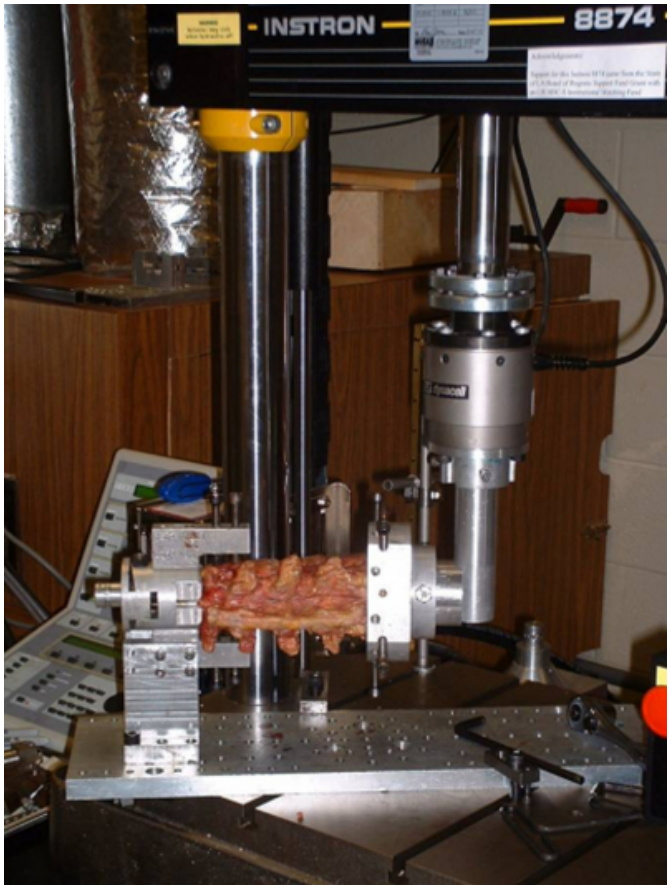

Figure 6

Figure 2.

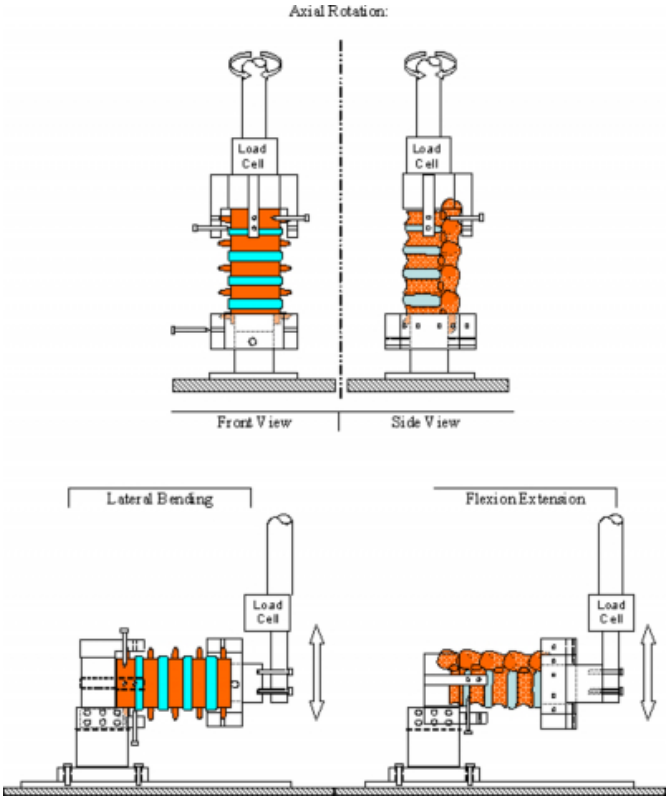

Diagram illustrating the methods and modes of testing the specimens using the Instron machine.

DISCUSSION

Lumbar spinal stenosis causing neurogenic intermittent claudication (NIC) is one of the most common conditions treated by spine surgeons in the United States. It is well known that the dimensions of the spinal canal change with posture. Encroachment of the neural elements at the degenerated segment of the lumbar spine is exacerbated by extension and relieved by flexion [2]. An interspinous process distraction device (X STOP, St. Francis Medical Technologies, Concord, CA) has recently been added to the armamentarium of procedures to treat NIC.

A randomized, prospective, multi-center study of the X STOP was carried out in the United States [5]. In this trial, 100 patients were randomized to receive the X STOP and 91 were randomized to receive conservative therapy. While this study demonstrated the effectiveness of this device in alleviating NIC symptomatology, it is important to mention that during the course of the trial, 4 patients had the implant removed and 5 patients elected to undergo a laminectomy due to lack of symptom relief.

Several studies have noted the effects of the X STOP on spinal biomechanics. Decreased intradiscal pressure and mean facet pressure were observed after implantation of this device [1,3,4]. The simultaneous use of the X STOP with other surgical modalities of spinal decompression and the effect on spinal stability has been described in the literature but to our knowledge no data has been published regarding the stability of the spine after removal of this implant [1].

By limiting extension of the affected segment, the X STOP prevents narrowing of the spinal canal and neural foramina, alleviating the patient's symptoms [2]. Anatomically and biomechanically speaking, this device appears to have many advantages. No bony or ligamentous removal is necessary, so preservation of the spinous processes, laminae, supraspinous and interspinous ligaments is possible. At the same time, spinal loading is redistributed and decreased facet and intradiscal pressures have been observed [3,4].

Since no substantial structural changes are induced by using this implant, its removal should not alter the biomechanics of the lumbar spine. While this statement seems logical, to our knowledge no studies have been done to prove it.

In the present study, six cadaveric specimens were tested in rotation, lateral bending and flexion/extension before any intervention (intact), with the X STOP placed at L3-4 and after the device was removed. The stiffness of the specimens in all ranges of motion was measured and compared before and after the implant had been used. Our results indicate that the stiffness of the specimens was significantly lower in all ranges of motion after the implant had been removed. The explanation for these biomechanical findings could be a combination of the defect left in the interspinous ligament by the implant, and the "distraction" effect of the implant on the facet joints (a well-described biomechanical effect of the X STOP is decreasing facet joint loading).
We hypothesized that the X STOP stretches the ligamentous fibers within the facet joints, rendering them lax after the device is removed. Further contributions to explain our findings should focus on structural analysis of the facets and disc space at the instrumented level.

The importance of our in vitro study resides in presenting the potential effects of interspinous process distraction on spinal stability if the implant has to be removed due to lack of symptomatic relief of NIC. Our results suggest that removal of the X STOP in these patients could mandate further stabilization procedures if they were to undergo traditional decompressive surgery (laminectomy). Perhaps our laboratory study could be validated if a cohort of patients who fail to improve with the X STOP are followed prospectively to evaluate if clinical instability develops after the implant is removed.

CONCLUSION

Insertion and removal of an interspinous distraction device significantly decreases the stiffness of the lumbar spine in all ranges of motion. This might have important implications in terms of stability in those patients in whom the implant is tried as a first line of surgical therapy and unsatisfactory results are obtained

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