

Stand-Alone Interspinous Fusion Devices Stabilize Lumbar Spines During Fatigue Loading

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INTRODUCTION: Lumbar spine degeneration can lead to a cascade of instability, nerve compression, pain, and neurological deficits that are often treated with fusion. Interspinous fusion devices (IFDs), placed between the spinous process of adjacent vertebrae to achieve posterior element distraction until fusion occurs, are gaining popularity as fusion devices. IFDs minimize operating time and invasiveness. IFD contact surfaces vary; common choices are textured, curved, or spiked, but it is unclear which are adequate. Biomechanical studies have evaluated the immediate stability provided by IFDs in a stand-alone condition but have not investigated long-term effectiveness with large volume cyclic loading. The purpose of this study was to determine if a spiked and / or textured implant provided stability during cyclic loading that modeled long-term use.

METHODS: Six lumbar spines were dissected to produce six L1-3 and six L4-S1 test specimens (3 female, 3 male; 50.7 ± 13.5 years). Each pair of specimens from a given spine were randomly divided between spiked and textured surface groups (Minuteman G1 and G5, Spinal Simplicity). The vertebrae on either side of the implant were instrumented with infrared markers for motion tracking (Certus, Northern Digital Inc.). Flexibility and fatigue testing were performed with a 6 DOF spine tester (Bose). Flexibility tests applied three 7.5 Nm 0.01 Hz sinusoidal loading cycles sequentially in flexion-extension (FE), lateral bending (LB), axial torsion (AT), and axial compression (AC). The flexibility tests were applied to the spine specimens in four different conditions: 'intact' with no implant, 'baseline' immediately after implantation, 'mid' after completion of 5,000 loading cycles, and 'post' after the stop criteria was met. FE, LB, AT, and AC ROM were calculated as the maximum relative motion of the vertebrae on either side of the implant during their respective third cycle of loading. All ROM data was normalized by the intact value. Cyclic loading was conducted at 1 Hz in FE for subsets of 1000 cycles per load level ranging from 0.5 Nm to 7.5 Nm increasing by 0.5 Nm (15000 cycles possible) or until failure. Failure was defined as three consecutive cycles with a ROM exceeding 125% of baseline motion. After the completion of fatigue testing, fatigue life (total cycles tested) and effective life (110% of baseline flexibility) were calculated. FE, LB, AT, and AC normalized ROM were each analyzed with a two-way repeated measures ANOVA with factors of implant type (spiked or textured) and test stage (baseline, mid, post); levels within a significant factor were compared pairwise with a Bonferroni correction. Fatigue and effective life were compared with t-tests to determine if differences due to implant type existed. Significant differences were indicated by p-values less than 0.05.

RESULTS: Test stage significantly impacted flexibility in FE ($p = 0.002$), LB ($p < 0.001$), and AT ($p < 0.001$). In FE, post had significantly more motion than baseline or mid. In LB and AT, motion increased significantly with each test stage. No significant differences were found between implant types (main effect or its interaction with test stage) in FE, LB, AT, or AC ROM. Cyclic loading resulted in consistent increases in motion with increasing load and cycle count. There were no significant differences in the fatigue ($p = 0.843$) or effective life ($p = 0.606$) due to spiked or textured surfaces (Figure 1).

DISCUSSION: The primary goal of spinal fusion implants is the reduction of motion to permit bone growth. FE ROM reductions to 31% and 34% of intact in baseline and 52% and 58% of intact in post indicate that both spiked and textured IFDs can effectively reduce motion (Table 1). The spiked and textured IFDs outperformed the Wallis IFD which only reduced FE ROM to 86.2% of intact motion [1]. Similarly, motion due to AC was reduced to 23% and 39% of intact in baseline by the spiked and textured implants, respectively. The spiked and textured IFDs reduced LB and AT motion whereas the Wallis IFD caused increases of 6.2% and 0.4%, respectively [1]. The current study does show an improved response to lateral bending and axial torsion ROM when compared to other devices such as Coflex, In-Space, Wallis, Daiam, and X-stop [2,3]. However, the impact of this residual motion in the coronal and transverse planes on interspinous fusion is unknown. Clinical evidence of fusion with standalone IFDs is limited, but early evidence points to a fusion rate of 84% which is comparable to fusion rates for PLIF or TLIF procedures [4,5]. While fatigue testing is common in spine biomechanics, it is novel in the realm of IFDs. This style of testing is effective in correlating the interface of the device to FSU to the success of the device. In turn, it is effective in predicting the longevity of the device and long-term success of fusion. On average, the effective life of the spiked device was 11515 cycles with a fatigue life of 12498 cycles, while the textured device had an effective life of 10907 cycles with a fatigue life of 12245 cycles. These results are comparable to those seen in other spine biomechanics studies for fusion devices [6].

SIGNIFICANCE/CLINICAL RELEVANCE: This study shows promising results for the stand-alone use of interspinous devices.

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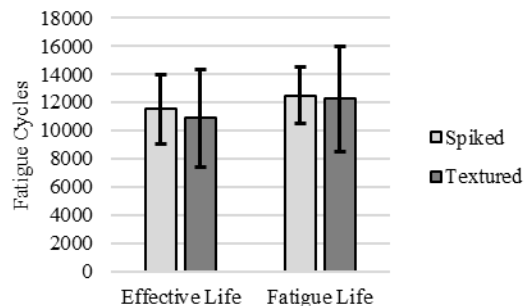


Figure 1: Average fatigue and effective life

Table 1: ROM during flexibility tests (mean \pm standard deviation)

	Spiked			Textured		
	Baseline	Mid	Post	Baseline	Mid	Post
FE	0.31 \pm 0.09	0.38 \pm 0.12	0.52 \pm 0.14	0.34 \pm 0.19	0.44 \pm 0.26	0.58 \pm 0.28
LB	0.88 \pm 0.14	0.94 \pm 0.16	1.01 \pm 0.16	0.81 \pm 0.26	0.88 \pm 0.29	0.94 \pm 0.26
AT	1.02 \pm 0.08	1.05 \pm 0.08	1.10 \pm 0.06	1.00 \pm 0.06	1.03 \pm 0.07	1.10 \pm 0.09
AC	0.23 \pm 0.10	0.25 \pm 0.10	0.26 \pm 0.10	0.39 \pm 0.40	0.40 \pm 0.29	0.42 \pm 0.28