Lumbar Spinal Stenosis Treatment with an Interspinous Spacer: 18 Month Mid-term Outcomes of a Randomized, Controlled Trial

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Introduction

The X-STOP device was the first interspinous device approved for the treatment of lumbar stenosis. The use of interspinous devices for the treatment of lumbar stenosis remains controversial. The purpose of this clinical trial was to evaluate the effectiveness of the Superion Interspinous Spacer (Vertiflex, Inc., San Clemente, CA) in patients with intermittent neurogenic claudication secondary to radiographically confirmed moderate lumbar spine stenosis (LSS).

Methods

This multicenter, prospective, randomized, controlled, investigational device exemption trial enrolled 145 patients with intermittent neurogenic claudication secondary to moderate LSS and unresponsive to conservative care. Patients were randomly allocated to treatment with the Superion (n=75) or X-STOP (n=70) interspinous spacer. (Figure 1) Main outcome measures included condition-specific Zurich Claudication Questionnaire (ZCQ), back function with Oswestry Disability Index (ODI), and back and leg pain severity with visual analogue scale (VAS) through 18 months post-treatment.

Results

ZCQ symptom severity and physical function scores improved 33% to 36% in both groups through 18 months (all $p<0.001$). ZCQ patient satisfaction scores at 18 months were 1.7±0.8 with Superion and 1.6±0.7 with X-STOP. Axial pain decreased from 55±28 mm at pre-treatment to 23±26 mm at 18 months in the Superion group ($p<0.001$) and from 55±27 mm to 26±28 mm with X-STOP ($p<0.001$) ($p=0.28$ between groups). Extremity pain decreased from 67±24 mm at pre-treatment to 20±28 mm at 18 months with Superion ($p<0.001$) and from 68±24 mm to 22±28 mm with X-STOP ($p<0.001$) ($p=0.71$ between groups). (Figure 2) Back function similarly improved with Superion (39±13% to 19±15%; $p<0.001$) vs. X-STOP (40±12% to 20±17%; $p<0.001$) ($p=0.46$ between groups). Oswestry scores improved with both the X-STOP and Superio devices. (Figure 3)

Conclusions

Clinical improvements in axial and extremity pain and function are similarly maintained through 18 months post-treatment with the Superion and X-Stop interspinous spacers. This study adds additional clinical data regarding the effectiveness of interspinous devices for the treatment of lumbar stenosis. Patients with symptoms relief in flexion may be appropriate candidates for an interspinous spacer.

Vertiflex Device on AP and lateral X-rays

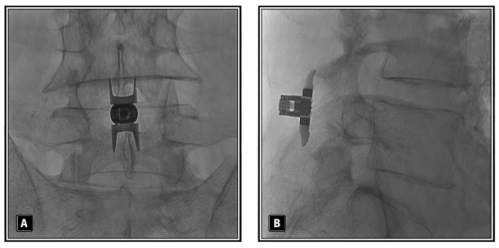

Figure 1

Learning Objectives

By the conclusion of this session, participants should understand the comparative effectiveness of interspinous spacers in patients with lumbar spinal stenosis.

References

VAS leg pain scores versus time

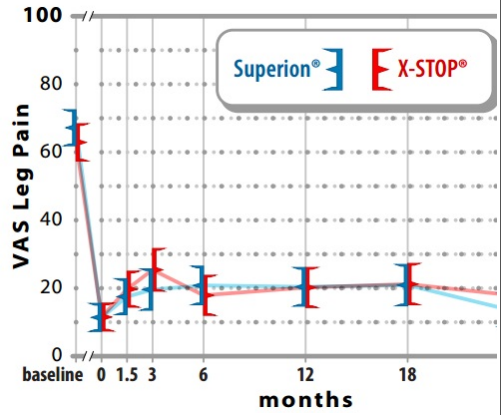

Figure 2

ODI versus time

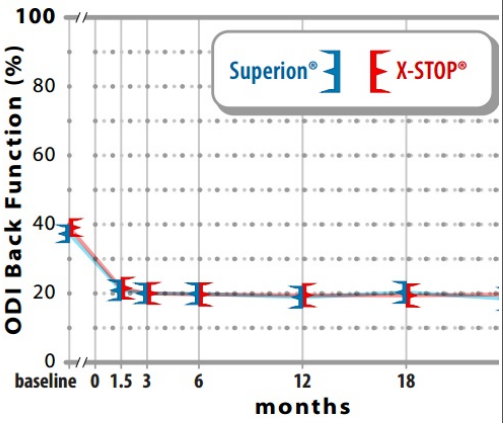

Figure 3