

Nerve Root Sedimentation Sign: Can It Predict the Success for Spinous Process Spacers?

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Introduction

- Use of interspinous process devices is a relatively new, less invasive surgical method to manage mild-moderate lumbar stenosis symptoms (LSS).
- Symptomatic relief is not seen in all patients undergoing this procedure.
- Nerve root sedimentation is one MRI parameter used to predict success of clinical outcomes in patients with symptomatic LSS.

Purpose

Determine the feasibility of nerve root sedimentation signs to predict long-term clinical outcomes in interspinous process device implanted patients with LSS.

Methods

- Prospective multicenter FDA IDE (Superion™ and X-STOP®) database used.
- Interspinous process implanted patients (n=177) were aged >45, suffered moderate symptoms of neurogenic intermittent claudication secondary to diagnosis of LSS at 1 or 2 contiguous levels from L1 to L5.
- Axial T2 weighted MRI images used to find nerve root sedimentation sign. **Positive nerve root sedimentation sign** was the absence of normal nerve root sedimentation in at least 1 axial T2 weighted MRI sequence image (at level above or below). **Negative nerve root sedimentation sign** was normal nerve root sedimentation.

- Patients grouped based on nerve root sedimentation signs (positive/negative) and compared clinical outcomes. **(Figure 1)**
- Preoperative, 1 and 2 year postoperative clinical outcomes measured using Oswestry Disability Index (ODI).
- Clinical outcomes were compared in the groups. P<0.05 was considered statistically significant.

Figure 1: Nerve Root Sedimentation Signs

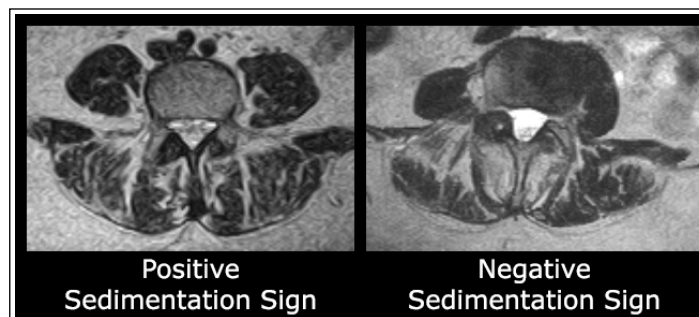


Table 1: All Patients with Interspinous Implants (Image Quality 3 and Determination 5)

	Positive Sedimentation Sign	Negative Sedimentation Sign	P value
Preop ODI	37±11 (n=116)	39±12 (n=61)	0.45
6 weeks ODI	21±15 (n=109)	28±18 (n=61)	0.012
1 year ODI	18±15 (n=88)	24±17 (n=53)	0.042
2 year ODI	16±14 (n=135)	22±18 (n=73)	0.039

Results

- Group 1 had positive nerve root sedimentation sign (n=116); Group 2 had negative nerve root sedimentation sign (n=61).
- No statistical difference in preoperative ODI values seen between groups.
- High clinical and statistically significant ODI improvement seen from preoperative to 2 year follow-up for Group 1 (17 point gain; p<0.0001) and Group 2 (22 point gain; p=<0.0001).
- Six-week, 1 and 2 year follow-ups, statistical difference seen between Group 1 and Group 2 (p=0.012, p=0.04, p=0.039, respectively), but differences just reached statistical significance; mean difference in ODI values were small at ~ 6 which is at edge of clinical relevance. **(Table 1)**

Conclusions

Good clinical improvement in ODI from preoperative to 2 year follow-up occurred in positive and negative nerve root sedimentation sign groups. Differences between groups, although statistical, were not clinically meaningful.

Learning Objectives

1. Clinical improvement was noticed in both abnormal and normal nerve root sedimentation patients who were managed by interspinous process devices for symptomatic lumbar stenosis.
2. Though clinical improvement was statistically different between both abnormal and normal nerve root sedimentation patients, it was not clinically meaningful.

References:

None