ACE Report - Author Verification

Introduction

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Online title

Trabecular metal spacers with or without pedicle screw fixation in posterior lumbar fusion

Article title

Trabecular metal spacers as standalone or with pedicle screw augmentation, in posterior lumbar interbody fusion: a prospective, randomized controlled trial

Link to Journal Abstract

http://link.springer.com/article/10.1007%2Fs00586-015-4229-y

Journal

Euro Spine J

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Therapy

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Journal Level of Evidence

Specialty 1

Spine

Specialty 2

OE Level of Evidence

Level II - Randomized Trial

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None disclosed

Synopsis

80 patients with chronic back pain and single-level degenerative disc disease were randomized to receive posterior lumbar interbody fusion with or without additional pedicle screw fixation. The purpose of this study was to compare radiological and clinical outcomes of Trabecular Metal spacers in terms of their ability to achieve a stable construct up to 6-years postoperatively. Results at 6-years displayed a similar rate of stable construct achieved in patients treated with trabecular metal spacers alone in comparison to those receiving additional pedicle screw fixation. Significant improvements were noted in both groups in terms of pain and function scores up to 24-months postoperatively, with no differences between groups.

Why was this study needed now?

Arthrodesis of lumbar vertebral segments using an interbody device and additional fixation is a common treatment of various spine disorders. Posterior lumbar interbody fusion (PLIF) is frequently performed and the stability of the construct depends on the characteristic of the device used. Additional pedicle screw fixation has been shown to increase stability but is not always beneficial. Standalone interbody fusion devices address the concerns associated with additional fixation but may have higher failure rates. Given the lack of evidence regarding the use of spinal trabecular metal spacers, the current study compared the ability of trabecular metal posterior lumbar interbody fusion with and without additional pedicle screw fixation in achieving a stable construct for the treatment of single-level lumbar degenerative disc disease.

What was the principal research question?

How did the radiological and clinical outcomes of Trabecular Metal spacers in posterior lumbar interbody fusion compare, with and without additional pedicle screw fixation, in terms of the ability to achieve a stable construct for the treatment of single-level lumbar degenerative disk disease?

Demographic and Methodological Characteristics

Population	80 patients were included from February 2003 to April 2004. Inclusion criteria were patients over the years of 18 with low back pain lasting for 6 or more months and non-responsive to conservative management, patients reporting with persistent low back, groin and/or non-radicular leg pain that worsened with axial loading and improved when lying down, and single-level degenerative disc disease confirmed by MRI. The Trabecular Metal (Zimmer Spine, USA) device, a porous tantalum interbody implant with an interconnected porous structure was used in both groups.
Intervention	Stand alone group: patients received stand alone posterior lumbar interbody fusion with the trabecular metal spacers (n=40, 33 completed; Mean final follow-up: 6.2 [6.1-7.6] years; Mean age: 47.28 +/- 9.9; 26M/14F).
Comparison	Pedicle screw fixation group: patients received posterior lumbar interbody fusion with the trabecular metal spacers, and after implantation of both devices the remaining posterior instrumentation was completed by securing the two rods to 4 pedicle screws (ASTM F-1 36; Zimmer Spine, USA) that were inserted with their positioning verified via lateral and anteroposterior fluoroscopy (n=40, 38 completed; Mean final follow-up: 6.8 [6.0-7.7] years; Mean age: 50.10 +/- 14.37; 24M/15F).
Outcomes	The primary radiological outcome measure was the 6-year implant stability and absence of migration and/or subsidence, assessed via X-ray (lateral, anteroposterior, and left and right lateral oblique and lateral flexion/extension views). A construct was considered stable when no halo was seen around implants and when movement of the two adjacent vertebral bodies was 5 degrees or less of flexion and extension on lateral X-rays. Subsidence was defined as significant loss of postoperative disc height and/or migration of the cage beyond the cortical endplate. Clinical outcomes included the Oswestry Disability Index (ODI), a 10-point visual analogue scale (VAS) for intensity of low back pain, quality of life measured via the SF-36, and complications.
Methods	RCT: prospective.
Time	The primary radiological assessment was conducted at 6 years. Clinical outcomes were assessed pre-operatively and at 6 weeks, 6, 12, and 24 months postoperatively.

Why is this study believable? (Risk of Bias)

1.	Was the allocation sequence adequately generated?	UNCERTAIN
2.	Was allocation adequately concealed?	YES
3.	Blinding Treatment Providers: Was knowledge of the allocated interventions adequately prevented?	NO
4.	Blinding Outcome Assessors: Was knowledge of the allocated interventions adequately prevented?	UNCERTAIN
5.	Blinding Patients: Was knowledge of the allocated interventions adequately prevented?	UNCERTAIN
6.	Was loss to follow-up (missing outcome data) infrequent?	YES
7.	Are reports of the study free of suggestion of selective outcome reporting?	YES
8.	Were outcomes objective, patient-important and assessed in a manner to limit bias (ie. duplicate assessors, Independent assessors)?	YES
9.	Was the sample size sufficiently large to assure a balance of prognosis and sufficiently large number of outcome events? (A minimum of 500 patients per group to ensure external validity)	NO
10.	Was investigator expertise/experience with both treatment and control techniques likely the same (ie.were criteria for surgeon participation/expertise provided)?	YES

What are the important Findings?

- At 6 years, the rate of stable construct between groups was not significantly different (Stand alone group: 94% vs. Pedicle screw group: 97%; p=0.594)
- At 6 years, instability of the superior adjacent level requiring additional surgical treatment was observed in 3 patients in the stand alone group and 1 in the pedicle screw fixation group (p=0.33)
- ODI and low back pain VAS scores improved significantly in both groups from preoperative values up to 24 months postoperatively (ODI: $p<0.0001$ | VAS: $p<0.05$), however, no significant differences were noted between groups at any point (both $p>0.05$)
- Physical health scores of the SF-36 improved significantly in both groups from preoperative values ($p<0.0001$). These scores were not significantly different between groups at any point ($p>0.05$)
- Mental health scores of the SF-36 were stable from preoperative values to 24 months postoperatively in both groups ($p>0.05$)
- Complications in the stand alone group included 2 dural tears (5%) and in the pedicle screw group included 4 dural tears (10%) and 1 pedicle screw revision (2.5%)
- Average blood loss was significantly greater in the pedicle screw fixation group ($p<0.01$), procedure duration was significantly greater in the pedicle screw group ($p<0.005$), and length of hospital stay was similar between groups ($p=0.11$)

What should I remember Most?

At 6-year follow-up, X-rays displayed a similar rate of stable construct in patients treated with a stand alone trabecular metal spacer in comparison to those that received additional pedicle screw fixation. Significant improvements were noted in both groups in terms of ODI scores, low back pain, and physical health SF-36 scores up to 24 months postoperatively, with no significant differences between groups. Complications were similar between groups, but greater blood loss and duration of procedure were associated with additional pedicle screw fixation.

How will this affect the care of patients?

The results of this randomized controlled trial suggest that stable constructs on X-rays may be achieved at similar, high rates for both trabecular metal spacers with or without additional pedicle screw fixation in posterior lumbar interbody fusion for the treatment of single-level lumbar degenerative disc disease, at 6-year follow-up. Clinical outcomes at 24 months were comparable between groups, showing significant improvements in pain and function in comparison to preoperative values. Future studies with larger population sizes and differing cohorts of patients are required to further determine if a significant long-term difference exists between these treatment methods.