Stabilization Using PEEK Rods - Clinical Outcomes in Patients with Grade 1 Degenerative Lumbar Spondylolisthesis

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ABSTRACT: Originates from Stabilization Using Peek Rods - Clinical outcomes in patients with grade 1 degenerative lumbar spondylolisthesis White Paper, Invibio Biomaterial Solutions™, 2018

LEVEL OF EVIDENCE: Level 2a Retrospective Cohort Study

Introduction

Instrumented rigid arthrodesis is commonly used for the surgical treatment of lumbar degenerative diseases. Nevertheless, rigid materials may contribute to stress shielding in the anterior column leading to risk of implant failure and adjacent segment disease (ASD),[1-10] responsible for a high rate of further surgery. Polyether ether ketone (PEEK) provides a modulus of elasticity similar to that of bone[11] that may limit these risks. Comparative biomechanical studies have shown that PEEK systems provide intervertebral stability comparable to rigid constructs, while allowing for a better redistribution of segmental loads and a reduced stress at the bone-screw interface.[12-15] This retrospective study was carried out to evaluate the efficacy and the safety of the flexible stabilization system Initial VEOS PEEK®-Optima (Innov'Spine, France) without arthrodesis in patients treated for grade 1 degenerative lumbar spondylolisthesis.

Methods

Out of a homogeneous cohort of 66 patients operated with the flexible stabilization Initial VEOS PEEK-Optima Osteosynthesis System (made with PEEK-OPTIMA™ polymer from Invibio Biomaterial Solutions, Figure 1) without arthrodesis for treatment of grade 1 degenerative lumbar spondylolisthesis associated with severe canal stenosis, 38 were included in the study (10 patients lost to follow-up and 18 patients with neurological disease, other spinal pathology, vertebral fracture, severe osteoporosis, neoplasia, inflammatory rheumatologic disease or active psychiatric illness were not included). Surgery was performed using PEEK-OPTIMA™ Rods and Pedicle Screws (Initial VEOS PEEK-Optima Osteosynthesis System), without arthrodesis and was associated with a foraminotomy. The patients' follow-up ranged from 1 to 4 years (mean 24 months). Clinical and radiological outcomes were assessed using the Oswestry Disability Index (ODI), complications, CT-scan, dynamic and static X-rays. Patient satisfaction was also investigated using the Patient Satisfaction Index (PSI).

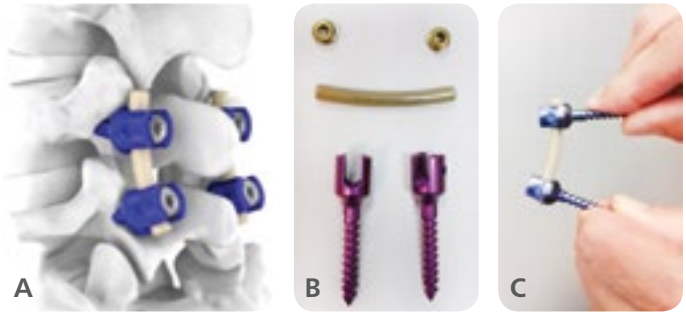


Image provided courtesy of Innov'Spine

Figure 1: The flexible stabilization system INITIAL VEOS PEEK®-Optima Osteosynthesis System (A) with PEEK-OPTIMA Rods and Pedicle Screws (B). PEEK rods provide elastic modulus similar to that of bone that offers both adequate rigidity for fusion and a flexibility that limits the stress created by rigid rods (C).

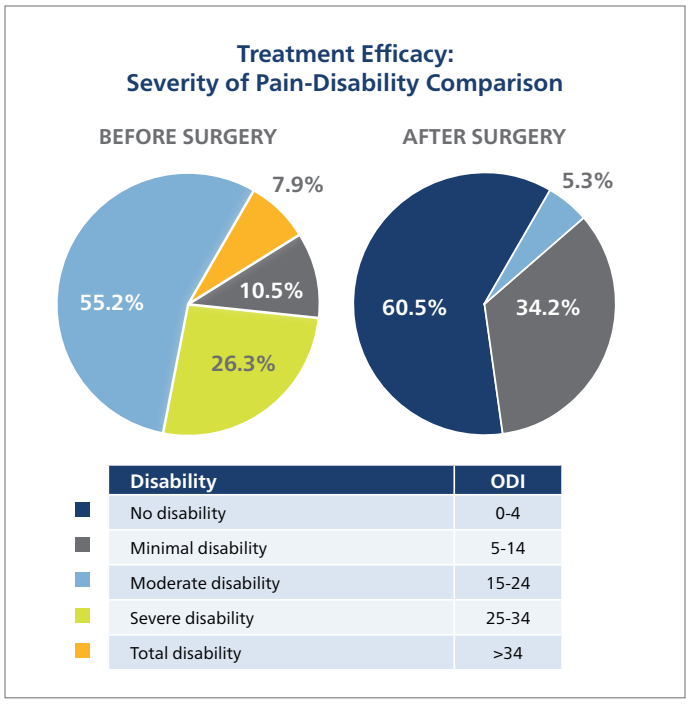
Results

The efficacy of the treatment was evaluated by comparing the preoperative and postoperative ODI. The average ODI decreased from 50.53% to 8.00% and the rate of patients with moderate to total disability (ODI >15) from 89.5% (N=34) to 5.3% (N=2) after 1 to 4 years of follow-up. At the end of follow-up, 60.5% of the patients (N=23 patients) had no more disability and no patient (0%) had severe or total disability (compared to 34.2%, N=13 before surgery). Results are summarized in Table 1 and Figure 2 illustrates the improvement of pain-disability after surgery. Static and dynamic radiographs showed a complete integration of the material without breaking or mobilization. Mobility on dynamic flexion/extension X-rays was observed in 63.2% of cases (N=24) and all the patients showed a perfect tolerance to the flexion/extension mobilization on clinical examination. Two (2) complications (one superficial sepsis and one misplaced screw) were associated with the

Treatment Efficacy: ODI Value Comparison

ODI Range	Before Surgery N = 38 (%)	After Surgery N = 38 (%)
0 – 4: no disability	0 (0%)	23 (60.49%)
5 – 14: minimal disability	4 (10.52%)	13 (34.19%)
15 – 24: moderate disability	21 (55.23%)	2 (5.26%)
25 – 34: severe disability	10 (26.3%)	0 (0%)
> 34: total disability	3 (7.89%)	0 (0%)

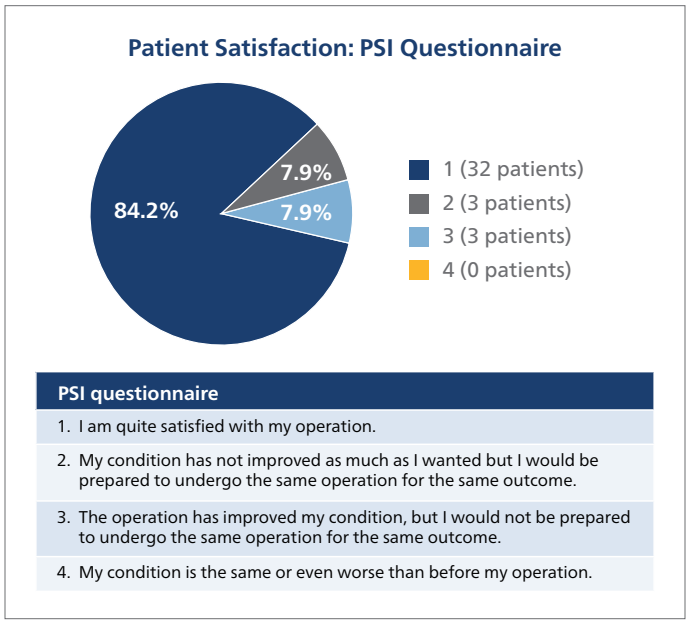
Table 1: Distribution in degrees of severity of pain-disability before and after surgery (1 to 4 years following surgery).



Disability	ODI
No disability	0-4
Minimal disability	5-14
Moderate disability	15-24
Severe disability	25-34
Total disability	>34

Figure 2: Improvement of the pain-disability after surgery (1 to 4 years following surgery).

surgical procedure and required an additional surgical procedure. Clinical outcomes were supported by patients' satisfaction, using the PSI questionnaire, with a majority of patients (84%) quite satisfied with the treatment (Figure 3).



PSI questionnaire
1. I am quite satisfied with my operation.
2. My condition has not improved as much as I wanted but I would be prepared to undergo the same operation for the same outcome.
3. The operation has improved my condition, but I would not be prepared to undergo the same operation for the same outcome.
4. My condition is the same or even worse than before my operation.

Figure 3: Patient satisfaction evaluated using the PSI questionnaire (answers to questionnaires collected between 1 to 4 years of follow-up)

Conclusion

The flexible Initial VEOS PEEK-Optima Osteosynthesis System, made from PEEK-OPTIMA Natural polymer, used as a rods-screws construct alone (without arthrodesis or instrumented interbody fusion) provides a safe and effective stabilization showing substantial improvement in ODI and a low rate of serious complications and reoperations, that may be considered as an alternative solution to rigid fusion systems in the treatment of grade 1 degenerative lumbar spondylolisthesis. Long-term, multicenter and comparative studies are nevertheless needed to demonstrate improved benefits over rigid fixation. ▲

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* Since 2017, Dr. Pablo Bouillot, has provided ad hoc consultancy services to Invibio Ltd.

* The abstract and conclusions presented have been provided by a practicing orthopedic surgeon. His view and experiences are his own and do not necessarily reflect those of others. "Invibio" disclaims any liabilities or loss in connection with the information herein.

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