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PEEK-OPTIMA® Spinal Rods: A Retrospective Clinical Study

Abstract

When treating degenerative lumbar spinal disease, a posterior pedicle screw construct with rigid (metal) rods are usually selected. However drawbacks due to the hyper rigidity of the construct have been reported. With PEEK-OPTIMA® Spinal Rod Components, a solution can be found to bridge the gap between rigid and dynamic stabilisation systems.

The objective of this paper is to report a series of 44 patients operated by two surgeons with PEEK-OPTIMA Spinal Rod Components, INITIAL / VEOS PEEK by Innov'spine (France), with a mean follow up of 25 months. No rod breakage was reported, re-intervention rate was 6.8%, ODI score of 25.7%, PSI of 1.8. The degenerative process was accelerated for only 7% of the adjacent levels and stable or improved for 84% of the patients.

Based on the results of this clinical study, the use of PEEK-OPTIMA Spinal Rods is a safe alternative to rigid systems in the treatment of low back pain. Longer follow up is still needed to evaluate the impact on adjacent levels disease.

Introduction

The global market for posterior pedicle screw systems in 2015 is estimated to be over $3.5 billion, and is forecasted to reach a value of almost $6 billion by 2020,[1] making it the largest segment of the spine surgery market. The vast majority of rods used in these systems are composed of titanium, stainless steel or cobalt chrome metals, but several manufacturers have introduced rods made with PEEK-OPTIMA in recent years. These rods allow for less stiff, or semi-rigid constructs, that can bridge the gap between rigid metal screw/rod constructs and constrained dynamic stabilization constructs.

PEEK-OPTIMA Spinal Rods have been recently introduced on the market with the objective of providing a better anterior/posterior load sharing[5] and reduced stress at the bone screw interface,[6] potentially reducing the risk of implant fracture and bone screw loosening. Semi-rigid PEEK-OPTIMA Spinal Rods also match more closely to the physiological movement at the adjacent level, possibly reducing the risk of Adjacent Disc Disease.[4]

In order to evaluate the clinical efficacy and safety of PEEK-OPTIMA Spinal Rod devices and confirm the clinical advantages, a retrospective clinical study has been carried out in collaboration with Innov'Spine using their INITIAL / VEOS PEEK device.

Material and Method

A protocol[2], specifying the requirements of this study, has been drafted according to the requirements of the European Council Directive 93/42/EEC of 14 June 1993, the standard ISO 14155 1 and 2, the standard 1993/42 amendment 2007/47 and the "Good Clinical Practices: Consolidated Guideline," ICH EWG E6, May, 1996.

This protocol has been submitted and approved by the National Authority Bodies: Commission Nationale de l'Informatique et des Libertés (CNIL) and to the Comité Consultatif sur le Traitement et de l'Information en matière de Recherche dans le domaine de la Santé (CCTIRS) in order to comply with local ethical and regulatory requirements.

The study was carried out with the two French Health Care Professionals (2 centres) having adopted to use the PEEK-OPTIMA® Spinal Rod System, INITIAL / VEOS PEEK.

The inclusion criteria were:

- Patients treated for a degenerative disease of the lumbar vertebral column, from T10 to S1, in the disc area, for an unstable lumbar stenosis, grade 1 or 2 spondylolisthesis, a recurrent disc hernia or an unstable degenerative disc disease, confirmed radiologically
- Patients treated with the initial osteosynthesis system - INITIAL / VEOS PEEK
- Surgery performed before 30th December, 2013
- Surgery performed after 1st June, 2011
- The patient must be 21 years of age or over at the time of surgery
- The patient has undergone a full set of pre-operative and post-operative radiographs
- The patient has agreed to participate and to disclose his/her Personal Health Information (PHI) and has signed the informed consent form

The exclusion criteria were:

- Patients treated for a different non-degenerative pathology of the spine, such as trauma, tumour or malformation
- Surgery performed after 30th December, 2013
- Surgery performed before 1st June, 2011
- Patients treated with a different osteo-synthesis device

The clinical results were analysed retrospectively by looking at the population characteristics, type of surgery, and the level(s) instrumented. The patients were contacted for their consent to participate and then they were asked to answer a questionnaire in order to evaluate their satisfaction with the following indexes: Oswestry Disability Index (ODI), Visual Analog Scale (VAS) and Patient Satisfaction Index (PSI).

Also, re-intervention rate, implant breakage and migration, degeneration of the upper and lower adjacent level (evaluation of the disc height) were recorded.

Among 94 screened patients, 44 (46.8%) were included.

CHARACTERISTICS		VALUES
Age (years)	Mean (std)	66.1 (10.4)
	Median (Q1-Q3)	67.5 (57.5-73.5)
Sex - N (%)	Men	18 (40.9)
	Women	26 (59.1)
Smoking status – N (%) Before surgery	Ex-smoker	16 (37.2)
	Smoker	10 (23.3)
	Non smoking	17 (39.5)
	Missing	1
Smoking status – N (%) Current status	Ex-smoker	11 (26.2)
	Smoker	7 (16.7)
	Non smoking	24 (57.1)
	Missing	2
History of lumbar surgery – N (%)		15 (34.1)

Table 1. Characteristics of included patients

Material and Method (Cont.)

Mean age was 66.1 years (std 10.4), 18 men were included (40.9%) and 26 women (29.1%).

Location of pain was mostly lumbo-radicular (N=30, 68.2%). Main indication for surgery was spinal stenosis (N=29, 44.6% of all indications, which could be multiple for the same patient). The most frequent level of surgery was L4-L5 (N=17, 38.6%). Surgery was performed on 1 level in 24 cases (54.6%), and on 2 or more levels in 20 cases (45.5%).

Results

Postoperatively, among the 44 patients included in this study 38 patients (86.4%) attended at least 1 follow-up visit (excluding the specific follow up visit for this study) and 43 patients (97.7%) were evaluated for radiological criteria (flexion / extension and dynamic). All patients completed the study questionnaire in order to evaluate their satisfaction.

The mean time between surgery and questionnaire was 25.3 months (std 7.0), with a median of 28 months.

The mean ODI (Oswestry Disability Index) was 25.7% (std 21.0%), with a median of 22%.

Mean ODI score was 34.2% (std 24.6%) for current smokers or ex-smokers vs. 22.1% (std 19.9%) for non-smokers (p=0.13).

ODI CLASSES	N (%)
0-4 : no incapacity	8 (18.2)
5-14 : light incapacity	9 (20.5)
15-24 : moderate incapacity	7 (15.9)
25-34 : severe incapacity	7 (15.9)
>34 : complete incapacity	13 (29.6)

Table 2. ODI Score.

The mean PSI score (evaluation of satisfaction on a scale ranging from 1 – completely satisfied – to 4 – same or worse condition than before surgery) was 1.8 (std 1.0), with a median of 1.

Results for pain evaluated on a visual analog scale (with a maximum value of 10) were:

Pain when moving = 4.1 (range 3.2 - 4.9)

Pain when standing up = 3.5 (range 2.7-4.4)

Pain when sitting = 3.1 (range 2.2 - 4.0)

Characteristics	Mean [95%CI]
Pain when moving	4.1 [3.2-4.9]
Pain when standing up	3.5 [2.7-4.4]
Pain when sitting	3.1 [2.2-4.0]

Table 3. Pain Evaluations.

Re-intervention rate was 6.8% (N=3), failure rate was 11.6% (N=5, rupture of the screw shank, no rod breakage reported), and migration rate was 4.7% (N=2). Correlation was found between the rupture rate and the number of level (p=0.15) with 4.2% (N=1 for 24 patients treated for 1 level surgery) and with 21.1% (N=4 for 19 patients treated for 2 or more levels).

Characteristics	1 level N (%)	2 or more levels N (%)	p
Ruptures	1/24 (4.2)	4/19 (21.1)	0.15*

*Fisher exact test

Table 4. Association between ruptures.

Main complications leading to re-operation were due to constant pain (N=2), and screw disassembly (N=1). For the latter, failure was located on the center area of the pedicular screw threads and detected during radiological examination.

Criterion	N	Frequency [95%CI]
Absence of re-intervention	41/44	93.2% [85.7%-100%]
Absence of rupture	38/43	88.4% [78.8%-98.0%]
Absence of migration	41/43	95.3% [89.1%-100%]

Table 5. Absence of Complications.

Looking at the degenerative process on upper and lower levels (N=86), no change was observed for 74.4% of the cases (N=64), improvement (disc height restored) for 9.3% (N=8), degeneration accelerated for 7.0% (N=6) and data was missing for 9.3% (N=8).

Characteristics	Lower level (N)	Upper level (N)	Total	Frequency (%)
No change	34	30	64	74.4%
Worsening	1	5	6	7.0%
Improvement	2	6	8	9.3%
Missing	6	2	8	9.3%

Table 6. Degeneration process evolution

Discussion and Conclusion

Spinal rods composed of metal have been used successfully for many years. However, they are not without their challenges – from rod breakage and screw loosening to accelerated degeneration at adjacent spinal segments.[10] The high stiffness inherent with all-metal constructs are believed to contribute to these clinical challenges and negatively impact patient outcomes.[1-5] In response, surgeons have indicated that a range of rod stiffness would benefit patients.[5]

PEEK-OPTIMA® Polymers from Invibio are increasingly being used as an alternative to metal rods to address these challenges. These semi-rigid constructs bridge the gap between very stiff metal rod and screw systems and dynamic stabilization constructs.

For more than a decade, PEEK-OPTIMA Polymers from Invibio have been utilized in spinal fusion surgeries, predominantly in the form of load-bearing cages. Today, PEEK is the most popular biomaterial for interbody fusion devices[3] for several reasons:

- Mechanical strength
- Modulus similar to cortical bone
- Imaging compatibility
- Biocompatibility

Spinal rod components made from PEEK-OPTIMA Polymers are being used to achieve semi-rigid fixation with posterior pedicle screw systems. The strength and flexibility these rods provide improve load sharing, allow more physiologic loading at adjacent levels, which may decelerate degeneration, and reduced stress at the bone-to-screw interface, which may prevent screw pull-out, especially in patients with questionable bone quality.[5-9]

In comparison to titanium (Ti), PEEK-OPTIMA Spinal Rods provide significantly more anterior loading in biomechanical tests.[6] This may allow a greater share of the force to be applied to the anterior graft, providing additional stimulus for bone to form and fusion to occur. Case studies are beginning to report short term clinical results indicating that PEEK-OPTIMA Spinal Rods:

- Perform as well as Ti rods for achieving fusion[8-11]
- May reduce the incidence of post-operative screw loosening[8-11, 15, 19]
- May maintain perceived reduction in pain longer than Ti rods*[12]

PEEK-OPTIMA Spinal Rod Components offer strength and flexibility that significantly reduce the range of motion[5,13] to stabilize the treated segment while allowing[14] for enough freedom to maintain physiological movement on adjacent upper and lower segments.[13] As a result, clinical results increasingly suggest that PEEK-OPTIMA Spinal Rod Components preserve or slow down the degeneration of adjacent discs.[15]

PEEK-OPTIMA Spinal Rod Components have been demonstrated to reduce screw toggling and maintain better screw purchase in biomechanical tests,[7] which may benefit patients with questionable bone quality. This leads to reduced stress at the bone-to-screw interface, which may prevent screw pull-out and device failure.*[7,16]

Finally, the stabilisation of the spinal unit after fatigue testing is also three times greater with PEEK-OPTIMA Spinal rods versus titanium rods,[17, 18] which correlates with the above statements, reducing the stress at the bone-to-screw interface while providing a significant range of motion reduction.

The main objectives of this study were to evaluate the patient satisfaction rate and the complications related to the use of PEEK-OPTIMA Spinal Rod Components.

*Biomechanical testing is not indicative of clinical performance

Discussion and Conclusion (cont.)

Based on this retrospective clinical study, we can say that the patient's satisfaction rate, when treated with PEEK-OPTIMA Spinal Rods, is as good or better than the one reported in the literature, for patients treated with titanium rod, with a mean ODI score of 25.7% versus 24[19] - 30%[15] for PEEK rods papers, and between 11.61[22] to 24.9%[21] for PLIF technique, and up to 34.5%[20] for MIS technique with a rigid system.

In terms of revision rate, this study reports a rate of 6.9%, which is in agreement with the literature for PEEK rod cases, ranging from 0%[19] to 19%.[8] It is also important to notice that no PEEK-OPTIMA Spinal Rod breakage was observed. Re-operation was decided because of screw misplacement to remove pain. We have also observed that the risk of revision and complication increased by 23.5% when the number of levels treated increase from one to two or more levels.

Finally, it is important to highlight the low rate of degenerative process for only 7% of the levels and an improved or identical state for 84% of the adjacent levels (9% of the data were missing).

The main objectives of this study were to evaluate the patient satisfaction rate and the complications related to the use of PEEK-OPTIMA Spinal Rod Components. It confirms the following points:

- No rod breakage, no screw pulled out of the pedicle
- Stabilisation of the segment treated
- Slowdown of the degenerative process on the adjacent levels
- Good level of patient's quality of life

Based on this retrospective clinical study and the points above, the use of PEEK-OPTIMA Spinal Rods can be considered as safe and effective, or possibly better than, rigid systems in the treatment of low back pain. Longer follow up is still needed to evaluate and validate the impact on adjacent level disease.

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