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Semi-rigid lumbar spine fixation with PEEK rods as a treatment option for mono-segmental degenerative disk disease

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ABSTRACT

Long lasting back pain due to degenerative disc disease is one of the major reasons for reduced quality of life and work incapacity. In some of these patients conservative treatment will not improve back pain significantly. Therefore fusion surgery as a surgical option is offered to these patients. The main aim of this kind of treatment is the reduction of segmental motion leading to an improvement in pain. Rigid fixation leads to high fusion rates but may also contribute to stress shielding and adjacent segment degeneration.

Therefore a semi-rigid stabilization with PEEK rods may be an option because it is associated with less implant related rigidity and is a less invasive procedure. The aim of this retrospective study was to evaluate the improvement in back pain after minimally invasive semi-rigid lumbar stabilization with screws and PEEK rods in 45 patients and to identify potential implant failures during a follow up of two years. Six weeks after surgery the patients showed a significant improvement in their back pain, which persisted during the whole observation time of two years ($p<0.01$). All patients who were still in working life returned to their jobs without extended work incapacity. No implant related complication associated with the surgical procedure was detected. During the follow up time of two years no implant failure was observed.

Keywords: PEEK rods; Semi-rigid stabilization; Lumbar degenerative disc disease (DDD); Lumbar fusion; Chronic low back pain

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Introduction

Back pain due to lumbar degenerative disc disease (DDD) is a common symptom in patients from middle age onwards. The degeneration is initiated by disturbed nutrition of the discs. The exchange of metabolites in intervertebral disks work by diffusion from the adjacent vertebral bodies. Due to reduced microcirculation at the endplates the penetration of nutrients into the intervertebral disk decreases to a critical level resulting in degeneration [19]. Remaining metabolites in the disk activate a proinflammatory cascade which distributes different substances like prostaglandins or cytokines. These substances influence the nociception at the outer parts of the annulus causing back pain [2, 4, 9]. MRI images indicate the onset of degeneration by so called black disks which are a sign of decreased intradiscal water content. Progression of the degeneration leads to reduced disk height and additional changes (Modic signs) in the endplates can be observed on imaging [26].

A secondary factor influencing back pain is related to the facet joints. Here many sensory and autonomic nerve can be detected [27]. Spondylarthrosis induces an inflammatory reaction which stimulates nociceptive nerve endings resulting in a pain response. Additionally, facet joint mechano-receptors are also involved in initiating the pain response. Taking into account all these factors it appears that the main pathophysiological trigger for persisting pain is continuous movement of the spine - in particular at the affected segment. Several conservative as well as surgical treatment options are used to help the patients improve their pain and quality of life. In every day practice conservative treatment of low back pain in DDD is not standardized. The therapy mostly starts with pain killers followed by physiotherapy and local treatment with facet blocks etc.. Comprehensive rehabilitation and back schools may help the patient to become more mobile with daily activities. Because the degeneration is a slow and gradual process the development of chronic pain is the main risk in many of these patients. If motion is hypothesized to be one major factor in persisting or increasing pain, a reduction of segmental load as well as motion can potentially be a solution. Therefore, lumbar fusion surgery takes center stage as a surgical treatment option. However, a rigid stabilization will change the physiological distribution of the load in the treated as well as adjacent segments. This can cause implant failure and adjacent segment disease. Therefore less rigid constructs like PEEK (polyetheretherketone) rods were introduced in lumbar surgery. On the one hand PEEK rods have a higher elastic module than titanium (3.6GPa versus 115GPa) but on the other hand they provide significant stabilization in the lumbar segments [24].

In this study we analyze a series of 45 low back pain patients treated using a semi-rigid stabilization with Viper screws and PEEK rods (DePuy Synthes) without an additional fusion. Early and late outcomes, complications, revision surgery, pain, and Oswestry Disability Index (ODI) were assessed and correlated to different surgical techniques.

Patients and Methods

Patients with severe low back pain due to monosegmental degenerative disk disease (DDD) who were unresponsive to conservative treatment including physiotherapy were included in this retrospective study. For inclusion into the study all patients had to receive conservative treatment at least for one year without a significant improvement. The diagnosis of DDD was based on the patient's history, a clinical examination and MRI imaging. The indication for surgery with semi-rigid stabilization was pain in combination with signs of osteochondrosis on

MRI imaging. This was identified by Modic I changes. An additional factor was a decreased disk height. A total of 45 patients (24 females and 21 males) were included in the study. Patients presenting with radiculopathy were also included in this study, but they had to have suffered from low back pain for a long time before the radicular pain developed and the low back pain had to be the predominant symptom. Twenty-two patients received stabilization for low back pain only, 23 received radicular decompression followed by a semi-rigid stabilization. Instability, radicular pain as the main complaint, acute development of symptoms, pain not attributed to degeneration and cauda syndrome were contraindications for the study.

All patients underwent consecutively the surgery between 2015 and 2018. For the semi-rigid stabilization the Viper PEEK rod system (DePuy Synthes) was used exclusively. In all cases the procedure was performed in a minimally invasive way using a percutaneous approach for inserting the screws and rods in one segment. An additional midline incision was done in those cases where a radicular decompression was necessary. In 37 patients a 3D navigation system was used for the implantation of the screws (O-Arm, StealthStation S7, Medtronic). In these patients an additional midline incision became necessary for fixation of the reference clamp for navigation. In 8 patients the implantation of the screws was performed by a robotic system (Rosa Spine, Medtech).

All patients were evaluated preoperatively, postoperatively before discharge, and at six weeks, one and two years after surgery, respectively. Besides clinical examination the patients had to fill out an Oswestry questionnaire. For assessment of their pain the visual analogue scale (VAS) for the back as well as leg was used. For inclusion for surgical treatment the VAS for back pain had to be above 5/10. MRI as a preoperative imaging was necessary (fig 1). Patients with an instability were excluded by standing flexion / extension X-rays (defined as a translational segmental movement of 3 mm or more) (fig 2). Intraoperatively all patients received 3D imaging after the pedicle screws were positioned. For the postoperative follow up the patients received X-ray imaging (fig 3). Intra- as well as postoperative complications were evaluated. A statistical analysis was done using mean values, standard deviation and students t'test for paired and unpaired samples as well as a Wilcoxon rank-sum test for nonparametric samples.

Figure 1 Example of a preoperative MRI showing a monosegmental osteochondrosis in L4/5 (Pat. ID 76247)

Figure 2 Standing and flexion / extension X-rays excluding an instability in L4/5 (Pat. ID 76247)

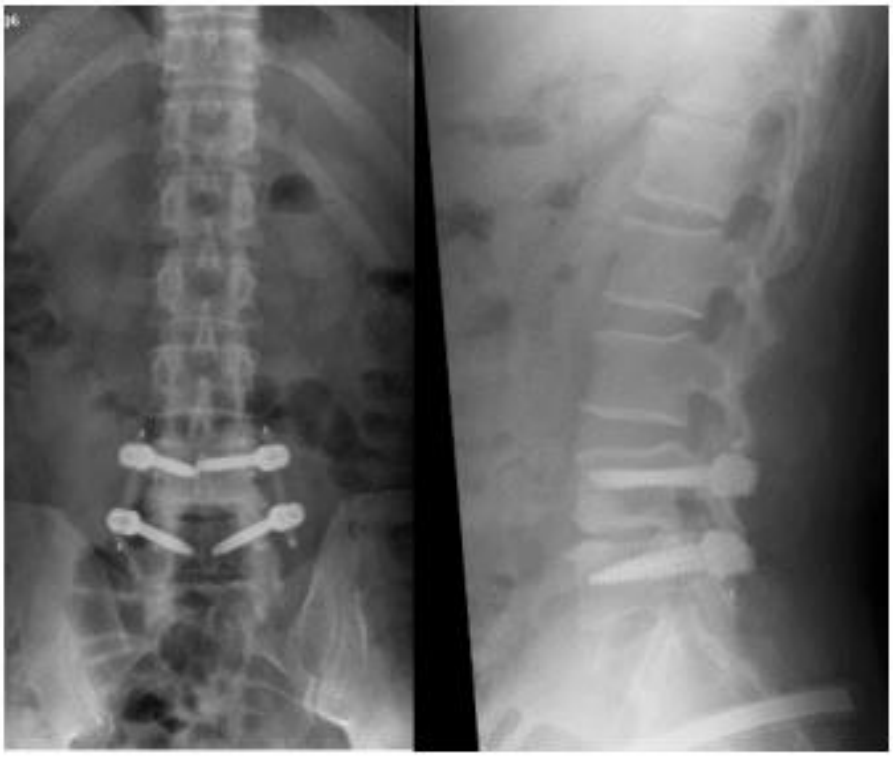

Figure 3 Postoperative X-rays after monosegmental stabilization of L4/5 with PEEK rods (Pat. ID 76247)

Results

Forty-five patients (24 female / 21 male) suffering from long lasting back pain were included in this study. The mean age was 57 +/- 13.3 years. The mean duration of pain was 4.5 +/- 1.7 years. All of the patients received intensive conservative treatment (Tab 1). In addition to medical therapy, nearly every patient attended physiotherapy and more than 80% of patients had additional fluoroscopy-guided injections into the facet joints. Fourteen patients had had prior minimally invasive decompression for lumbar disk herniation.

Table 1 Preoperative treatment of back pain (number of patients)

Preoperative Treatment	Number of Patients
Medication alone	1
Medication / Physiotherapy	4
Medication / Injections	2
Medication / Physiotherapy / Injections	23
Prior Decompression / Medication / Physiotherapy	1
Prior Decompression / Medication / Injections	1
Prior Decompression / Medication / Physiotherapy / Injections	12

The reason for surgical treatment in 22 patients was isolated back pain. In 23 patients a combination of back pain and leg pain was observed. 22 patients with back pain as their predominant pain received only a stabilization procedure using screws and PEEK rods. The patients with back and leg pain received a decompression first and stabilization at a second stage during the same operation. Prior to surgery all of the patients complained of severe back pain with a mean preoperative VAS of 6.9 +/-1.3 of 10 (fig 4). In those patients with additional leg pain mean preooperative intensity was evaluated by VAS (leg) 3.7 +/- 2.7 of 10 (fig 6). The patients received an ODI questionnaire. All of them reported a considerable reduction in daily activity, which is shown by a mean ODI of 48.89 +/-12.2 (fig 7) preoperatively.

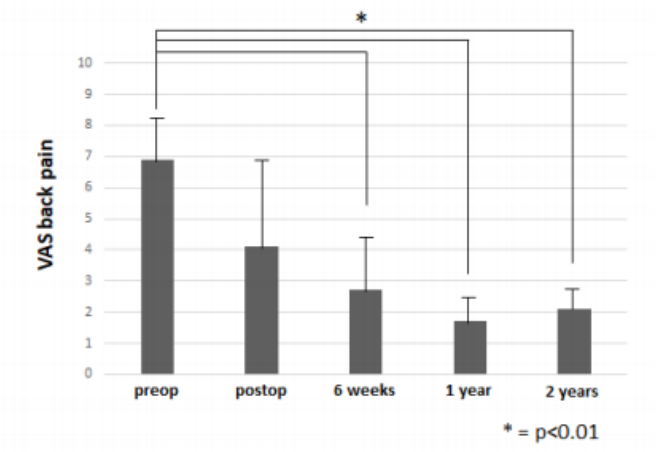

Figure 4 Back pain on the visual analogue scale (VAS)

Osteochondrosis with Modic changes was observed predominantly in L4/5 (20 cases). Less often, the signs were seen in the segment L5/S1 with 14 cases followed by L3/4 (7 cases) and L2/3 (4 cases) (fig 5). All patients received a monosegmental stabilization using screws and PEEK rods. The implants were inserted in a minimally invasive and percutaneous way. For this procedure navigation was used in 37 procedures and a robot in 8 procedures. The mean operation time by navigation was 58.1 +/- 12.94 minutes. Because of the different system requirements including hardware preparation and data acquisition, positioning of the screws etc.

the robotic surgery needed more time in total (141.1 +/- 17.4 minutes). The surgical procedure time (skin to skin) by the robot was 51 +/-16 minutes.

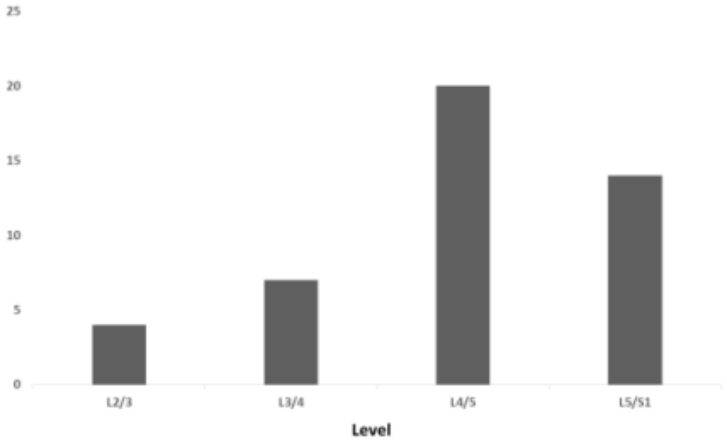

Figure 5 Levels treated by semi-rigid stabilization

Those patients with severe back pain and additional leg pain due to nerve root compression received minimally invasive decompression followed by percutaneous PEEK rod stabilization. The mean operation time in these patients was 97.7 +/- 18.2 minutes. No intraoperative complication was observed in any patient. In the early postoperative phase one patient showed prolonged wound healing without an indication for revision surgery.

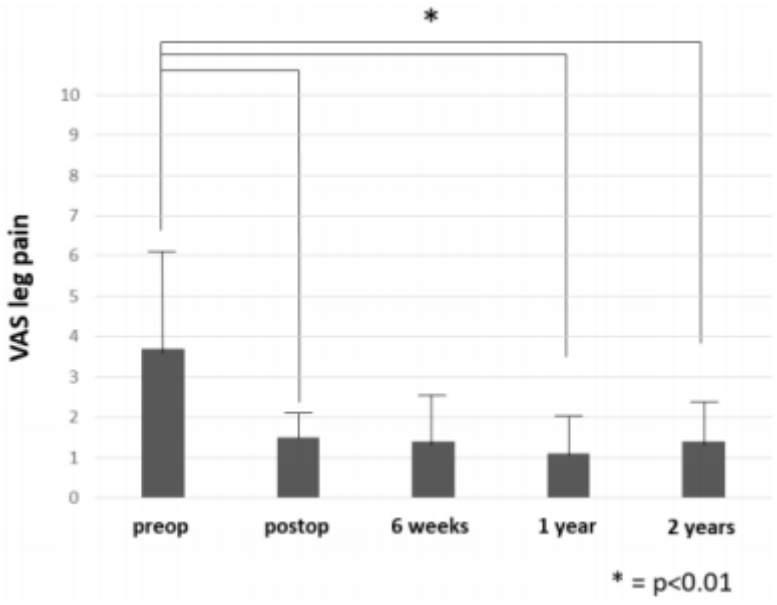

Figure 6 Leg pain on the visual analogue scale (VAS)

Five days after surgery all patients received an Oswestry questionnaire and were asked to evaluate their remaining pain by VAS for back pain as well as leg pain. The back pain improved from VAS 6.9 +/- 1.3 to 4.1 +/- 2.3 which was not a statistically significant improvement ($p<0.06$) (fig 4). The main reason for only a slight improvement of back pain was the pain related to the surgical procedure itself. Due to the decompression of the radicular nerve, the leg pain improved more, from VAS 3.7+/-2.7 to 1.5+/-1.1, which was seen to be statistically significant ($p<0.01$) (fig 6).

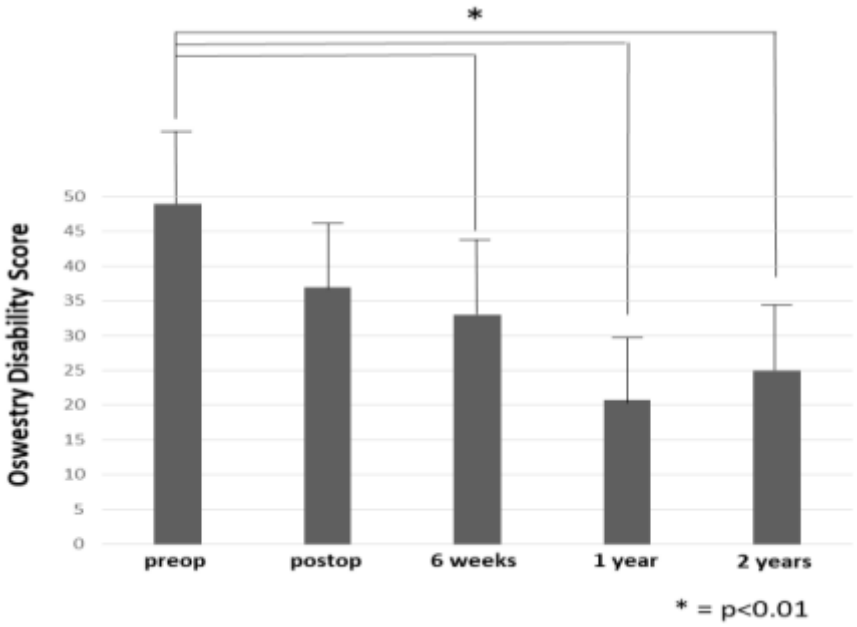

Figure 7 Oswestry disability score (ODI)

The early postoperative ODI was 37+/-10.9 in comparison to preoperative one with 48.89 +/-12.2 (fig 7). After 6 weeks the back pain improved to a VAS 2.7+/-1.6. This was a significant improvement in comparison to the preoperative values for back pain (fig 4) p<0.01. At this time the VAS for the leg pain was measured at 1.4+/-1.3 (fig 6). During the 6 weeks postoperative visit, the ODI improved also significantly to 33+/-13.6 (p<0.01) (fig 7). One year after surgery the VAS back pain values were stabilized with no further improvement (mean VAS back pain 1.7+/-0.9). The 1 y e a r VAS score was evaluated for the leg pain as (1.1+/-1), also showing no significant improvement from the 6-week postoperative visit. The patients' daily life skills were assessed using ODI at 1 year. A further improvement to 20.7+/-11.8 was observed (p<0.01) (fig 7). From the 45 patients treated with a semi-rigid segmental fixation thirty were still employed. All of them returned to their original work during the first year. The sick leave period was 8+/- 6 weeks (this long period of sick leave can be accounted for by particular features within the German health care system). To know whether the semi-rigid stabilization worked in the long term, the two-year values were important. The analysis of the VAS for back pain showed a slight increase of intensity to 2.1+/-0.7 (fig 4). These values were still significant when compared to preoperative back pain (p<0.01). Fortunately, the increased pain was not seen to be significantly more than the one-year results. The VAS for leg pain remained in the same range as one year after decompression (1.4+/-1.2) (fig 6). The patients gave a similar 2-year evaluation of the ODI questionnaire as they did for the one-year results with a stable and significant improvement by 25+/-10.9 (p<0.01) (fig 7). One special aspect of the long-term evaluation was to identify implant failure of the pedicle screws or PEEK rods. Neither one year nor two years after surgery was an implant failure by screw or rod fracture or by loosening of the pedicle screws observed. There was no implant related complication registered in the whole study population.

Discussion

Low back pain is a frequent problem in adults.

Up to 80% of the population may be affected at some time during their life [1]. When considering these statistics non-specific low back pain has to be differentiated from back pain with specific causes. Non-specific low back pain is often not a static but a fluctuating condition, diagnosed after exclusion of any structural causes or conditions which could result in the symptoms, such as tumors, infections or spondylo-arthropathies [10].

The percentage of people suffering from low back pain in combination with leg pain is up to 85%. Due to the changing age demographic, nowadays degenerative changes in the spine in particular the lumbar spine are a major reason for specific low back pain in western populations. However, making the diagnosis for low back pain due to degeneration in elder patients we have to keep in mind that in the population above 50 years of age significant degenerative changes can be detected in asymptomatic patients [8]. Therefore adequate diagnostic examination is necessary to be sure that the patients' low back pain has a real focal origin in the spine.

The treatment of non-specific low back pain is multidisciplinary in general [15]. In those patients where a structural reason for the pain is detected in the spine, treatment should also be focused on the local pathology [1]. This specific spine orientated treatment is first of all a symptomatic one with the aim to improve the problems deriving from the spinal alterations. Analgesic drugs as well as local injections can contribute to an improvement in pain. Exercise therapy and guidance in self-management including physiotherapy may help in maintaining the patients' mobility [21]. Facet joint denervation through radiofrequency ablation can be a more invasive treatment option in those cases with facet degeneration and persisting low back pain when no significant improvement is observed by the above-mentioned methods [5].

When the structural changes triggering the pain do not heal, repeated flare-ups of the pain as well as progression towards chronic symptoms is possible. In those cases a surgical procedure may be helpful to improve the quality of life and daily activities of the patients. Studies show that vertebral motion parameters are strongly predictive of pain in patients suffering from chronic low-back pain [6]. In these patients usually a spinal stabilization with Titanium screws and rods as well as an intervertebral cage fusion is recommended to reduce the segmental mobility [25]. This construct will ensure high rigidity in the affected segments [28]. However, there is a lot of discussion as to whether this kind of rigidity is necessary and helpful in every case. Some studies show that with degeneration load transfer to the posterior elements of the spine is introduced [20]. Rigid titanium rods can shift compression forces from the anterior part of the spine towards posterior and put the bone-screw interface at a high level of tension. This increases the risk of avulsion or fracture of the rigid constructs [17, 20].

In contrast with the reduced rigidity of PEEK rods, a more physiological situation is simulated, which gives load sharing between anterior and posterior vertebral elements of the spine which is closer to normal. Possibly the risk for implant failure is reduced due to less stress on the bone-screw interface [12, 23]. The risk of revision surgery during the following year after rigid lumbar spine fixation is about 40%. The majority is attributed to the materials which were implanted [14]. In using PEEK rods for stabilization several studies show no single rod break even after a long observation time [3, 13]. Although a posterior semi-rigid fixation increases the workload of the adjacent segments, this increase is significantly smaller than those measured in rigid fixation [11]. In our clinical study the patients had benefit from

the surgery with a significant reduction in back pain as well as an improvement in their daily activity.

Comparing these data with the literature, the clinical results in reduction of pain and improvement of quality of life are the same in patients with rigid as with semi-rigid fixation [7, 16, 18]. Usually PEEK rod patients demonstrate a clinically meaningful improvement [22]. In controlled studies comparing VAS data, no significant differences between titanium and PEEK rod treated patients were measured [18]. In our patients the evaluation of pain as well as every day activity using the ODI showed a good improvement also during the long term follow up. One important factor for good results in surgical treatment of low back pain is good patient selection which is based on clinical and radiological tools and the experience of the treating surgeons. By achieving good clinical results with significant pain reduction without additional surgical complications and missing implant failures these findings indicate that lumbar fixation with PEEK rods is a good alternative for lumbar spine surgery in selected patients with segmental lumbar degeneration.

Conclusion

Minimally invasive semi-rigid lumbar spine stabilization with PEEK rods is a safe treatment option in patients where conservative treatment has not been successful. The clinical results of this technique are good without a major risk for implant failure during the follow up. Based on our findings this statement can be made for single level lumbar stabilization. Further studies are required to show if the results can be transferred to multilevel pathology.

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