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ORIGINAL RESEARCH

A PEEK Rod-Based Dynamic Instrumentation Construct for the Degenerative Lumbar Spine Disease, First Appraisal Based on Five-year Clinical and Radiological Findings

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Purpose: The present retrospective study delivers first results after the use of a pedicle based, screw and peek rod system. Emphasis was placed on the ability of the construct to prevent adjacent segment disease at an average of 5 years follow-up by maintaining a certain degree of movement in the index segment. This was evaluated via functional X Rays before and after surgery.

Patients and Methods: The cohort comprised 100 patients which received decompressive surgery in one or more segments with dynamic instrumentation for stenosis of the lumbar spinal canal and degenerative spondylolisthesis. We analyzed diagnostic imagery including functional X Rays prior and after surgery as well as cohort demographics such as reoperation rate, complications and overall patient satisfaction.

Results: The average age was 68 years, at 58 months follow-up there were 43 cases of radiological adjacent segment disease. We defined a radiological ASD as an increase of the osteoarthritis on the Wiener scale and stenosis of the spinal canal on the MRI scans. In our cohort 80 patients benefited from the surgery, either being pain free or having improved symptoms at the mean follow-up with the others either requiring renewed surgery or having developed clinically significant ASD. There was no significant statistical correlation between area of spinal canal, gender and outcome.

Conclusion: In one segment constructs the system being evaluated showed no major disadvantage when compared to similar non-fusion pedicle-based techniques nor was it able to consequently prevent ASD. Under the clinical point of view there was in our opinion no marked benefit when compared against decompressive surgery and fusion as the accepted standard. Regarding the multi segment instrumentation further larger number studies are needed to reach a conclusion.

Keywords: semi constrained screws, dynamic instrumentation, degenerative spondylolisthesis, spinal canal stenosis

Introduction

Dynamic instrumentation of the spine is no longer a new concept. Many different implants have found their way into the ever more complex world of spine surgery only to leave it just as quickly.

It is by no means an easy task to find the balance between adequate range of motion and stability of the spine, and a lot more so when it has to be done taking into consideration that surgery itself may lead to some degree of abnormal biomechanical stress. That concerns not only the index segment but the adjacent segments as well. It is through that biomechanical stress that adjacent segment pathology (ASP) most likely occurs, whereas a conclusive answer to the degenerative or iatrogenic origin of ASP still remains elusive.[1]

To further put the importance of this theme into perspective, in Germany alone in 2015 some 72,000 spinal fusion surgeries and 111,000 decompression surgeries were conducted. This represents a 56% increase from 2005 fusion surgery and a 130% increase from 2007 in decompression alone surgery.[2]

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The surge in spine surgery has also fueled the interest towards a better understanding of the pathology of the adjacent segment which can range between 5% and 35% at 5–10 years after a fusion surgery.[3]

The scope of this retrospective review was to assess the five-year results of a novel pedicle screw and rod-based construct consisting of regular Viper and Viper semi-constrained (SC) Screws from DePuy Synthes combined with polyetheretherketone (PEEK) Rods. To our knowledge, there is only one finite element model where the Viper SC screw is being evaluated together with a PEEK rod to demonstrate good results in reducing the stress in the adjacent level but only as topping off a fusion.[4]

More recent studies evaluate the clinical and radiological development over two years of similar PEEK-based systems but without the SC screw and as topping off, only to show a large implant-failure rate.[5] Other PEEK-based systems show good results but in small patient cohorts.[6]

The Viper Semi Constrained Screw is a titanium alloy-based screw which can be combined with a PEEK Rod with a lordotic bend to form a pedicle-based dynamic instrumentation device to ensure stabilization of the spine.

Keeping in mind that dynamic instrumentation may reduce the rate of ASP,[7] this combination could accompany the decompression of the spinal canal in patients with lumbar stenosis and light degenerative spondylolisthesis either manifested or in the form of clinically active discopathy as surrogate for micro instability.[8]

Patients with symptomatic lumbar stenosis and I° degree slippage and without relevant osteoarthritis often have limited surgical options but to have a fusion operation, as the decompression alone could, when risk factors are present, lead to a worsening of the slippage.[9]

This is where the combination of the Viper Semi-constrained Screws and PEEK Rods may fill in the void. The combination of the two elements is expected to deliver on both stability and preservation of ROM of the vertebrae relative to each other in order to avoid ASP and a worsening of the spondylolisthesis. By avoiding a fusion operation there is also the benefit of the reduced surgical time and complications seen in the interbody fusion surgery.[10]

Materials and Methods

Study Design

The study was conducted as a retrospective single-arm evaluation of de identified data from 100 patients that have had surgery in our hospital and had returned after surgery, for ordinary clinical and radiological checkup. Clinical outcome as well as radiological results was assessed. The clinical outcome was documented by a second surgeon within the scheduled appointments and the radiological assessment was done by a third surgeon on standing x rays of the lumbar spine. The radiological assessment was done by a single spine surgeon to avoid inter-observer reliability issues.

Approval of the Ethics Committee and the clinic was obtained, no personal data was revealed to a third party.

The main indications for surgery were spinal stenosis of the lumbar spine where conservative therapy had proved unsuccessful in the long run. The inclusion and exclusion criteria are displayed in Table 1. Furthermore, the patients had either radiological findings of spondylolisthesis of I° based on radiological evidence from standing x rays of the spine or had an axial pain in the clinical evaluation as a sign of micro instability. The Spondylolisthesis was graded according to the Meyerding classification which can be found in Addendum.

The Implant

The pedicle-based dynamic instrumentation system consists of Viper and Viper semi-constrained (SC) screws as well as polyetheretherketone (PEEK) rods 5.5 mm in diameter with lordotic bend. All 100 Patients received instrumentation over the index segments.

Table 1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1. Symptomatic stenosis of the lumbar spinal canal in 1, 2 or more segments with exhausted conservative measures. 2. Spondylolisthesis 1° in standing x Rays, clinical evidence of microinstability.	1. Relevant osteoarthritis in the index segments. 2. Spondylolisthesis of 2° or more. 3. Scoliosis of 25° or more.

The screws were placed in an alternate fashion with the most cranially placed screw being a semi-constrained screw.

The main difference of the semi-constrained screw is that it retains its full polyaxiality even after having tightened the rod in its housing. Such a construct is displayed ex vivo in Figure 1.

The Surgery

The surgeries have been performed by experienced spine surgeons with at least 5 years experience within the time frame of January 2011 and December 2012. All surgeries have been performed based upon the same operating algorithm, long established in our clinic.

The surgery consisted of central decompression of the spinal canal in one, two or more segments and instrumentation of all decompressed segments. An example of a one segment instrumentation can be seen in Figure 2.

The arthrotomy of the facet joints was kept to a minimum in order to avoid an iatrogenic instability. The correct position of the titanium screws was controlled intraoperative by anteroposterior and lateral fluoroscopy. Just like in other dynamic instrumentation devices were good results were achieved we also gave a great deal of attention to the placement of the screws such as not to injure the facet joint and to have the screw parallel to the upper end plate of the corresponding segment.[11] The PEEK rod was tightened with the specified preload. Adhering to the concept of dynamic instrumentation no bone grafts were used.

There was no intentional distractive or compressive force applied to the segment and no attempt was made to reduce the existing spondylolisthesis except postural reduction by positioning.[11]

Figure 1 Ex vivo construct with SC Screws on the top and bottom of the construct and regular Viper screws in the middle, PEEK Rod.

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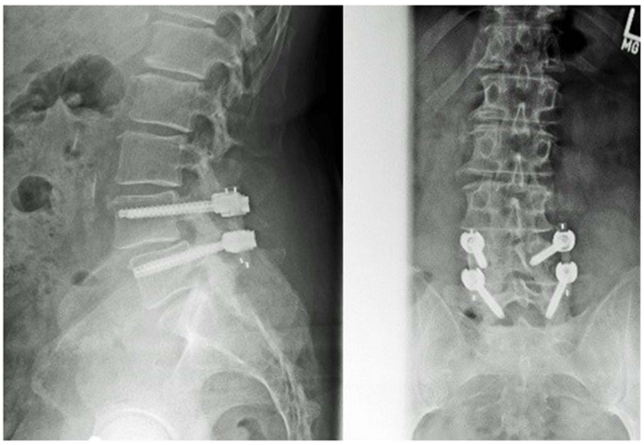

Figure 2 Postoperative X-rays after decompression and instrumentation L4/5.

Prior to surgery, all patients had received standing x rays of the lumbar spine, MRI of the spine and a thorough clinical consult.

Within the studied cohort 53 patients received decompression and instrumentation over one segment, 35 over two segments, 11 over three segments and 1 over four segments.

Data Collection and Outcomes

Data that has been collected was devised into three fields: preoperative, operative and postoperative. The patient reported outcome was the primary end point, postoperative complications were seen as secondary end points.

Under preoperative data, we gathered the age at time of surgery, the gender (patient demographics) as well as the indication for surgery and previous surgical interventions.

Within the field of operative data, we gathered the surgical time and intraoperative complications related to the procedure and/or device.

For postoperative data, we gathered the reoperations, duration of follow-up, postoperative complications and patient-reported outcomes after at least one year or sooner when complications arose.

Statistical Analysis

Chi Quadrat tests, Phi coefficient and Cramer V were used to determine whether any statistically significant correlation can be proven among gender, area of spinal canal and previous surgeries and outcome. With a level of significance set to 0.05 throughout the study, we were unable to show statistically significant correlations between the above mentioned parameters. This is one of the limitations of the study. All statistical analyses were conducted using IBM SPSS 25.

Results

Preoperative

Age

We included 100 patients in our study with ages between 38 and 85 years of age and an average of 68. Mean age was the same for women and men. Out of the total, seven patients were either in excess of 80 years. The study cohort on average was some five years older than in other publications where decompression alone was performed.[12]

Gender

Out of the total of 100 patients 56 (56%) were women, the rest of 44 (44%) were men, thus making for a heterogeneous population.

Pathology

Ninety-six patients showed the most severe form of stenosis after Schizas,[13] classified as D of which eight 42 were men and 54 females. The average age of the men was 69 years and of the women 68 years, means were rounded down when smaller than 0.5 or up when above it. The classification relies on the morphology of the dural sac as observed on T2 axial magnetic resonance images based on the rootlet/cerebrospinal fluid ratio and can be seen in Figure 3.

Only 2 patients exhibited a C type stenosis and only 2 a B type.

Out of the 100 patients, 98 had a spondylolisthesis in standing x rays of the spine and 2 had a clinical active discopathy as sign of micro instability. The most frequent level of spondylolisthesis for the patients with radiographic evidence in standing x rays was L4/5, 75 out of the 98 with the rest of the patients exhibiting the degenerative slippage at level L3/4, L2/3 or L5/S1.

Previous Surgeries

Seventeen patients have had previous surgery performed on their lumbar spine, eleven had surgery for a herniated disc, five in index segments and six in adjacent segments, two had a lateral Decompression of which one in index segment, two had a central decompression and two had a prior fusion surgery outside the index segments.

Intraoperative

Surgical Time

The average surgical time was 183 minutes, with an average of 148 minutes for one segment (53 patients), 223 minutes for two segments (35 patients) and 225 minutes for three segments or more (12 patients).

Intraoperative Complications

Altogether thirteen patients had a dura lesion (13%), three in a one-segment surgery, eight in a two-segment surgery and two in a three and more segment instrumentation, which does not differ greatly from other studies.[14]

We also observed two screw malposition, thus resulting in fifteen complications or 15% of all patients.

Postoperative

Follow up

The average follow-up was 58 months with a maximum of 96 months and a minimum of 12 months. We also accepted a follow-up of less than 5 years where secondary end points such as screw loosening had been achieved.

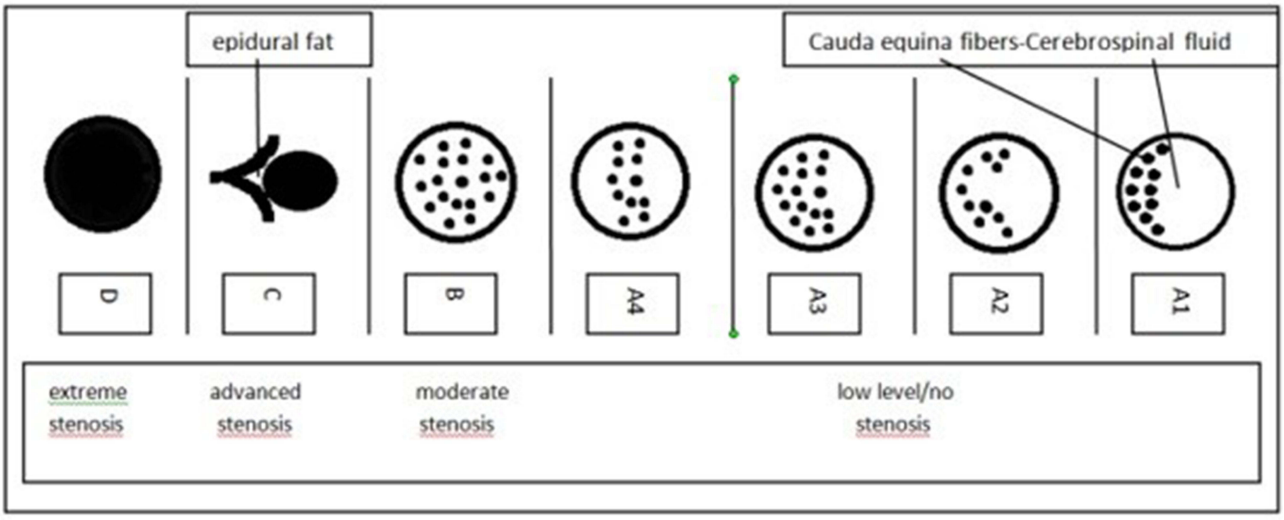

Figure 3 Graphic picture of the classification after Schizas.

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Reoperation Rate

Out of the studied cohort, 33 patients required further surgery.

In the early postoperative period (3 months) there were 9 patients, three due to wound dehiscence, one due to a symptomatic screw malposition, two due to hematoma and three because of persistent stenosis. This numbers do not exceed the complication rate for similar procedures provided by the literature.[14,15]

The rest of 24 had required further surgery up to 6 years postoperatively. Fourteen patients because of a symptomatic screw loosening or breakage, one had developed a metastasis and had the implants removed in order to facilitate radiotherapy, nine patients required further surgery because of symptomatic in segment restenosis, herniated disc or ASP.

Radiological Outcome

There were twenty-five cases of screw loosening determined by the presence of radiolucent lines at the screw/bone interface or cut out of the screws in normal or dynamic X-rays, as well as CT scans documented. Ten in a one segment instrumentation out of which 8 required surgery because of symptomatic radiculopathy, surgeries were performed within 2 months and 6 years of the primary instrumentation. Eight in 2 segment instrumentations out of which 4 showed no symptoms and required no renewed surgery up to the time of the study, but the rest did require surgery 1 to 3 years later. Seven in 3 segment instrumentation, out of which 2 required renewed surgery. We also recorded 2 screw malpositions which were all revised. There was also recorded a screw breakage and a patient with a malposition and loosening which was not included in either category. A screw loosening in a 3 segment instrumentation can be seen in Figure 4.

In the case of the 53 patients having received a one segment instrumentation, the rate of radiological ASP was noted as 24 (45%) at an average of 69 months. Out of those 16 had also relevant clinical symptoms. In the literature, the rate of RASP can vary from 8% to 100% but given an observation time of 36 to 396 months,[16] which given our follow-up renders a comparison as impossible.

We considered a radiological ASP in patients with modification of the Weiner score.[17] Analog, we considered a worsening of the in-segment slippage were a modification of the Meyerding classification occurred.[18]

Out of the rest of 47 patients with 2 or more segments 19 (40%) developed radiological and also clinical relevant ASP. The Wiener Score can be found in Addendum.

One has to judge this within the given context and no population-valid conclusion is possible. Further prospective studies are required to see the long-term results.

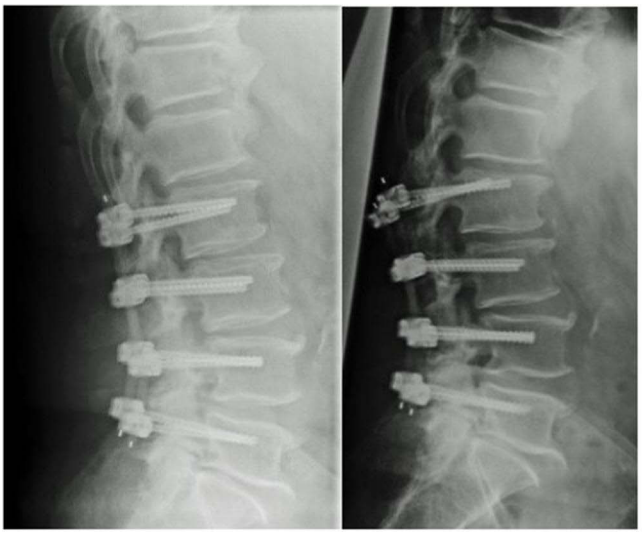

Figure 4 Postoperative X-ray (left) and 18 months later (right).

Patient Reported Outcome

Out of the 100 patients, 32 were pain free with the outcome after 56 months after surgery, minimum of 24 and maximum of 95 months. Out of the rest, 48 patients reported an improvement of their symptoms 59 months after surgery minimum of 24 and maximum of 96 months after surgery, and the rest reported no significant improvement of the symptoms 65 months after surgery.

Discussion

The problem of ASP is one that has troubled surgeons and industry alike for many years now. Although many systems have been presented to the market, only a few have proven worthy of being large scaled to answer the ever-increasing demand.

Through conducting this study, we were able to evaluate the clinical and radiological results of 100 patients having received implants in form of a novel pedicle-based dynamic instrumentation device. Because this was not a prospective study there was no documentation of otherwise proven scores such as Oswestry and COMI but nonetheless we were able to draw conclusions based on the improvement of symptoms as reported by the patients.

The patient-reported outcome is comparable to the expected improvement after decompression in patients with presence of degenerative spondylolisthesis when it comes to symptoms directly linked to spinal stenosis like claudicatio spinalis. When it comes to mechanical pain there is a different story all together to tell. Here there was a high number of recurrent lumbar pain and sometimes leg pain which can at least to some extent be attributed to the rather high number of screw loosenings or breakage. In our study, 32% of patients were pain free and another 48% had improved which brings us to a total of 80% of patients which benefited from the surgery. This compares well with other published studies were 82% and respectively 68% benefited from the surgery.[12,14]

The reoperation rate stands at 9% for intra and early postoperative complications and 24% for surgery being performed 3 months or later. This does not exceed the numbers being presented in the literature with a reoperation rate of 21%[19] at an average of 6.5 years.[14]

The radiological findings showed a conspicuously high number of screw loosening which were also confirmed in CT Scans. Altogether we recorded 25 patients with screw loosening, although not all symptomatic, only 14 required renewed surgery. There was no big difference between one segment and two segment instrumentation with one segment instrumentation having a rate of 19% screw loosening and two segment surgeries of 23%. There was however a big difference when it comes to three segment instrumentations, here we saw a rate of 63% of screw loosening, 7 patients out of a total of eleven.

It seems that the instrumentation of more than 2 segments is very demanding from a biomechanical point of view and there are a lot of factors such as the anatomy of the patient, intrinsic movement of the spine, ROM after decompression, sagittal profile and many more that have to be considered in order to obtain a positive result.

Limitations

Being a single-arm cohort study without a control group, for example, patients treated with decompression alone or fusion, presents limitations regarding the evidence level.

Being a retrospective study, we do not have standardized questionnaires to assess the life quality.

Nevertheless, our study represents to the best of our knowledge, the only patient cohort with degenerative spondylolisthesis treated in the described manner.

Conclusion

Five-year results of the entire cohort do not exceed those of reported literature for decompression and fusion either under the clinical aspect nor under the radiological aspect with 25% having a screw loosening, and almost half of them having developed ASP. This makes a big difference to one year results where only 5% of one and two segment surgeries developed ASP and is worse than reported outcome for similar hydroxyapatite coated systems.[15]

When only the one and two segment operations are being considered than one can regard it as a non-inferiority outcome to decompression and fusion. However, the three and four segment instrumentations seem to overstrain the system more so, thus providing for more screw loosening and overall for a worse outcome.

The rates of intra-operative and postoperative complications did not exceed those that are normally seen in the surgery of the lumbar spine.

Patients who received instrumentation over 3 segments showed an increased rate of screw loosening, not always symptomatic, which goes to show the mechanical strain the system comes under when used in multisegmental surgery. This is a fact that only comes to strengthen the conclusion in a previous one year analysis.

Regarding the clinical decision-making process, the system best suits those patients that require extended decompression of the lumbar spinal canal and exhibit axial pain or mild slippage in the standing X Rays.

Encompassing the clinical and radiological results, the present combination of Viper SC Screws, Viper Screws and PEEK Rods does not fulfil in our opinion the criteria for a better alternative to decompression and fusion, but is rather a more time saving alternative. Thus, this system being nowadays used in our clinic only for highly selected indications, mostly patients where the surgery is time sensitive.

Abbreviations

ASD, Adjacent segment disease; ASP, Adjacent segment pathology; COMI, Core outcome measure index; FU, Follow-up; LSS, Lumbar spinal stenosis; MRI, Magnetic Resonance Imaging; PEEK, Polyether ether ketone; ROM, Range of motion; SC screws, semi-constrained screws.

Ethics Approval and Informed Consent

The study was reviewed by the "Ethik Komission bei der Landesärztekammer Hessen", Votum 2020-1818-evBO from 15.09.2020. This study was conducted in accordance with the guidelines of the Declaration of Helsinki. Informed consent was not needed as this was a retrospective study and the appropriate legislation does not require one in these type of studies, such this was waived by the ethics committee.

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Level 4 – Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence.

Disclosure

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