"TITU MAIORESCU" UNIVERSITY OF BUCHAREST

DOCTORY SCHOOL – MEDICINE

DOCTORAL THESIS

DEGENERATIVE LUMBAR SPINAL CANAL STENOSIS. EVALUATION OF RESULTS 5 YEARS AFTER TRANSPEDICULAR DYNAMIC INSTRUMENTATION

PhD Supervisor,
Prof.univ.dr. Ungureanu Florin Dan

PhD Candidate,
Anghel Andrei-George

Bucharest, 2025

INTRODUCTION

Dynamic instrumentation of the lumbar spine is no longer a new concept. Over the last two decades, various devices have been developed to meet the increasingly demanding requirements brought about by improved understanding of lumbar spine anatomy, and especially its biomechanics. Unfortunately, out of the many devices that reached the market, only a small portion proved convincing, while the rest disappeared from this highly competitive landscape as quickly as they appeared.

Designing a dynamic instrumentation device for the lumbar spine that strikes a balance between maintaining an adequate range of motion and providing good stability for the index segment is by no means an easy task. This challenge is further complicated by the fact that the surgery often involves decompression, which in itself introduces a degree of instability that cannot be evaluated either pre- or postoperatively. This applies not only to the index segment but also to the adjacent segments, both superior and inferior. Most often, it is this additional biomechanical stress that contributes to adjacent segment pathology, although a definitive answer to this highly complex topic remains elusive.[1]

To further substantiate the relevance of this topic in the current context, in Germany alone in 2015, approximately 72,000 spinal fusion surgeries and about 111,000 decompression surgeries were recorded. These numbers represent a 56% increase in fusion surgeries compared to 2005, and a 130% increase in decompressions compared to 2007.[2]

The increase in spinal surgeries has had a dual effect—it has generated both questions and answers regarding its biomechanics and pathophysiology. There has been significant interest in

[1] Riew KD, Norwell DC, Chapmann JR et al. Introduction/Summary statement: adjacent segment pathology. Spine (Phila Pa 1976) 2012;37(22 Suppl):S1-7

[2] Faktencheck Gesundheit, Bertelsmann Stiftung, Juni 2017

better understanding adjacent segment pathology, which currently varies from 5% to 35% over 5 to 10 years following a spinal fusion.[3]

The aim of this retrospective study was to evaluate the clinical and radiological outcomes, over an average of 5 years, of a new dynamic lumbar spinal instrumentation device composed of standard Viper screws and Viper SC screws from DePuy Synthes, combined with polyetheretherketone (PEEK) rods. No such study currently exists in the literature; only one paper evaluates the Viper SC screw in conjunction with a PEEK rod to demonstrate positive outcomes in terms of reducing mechanical stress in adjacent segments, but only as a "topping off" or extension of a fusion surgery. [4]

More recent studies evaluate clinical and radiological outcomes over a two-year period for similar systems with PEEK rods but without Viper SC screws, also used as topping-off devices, with high device failure rates. Other systems with PEEK rods show good results but in small cohorts.[5,6]

The Viper Semi-Constrained screw is made of a titanium alloy and can be combined with a pre-lordosed PEEK rod to create a dynamic lumbar spinal instrumentation system designed to offer stability.

Since dynamic instrumentation can reduce the incidence of adjacent segment pathology, this combination may be used alongside spinal canal decompression in patients with spinal stenosis and mild degenerative spondylolisthesis.[6]

Patients with symptomatic lumbar spinal stenosis and grade I spondylolisthesis without significant osteoarthritis often have no other alternative than fusion surgery, since decompression

---

[3] Ghiselli G, Wang JC, Bhatia NN et al. Adjacent segment degeneration in the lumbar spine. J Bone Joint Surg Am. 2004 Jul;86(7):1497-503.

[4] M. Moumene. Basic science: Posterior dynamic pedicular stabilization 104 Biomechanical Effect of Posterior Dynamic Stabilization Topping-off Fusion, DePuy Spine Inc., Reseach & Development, Raynham, MA, United States,

[5] Jacques Benezech, Bruno Garlenq and Gilles Larroque. Flexible Stabilisation of the Degenerative Lumbar Spine Using PEEK Rods Hindawi Publishing Corporation Advances in Orthopedics Volume 2016, Article ID 7369409

[6] Jae Chul Lee, Sung-Woo Choi. Adjacent Segment Pathology after Lumbar Spinal Fusion. Asian Spine J 2015;9(5):807-817

alone when risk factors are present can lead to segmental decompensation and worsening of spondylolisthesis.[7]

This is where the system made of Viper SC screws and PEEK rods finds its purpose. This combination promises a good compromise between stability in the index segment and preservation of motion, to prevent adjacent segment pathology and possible worsening of spondylolisthesis. By avoiding a fusion surgery, advantages include shorter operative times and lower complication rates. [8]

THORACO-LUMBAR DORSAL INSTRUMENTATION

One of the first methods of dorsal instrumentation was developed by Harrington, in the form of the rod that now bears his name. This happened in 1975 and represented a significant step forward in spinal surgery. The rod developed by Paul Harrington for the correction of spinal deformities was quickly adopted for the treatment of traumatic spinal injuries, as well as degenerative and metastatic unstable lesions. Over time, the limitations of this system became apparent. Although the system allowed for both compression and extension to help achieve a balanced coronal profile, it could not do the same in the sagittal plane. This was one reason why patients often experienced significant loss of lumbar lordosis or thoracic kyphosis after using the system for thoracolumbar scoliosis correction—earning the nickname “flat back.”.[9]

---

[7] Joo Chul Yang, Sung Gon Kim, Tae Wan Kim, et al. Analysis of Factors Contributing to Postoperative Spinal Instability after Lumbar Decompression for Spinal Stenosis. Korean J Spine 10(3):149-54, 2013

[8] Bobby D. Kim, Wellington K. Hsu, Gildasio S. De Oliveira et al. Operative Duration as an Independent Risk Factor for Postoperative Complications in Single-Level Lumbar Fusion https://www.ncbi.nlm.nih.gov/pubmed/24365901

[9] Lagrone MO, Bradford DS, Moe JH, et al: Treatment of symptomatic flatback after spinal fusion. J Bone Joint Surg (Am) 70:569-580, 1988

Other issues with the system included its lack of primary stability, often requiring patients to wear a plaster corset postoperatively, which was frequently impractical. Without proper spinal motion restriction, repeated mechanical stress often led to rod or hook failure.

Eduardo Luque offered a solution to these problems by introducing an innovative concept in the mid-1970s. A key aspect for Luque was the primary stability of the construct. Practicing in Mexico, where the hot climate made wearing a corset nearly impossible, and serving rural patients with poor access to care, Luque proposed using a metallic rod fixed to the lamina via sublaminar wiring. His idea was that multiple fixation points along the spine would reduce the forces at the metal-bone interface, eliminating the need for a corset. Another advantage was the ability to shape the sagittal and coronal profiles for a more harmonious alignment.

This concept of segmental fixation along a contoured rod proved highly successful, allowing for greater rigidity while achieving a balanced coronal and sagittal profile. However, some surgeons avoided sublaminar wiring due to reports of neurological injuries, either from direct trauma caused by the wire or hematomas following wire insertion.

This concern accelerated the development of new spinal instrumentation systems. Drummond introduced a system using wires passed through the spinous process. While it reduced the rigidity of the construct, it also significantly lowered the risk of neurological insult.

Throughout the decade, increasingly advanced rod-and-wire instrumentation systems appeared, one of the most notable being the Cotrel-Dubousset system. Introduced in the U.S. in 1984, it consisted of metal rods and multiple hooks that allowed surgeons to apply compression or extension at various points. A unique advantage was the ability to rotate the rod, facilitating deformity correction, particularly in scoliosis surgery. A downside, however, was that once the hooks were fixed, they were difficult to remove without cutting the rod or hook—a disadvantage addressed in the Texas Scottish Rite Hospital (TSRH) system. Other variations followed, such as the Moss-Miami and Isola systems, which mainly varied in fixation points.

A major advancement came with Roy-Camille’s system, which used the vertebral pedicle for segmental fixation. Although the first surgery was performed in 1963, results weren’t published until 1970. Pedicle screws offered many advantages over earlier systems: mechanically superior, capable of bearing greater loads, usable even in the sacrum, and insertable even after laminectomy without opening the spinal canal. This innovation expanded spinal instrumentation beyond deformity correction to degenerative spinal pathology.

In the U.S., transpedicular screws were used alongside metal plates to transfer loads longitudinally, while in Europe, Yves Cotrel used rods incorporated into the Universal CD system. Although both systems coexisted for a while, rods eventually prevailed due to their intraoperative flexibility and contouring capabilities.

One more important development in spinal instrumentation was the advent of polyaxial screws, which form the foundation of modern systems.

In recent years, numerous dynamic instrumentation systems have emerged and proliferated, including the Graf, Dynesys, X-Stop, and Coflex systems. These are shown in figures 6 through 9.

These systems aim to stabilize the instrumented lumbar spine while accompanying decompressions in degenerative pathologies, without exacerbating the chronic instability that initially caused spinal stenosis. A notable advantage of dynamic implants is their apparent superiority in preventing adjacent segment pathology, a common issue with rigid instrumentation used for spinal fusion.

Imagine 6. Reprezentare a ligamentului Graf

Imagine 7. Reprezentare a sistemului Dynesis

Imagine 8. Reprezentare a sistemului X Stop

Imagine 9. Reprezentare a sistemului Coflex

GENERAL METHODOLOGY OF THE RESEARCH

MATERIALS AND METHODS

The study was designed as a retrospective cohort study and included 100 patients who underwent surgery in our clinic and presented for subsequent clinical and radiological follow-ups. To comply with data protection regulations, patient data was anonymized

To achieve the defined objectives, both clinical and radiological aspects were evaluated.

The clinical course of the patients was documented by a surgeon different from the one who performed the surgery, and the radiological results were evaluated by a third surgeon. This approach aimed to ensure an objective assessment of the collected data. The analysis of patient progress from a radiological perspective was based on lumbar spine X-rays (anteroposterior and lateral views) taken in a standing position before and after surgery at preset intervals. All X-rays were evaluated by a single surgeon to avoid discrepancies from multiple assessments.

Ethics committee approval from the state of Hessen was obtained, and no personal data was shared with any third party.

The main surgical indication was symptomatic lumbar spinal canal stenosis for which conservative therapy proved insufficient. Additionally, patients presented with radiological signs such as grade I° spondylolisthesis based on lateral lumbar X-rays or clinical features indicating segmental or micro-instability.

SPINAL FIXATION SYSTEM

The spinal fixation system used in the index segment consisted of a dynamic transpedicular instrumentation system comprising Viper and Viper SC screws (DePuy Synthes), along with PEEK rods.

- Viper screws: Made of titanium, available in various diameters and lengths depending on intraoperative requirements. In this study, screws with 5 or 6 mm diameters and 40, 45, or 50 mm lengths were predominantly used. These screws feature a polyaxial head for rod insertion, which becomes monoaxial once the rod is locked using a locking nut.
- Viper SC screws: A derivative product that retains 30° polyaxial movement in the screw head even after rod fixation.
- PEEK rods: Made of a biocompatible polymer, semi-rigid, with preformed curvature appropriate to lumbar lordosis. Rods are 5.5 mm in diameter and come in various lengths as needed.

Screws were placed to stabilize the decompressed lumbar segment and prevent the progression of spondylolisthesis and associated symptoms, while maintaining motion in the index segment. Screw placement alternated as follows:

- Caudal vertebra: Viper screws
- Cranial vertebra: Viper SC screws

This construct can be extended up to 3 segments as per manufacturer recommendations.

Figures 8.1 – 8.3 show ex vivo examples of mono- and bi-segmental decompression and instrumentation using this construct.

Figura 8.1 Ex vivo monosegmental construct with Viper SC screw cranial and normal Viper screw caudal and PEEK rod.

Figura 8.2 Ex vivo two segment construct with Viper SC screw cranial and caudal and normal Viper screw in the middle and PEEK rod.

Figura 8.3 The Viper SC screw retains its polyaxial character even when the rod has been tightened within the housing.

INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria:

- Symptomatic lumbar spinal canal stenosis (1–3 segments)
- Failure of conservative therapy
- Grade I spondylolisthesis on lateral lumbar spine radiographs
- Clinical signs of micro-instability (e.g., non-radiating lumbar pain exacerbated by prolonged standing or sitting, or by lumbar extension)

Exclusion criteria (3):

1. Osteochondrosis and associated spondylosis in the index segment — indicating reduced segmental motion and making dynamic instrumentation ineffective.
2. Grade II spondylolisthesis — which could overload the dynamic system and compromise the construct.
3. Lumbar scoliosis ≥25° (Cobb angle) — which may excessively stress the construct in the coronal plane and compromise its integrity.

SURGICAL TECHNIQUE

- Surgeons: All surgeries were performed by DWG-certified spinal surgeons with at least 5 years of experience.
- Timeframe: Surgeries performed between January 2011 and December 2012.
- Approach: A standardized surgical algorithm was followed.

Procedure:

- Decompression: One or more lumbar segments were decompressed based on clinical symptoms and MRI findings.
- Instrumentation: Applied to decompressed segments according to section 9.2.

Decompression was done through a midline dorsal lumbar incision by removing interspinous structures and ultimately the ligamentum flavum. The ligament was removed from its cranial origin under the lamina to its caudal insertion. Microsurgery was performed under 5–10x magnification.

Special attention was given to:

- Lateral recess decompression
- Preserving facet joint integrity (to maintain segmental biomechanics)

Where necessary, partial facetectomy was performed to decompress neural structures.

For associated pathologies (e.g., herniated discs), disc resection was performed.

Screw placement: done freely under fluoroscopic guidance in both AP and lateral views. care was taken to:

- Align screws parallel to the cranial vertebral body edge
- Preserve facet joints

Rod placement:

- PEEK rods were positioned and locked without applying compression or distraction between screws, avoiding mechanical overload.
- Locking nuts were tightened using a torque wrench provided by the manufacturer for uniform force.
- No attempt was made to actively reduce spondylolisthesis beyond what was corrected posturally by patient positioning.

Preoperative evaluation: All patients underwent:

- Lumbar MRI
- Lumbar spine X-rays (AP and lateral, standing, plus flexion/extension)
- Detailed clinical examination

Patient distribution:

- 53 patients: single-segment decompression and instrumentation
- 35 patients: two adjacent segments
- 11 patients: three segments
- 1 patient: four segments

In most cases, instrumentation preceded decompression, though the order was at the surgeon’s discretion.

Figures 9.1 and 9.2 show standing AP and lateral X-rays after single-segment instrumentation. Additional radiographs (Annex 1) show examples for one, two, or three segments.

Figura 9.1 Standing X Ray antero-posterior after a monosegmental instrumentation with decompression.

Figura 9.2 Standing profile X-Ray after a monosegmental instrumentation.

POSTOPERATIVE RESULTS

Postoperative Follow-Up Period

The average follow-up period was 58 months, with a maximum of 96 months and a minimum of 12 months. Patients with follow-up periods of less than 5 years were also included in the study, provided that one of the predefined secondary objectives—such as screw loosening—was achieved. Full results can be found in Table 4.

Surgical Reintervention Rate

Out of the 100 patients in the cohort, 33 required surgical reintervention during the study period.

- In the early postoperative period (first 3 months), 9 patients required reoperation:
    - 3 due to wound dehiscence
    - 1 due to malposition of a screw
    - 2 due to postoperative intraspinal hemorrhage
    - 3 due to persistent spinal canal stenosis

These rates do not differ significantly from complication rates in similar surgeries described in the literature.[10],[11]

---

[10] Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D. et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. April 14, 2016, N Engl J Med 2016; 374:1413-1423 DOI: 10.1056/NEJMoa1513721

[11] Rienmüller C. Anna, MD, Sandro M. Krieg, MD, MBA, Franziska A. Schmidt, et al. Reoperation rates and risk factors for revision 4 years after dynamic stabilization of the lumbar spine. The Spine Journal 19 (2019) 113ß120

- Of the remaining 24 patients, reoperation occurred up to 6 years after the initial procedure in the index segment:
    - 14 patients required revision surgery due to screw loosening or breakage with symptoms unmanageable by conservative treatment
    - 1 patient developed a metastasis in an instrumented vertebral body, requiring hardware removal to enable radiotherapy
    - 9 patients required reoperation due to restenosis, disc herniation, or symptomatic adjacent segment disease resistant to conservative treatment

Radiological Results

- 25 cases of implant loosening were identified in the cohort. Loosening was diagnosed based on:
    - Reduced radiodensity at the screw–bone interface
    - Screw displacement in follow-up AP and lateral lumbar radiographs
    - Movement observed in flexion/extension lateral X-rays

In these patients, CT imaging was used to further evaluate the nature and extent of the complications.

Breakdown:

- 10 patients had single-segment instrumentation, of whom 8 required reoperation for persistent radiculopathy. Reoperations were performed between 2 months and 6 years post-op.

- 8 patients had two-segment instrumentation, of which 4 were asymptomatic and observed without surgery; the rest required reoperation within 1–3 years post-op.
- 7 patients had three-segment instrumentation, and 2 of them required reoperation.

Also identified:

- 2 patients with screw malposition (both reoperated)
- 1 patient with a screw fracture
- 1 patient with both screw malposition and loosening (not counted in any group above)

To highlight the characteristics of the proposed device, segmental angles (index, adjacent superior, and adjacent inferior) were measured pre- and postoperatively using lateral lumbar spine radiographs. In most cases, a slight reduction in mobility was observed in the index segment postoperatively; a similar trend was noted for adjacent segments.

- Preoperative measurements: see Table 4
- Postoperative measurements: see Table 5

Measurements were performed using Impax/Agfa software and the "angle" function. Lines were drawn along:

- The inferior edge of the vertebral body above the segment

The superior edge of the vertebral body below the segment

Incidence Rate of Adjacent Segment Disease

Among the 53 patients with single-segment instrumentation, 24 cases of radiologically confirmed adjacent segment pathology were identified — 45% incidence. The average observation period was 69 months.

Literature shows radiological adjacent segment disease rates between 8% and 100%, with observation periods ranging from 36 to 396 months, making direct comparison difficult.[12]

- A segment was considered to have adjacent segment disease if:
  - There was a change in the initial Weiner classification
  - There was progression of spondylolisthesis as measured by Meyerding classification

Among the remaining 47 patients with two or more segments instrumented, 19 patients (40%) developed radiologically significant adjacent segment pathology. These findings must be interpreted in light of the study's limitations.[13, 14]

Patient-Reported Clinical Outcomes

- 32 patients reported complete absence of pain at an average of 56 months postoperatively (range: 24–95 months).
- 48 patients reported improvement of symptoms at an average of 59 months (range: 24–96 months).
- The remaining 20 patients reported no significant improvement at a follow-up average of 65 months.

---

[12] Park P, Garton HJ, Gala VC, Hoff JTet al. Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature. Spine (Phila Pa 1976). 2004 Sep 1;29(17):1938-44

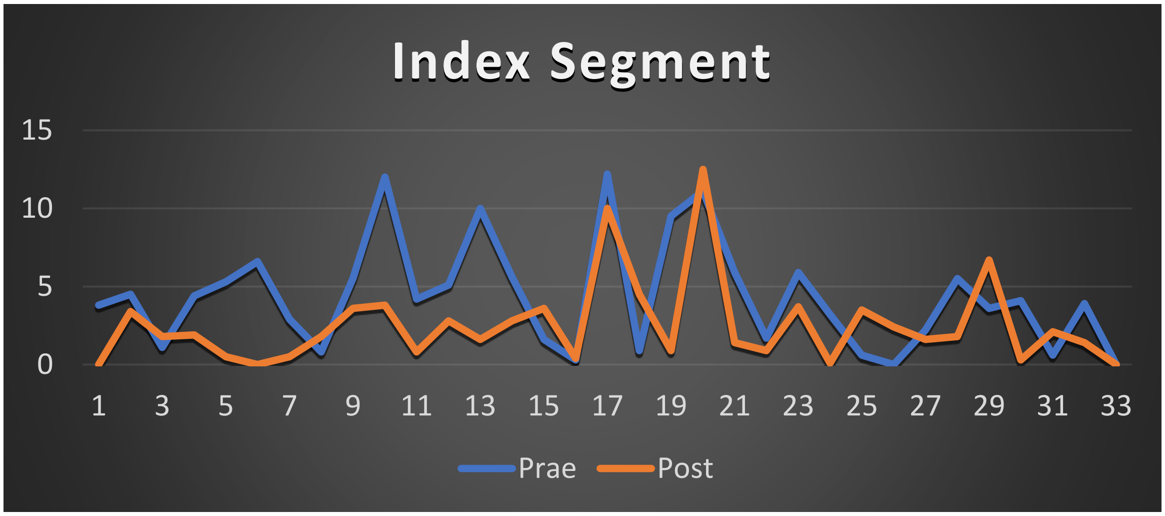
[13] Weiner DK, Distell B, Studenski S, et al. Does radiographic osteoarthritis correlate with flexibility of the lumbar spine? JAm Geriatr Soc. 1994;42(3):257–63

[14] Meyerding HW - Spondyloptosis. Surg Gynaecol Obstet. 1932;54:371–377

Mobility of the Index Segment and Adjacent Segments

To obtain values suitable for comparison with the existing literature, measurements were performed only on patients with single-segment instrumentation.

- Patients without complete pre- or postoperative flexion-extension lateral lumbar spine radiographs were excluded.
- A total of 33 patients with monosegmental instrumentation were included.
- Graph 1: Shows pre- vs. post-op motion in the index segment (measured as the angle delta between flexion and extension).



Grafic 1. Pre- vs postoperative movement in index segment.

CONCLUSIONS

The problem of adjacent segment disease is not yet fully understood, even today, and remains a real concern for patients despite the wide range of surgical techniques and devices available. Among the many devices that have reached the market, only a few have proven suitable for widespread use and capable of offering a solution to this increasingly frequent issue.

By conducting this study, we were able to evaluate the clinical and radiological outcomes of a cohort of 100 patients who underwent central spinal canal decompression accompanied by instrumentation with a new dynamic system. This system is intended to provide the necessary stability to bear daily axial loads without creating conditions that promote adjacent segment disease.

Since this was a retrospective study, internationally validated pain assessment forms such as COMI or Oswestry were not used. However, this did not prevent us from evaluating patients' clinical status and surgical outcomes based on the remission of symptoms, as described by the patient during regular postoperative follow-up visits.

The patient-reported results are comparable to the expected improvement in symptoms following decompression surgery in cases of spinal stenosis and moderate spondylolisthesis. Neurocompressive symptoms improved, while mechanical pain did not show as significant remission.

In our study, 32% of patients were free of any pain, and an additional 48% experienced a significant improvement in symptoms. This means that a total of 80% of patients benefited from the surgery.

This outcome is comparable to other published studies, where 82% and 68%, respectively, of patients benefited from surgical intervention.[15]

---

[15] Sarfraz Ahmad, Abdulkader Hamad, Amit Bhalla et al. The outcome of decompression alone for lumbar spinal stenosis with degenerative spondylolisthesis. Eur Spine J (2017) 26:414–419, DOI 10.1007/s00586-016-4637-7

The reintervention rate was:

- 9% for intra- and early postoperative complications
- 24% for reinterventions occurring three months or later after surgery

These rates do not exceed the figures reported in the literature, where reintervention rates are around 21% for a mean follow-up of 6.5 years.[16]

Radiological outcomes showed a slightly higher number of screw loosenings, confirmed by CT imaging. In our cohort, 25 patients presented with screw loosening, although not all cases were symptomatic. Of these:

- 14 patients required reoperation due to persistent symptoms associated with the loosened screws.

Comparing instrumentation types:

- Monosegmental instrumentation had a screw loosening rate of 19%
- Bisegmental instrumentation had a rate of 23%
- However, in three-segment instrumentation, a significantly higher rate of 63% was observed (7 out of 11 patients)

---

[16] Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D. et al. A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis. April 14, 2016, N Engl J Med 2016; 374:1413-1423 DOI: 10.1056/NEJMoa1513721

This observation strongly suggests that implant systems are under immense stress in constructs involving more than two segments. Despite the dynamic nature of the construct, this mechanical stress ultimately results in:

- Failure of bony integration of the screws
- Or, in some cases, screw fracture

Clearly, multiple factors must be considered to achieve a positive outcome, including:

- Lumbar spine biomechanics
- Range of motion after decompression
- Sagittal profile
- And others

The 5-year results of this cohort do not surpass the outcomes typically found in the literature for decompression combined with fusion, either clinically or radiologically:

- 25% of patients experienced screw loosening
- Nearly half developed adjacent segment pathology

However, when considering only monosegmental and bisegmental instrumentations, this study meets the criteria for a non-inferiority trial compared to decompression and fusion procedures.

In contrast, instrumentation involving three or more segments seems to exceed the system's limits. This leads to:

- Screw loosening

- Loss of segmental stability
- Screw fractures
- And poorer clinical outcomes

The incidence of intra- and postoperative complications remained within the normal range typically encountered in spinal surgery, especially in geriatric populations.

Patients who underwent three or more segment instrumentation exhibited a higher rate of screw loosening, not always accompanied by symptoms. This further supports the idea of significant mechanical stress in multisegmental constructs.

Considering both the clinical and radiological results, the presented combination of: Viper semi-constrained screws, Standard Viper screws and PEEK rods represents a viable alternative to decompression and fusion surgery. Its main advantage is the shorter operative time, which can be particularly beneficial in geriatric degenerative spinal pathology.

A crucial factor, however, is the appropriate selection of patients and limiting the instrumentation to one or two segments.