DYNAMICS OF THE SAGITTAL PROFILE OF THE SPINE AFTER ISOLATED DECOMPRESSION OF INTRACANAL NEUROVASCULAR FORMATIONS IN DEGENERATIVE LUMBAR STENOSIS: PROTOCOL OF A PROSPECTIVE MULTICENTER STUDY*

A.V. Krutko, V.R. Zakharin, E.S. Baykov, A.I. Kokorev, G.E. Balychev, O.N. Leonova
National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, Moscow, Russia

Objective. To determine the impact of isolated decompression of intracanal neurovascular structures of the spine on sagittal balance in patients with degenerative lumbar stenosis. Study registration number: NCT07139938, clinicaltrials.gov.
Material and Methods. Adult patients with neurological and/or pain syndromes caused by degenerative lumbar stenosis confirmed by MRI will be enrolled in research centers across Russia. All patients will undergo isolated decompression of neurovascular structures without the use of any implants. The dynamics of sagittal balance parameters will be assessed at 3 and 12 months after surgery by comparing with preoperative data. The sample size was calculated in accordance with the hypothesis of non-inferiority. The study aims to enroll 165 patients. Patient recruitment will take 12 months, and the total duration of the study will be approximately 2 years.
Anticipated results. This study will provide valuable information on the potential for spontaneous correction of sagittal spinal parameters following isolated decompression without the use of implants.
Key Words: isolated decompression; degenerative spinal diseases; spontaneous correction of sagittal balance.
Please cite this paper as: *Krutko AV, Zakharin VR, Baykov ES, Kokorev AI, Balychev GE, Leonova ON. Dynamics of the sagittal profile of the spine after isolated decompression of intracanal neurovascular formations in degenerative lumbar stenosis: protocol of a prospective multicenter study. Russian Journal of Spine Surgery (Khirurgiya Pozvonochnika). 2025;22(4):49–55. In Russian. DOI: http://dx.doi.org/10.14531/ss2025.4.49-55*

Degenerative spinal diseases are manifested by pain and neurological syndromes and are often characterized by the development of sagittal imbalance [1], which unavoidably results in a decrease in the quality of life [2]. Decompression of intracanal neurovascular structures is the technique of choice for compression radicular syndromes, and for neurogenic intermittent claudication [3]. Surgical treatment of patients suffering from the sagittal imbalance is performed using corrective surgical procedures and instrumentation [4–6].

Nevertheless, in some cases, patients with sagittal imbalance associated with the degenerative spinal disease after isolated decompression also experience balance correction without the use of any corrective maneuvers or implants [7]. The causes for this spontaneous correction of sagittal imbalance are functional imbalance or antalgic postural abnormalities [8]. Thus, neurogenic intermittent claudication caused by spinal canal stenosis is a typical cause of sagittal imbalance – a patient bends forward to alleviate symptoms [5]. Sagittal imbalance may also be associated with cervical radiculopathy [9].

However, the question of the effect of isolated decompression in degenerative lumbar stenosis on the global sagittal balance remains controversial. Some studies report a positive effect [7, 10, 11]; others consider it impossible [2]. Therefore, it remains undetermined whether sagittal imbalance associated with the degenerative spinal disease after isolated decompression can be corrected in all patients and what is the possible decompression extent.

The objective is to determine the impact of isolated decompression of intracanal neurovascular structures of the spine on sagittal balance in patients with degenerative lumbar stenosis.

Material and Methods

Study design: a multicenter prospective observational study.

Patient selection

Adult patients with pain and/or neurological syndromes associated with degenerative lumbar stenosis, confirmed by MRI data (grade C or D according to Schizas et al. [12]), who received conservative treatment for at least three

* *Dear colleagues! We invite you to participate in a multicenter prospective study of spontaneous correction of spinal sagittal balance in patients with degenerative spinal pathology after isolated decompression. The person responsible for inclusion in the multicenter study is Alexandr Vladimirovich Krutko, MD, PhD (National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, Moscow), e-mail: KrutkoAV@cito-priorov.ru.*

months before surgery, will be enrolled in research centers across Russia.

At least 1,000 spinal surgeries per year should be performed in the research centers where this study is planned, including 200 decompressive microsurgical and/or endoscopic procedures for degenerative spinal disease of the lumbar spine. In the study, surgical treatment should be performed by neurosurgeons and/or orthopedic traumatologists with more than seven years of surgical experience, who perform at least 100 independent surgeries per year for degenerative spinal disease.

It is planned that 165 patients will participate in the study. Patients will be enrolled within 12 months. Since the patients will be followed up for 12 months after surgery, the total duration of the study will be approximately 2 years. Patient enrollment began in October 2025, and the final visit of the last patient is expected in October 2027.

The initial data will include demographic information, the presence of comorbidities, the results of clinical questionnaires, the parameters of sagittal balance determined by postural spinal radiography, as well as the parameters of recalibration of the spinal canal according to MRI of the lumbar spine in the postoperative period.

When performing a postural spinal radiography, it is mandatory to correctly position the patient: the patient is in a standing position, with knee and hip joints in a neutral, comfortable position. The arms are bent at the shoulder and elbow joints with the hands on opposite collarbones; no external support during exposure.

Inclusion criteria:

1. Patients aged 45 and over.

2. Compression and/or compression-ischemic (including those accompanied by neurological deficits) radiculopathy with or without back pain associated with single- or multi-level degenerative lumbar stenosis with or without spondylolisthesis, intermittent claudication syndrome, confirmed by lumbar spine MRI.

3. Planned isolated decompression of intracanal neurovascular structures of the spine without the use of any stabilizing, corrective, dynamic, or other implants.

4. The symptoms remain for at least 3 months before surgery.

5. Written informed consent is obtained.

6. The patient's ability to fully comply with the clinical guidelines and follow-up schedule.

Non-inclusion criteria:

1. Any history of lumbar spine surgery.

2. Scoliosis of any non-degenerative origin (vertebral fractures, idiopathic, etc.).

3. Degenerative lumbar scoliosis greater than 20° in the frontal view.

4. Neurodegenerative diseases (Parkinson's disease, amyotrophic lateral sclerosis, etc.).

5. Any other condition or situation that, in the researcher's opinion, may affect the safety of the subject or the purpose of the study.

Exclusion criteria:

1. Discectomy.

2. Resection of the posterior support elements on at least one side and at least at one lumbar segment (including foraminotomy, laminectomy, resection, and dissection of the interspinous and supraspinous ligaments, etc.).

Clinical protocol

All patients who meet the selection criteria will be considered for inclusion. After receiving informed consent, the patient will be assigned an identification number. Each patient will undergo microsurgical (endoscopic) decompression at one or more lumbar levels.

Five visits are planned as part of the study (Table 1):

- visit 1: screening + inclusion (from day 7 to day 1 before surgery)[1];
- visit 2: surgery (day Zero);
- visit 3: discharge or day 14 of hospital stay (from day 1 to day 14 or day 14 ± a day);
- visit 4: assessment 3 months after surgery (day 90 ± 14 days). It can be replaced by e-mail correspondence in case of remote residence of the patient[2];
- visit 5: assessment 12 months after surgery (day 365 ± 56 days). It can be replaced by e-mail correspondence in case of remote residence of the patient[2].

Surgical treatment

All patients will undergo decompression of intracanal neurovascular structures at clinically significant lumbar levels while maintaining the posterior support column of the spine (unilateral, bilateral, or bilateral from a unilateral approach – overtop), including both microsurgical and endoscopic decompression.

The simultaneous achievement of the following criteria is considered to be an intraoperative sign of appropriate decompression:

1) no compression with bone and other dense formations;

2) the possibility of free displacement of neural structures;

3) distinct pulsation of the dural sac;

4) no constrictions of the dural sac.

Degenerative lumbar stenosis can be caused by hypertrophy of the ligamentum flavum, the posterior longitudinal ligament, facet joint hypertrophy, posterior vertebral body osteophytes, synovial cysts (facet joint cysts), or a combination of these factors.

Medial facetectomy is possible within 30%. All substrates compressing neurovascular structures are resected until the criteria for sufficient decompression described above are reached. Nevertheless, during the procedure, the surgeon preserves the supporting structures of the spine as much as possible, guided by the principle of minimal sufficiency.

The structures of the spine that do not compress the intracanal neurovascular structures (the tip of the spinous

[1] *It is recommended to perform a full-spine radiography and a lumbar spine MRI no later than 3 months prior to surgery.*

[2] *If the patient lives remotely, he/she will be asked to complete clinical questionnaires electronically and send the MRI and radiological images by e-mail.*

processes, supraspinous, interosseous ligaments, etc.) remain intact.

Results

The primary endpoint is the main indicator that is used to assess the achievement of the research goal. In this study, the primary endpoint is a change in the SVA value at 3 months after surgery compared with its preoperative value.

The correlation between the spinal surgery outcomes and the restoration of the patient's sagittal profile has been determined [13]. Thus, it has been shown that among the parameters of sagittal balance, PT and PI-LL are the key factors influencing the degree of disability [14]. And SVA is of particular relevance [15], as it shows the greatest correlation with the quality of life of patients, is a tool for assessing the success of surgery, and can be used as a determining factor in surgery planning; SVA >80 mm indicates the need for surgical correction with instrumentation [10].

It was found that after decompression at the lumbar spine, SVA normalization occurs in patients with initial sagittal imbalance: 45% [10] and 52% [16] when using a threshold value of 50 mm; and 25% [17], 43% [18], and 73% [1] when using the threshold values in 40 mm.

In this regard, we expect that as a result of decompression performed for degenerative lumbar stenosis, the sagittal profile of patients will at least not worsen (and in some cases will improve). This explains the choice of non-inferiority study design.

The 3 months term of the initial analysis of the outcomes (sagittal profile change) was chosen since it is the most sensitive in assessing the surgical outcomes of degenerative spinal disease. An earlier term (from 2 weeks to 3 months) may be insufficient to relieve postoperative pain. In turn, pain that persists for more than 3 months after surgery is considered to be chronic [19]. For longer term of initial analysis (more than 6 months after surgery), the patient's sagittal profile may be influenced less by the surgery performed than by the progression of the degenerative spinal disease itself [20]. In the analysis at a later stage of follow-up, the regression is less pronounced and less statistically significant [21].

The dropout rate of 20% lies in the guidelines for calculating the sample capacity for prospective studies [22], and we have also provided a margin for unexpected circumstances.

Secondary results

A secondary endpoint is an additional indicator or indicators that provide data about the patient's condition or describe the trends in the condition, for example, after surgery. Secondary results do not affect the sample size and null hypothesis.

The secondary endpoints in this study are the trends (or values) in the results of clinical questionnaires and sagittal balance parameters. Clinical questionnaires include the Oswestry Disability Index (ODI) [23], the numeric pain rating scale (NPRS) for back and leg pain [24], and the presence and intensity of neuropathic pain syndrome DN4 [25].

To assess the patient's satisfaction with the treatment, one of the questions in the SF-36 "Health perspective of the patient and life quality" (HTI) questionnaire was selected. This approach is widely used to assess the trends in the patient's health condition after surgery [26]. It can be replaced by a 5-point Likert scale [27].

There are well-known questionnaires for self-assessment of posture [28, 29], but they are applicable to patients with scoliosis, have tricky options of answer, and do not reflect changes in posture over time (which is essential for the study). Questionnaires that use a simple and intuitive form of responses, for example, "improved"/ "no changes"/ "worsened" (Table 2) are more suitable These are the so-called transition change questionnaires [30], which were taken as a prototype.

The validation of this questionnaire was performed with the participation of 15 patients who underwent decompression for degenerative stenosis of the

Table 1
Schedule of visits and assessment of instrumental and clinical data

Parameters	Visit 1: screening + inclusion	Visit 2: day of surgery	Visit 3: day of discharge	Visit 4: 3 months after surgery	Visit 5: 12 months after surgery
Informed consent	X				
Clinical assessment	X				
ODI	X			X	X
NPRS back, NPRS leg	X		X	X	X
DN4	X		X	X	X
Satisfaction (SF-36, Likert Scale)			X	X	X
Self-assessment of posture			X	X	X
Surgery		X			
Postural radiography of the spine	X			X	X
MRI of the lumbar spine	X			X	X
Adverse events	X	X	X	X	X

lumbar spinal canal. Radiological findings include changes in sagittal balance parameters: PI; PT; SS; L1–S1; L4–S1; C2HA (the angle between the vertical plumb line and the line connecting the center of the bicoxofemoral axis to the C2 odontoid apex); FOA (the femur obliquity angle); SVA; and SFD (the sacro-femoral distance). Changes in the cross-sectional area of the dural sac at the operated lumbar spine were assessed using RadiAnt DICOM Viewer software (mm^2).

Sample size calculation

In our calculations, we relied on the study by Ogura et al. [10], where the clinical and radiological results of decompression in lumbar stenosis were assessed. In this study, the value of the standard deviation (SD) of SVA was 37.4 mm before surgery and 38.5 mm after surgery, and *r,* a coefficient of correlation between the standard deviations before and after surgery (conservative estimate), was 0.8.

Since the study will be single-sample, with the hypothesis of non-inferiority (no less effective) to demonstrate a non-increase in SVA after surgery compared to the measurement before surgery (hypothesis limit = 0), a one-tailed T-test for paired samples will be used to test the hypothesis. The one-tailed significance value will be 0.025, and the power will be 90%. Under these assumptions, the minimum sample size will be 131 participants; with a dropout of 20%, the sample size will be 165 participants.

Ethics Committee

This study will be undertaken in accordance with the rules of the ICH GCP, the requirements of the Helsinki Declaration (2013 edition), and the requirements of the state standards of the Russian Federation (14155-2014). The study protocol was approved by the local Ethics Committee of the National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov of the Ministry of Health of the Russian Federation (No. 4/25 dated July 3, 2025).

Table 2

The questionnaire used to assess posture dynamics. How has your posture changed after surgery?

1 — improved	0 — no changes	1 - worsened

Discussion

In some cases, isolated decompression of intracanal neurovascular structures at the lumbar spine eliminates patient's orthopedic problems that are not an initial aim for surgical treatment.

Correction of sagittal balance by decompression without fixation provides a number of benefits, including improved posture, mobility, and functional recovery. In addition, the elimination of sagittal imbalance improves both neurological symptoms and long-term quality of life [31, 32].

Currently, there are a number of studies on the changes of sagittal balance parameters after isolated decompression in patients with degenerative lumbar stenosis.

Silva et al. [2] (n = 95) indicate the absence or very weak impact of isolated decompression on the spinal and pelvic parameters. Nevertheless, in this retrospective study, the authors use non-standard data analysis techniques that limit the application of the results to another cohort, and the study was conducted in one center that does not exclude the presence of a systematic error (for example, parameter measurement, lack of a strict standardized positioning protocol for all images).

Park et al. [31] describe a significant improvement in sagittal parameters in elderly patients (n = 49) after lumbar decompression, calling decompression a 'good tool' for correcting sagittal imbalance.

Ogura et al. [10] state that decompression can result in a reactive improvement in lumbar and global sagittal balances (n = 89) if sagittal disorders were reversible.

In our opinion, such a global discrepancy in results is associated with the low degree of evidence of these studies, since they have a retrospective design and a small single-center sample of patients.

For this reason, we found it appropriate to collect convincing evidence of the correlation between decompression and sagittal imbalance in degenerative spinal disease. It is highly important to find predictors of spontaneous correction using preoperative data, since residual sagittal imbalance has a negative impact on clinical outcomes.

Achieving results that can be trusted and extrapolated to other cohorts will open up new options for providing the best care to patients with degenerative spinal diseases.

Limitations

The limitation of the study is the lack of stratification according to the assumed risk factors (age, Schizas grade of stenosis, and initial alignment in SVA). Also, the design of this study does not imply randomization.

Moreover, we do not have the technical capability to control the accuracy of stitching postural radiographs because of the lack of EOS machines in the hospitals participating in the study.

The study had no sponsors. The authors declare that they have no conflict of interest.
The study was approved by the local ethics committee of the institution.
All authors contributed significantly to the research and preparation of the article, read and approved the final version before publication.

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Address correspondence to:
Zakharin Vitaly Romanovich
National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, zakhvit@gmail.com

Received 30.10.2025
Review completed 25.11.2025
Passed for printing 30.11.2025

Aleksandr Vladimirovich Krutko, DMSc, head of Department of spine surgery, National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, eLibrary SPIN: 8006-6351, ORCID: 0000-0002-2570-3066, KrutkoAV@cito-priorov.ru;
Vitaly Romanovich Zakharin, MD, PhD, orthopedic surgeon, National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, eLibrary SPIN: 2931-0703, ORCID: 0000-0003-1553-2782, zakhvit@gmail.com;
Evgenii Sergeyevich Baykov, MD, PhD, neurosurgeon, Department of spine surgery, National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, eLibrary SPIN: 5367-5438, ORCID: 0000-0002-4430-700X, Evgen-bajk@mail.ru;
Alexey Ivanovich Kokorev, MD, PhD, orthopedic surgeon, National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, eLibrary SPIN: 7734-8476, ORCID: 0000-0002-5829-6372, KokorevAI@cito-priorov.ru;
Gleb Evgenyevich Balychev, orthopedic surgeon, National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, eLibrary SPIN: 9647-8748, ORCID: 0000-0001-7884-6258, balichev.gleb@gmail.com;
Olga Nikolayevna Leonova, MD, PhD, scientific secretary, National Medical Research Center of Traumatology and Orthopedics n.a. N.N. Priorov, 9 Novospassky lane, Moscow, 115172, Russia, eLibrary SPIN: 4907-0634, ORCID: 0000-0002-9916-3947, onleonova@gmail.com.