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Optimization of Treatment Outcomes in Patients with Segmental Instability in the Lumbar Spine Using a Minimally Invasive Spinal Fusion Technique

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Open transforaminal lumbar interbody fusion (TLIF), which is used to treat segmental instability, is associated with a significant paravertebral muscle and ligament injury. A new rigid fusion technique was introduced to improve patients' treatment outcomes. **Objective.** The objective of the study was to conduct a comparative analysis of the effectiveness of minimally invasive fusion technique and TLIF technique to improve treatment outcomes in patients with symptomatic degenerative lesions in the lumbar spine accompanied with moderate lumbar segmental instability. **Material and Methods.** The study involved 90 patients divided into 2 groups. Transforaminal interbody fusion using the pezo-T PEEK cage was performed in both groups after spinal canal reconstruction. In group 1 (n=45), conventional TLIF technique was performed by four-point transpedicular fixation using the CONMET system; in group 2 (n=45), the coflex-F rigid interspinous implant was used. Patients were followed up and treatment outcomes were assessed within approximately 24 months after surgery. **Results.** Intergroup comparison of pain intensity level on the visual analogue scale, the need for painkillers, and the quality of life according to the Oswestry Disability Index scale during the early postoperative period demonstrated significantly better outcomes in group 2 of patients due to a less severe operative trauma to the paravertebral soft tissues. Meanwhile, the formation of interbody bone block after 20—36 months was observed in 95% of patients in group 1 and in 94% of patients in group 2 (p>0.05). Postoperative complications occurred in 17.8% of patients in group 1 and in 2.2% of patients in group 2 (p<0.001). **Conclusion.** The use of rigid interspinous stabilization and transforaminal interbody fusion provides better clinical outcomes and fewer postoperative complications as compared to the TLIF technique in the case of similar X-ray pictures of the bone block formation in patients with moderate segmental instability of the lumbar spine, thus optimizing treatment outcomes in a given category of patients.

Keywords: *segmental instability, lumbar spine, degenerative disc disease, TLIF, rigid interspinous fixation, transpedicular fixation, decompression.*

More than 80% of the adult working-age population in the world experience low back pain [1]. The study of the causes of the vertebrogenic syndrome revealed that 80—90% of lumbosacral pain cases are associated with intervertebral disc pathology [2, 3], including segmental instability to be present in more than a half of the patients [4, 5].

The modern approach to eliminating clinically significant abnormal vertebral dislocation of one of the vertebra relative to another includes interbody cage placement and transpedicular fixation of an unstable spinal motion segment (SMS) [6, 7]. On the one hand, this type of fusion is associated with significant aggression against paravertebral soft tissue and damage to the muscular and ligamentous apparatus, which results in significant intracranial and paravertebral cicatricial and adhesive changes. The latter requires long period of healing and recovery and in some cases can worsen patients' quality of life and affect their working capacity. [8] On the other hand, in the case of less radical surgical intervention, the remaining segmental instability is one of the common causes of recurrent pain in the postoperative period [2, 9].

The search for new technological solutions to improve the treatment outcomes of patients with symptomatic lumbar segmental instability is aimed at the development of surgical interventions for optimal decompression of neural structures and effective stabilization of the operated segment with minimal trauma to the surrounding tissues. A new fusion technique, comprising rigid interspinous stabilization with coflex-F implant (Paradigm Spine GmbH, Germany) and transforaminal interbody placement of pezo-T cage (Ulrich Medical GmbH, Germany), has been used at the Railway Clinical Hospital (Irkutsk, Russia) since 2010. This study focuses on the comparative evaluation of the results of the new technique and the conventional TLIF technique.

The objective of the study was to conduct a comparative analysis of the effectiveness of minimally invasive rigid stabilization technique and conventional transpedicular fixation for improving the treatment outcomes of patients with lumbar segmental instability.

Material and Methods

The study included 90 patients who meet the inclusion criteria, but not the exclusion criteria, and underwent surgery in 2010—2013. The study was approved by the Committee on Ethics of the Scientific Center of Re-

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constructive and Restorative Surgery of the Siberian Branch of Russian Academy of Medical Sciences. The criteria for inclusion and exclusion in the study were indications and contraindications for minimally invasive interbody fusion for the treatment of the SMS instability.

Inclusion criteria were as follows:

— in the case of ineffective conventional treatment: prolonged or recurrent pain syndrome, permanent neurological deficit that may range from radiculoneuralgia to radiculopathy and is accompanied with peripheral nerve palsy;

— signs of moderate segmental instability (vertebrae are displaced relative to each other by more than 9 mm, but less than 15 mm) based on the results of functional radiography of the spine;

— grade I spondylolisthesis according to H. Meyerding (without spondylolysis);

— according to the data of neuroimaging, herniation or protrusion of the intervertebral disc followed by disc space or spinal canal narrowing that causes corresponding clinical symptoms.

Contraindications:

— central stenosis;

— grade II—IV spondylolisthesis according to H. Meyerding (with or without spondylolysis);

— severe comorbidity.

The patients were divided into two groups; both groups were subjected to transforaminal interbody fusion using the pezo-T polyetheretherketone (PEEK) cage. The inner cavity of the cage was filled with the bone autograft obtained from surgical approach. Group 1 (n=45) underwent four-point transpedicular fixation using the CONMET system (Russia) after the spinal canal reconstruction via laminectomy with unilateral or bilateral partial or total facetectomy; group 2 (n=45) underwent decompression via unilateral access using an original technique [10] in the extent of unilateral partial facetectomy followed by stabilization with the coflex-F rigid interspinous implant.

After surgery, minimum follow-up was 8 months and maximum follow-up was 36 months (median time of 24 months). The following parameters were examined for a comparative analysis: gender, age, body mass index, technical features of surgical intervention (timing of surgery, blood loss, and the length of incision), activation time, duration of treatment at hospital, radiographic parameters for assessing the bone block formation capability (anteroposterior and lateral radiographs of the spine), and data of neuroimaging (1.5T MRI scanner, Siemens Magnetom Essenza, Germany). Clinical parameters were also assessed: the severity of pain according to the visual analog scale (VAS), the need for painkillers according to the number of nonsteroidal anti-inflammatory drug injections per day, and the quality of life in patients with low back pain according to the Oswestry index (ODI) [2, 11].

All patients were operated on using original instruments by one surgical team, who had no social and economic interest in surgical outcomes.

Statistics and analytics application software (Microsoft Excel and Statistica 8) was used for statistical analysis of research results.

Results

In order to assess significant differences in samples, criteria of nonparametric statistics were used with the lower limit of validity of less than 0.05. The results were presented by median and interquartile range (IQR, 25th to 75th percentile). Statistically significant differences were detected in repeated measurements (3, 6, 12, and 24 months after surgery) with allowance for the Bonferroni correction (p<2.5%). Criteria of nonparametric statistical analysis included: the Mann–Whitney U test (U) for intergroup comparisons, the Wilcoxon test (W) for dependent samples, and the chi-square (χ^2) for binomial properties.

Medical background of the study population is presented in **Table 1**. During the intergroup comparison, no statistically significant differences were found (p>0.05). Summary data on the duration of surgery, blood loss, the length of incision, time of patient's activation and stay at hospital are presented in **Table 2**.

Comparative analysis revealed that the studied technical parameters were significantly lower in group 2 compared to group 1 (p<0.05). This fact indicates that the interspinous stabilization with interbody fusion can be performed much faster (by 30% on average) and the access is less traumatic as compared to transpedicular fixation.

Analysis of the need for painkillers in the postoperative period was conducted **(Fig. 1)**. A gradually decreased frequency of administration of painkillers in both study groups was noted; at the same time, total need for painkillers was significantly lower in group 2 over the time at hospital (p_{M-U}=0.014). When analyzing the pain intensity level at the area of surgical site **(Fig. 2)**, group 1 revealed significantly higher pain intensity level compared to group 2 (p_{M-U}=0.035). Intergroup comparison of pain intensity according to the VAS scale **(Fig. 3)** revealed no statistically significant differences in the preoperative score (p>0.05). At discharge and over the follow-up period (IQR within 2 years), significantly lower pain intensity level was detected in group 2 (p<0.05), which may be associated with less severe operative trauma to paravertebral soft tissues.

Comparative evaluation of the quality of life in patients according to the ODI (**see Fig. 3**) revealed that preoperative values were comparable in both groups (p>0.05); however, at discharge and during follow-up (mean time of 24 months), significantly higher scores of patients' quality of life were observed in group 2 (p<0.05), which may be associated with preserved functions of the

Table 1. **Comparison of initial characteristics of the study population**

Criteria	Group 1 (*n*=45)	Group 2 (*n*=45)	*p*
Age, years, IQR (25%—75%)	38 (32; 44)	39,5 (33; 49)	0.3
Male patients, *n* (%)	33 (73)	31 (69)	0.2
Body mass index, kg/m^2	25,8 (22.9; 29.1)	26,4 (23.5; 29.7)	0.7

Table 2. **Comparison of two study groups according to surgical intervention technique and specificity of follow-up, IQR (25%—75%)**

Criteria	Group 1 (*n*=45)	Group 2 (*n*=45)	*p*
Timing of surgery, min	205 (160; 220)	145 (115; 190)	0,01
Blood loss, mL	350 (300; 550)	50 (30; 100)	0,008
Length of incision, mm	100 (90; 150)	55 (45; 70)	0,0015
Activation time, days	4 (3; 5)	2 (2; 3)	0,02
Length of stay at hospital, days	13 (12; 15)	11 (9; 12)	0,04

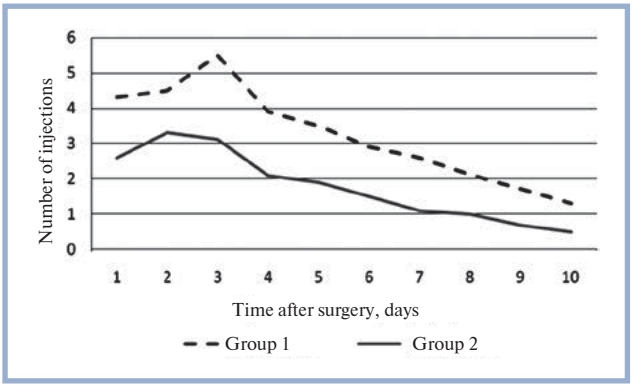

Fig. 1. **The need for painkillers in two groups of patients in the postoperative period.**

posterior muscular and ligamentous apparatus and less severe intracranial cicatricial and adhesive changes.

During follow-up (mean time of 24 months), control X-ray pictures of the spine in patients of both groups revealed no dislocation and migration of an implant, as well as no signs of segmental instability **(Figs. 4, 5)**. The interbody bone block formation was detected in 86% of patients of group 1 and in 84% of patients in group 2 (p>0.05) 10—15 months after surgery and in 95% of patients in group 1 and in 94% of patients in group 2 (p>0.05) 20—36 months after surgery.

Sixty-two (69%) patients underwent control MRI of the lumbar spine 36 months after surgery. No data on the additional compression of the neural structures by structural elements were obtained. Signs of progressive degeneration of the segments adjacent to the operated ones were detected in 9 (20%) patients of group 1 **(Figs. 6, 7)**.

No complications associated with the direct placement of stabilizing constructs were observed in both groups during the study. A comparative analysis of the number of postoperative complications revealed them to occur significantly often in group 1 compared to group 2 (p=0.0017). Interbody fusion and transpedicular fixation caused 8 (17.8%) complications. Soft-tissue infection was identified due to hematoma infection symptoms (surgical wound drainage and local antibiotic therapy enabled the elimination of infection) in 3 cases; in 1 case, incorrect biomechanics restoration caused overload of facet joints at the adjacent surgical level and bilateral facet syndrome (after other possible causes of the pain syndrome had been excluded, facet joint radiofrequency denervation was performed resulting in complete regression of symptoms). In 2 patients, recurrent pain occurred due to disc herniation in segments adjacent to those subjected to fusion as the disc degeneration progressed and thus revision surgery was performed in the extent of microdiscectomy. In another 2 patients in the late postoperative period (4 and 7 months after surgery), recurrence of radicular symptoms was caused by the development of postoperative epidural fibrosis with no radiographic signs of foraminal and spinal stenosis, as well as with no signs of segmental instability according to the data of multislice computed tomography with myelography. In these cases, courses of conventional therapy significantly reduced the pain.

After interbody fusion and rigid interspinous stabilization, one (2.2%) complication was verified as a postoperative wound infection on the background of subcompensated type 2 diabetes. Local application of antiseptics and prolonged antibiotic course enabled to stop the inflammatory process.

Published materials of different authors that are devoted to lumbar spine fusion were compared with our results and these data are presented in **Table 3**.

Discussion

The relevance of studying new techniques of treatment for degenerative segmental spinal instability is linked to the lack of standard treatment approaches in the modern spine medicine, as well as to the efforts to improve the effectiveness of surgical interventions followed by negative outcomes in 3—20% of cases according to

different authors [8, 9]. These complications are associated with the insufficient bone block formation and with recurrence of neurological symptoms and pain syndrome after surgery. The objectification of indications for decompression and stabilization surgery, which is based on studying the severity of degeneration of the elements in the SMS [19], outcomes of surgical treatment, and mechanisms of fusion, cause decrease in the aforementioned adverse health consequences [7, 8]. It was found that the success of surgery for symptomatic instability in the SMS depends not only on decompression of neural and vascular structures in the intervertebral disc spaces and spinal canal, but also on the correctly performed orthopedic procedure, i.e. reconstruction, optimization, and stabilization of the space between osteocartilaginous structures of the spine [7, 20].

Significant intraoperative trauma, as well as a relatively high risk of early and late adverse effects in the form of recurrent spinal stenosis, insufficient bone block formation, and a false joint formation limits the use of open transpedicular fixation at the first signs of segmental instability [2, 15]. There is a direct correlation between the extent of resection of structural elements of the SMS and the development of postoperative instability in the case of spinal canal reconstruction via posterior approach [15, 20, 21]. In addition, insignificant presurgical spondylolisthesis, even in the case of insignificant surgical aggression towards elements of the posterior support complex (e.g., facetectomy) causes spondylolisthesis progression [22]. In such cases, there are indicators for stabilization procedure followed by rigid [12] or dynamic [14] transpedicular fixation via either open [13] or transcutaneous access [15] in most cases. A significant role in functional recovery of patients after open transpedicular fixation is played by the following factors: (1) severity of intraoperative injury of the muscular and ligamentous apparatus; (2) adequate correcting the abnormal segmental instability; (3) reliability of the bone block formation and its stability within prolonged period of time [7, 23].

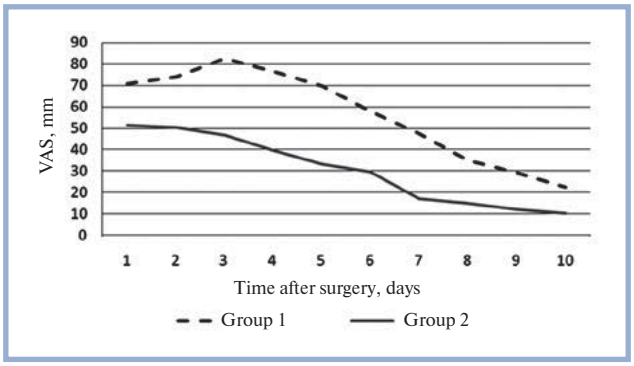

Fig. 2. **Dynamics of pain intensity at the surgical site area according to the VAS pain scale.**

Biomechanical studies [12—14, 24] have shown that a single transpedicular fixation in the case of unstable SMSs causes redistributed axial load on the pedicle screws, resulting in screw breakage (up to 10% of cases) and failure of the fixation system. In order to avoid such complications, the modern concept of rigid fixation combines interbody fusion and transpedicular fixation techniques and is regarded as "gold standard" of treatment for segmental spinal instability [14, 15].

The progression of the degenerative disc disease causes the interbody space to gradually sink and decrease in size and also the foraminal compression of neurovascular structures [5, 18]. Treatment options for correcting

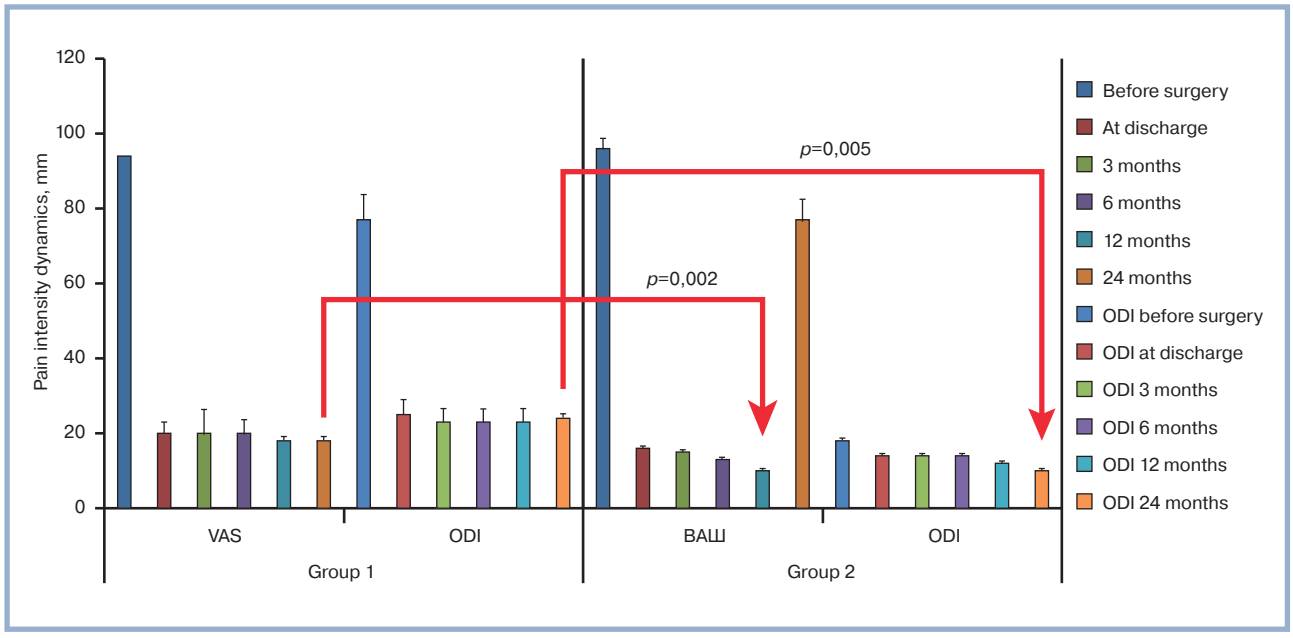

Fig. 3. **Pain intensity dynamics on the VAS pain scale (0—100 mm) and quality of life dynamics according to ODI (0—100) in groups.**

Footnote. The values are given as median and IQR (25%—75%).

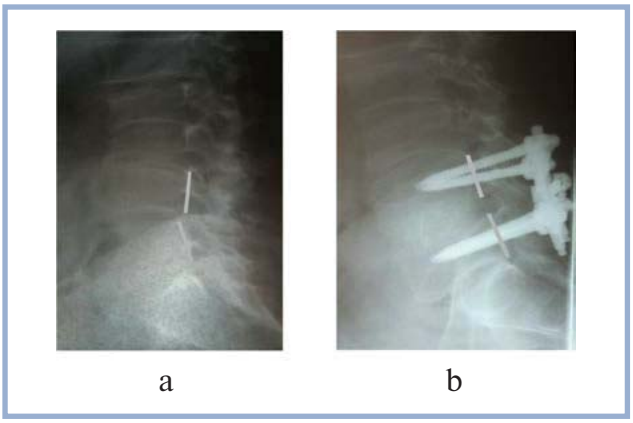

***Fig. 4*. X-ray picture of the lumbosacral spine of a male patient *P.* (group 1), lateral view.**

a — before surgery (sagittal translation of the SMS at the L4—L5 level, 11 mm); b — 10 months after the L4—L5 interbody fusion using the pezo-T cage (Ulrich Medical GmbH, Germany) and four-point transpedicular fixation using the CONMET system (Russia): no sagittal translation in the SMS at the L4—L5 level and X-ray signs of full bone block formation.

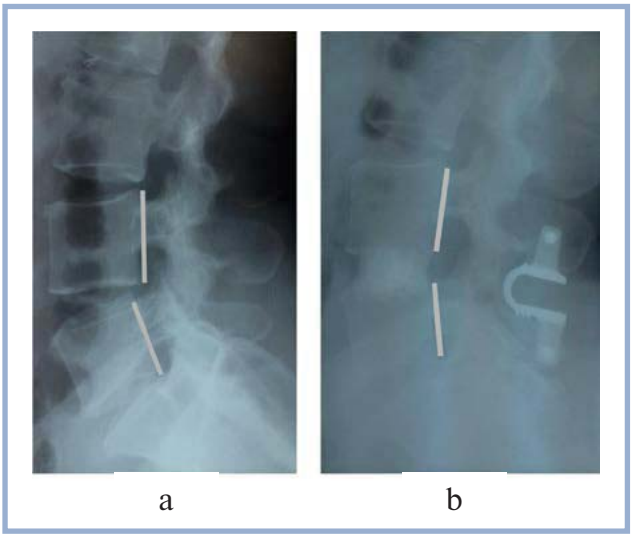

***Fig. 5*. X-ray picture of the lumbar spine of a female patient *S.* (group 2), lateral view.**

a — before surgery (sagittal translation of the SMS at the L4—L5 level, 10 mm); b — 9 months after the L4—L5 interbody fusion using the pezo-T cage (Ulrich Medical GmbH, Germany) and rigid interspinous stabilization using the coflex-F cage (Paradigm Spine GmbH, Germany): no sagittal translation in the SMS at the L4—L5 level and X-ray signs of full bone block formation.

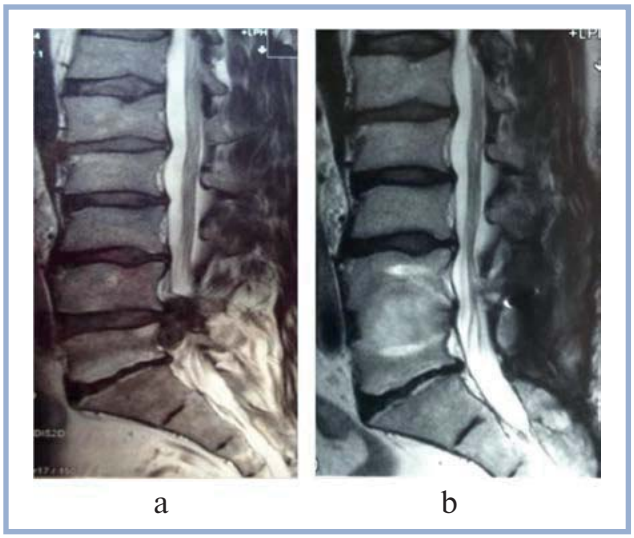

***Fig. 6*. MRI of the lumbar spine of a male patient *P.* (group 1), sagittal view.**

a — before surgery (sequestered disc herniation at the L4—L5 level); b — 20 months after the L4—L5 interbody fusion using the pezo-T cage (Ulrich Medical GmbH, Germany) and four-point transpedicular fixation using the CONMET system (Russia): no MRI-based signs of progressive degeneration in the SMS adjacent to the surgical site.

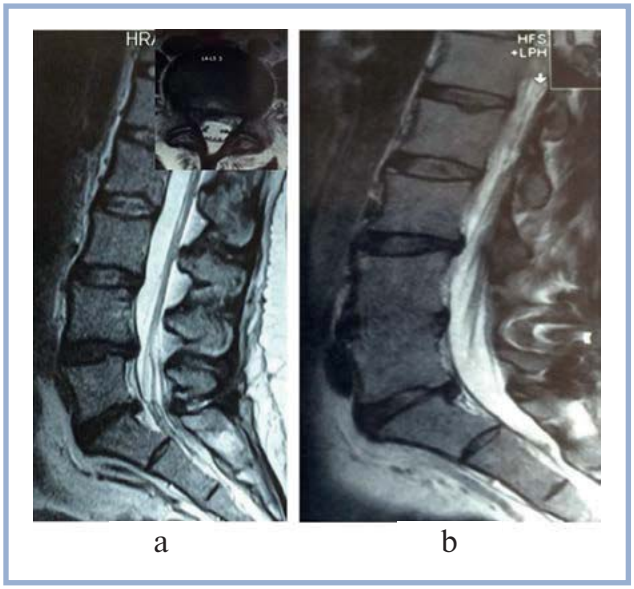

***Fig. 7*. MRI of the lumbar spine in female patient *S.* (group 2), sagittal view.**

a — before surgery (fragmented disc herniation the L4—L5 level); b — 19 months after the L4—L5 interbody fusion using the pezo-T cage (Ulrich Medical GmbH, Germany) and rigid interspinous stabilization using the coflex-F cage (Paradigm Spine GmbH, Germany): no MRI-based signs of progressive degeneration in the SMS adjacent to the surgical site.

the height of interbody space include placement of osteoinductive or osteoconductive materials [14, 16]. A bone autograft was initially inserted into a disc space in order to form the fusion [23], but the tendency of an autograft to be resorbed and the high rate of pseudarthrosis caused the development and use of threaded cages [25, 26]. Interbody cage placement causes the disc space of indirect decompression of spinal nerve roots to widen by increasing the height of the intervertebral disc [5, 13]. This approach enabled quick and reliable fixation of the segment, increased the effectiveness of treatment, and reduced postoperative bed rest [24, 26, 27]. Invasiveness of bilateral placement of threaded cages and remaining risks of implant displacement after a wide decompression of the spinal canal [29, 30] required further search for interbody fusion options. The routine method uses a threadless bean-shaped cage, which is placed via unilateral

Table 3. Comparison between published treatment outcomes of the lumbar spine fusion and results of our research

Author, year of publication	Lumbar spine fusion, absolute value	Blood loss, mL	Before surgery/after surgery		Bone block formation (long-term results), %
			VAS (0—100 mm)	ODI (0—100)	
A.E. Simonovich, 2004 [12]	NiTi cage and open TPF, *n*=143	—	38±7/7±6*	61.5±10.04/ 13.88±5.52*	94.8
D.H. Kim et al., 2009 [13]	Ti cage and open TPF, *n*=53	933.3—1011.6	65/18	70/37.9	94.6
C.A. Logroscino et al., 2011 [14]	TraXis PEEK cage and percutaneous TPF, *n*=20	126.0	71 (59—88)/ 21 (10—35)**	52,8 (40.2—72.7)/ 27.1 (11.2—34.8)**	85
Y. Park et al., 2011 [15]	CAPSTONE PEEK cage and percutaneous TPF, *n*=66	—	62±19/26±21*	60,2±16.5/ 25.9±17.9*	77.3
A.V. Krut'ko, 2012 [16]	Olis PEEK cage and open TPF, *n*=328	1052.1±492.6*	—	—	—
	Olis PEEK cage and percutaneous TPF, *n*=44	545.6±283.0*	72±10/ 19±10*	76.3±8.4/20.2±6.9*	—
S.G. Lee et al., 2012 [17]	PEEK cage and percutaneous TPF, *n*=17	550.0 (300.0—1500.0)**	67 (50—90)/ 41 (20—50)**	71.2 (67—81)/ 38 (29—61)**	88.2
L. Marchi et al., 2012 [18]	PEEK cage, *n*=52	50.0	78/31	66/30	86.5
Our results (results of this study)	Pezo-T PEEK cage and open TPF, *n*=45	350.0 (300.0; 550.0)***	75 (62; 82)/ 10 (10; 12)***	58.5 (50; 60)/ 20 (16; 20)***	95
	Pezo-T PEEK cage and rigid ISS, *n*=45	50.0 (30.0; 100.0)***	79 (73; 84)/ 4.5 (4; 6)***	53 (46; 60)/ 8 (6; 12)***	94

Footnote. * — *M*±*m*, ** — M (min—max), *** — IQR (25%—75%); TPF — transpedicular fixation, ISS — interspinous stabilization.

transforaminal access. PEEK cages became particularly popular due to a number of physical and chemical features, such as full biocompatibility, absence of cytotoxic and mutagenic effects, and parameters in biomechanics similar to those of a bone [31, 32].

Treatment outcomes of patients with posterior interbody stabilization are various. The technique of bilateral interbody fusion using cages that is combined with transpedicular fixation contributes to the formation of a bone block in 90% of cases, with good treatment outcomes amounting to 67% [33, 34]. In 1985, the search for a less traumatic posterior interbody fusion technique lead Blume [16] to develop the unilateral transforaminal access with placement of a bean-shaped cage into the intervertebral disc space that was followed by transpedicular fixation. T. Lowe et al. [35] found that fusion rate reaches 90% for the TLIF procedure, with good and excellent clinical outcomes being observed in 85% of patients, which was also confirmed by various studies [15, 20].

A minimally invasive TLIF technique using percutaneous screw placement under navigation from the field of paramedian incision via tube retractor is known [17, 36]. Being a significantly less traumatic technique, the rate of total fusion compared to the standard open TLIF technique amounted to 80 and 87%, respectively [6, 37].

In recent years, various interspinous implants used for stabilization procedure after microsurgical discectomy became popular [2, 38]. Meanwhile, titanium U-shaped constructs became accepted due to the capability of intralaminar placement [2, 39—41]. The use of these implants allows widening the size of the spinal canal and disc spaces due to widening the posterior and middle parts of disc spaces without kyphosis development [2] as well as allows restricting the SMS movement in sagittal plane [39]. The question whether to use interspinous implants or not remains unresolved. There is a large variety of indications for their use: spinal stenosis [38], initial instability in the SMS or preventive measures after discectomy [40], degenerative facet disease [42], preventive measures for the adjacent segment syndrome after rigid stabilization [43], and grade I degenerative spondylolisthesis [41]. Contraindications to the interspinous stabilization are regarded as follows: grade II—IV spondylolisthesis, patients older than 70 years of age, signs of osteoporosis, and vertebral body fractures [37, 39].

No data on using both the interbody fusion and rigid interspinous stabilization for the treatment of patients with segmental instability in the lumbosacral spine were found in the specialized literature.

The presented series of our observations showed a stabilization technique using rigid interspinous implant placement to result in comparable clinical outcomes between levels of pain intensity and quality of life and the data of other published studies analyzing posterior lumbar interbody fusion **(see Table 3)**.

Compared to the TLIF technique, the advantages of rigid interbody fusion with interspinous stabilization in the case of moderate abnormalities in spatial relationships in the SMS (translation of vertebrae relative to each other in sagittal plane according to the data of functional radiography of the spine, from 9 to 15 mm) are as follows:

(1) less traumatic surgical approach with remaining optimal visualization of the spinal canal structures;

(2) simple rigid interspinous implant placement with minimum number of supplementary surgical instruments;

(3) effective unstable segment fixation and high incidence of bone block formation followed by fewer postoperative complications.

Conclusion

Treatment of symptomatic lumbosacral degenerative disc disease combined with moderate segmental instability by means of the surgical technique using both rigid interspinous stabilization and transforaminal interbody fusion enables to achieve better clinical outcomes and causes fewer postoperative complications compared to conventional TLIF in case of similar X-ray results of the bone block formation.

Thus, the minimally invasive stabilization technique enabled to optimize the outcomes of surgical treatment of patients in a given category.

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Commentary

The presented article is devoted to the topical issue — the treatment of degenerative disc diseases in the lumbosacral spine. At present, surgeons are familiar with a variety of surgical techniques developed for the treatment of this group of diseases. Despite the strict indications for all techniques, we should admit that occasionally we still use creativity in selecting the optimal surgical treatment. The article is a prime example of this.

It is no secret that implants, a part of which is intended to form the fusion, are used intraoperatively in some cases. The concept of this approach is that the pain caused by excessive segment movements regresses when the segment is fixed. Different technologies have been developed to stabilize spinal segments; the "gold standard" is regarded to be the 360° fusion. In this article, the authors propose for achieving this goal to use a combination of interspinous implant, which is positioned by the manufacturing company as a device for rigid stabilization, and an interbody cage made in Germany. Transpedicular stabilization using domestic system and interbody stabilization using cages made in Germany are compared.

All patients were divided into two equal groups of 45 patients. It should be noted that patients were also divided according to the extent and technique of neural structure decompression: decompression using unilateral approach was performed in group 2. The authors compared a complex of signs (duration of surgery, length of incision, blood loss, patient's activation time, length of stay at hospital, etc.). Cumulative analysis of these indicators shows the advantages of combination technique with rigid interbody implant and interbody cage placement. Group 1 of patients who underwent transpedicular fixation combined with interbody fusion showed 17.8% incidence rate of complications, whereas this index reached 2.2% in group 2. From the perspective of case-based medicine, this study is near the base of the pyramid, which reflects the general state of affairs in the medical periodical literature. The article includes a number of inaccuracies, in particular, the authors said: "All patients were operated on using original instruments by one surgical team, who had no social and economic interest in surgical outcomes". The interest in the treatment outcome certainly must be present.

Despite some comments, the study should be recognized as new, interesting, and worthy to be publicated in the journal; however, in my opinion, it is reasonable to conduct such researches not only within a single clinic, but also using the Spine Registry.

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