

## REVISION SURGERY FOR FAILURE OF THE DYNAMIC STABILIZATION SYSTEM OF THE LUMBAR SPINE

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### ABSTRACT

**The aim of the study.** To study the frequency and treatment options for dysfunction of the dynamic stabilization system of the lumbar spine.

**Materials and methods.** We carried out a retrospective analysis of the treatment of 58 patients with degenerative pathology of the lumbar spine and instability of the spinal motion segments, who were treated at the neurosurgical unit of the Irkutsk Scientific Centre of Surgery and Traumatology in 2011–2020. The stability of spinal motion segment was assessed using X-ray imaging, magnetic resonance imaging and tomography of the lumbar spine. Revision surgery was performed in 7 out of 58 previously operated patients using the Coflex dynamic fixation system of spinal motion segments (Paradigm Spine LLC, Germany).

**Results.** Revision surgery was performed in 7 out of 58 patients with dynamic fixation of the spinal motion segments with an interosseous implant due to an increase in pain syndrome. In 1 patient, the reason for repeated surgery was primary instability of the fixation system caused by a fracture of the spinous process. In the delayed period, 4 patients had an X-ray picture with heterotopic ossification of the implant and instability of spinal motion segments. In two observations, a recurrence of intervertebral hernia was diagnosed at the level of the operated spinal motion segment. During revision surgery, a facetectomy was performed with stabilization by a peek cage, followed by pain management and clinical manifestation regression.

**Conclusion.** The conducted study shows that a number of patients after discectomy and dynamic stabilization of the spine using “Coflex” system have inconsistency and heterotypic ossification of the implant and neoarthrosis. Implantation of a lumbar peek cage while maintaining the “Coflex” device makes it possible to form a rigid interbody fusion, which means it is sufficient and justified surgical technology for treating the failure of the dynamic stabilization system.

**Key words:** segmental instability of the spine, dynamic stabilization, heterotypic ossification, repeated surgical interventions, revision surgery

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## РЕВИЗИОННАЯ ХИРУРГИЯ ПРИ НЕСОСТОЯТЕЛЬНОСТИ СИСТЕМЫ ДИНАМИЧЕСКОЙ СТАБИЛИЗАЦИИ ПОЯСНИЧНОГО ОТДЕЛА ПОЗВОНОЧНИКА

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### РЕЗЮМЕ

**Цель исследования.** Изучить частоту и варианты лечения дисфункции системы динамической стабилизации поясничного отдела позвоночника.

**Материалы и методы.** Проведён ретроспективный анализ лечения 58 пациентов с дегенеративной патологией поясничного отдела позвоночника и нестабильностью позвоночно-двигательных сегментов (ПДС), находившихся на лечении в отделении нейрохирургии ФГБНУ «Иркутский научный центр хирургии и травматологии» в период с 2011 по 2020 г. Оценка стабильности ПДС осуществлялась при рентгенографии, магнитно-резонансной томографии и мультиспиральной компьютерной томографии поясничного отдела позвоночника. Ревизионные вмешательства выполнены 7 из 58 ранее оперированных пациентов с применением системы динамической фиксации ПДС «Coflex» (Paradigm Spine LLC, Германия).

**Результаты.** Ревизионные хирургические вмешательства выполнены 7 из 58 пациентов с динамической фиксацией ПДС межостистым имплантом в связи нарастанием болевого синдрома. У одного больного поводом к повторной операции послужила первичная нестабильность металлоконструкции, обусловленная переломом остистого отростка. В отсроченном периоде у 4 пациентов выявлена рентгенологическая картина гетеротипической оссификации конструкции и нестабильность ПДС. В двух наблюдениях на уровне оперированного ПДС диагностирован рецидив межпозвонковой грыжи. При ревизионном вмешательстве проведена фасэктомия со стабилизацией реек-кейджером с последующим купированием болевого синдрома и регрессом клинических проявлений.

**Заключение.** Проведённое исследование свидетельствует о том, что у ряда пациентов после дискэктомии и динамической стабилизации позвоночника системой «Coflex» развивается несостоятельность и гетеротипическая оссификация импланта, формируется неоартроз. Имплантация поясничного реек-кейджа при сохранении устройства «Coflex» позволяет сформировать ригидный межтеловой спондилодез, то есть является достаточной и обоснованной хирургической технологией лечения несостоятельности конструкции динамической стабилизации.

**Ключевые слова:** сегментарная нестабильность позвоночника, динамическая стабилизация, гетеротипическая оссификация, повторные хирургические вмешательства, ревизионная хирургия

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## INTRODUCTION

One of the actual problems of spinal neurosurgery is the treatment of degenerative pathology of the lumbar spine. The existing methods of surgical treatment of degenerative-dystrophic spine diseases, unfortunately, cannot be considered ideal [1, 2]. The use of microsurgical techniques and modern instrumental technologies in spine surgery does not exclude the recurrence of pain syndrome [3–5]. Attempts to improve outcomes and avoid exacerbation of pain have motivated specialists to search for new solutions to the problem [6–8]. Biomechanically based technologies of dynamic and rigid stabilization of the spinal motion segment (SMS) have been actively used over the last decades. The range of surgical interventions is quite diverse and includes techniques of transpedicular fixation and articular, interspinous or anterior spondylodesis with implants of various modifications [9–12].

## THE AIM OF THE STUDY

To study the incidence and treatment options for failure of the posterior dynamic stabilization system.

Lumbar spine herniation surgery is often accompanied by structural transformation of the SMS support complex and disturbance of the spine biomechanics. A recent study has established a correlation between degenerative changes in SMS structures and sagittal balance or spatial stability, while the volume of active and passive movements of the vertebral column is usually dependent on the severity of bone and joint transformations [11, 13]. The study by D. Butler et al. was a prerequisite for the use of dynamic spinal segment stabilization [14], in which the authors revealed the interdependence of degenerative changes in the facet joints and intervertebral discs. The results of studies have shown that as a result of impaired SMS biomechanics, the intervertebral disc is primarily affected. Further limitations of segment mobility, rearrangement processes and redistribution of mechanical loads cause damage to facet joints, development of osteoarthritis and joint instability.

Dynamic stabilization devices are used to unload the posterior support complex, which includes the facet joints, spinous processes and part of the fibrous ring of the intervertebral disc, in order to preserve the range of physiological motions and prevent adjacent level pathology [11, 15]. The need to preserve the biomechanics of the supporting structures of the spinal motion segments and prevent disease progression was the basis for the use of the dynamic interspinous system [15]. Interosseous fixators are made of titanium alloy, which ensures sufficient strength, stiffness, and biocompatibility with a low risk of artefact formation during magnetic resonance imaging (MRI) [16–19]. The main objectives of the design include reducing the load on the facet joints, preserving the physiological volume of move-

ment in the SMS with adequate stress distribution over the pathologically altered and adjacent SMS.

## MATERIAL AND METHODS

The study was based on a retrospective analysis of treatment of 58 patients with degenerative lesions of the lumbar spine who underwent surgery using dynamic spinal stabilization with the Coflex system (Paradigm Spine LLC, Germany) and were treated at the Department of Neurosurgery of the Irkutsk Scientific Center for Surgery and Traumatology from 2011 to 2020. They included 18 females and 40 males aged 17 to 63 years ( $47.4 \pm 9.4$  years). Instrumental and neuroimaging methods of spinal examination included review and functional radiography, computed tomography (CT) (42 cases), MRI (58 cases), and CT-myelography (27 cases) of the lumbar spine. The functional state of the SMS was assessed by analyzing lumbar spine radiography data with loading tests in the 30° and 90° flexion positions. To study the biomechanical stability of the operated spinal segment with the implanted interosseous fixation system at adjacent levels, morphometric parameters were studied: frontal, oblique, and sagittal dimensions of the spinal canal; dimensions and angular indices of the facet joints conjugation.

Surgical treatment – excision of disc herniation or bone and cartilage formation with stabilization of the segment with the Coflex interosseous dynamic system was performed in 58 patients.

The indications for revision surgery were persistent pain syndrome that could not be treated with nonsurgical methods of treatment; MRI or CT data showing radicular compression in the area of the degeneratively altered segment; detection of SMS instability. Interosseous fixation at the level of  $L_{IV}-L_V$  was performed in 48 (83 %) patients, at the level of  $L_{II}-L_{III}$  – in 2 (3 %) patients, at the level of  $L_{III}-L_{IV}$  – in 3 (5 %) patients, at the lumbosacral  $L_V-S_I$  level – in 5 (9 %) patients. In 35 cases, the implant was installed during revision intervention, of which 6 patients had posterior interosseous stabilization due to recurrence of herniated disc  $L_{IV}-L_V$  and  $L_V-S_I$ ; in 11 cases, degenerative spinal canal stenosis at an adjacent level due to spondyloarthrosis with marginal osteophyte growths; in 18 patients, a combination of herniation occurred or protrusions with degenerative stenosis. Surgical intervention with dynamic fixation using the Coflex system was performed initially in 23 patients in the course of disc herniation excision.

Revision intervention in patients with device failure, neoarthrosis and heterotopic ossification of the Coflex system included anterior stabilisation using an interbody lumbar peek cage. In one patient, the reason for a second surgery was the primary instability of the surgical hardware associated with a fracture of the implant-fixed spinous process. During a delayed period, 2 and 4 years after surgery, 4 patients revealed a radiological picture of heterotopic ossification of the structure and SMS instability; recurrence

of the intervertebral hernia was diagnosed in 2 patients. The study protocol was approved by the local ethical committee of Irkutsk Scientific Centre of Surgery and Traumatology (minutes No. 1 dated January 22, 2019).

All data are submitted as quantities and percentages. Differences between groups were assessed using Chi-square with Yates correction and Fisher's criterion.

## RESULTS AND DISCUSSION

Repeated intervention in cases of dynamic stabilisation system failure was performed in 7 (12 %) out of 58 patients, and spondylodesis was formed using a lumbar peek-cage and retaining the Coflex device integrated with the osseous tissue of the spinous processes.

Progressive intervertebral disc degeneration was diagnosed by CT and MRI based on the detection of hypertrophy of the articular processes, the presence of gas in the joint cavity (vacuum phenomenon) in 6 patients and spinal canal stenosis in 2 patients.

A complete regression of neurological deficit after revision surgery was observed in 6 (86 %) patients. The dynamics of sensory and motor impairments in the early

and remote postoperative periods is summarised in Table 1.

Analysis of the treatment results revealed that in the process of intervertebral disc degeneration, its cushioning properties are impaired, which is a prerequisite for the development of linear and angular displacement of adjacent vertebral bodies and, subsequently, the formation of segment instability. The use of an interosseous implant is aimed at prosthetic disc properties, preventing further SMS degeneration and instability. The tissue ossification in the area of the working surfaces of the fixator eventually causes a significant decrease in the Coflex's shock-absorbing properties, and the device acquires the characteristics of a fixation spacer.

The fact that interosseous implants are not biologically inert cannot be ignored. Furthermore, such factors as metal stress and, as a consequence, micromobility cause changes in the implant structure and are a predisposing factor in the formation of imbalance of mechanical loads on the articular processes with the development of clinical manifestations of construct failure [20, 21].

Prolonged use of the Coflex fixator leads to the formation of another specific complication, namely, heterotopic ossification of the interosseous stabilization de-

**TABLE 1**  
**DYNAMICS OF SENSORY AND MOTOR IMPAIRMENTS (*n* = 7)**

Impairments revealed	Before the surgery	9, 24 months after surgery	48 months after surgery
Vertebrogenic syndrome	7 (100 %)	5 (71 %)	1 (14 %)
Sensation disorders			
hypesthesia	7 (100 %)	2 (29 %)	1 (14 %)
anesthesia	4 (57 %)	1 (14 %)	1 (14 %)
hyperesthesia	2 (29 %)	1 (14 %)	–
paresthesia	3 (43 %)	1 (14 %)	–
Decreased muscle strength in the lower extremity:			
weakness of the thigh and lower leg muscles	4 (57 %)	1 (14 %)	1 (14 %)
foot muscle weakness	5 (71 %)	2 (29 %)	2 (29 %)
paresis of the extensor muscles of the foot	3 (43 %)	–	–
Reflex disorder:			
knee	5 (71 %)	2 (29 %)	1 (14 %)
Achilles'	2 (29 %)	1 (14 %)	1 (14 %)
Straight leg raise	7 (100 %)	–	–



vice, which leads to the development of “adjacent level” pathology. For instance, implant failure with ossification was reported in 3 out of 35 cases in repeat surgeries and in 1 out of 23 cases in primary surgeries. Chi-square with Yates’ correction ( $p = 0.928$ ) and Fisher’s two-sided test ( $p > 0.05$ ) were used to identify the dependency of the risk of implant failure with the incidence of surgery. The results of the analyses indicate that the relationship of implant failure with repeat or primary surgery is very weak. Consequently, repeated intervention does not have a statistically significant effect as regards the risk of construct dysfunction. The problem requires further investigation, however, to identify the cause-and-effect relationships of the dynamic stabilization system failure.

The clinical observation presented below is a clear evidence of this postulate.

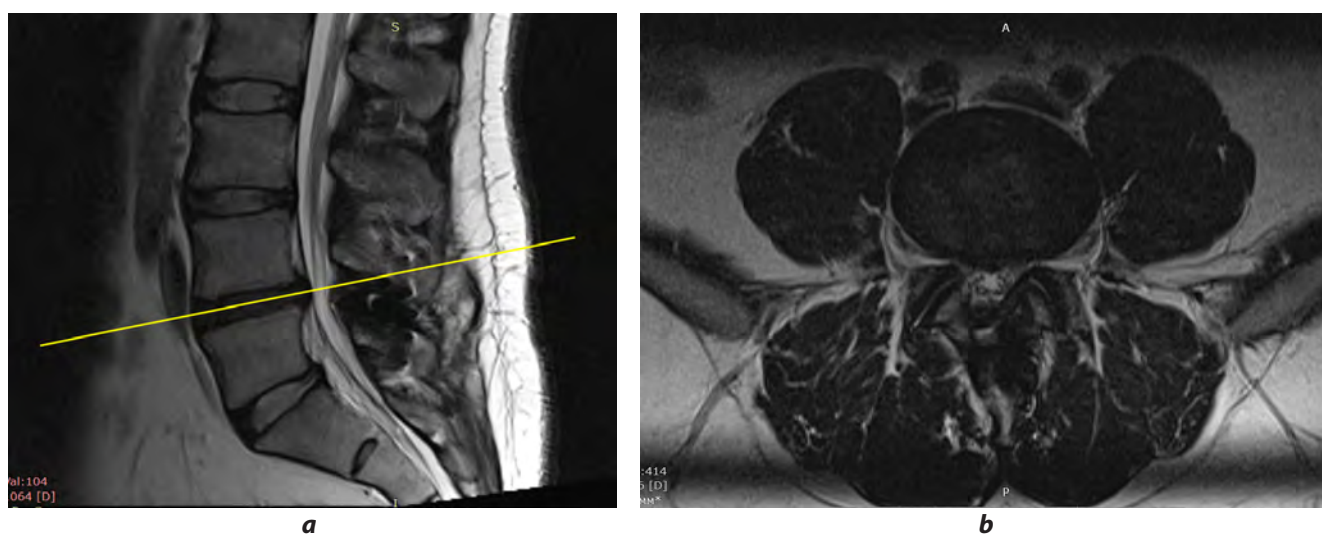
## CLINICAL CASE STUDY

Patient P., 48 years. Diagnosis: degenerative lateral (foraminal) stenosis of the spinal canal at the level of  $L_{IV}$ – $L_V$  on the left. Bone and cartilage junction  $L_{IV}$ – $L_V$ . Deforming spondylosis. Spondyloarthrosis. Postoperative epidural fibrosis, the presence of a system of interosseous dynamic fixation of the spine at the level of  $L_{IV}$ – $L_V$ .  $L_5$  radiculopathy on the left. Severe pain and musculo-tonic syndromes.

Pain in the lumbar spine and the left lower limb has been bothering for 3 months. The pain is accompanied by restriction of active movements in the lumbar spine, intensifies in the vertical position and when walking, irradiates to the outer surface of the left thigh and lower leg.



**FIG. 1.**  
Patient P. Computed tomography of the lumbar spine. Multiplanar reconstruction in the sagittal plane (a), axial section (b)



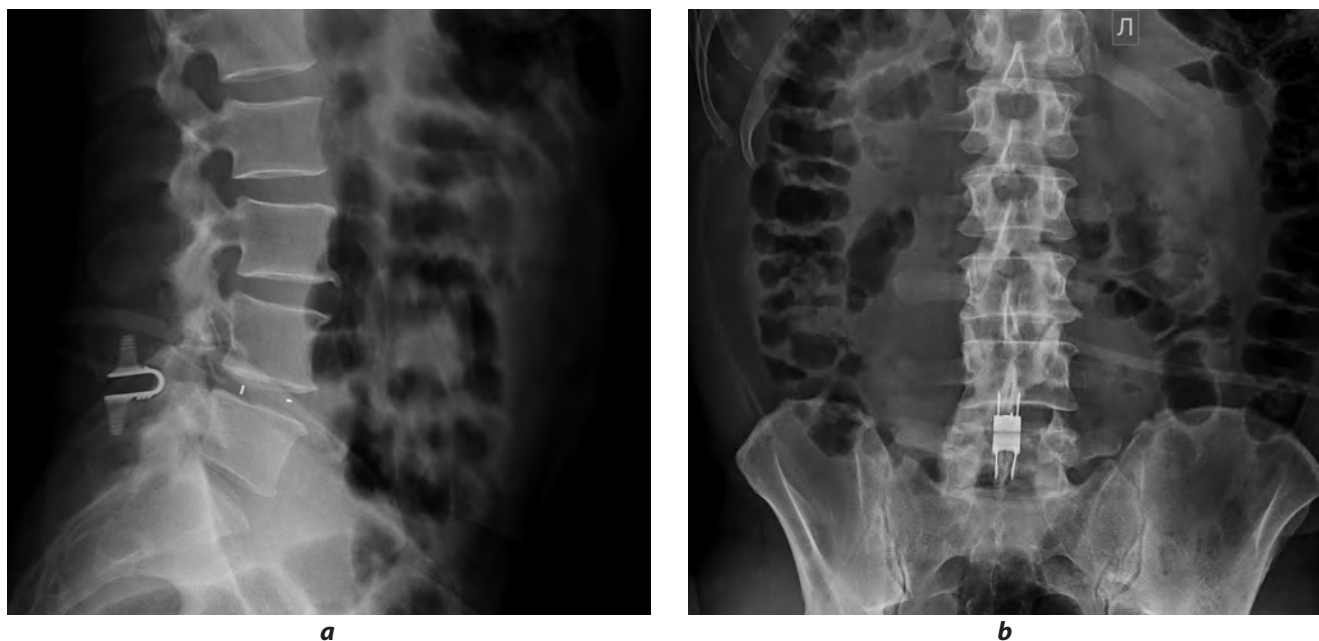
**FIG. 2.**  
Patient P. MRI of the lumbar spine. T2 weighted images: sagittal (a), axial section (b)

Past medical history: twice underwent surgery on the lumbar spine: in 2011 – excision of  $L_{IV}$ – $L_V$  disc herniation on the left side with installation of Coflex dynamic system (Paradigm Spine LLC., USA). In 2014, a revision and microsurgical foraminotomy was performed along the  $L_5$  root on the left.

According to the patient, over the past year, he began to notice an increased in pain in the lumbar spine associated with physical exertion. The conservative treatment per-

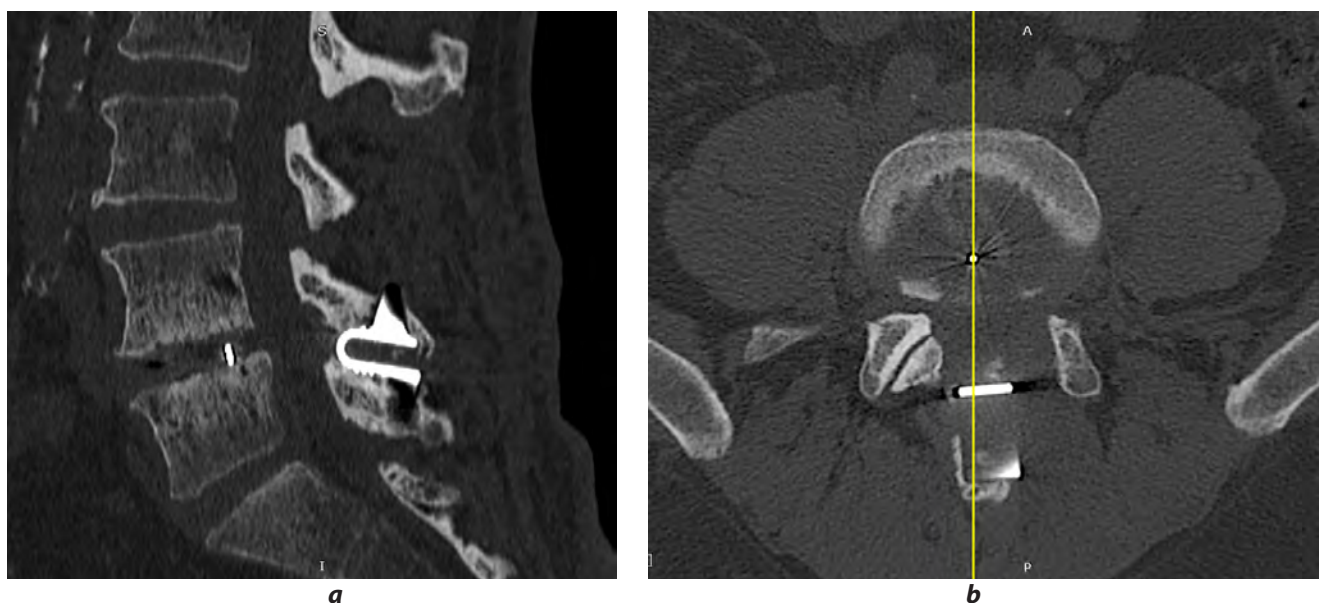
formed by a neurologist has no effect. According to MRI of the lumbar spine, the patient had a recurrence of median herniated disc  $L_{IV}$ – $L_V$  (Fig. 2).

CT of the lumbar spine revealed a number of features of the condition of the interosseous fixator, which integrated into the bone tissue of the spinous processes; the space of the working dynamic loop of the metal structure was filled connective tissue with elements of bone restructuring (Fig. 1).



**FIG. 3.**

Patient P. Spondylograms in lateral (a) and frontal (b) view in the postoperative period



**FIG. 4.**

Patient P. Computed tomography of the lumbar spine 6 months after the surgery. Multiplanar reconstruction in the sagittal plane (a), axial section (b). The marks of the anterior and posterior edges of the interbody cage are determined. Formation of the anterior fusion

Surgery (June 18, 2020): interlaminectomy, medial facetectomy, microsurgical decompression of the L<sub>5</sub> root on the left. Removal of the osteochondral junction L<sub>IV</sub>–L<sub>V</sub>. L<sub>IV</sub>–L<sub>V</sub> interbody spondylodesis with lumbar peek cage.

The postoperative period proceeded without complications. Activated on the day 2 after surgery. Regression of pain vertebrogenic and radicular syndromes was observed. Discharged from the department for rehabilitation treatment on the day 7 in a satisfactory condition. No complaints during the follow-up period, the implant and interosseous fixator are stable radiologically (Fig. 3, 4).

## DISCUSSION

Analysis of the treatment results of patients who underwent discectomy with dynamic fixation of the spinal motion segment using an interosseous implant demonstrates its effectiveness and ability to prevent recurrence of pain syndrome as well as the development of pathology at the adjacent level. At the same time, although the dynamic interosseous fixation system does not result in closure of the spinal motion segment, the radiological signs of degeneration of the intervertebral disc and the facet joints of the overlying segments revealed indicate a risk of spinal canal stenosis. The interosseous dynamic implant becomes functionally deficient over time and is involved in the formation of heterotopic ossification or posterior "bone-metallic" pseudoarthrosis [15]. According to A.E. Simonovich (2005) and C. Thome et al. (2005) [13, 22], the dynamic systems' design features do not simultaneously ensure the preservation of biomechanics and reliable support of the spinal segment.

Additional implantation of a lumbar peek cage while retaining the Coflex system created a rigid interbody spondylolysis without the use of SMS transpedicular fixation. This tactic is justified both from the point of view of preserving the support of the anterior complex and from the point of view of treating segment instability. The spinal canal and intervertebral disc are accessed by interlaminectomy and medial facetectomy, which reduces the traumatic nature of the surgery itself.

Formation of spondylodesis without removal of the Coflex system using an intervertebral cage is a sufficient and reasonable technique, but in some cases it can be supplemented with monosegmental transpedicular fixation.

The implant's integration with the spinous process bone tissue, as well as the peek-cage with the closing plates of the adjacent vertebrae, ensures consolidation sufficient for spondylodesis. The existence of hollow spaces in the body of the cage, filled with bone material, favours the formation of a solid spondylodesis and accelerated formation of the bone block. The posterior interosseous dynamic stabilization technique can be used

as an alternative and in some cases as a preliminary stage of spondylodesis formation.

## CONCLUSION

This study reveals that a number of patients after discectomy and dynamic spine stabilisation with the Coflex system suffer from segmental instability as a consequence of heterotypic ossification and neoarthrosis formation and often require revision intervention. Formation of a spondylodesis using an intervertebral cage and retention of the Coflex system is an effective means of resolving the problem.

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## Conflict of interest

The authors declare the absence of apparent and potential conflicts of interest related to the publication of this article.

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