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OUTCOME ANALYSIS OF USING ARTHROPLASTY OF INTERVERTEBRAL DISC OF LUMBOSACRAL SPINE WITH "M-6 L" PROSTHESIS

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Abstract

Intervertebral disc pathology is the dominant cause of lower back pain. The main method for surgical treatment of discogenic lesions is discectomy followed by spinal fusion. It is established that rigid stabilization contributes to the progression of degenerative changes in adjacent intervertebral discs. Development of artificial intervertebral discs allowed preventing the adjacent segment degeneration due to the restoration of natural biomechanics and physiological range of motions in the operated spinal motion segments. However, the results of using artificial prostheses are still contradictory.

The study was aimed to analyze the results of using arthroplasty of intervertebral disc of lumbosacral spine with "M-6 L" prosthesis.

Present study included 41 patients with symptomatic relative spinal stenosis of herniated intervertebral disc of lumbosacral spine, who underwent total arthroplasty of intervertebral discs with "M6-L" prosthesis. The data on radiological and clinical effectiveness of interventions were analyzed. Follow-up observation and complex assessment of treatment outcomes averaged 24 months.

While assessing the level of pain by visual analogue scale and life quality by Oswestry Disability Index in the early and long-term postoperative periods statistically significant positive indicators were registered compared to the preoperative ones. Instrumental examination of patients revealed the preservation of movement amplitude in the operated spine region with restoration of reserve interbody spaces and sagittal profile of the spine.

Thus, it is established that the use of "M6-L" artificial intervertebral disc allows to significantly reduce pain level, to improve life quality and preserve physiological range of motions in the operated spinal motion segment. "M6-L" disc can be used in patients with single-level destruction of intervertebral discs of lumbar spine.

Keywords: *lumbar spine, intervertebral disc, degeneration, dynamic fixation, total arthroplasty, "M6-L" disc prosthesis.*

Introduction

Back pain is one of the most topical healthcare problems in the industrialized countries [*Byvaltsev V et al., 2011*]. More often, back pain is associated with early and persistent disability of patients [*Byvaltsev V et al., 2015*]. Depending on the intensity of clinical picture and the degree of degenerative changes in intervertebral disc, detected by neuroimaging, a decision is made on the possibility of conducting conservative therapy or on the method of performing surgical intervention [*Zigler J et al., 2007*].

Microdiscectomy is the main method for surgical treatment of discogenic lesions in the lumbar spine. Taking into account the development in some

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cases of decreased intervertebral disc height and recurrent hernia protrusion, as well as the formation of abnormal segmental mobility with the resumption of spinal canal content compression, various methods of instrumental fusion and fixation are developed [*Krutko A, 2012; Byvaltsev V et al., 2015*].

It is known that rigid stabilization is used to remove or prevent the instability of the injured vertebral-motor segment with the formation of bone block and complete restriction of its mobility. The main disadvantage of spinal fusion is the progression of pathomorphological changes in adjacent intervertebral discs due to the improper load distribution in them [*Sasso R et al., 2008*].

Development of artificial intervertebral discs allowed preventing the degeneration of adjacent segments by restoring the natural biomechanics and physiological range of motions in the operated spinal motion segments [*Guyer R et al., 2009*].

Conducted studies on the use of artificial discs clearly demonstrated their high effectiveness towards clinical and instrumental outcomes in patients with degenerative lesions of intervertebral discs compared to the spinal fusion surgery [*Guyer R et al., 2009*]. Development of various constructions in terms of functional prostheses of intervertebral discs is aimed at optimization of postoperative outcomes, however, the results of their application are interpreted ambiguously [*Katz J, Melzack R, 1999; Siepe C et al., 2006; Delamarter R et al., 2011; Zigler J, Delamarter R, 2012*].

The study was aimed to analyze the results of using arthroplasty of intervertebral disc of lumbosacral spine with "M-6 L" prosthesis.

Material and methods

The study included 41 patients (29 men, 12 women) aged 27-45 years (mean age 33.8 years) operated in Neurosurgery Center of Road Clinical Hospital Irkutsk-Passenger station JSC "Russian Railways" over the period from 2013 to 2016. Indications for surgery were the presence of symptomatic relative spinal stenosis of the herniated intervertebral disc of lumbosacral spine providing the maintenance of interbody space height (more than 50% of the overlying) and the physiological range of motions in the operated segment (linear broadcast of no more than 4 *mm*, sagittal angulation no more than 10°). All patients underwent standard conservative treatment during 6-8 weeks before surgery, which was not effective enough.

In the preoperative period complaints, anamnesis and neurologic status of patients were estimated. In the pathological process the most frequently involved spinal segment was L_V-S_I (54%) (Table 1). "M6-L" prosthesis (Spinal Kinetics, USA) was used in the clinical study series for total arthroplasty of intervertebral discs of lumbosacral spine. All patients were operated by one surgical team.

Follow-up observation lasted minimum 16 months, maximum 36 months, median – 24 months. Following parameters were examined for the analysis: sex, age, body mass index, technical features of the intervention (operation duration, extent of blood loss), activation time, length of hospital stay, clinical parameters (pain level by visual analogue scale, life quality of patients with back pain by Oswestry questionnaires, radiographic parameters (interbody space height, range of motions in the operated spinal motion segment, lumbar lordotic angle) and neuroimaging data, particularly magnetic resonance imaging, on Magnetom Essenza 1.5 *T* scanner (Siemens, Germany).

Statistical analysis of the study results was performed on a personal computer using the Microsoft Excel and Statistica-8 database software. To assess the significance of differences in sample populations the criteria of non-parametric statistics were used. The level of $p<0.05$ was considered as the lower confidence limit. Data are presented in median and interquartile range as Me (25%; 75%).

Results

General information about examined patients is presented in table 2.

Summarized data on operation duration, extent of blood loss, activation time and length of hospital stay are shown in table 3.

Assessment of pain by visual analogue scale showed a significant decrease in its intensity after surgery ($p_W<0.001$), both in the early postoperative and in the long-term period (Fig. 1).

While analyzing life quality indicators of patients by Oswestry Disability Index a significant positive dynamics of the functional state was established after surgery compared to the preoperative indicators ($p_W<0.001$) during the entire period of observation (Fig. 2).

TABLE 1

Localization of lumbar spine lesion level

Level of lesion (segments)	Study group (n=41)
L_{III}-L_{IV}	3
L_{IV}-L_{V}	12
L_{V}-L_{VI}	4
L_{V}-S_{I}	22
Total	41

TABLE 2

Baseline characteristics of study group patients

Criteria	Study group (n=41) (Me 25%-75%)
Age (*years*)	33 (29; 36)
Male sex (n, %)	29 (71%)
Body mass index (kg/m^2)	24.2 (23.4; 28.1)

TABLE 3

Technical features of surgical interventions and specificity of postoperative management of patients

Criteria	Study group (n=41) (Me 25%-75%)
Operation time (*min*)	105 (95; 130)
Extent of blood loss (*ml*)	100 (70; 150)
Activation time (*days*)	1 (1; 2)
Length of hospital stay (*days*)	9 (8; 11)

TABLE 4

Analysis of instrumental data of the operated lumbar spine segment in pre- and postoperative periods

Indices	Study group (n=41) Me (25%-75%)	
	Before surgery	After surgery
Interbody space height in the middle section (*mm*)	10.5 (9.2; 11.6)	12.8 (12.0; 13.5)
Movement amplitude (°)	26 (22; 30)	39 (36; 40)
Lumbar lordotic angle (°)	28 (25; 34)	40 (38; 52)

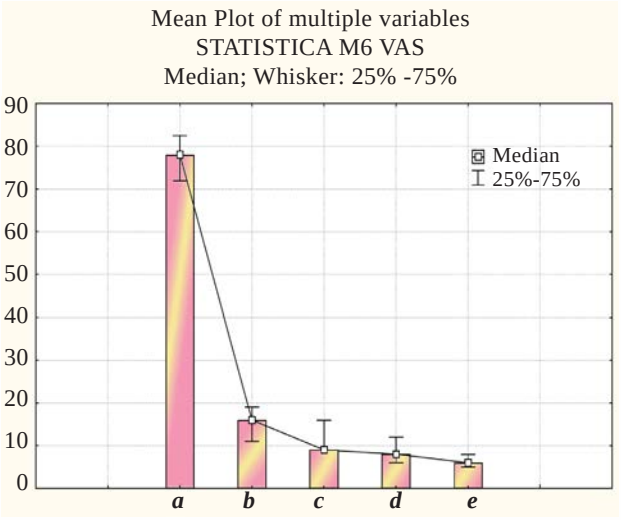

FIGURE 1. *Dynamics of the pain level in study group patients by visual analogue scale before surgery (a), on the 10th day (b), in 6 (c), 12 (d) and 24 (e) months*

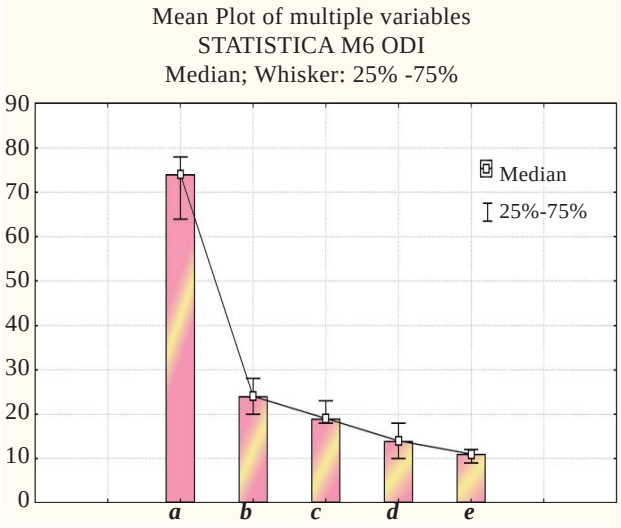

FIGURE 2. *Dynamics of the functional state of study group patients by Oswestry Disability Index before surgery (a), on the 10th day (b), in 6 (c), 12 (d) and 24 (e) months*

During follow-up observation (on average during 18 months) of study group patients on postoperative spondylograms no dislocation or migration of the construction elements, as well as signs of segmental instability were revealed. Assessment of functional X-ray images revealed that the range of motions in the operated segment remained within physiological limits, also a statistically significant recovery of the lumbar lordotic angle and increase of the interbody space height in the middle section of the operated segment were noted (Table 4).

All the complications observed during present study are associated with the surgical access to the lumbosacral spine and particularly the stage of performing total arthroplasty. So, the formation of

abdominal wall hematoma was noted in 2 (4.8%) cases. Left common iliac venous laceration occurred in 1 (2.4%) patient intraoperatively in mobilizing iliac vessels. The imposition of microsurgical vascular suture allowed eliminating an adverse outcome.

Clinical example

Patient K., aged 29 years, was admitted to the Neurosurgery Center of Road Clinical Hospital Irkutsk-Passenger station JSC "Russian Railways" complaining of severe pain in the lumbar spine, intensifying while moving, irradiated to the right buttock across the lateral and posterior surfaces of the right thigh, lower leg, numbness in the area of pain.

Medical history: Pains in the lumbar spine and right lower extremity have bothered for two years. Conservative treatment – with no observable significant effect. Subsequently, there was an irradiation of the pain to the right leg. The patient was hospitalized – directed to the Neurosurgery Center of Road Clinical Hospital.

Neuro-orthopaedic status: Consciousness is clear, focused, cranial nerves – in norm. Lumbar lordosis is smoothed. Movements in the lumbar spine are painful, limited due to pain. Défense of paravertebral muscles of III degree. Knee-jerk reflexes D=S, Achilles reflexes D – reduced, S – alive. Lasegue sign D – 45°, S – 55°. No pathological reflexes. Muscle tone in norm. Strength in hands and feet – 5 points. Sensory disorders in the form of hypesthesia along the right S_1 roots.

The level of pain by visual analogue scale was 97 *mm*, the value of life quality according to Oswestry questionnaire – 68 points [*Byvaltsev V et al., 2011*].

Results for additional methods of examination: MRI of the lumbosacral spine (Fig. 3 A, B): Right-sided hernia of L_V-S_I disc.

Lumbar spondylography with functional tests (Fig. 4). Osteochondrosis, spondylarthrosis. No signs of segmental instability were revealed.

Detailed study of the clinical data and results of additional examination diagnosed: "Dorsopathy. Exacerbation. Osteochondrosis of the lumbosacral spine. Herniated disc L_V-S_I on the right. Radiculoneuritis S_1 on the right. Right lumboischialgia syndrome. Expressed pain and muscular tonic syndromes".

The surgical intervention was performed in the volume: microsurgical discectomy L_V-S_I from anterior pararectal approach on the left, decompression of the dural sac and S_1 roots from both sides, prosthetics of L_V-S_I intervertebral disc with dynamic M6 Lumbar prosthesis (Spinal Kinetics, USA).

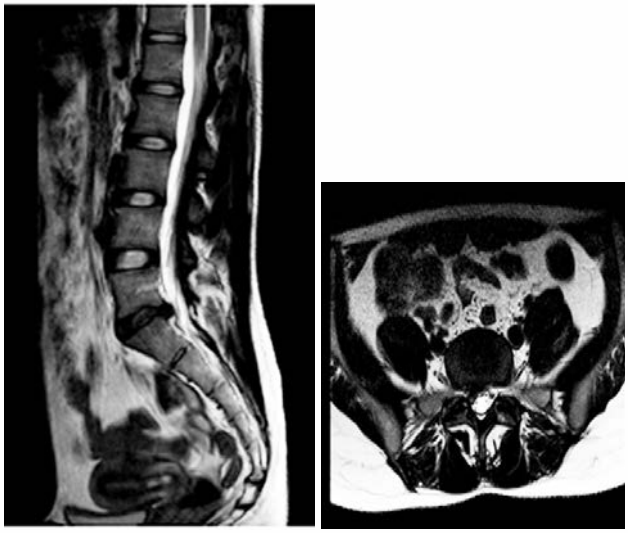

Figure 3. *Preoperative MRI-grams of lumbosacral spine:* ***(A)*** *– sagittal section;* ***(B)*** *– axial section, MRI-gram of lumbar spine (herniated intervertebral disc L_V-S_I is marked by arrow)*

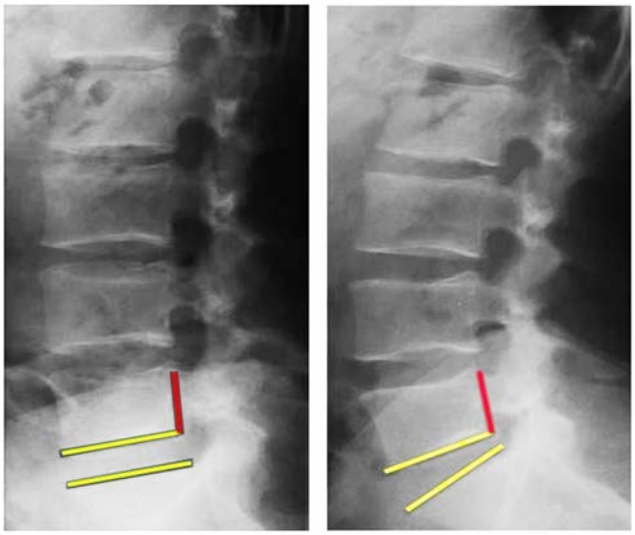

Figure 4. *Lumbar spondylography with functional tests – maintenance of the interbody space height L_V-S_I – 10.1 mm (in the middle third), reduction of movement amplitude in L_V-S_I segment – 25°, flattening of lumbar lordosis – 29°*

Radiological markings were performed in the projection of the intervertebral disc L_V-S_I (electro-optical converter Siemens, Germany) after processing the surgical field in the Trendelenburg position on back. With the help of SynFrame retractor (Synthes, Switzerland) a typical classic pararectal approach was carried out from the left in the

projection of intervertebral disc L_V-S_I with the incision of skin, subcutaneous fat, fascia of the rectus abdominis muscle. The method of blunt dissection produced retroperitoneal approach to the anterior surface of the spine with the mobilization of iliac vessels. After fixation of L_V and S_I metal delimiters in the bodies under magnification of 8-12 a total discectomy L_V-S_I was performed with foraminotomy for S_1 roots from both sides. With the help of specialized instruments the prosthetics of L_V-S_I disc was performed with dynamic prosthesis of M-6 Lumbar disc (Spinal Kinetics, USA). Prosthetic disc size was 12 *mm*, 6° (M). X-ray inspection: position of the prosthetic disc is correct. Hemostasis with electrocoagulation, H_2O_2. Hemostasis. The wound is sutured in layers. Operation time – 2 *h* 00 minutes. Blood loss – 30 *ml*.

As a result of operation an increase of intervertebral disc height was noted with the restoration of range of motions in the operated lumbosacral segment, no signs of migration and instability of fixing elements were revealed (Fig. 5).

The patient was activated the next day after surgery. Sutures were removed in 10 days, healing with primary intention. She was discharged under the supervision of a neurologist on the 10th day with complete regression of pain.

Neuro-orthopedic status: Cranial nerves, upper limbs are intact. Lumbar lordosis is smoothed. Movements in the lumbar spine are slightly painful, in full. No défense of paravertebral muscles. Knee reflexes D=S, Achilles D=S are alive. Lasegue sign D – no, S – no. No pathological reflexes. The muscle tone in arms and legs is normal. Strength in hands and feet – 5 points. No sensation disorders. No pelvic disorders. Pain level by visual analogue scale is 3 *mm*, life quality by Oswestry Disability Index – 15 points.

The patient was examined in 4 weeks by a neurosurgeon: complete social and physical rehabilitation. MRI of the lumbar spine was performed in 12 months after surgery (Fig. 6 A, B): no signs of the degenerative process progression in the adjacent segments.

Discussion

Despite the active implementation of decompression and stabilization techniques for degenerative lesions of intervertebral discs of lumbosacral spine, the high percentage of non-physiological biomechanical distribution of load to adjacent segments is a serious problem in the treatment of such patients. It was shown that 20% of patients, who underwent spinal fusion over the degeneration of intervertebral discs, subsequently needed repeated operations on adjacent spinal motion segments [*Schmidt R et al., 2010*]. These factors contribute to the development of new technological solutions in spinal surgery, which will help to keep the motion in the affected segment, to reduce the load on adjacent levels and prevent the progression of the degenerative process. Such an innovative direction

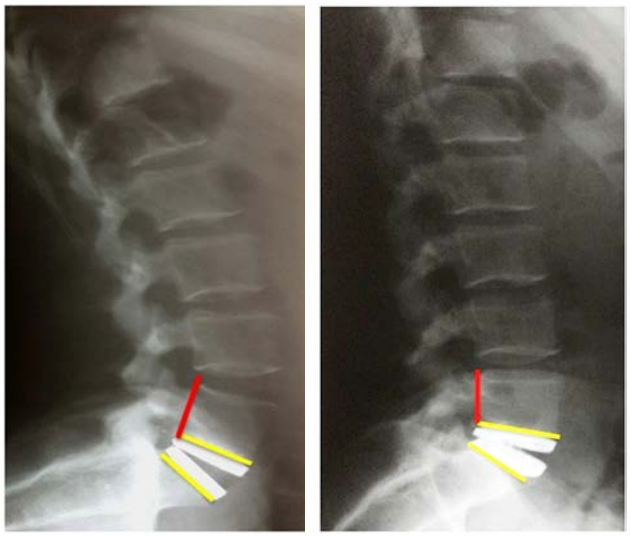

Figure 5. *Lumbar spondylography with functional tests – increase of interbody space height L_V-S_I – 12.6 mm (in the middle third), increased movement amplitude in L_V-S_I segment – 38°, restoration of lumbar lordosis – 39°*

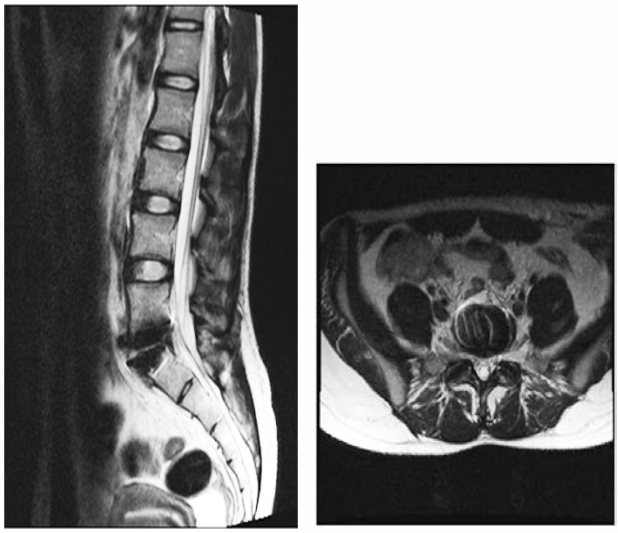

Figure 6. *Postoperative MRI-grams of lumbosacral spine:* ***(A)*** *– sagittal section,* ***(B)*** *– axial section*

was the method of total arthroplasty of intervertebral discs, which is currently a popular method of treating patients.

To date, a new generation of prostheses is developed for total arthroplasty of intervertebral discs in which the nucleus from hydrogel or polyurethane is used. Their main task is the restoration of intervertebral disc function by absorbing and impact of fluid in the intervertebral space, as well as the proper distribution of the axial loading [*Chung S et al., 2006*]. Among these physiological prostheses, the most widely used ones are Charite (Link Spine Group), ProDisc (Spine Solutions), AcroFlex (DePuyAcroMed), M6 (Spinal Kinetics) [*Canbulat N et al., 2011*].

In this clinical case "M6-L" prosthesis was used for the total arthroplasty of intervertebral discs of lumbosacral spine. Its innovative system includes an artificial nucleus pulposus, providing mobility with controlled amplitude and with six degrees of freedom, artificial fibrous ring of fibrous material, counteracting axial compression. Physiological mobility is meant for preservation of spinal segment mobility and prevention of further degeneration in adjacent intervertebral discs [*Ritter-Lang K et al., 2013*].

Clinical efficiency of intervertebral disc prostheses in the specialized literature is interpreted ambiguously. Thus, in the study conducted using FlexiCore artificial disc (Stryker Spine, USA) in the early postoperative period, a decreased intensity of pain was noted according to visual analogue scale with 86 *mm* up to 36 *mm* and life quality by Oswestry Disability Index from 62 to 36 points [*Sasso R et al., 2008*]. In another case with the use of Maverick prosthesis (Medtronic, Sofamor, Danek, Inc., Memphis, TN, USA), the severity of pain decreased from 84 *mm* to 28 *mm*, and the life quality – from 69 to 35 points [*Oktenoglu T et al., 2013*]. In the domestic observation of M. Abakirov and co-authors (2016), the following clinical results were achieved in prosthetics of intervertebral discs with "M6-L" prosthesis: decreased severity of pain from 55 *mm* to 34 *mm* and life quality from 56 to 27 points.

It should be mentioned that the results of using techniques for total prosthetics of intervertebral discs of lumbosacral largely depend on the type of used prosthesis and preferences of the neurosurgeon. Despite the obtained ambiguous results concerning the use of structurally different prostheses, the studies confirm the clinical effectiveness of using total intervertebral disc prosthesis during its degeneration. Taking into account the novelty and high cost (instruments, implants) of the described techniques, the amount of information accumulated at the present time referring to the clinical and radiological effectiveness of the use of artificial intervertebral disc prostheses is insufficient. Multicenter studies are required with the generalization of experience of their use, analysis of the results and refinement of indications for the use of dynamic fixators.

Thus, the use of "M6-L" artificial intervertebral disc allows to significantly reduce the level of pain, improve quality of life and preserve the physiological range of motions in the operated spinal motion segment and can be used in patients with single-level destruction of intervertebral discs of lumbar spine.

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