TOTAL LUMBAR DISC ARTHROPLASTY

M.D. Abakirov[1], I.A. Kruglov[2], R.R. Abdrakhmanov[1], A.S. Seleznev[2], A.E. Mader[1]
[1]*Peoples' Friendship University of Russia, Moscow, Russia*
[2]*District Military Hospital, Moscow, Russia*

Objective. To evaluate clinical efficacy and safety of M6-L artificial disc in lumbar degenerative disc disease (DDD).
Material and Methods. A total of 109 patients with diagnosed lumbar DDD and spinal stenosis were operated on after 6 months of unsuccessful conservative treatment in 2011–2015. All patients underwent M6-L artificial lumbar disc implantation. Average follow-up period was 1.5 years (range: 4 months to 6 years). Patient satisfaction after treatment, regression of pain score, increase in activities of daily living, as well as radiographic parameters (recovery of intervertebral space height, mobility in the operated segment), and frequency of complications, reoperations and revision surgeries were evaluated.
Results. Good and excellent clinical outcomes were revealed in most of patients. The average VAS score of back and leg pain regression was 27 mm, improvement in daily activity – 24.3 points on ODI, increase in the disc space height – 7.6 mm, and mobility in the operated segment – 8.5°. Serious complications were not detected, spontaneous fusion at the operated level was noted in 2.0 % of cases, revision surgery due to implant migration (implant removal and ALIF with cage) was required in 0.9 % of cases.
Conclusion. Intervertebral disc arthroplasty with M6-L is a safe and highly effective procedure that maintains mobility in the operated segment and prevents adjacent disc degeneration.
Key Words: disc herniation, M6-L implant, degenerative disease of the spine, lumbar spine.

Please cite this paper as: *Abakirov MD, Kruglov IA, Abdrakhmanov RR, Seleznev AS, Mader AE. Total lumbar disc arthroplasty. Hir. Pozvonoc. 2016;13(1):59–66. In Russian.*
DOI: http://dx.doi.org/10.14531/ss2016.1.59-66.

Organ-preservation technologies in the treatment of degenerative disc disease (intervertebral disc arthroplasty) have been introduced as an alternative method to avoid negative effects associated with spinal fusion.

Artificial intervertebral discs have undergone several revolutionary changes during their development [2, 13]: from metal ball endoprostheses to complex multicomponent devices aimed at maximum imitation of natural intervertebral disc function.

Currently, the following artificial discs are most often used for lumbar arthroplasty: SB Charit III, ProDisc II, Maverick, and M6-L. In Russia, A.K. Chertkov replaces discs witha prosthesis of original design named Kinezis-1 since 1992 [4].

SB Charite. In 1982, an intervertebral artificial disc was developed in the Charite clinic in Berlin [12]. This prosthesis was implanted for the first time in 1984. It consisted of circular steel plates with 11 teeth-like structures connected with a polyethylene core of the supramolecular low-density polyethylene Chirulen. Later, these implants were modified and the third version was introduced in 1987 (Fig. 1). The endplates were made of cobalt-chromium-molybdenum alloy coated with porous titanium with hydroxyapatite to promote bone ingrowth [3, 12].

ProDisc. In 1990, the Du Parc clinic (France) started to implant [the] ProDisc artificial discs [8], which consist of two cobalt chromium molybdenum endplates with a porous titanium coating and high molecular weight polyethylene core (Fig. 2).

Maverick. The Maverick artificial disc consists of two metal endplates: the lower plate with a hemispheric convex and a congruent upper surface. Maverick is anchored into the vertebrae with two longitudinal keels, one on each endplate [3]. The implant components [of the prosthesis] are made of cobalt and chrome alloy and coated with hydroxyapatite (Fig. 3).

Kinezis-1. In Russia, A.K. Chertkov [4] analyzed benefits and drawbacks of the SB Charite artificial disc and developed, on its basis, the original functional artificial disc named Kinezis-1 (Fig. 4). In particular, improvements were made to change the shape of anchor fixators (spikes) and increase the endplate surface. Also the implant material was changed: cobalt chromium molybdenum alloy has been replaced by titanium.

M6-L. The M6 artificial disc belongs to a new generation of functional implants providing all the functionality of a native disc (Fig. 5). In contrast to multicomponent Charite and ProDisc devices, the M6 artificial disc (Spinal Kinetics) is implanted in a single step. Conventionally, the structure of the M6 implant has two functional parts: movable core and fixed endplates [10].

The aim of this study is to evaluate the clinical efficacy and safety of the M6-L

artificial disc in lumbar degenerative disc disease.

Material and Methods

In 2011–2015, a total of 109 patients were operated on using the M6-L artificial disc replacement. Of these, 80 (73.4 %) were men and 29 (26.6 %) were women. The distribution of patients according to age was as follows: under 20 years – 1 (0.9 %), 20–29 years – 17 (15.6 %), 30–39 years – 53 (48.6 %), 40–49 years – 22 (20.2 %), 50–59 years – 15 (13.8 %), and older 60 years – 1 (0.9 %). According to the level involved, patients were distributed as follows: levels L3–L4 – 2 (1.8 %), L4–L5 – 34 (32.0 %), L5–S1 – 56 (51.0 %), and L5–L6 – 7 (6.0 %). Five (4.6 %) patients were operated on at two adjacent levels L4–L5 and L_5–S_1; and another 5 patients (4.6 %) at levels L5–L6 and L6–S1. In 4 cases, M6-L discs were implanted at levels L4–L5 and rigid implants (titanium cages) were implanted at L5–S1 adjacent levels.

The study included patients older than 18 years who signed a written informed consent for participation and disc replacement. The peculiarities of the operation, postoperative period, possible complications, strengths and weaknesses of the technique were explained to the patients in an understandable way. The operation was performed on patients with chronic persistent radicular and/or vertebral syndrome who had been unresponsive to nonsurgical treatments for 6 months, with indications of degenerative disc disease at L3–S1 level (a herniated disc with sequestration, osteophytes, decreased height of the intervertebral disc space) and possible segmental instability during anteroposterior vertebral subluxation less than 3–4 mm [5, 7, 12, 15].

Study exclusion criteria and contraindications to disc arthroplasty [5, 6, 12] were:

1) previous surgical intervention in the considered spinal motion segment, including hemi- or laminectomy, facetectomy, spinal fusion, pseudarthrosis at the operated level; an increased segmental instability (anteroposterior subluxation greater than 3 mm), consequences of posterior spinal surgery;

2) intervertebral disc height of less than 3 mm, the final stage of degenerative cascade and disc collapse;

Fig. 1
The SB Charite III artificial disc: general view and postoperative radiographs [12]

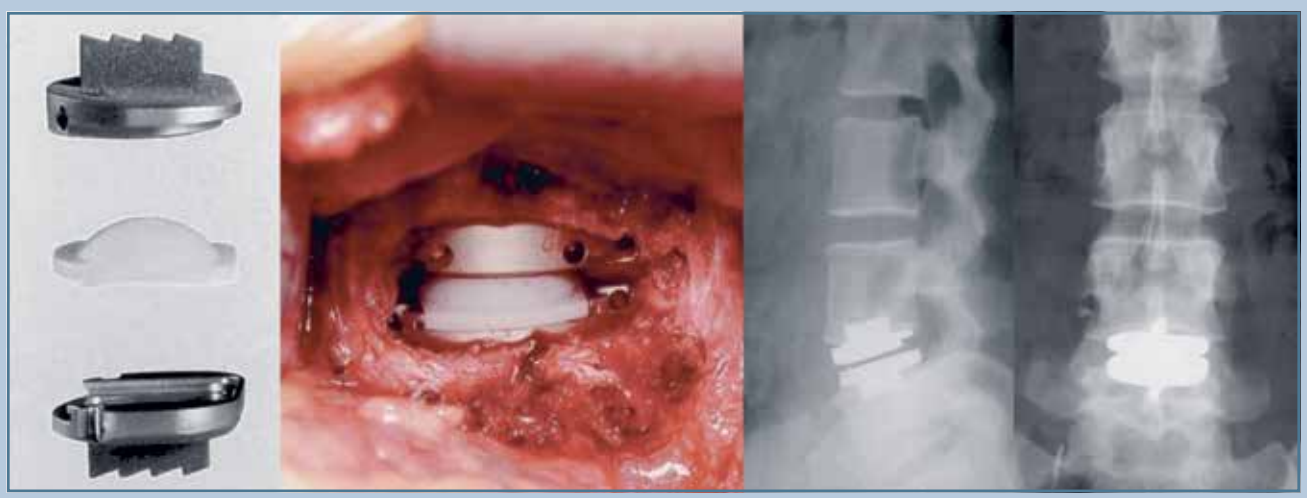

Fig. 2
The ProDisc II artificial disc: components of the disc, intraoperative image of implanted artificial disc and postoperative radiographs [8]

3) scoliosis, anterolisthesis, spondylolysis, retrolisthesis greater than 3 mm, isthmic spondylolisthesis;

4) defects of interarticular part, vertebral body fractures, and abnormalities of endplates.

5) degenerative lesions of facet joints, ankylosis, facet joint arthrosis;

6) endocrine and metabolic diseases: osteoporosis, osteopenia, osteopathy, Paget's disease, chronic use of steroids, rheumatoid arthritis or other autoimmune diseases, systemic disorders;

7) allergy to titanium, polyurethane, polyethylene, ethylene oxide;

8) contraindications associated with anterior approach: obesity (BMI > 30), vascular anatomy anomalies, vessel wall calcification, previous interventions within the abdominal cavity and vessels, abdominal hernia, previous iliofemoral phlebitis, previous radiation therapy in the retroperitoneum;

9) pathology not amenable to disc arthroplasty : spinal nerve root compression, radicular symptoms, arachnoiditis, degenerative spinal stenosis involving two or more levels;

10) general contraindications: skin infection in the area of approach, sepsis, generalized infection, active viral hepatitis, malignant tumors, autoimmune diseases, pregnancy, mental illness, osteomyelitis, spondylodiscitis, chronic diseases (chronic heart failure, diabetes, hepatitis), neuromuscular disease, ankylosing spondylitis, primary neoplasms and metastatic lesions of the spine.

In the preoperative period, physical and instrumental examination was performed; clinical history was obtained in order to identify contraindications to surgery. The VAS and SF-36 scores were used in pain assessment; the ODI questionnaire was used to measure the patients' perceived level of disability related to daily activity. MRI of the lumbar spine, standard anteroposterior and lateral radiographs , as well as functional flexion-extension radiographs were performed to reveal any signs of instability in the spinal motion segment and to assess mobility in adjacent motion segments prior to surgery. The intervertebral disc space height was measured; grades of spinal canal stenosis and degenerative changes of discs, facet joints, paravertebral muscles in the lumbar spine were evaluated before surgery. In the postoperative period, clinical (severity of pain in the leg, in the back based on VAS, ODI, neurological examination) and radiological (anteroposterior, lateral views in a neutral position and in flexion and extension) examinations were performed immediately and at 3, 6, 12, and 24 months after surgery. Digital radiographs (DICOM files) were analyzed using special software, anterior and posterior disc heights were measured, and mean disc height, segmental lordosis angle, and the difference between pre- and post-surgical measurements of these paramenters. On the functional radiographs before and after surgery the mobility in the spinal motion segment

Fig. 3
The Maverick artificial intervertebral disc

Fig. 4
The Kinezis-1 artificial disc [4]

Fig. 5
The M6-L artificial disc [10]: **a** – a general view; **b** – view of prosthesis in section; **c** – artificial nucleus pulposus; **d** – kinematic part of the disc assembly (nucleus pulposus, artificial fibrous ring, internal endplates); **e** – polyethylene sheath; **f** – external titanium endplate

(the range of motion from flexion to extension) was examined and postoperative changes at every follow-up visit were assessed [9]. Control MRI of the lumbar spine was performed 12 and 24 months after surgery, or earlier if lumbar pain occurred. The condition of facet joints at the operated and adjacent levels, progression of disc degeneration at adjacent levels, and spinal canal stenosis were analyzed. Complaints, treatment satisfaction, willingness to repeat a similar operation, the need for analgesics were identified in patients during all control examinations. Complications in the intraoperative, early and late postoperative periods, operation time, amount of blood loss, and length of hospital stay were recorded.

A total of 109 patients with symptomatic degenerative disc disease were operated on, out of them 95 were subjected to disc arthroplasty at one level. Fourteen patients uderwent implantation at two levels, with two M6-L artificial discs in 10 of them, and with one artificial disc at one level and interbody fusion with titanium cage at the adjacent level – in 4 remaining patients. The choice of method was based on clinical, radiological, and MRI data. The patients operated on at one level were included in Group 1, and on two levels – in Group 2.

Surgical technique. The operation was performed via standard medial minimally invasive retroperitoneal approach [1, 2]. Transperitoneal access was used as a reserved approach for patients who had undergone previous surgery with a retroperitoneal approach [5]. The patient was positioned supine on a radiolucent orthopedic table. General endotracheal anesthesia was used. After disc exposure, a Cobb elevator for discectomy was used; posterior longitudinal ligament was not removed. The M6-L implant size was selected after endplate preparation using trial implant components under fluoroscopy control according to normal disc height at the upper and lower levels and angle of lordosis. The final artificial disc was inserted, vacuum drainage in the retroperitoneum was installed and the wound was closed in layers (Fig. 6–10).

Some of patients had artificial disc replacement at two levels and the others – disc prosthesis at one level and rigid implant (interbody fusion with titanium mesh cage) at the adjacent level. Total disc replacement at an adjacent level was performed as described. The cages were implanted using a standard ALIF procedure. In the postoperative period, the patients were allowed to sit up and walk the next day after surgery and were subjected to physical therapy. Sutures were removed on day 10 after surgery.

The goals of total disc arthroplasty are:

1) the same as of ALIF – to restore disc space, reliably connect and hold adjacent vertebrae;

2) specific – to preserve natural mobility of a spinal motion segment, to recover shock absorbing effect, homogeneous axial load distribution to adjacent spinal motion segments, and to prevent facet joint degeneration [14] and degenerative process at adjacent levels.

The interventions were considered successful according to the following criteria: patient satisfaction (according to results of the survey – yes/no), improvement in daily activities (a decrease of more than 10 points on theODI questionnaire), back and leg pain reduction (more than 2 cm on VAS) [11], absence of serious complications requiring reoperations, and absence of revision surgery, removal of artificial disc or complications associated with the implant.

Results

Of 109 patients, 106 were examined in dynamics. Mean follow-up period was 1.5 years (range, 6 months to 4.2 years).

As expected, mean operative time in 2-level surgery was greater, as well as blood loss. Blood transfusion was not required in any case. Length of hospital stay was greater in the group of patients who underwent more extensive surgery (table).

Based on VAS and ODI scores, there was a statistically significant pain regression compared to preoperative pain severity. Moreover, the improvement sustained for a long time on control examinations immediately and at 1.5, 3, 6, 12, and 18 months after surgery. The dynamics of pain regression and maintenance according to VAS and ODI are shown in Figs. 11, 12.

The average Mean rate of VAS score regression was 2.7 cm in both groups. According to the literature, the minimum clinically significant pain regression on VAS is 1.8–1.9 cm [11]. In our study, this level was achieved in 72 % of patients.

Reduction in ODI scores (that is, improvement in daily activity) was 24.3 points. According to the literature [11], the minimum clinically significant ODI score improvement is 10 points, which was achieved in 78.4 % of the patients studied.

76.8 % of patients in both groups were satisfied with the treatment outcome (condition has improved significantly), and 69.0 % would agree to repeat the same operation under the same conditions.

Radiological features. In the early postoperative period, patients in both groups retained mobility at the operated level on an average of 9.2° ± 2.8°, as seen from a comparison of lateral flexion/extension radiographs taken before and after surgery. The difference between groups with one or two operated segments was insignificant. Two years after surgery, 77 (71.0 %) patients were available for follow-up examination and underwent lateral radiography in neutral position and in flexion/extension. There was a slight decrease in range of motion at the operated segment, which reached 8.5° (±2.2°). Mean intervertebral disc space height before surgery was 6.1 ± 2.0 mm. After surgery, the intervertebral space increased up to an average of 13.7 ± 3.6 mm, with an improvement by 7.6 mm. At 1.5 years after surgery, prosthesis migration by an average of 1.6 mm (range, 0 to 2.8 mm) was observed in 27.3 % of 77 patients available for examination.

Complications. No serious complications were observed in the intraoperative and postoperative periods: there were no cases of spondylitis, peritonitis and other infectious complications, critical major vascular injury, dural tears, neural injury to lumbar plexus, spinal cord and cauda equina, epidural hematoma,

Fig. 6
Total discectomy

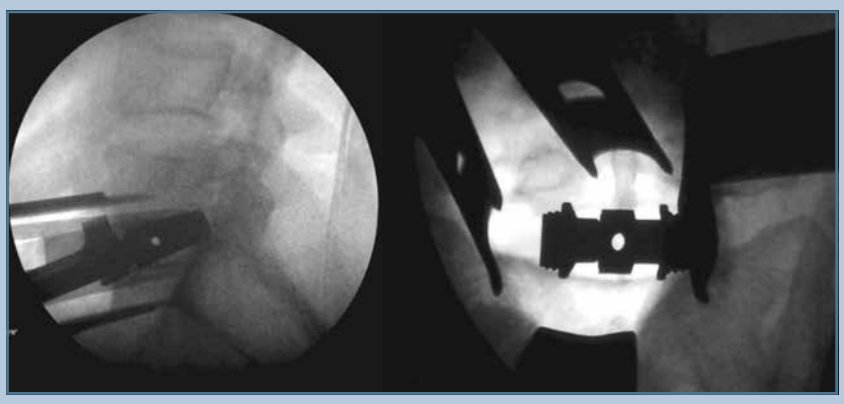

Fig. 7
Trial implant selection under X-ray image intensifier control (lateral and frontal views)

Fig. 8
Schematic image of the M6-L disc implantation at the L4–L5 segment [10]

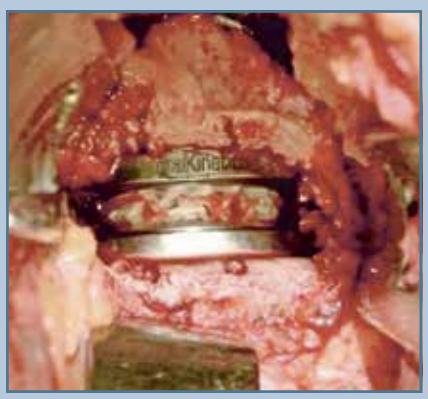

Fig. 9
Implanted M6-L disc

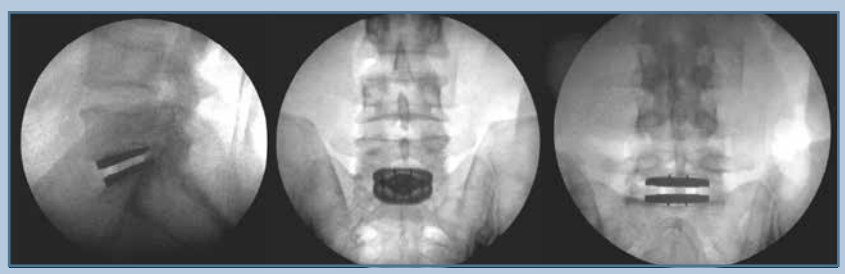

Fig. 10
X-ray control of the M6-L disc implanted at the L5–S1 segment (lateral and frontal views)

spinal cord ischemia. The total number of complications was 9 (8.3 %): 3 (2.8 %) cases of minor vascular injury, 1 (0.9 %) – injury to the sympathetic trunk resulted in warming of the left lower extremity, 2 (1.8 %) – heterotopic ossification at 6 months after surgery leading to spontaneous fusion. Two patients had serous discharge from the wound for a long time (19 and 25 days) that required prolonged dressings of wounds with antiseptics and stopped spontaneously. Vascular complications: one case of injury to *v. iliolumbalis* during approach to L_4–L_5 due to excessive tension on *v. iliaca communis*. The iliolumbar vein was ligated, hemostasis was achieved, and blood loss during surgery was 350 ml. Two more cases of superficial injury to the wall of *v. cava inferior* were identified intraoperatively and sutured, bleeding stopped, and blood loss in these cases was 430 ml on average. Blood transfusion in the postoperative period was not required in any case.

Conclusions

1. Arthroplasty using the M6-L disc is an effective and safe procedure. Good results have been achieved in 67.8% of patients, without serious complications. Arthroplasty is a procedure with a sloping learning curve; the major challenge of this technique is related to peculiarities of the anterior retroperitoneal approach to the spine. If the technique is well mastered and appropriate selection of patients is performed, arthroplasty becomes a promising, safe, and highly effective procedure.

2. Arthroplasty with the M6-L artificial disc restores and maintains natural biomechanics of the spinal motion segment, i.e., restores intervertebral disc space height up to 13.6 mm, and preserves range of motion of 8.5° at 1.5 years after surgery. In 27.0 % of the cases there was an insignificant artificial disc migration by an average of 1.6 mm.

3. Due to restoration of normal biomechanics in the spinal motion segment, there is no load redistribution to adjacent intervertebral discs and, thus, this presumably prevents a progression of degenerative cascade. This hypothesis needs to be confirmed or denied by further investigation, subjective and objective data, additional methods of examination of operated patients, and interim MRI studies.

4. The M6-L artificial disc replacement provides early rehabilitation of patients (patients are permitted to walk the next day after surgery without need of bracing, operation time and length of hospital stay are reduced).

5. Total disc replacement with functional M6-L artificial disc provides a statistically significant pain regression, allows a patient to improve daily activity. Patient satisfaction is high.

Table

Mean surgery time, length of hospital stay, and blood loss in groups of patients

Parameters	Group 1	Group 2
Operative time, min	102,4 ± 45,8	120,2 ± 36,4
Amount of blood loss, ml	232,3	458,7
Length of hospital stay, days	6,4	8,2

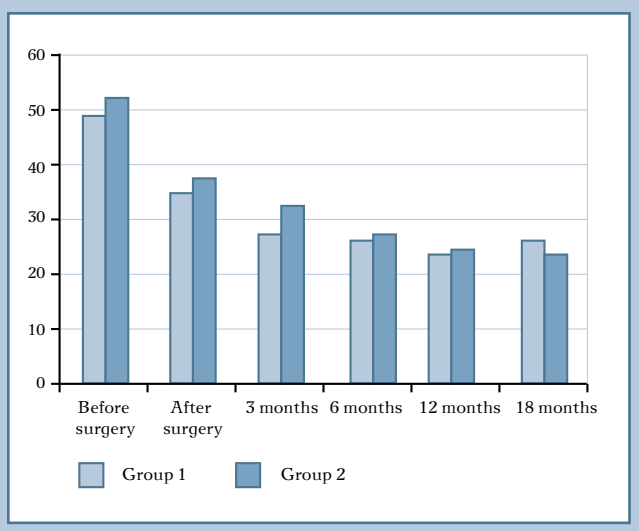

Fig. 11
Change in VAS pain score

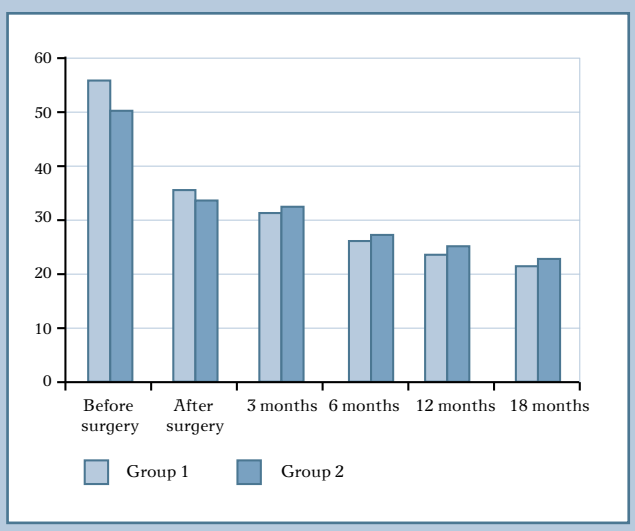

Fig. 12
Daily activity change scores on ODI

References

1. Dotsenko VV, Zagorodniy NV. Spondylolisthesis, Anterior Less Traumatic Surgery. Moscow, 2005. In Russian.
2. Kruglov IA, Gizatullin ShKh, Seleznev AS, Vovkogon VB, Sychev VA. Experience in surgical treatment of herniated intervertebral discs in the lumbar spine. Proceedings of N.N. Burdenko Main Military Clinical Hospital. 2012;(9, Pt.1). In Russian.
3. Nazarenko GI, Geroeva IB, Cherkashov AM, Rukhmanov AA. Low back pain. Diagnostic and treatment technique. Manual for physicians. Moscow, 2008. In Russian.
4. Chertkov AK. Lumbar Artificial Disc Replacement in Neurosurgery. Moscow, 2011. In Russian.
5. Artificial discs for lumbar and cervical degenerative disc disease – update: an evidence-based analysis. Ont Health Technol Assess Ser. 2006;6:1–98.
6. Artificial Lumbar Disc Replacement (update), January 2006. Horizon Scanning Report. Department of Health and Ageing, Australian Government, 2006.
7. Benini A. Indications for single-segment intervertebral protesis implantation. Neuroradiol J. 1999;12(1 Suppl):171–173. DOI: 10.1177/19714009990120S124.
8. Delamarter RB, Fribourg DM, Kanim LE, Bae H. ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. Spine. 2003;28:S167–S175.
9. Geisler FH. Lumbar Spinal Arthroplasty: Clinical Experience, Recent Advances in Arthroplasty. In: Fokter S, ed, Recent Advances in Arthroplasty. In Tech, 2004. URL: http://www.intechopen.com/books/recent-advances-in-arthroplasty/lumbar-spinal-arthroplasty-clinical-experience.
10. Gelenk-Klinik. Spinal Disc Replacement: supporting pain free mobility through next generation Spinal Prosthesis: Next generation Spinal Disc Replacement using the dynamic M6 spinal disc prosthesis. In: Joint Surgeons in Germany: Electronic resource. Germany, 2012. URL: http://www.joint-surgeon.com/orthopedic-service/spine-surgery/artificial-spinal-disc-replacement/lumbar-disc-replacement.html.
11. Hagg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. Eur Spine J. 2003;12:12–20.
12. Link HD. History, design and biomechanics of the LINK SB Charite artificial disc. Eur Spine J. 2002;11 Suppl 2:S98–S105. DOI: 10.1007/s00586-002-0475-x.
13. Sakalkale DP, Bhagia SA, Slipman CW. A historical review and current perspective on the intervertebral disc prosthesis. Pain Physician. 2003;6:195–198.
14. Shim CS, Lee SH, Shin HD, Kang HS, Choi WC, Jung B, Choi G, Lee S, Lee HY. CHARITE versus ProDisc: a comparative study of a minimum 3-year follow-up. Spine. 2007;32:1012–1018. DOI: 10.1097/01.brs.0000260795.57798.a0.
15. Warachit P. Results of Charite artificial lumbar disc replasment. experience in 43 Thais. J Med Assoc Thai. 2008;91:1212–1217.

Address correspondence to:
Abakirov Medetbek Dzhumabekovich
Peoples' Friendship University of Russia,
Miklukho-Maklaya str., 6, Moscow, 117198, Russia,
medetbek@mail.ru

Received 13.08.2015

Medetbek Dzhumabekovich Abakirov, DMSc, Professor in the department of traumatology and orthopaedics, Peoples' Friendship University of Russia, Moscow, Russia;
Ivan Aleksandrovich Kruglov, head of neurosurgical department, District Military Hospital, Moscow, Russia;
Rinat Raviljevich Abdrakhmanov, fellow in the department of traumatology and orthopaedics, Peoples' Friendship University of Russia, Moscow, Russia;
Aleksandr Sergeyevich Seleznev, physician in neurosurgical department, District Military Hospital, Moscow, Russia;
Aleksandr Evgenyevich Mader, MD, PhD; doctoral candidate in the department of traumatology and orthopaedics, Peoples' Friendship University of Russia, Moscow, Russia.