THE USE OF NITINOL RODS FOR LUMBOSACRAL FIXATION IN SURGICAL TREATMENT OF DEGENERATIVE SPINE DISEASE

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Objective. To analyze the results of treatment of degenerative spine disease with the use of nitinol rods for lumbosacral fixation as compared with conventional rigid fixation.
Material and Methods. The prospective randomized study included 75 patients (34 males, 41 females; mean age 43 years) with degenerative lesion at the L5—S1 level. Surgical treatment was performed with nitinol rods in 35 patients (Group 1), and with standard titanium rods in 40 patients (Group 2). Clinical and radiological results were assessed in 1.5 years after surgery.
Results. The VAS leg-and-back, ODI, and SF-36 scores showed improvement in patients of both groups such as a significant reduction in pain intensity and improvement in psychological and physical health. The X-ray examination showed the restoration of the lumbar lordosis in both groups. In Group 1, there was no evidence of screw instability, bone resorption around screws and the adjacent segment disease, and functional radiography demonstrated preservation of mobility (5.0° ± 1.2°). There were seven patients with pseudoarthrosis, and six — with adjacent segment disease in Group 2, surgical intervention was required in four of them.
Conclusion. Transpedicular fixation in the lumbosacral spine using nitinol rods is an effective technology allowing for mobility preservation in combination with stable fixation.
Key Words: degenerative diseases of the spine, lumbosacral spine.

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Over the past century, surgical activity in the treatment of degenerative spine diseases has increased several-fold. For example, the level of surgical activity for these diseases in the USA has increased by 30 % in 2000–2009 [19, 22, 32, 47]. In the Russian Federation, back pain related disorders cause over 1 million doctor visits each year [3]. The clinical practice of the Department of Spine Pathology of the Central Institute of Traumatology and Orthopedics (CITO) may be used to estimate the level of surgical activity: over the last 20 years, it has increased more than 3-fold, from 33 patients in 1994 to 110 patients in 2013. In turn, surgery for spinal canal stenosis ranks first among spinal interventions in the orthopedic and neurosurgical practice in the elderly patients [5]. Treatment costs in developed countries are estimated in billions of dollars [17, 29].

Disc degeneration is a natural process associated with a number of factors. For example, changes in the endplate lead to malnutrition of the intervertebral discs and, consequently, to their degeneration. Aging, apoptosis, disturbance of collagen synthesis, neovascularization, and pathologic proteoglycans are the factors of disc degeneration. The pathological processes cause disc height loss that leads to impaired biomechanics of vertebral segment motion manifested as instability [35]. White and Panjabi [37, 46] define instability as a f nts and facet joints as well as a certain degree of intervertebral disc protrusion, i.e. spinal canal stenosis, develop [12].

The clinical manifestations of spinal canal stenosis include radicular pain or vertebrogenic intermittent claudication [15]. Patients with degenerative spine diseases who receive conservative treatment develop worsening of the clinical picture in 85% of cases over time [24].

For the last 20–30 years, the standard of surgical treatment for degenerative diseases of the lumbar spine has been decompression of neural structures of the spinal canal using fusion (with or without instrumentation) because numerous studies have proven the development of instability after decompression surgery [9, 40, 44].

However, these interventions lead to a large number of complications, which very negatively affects the patient quality of life. The rate of adjacent segment degeneration amounts to 89 % [36]; the rate of pseudarthrosis is 5–7 %; the rate of graft fracture is 5–10 %; the rate of bone resorption around transpedicular screws is 10–15 % [41, 42].

The L5–S1 segment that is the transition between the flexible lumbar spine and the sacrum is of the greatest interest. Biomechanically, this segment is the region of the maximum load (the range of motion in the lumbosacral region is maximal, 18°; Table 1) [7, 13] and the largest degenerative changes [14]. It is known that 95 % of pathology in degenerative diseases of the lumbosacral spine is associated with the L5–S1 segment [25, 33]; according to several authors [1, 6, 23, 46], the rate of complications due to surgery at this level ranges from 12.5 to 57.0 %. In a study by Pihlajamaki et al. [39] who analyzed complications of lumbosacral junction fixation in 102 patients, 48 patients had complications, with nearly half of them having more than one complication. For example, pseudarthrosis occurred in 19.6 % of cases, bone resorption around grafts in 17.6 % of cases, and fractures of elements of a metal construct in 19.6 % of cases.

It is worth noting that the number of patients among people under 20 years more than doubled in recent decades [4].

Nitinol is a unique alloy of nickel (55 %) and titanium (45 %), possessing properties such as shape memory and superelasticity. The effective elasticity modulus of nitinol is 15–20 GPa, which is actually equal to the cortical bone modulus of elasticity (18 GPa). Plasticity of nitinol is eight-fold higher than that of titanium. The crystal lattice has high resistance to dynamic loads [30]. Nitinol, which is used in dynamic rods, has the shape recovery start and finish temperature of 27 and 35 °C, respectively. The rods are used in the superelastic state at the body temperature (36–37 °C), providing mechanical compatibility of a transpedicular fixator with mechanical behavior of the spine [2].

The use of these nitinol properties is promising for dynamic stabilization of the lumbosacral spine using a non-fusion technique.

However, the literature lacks publications dedicated to the use of nitinol rods in combination with transpedicular screws in degenerative lumbosacral spine diseases.

The study purpose was to analyze the outcomes of treatment of degenerative spine diseases using nitinol rods for fixation of the lumbosacral spine compared to outcomes of traditional rigid fixation.

Material and methods

The prospective randomized study included 75 patients (34 males and 41 females) with degenerative lumbosacral spine diseases, in whom the pathological process necessarily involved the L5–S1 segment as well as herniated discs with spinal canal stenosis and instability of the lumbosacral spine.

The mean patient age was 43 years (35 to 81 years). Nineteen patients had been or remained smokers; 15 patients were retired; the other 60 patients were working, with 29 of them being on sick leave at the time of admission or for the past 3 months. All patients complained of lumbar spine pain, unilateral or bilateral leg pain, and radicular disorders (reduced sensitivity and muscle strength). Before surgery, all patients underwent a course of conservative treatment for 3 to 6 months, without significant clinical effect.

Comorbidities: 7 (9.33 %) cases of diabetes mellitus type II, 12 (16.00 %) cases of ischemic heart disease, 19 (25.33 %) cases of arterial hypertension, 2 (2.66 %) cases of bronchial asthma, 6 (8.00 %) cases of gastric ulcer and duodenal ulcer, and 1 (1.33 %) case of polyvalent drug allergy. Among patients with comorbidities, 8 (17.02 %) patients required preoperative preparation at the hospital.

All operations were performed by two surgeons, with equal participation, at the Department of Spine Pathology of CITO in 2010–2013.

Clinical evaluations. All patients completed VAS, Oswestry, and SF-36 questionnaires before and after surgery. Evaluation was performed 3, 6, and 18 months after surgery.

Radiologic examination. The planned algorithm of preoperative examination included standard radiography in two projections, functional radiography with the patient in the upright position, and MRI of the lumbosacral spine in all patients (Fig. 1).

Lumbar lordosis was measured using radiographs. Functional radiographs were used to evaluate mobility of the lumbosacral spine and to measure the Cobb range of flexion-extension movements in each lumbosacral motion segment. MRI scans were used to evaluate the level of spinal canal stenosis, degree of neural structure compression, and condition of segments adjacent to those planned for fixation. On control examinations 3 and 6 months after surgery, radiography in the standard projections, functional radiography, and questionnaire surveys were performed.

On control examination after 18 months, all patients underwent standard radiography in two projections, functional radiography in the upright position (Fig. 2), and MRI and CT of the lumbosacral spine.

Table 1

Range of motion in the lumbar spinal motion segments [37], degrees

Level	Flexion-extension movements	One-sided lateral bending	One-sided axial rotation
L1–L2	12	6	2
L2–L3	14	6	2
L3–L4	15	8	2
L4–L5	16	6	2
L5–S1	17	3	1

Mobility of the lumbar spine 18 months after surgery was evaluated using functional radiographs. Radiographs in flexion and extension positions were used to measure the Cobb angle between the superjacent and subjacent vertebrae involved in the fixation region. Additionally, the Cobb's measurement of a flexion-extension range in each fixed segment was performed. After 18 months, all patients underwent CT to evaluate bone resorption around transpedicular screws and MRI to evaluate the condition of adjacent segments. Therefore, all patients preoperatively underwent MRI of the lumbosacral spine, radiography in two standard projections, and functional imaging (flexion/extension). In the postoperative period, radiography was performed after 6 and 12 months. After 18 months, all patients underwent repeated examination and additional CT and MRI.

Surgical technique. All patients were divided into groups by adaptive randomization; study and control groups were comparable by type of surgical treatment, which greatly improved objectivity of the study. Both groups were equivalent; it is unreasonable to indicate ratios of various interventions because the study was not aimed at improving surgical techniques, but at studying the clinical properties of nitinol rods, in contrast to rigid titanium ones, in relation to degenerative-dystrophic diseases of the lumbosacral junction.

Group 1 consisted of 35 patients (17 males and 18 females; mean age, 41 year). The standard posterior medial approach was used. Transpedicular screws were passed carefully to preserve the intervertebral joints intact. After placing screws, decompression of neural structures using inter-, hemi-, and laminectomy was performed. If indicated, standard discectomy and resection of a hypertrophied yellow ligament and articular processes were performed. If instability at an affected segment level was predominant, and there was no compression of neural structures, only stabilization of spinal motion segments was carried out. After that, we implanted two nitinol rods that were industrially fabricated to fit the lumbar lordosis (35–40°). Before implantation, the rods were stored in cold saline; the storage temperature did not exceed +10 °C because these materials can repeatedly reversibly deform during thermal cycles, which allows for reversibility of an inelastic deformation, i.e. the shape memory effect. The shape memory effect enables nitinol rods to correct spine curvatures due to a return to a predetermined shape at the body temperature. Upon fixation of one or two segments, the rods can be used without preliminary cooling. Spinal fusion and bone grafting were not performed. L5–S1 fixation was performed in 12 patients; L4–L5–S1 fixation was performed in 14 patients; L3–L4–L5–S1 fixation was performed in 9 patients.

Group 2 included 40 patients (15 males and 25 females; mean age, 44 years). The standard posterior approach was used. Transpedicular screws were placed. Neural structures were decompressed using inter-, hemi-, and laminectomy. Because the L5–S1 segment was involved in the fixation region, L5–S1 interbody fusion was performed according to a PLIF or TLIF procedure using a cage. Like in the study group, if indicated,

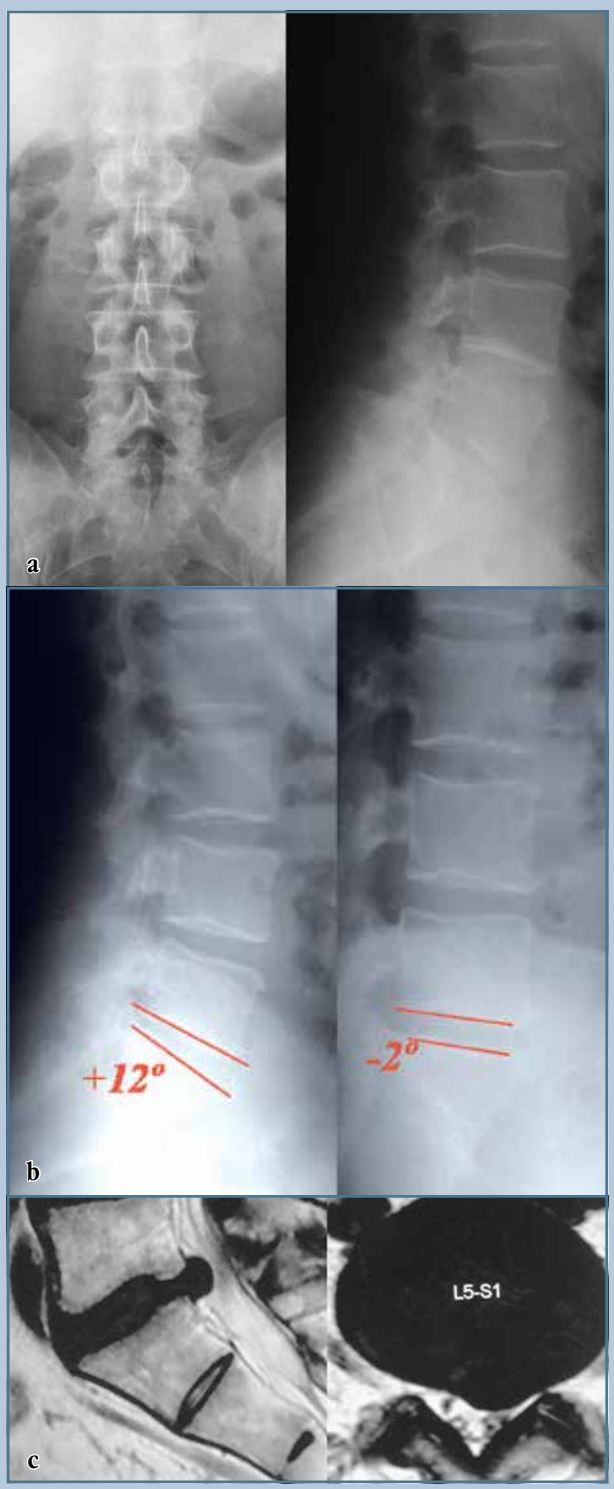

Fig. 1
Radiographs in two projections **(a)**, functional radiographs (flexion and extension) with a patient in the upright position **(b)** and MRI of the lumbosacral spine **(c)** before surgery

standard discectomy and resection of a hypertrophied yellow ligament and articular processes were performed. If instability at an affected segment level was predominant, and there was no compression of neural structures, only stabilization of spinal motion segments and a mandatory TLIF procedure at the L5–S1 level were performed. Rigid titanium rods were implanted. Additionally, bone grafting on the transverse processes and posterior elements of the vertebrae was performed using autografts. L5–S1 fixation was performed in 12 patients; L4–L5–S1 fixation was performed in 17 patients; L3–L4–L5–S1 fixation was performed in 11 patients

Each patient received antibiotic prophylaxis (1.0 g of ceftriaxone before surgery and for three days after surgery). After surgery, patients stayed in bed for one day and then were activated under doctor's supervision. The mean length of hospital stay after surgery was 10 days.

The study and control groups were equivalent in the type of surgical treatment.

Results

The lumbar lordosis was recovered in both groups: 20.0° ± 1.0° before surgery and 35.0° ± 1.0° after surgery; 23.0° ± 1.0° before surgery and 37.0° ± 1.0° after surgery, respectively. However, an analysis of functional radiographs 18 months after surgery revealed mobility of the stabilized segments (5.0° ± 1.2°) in Group 1 patients. No mobility at the fixed levels was found in Group 2 patients (Table 2).

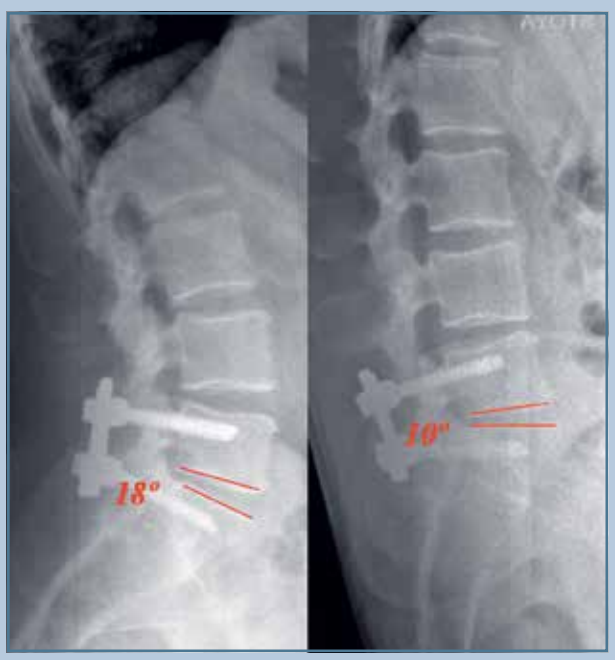

Fig. 2
Radiographs in a lateral projection 18 months after surgery: extension and flexion

The mean surgery time was 155 ± 15 min in Group 1 and more than 213 ± 15 min in Group 2. This difference was associated with the time spent for interbody and posterior fusion. The mean blood loss was 200 ± 50 mL in Group 1 and 700 ± 50 mL in Group 2, which was due to PLIF and TLIF procedures and decortication of the posterior structures during posterior spinal fusion. These surgery stages were associated with hemorrhage usually from the epidural veins and bone.

The treatment outcomes were analyzed by questionnaires. The VAS scores for the back and lower extremities decreased significantly in both groups and remained at a comparable level after 18 months (Fig. 3). The ODI tended to significantly decrease in both groups; however, the result was statistically better in Group 1 than that in Group 2: 64.6 before surgery and 17.8 after surgery versus 65.2 and 25.6, respectively; $p < 0.05$ (Fig. 4). According to the SF-36 data, a comparable improvement was observed in both groups. For example, in Group 1, the physical health component was 37.2 before surgery and 66.5 after surgery; the mental health score was 41.5 before surgery and 74.3 after surgery. In this case, a poorer indicator of physical health was observed in Group 2: the physical health component was 36.2 before surgery and 55.2 after surgery; the mental health score was 42.5 before surgery and 73.7 after surgery; $p < 0.05$ (Fig. 5).

Twenty six patients, including 14 patients from Group 1 and 12 patients from Group 2, returned back to their work within 18 months.

Complications. In Group 1, no implant instability was detected 18 months after surgery; according to the CT data, there was no bone resorption around screws and no worsening of adjacent level instability. One patient had an infectious complication (surface abscess) that required open wound management followed by secondary suturing. In Group 2, there were more complications. An abscess developed in 1 patient who underwent open surgical wound treatment, debridement, and secondary suturing. Pseudarthrosis was detected in 7 patients; adjacent segment disease developed in 6 patients; there were 4 cases of severe pain, which required revision surgery. In 2 cases, the indications for surgery included the development of adjacent segment syndrome with severe clinical signs that could not be relieved by conservative treatment: lumbar pain radiating to a lower extremity. In 2 cases, instability and pseudarthrosis required revision surgery with rearrangement of a metal construct and additional bone grafting with allografts and autografts.

Therefore, according to the number of complications and the quality of life assessed with various questionnaires, the treatment outcomes after 18 months were better in the group with nitinol rods.

Table 2
Mean parameters of spinal motion segment mobility in patients before and after surgery, degrees

Parameters	Group I		Group II	
	Before surgery	18 months after surgery	Before surgery	18 months after surgery
Lumbar spine lordosis angle	22	35	23	37
Global mobility	95	56	96	24
T12–L1	12	12	11	12
L1–L2	11	11	11	13
L2–L3	14	7	14	0
L3–L4	19	10	19	0
L4–L5	20	9	21	0
L5–S1	19	7	20	0

Discussion

Posterior spinal fusion is widely used as surgical treatment of degenerative spine diseases. A bone block prevents abnormal movements, eliminating the source of pain. On the other hand, even in patients in whom a 100 % bone block was achieved by high-quality fusion, the satisfaction level, according to some authors, reaches only 30 % [8, 27, 28, 31, 34].

Posterior dynamic stabilization systems were designed to improve the quality of patient care and eliminate bone block-associated complications, such as adjacent segment disease (12.2–18.5 %) [38], the stress-shielding effect (2–3 % per year after stabilization) [21], pseudarthrosis (3–55 %) [18, 26, 45], developing osteopenia in the fixation region and around implants [36], and loss of mobility in the fixed segments. In addition, significant improvement of clinical results, even in the presence of good X-ray signs, was not always observed [10, 20]. Therefore, the use of posterior dynamic stabilization devices in surgical treatment of degenerative spine diseases may result in greater satisfaction of patients due to a reduced number of bed-days, shorter rehabilitation time, and also the absence of drawbacks typical of rigid systems.

Over the last 10 years, a large number of dynamic implants have been proposed, without a clear understanding of their action mechanisms [42]. The common feature of all these devices is the ability to maintain mobility of the operated segment. In other words, the device should limit pathological mobility of the spinal motion segment and preserve the physiological range of movements. However, some mobility loss is inherent to application of any devices [41, 43].

According to the results of our study, the clinical outcomes in the short-term postoperative period were satisfactory in both groups, which was due to adequate decompression and elimination of stenosis and instability. In Group 1, there were no adjacent level problems 18 months after surgery. In Group 2, there were 6 (15 %) cases of adjacent segment instability, 4 of which manifested clinically. According to the literature data, the rate of these complications amounts to 42.6 %, of which 56.0 % of cases are manifested clinically [16]. An analysis of clinical material according the Oswestry questionnaire demonstrated that the outcomes were better in Group 1 than in Group 2.

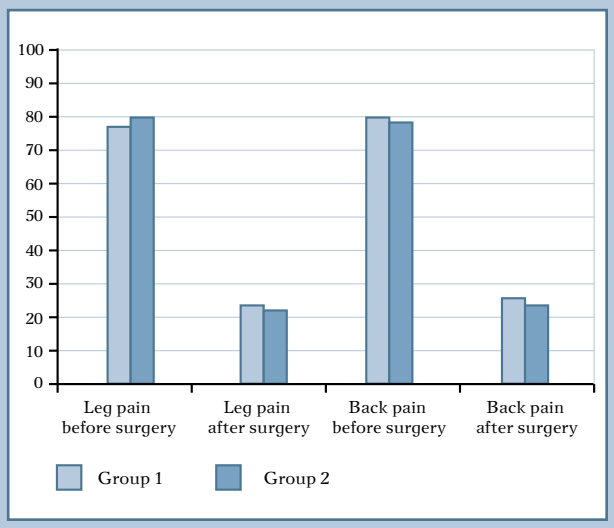

Fig. 3
The VAS score before and 18 months after surgery

No fractures and loosening of the rods were observed 18 months after surgery. However, a higher reliability of the study requires a longer follow-up period.

The properties of nitinol, when it is used together with transpedicular screws, enable achieving a more physiological distribution of dynamic load, preserving the range of movements, and reducing loads on support elements. This prevents their loosening, which is important in the case of osteoporosis and decreased bone quality.

A surgical technique for implantation of nitinol rods is simple and easy in the case of revision surgery.

According to the literature data, some dynamic fixators insufficiently limit movements during body rotation [42]. The

use of dynamic transpedicular fixators is associated with the development of complications. The rate of complications associated with implantation of a dynamic fixator can amount to 27 % [11]. Bothmann et al. [11] demonstrated that, despite preservation of mobility upon spine stabilization by dynamic systems, the risk of complications was quite high: the rate of bone resorption around screws was 17.5 %; the rate of implant fractures was 2.5 %; the rate of adjacent segment disease was 2.5 %.

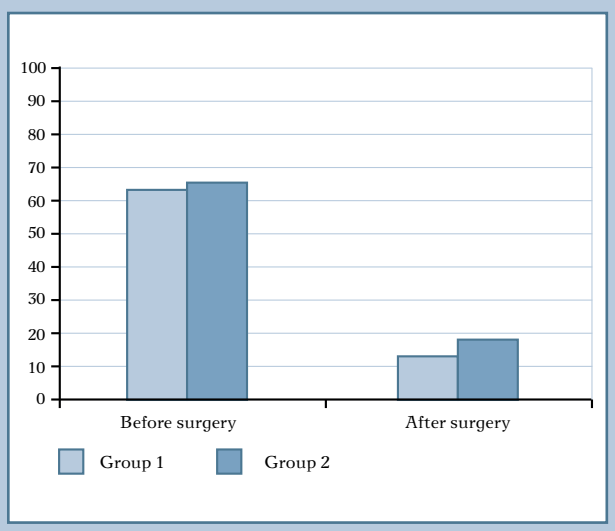

Fig. 4
ODI before and 18 months after surgery

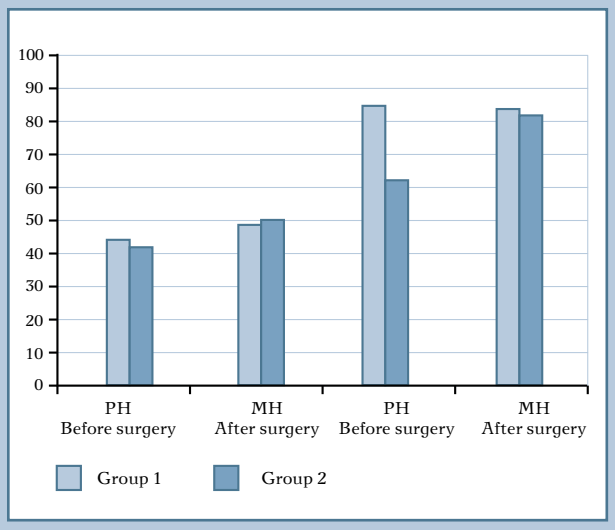

Fig. 5
SF-36 before and 18 months after surgery:
PH physical health; MH mental health

The properties of nitinol ensure its uniform function in all planes [30].

The data of our prospective randomized study demonstrated the efficacy of nitinol rods.

Conclusions

1. Transpedicular fixation using nitinol rods, without fusion, for dynamic stabilization of the lumbosacral junction in patients with degenerative lumbar spine diseases results in better outcomes compared to those in traditional rigid fixation 18 months after surgery.

2. Nitinol rods preserve mobility of the spinal motion segment 18 months after surgery, which reduces the number of complications typical of rigid fixation.

3. Further accumulation of clinical data and analysis of long-term results of this treatment option are required.

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