

Conference paper

Porous TiNi Implants in Surgery of Spine Degenerative Diseases

A.E. Simonovich^{1*}, N.G. Fomichev²¹Novosibirsk State Medical University, Novosibirsk, Russia²Novosibirsk Research Institute of Traumatology and Orthopaedics n.a. Ya.L.Tsivyan, Novosibirsk, Russia*

*Corresponding author:

A.E. Simonovich email:

alsimonovich@yandex.ru

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Abstract

Objective. To evaluate the efficacy of using porous TiNi implants for interbody fusion in the treatment of lumbar spine degenerative diseases.

Material and Methods. A total of 570 patients with degenerative lumbar spine disease were operated on with porous TiNi implants. Surgical treatment included stabilization and decompression and stabilization operations through posterior and anterior approaches and endoscopic transabdominal operations. Results of surgical treatment were followed-up for the period of 3 to 24 months. The change of pain syndrome was evaluated using a Visual Analogue Scale (VAS) and Oswestry Disability Index. The degree of interbody bone block formation was assessed based on X-ray and spiral CT data.

Results. Functional results of treatment were evaluated at 18-24 months after surgery as good and satisfactory in 94.1% of cases, and the formation of interbody bone-metal block was noted in 94.8% of cases.

Conclusion. Nickelid Titanium exhibits good osseointegration properties and can be used as osteoplastic material without additions of bone tissue, which simplifies operation, reduces its traumaticity, and provides good and satisfactory treatment results in 94.1% of cases.

At the Department of Maxillofacial Surgery I.M. Sechenov First Moscow State Medical University 120 patients with zygomatico-orbital complex fractures were treated during the period from 2011 to 2015. Different methods of the osteosynthesis are presented and discussed. Successful application experience of superelastic nickelid titanium mesh and porous nickelid titanium implants for the lower orbital wall reconstruction was reviewed.

1 Introduction

Interbody fusion is one of the most common ways to stabilize the spine. For many years, bone autograft remained the only plastic material used in this operation. Bone allograft is a material which needs much time for rebuilding, is immunologically active, and requires particularly thorough sterilization and conservation.

At present, polymers, carbon materials, porous ceramics, and metal implants are used to perform interbody fusion. As concerns to carbonaceous materials and porous ceramics, the main drawback is their fragility and lack of flexibility inherent to bone tissue. An analysis of long-term results showed that the stabilizing effect of porous ceramics is maintained for 3-4 months after operation. Subsequently, the bone resorption at the border with the implant leads to implant loosening and neoarthrosis, and a wedging effect of the implant is lost because of its intrusion into the vertebral body cancellous bone [4, 8-10]. It should be noted that not all the authors using ceramics indicate such complications [2].

A variety of implants made of titanium and polymer materials were developed. However, in any case, these materials represent a foreign body unable to integrate with host tissue and can be used only in conjunction with bone grafts.

From this perspective, a nickelid titanium alloy which has a number of unique properties is of undoubted interest. The porosity of this material similar to that of cancellous bone, and its high biocompatibility facilitate the fibrous and bone tissue in growth into the implant and its fixation in the bone bed. Due to superelasticity of TiNi alloy and its stress-strain characteristics similar to the bone, the contact between the bone bed and the implant is kept constant in varying mechanical load of the spine [1, 3, 5-7].

The aim of the study was to evaluate the efficacy of interbody implants made of porous TiNi for different types of decompression and stabilization operations for degenerative diseases of the lumbar spine.

2 Experimental

A total of 570 patients with degenerative diseases of the lumbar spine were operated on using interbody implants made of porous TiNi in 1998-2014. Among

patients, 373 (65.4%) were men and 197 (34.6%) women aged 28 to 69 (median age 48.7).

Preoperative assessment included clinical, neurological and X-ray examination (in some cases - myelography), MRI, and spiral CT.

Patient selection criteria were the presence of radicular and reflex pain resistant to conservative treatment, and of lower back pain with or without neurological deficit.

Indications for surgery were the following clinically significant pathological changes in the spine: disc herniation, degenerative discopathy, degenerative spinal stenosis, and degenerative spondylolisthesis. Operations were performed through posterior or anterior retroperitoneal approach, as well as through endoscopic transabdominal approach at the levels of L4-L5 (48,8%), L5-S1 (41,6%), L3-L4 (4,6%), L4-L5 -S1 (3,7%), and L3-L4-L5 (1,3%) vertebra. Posterior interbody fusion was performed not only as an independent way to stabilize the spine, but also in conjunction with pedicle fixation.

Implants for posterior interbody fusion have a cylindrical shape 20 and 25 mm in length and 12, 14 and 16 mm in diameter, for anterior interbody fusion – a discoid shape 20 and 25 mm in diameter, and for endoscopic transabdominal fusion – a trapezoid shape 20 and 25 mm in length, 12 to 16 mm in height, and 10 mm in width (Fig. 1).

Posterior interbody fusion was performed with two porous TiNi implants in 362 cases and with one implant in 23 cases when fusion was combined with pedicle fixation.

Porous TiNi implants have a safety margin which is in large excess over that prescribed by specification (not less than 600 kgf). Benchmark trials demonstrated that failure load for a cylindrical implant 14 mm in diameter and 25 mm in length was 2125 kgf at 750,000 loading cycles, for a discoid implant 20 mm in diameter - 2019 kgf , and for a trapezoid implant - 2575 kgf at 1 million loading cycles.

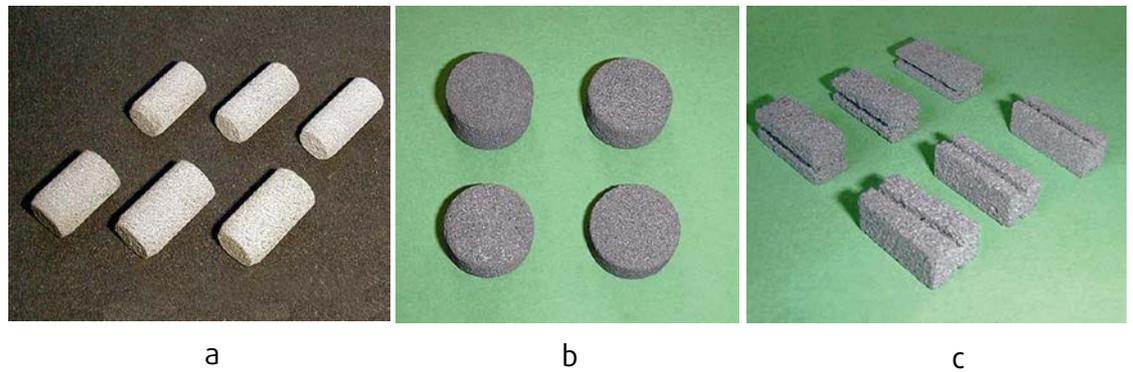


Fig.1. Implants for posterior interbody (a), anterior interbody (b), and endoscopic transabdominal lumbar fusion (c)

The results of surgical treatment were studied in a prospective study of 248 patients at 3, 6-12, 18-24 and more months after surgery (Table 1).

The change of pain was evaluated using a Visual Analogue Scale (VAS) and Oswestry Disability Index to determine the violations of functional capability. The degree of interbody bone block formation was assessed based on X-ray, MRI and CT data. X-ray studies included measurement of the *anterior and posterior disc space heights* before and after surgery, and assessment of the difference between segmental angles in flexion and extension at the operated level.

Functional results of surgical treatment were evaluated based on the degree of physical and social recovery of patients. Criteria for assessing the results of treatment were as follows:

- Good: complete or almost complete return to the previous (before or after the last flare-up) level of social and physical activity, with possible limitation of strenuous exercise;
- Satisfactory: activity of daily living and social activity are not fully recovered, only light physical activity is possible; and
- Unsatisfactory: no effect of operation, or worsening.

3 Results and discussion

Immediate results of surgery depended on the correct choice of surgical approach and the adequacy of surgical intervention aimed at neurovascular decompression and stabilization of the spine. There are different opinions about the exceptional advantages of various surgical techniques and approaches to the spine. In our view, the choice of method of surgical treatment should be differentiated and

based on the clinical and pathological features of a particular case. In the presence of degenerative spinal canal stenosis, sequestered migrate one, we gave preference to decompression and stabilization operations performed through a posterior approach.

The pain in most cases regressed in the first days after surgery, suggesting an adequate neurovascular decompression and spinal segment stabilization. Postoperative change in pain intensity measured by VAS is presented in Table 1.

Oswestry Disability Index was measured on a scale of 0 to 100%. Index value between 0 and 20% means minimal disability, between 20 and 40% - moderate, between 40 and 60% - heavy, and between 60 and 80% - disabling condition. The change in the Oswestry index after surgical treatment is presented in Table 2.

In most cases, a complete or partial restoration of functional activity was noted 12-24 months after surgery, which allowed to consider the results of treatment as good and satisfactory (Table 3).

X-ray examination showed no signs of implant destruction and peri-implant bone resorption, as well as of its intrusion into the vertebral body in any of cases. According to X-ray data, the difference between segmental angles in flexion and extension at the operated level after posterior interbody fusion exceeded 5° only in 6 out of 102 (5.2%) cases. The remaining (94.8%) patients the mean amplitude of segmental angle in flexion and extension was less than 5° (on average 2.4°). After anterior interbody fusion, the flexion-extension amplitude of segmental angle exceeded 5° in one case out of 32 (3.1%), and after endoscopic transabdominal fusion - in one case out of 20 (5%). There were no cases of interbody implant destruction and its intrusion into the vertebral body.

Table 1. Change in pain intensity after surgery by Visual Analogue Scale (VAS)

Type of surgery	Back (leg) pain VAS score, from 0 to 5, [M ± σ]			
	before surgery	after surgery [months]		
		3	6-12	18-24
I	2.5 ± 0.7 (3.8 ± 0.7) n = 165	1.1 ± 0.5 (1.1 ± 0.5) n = 120	0.7 ± 0.4 (0.7 ± 0.6) n = 80	1.1 ± 0.5 (0.7 ± 0.6) n = 52
II	3.2 ± 0.4 (3.6 ± 1.3) n = 63	0.9 ± 0.4 (0.9 ± 0.3) n = 48	0.8 ± 0.6 (0.6 ± 0.3) n = 42	1.2 ± 0.3 (0.6 ± 0.4) n = 30
III	2.3 ± 0.5 (2.9 ± 0.8) n = 20	0.7 ± 0.6 (0.7 ± 0.4) n = 19	0.9 ± 0.4 (0.5 ± 0.6) n = 17	1.1 ± 0.3 (0.5 ± 0.4) n = 14

I - posterior lumbar interbody fusion; II - anterior lumbar interbody fusion; III - endoscopic transabdominal lumbosacral fusion.

Table 2. Change in the Oswestry index in operated patients

Type of surgery	Oswestry index [% (M ± σ)]			
	before surgery	after surgery [months]		
		3	6-12	18-24
I	61.52 ± 10.04 n = 165	19.12 ± 7.53 n = 120	18.82 ± 4.84 n = 80	13.88 ± 5.52 n = 52
II	54.23 ± 7.24 n = 63	14.57 ± 6.74 n = 48	16.42 ± 3.12 n = 42	17.48 ± 5.49 n = 30
III	52.68 ± 9.24 n = 20	17.43 ± 4.32 n = 19	15.58 ± 6.22 n = 17	12.72 ± 3.78 n = 14

X-ray and CT data obtained in the period of six months to two years after surgery showed an osseointegration of implants with a formation of interbody bone-metal block (Fig. 2).

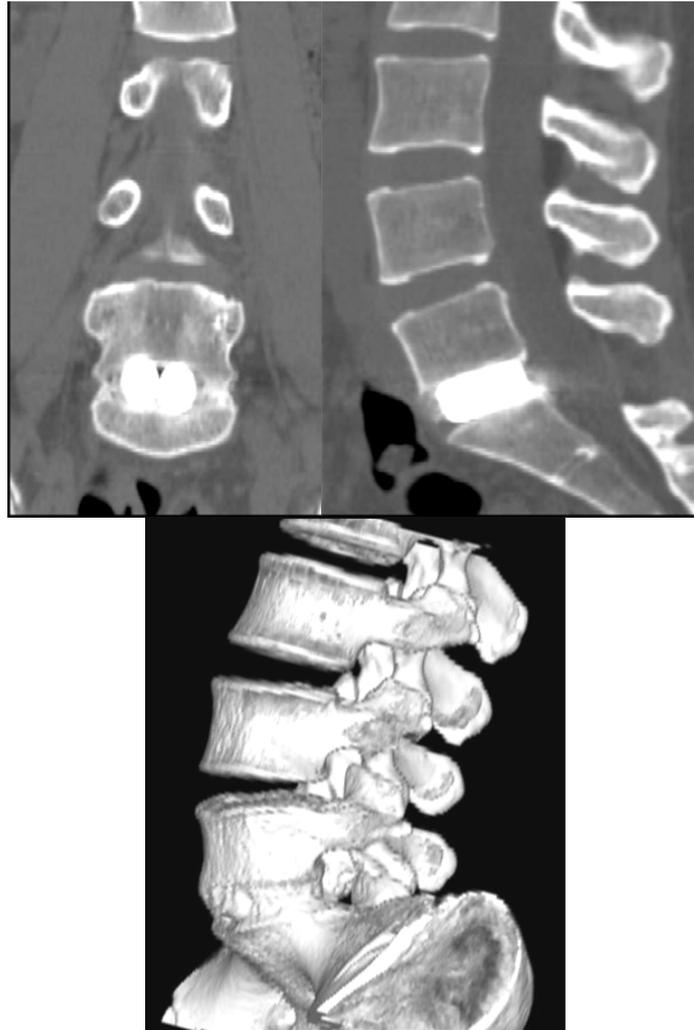


Fig. 2. Lumbo-sacral spine SCT scans of L5-S1 bone-metal block after posterior interbody fusion with porous TiNi implants at 32 months after surgery

Complications. Two patients developed suppuration of subcutaneous hematoma not extending deeper than the aponeurosis; skin wounds healed by secondary intention not requiring removal of implants. In one case, a subcutaneous seroma formed. After seroma drainage and dressing, the wound healed without removal of the implant. Migration of implants was noted in five cases (0.9% of the total number of operated patients). The cause of implants' migration was their insufficient size which did not correspond to the disc space height.

4 Summary

1. TiNi exhibits good osseointegration properties and can be used as osteoplastic material without additions of bone tissue, which simplifies operation and reduces its traumaticity.
2. Performing various types of lumbar intervertebral fusion with porous TiNi implants provided reliable formation of interbody bone-metal block in 94.8% of cases, which made for the achievement of good and satisfactory clinical results of surgical treatment of degenerative disc disease in 94.1% of cases.

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