

The Implaspin biotitanium intervertebral disk replacement used in treatment of cervical spine degenerative diseases – the first experience

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Summary

The authors present their short-term results of surgical treatment of cervical spine degenerative disease via Implaspin biotitanium replacement. Surgery was indicated for a group of 12 patients with symptoms of cervical spondylogenic myelopathy or the irritation decay root syndrome non-reacting to conservative treatment. Pre-surgery X-ray and MRI examinations showed spinal canal stenosis caused by the intervertebral disk osteochondrosis combined with prolapse or dorsal osteophytes. Clinical problems of the group of patients were evaluated through the JOA classification before surgery (11.6 points) and during the 2nd and the 6th month after surgery (15.5 and 15.0 points). The surgery rate of success was evaluated in percentages during post-surgery examinations that took place in the 2nd and the 6th month (72.2 % and 62.0 %). Based on the JOA classification, that rate of success falls into the good surgery results zone. The post-surgery X-ray examinations showed no replacement damage or dislocation. Based on our short-term experiences, the Implaspin bioactive titanium replacement seems to be a suitable alternative to the other types of replacements designed for intervertebral fusion in the lower cervical spine area.

Key words: cervical spine degenerative disease, interbody fusion, Implaspin biotitanium replacement

Introduction

In the year 1934, Mixter and Bar completed the first laminectomy for the lumbar intervertebral disk prolapse.¹ This method of spinal canal decompression subsequently became a standard procedure used during spinal canal obturation due to various reasons.² In the years 1955-1958 Robinson, Smith, and Cloward gradually published their first experiences with spinal canal decompression completed in the cervical section from the front.^{3,4} Thanks to those findings, the degenerative cervical spine disease treatment significantly advanced during the past 40 years. Various methods of decompression modification and fixation of the cervical spine from the front become available.

They include plain decompression without or with interbody fusion by means of bone grafts or various replacements with or without splints, including the intervertebral disk functional replacement⁵⁻¹⁵. We have been dealing with these issues at our clinic for already 30 years. In June 2003, we started completing interbody fusions through the biotitanium cervical replacement Implaspin made by LASAK, Ltd., Czech Republic¹⁶. During one year, we provided this implant to 12 patients. We evaluated our results via JOA classification-based examinations and X-ray images.

Material and methodology

In the year 2003, based on our positive experiences with the lumbar spine bioactive titanium replacement that gradually replaced the glass ceramic replacement we also developed a replacement for the cervical spine of the same material. The material osseointegrative properties applied in the lumbar spine replacement were preserved and the strength significantly increased. Thanks to that we were also able to use smaller sizes than in the case of the glass ceramic replacement. The implant's basic shape is a tapered prism narrowed by 1 degree towards the spinal canal with a length of 13-15 mm and a graded height of 8-5 mm, and a width of 13 mm. On the opposite sides of the prism attached to vertebra bodies upon application, the implant features sharp wings with a height of 0.5 mm. They secure primary stability necessary for undisturbed implant healing in the surrounding vital bone tissue. The implant is made of commercially pure titanium with chemically treated surface securing its bioactive properties (BIO surface). The implant bioactive surface allows creating of firm bonds with bone tissue and features osseointegrative properties.

The material is black-gray and its density is 4,500 kg/m³. Its tensile strength is at least 450 MPa. The implant is designed for intervertebral replacements preventing instability of the affected cervical spine motor segment. The anterior decompression of spinal canal with interbody fusion in the lower section of the cervical spine was completed in patients with permanent or prograding irritation decay root syndrome or spondylogenic cervical myelopathy after unsuccessful conservative therapy caused by dorsal osteophytes, osteochondrosis or cervical spine intervertebral disk prolapse.

Clinical findings were evaluated through the JOA (Japanese Orthopaedic Association) classification. JOA uses 0-4 points for evaluation of the upper limb motor function and the lower limb motor function, 0-2 points for sensitive failures, and 0-3 points for bladder functions. The smaller the number of points, the bigger the problems faced by the patient.

The surgical treatment rate of success evaluated via the JOA classification was expressed as a percentage based on the comparison of points available before surgery and after during post-surgery examinations in line with the following formula:

$$\text{Success rate (\%)} = (A - B) / (C - B) * 100$$

A – post-surgery JOA score of the group, B – pre-surgery average JOA score of the group, and C – JOA score of a healthy individual¹⁷

The surgery success rate evaluations are available in Table 1. Imaging methods (X-ray and MRI) applied to all the patients

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Tab. 1: Evaluation of surgery success rate according to the JOA classification

Success rate percentage based on the JOA formula	Evaluation
100 – 75 %	Excellent result
75 – 50 %	Good result
50 – 25 %	Poor result
25 – 0 %	Bad result

Tab. 2: Type of degenerative disease, as revealed by X-ray and MRI examinations

Area	Number of patients
C4/5	3
C5/6	7
C6/7	2
Combination of 2 areas	2

Tab. 3: Type of degenerative disease, as revealed by X-ray and MRI examinations

Area	Number of patients
Plain prolapse	2
Prolapse and dorsal osteophytes	8
Disk osteochondrosis + osteophytes	2

Tab. 4: Implaspin replacement positions in X-ray images obtained during the 2nd and the 6th month after the surgery

Biotitanium replacement position in X-ray images	Examination completed in the 2 nd month	Examination completed in the 6 th month
No changes, well-preserved lordosis without propagation into the spinal canal	12 patients	12 patients

showed degenerative changes that narrowed the spinal canal anterior part, most often via dorsal osteophytes with or without intervertebral disk prolapse¹⁷ – Fig. 1.

Surgery technique

The surgery technique based on the anterior access was applied in accordance with Smith and Robinson and it was supplemented by Caspar's instrumentation and surgery microscope.³ Under the surgery microscope a degenerated disk and dorsal osteophytes were removed from the anterior section, including remainders of both parts of the rear longitudinal ligament up to the dura matter to nerve roots. After that, cover disks of adjacent vertebra bodies were removed by a high-speed milling machine. The operated area was dilated by Caspar's instrumentarium and a biotitanium replacement of the right size was inserted. After that, the dilation ended and the blood-covered surfaces of vertebra bodies were attached to the implant. Thanks to compression, the wings, and the bioactive properties, the

implant firmly attaches to its surrounding bone tissue. As a result of that, the whole operated spine segment gets fixed. After their surgeries, the patients were verticalized via Schantz collar on the second day after surgery in the same way as during surgeries utilizing different types of replacements (LASAK Ltd. glass-ceramic replacement, Ti-bone, bone grafts etc.). The implant healing period lasts 6-8 weeks. That causes a permanent fixation of the operated section without any risk of newly created osteophytes with further narrowing of the spinal canal.

Results

The group comprised 12 patients – 4 women and 8 men with an average age of 48 years³⁶⁻⁵⁷. Tables No. 2 and 3 show the numbers of patients with medical problems in their intervertebral areas and types of diseases, as indicated by pre-surgery X-ray and MRI examinations.

The pre-surgery JOA score of our group was 11.6 points. During an examination conducted in the 2nd month the group received its JOA score of 15.5 points and 15.0 points in the 6th month. The success rate of surgery treatment based on the Implaspin replacement expressed as a percentage in accordance with the JOA classification was 72.2 % in the 2nd month and 62.4 % in the 6th month after the surgery. The success rate expressed as a percentage falls in the good result zone (both examinations) – see table 1.

Our clinical examinations also included X-ray examinations of operated areas with a focus on implant positions – see table 4. Examinations of no patient revealed implant dislocation or damage – fig. 2 and 3.

Discussion

During recent treatments of cervical spine degenerative diseases renaissance of functional replacements of the intervertebral disk takes place. It generally applies that those replacements are applied in those cases where degenerative changes are associated mainly with affected intervertebral disks without any changes of their surrounding bone skeleton. Despite the first optimistic references, we still have to wait for long-term results^{14, 15}. Intervertebral fusion based on anterior access remains a verified standard method of treatment applied to the distal section of cervical spine in connection with mono- and bisegmental serious degenerative stenoses caused by osteophytes or osteophytes in combination with intervertebral disk prolapse.^{5, 8, 9, and 13} Approximately in the second half of the 1980s the world started to use the interbody fusion materials^{16,18,19,20 and 21}. Our clinic began using bioactive glass ceramic replacements in treatment of lumbar spine degenerative diseases in the year 1993¹⁹ and in the year 1995 also in treatment of cervical spine degenerative diseases¹¹. Growing experiences with glass ceramic replacements contributed to development of precise indications for their applications¹¹. The disadvantages and limitations deriving from mechanical properties of glass ceramics became clear as well. The limiting factor concerning the use of glass ceramic replacements in the cervical spine area, like in the case of the lumbar spine, remains the implant strength linked to its size. Another limiting factor deriving from mechanical properties of glass ceramics became clear as well. The limiting factor concerning the use of glass ceramic replacements in the cervical spine area, like in the case of the lumbar spine, remains the implant strength linked to its size. Another limiting factor is the fragility of glass ceramics that requires

elimination of contact with metal tools during surgeries. The application instrumentarium may not be attached to the glass ceramic replacement. When the replacement size was respected due to the significantly narrowed intervertebral area it was necessary to remove not only the degenerated disk and its cover vertebra, but also its adjacent cancellous tissue. That situation represents a risk of replacement propagation into the adjacent vertebra bodies and creation of lateral stenosis. When the replacement size was insufficient it was damaged in the intervertebral area without fragment dislocation into the spinal canal. For the time being, similar complications were not observed among the group of patients operated by means of the Implaspin replacement produced from bioactive titanium^{9, 16}. It seems that the properties of bioactive titanium of the LASAK, Ltd.

minimize complications associated with the size and mechanical strength.

Mechanical properties of the Implaspin replacement were compared to properties of the Ti-bone replacement made by the Biomed company. The Ti-bone replacement has been used in our clinical practice together with the Implaspin replacement since the year 2002. The surgery techniques and approaches of both implants are similar. The Ti-bone advantage rests in the fact that during surgery its size is determined through a model before its application into the interbody area. The Implaspin replacement does not allow that. Unlike the Ti-bone replacement, our replacement should feature benefits in the form of its shape, the wings on the opposite sides, and its surface treatment.

Implaspin is produced in the form of tapered prisms of various sizes. It provides better conditions for preservation of cervical spine lordosis in the post-surgery period, compared to the Ti-bone replacement shape. It looks like a prism but it is not tapered.

The Implaspin replacement wings aiming towards adjacent vertebra bodies and the compression increase stability and secure direct contact of the implant with bone tissue. As a result of that, the wings help fix the mechanically operated section during the first hours before the bone-implant chemical bond is produced. The Ti-bone replacement does not have those wings and mechanical stability of the operated section only depends on compression of neighboring vertebrae.

Thanks to the bioactive material application to the whole surface of the titanium replacement, a bone-implant chemical bond covering the whole surface that is in contact with adjacent vertebral bodies is produced within 24 hours. That chemical bond increases fusion strength. Osseoconductive properties of the bioactive surface facilitate the growth of osteoblasts on the replacement walls and they allow creation of bone intersomatic fusion of the operated section within a few weeks. The Ti-bone replacement contains a cavity filled with bioactive material. The surrounding supporting titanium features no bioactive properties. The chemical bond and the subsequent interbody fusion occur only at that location. The bioactive material is not homogeneous and that could slow down intergrowing of osteoblasts during the creation of fusion. That subsequently increases the risk of the operated area's instability.

The Implaspin replacement does not have to be filled with bone grafts or hydroxyapatite in order to create fusion like in the case of the other replacements^{10, 12, and 13}. The patient does not have to provide any graft. That shortens the time of the surgery itself and the patient is spared of another risk associated with obtaining a bone graft (pain, cosmetic effect). These expected benefits of the Implaspin replacement, compared to the Ti-bone replacement, must be confirmed by long-term clinical results that are not available so far.

Conclusion

Based on the first short-term results, the Implaspin cervical replacement perfectly combines the osseoconductive properties of glass ceramics with titanium strength.

During a six-month monitoring the group of 12 operated patients demonstrated no complications associated with replacement damage, its dislocation into the canal or the prevertebral area. X-ray images showed positive surgery results and the JOA score was good as well. We have to wait for a final evaluation of results for at least 2 years. Now, it seems that the Implaspin replacement made by the LASAK, Ltd. applied in connection with indications of interbody fusion in the cervical spine area could be a perfect alternative to the other replacements.



Fig. 1: Disk prolapse in the C5/6 area, pre-surgery examination, side projection

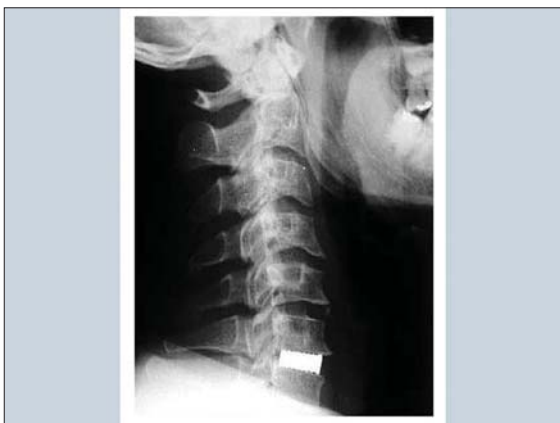


Fig. 2: Implaspin in the C5/6 area – X-ray side projection completed 6 months after surgery



Fig. 3: Implaspin in the C5/6 area – X-ray image, anteroposterior projection completed 6 months after surgery

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