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Bioactive titan cage Implaspin in treatment of degenerative disease of the cervcal spine – the results from 2007 till 2008

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Summary
The authors present results of surgical treatment of cervical spine degenerative disease via Implaspin biotitanium replacement. Surgery was indicated for a group of 24 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 and during the 2nd ,the 6th and month 12th after surgery. The surgery rate of success was evaluated in percentages during post-surgery examinations that took place in the 12th month . Based on the JOA classification, that rate of success falls into the good surgery results zone. The post-surgery X-ray examinations showed two sank replacements by 1/3 of its height into the surrounding vertebral bodies. In these cases we performed the control MRI. No signs of the new spinal compression were found and the spinal canal was free in the operated site. Based on our short-term experiences, the Implaspin bioactive 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

Bioaktywna tytanowa stabilizacja międzytrzonowa Implaspin w leczeniu choroby zwyrodnieniowej w odcinku szyjnym kręgosłupa – wyniki leczenia z lat 2007-2008

Streszczenie
Autorzy przedstawiają wyniki leczenia operacyjnego choroby zwyrodnieniowej kręgosłupa z użyciem Implaspin biotitanium. Operacja została wykonana u 24 pacjentów z objawami mielopatii szyjnej lub podrażnienie korzeni, nie reagującego na leczenie zachowawcze. Wykonane przedoperacyjnie RTG oraz MRI wykazało zwężenie kanału kręgowego, spowodowane zwyrodnieniem krążka międzykręgowego w połączeniu z jego ekstruzją lub tworzeniem osteofitów. Problemy kliniczne w grupie pacjentów były oceniane w oparciu o klasyfikację JOA przed zabiegiem oraz w 2., 6. i 12. miesiącu po zabiegu. Odsetek dobrych wyników był oceniany w procentach w okresie 12 miesięcy po zabiegu. Na podstawie klasyfikacji JOA, wyniki leczenia operacyjnego zostały opsiane jako dobre. W dwóch przypadkach w kontrolnym badaniu RTG uwidoczniono zagłębienie się implantu na 1/3 jego wysokości. W tych przypadkach przeprowadzono kontrolne badanie MRI. Nie znaleziono oznak ucisku rdzenia znaleziono, kanału kręgowy był prawidłowy. Na podstawie naszych doświadczeń, Implaspin wydaje się być odpowiednią alternatywą dla innych typów protez przeznaczonych do stabilizacji międzytrzonowej w szyjnej części kręgosłupa.
Słowa kluczowe: choroba zwyrodnieniowa kręgosłupa, stabilizacja międzytrzonowa, Implaspin

Introduction

Between 1955 and 1958, Robinson, Smith and Cloward [1, 2] published gradually their first experience with a decompression of the spinal canal in the cervical part from the anterior approach. Due to this knowledge the surgical therapy of the degenerative disease of the cervical spine achieved a great development in the recent 40 years. The various methods, modifications of decompression and fixation of the cervical spine from the anterior approach gradually appear.From the simple decompression with or without the interbody fusion using the bone graft or various cages with or without the splint to the functional replacement of the intervertebral disk [3-16]. Between 2007 and 2008, we operated 61 patients with a degenerative disease of the cervical spine at the neurosurgery department of the KNTB Zlín. In 24 patients we performed a decompression with the fusion from the anterior approach by means of the biotitanium cage Implaspin. The clinical condition of the patients was evaluated using the JOA classification before and 2, 6 and 12 months after the surgery.The position of the implants in the operated field was evaluated in the same time period using the X-ray images. The presence of the fusion was evaluated using the CT between the 6. and 12. month after the surgery. According to the JOA classification we achieved the efficacy of 50% which lies in the range of the good surgical results. According to the post-operative X-ray images no impairment or dislocation of the cage occurred. The CT examination in four patients performed between the 6. and 12. month after the surgery found a development of the osseous fusion.

Material and methods

In 2005, based on good practice with the bioactive titanium cages of the lumbar spine, we developed a cage for the cervical spine from the same material, as well. Similarly as in the case of the lumbar spine cage the osteoconductive properties of the material remained the same and the rigidity was significantly improved. The cage has a shape of the skewed prism narrowed by 1 grade towards

the spinal canal of 13-15 mm in length and a graduated height of 8-5 mm and 13 mm in width. It is produced from the technically pure titanium with chemically modified surface that ensures its bioactive properties. The bioactive surface enables to create a rigid binding with the osseous tissue and has oseoconductive properties [17, 18]. The material is grey-black with a density of 4500 $kg.m^{-3}$ and it is rigid in traction to a maximum of 450 MPa. The replacement is intended for a replacement of the intervertebral disk to prevent the instability of the affected locomotive segment of the cervical spine.

On the opposite parts of the prism which are attached to the vertebral bodies the replacement has sharp wings of 0.5 mm in height and the angle of 30 grades. They ensure the primary stability for an undisturbed healing of the implant into the surrounding vital bone tissue. The shape and size were supported by the biomechanical studies.

The patients with persisting or progressive irritation-extinction radicular syndrome and/or spondylogenic cervical myelopathy after unsuccessful conservative therapy were indicated for the anterior decompression of the spinal canal with interbody fusion in the area of the lower part of the cervical spine [5].

The clinical finding was evaluated by means of the JOA (Japan Orthopaedic Association) classification. According to the JOA classification the motor function is rated from 0 to 4 points on the upper limb, 0 to 4 points on the lower limb, 0 to 2 points for sensitive disorders and 0 to 3 points in the urinary bladder function. The less rate the more severe is the affection of a patient.

The successfulness of the surgical therapy according to the JOA classification was in our set of 24 patients evaluated **in percents** by comparison of the points in the group before the surgery and during the preoperative check-ups on the 2., 6. and 12. month after the surgery and by using the formula:

$$\text{successfulness (\%)} = (A - B) / (C - B) \cdot 100$$

A – Postoperative JOA score in the group
B – Preoperative mean JOA score in the group
C – JOA score in a healthy human [17]

Evaluation of the successfulness of the surgery is displayed in the table I.

Table I. Evaluation of the successfulness of the surgery according to the JOA classification
Tabela I. Ocena skuteczności leczenia operacyjnego w skali JOA

Percent of the successfulness according to the JOA formula	Evaluation
100–75%	excellent result
75-50%	good result
50-25%	weak result
25-0%	bad result

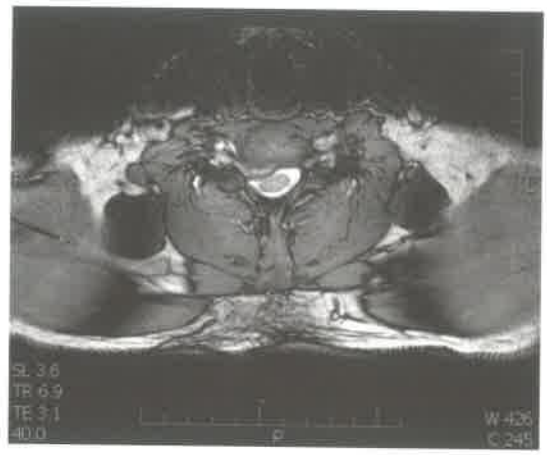

Fig. 1a. Preoperative MRI: a prolapse in the right side of the disk C6/7 with the osteopyhte horizontal cut.
Ryc. 1a. Przedoperacyjne MR: przepuklina prawostronna krążka międzykręgowego C6/7 z poprzecznym przekrojem osteofitu.

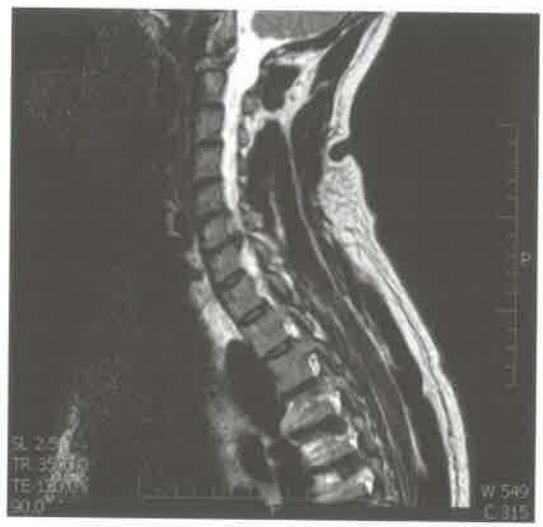

Fig. 1b. Preoperative MRI: a prolapse in the right side of the disk C6/7 with the osteopyhte sagital cut
Ryc. 1b. Przedoperacyjne MRI: przepuklina prawostronna krążka międzykręgowego C6/7 ze strzałkowym przekrojem osteolitu.

The imaging methods (X-ray and MRI) found degenerative changes in all patients. These changes narrowed the spinal canal in the anterior part, most often by the dorsal osteophytes with or without the prolapse of the intervertebral disk (Fig. 1a and 1b).

The own surgical technique via the anterior approach is performed according to Smith and Robinson including the Caspar's instruments and the surgical microscope. From the anterior approach under the control of the surgical microscope we remove the degenerated disk including the dorsal osteophytes and remove the residua of both parts of the posterior longitudinal ligament up to the dural sac to the neuronal radices. Then we remove the covering disks of the adjacent vertebral bodies using the high-speed rotational cutter.Using the Caspar's instruments we distract the operated space and insert the biotitanium cage to fit the size of the bed. Then we cancel the distraction and the vertebral bodies are going to lie on the implant with their sanguinous side which is, due to the compression,

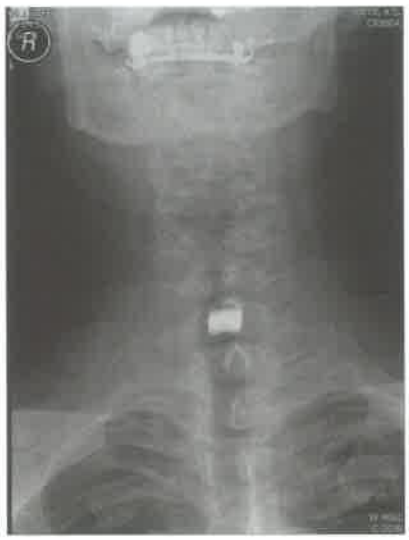

Fig. 2a. Postoperative X-ray Implaspin C6/7 AP projection.
Ryc. 2a. Pooperacyjne RTG w projekcji AP
po implantacji klatki Implaspin na poziomie C6/7.

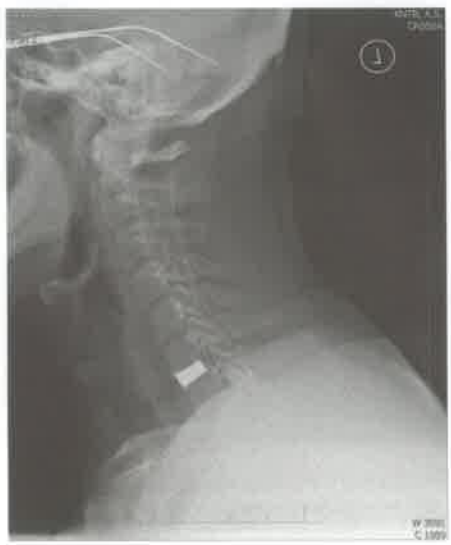

Fig. 2b. Postoperative X-ray Implaspin C6/7 lateral projection.
Ryc. 2b. Pooperacyjne RTG w projekcji bocznej
po implantacji klatki Implaspin na poziomie C6/7.

wings and the bioactive properties firmly fixed in the space on to the surrounding osseous tissue. Due to this mechanism it fixes the whole operated segment of the spine. The operated segment does not have to be fixed by the splint (Fig. 2a and 2b).

Within 48 hours from the surgery the chemical rigid binding should be established on the implant-osseous tissue interface and the osseous fusion should develop within 6 months due to the bioactive properties of the implant.

Results

In our set of 24 patients who were operated between 2007 and 2008 at the neurosurgery department of the KNTB Zlín the localization and type of the affection of the impaired segments according to the preoperative X-ray and MRI examinations [19] is described in Tables II and III.

Table II. Localization of the affected space
Tabela II. Lokalizacja zmian w krążku międzykręgowym

Space	Number of patients 2007-2008
C3/4	2
C4/5	4
C5/6	10
C6/7	8
Combination of 2 spaces	6

Table III. Type of the degenerative disease
Tabela III. Nasilenie choroby zwyrodnieniowej

Type of the disease	Number of patients 2007-2008
Simple prolapse	1
Prolapse and dorsal osteophytes	16
Osteochondrosis of the disk + osteophytes	7

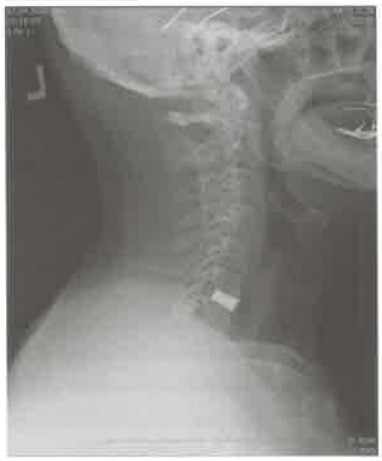

Fig. 3a. X-ray after 6 months Implaspin C6/7 AP projection.
Ryc. 3a. RTG w projekcji AP po 6 miesiącach
po implantacji klatki Implaspin na poziomie C6/7.

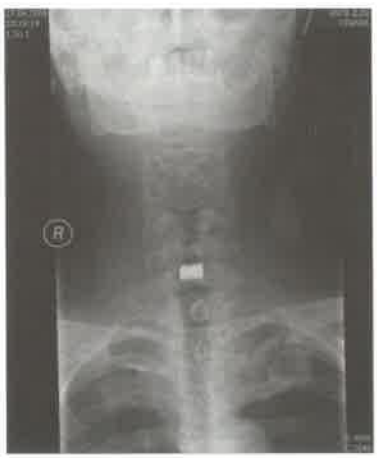

Fig. 3b. X-ray after 6 months Implaspin C6/7 lateral projection.
Ryc. 3b. RTG w projekcji bocznej po 6 miesiącach
po implantacji klatki Implaspin na poziomie C6/7.

Preoperative JOA score in our group was evaluated to 12.5 points.

Two months after the surgery the group was evaluated according to the JOA score to 15 points and in the 6. month to 16 points. During the check-up 12 and more months after the surgery the JOA score was again 15 points. The successfulness of the surgical therapy was expressed in percents after applying all the values into the formula according to the JOA. It was 50% twelve and more months after the surgery. The successfulness in percents ranges within the good results at all check-ups – see Table I.

During the clinical check-up we performed the X-ray control of the operated part as well with the focus on the position of the implant – see Table IV (Fig. 3a and 3b).

Table IV. Position of the Implaspin replacement on the X-ray images after 12 months
Tabela IV. Położenie klatki Implaspin po 12 miesiącach w ocenie RTG

The position of the biotitanium replacement on the X-ray images – a group of 24 patients	Control 12. month
No changes, preserved lordosis, without propagation into the spinal canal, without any new osteophytes	22 patients
Sinking into the bodies of the surrounding vertebra, without propagation into the spinal canal, without any new osteophytes	2 patients

In our group, we found two sank replacements by 1/3 of its height into the surrounding vertebral bodies. In these cases we performed the control MRI. No signs of the new spinal compression were found and the spinal canal was free in the operated site.

Between the 6. and 12. month after the surgery we tried to find out the direct signs of the osseous fusion using the ultrathin cuts by means of the CT (Fig. 4a and 4b) in four patients. The fusion was developed due to the osseoconductive properties of the replacement (a growth of the osteoblasts on the walls of the implant as it is seen in the CT cuts).

Discussion

The interbody fusion via the anterior approach remains the verified standard therapeutic procedure in the subaxial part of the cervical spine in mono and bisegmental severe degenerative stenoses caused by the posterior osteophytes and/or by the osteophytes in combination with the prolapse of the intervertebral disk [6-9].

Using of the various materials for the purpose of the interbody fusions was initiated worldwide approximately in the second half of 80's. We compared the properties of the Implaspin cage with the similar implants manufactured by Medtronic, Biomed, Synthes, Aesculap, and Johnson which we use concurrently with this implant or we

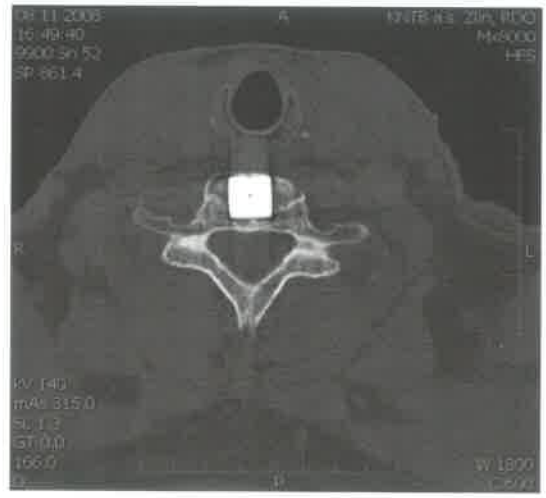

Fig. 4a. CT after 6 months Implaspin C6/7 horizontal cut.
Ryc. 4a. Przekrój poprzeczny TK 6 po 6 miesiącach po implantacji klatki Implaspin na poziomie C6/7.

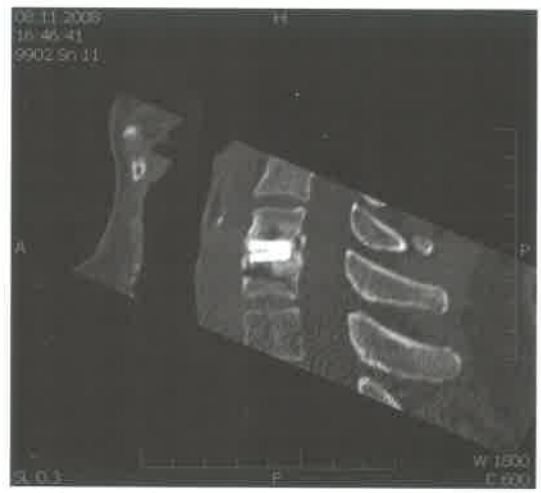

Fig. 4b. CT after 6 months Implaspin C6/7 sagital cut.
Ryc. 4b. Przekrój strzałkowy TK 6 po 6 miesiącach po implantacji klatki Implaspin na poziomie C6/7.

used them at the previous departments in the same indications [4, 8-12, 16].

The surgical procedure and the own surgical technique was similar in all the implants. We compared the shape, function of the wings at the opposite sides and the bioactivity of its surface with other implants. Implaspin has a shape of a skewed prism in various sizes. It provides better prerequisites for maintaining the lordosis of the cervical spine in the postoperative period compared to some types of the cages. They have a shape of a prism or oval but without skewing.

The wings of the Implaspin cage pointing at the surrounding vertebral bodies. Together with the compression they increase a stability and ensure a direct contact of the implant with the osseous tissue. The wings help to mechanically fix the operated part in the first hours until the chemical binding bone-implant develops. Some implants available on the market such as Ti-bone of Biomed do not have these wings and the mechanical stability of the operated part is provided only by the compression of the surrounding vertebra.

Due to the bioactivity of the surface of the Implaspin implant a chemical binding between the bone and implant at the contact side with the adjacent vertebral bodies occurs. The chemical binding increases a stability of the operated part and is a prerequisite for a development of the osseous fusion within 6 months after the surgery. We managed to verify this prerequisite in four patients who were randomly selected for examination using the ultrathin CT cuts.The osseoconductive properties of the bioactive surface facilitate growing of the osteoblasts on the walls of the replacement and, within several months, they enable development of the osseous interobdy fusion of the operated part. The replacements of other companies have a central cavity which is filled either by bone grafts of hydroxyapatite [16, 20, 21]. The surrounding bearing material (Titanium, Peek) does not have the bioactive properties [11]. The chemical binding and a subsequent interbody fusion occurs only at this place.The bioactive material is not homogenous which may cause retardation of growing of the osteoblasts duringthe fusion. There is also a higher risk of sinking of the implant into the surrounding vertebral bodies due to a hollow center of the implant [9]. This risk is minimized in case of the Implaspin replacement as confirmed by the postoperative X-ray. A sinking of the cervical implant into the surrounding vertebral bodies without any clinical finding occurred only in two patients. We assume that the sinking occurred due to impairment of the spongious tissue during milling of the bed for the implant.

During the application of the Implaspin replacement there is no need to fill the implant with the bone grafts or hydroxyapatite as in other replacements. It is not necessary to take the bone graft from the patient. Therefore the time of the own surgical procedure is reduced and the patient is not traumatized by the collection of the bone graft from the hip bone. Therefore, we consider the shape, wings and the bioactive surface as an advantage compared to other replacements.

Conclusion

Based on the clinical results and imaging examinations it appears that we use the Implaspin cage separately for the fusion in serious preoparative clinical findings (preoperative JOA score of 12.5 point) caused by the compression of the nervous structures most often due to prolapse of the disk with the dorsal osteophytes based on the imaging methods (X-ray, MRI). The postoperative results (JOA, X-ray, CT) show the Implaspin is a good alternative to other cages intended for the anterior interbody fusion of the cervical spine. It successfully competes with the foreign products as for its quality and price.

Literature

[1] Robinson R.A., Smith G.W.: *Anterolateral cervical disc removal and interbody fusion for cervical disc syndrome.* Bull. John Hopkins Hosp., 1955; 96: 223-224.

[2] Cloward R.B.: *The anterior approach for removal of ruptured cervical disks.* J. Neurosurg., 1958; 15: 602-617.

[3] Simmons E.H., Bhalla S.K.: *Anterior cervical discectomy and fusion. A clinical and biomechanical study with eight-year follow-up.* J. Bone Joint Surg. Br., 1969; 51: 225-237.

[4] Matge G.: *Cervical cage fusion with 5 different implants: 250 cases.* Acta Neurochir., 2002; 144: 539-550.

[5] Gregorius F.K., Estrin T., Crandall P.H.: *Cervical spondylotic radiculopathy and myelopathy.* Arch. Neurol., 1976; 33: 618-625.

[6] Dunsker S.B.: *Anterior cervical discectomy with and without fusion.* Clin. Neurosurg., 1977; 24: 516-520.

[7] Capen D.A., Garland D.E., Waters R.L.: *Surgical stabilization of the cervical spine. A Comparative analysis of anterior and posterior spine fusions.* Clin. Orthop., 1985; 196: 229-237.

[8] Kostuik J.P., Connolly P.J., Esses S.I., Suh P.: *Anterior cervical plate fixation with the titanium hollow screw plate system.* Spine, 1984; 18: 1273-1278.

[9] Matge G.: *Anterior interbody fusion with the BAK-cage in cervical spondylosis.* Acta Neurochir. (Wien), 1998; 140: 18.

[10] Filip M., Veselský P., Paleèek T., Wolný E.: *The glass-ceramic replacement of the intervertebral disk in the degenerative diseases of the cerivical spine - the first experience.* Èes. Slov. Neurol. Neurochir. 2000; 1: 31-36.

[11] Cho D., Liau W., Lee W., et al.: *Preliminary experience using a polyetheretherketone (PEEK) cage in the treatment of cervical disk disease.* Neurosurgery, 2002; 51: 1343-1350.

[12] Hacker R.J., Cauthen J.C., Gilbert T.J., Griffith S.L.: *A prospective randomized multicenter clinical evaluation of an anterior cervical fusion cage.* Spine, 2000; 25: 2646-2655.

[13] Goffin J., Van Calenbergh F., van Loon J., et al.: *Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level.* Spine, 2003; 28: 2673–2678.

[14] Hrabálek L., Vaverka M., Køupka B., Houdek M.: *Komplikace operací z předního přístupu pro degenerativní onemocnìní krèní páteře.* Èes. Slov. Neurol. Neurochir., 2007; 70/103(2): 23-28.

[15] Sekhon L.H.S.: *Cervical arthroplasty in the management of spondylotic myelopathy.* J. Spinal Disord. Tech., 2003; 16: 307–313.

[16] McConnell J., Freeman B., Dabnath U., et al.: *A prospective randomized comparison of coralline hydroxyapatite with autograft in cervical interbody fusion.* Spine 2003; 28: 317-323.

[17] Strnad J., Helebrant A., Mráz R.: *Effect of titanium processing on the bioactivity of sodium titanate gel layer.* Proceedings Euromat 99, Materials for Medical engineering, Wiley-VCH, 1999; 2, D1: 967.

[18] Yamamuro T.: *AW Glass-Ceramic in Spinal Repair*, ed. J. Wilson, L. Henche, D. Greenspan, Ponte Verda, Florida, USA, November, Bioceramics, 1995; 8: 123.

[19] Mehalic T.F., Pezzuti R.T., Applebaum B.I.: *Magnetic resonance imaging and cervical spondylotic myelopathy.* Neurosurgery 1990; 26: 217-227.

[20] Madawi A.A., Powell M., Crockard H.A.: *Biocompatible osteoconductive polymer versus iliac graft.* Spine, 1996; 21: 2123-2130.

[21] Vaccaro A.R., Madigan L.: *Spinal applications of bioabsorbable implants.* J. Neurosurg., 2002; 97(supl. 4]: 407-412.