

Bioactive Implants in Cervical Spine Injury -Original Research(From 1995 To 2011)

J. Strnad¹ and Alena Prochazkova²

¹ 1. Neurosurgical department KNTB ZlAn, Czech Republic; 2. Research and Development Center for Dental Implantology and Tissue Regeneration, LASAK Ltd.

Received: 16 December 2013 Accepted: 1 January 2014 Published: 15 January 2014

Abstract

Objectives: The paper deals with the development and clinical evaluation of a new bioactive implant designed for anterior cervical interbody fusion (ACIF) in the surgical treatment of unstable injury in subaxial part of cervical spine (type A2, 3 and B3 fractures according to Aebi and Nazarian classification). Significance of the topic: In the middle of the nineties of the last century the glass-ceramic prosthesis BAS-0 made it possible to gain the first experiences in materials replacing allografts for ACIF. Its major disadvantage lay in insufficient resistance. Given these complications, we searched for a stronger material while maintaining the bioactive properties of the glass-ceramics. Bioactive titanium with a special surface treatment by the company LASAK proved to be such a material. New Implant suitable for ACIF was developed in the year 2003. This type was introduced into clinical practice in 2004 after experimental mathematical verification of the design and cadaver testing. Brief methodology: The new implant has a basic shape of a full truncated prism narrowed by 1 degree towards the spinal canal; its length is 13-15 mm with a graded height of 8-5 mm and width of 13 mm. We have used this implant successfully in the treatment of patients with cervical spine injury in unstable fractures. It was indicated the anterior decompression of the spinal canal with interbody fusion together with plate systems.

Index terms—

1 Introduction

Injuries of the lower cervical spine occurs as monotrauma or compound injury. They are rarely caused by only direct force on the spinal structures. Typically there is an indirect injury of spinal segment due to non-physiological forces (compression, flexion, extension or rotation). Cervical spine injuries result in the spine segment instability which poses a threat to the nerve structures of the spinal canal (spinal cord, roots) (Aebi 1991, Bohlman 1979, Caspar 1989). Modern classifications of lower cervical spine injuries respect these pathological anatomical characteristics and determine the level of injury severity and the prognosis. Detailed and frequently used classification by Aebi and Nazarian (Aebi 1987) divides injuries into type A, type B and type C and into groups and subgroups 1 to 3, and respects the extent of traumatic instability or residual stability, distinguishes anterior and posterior column of the spine and differentiates between mostly osseous, mostly ligamentous, and combined injury. Conventional X-ray and CT examinations are needed for the determination of injury classification. In many cases it is also necessary to add MRI examination to determine the damage to the soft tissues -ligaments, joint capsules and intervertebral discs. Depending on whether the injury is classified as stable or unstable, a decision is made about the management (surgery/conservative therapy). Surgical intervention is required for unstable spine injuries (Bohlman 1992, Fehlings 2005. Kandziora 2005, Osti 1989 ?sti, ?ulík 2003). It allows stabilization and decompression of the spinal cord and reconstruction of the anatomical structures

3 B) IMPLANT FOR USE IN ACIF MADE OF BIOACTIVE TITANIUM 2007 -2011

43 of the spine to prevent secondary damage to the spinal cord and late posttraumatic changes. It is not possible
44 to heal the "unstable" type of injury using conservative management. The most common surgical technique in
45 ligamentous (A3, B3, C3) and osteoligamentous injuries (A2, C2) is anterior approach using a plate and the
46 anterior cervical interbody fusion (ACIF) similarly as in degenerative cervical spine disease (Norrell 1970, Perret
47 1968, Caspar 1989, Connolly 1996).

48 In 1960 Bailey (Bailey 1960) and then Robinson and Southwick published their first experience with surgical
49 treatment of lower cervical spine injuries using the anterior approach technique described between 1955 and 1958
50 by Robinson and Cloward for the treatment of degenerative diseases (Cloward 1958). Standard surgical
51 procedure includes decompression of the spinal canal (reduction of luxation, removal of damaged intervertebral
52 disk, etc.), anterior cervical interbody fusion using bone grafts and fixating the operated segment with a plate
53 and monocortical or bicortical screws. Because of problems associated mainly with bone graft harvest (Banwart
54 1994, Hrabálek 2007) implants designed for use in ACIF made of various materials (glass-ceramics, titanium,
55 PEEK, polylactide) have been developed since the 80's of the last century (Yamamuro 1995, Matge 1998, Filip
56 2000, Cho D 2002, McConnell 2003, Vaccaro 2002). They should eliminate the problems inherent to bone grafts
57 and copy as much as possible the biological properties of bone tissue. Based on biomechanical studies we have
58 developed an implant made of bioactive glassceramics in the first half of 1990's. Its strength parameters and
59 bioactive properties simulated bone tissue (Kokubo 1982 ?? Bienik 1991, Urban1992). In clinical practice it
60 gradually replaced bone grafts in surgical treatment of degenerative disease (Filip 2000) and unstable, mainly
61 osteoligamentous injuries to the lower cervical spine. At the Neurosurgical Department of the University Hospital
62 in Ostrava we operated 10 patients with cervical spine injuries using this implant supplemented with a plate fixed
63 by screws during the period of 1997 to 1999. Neurological findings improved by one grade on the Frankel scale
64 in 3 patients. According to imaging examinations (RTG, CT) no dislocation of glass-ceramics implant occurred
65 after a period of one year and more since the time of the operation. After two months, we observed in two
66 operated that a screw in the plate became partially loose without a need for re-operation. The main advantages
67 for the patients included mainly shorter time of the operation and elimination of complications associated with
68 the bone graft harvest. Bioactive properties of the surface contributed to bone fusion without supplementing
69 additional material. Implant fragility was the main disadvantage (Filip 2000). During the application there
70 was a risk of damage to the implant by the contact with metal instruments. In 2003-2004 we eliminated this
71 disadvantage by developing an implant made of a new material -bioactive titanium. It has shown several times
72 higher strength while retaining its bioactive properties as a result of a special surface treatment [Strnad 2001].
73 We have gradually implemented this to the clinical practice for the same indications as in case of the preceding
74 glass-ceramics implant. In 2007-2011 we used it at Neurosurgical Department of KNTB Zlín in 12 of 34 patients
75 who underwent anterior approach surgery due to unstable injury to the lower cervical spine. Compared to the
76 glass ceramic implant the new implant handling during the surgical procedure was easier without a risk of damage.
77 Its shape and bioactive properties contributed to bone fusion without the need of additional material (Filip 2005,
78 Filip 2010). In the monitored post-operative period of at least one year neither any dislocation nor deterioration
79 in the clinical condition was observed in a set of all 34 operated patients. Cage implants made of polylactide or
80 PEEK (Vaccaro 2002, Hacker 2000 ?? ChoD 2002, Matge 2002, Suchomel 2004) were applied to the remaining 22
81 patients who were operated in the same period. Their cavity needed to be filled with additional material (bone,
82 BCP, TCP) to initiate interbody fusion. Compared with the application of a titanium implant with bioactive
83 surface, cage implants with filling material are more demanding with regards to their insertion, which prolongs
84 the duration of the operation.

85 2 II.

86 Material and Methodology a) Implant for use in ACIF made of glass-ceramics ??AS-O (1996 ??AS-O (-1999) In
87 1997 we used an implant made of bioactive glass-ceramics for ACIF in unstable injury to the lower cervical spine
88 as an equivalent replacement of autologous bone grafts (Kokubo 1982, Urban 1992, Yamamuro 1995). It imitated
89 bone tissue properties by its mechanical strength and bioactive properties. In vertical compression glass-ceramics
90 exceeded twice the strength of cortical bone tissue and it was identical in bending strength. Disadvantage of
91 BAS-O glass-ceramics is its fragility causing problems in optimizing the implant shape during biomechanical
92 modelling. Based on mathematical studies we have retained the implant's shape as a tapered prism with the
93 following dimensions: length 15mm, height 7.8mm ventrally and 6.9mm dorsally, and width 13mm. Strength
94 parameters of this shape exceeded the strength of an autograft (see Figure ??, Figure ??). Implant surfaces
95 that face the vertebral bodies have small indentations of 1mm high. They are intended to secure a firm fixation
96 immediately after the surgery before the fusion due to chemical bond occurs. During the insertion the implant
97 had to be protected from a contact with the metal because of the risk of a damage. We used instruments covered
98 with rubber for handling the implant.

99 3 b) Implant for use in ACIF made of bioactive titanium 2007 100 -2011

101 Based on the experience with the application of the glass-ceramics implant (Filip 2000) we were looking for
102 material with better strength parameters while maintaining the surface bioactive properties. The material was

103 required to enable more convenient handling during the surgical procedure without the risk of a damage. Titanium
104 with special treatment ensuring surface bioactive properties developed in 1998-2001 (Strnad 1999(Strnad , 2001)
105) appeared to be the material.

106 In 2004-2005 we developed an implant for use in ACIF made of bioactive titanium. After the surface treatment
107 this material retains its osteoconductive properties similar to the BASO glass-ceramics while its strength increases
108 significantly. This implant has a basic shape of a full truncated prism narrowed by 1 degree towards the spinal
109 canal; its length is 13-15 mm with a graded height of 8-5 mm and width of 13 mm It is made of technical pure
110 titanium with a chemically-treated surface providing its bioactive properties. This enables it to form a firm bond
111 with the bone tissue and features osteoconductive properties, see Figure ???. The material is of black-gray color
112 with a density of 4,500 kg*m⁻³ and its tensile strength is at least 450 MPa. On the prism's opposite sides
113 adjacent to vertebral bodies after the application, the implant is fitted with sharp wings of 0.5 mm in height and
114 30degree angulation. These ensure primary stability for undisturbed healing and incorporation of the implant
115 into the surrounding vital bone tissue. The shape and size was supported by biomechanical studies, see Figure 5.

116 4 New bone

117 5 Glassceramics

118 6 Results

119 In both types of implants (glassceramics/bioactive titanium) developed by us we indicated patients for the
120 operation according to the instability of the injured lower spine defined in the preoperative stage according to
121 the imaging methods (X-ray, MRI, CT) and using the classification according to Aebi and Nazarian and according
122 to the neurological findings using the Frankel scale. We carried out the surgery by the Caspar technique (Caspar
123 1989, Klézl 1999). Under general anesthesia from the prevertebral incision and after exposing anterior surface
124 of the vertebral bodies we removed the structures compressing the spinal canal (intervertebral disk, posterior
125 ligament residues, fragments of the edges of the vertebral bodies, haematoma, etc.) using an operating microscope.
126 Then we prepared a bed for inserting the implant into the interbody space. We removed the endplates from the
127 vertebral bodies and exposed cancellous bone. In traction and using the Caspar's instrumentarium we inserted
128 the implant into the interbody space under the control of X-ray, see Figure ???.

129 Figure ?? : Inserting the bio-titanium implant into the interbody space C5/6 using the X-ray control After
130 releasing traction and checking the position on X-ray we fixed the impaired segment by a plate secured with
131 monocortical or bicortical screws into the neighboring vertebral bodies. Surgical procedure is similar for both
132 the glass-ceramics implant and the biotitanium implant. We used the same surgical procedure for other types of
133 implants as well (polyactide/PEEK). We carried out verticalization in operated patients in case of all implants
134 on the first post-operative day in a collar for a period of 6 weeks until the expected bone fusion occurrence.

135 At Neurosurgery Department of the University Hospital in Ostrava we operated 10 patients with unstable
136 injury to the lower cervical spine using glassceramics implants between 1997 and 1999, see Figures ?? and 10 The
137 implant for use in ACIF made of glassceramics fulfilled our expectations. It removed complications associated
138 with bone graft harvest and due to its shape and bioactive properties it enabled a chemical bond with surrounding
139 osseous tissue to create bone fusion without a need for filling with other material (Bienik 1991, Madawi 1996,
140 Filip 2000). Its disadvantages included fragility in contact with metal and threshold bending strength. These
141 disadvantages were eliminated by a new implant made of bio-titanium that we introduced into clinical practice
142 for identical indications in 2004. In years 2007-2011 at the Neurosurgery Department of KNTB Zlín we operated
143 34 patients with unstable lower cervical spine injury. In 12 patients we used a bio-titanium implant in ACIF
144 (Figures 11 and 12). In 22 patients we used an implant made of different materials (Figure ??3). In our own set
145 of patients we evaluated the neurological finding according to the Frankel scale with a finding from the imaging
146 methods (X-ray, CT, MRI) preoperative and 2, 6 and 12 months after the surgery.

147 We indicated the actual surgical approach (ACIF + plate) according to the type of traumatic instability from
148 the imaging examinations evaluated according to Aebi-Nazarian (Table 1). The most common type of unstable
149 injury operated using the ACIF approach with a plate and all types of implants was diagnosed as osteoligamentous
150 injury type A (about 35%) and type C (about 65%).

151 We evaluated the neurological finding according to the Frankel scale (A-Complete lesions, B -Preserved
152 sensitivity only, C -Preserved nonfunctional motorics, D -Preserved sensitivity and functional motorics, E -No
153 lesions) before the surgery and 12 months after the surgery (Table 2).

154 Table 2 shows that improvement in the neurological finding 12 months the surgery occurred regardless of the
155 implant type in 30% of patients (28-32%) by at least one grade of the Frankel scale, most frequently in incomplete
156 spinal lesions. In addition to the neurological finding we also evaluated findings from imaging examinations
157 performed 2, 6 and 12 after the surgery.

158 Here we focused on a change in the implant position (ventral or dorsal dislocation and sinking into the vertebral
159 bodies) and signs of instability (reduced density of bone tissue surrounding the implant, plate loosening).

160 Using postoperative imaging methods (X-ray, CT) we did not observe any dislocation or instability signs in
161 the used implants in the entire group of patients. In two patients (glass -ceramics) partial loosening of screws in
162 the plate was observed without the implant or the plate being dislocated. Steady position of fixation on images

9 ? AFFORDABILITY

163 correlates with postoperative evaluation of neurological lesion according to the Frankel scale (30% of improved
164 patients).

165 Complications associated with the surgical procedure (secondary healing of surgical wound, temporary paresis
166 of the recurrent laryngeal nerve, permanent partial paresis of the recurrent laryngeal nerve) which we observed
167 in our group is shown in We observed permanent complications associated with the surgical technique in two
168 patients of the group (4%), namely it was unilateral partial lesion of the recurrent laryngeal nerve, which slightly
169 limits patients in loud vocal expression (Ebraheim 1997). We did not observe any other complications associated
170 with the surgery.

171 7 IV.

172 8 Discussion

173 Anterior interbody fusion with splint remains a verified standard treatment method of unstable injury in subaxial
174 part of cervical spine fractures (An HS. 1998, Bohlman 1979, Fehlings 2005) and in the subaxial section of the
175 cervical spine in mono-and bisegmental degenerative stenoses caused by posterior osteophytes and/or osteophytes
176 combined with the intervertebral disc prolapse (Bailey 1960 ?? Bohlmann 1992, Cloward 1958, Dunske 1977).

177 Application of allografts made of artificial material for the interbody fusions started to be used globally in
178 the second half of the 1980s. After many years of experience with the application of autograft we developed
179 the first implant for use in ACIF made of bioactive glass-ceramics at the beginning of the 90s. We started to
180 use it in the clinical practice in 1995 in surgical treatment of degenerative disease of the cervical spine (Filip
181 2000) and from 1997 also in the treatment of unstable ligamentous or osteoligamentous injuries to the cervical
182 spine. Compared with the autograft the advantages of this implant include shortening the time of the surgical
183 procedure, elimination of complications associated with bone graft harvest and active bonding of the implant
184 with the surrounding osseous tissue within 48 hours. Bioactive properties of the implant (active hydroxyapatite
185 layer) allows the migration of osteoblasts around its surface ?? Kokubu 1982, Yamamoto 1995). Implants made
186 of bioinert materials started to appear in the market at the Compared with other implants its disadvantage was
187 that it was fragile. There was a danger of damage during insertion into the interbody space due to an inadvertent
188 contact with metal instruments or a failure to fix it with the plate. This would have resulted in deterioration
189 of the position in the postoperative period with a possible deterioration of the clinical finding. Therefore at the
190 beginning of the 90s we developed a similar implant made of bioactive titanium and we gradually introduced it
191 in the clinical practice for the same indications during the period of 2004-2006. In the treatment of unstable
192 injuries to the lower cervical spine we use it simultaneously with the implants made of absorbable (polyactides) or
193 bioinert (PEEK) materials. The evaluation was based on the recommended optimal properties for the allograft
194 ?? ChoD 2002, Vaccaro 2002) which should, with a splint, meet the following criteria.

- 195 ? Firm structure resistant against damage
- 196 ? Active formation of fusion without the addition of other materials (bone, TCP, BMP. etc.)
- 197 ? Compatibility with human tissue
- 198 ? Radiological evaluation of bone fusion
- 199 ? Physical properties of the bone tissue

200 9 ? Affordability

201 At present, we can find a large number of implants made of various types of material on the market. According
202 to the criteria, these materials meet the requirements for implants for the ACIF as shown in Table ??o. 5. same
203 time. They were mostly designed as a hollow cage (Matge 2002, Suchomel 2004). The cage had to be filled with
204 bone grafts to initiate the fusion. As a result of its bioactive properties our implant had a solid design without a
205 cavity and did not require any bone graft filling. From the table above it follows that, when compared to other
206 materials, the properties of bioactive titanium make it a very-close-to-optimum material for ACIF.

207 Out of all the properties, the emphasis must be on the bioactivity of the overall surface of the biotitanium
208 implant specified in point 2 of the table. Bioactivity enables the osteoconduction of bone cells at the implant/bone
209 interface with their subsequent migration over the implant surface (Strnad 1999, 2001 Filip 2010). Most of the
210 other implants do not have this property. Only glass-ceramics have similar bioactive properties, however without
211 sufficient strength parameters. The active formation of fusion is enabled by the surface treatment of the titanium
212 using the technology, as mentioned in the Material and Methodology section. It enables the new formation of
213 bone cells and their migration on the implant surface, as we have verified using the CT, see Figure 14. Hence
214 there is no necessity to fill the implant inside with supplementary material (bone / artificial material) as is the
215 case with the other implants (Hacker 2000, Matge 2002, Suchomel 2004, Kandziora 2005). Its application is,
216 therefore, made easier and the state of the operated-on patient is not impaired when expanding the surgery time
217 by taking an autograft or preparing an implant with filling. This results in a lower surgical burden and better
218 affordability. The other implants do not have this property. They are in the shape of hollow cages increasing
219 only mechanical strength without any bioactivity of the material itself. To develop fusion the hollow of the cage
220 must be filled with one of bioactive materials (BCP, TCP, BMP).

221 The chemical bond and the subsequent interbody fusion develop only in the contact area of
222 bone/supplementary material outside the implant itself. If, for various reasons, the filling homogeneity

223 is impaired, the fusion formation may be slowed down or stopped with the development of later instability in
224 the operated-on region. Regarding the other properties, biotitanium is not significantly different from the other
225 materials as seen in table No. 5.

226 Another benefit of our implant compared to the other ones is its shape of a full truncated prism in different sizes
227 with surface treatment on the opposite sides. This provides primary stability minimizing the danger of migration
228 in all directions. It gives a better chance to maintain the cervical spine lordosis in the postoperative period
229 compared to some other implants of a shape without truncation. Implant dislocation endangers the operated-on
230 patient by new instability with compression of the spinal canal and by worsening of the clinical findings. Due
231 to its surface bioactivity, our implant has no hollow in the shape of an oval or square. When comparing the
232 operation techniques using different types of implants to our implants we did not find any significant differences.
233 Always the Smith-Robinson technique with splint with Caspar instrumentation is used. The only difference is
234 seen in simpler handling during the surgery. Thanks to the bioactive properties of the surface it is not necessary
235 to fill it with further material. This shortens the surgery time as well as the surgery burden on the operated-on
236 patient.

237 V.

238 **10 Conclusion**

239 It follows from the results above that the our implant from bioactive titanium is a good alternative for operation
240 treatment of unstable injury in subaxial part of cervical spine to the anterior cervical interbody fusion with splint.
241 Regarding the quality and price it successfully competes with the other products for ACIF. This has been proven
242 by clinical evaluation of our group by Frankel scale (30%) improve surgery within the interval of 12 months after
243 surgery in all types of implants supplemented by imaging examinations (Xray, CT).

244 **11 VI.**

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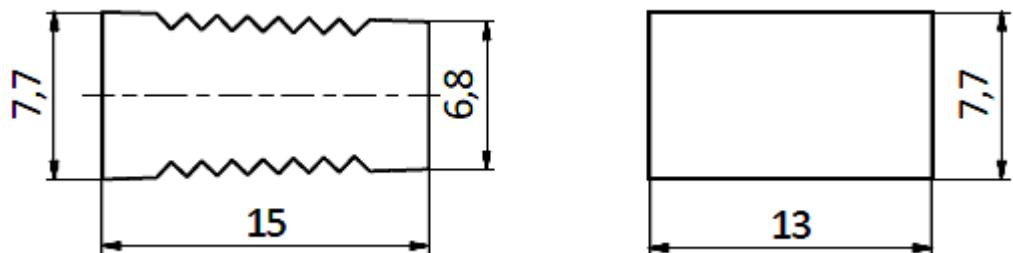
¹



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Figure 1: Figure 1 :Figure 2 :

245



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Figure 2: Figure 3 :Figure 3



44

Figure 3: Figure 4 :Figure 4

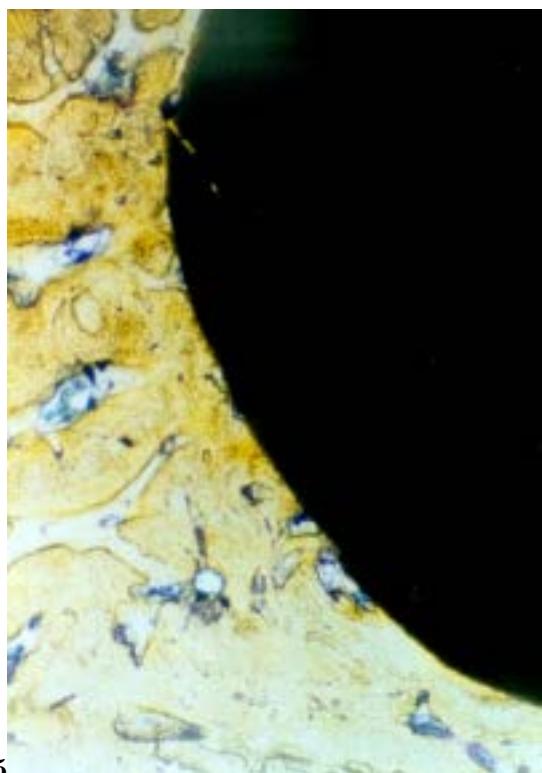


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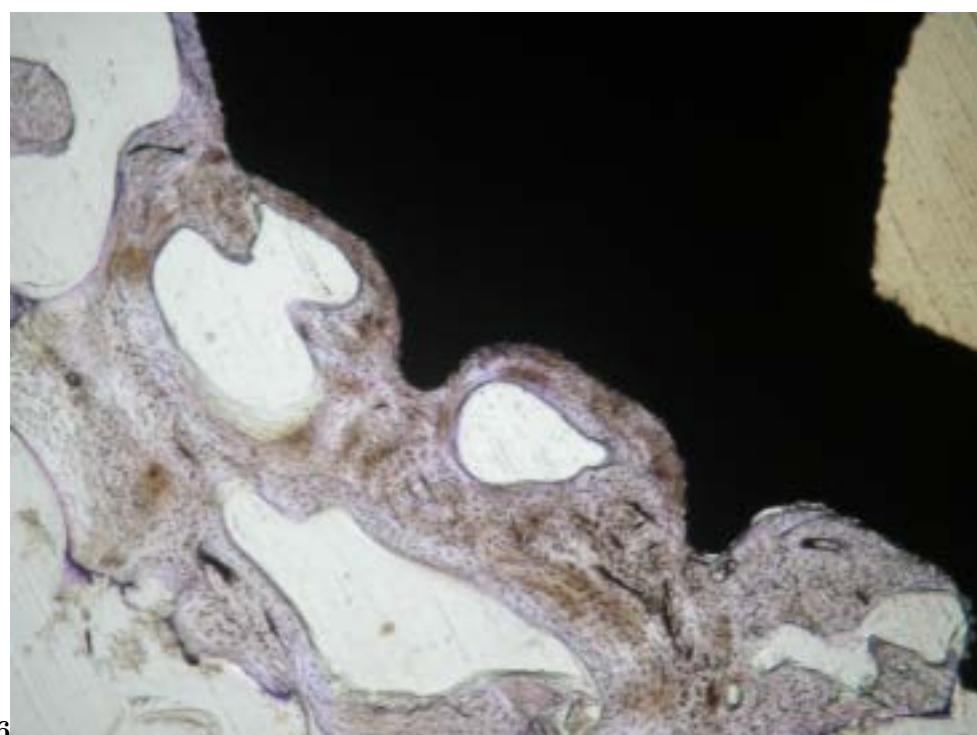
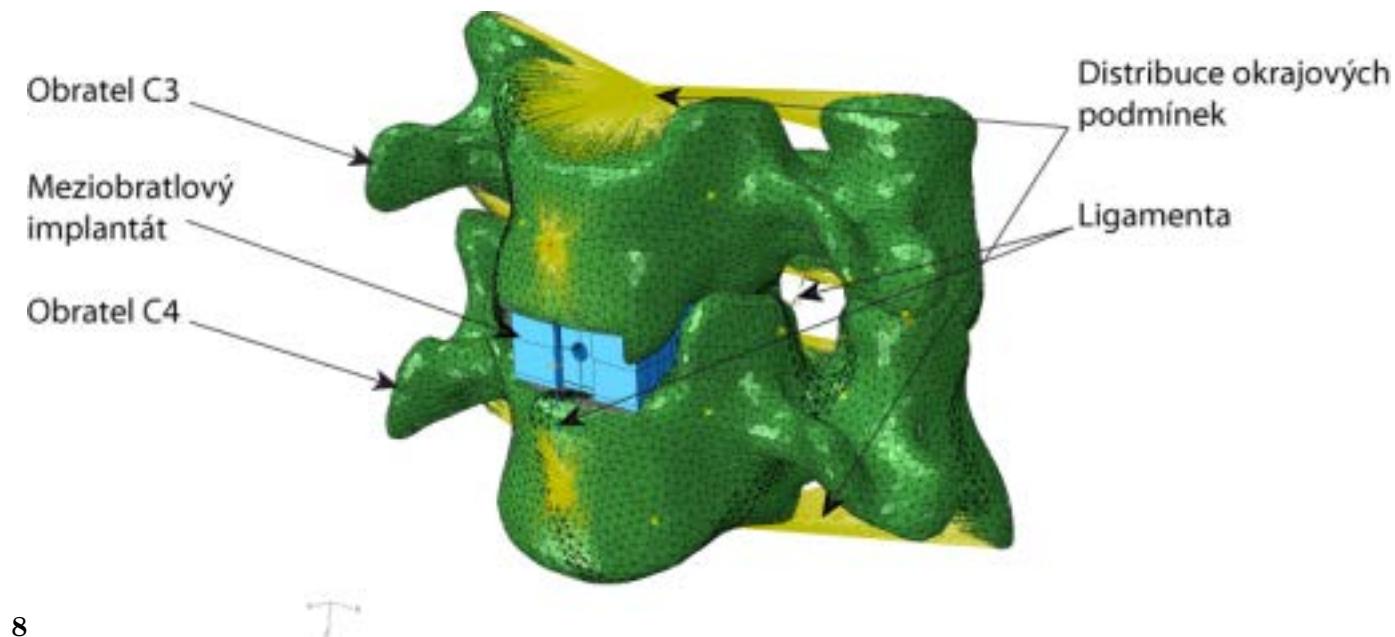


Figure 5: Figure 6 :



8

Figure 6: Figure 8 :

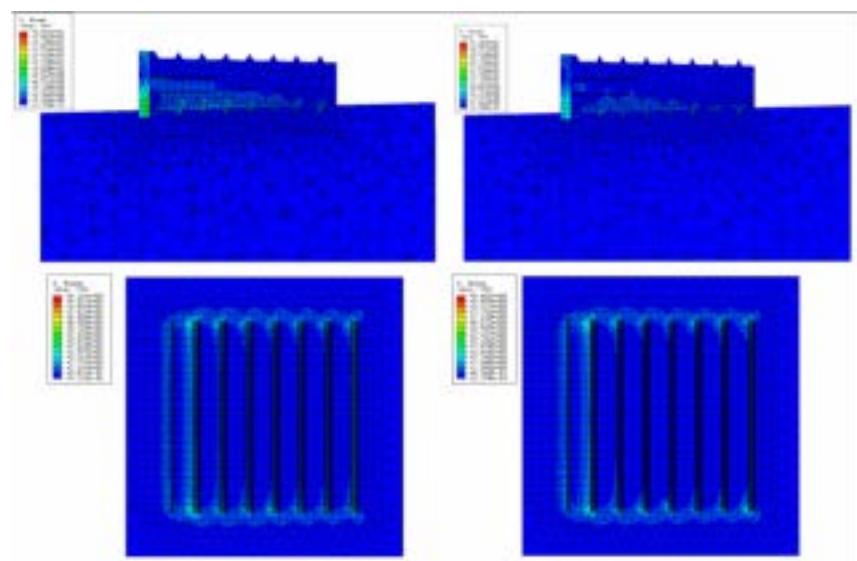
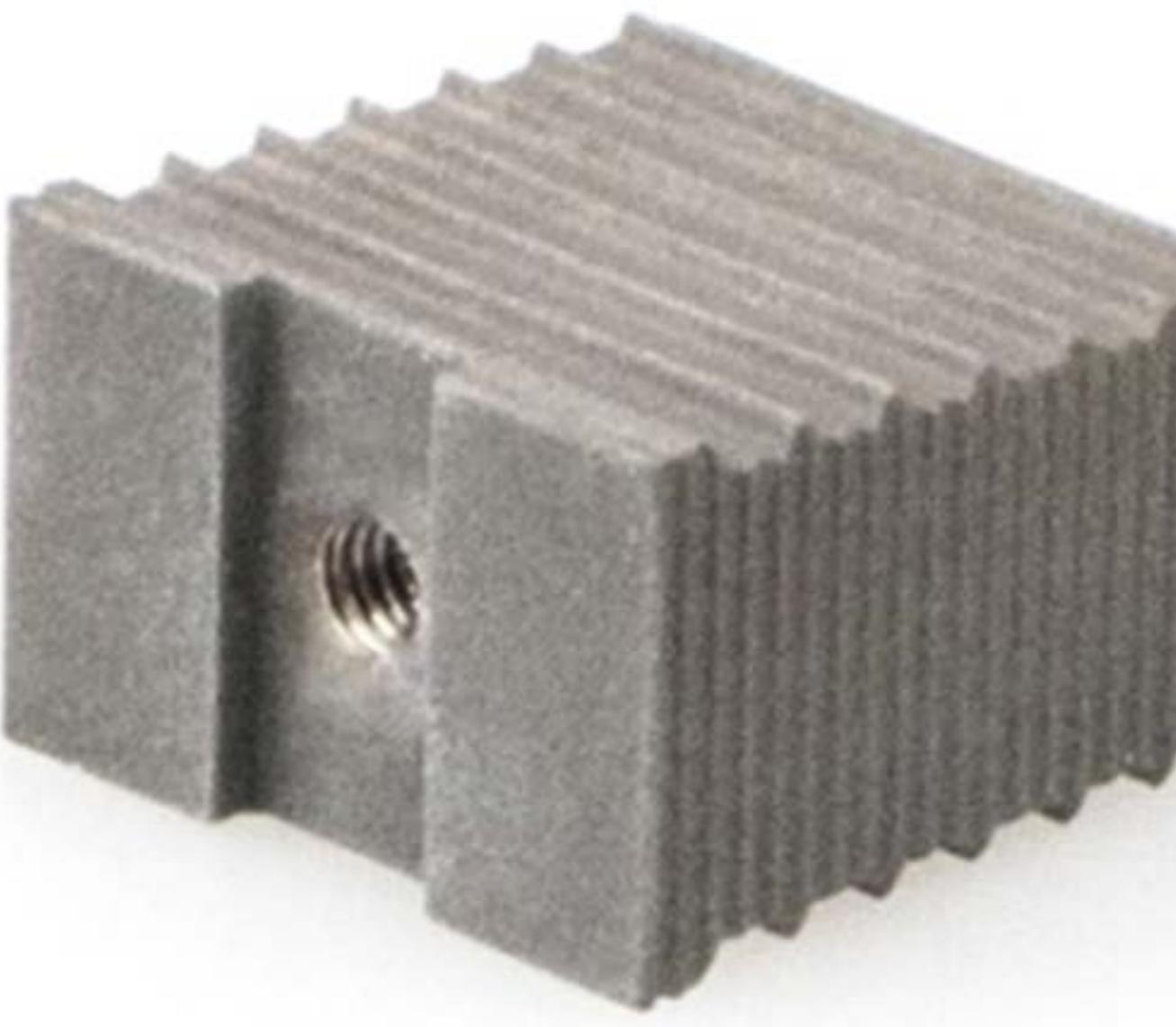


Figure 7:



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Figure 8: Figure 9 :Figure 10 :



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Figure 9: Figure 11 :



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Figure 10: Figure 12 :



14

Figure 11: Figure 14 :



Figure 12:

1

Classification according Aebi-Nazarian in our patients	Glass-ceramics + Aesculap plate	Bioactive titanium + plate	Polylactide/BCP PEEK/TCP + plate (Zephire, Reflex, Eagle)	Polylactide/BCP PEEK/TCP + plate (Zephire, Reflex, Eagle)
		(Zephire, Venture, Reflex, Eagle)	(2007-2011)	(2007-2011)
(1996-1999)	(2007-2011)	(2007-2011)		
A2	1	3	1	2
A3	2	2	3	3
C2	3	2	4	1
C3	4	5	3	5

Figure 13: Table 1

2

Neurological lesions according to the Frankel system	Glass-ceramics (1996-1999)	Bioactive titanium (2007-2011)	Polylactide/BCP PEEK/TCP (2007-2011)
preoperative/12 months			
postoperative			
A	2/2	2/1	1/1
B	3/1	2/2	2/1
C	2/3	2/1	3/3
D	1/2	3/4	4/4
E	2/2	3/3	1/2
Number of improved	3 (30%)	4	3 (28%)
			3 (28%)

Figure 14: Table 2

4

Complications associated with the procedure	Glass-ceramics (1997-1999)	Bioactive titanium (2007-11)	Polylactide/BCP PEEK/TCP (2007-2011)
Secondary wound healing	1	0	0
Temporary paresis of the recurrent laryngeal nerve	2	1	2
Permanent paresis of the recurrent laryngeal nerve	0	1	1
			0

Figure 15: Table 4

5

Material properties	PEEK	Glass-ceramics	Polylactide	Biotitanium
1. Rigid support	+/-	-	+/-	+
2. Active formation of fusion (Osteoconduction)	-	+	-	+
3. Compatibility with human tissue	+	+	+	+
4. Radiological rating of fusion	+	+	+	-
5. Physical and biochemical properties of bones	+	+/-	+/-	+/-
6. Affordability	+/-	+	+/-	+

Figure 16: Table 5 :

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