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First experiences with a distractible titanium implant in ventral cervical disc surgery: report on 30 consecutive cases

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Abstract A new titanium implant for ventral cervical fusion after microsurgical discectomy via a conventional antero-lateral approach is presented. The implant consists of a ventral fixation plate and a distractible disc space graft whose extension can be changed by adjusting a set screw. Additional fixation is achieved by four monocortical spongiosa screws. Thirty patients (14 men, mean age 46.5 years; 16 women, mean age 46.8 years), in whom the implant was used, were the subjects of this investigation. Twenty-eight patients suffered from monosegmental cervical disc herniations (C4/5: $n = 3$; C5/6: $n = 14$; C6/7: $n = 12$; C7/T1: $n = 1$) and two patients showed traumatic discoligamentary instability (C5/6: $n = 1$, C6/7: $n = 1$). The post-operative follow-up was at least 12

months (range 12–26 months, average 16.6 months). All patients underwent a clinical control including functional X-rays 6–8 weeks and again 10–14 months after surgery. All had benefitted from the procedure and the clinical results were comparable to other ventral cervical fusion techniques. We observed neither overdistraction or dislocation of the implant nor loosening or breaking of the screws. The advantages of the implant are: simple handling, controlled distraction of the intervertebral space and avoidance of a “second operation” to obtain an iliac crest bone graft for fusion.

Key words Disc herniation · Cervical · Plate · Distraction · Interbody fusion · Titanium

Introduction

Several techniques of ventral fusion have occupied the field of surgical treatment of cervical degenerative disc disease. However, there is no real consensus on the use – if at all [2, 7, 11] – of autologous [6, 7, 9, 11, 12], heterologous [16, 17] or alloplastic materials [3, 5, 10, 13, 14] for the disc space graft for ventral fusion, the goal of which is either solid ossification or at least osseous fit. There is no doubt that autogenous iliac bone graft, with all the well-known disadvantages, is preferred. To avoid a second operation for obtaining iliac crest bone for interposition, a new titanium implant for anterior cervical spinal fusion has been developed and is presented. This

study demonstrates the features and presumed advantages of the implant, which may be a useful alternative to commonly used procedures.

Materials and methods

After a typical antero-lateral approach to the ventral surface of the cervical spine and radiographic control of the correct segment, the disc is removed. The disc space is cleared out by drilling and the posterior and postero-lateral osteophytes as well as the posterior ligament are resected. After this procedure, the titanium implant is inserted into the intervertebral disc space. It is sometimes necessary to take away some of the ventral spondylosis for good contact between the ventral spinal surface and the ventral plate of the implant. The next step is to extend the distractible disc space graft by adjusting the central set screw. This is best done under radio-

Fig. 1A, B Frontal view of the implant with **A** low and **B** high distraction (*thick arrow* set screw, *thin arrow* position screws)

Fig. 2A, B Lateral view of the implant with **A** high and **B** low distraction

Fig. 3 Dimensions of the implant. Distraction ranges from 6 to 11 mm, note the axial depth of 14 mm

Fig. 4 Implant in situ

Fig. 5A, B Plain radiograph of a ventral fusion at C5/6. **A** AP view, **B** lateral view

Fig. 6A, B CT scan at the level of **A** the upper spongiosa screws and **B** the intervertebral disc space. Note osseous enclosing of the distractor plates (*arrow*)

Fig. 7A–C Three-dimensional CT reconstruction. **A** Lateral view, **B** oblique view and **C** axial view

Fig. 8 Magnetic resonance imaging at the level of the distractor plates. Moderate artefact permits assessment of the spinal canal and myelon

graphic control. Distraction should be stopped when the implant is so tight that it cannot be removed except by increased force. Usually this is achieved when the evacuated intervertebral disc space has been enlarged by 1–2 mm, 1.5 mm on average. The shear winding between the two distraction plates provides a proportionate lifting. The maximum distance between the distraction plates is 11 mm, the minimum 6 mm. The size of the implant is such that it is suitable for all “average cervical spines”, male or female, between the levels C3/4 and C7/T1. The distraction is then permanently positioned by adjusting four fixation screws. Additional fixation is obtained with four monocortical spongiosa screws. The whole implant including the endplate is left intact, removal is not necessary. The stability of the implant was investigated in several crash tests by the German TÜV (Technischer Überwachungs-Verein), who confirmed the technical requirements for implantation. These tests included continuous axial and longitudinal weight and tension stress in a wooden model of a fused segment up to 1000 kp, a situation that does not occur in vivo. At this level of stress, the implant began to deform, but did not break.

Patients

Thirty patients treated by the method described above with a follow-up time of at least 1 year were included in this investigation. There were 14 men (age range 30–64 years, mean age 46.5 years) and 16 women patients (age range 32–58 years, mean age 46.8 years). Twenty-eight patients suffered from monosegmental cervical disc herniation (C4/5: $n = 3$, C5/6: $n = 14$, C6/7: $n = 12$, C7/T1: $n = 1$), two patients had traumatic discoligamentary instability (C5/6: $n = 1$, C6/7: $n = 1$). All patients with degenerative cervical disc disease ($n = 28$) had local cervical symptoms as well as a radicular syndrome ranging from intractable pain to severe paresis. Four of these, together with the two traumatic patients, presented with signs of myelopathy. Diagnosis was usually made on the basis of clinical investigation, radiography and magnetic resonance imaging (MRI). The follow-up was 12–26 months, 16.6 months on average.

Results

All patients benefitted from surgery and suffered no major complaints immediately after surgery. They could be mo-

bilized on the 1st postoperative day and were usually discharged on the 8th postoperative day. We recommended a smooth cervical collar for 4 weeks. All patients were reinvestigated clinically after 6–8 weeks and again after 10–14 months and had functional X-rays. All patients stated that their condition had improved after surgery and 24 (80%) were free of pain and had no complaints. Six weeks after surgery four patients (13%) suffered a local cervical syndrome with more or less distinct muscle spasm and pain in the neck and/or shoulders. There was no correlation between degree of distraction and neck pain. In five patients (16%), slight hypoaesthesia in the corresponding dermatome was identified, and three patients (10%) had moderate weakness of the initially affected myotome. However, all patients had improved in comparison with their preoperative status. One patient complained of a transient impairment of swallowing. In the two patients with discoligamentary instability, we found signs of myelopathy with proximal and distal hyperreflexia. At reinvestigation 10–14 months after surgery all patients were free of neurological signs. In no case did we note recurring radicular pain and we did not see any loosening or dislocation of the implant: all the spongiosa screws were intact and in place as shown by functional X-rays. No cases of overdistracted were encountered.

Discussion

Ventral fusion with an autologous iliac bone graft, usually completed by ventral plate osteosynthesis, is widely accepted as the method of choice in the treatment of cervical degenerative disc disease. It is burdened by the problem of “the second operation”. Although this second intervention is of minor surgical importance, many patients complain more about this than about the operation on the neck. Long-lasting local pain, meralgia paraesthetica as well as fractures of the iliac bone [1, 8, 15] have been observed in addition to the second “unrepresentative scar”. Furthermore, the interposed bone graft is not even certain to lead to complete ossification of the fused segment. In about 10%, adequate osseous fusion is not obtained [6, 12], though this does not necessarily affect the patient's condition.

Many surgeons do not interpose a graft into the empty intervertebral disc space [2, 7, 11]. In our opinion, this procedure is unsafe and not advisable because of the danger of subsequent kyphosis of the cervical spine [2, 6], especially if the uncinate processes are resected for adequate nerve root decompression. Substitute methods have long been sought to avoid iliac bone grafting. Isu et al. [9] described an elegant method of gaining autologous bone from the cervical segment intended for fusion. Hitherto, this “bone graft” has been partly of spondylotic origin and therefore of lesser quality, perhaps jeopardizing adequate osseous fusion. The use of polymethyl methacrylate (Pala-

cos) as an interbody graft is still a widespread and popular method. It is easy to handle, cheap and gives good results [3, 5, 13, 14]. However, it has been shown that tight fusion does not take place, but only tissue consolidation that still allows movement in the "fused" segment [3, 5, 16]. This may be seen to be favourable from a physiological point of view, but does not comply with the intention of a segmental fusion. Such persisting mobility of the treated segment – especially when in an axial direction – is probably the cause of severe persisting local cervical pain as observed in our own series [16]. Other heterologous materials such as bioceramics, artificial bone [17] or several titanium disc grafts [10] have not yet become generally accepted.

In summary, there is no ideal method for ventral cervical fusion. We have developed a method of maximal simplicity and security. Protracted modelling or grinding of the graft should be avoided and there should be a maximum of segmental stability, particularly in the axial direction. The implant, consisting of a ventral plate and an intervertebral graft, should be a single entity, the intervertebral graft should be distractible to enable controlled distraction of the adjacent vertebral bodies, providing for a tight fit of the implant as well as a widening of the intervertebral foramina. Furthermore, the implant should be

absolutely biocompatible and should allow subsequent MRI investigations. The surgical results must be excellent or at least as good as those achieved by other methods.

In our view the implant described above satisfies these criteria. As we could confirm in a three-dimensional CT examination 6 months after implantation, there is no complete ossification of the intervertebral disc space, but a solid osseous enclosing of the distraction plates. Because of the tight fit of the distractor plates, we abandoned bicortical screw fixation of the ventral plate and used monocortical spongiosa screws (11 mm) exclusively. We did not see any screw loosening or loss of distraction in the follow-up period. As we had been able to prove the high stability of the implant in vitro and as the biocompatible features of titanium are well known [10, 18], we saw no necessity for animal investigations. A postoperative follow-up of at least 12 months (16.6 months on average) is, in our opinion, sufficient for a first representative validation.

In summary, the titanium implant is easy to handle, provides high stability and security and achieves clinical results comparable to other accepted methods. It can therefore be seen as equivalent to other ventral cervical fusion methods in degenerative disc disease as well as in discoligamentary instability.

References

- Asano S, Kaneda K, Satoh S, Abumi K, Hashimoto T, Fuyiya M (1994) Reconstruction of an iliac crest defect with a bioactive ceramic prosthesis. *Eur Spine J* 3:39–44
- Bertalanffy H, Eggert HR (1989) Complications of anterior cervical discectomy without fusion in 450 consecutive patients. *Acta Neurochir* 99:41–50
- Böcker DK, Schultheiss R, Probst EM (1989) Radiologic long-term results after cervical vertebral interbody fusion with polymethyl methacrylate (PMMA). *Neurosurg Rev* 12:217–221
- Frykholm R (1969) Die cervicalen Bandscheibenschäden. In: Olivecrona H, Tönnis W (eds) *Handbuch der Neurochirurgie*, vol 7 (1). Springer, Berlin Heidelberg New York
- Grote W, Kalff R, Roosen K (1991) Die operative Behandlung cervicalen Bandscheibenvorfälle. *Zentralbl Neurochir* 52:101–108
- Grumme Th, Kolodziejczyk (1994) Komplikationen in der Neurochirurgie, vol 1. Blackwell, Berlin, pp 121–149
- Husag L, Probst C (1984) Microsurgical anterior approach to cervical discs. Review of 60 consecutive cases of discectomy without fusion. *Acta Neurochir* 73:229–242
- Hu RW, Bohlmann H (1994) Fracture at the iliac bone graft harvest site after fusion of the spine. *Clin Orthop* 309:208–213
- Isu T, Kamada K, Kobayashi N, Mabuchi S (1994) The surgical technique of anterior cervical fusion using bone grafts obtained from cervical vertebral bodies. *J Neurosurg* 80:15–19
- Kaden B, Schramm J, Fuhrmann G, Hoffmann C (1995) Titanium intervertebral disc and instrumentation for fusion in anterior cervical discectomy (technical note). *Neurosurg Rev* 18:25–29
- Martins AN (1976) Anterior cervical discectomy with and without interbody bone graft. *J Neurosurg* 44:290–295
- Mosdal C (1989) Cervical osteochondrosis and disc herniation. Eighteen years' use of interbody fusion by Cloward's technique in 755 cases. *Acta Neurochir* 70:207–225
- Roosen K, Grote W (1981) Neurologische und radiologische Langzeitergebnisse nach ventraler Spondylodese mit Polymethylmethacrylat bei cervicalen Bandscheibenerkrankungen. *Z Orthop Ihre Grenzgeb* 119:731–734
- Samii M, Völkening D, Sephernia A, Penkert G, Baumann H (1989) Surgical treatment of myeloradiculopathy in cervical spondylosis. A report on 438 operations. *Neurosurg Rev* 12:285–290
- Saxer U, Magerl F (1974) Komplikationen nach Spanentnahme aus dem Beckenkamm. *Helv Chir Acta* 41:251–255
- Schröder U, Russeger L (1995) Operationsindikation beim cervicalen Bandscheibenvorfall – wann und wie? In: Russeger L (ed) *Cervikalsyndrom und cervicaler Bandscheibenschaden*. Oder Anzeiger Media, Frankfurt an der Oder, pp 34–40
- Vitzthum HE (1995) Erfahrungen mit dem VCS-Instrumentarium bei Patienten mit degenerativen Halswirbelsäulenerkrankungen. In: Russeger L (ed) *Cervikalsyndrom und cervicaler Bandscheibenschaden*. Oder Anzeiger Media, Frankfurt an der Oder, pp 47–51
- Young D, Robb R, Rock M, Chao E (1994) Analysis of periprosthetic tissue formation around a porous titanium endoprosthesis using CT-based spatial reconstruction. *J Comput Assist Tomogr* 18:461–468