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Clinical Experience With Cespace, the New Intervertebral Disc Spacer by Aesculap for Spondylodesis of the Cervical Spine, in Comparison With Similar Products by Weber, Intromed, and AcroMed

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Summary: Ventral spondylodesis by autologous bone grafting in cases of degenerative disease of the cervical spine bears the disadvantage of the complication of pain at the iliac crest. The question is if these problems can be avoided by implanting intervertebral disc spacers. Between September 1997 and December 2000, we operated on 145 patients suffering from degenerative diseases, including osteochondrosis and/or disc prolapse, of the cervical spine. Without any patient diagnosis selection, we implanted various randomly chosen disc spacer types, including 52 titanium disc spacers (Cespace) by Aesculap, 40 titanium spacers by Weber, 36 titanium spacers by Intromed, and 17 carbonium spacers by AcroMed, through anterior access and after microsurgical discectomy and removal of the dorsal osteophytes by a high-speed drill. We evaluated the handling, radiographic contrast, and costs of implantation as well as the clinical outcome after 3 months and 1 year, respectively. All four disc spacer models are suitable for the anterior spondylodesis of the cervical spine. The titanium spacer by Weber features good handling characteristics and a moderate purchase price. Cost efficiency and easy handling characterize the Intromed cage. The radiographic contrast of the carbonium spacer by AcroMed is insufficient for a controlled implantation in some cases, especially in the lower cervical spine. The handling is good, but the price is high. The AcroMed and Intromed spacers show a tendency to penetrate the base and/or cartilaginous plate of the adjacent vertebrae. Results lead us to favor the Aesculap Cespace, which impresses us by its handling and moderate price. The final assessment depends on the long-term clinical outcome for the cases studied. **Key Words:** Intervertebral disc spacer—Spondylodesis—Cervical spine—Degenerative disease—Clinical outcome.

The diagnosis and therapy of degenerative disorders of the cervical spine are still fraught with difficulties because of the multifactorial genesis of this group of illnesses and the multitude of courses they can take. The minimization of possible complications and the best possible perioperative and postoperative comfort for these patients should be high priorities as well. Anterior spondylodesis by autologous bone grafting from the iliac crest suffers from a high rate of complications at the iliac crest.[1] Because there is no evidence for autologous implants being superior in principle, one has to consider alternatives to bone grafts from the iliac crest. Such alternatives exist in the form of various implants. The subject of this article is the comparative assessment of different constucts, also referred to as disc spacers or cages, with regard to their intraoperative, anatomy-relevant, and design-specific characteristics of use; their radiographic contrast performance or the radiographic artifacts caused by them; the implant costs; and the clinical outcome for the patients.

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MATERIALS AND METHODS

In the course of a prospective study carried out at the Department of Neurosurgery of the Unfallkrankenhaus Berlin between September 1, 1997, and January 1, 2001, 145 patients underwent surgical treatment of degenerative disorders of the cervical spine in the form of a ventral fusion. The indication criteria for surgical intervention were the diagnosis of radiculopathy or myelopathy and corresponding evidence of a disc prolapse with compression of nerve structures and/or osteochondrosis of the cervical spine with a narrow spinal channel in the affected segment as visualized by the imaging techniques used in neuroradiology (computed tomography [CT], magnetic resonance imaging [MRI]). In cases of a cervical disc prolapse (soft disc) without marked osteochondrosis, a conservative therapeutic approach involving physiotherapeutic treatment was pursued for at least 6 weeks before surgery.

Operation Method

The 76 (52%) male and 69 (48%) female patients with an average age of 48 years (range: 25–68 years) were operated on, with the usual microsurgical precautions, using a modified Smith/Robinson technique with the Caspar set of instruments provided by Aesculap. After height localization using radiologic imaging and a one-sided (right) Kocher collar incision, the surface neck muscles were split and the blunt median preparation of the musculus sternocleidomastoideus, including lateralization of the arteria carotis communis as well as medialization of the trachea, esophagus, and glandula thyreoidea ventrally on the cervical spine, were carried out. After severing the deep neck fascia, the intervertebral space was marked with a lumbar cannula, and the precise height localization was performed by means of radiography. The positioning of the soft tissue retractor and the opening of the anterior longitudinal ligature of the respective intervertebral space were followed by the removal, under the microscope, of all parts of the disc tissue. Using the Caspar instruments, the distraction screws of the vertebra distractor were positioned centrally so as to widen the intervertebral space for milling off by means of a high-speed drill (motor system) the osteophytes at the rear edges of the intradiscal space under the operation microscope. After a partial resection of the posterior longitudinal ligament, disc sequesters could now be extirpated from the spinal channel, and lateral osteophytes could be beveled off. The complete (as nearly as possible) decompression of the spinal channel was considered the most crucial step of the operation. Still under moderate distraction, the selection and positioning of the disc spacer was next carried out, monitored by radiographic techniques. Finally, the instruments were removed and the wound closed, layer by layer.

Cage Systems

For this study, three titanium spacers and one carbonium spacer were used, randomly chosen by the surgeon without other patient selection criteria.

1. Using the method of Böker and Schultheiß,[2] the titanium Cervidisc supplied by G. Weber GmbH (Minden, Germany), henceforth referred to as "Weber," was implanted with and without hydroxylapatite ceramic (HAC) coating into 40 patients.
2. According the method of H. Steffen, the titanium intervertebral and vertebral replacement system supplied by Intromed Medizintechnik GmbH (Berlin, Germany), henceforth referred to as "Intromed," was implanted into 36 patients.
3. The cervical cage made of a carbon fiber–reinforced polymer and supplied by AcroMed (Raynham, Massachusetts, U.S.A.), henceforth referred to as "AcroMed," was implanted into 17 patients. Because of the high incidence of calcification of this cage accompanied by penetration of the base and cartilaginous plate of the adjacent vertebrae (and following notification by the manufacturer that the company's liability according to German law with regard to medical products [*Medizinproduktehaftungsgesetz*] would apply to the 18th patient only if the cage were filled with additional spongiosa), we decided to abandon the implantation of this cage.
4. The Cespace HWS Fusion Cage supplied by Aesculap (Tuttlingen, Germany) is a titanium implant with a Plasmapore coating and is henceforth referred to as "Cespace." This spacer was implanted into 52 patients.

All these spacers are available in various sizes and hence can be adapted to the individual situation. Cespace and Intromed cages are supplied in straight and conical shapes. The AcroMed cage and the Weber cage are wedge shaped (7° and 5°, respectively).

Examination Protocol

The clinical examination of the patients took place immediately before and after the operation as well as 3 months and 1 year later. For assessment of the clinical symptoms, all symptoms relevant to the development of both radiculopathy and myelopathy could be assigned a Japanese Orthopedic Association (JOA) score.[3] As a

result of the different conditions of life in Europe, the JOA score had to be modified slightly. For instance, "impaired use of chopsticks" had to be replaced by "impaired when eating, writing, or reading." The maximum score of 17 points on the adapted JOA scale corresponds to a healthy individual (Table 1).

Following Yoshida et al.,[4] the recovery rate

$$\text{Recovery Rate (RR)}$$

$$\text{RR} = \frac{\text{JOA postoperative} - \text{JOA preoperative}}{17 - \text{JOA preoperative}}$$

was used to compare patients arriving with different original conditions. The RR was calculated by dividing the difference between a patient's postoperative and preoperative JOA scores by the difference between 17 (the JOA maximum score) and the patient's preoperative score. This ratio made possible the comparison of improvements among patients. In this scheme, the following assessment scale was used:

≥75% excellent
≥50% good
≥20% satisfactory
<20% poor

In addition to the clinical examination of every patient at the times given previously, radiographic images of the cervical spine were produced for a radiologic assessment. These images were analyzed, with respect to the implant location and the possible penetration of adjacent vertebrae by the implants, by two independent experienced radiologists. Penetration into the adjacent vertebrae was positively diagnosed and described as calcification from a depth of 1 mm.

Statistics

For the statistical evaluation of the data, the statistics software program WinStat (Microsoft, Redmond, WA, U.S.A.), version 1999.1, for Microsoft Excel was used. The analysis included a single-factor ANOVA and an H-test (Kruskal-Wallis). The error probability is defined as $P < 0.05$.

RESULTS

All 145 patients we operated on (100%) underwent a checkup 3 months after surgery. The checkup 1 year after surgery was completed by 137 patients (95%). The cage group sizes (Weber with 37 patients, Intromed with 35 patients, AcroMed with 16 patients, and Cespace with 49 patients) followed an expected distribution. The distribution of the cages with regard to their use for one, two, or three spine segments, respectively, was approximately equivalent (Fig. 1). One hundred three patients had a monosegmental operation (27 patients with Weber, 25 patients with Intromed, 11 patients with AcroMed, and 40 patients with Cespace), 40 patients had a bisegmental operation (13 patients with Weber, 9 patients with Intromed, 6 patients with AcroMed, and 12 patients with Cespace), and 2 patients had a trisegmental operation (2 patients with Intromed). For the cervical spine segments (Fig. 2), the height C5/6 was most common, followed by the levels C6/7 and C4/5.

The results of the radiologic examinations 1 year after the operation are shown in Figure 3. Calcification with penetration of the base and/or cartilagious end plate of the adjacent vertebrae was predominantly found for the AcroMed and Intromed spacers after both 3 months and 1 year. In a total of 23 patients (17%), penetration of the base end plate of the adjacent vertebrae by the spacer was found by radiologic examination. Three months after the ventral spondylodesis, three spacers by Weber, six by Intromed, three by AcroMed, and three by Aesculap were found to have penetrated into the base end plate of the adjacent vertebrae. At the 1-year checkups, five Weber, nine Intromed, three AcroMed, and six Aesculap

TABLE 1. *Japanese Orthopedic Association score*

Points	0	1	2	3	4
Arm movement	Complete paralysis	Eating, reading, and writing impossible	Impairment when eating, reading, and writing	Minor loss of strength in hands and upper arms	Normal function
Leg movement	Walking and standing impossible	Walking some steps possible, with support	Support needed for climbing stairs	Walking unsteady, stumbling	Normal function
Arm sensitivity	Reduced sensation, heavy pain	Minor loss of sensation, slight pain	Normal sensation, no pain		
Leg sensitivity	Reduced sensation, heavy pain	Minor loss of sensation, slight pain	Normal sensation, no pain		
Trunk sensitivity	Reduced sensation, heavy pain	Minor loss of sensation, slight pain	Normal sensation, no pain		
Bladder function	Anuria	Incomplete emptying, incontinence	Frequent urge	Normal function	

Adapted from (3).

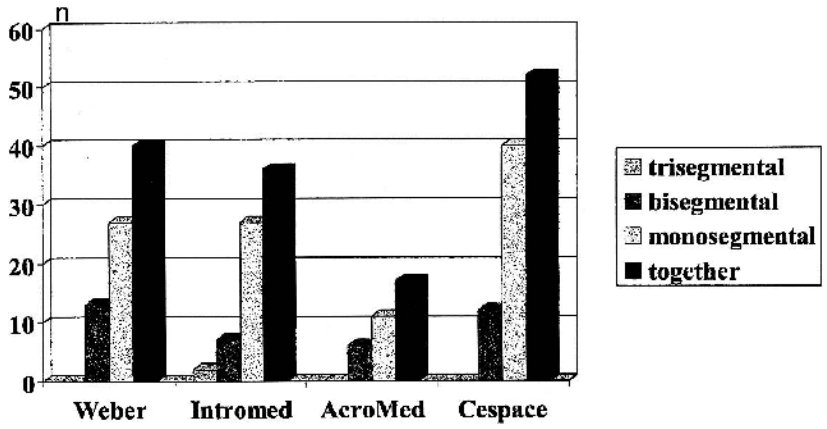

FIG. 1. Number and segmental distribution of the spacers implanted.

spacers showed radiologic evidence of penetration into the base end plate of the adjacent vertebrae (see Fig. 3). Spacer dislocations or implant breakage did not occur. Two patients (1 with Intromed and 1 with AcroMed) suffered a ventral kyphosis of the cervical spine caused by the ventral side penetration of a cage into the end plate of the lower vertebra and a reoccurrence of clinical symptoms necessitating surgical revision. In those patients, the spondylodesis was carried out by means of an autologous bone graft according to Bailey-Badgley and an anterior plate osteosynthesis. There were no infections. A superficial healing disorder of the wound, with no evidence of any infection involved, was observed in a female patient with diabetes mellitus and was treated in a conservative manner. The follow-up period ended on January 1, 2002.

Figure 4 shows the clinical outcome for our patients graded according to the recovery rate calculated on the basis of the JOA score. Immediately after the operation, the recovery rate in the patient group treated with the Weber cage was 51% ± 25%; 3 months after surgery, it was 60% ± 34%; and after 1 year, it was 61% ± 35%. For the patients who had received an Intromed cage, the postoperative recovery rate was 55% ± 30%; after 3 months, it was 60% ± 37%; and after 1 year, it was 60% ± 41%. After a spondylodesis with an AcroMed spacer, the patients experienced the following recovery rates: 59% ± 31% immediately after surgery, 78% ± 31% after 3 months, and 66% ± 36% after 1 year. In the Cespace group, the recovery rates were 58% ± 28% after surgery, 65% ± 33% after 3 months, and 64% ± 36% after 1 year (see Fig. 4). The overall average improvement of clinical symptoms was found to be 51% to 59% at the time of discharge 4 to 6 days after the operation, 60% to 78% after 3 months, and 60% to 66% after 1 year. In the statistical evaluation of the examination results, no significant difference between the recovery rates of the four spacer groups could be found either after surgery or after 3 months and 1 year, respectively. In the examination of all 137 patients 1 year after the operation, 59 patients (43%) (16 [43%] with Weber, 15 [43%] with Intromed, 8 [50%] with AcroMed, and 20 [41%] with Cespace) showed an excellent outcome with an almost complete improvement of clinical symptoms by 75% to 100% with

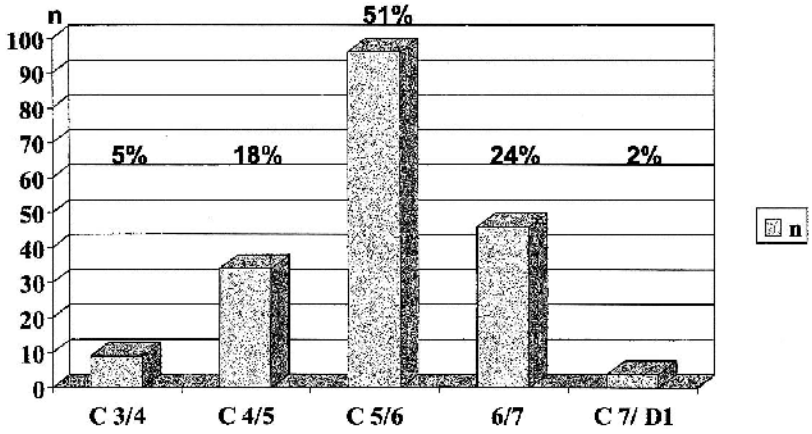

FIG. 2. Operation heights for 189 cervical spine segments.

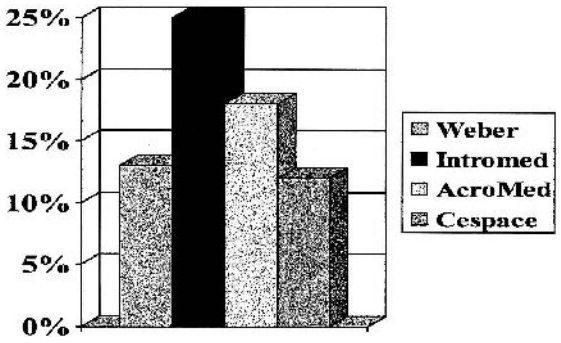

FIG. 3. Percentage of spacers that penetrated the base and/or cover plate of the adjacent vertebral bodies 1 y after operation.

respect to the recovery rate; 44 patients (32%) enjoyed a good clinical outcome (9 [24%] with Weber, 12 [34%] with Intromed, 6 [38%] with AcroMed, and 17 [35%] with Cespace) with a significant improvement of clinical symptoms by 50% to 74% in terms of the recovery rate; and 13 patients (10%) (7 [19%] with Weber, 0 [0%] with Intromed, 0 [0%] with AcroMed, and 6 [12%] with Cespace) showed a satisfactory outcome with a gradual improvement of clinical symptoms by 20% to 49%. For 21 patients (15%) (5 [14%] with Weber, 8 [23%] with Intromed, 2 [12%] with AcroMed, and 6 [12%] with Cespace), the outcome was poor, with an insufficient or failed improvement of clinical symptoms as reflected by a recovery rate of less than 20%. For 116 patients (85%), clinical symptoms had improved 1 year after the operation.

The radiographic contrast produced by a spacer is of particular importance during the operation while implanting the spacer and monitoring the implant position by means of radiologic imaging. The titanium spacers by Weber (Fig. 5A) and Intromed (see Fig. 5B) as well as the Cespace by Aesculap (see Fig. 5D) show good radiographic contrast even in the region of the lower cervical spine. The carbonium spacer by AcroMed (see Fig. 5C) has three tantalum radiographic markers enclosed in the carbonium. These markers may ensure the safe localization of the implant in the upper and middle cervical spine; in the region of the lower cervical spine, however, the operator has difficulties in seeing the tantalum markers because of insufficient contrast, even with the best possible radiologic technology. In our opinion, this increases the risk of incorrect positioning of the AcroMed spacer, especially in the lower cervical spine, with possible compression of the spinal cord.

Exactly the opposite was found with regard to the artifacts produced in postoperative CT and/or MRI examinations. There, the carbonium spacer by AcroMed produces hardly any artifacts. Biologic structures such as the spinal cord at the level of the spacer are visible with enough contrast to keep them assessable through CT and/or MRI regardless of the implant. Conversely, with each of the titanium spacers, an assessment of the neighboring biologic structures during postoperative CT and/or MRI is hampered by artifacts superimposed on the images.

A correction of the kyphosis of the cervical spine can be performed easily with any of the wedge-shaped implants supplied by the four manufacturers. The Weber cage offers the largest support surface of the four models, followed, in order, by the Cespace cage, the Intromed cage, and the AcroMed cage with the smallest support surface. This finding explains, in our opinion, the higher incidence of penetrations into the base and/or cover plate of the adjacent vertebrae observed with the AcroMed spacer. It does not necessarily imply a worse clinical outcome or no improvement of the clinical symptoms after the operation, however. Only 2 of the 23 patients (9%) who suffered penetration of the interponate into the base and/or cover plate of the adjacent vertebrae had to undergo operative revision.

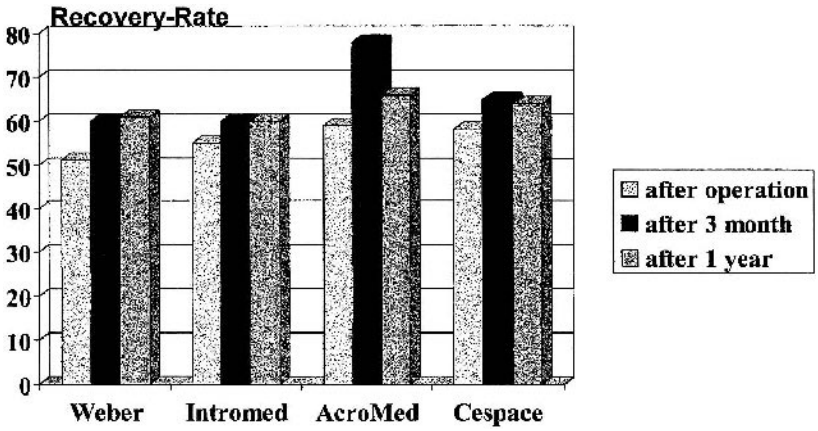

FIG. 4. Improvement of clinical symptoms in terms of recovery rate.

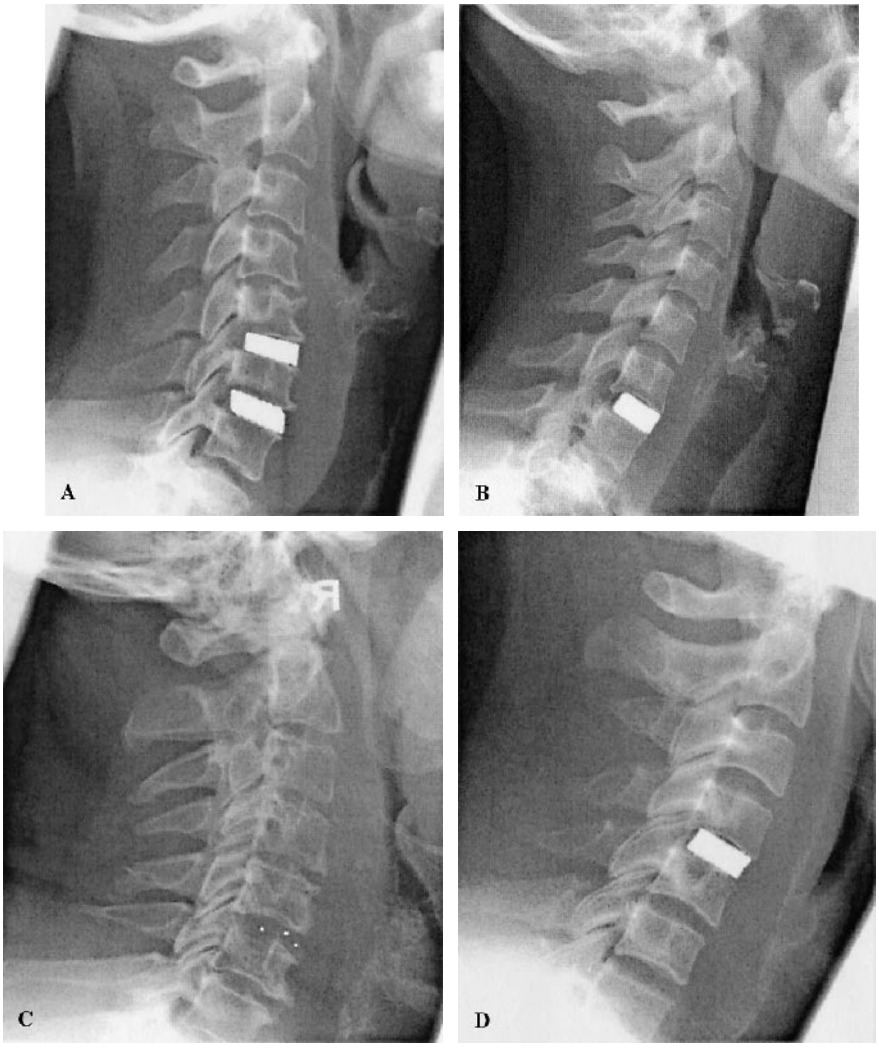

FIG. 5. Radiographic contrast of (**A**) Weber, (**B**) Intromed, (**C**) AcroMed, and (**D**) Cespace spacers.

The operations were carried out by four operators with comparable levels of experience. The assessment by the operators is summarized in Table 2. Overall, the Weber spacer and the Cespace by Aesculap showed some advantages compared with the Intromed and AcroMed cages, although the latter two are still suitable for ventral spondylodesis at the cervical spine. The purchase prices of the individual spacers are a matter of negotiation and depend on the quantities of implants required per year. Therefore, we can only quote guide prices. The Weber cage is priced at about 280 euros without HAC coating and at about 380 euros with HAC coating. The Intromed implant costs about 200 euros, the AcroMed spacer about 450 euros, and Aesculap Cespace about 350 euros.

TABLE 2. *Assessment of intervertebral disc spacers*

Assessment criteria	Weber	Intromed	AcroMed	Cespace
Material	Titanium	Titanium	Carbonium	Titanium
Support surface	+++	++	−	++
Anatomically adapted wedge shape for physiological lordosis	+	++	++	++
X-ray contrast	++	++	−	++
Handling	++	++	++	+
Penetration	+	−−	−	+
Price	+	+++	−−−	+

Advantages + to +++; drawbacks − to −−−.

DISCUSSION

Access to the cervical spine is achieved from anterior, posterior, and posterolateral approaches, respectively. Operations from the front are the easiest to perform in terms of operative technique.[5] The need for a spondylodesis is a subject of controversial discussion, as is the

necessity of the intraoperative opening of the posterior longitudinal ligament. Further problems arise when having to choose the implant for the ventral fusion.[1] In 1958, Smith and Robinson[6] reported that ventral procedures are characterized by a lower morbidity than a laminectomy or foraminal decompression. Among the possible complications involved in the surgical treatment of degenerative disorders of the cervical spine through ventral access followed by a spondylodesis using autologous bone grafts, problems at the graft removal site on the iliac crest are predominant.[1,5] This finding is independent of the choice of surgical method, be it the method according to Cloward[7] or Smith and Robinson.[6] Because there is no evidence for autologous implants being superior in principle, one has to consider alternatives to bone grafts from the iliac crest, by which means the perioperative and postoperative comfort of the patient is improved significantly. Such alternatives exist in the form of various implants.

Implants for Spondylodesis of the Cervical Spine

In 2001, Schröder and Wassmann[8] performed an analysis commissioned by the German Association of Neurosurgery on fusion materials after a ventral discectomy of the cervical spine. One hundred clinics in Germany, with 8,608 spondylodeses at the cervical spine over the report period, took part in that study. Forty percent of the ventral fusions were carried out using polymethyl methacrylate (PMMA), also known as Palacos; 27% of each were performed with bone grafts or titanium spacers, respectively, 5% with carbonium cages or carbon fiber–reinforced polyether etherketon (PEEK), and 1% without using any fusion materials. Material breakage was observed in 33 cases (0.53% per year) with bone grafts, in 13 cases (0.15% per year) with PMMA, in 1 case (0.05% per year) with carbonium cages, and in no case with titanium spacers. Displacements of the spacer are reported in 32 cases (0.73% per year) for bone, in 66 cases (0.7% per year) for PMMA, in 20 cases (0.37% per year) for titanium spacers, and in 4 cases (0.33% per year) for carbonium cages. On the whole, PMMA is the construct most commonly used in Germany after the removal of the cervical disc. A prospective randomized study on the scientific assessment of the advantages and drawbacks of each procedure was undertaken by the German Association of Neurosurgery in 2002.[8]

Polymethyl Methacrylate

Roosen and Grote[9] presented their results obtained with 392 patients who underwent a ventral cervical fusion by means of a PMMA construct implanted at 478 levels. Of these 392 patients, 321 were evaluated. For patients with a cervical myelopathy, a good clinical outcome occurred in 45% of the cases; for radicular and discogenic syndromes, the number of good clinical outcomes was 73%. After the use of autologous bone grafts, the examiners found signs of instability in 50% more cases than with the use of bone cement. The assessment of the segment height, the graft position, the width of the intervertebral foramina, and the configuration of the spine was monitored by means of radiologic examination. In addition to this, signs of deformity and the extent of bone growth were monitored. The authors state that all these observations are parameters from which no conclusions can be drawn concerning the clinical outcome of the respective complaint. The prognosis for the illness was determined exclusively by the severity of the primary disease. Böker et al.[2] investigated the radiologic long-term results after ventral cervical fusion with PMMA for 83 patients in a retrospective study with a follow-up period of between 15 and 20 years. The configuration of the spine changed in 17 cases, showing an increased lordosis or a shift from kyphosis to lordosis. In 10 cases, a distinct kyphosis developed. Osseous fusion was achieved in more than 90% of the cases. In 5 cases, anterior osseous fusion was completely absent. The dorsal bone bridge was absent in none of the cases. Conversely, maximum ossification was observed at the rear of the implant in 37 cases and at the front of the implant in 14 cases. The radiologic results for patients who had received multisegmental surgery were better than for those treated by monosegmental surgery. No indication was found of the development of a neoplastic disorder. In 1993, Shono et al.[10] carried out a biomechanical analysis with PMMA interponates in animals. In 8 of the 12 flexion/extension tests performed, a deformity in the border region between bone and bone cement was registered when using PMMA. In a prospective randomized trial, van den Bent et al.[11] investigated the anterior cervical fusion with and without PMMA. Between April 1986 and April 1990, patients showing a radicular syndrome and a radiologically confirmed disc prolapse were included in the study covering a follow-up period of 2 years. The follow-up involved clinical and radiologic examinations. In 70% of the cases with PMMA and for 77% of the patients who had not undergone fusion, the outcome was judged to be good. Overall, a significantly lower osseous fusion rate as well as a high incidence of penetration into the adjacent vertebral bodies was observed when PMMA had been implanted. Therefore, the authors asserted that implantation of PMMA should not be recommended.

Titanium Spacer

The first results in 15 patients who underwent anterior fusion using a titanium spacer were published by Kaden et al.[12] in 1995, who reported good clinical results. With the implant, collapses or dislocations were completely absent. The formation of bone bridges on both the ventral and dorsal sides of the implant was observed, provided that the diameter of the titanium element was smaller than that of the adjacent vertebral body. Profeta et al.[13] reported their experience with the Novus titanium cage by Sofamor Danek (Düsseldorf, Germany), comparing results from 58 patients with autologous bone grafts and 52 patients with an implanted titanium cage. The authors came to the conclusion that a considerable reduction in the pain suffered by patients, a shorter stay in hospital, an earlier return to work, and high stability in the fusion region were the main advantages of the titanium implant. Complications such as a collapse or dislocation of the spacer did not occur. Lange et al.[14] reported their clinical experience with the RABEA titanium cage (Signus GmbH, Alzenau, Germany). The authors had operated on 63 patients suffering radicular (43 cases) and myelopathic (20 cases) symptoms. The average follow-up period was 8 months. Excellent or good outcomes of the treatment were registered for 50 patients (79%), a satisfactory outcome for 10 patients (16%), and a poor clinical outcome for 3 patients (5%). Two patients (3%) had to undergo an operative revision because of a ventral dislocation of the titanium spacer in the first case and a radicular compression in the second case. Between 1995 and 1998, Matgé and Leclercq[15] operated on 138 patients with degenerative disc prolapses, carrying out the fusion with the BAK titanium cage by Spinotech (Sulzer Medica, Munich, Germany). The postoperative checkups took place after 6 and 12 months. After 1 year, a 1-mm to 2-mm penetration of the titanium spacer into the adjacent vertebrae was observed, which was of no consequence for the clinical outcome. CT examinations showed a fusion rate of 90% after 6 months and a fusion rate of 100% after 12 months. An early revision operation was necessary in 2 patients because of the migration of the titanium cage into the adjacent vertebral body in the first patient and because of vertebral calcification with massive kyphosis in the second patient. The authors cite the immediate postoperative stability and absence of complications experienced after bone grafting as the main advantages of spondylodesis using titanium cages.[15] Research by Matsuno et al.[16] confirmed the biocompatibility and osteogenesis of titanium as an implant material.

Hydroxylapatite

Böker et al.[2] reported on a HAC for fusion. This material was predominantly used in dental surgery before it was applied for plastic covering of skull defects. HAC is chemically identical to inorganic bone substance and is described as biocompatible, nontoxic, nonantigenic, and osteotropic. Because HAC is too porous to be used as the sole material for an implant, it is presently used as a surface coating on ceramics or titanium elements. In a study with dogs used as test animals, Cook et al.[17] investigated the behavior of implanted HAC. Radiologic examinations showed an increasing incorporation of the implanted material. No significant difference in rotation was found. In terms of tilting, the HAC spacer was significantly stiffer than autogenous bone implants after 6 weeks. There was no histologic evidence for bone apposition or for the bone growing into the HAC implant. The authors draw the conclusion that HAC represents an alternative to autologous implants.

Carbonium Spacers

Experience with carbon fiber cages is reported by Brooke et al.[18] The carbon fibers are embedded in a polyether ketone–ether ketone matrix. This type of spacer features indentations, by which means it is braced to the adjacent vertebral body. For radiographic contrast, a radiographic opaque tantalum marker was incorporated. Osseous fusion was diagnosed radiologically in all 19 cases studied. Therefore, the authors debate the need for introducing autologous bone material (spongiosa) into the cavity of the carbonium cage, because the osseous fusion obviously proceeds from the base and cover plates. Bartels et al.[19] investigated the height of the intervertebral foramina after a ventral cervical fusion through the implantation of a carbon fiber cage. The imaging diagnostics were carried out by way of thin-layer CT on the day before the operation, the first day after the operation, and after 1 year. The major finding was a significant postoperative increase in the height of the foramina. It was further shown that the wedge-shaped implants were able to improve the cervical spine lordosis. In a critical survey of the relevant literature, van Limbeek et al.[20] came to the conclusion that none of the treatment methods constitutes a "gold standard." Of eight randomized and controlled trials, only three proved to be of sufficient quality. The same results were presented by Wiegfield and Nelson[21] in their review article, in which they assessed 42 clinical studies and 10 laboratory investigations. Only four of the clinical projects met the

requirements of a randomized trial and presented independent findings.

Primary Stability

The calcification characteristics of the implant depend on the condition of the base and cover plates in the area of fusion. In an experimental study, Lim et al.[22] arrived at the result that the end plates should be preserved as far as possible during surgical preparation so as to prevent the implants from caving in. In another experimental study, Hasegawa et al.[23] looked at the effects on bone density of the forces between the vertebral body and a titanium cage. The result was that a titanium cage of a large diameter allows for a significant increase in the force at the interface between the implant and the end plate. The importance of the bone density is underlined by the positive correlation between the force and bone density, implying that the finding of massive osteoporosis should lead to a different surgical approach. Lange et al.[14] reported that the diagnosis of osteoporosis was eventually followed by surgical revision, necessitated by a ventral dislocation or radicular compression, in 3% of all cases. Kaden et al.[24] also described two cases of an unsatisfactory outcome for patients with osteoporosis. The more stable a segment is immediately after the operation, the more likely is an osseous fusion. In a comparative experiment using a sheep model, Kandziora et al.[25] tested eight cervical fusion cages of three existing designs: screw, box, and cylinder. The authors arrived at the conclusion that cylinder implants better control extension and sideward tilt than cages of a screw design. The issue of primary stability was also investigated by Eysel et al.,[26] who found, when using the operation method according to Cloward[7] (BAK cage), progressive calcification caused by the disintegration of the base and cover plates in the course of the operation. According to Wilke et al.[27], the AcroMed implant showed the strongest stabilizing effect for sideward tilting, flexion, and rotation, followed by the Wing spacer (Quierschied, Germany) and the BAK/C cage. The smaller the surface area, the higher is the pressure acting on the surface (p [pressure] = F [force] per A [area]). In this study, the largest support area is clearly offered by the Weber spacer, followed by the Cespace, the Intromed, and the AcroMed. This is reflected in the calcification rates emerging from our prospective data. Another point to be considered with regard to implantation is the individual size of the vertebral body of the patient to be operated on. All four cages are available in various sizes. The Cespace and Intromed spacers are offered straight shaped (0°) and wedge shaped (5°). The AcroMed cage can be ordered with a slope of 7°, and the Weber implant is available slightly wedge shaped (2°–3°).

Radiographic Contrast

The bearing of the spine and the position of the implant in our patients were radiologically monitored immediately after surgery, after 3 months, and after 1 year. The titanium spacers show the advantage of strong radiographic contrast. Although the AcroMed spacer is made radiographically visible by its tantalum marker, visual assessment turned out to be difficult, especially in the region of the lower cervical spine. Biederer et al.[28] carried out control examinations with lateral radiologic imaging and function monitoring of the cervical spine before the operation and 4 days, 6 weeks, and 7 months after a cervical spondylodesis by means of implantation of titanium spacers. Immediately after the operation, an extension of the intervertebral space and a slight lordosis were found. Within the first 6 months, patients suffered a loss of distraction height and rekyphoses developed, caused by the implant sinking into the end plates to a small degree. A partial infraction of the spacers into the neighboring base and/or cover plates was detected in 10 of the 42 segments (24%) operated on. Brooke et al.[18] did not find any dislocation or cage movement with carbonium implants when examining lateral radiographic images. The cage itself could not be made visible by radiographic methods. An essential advantage of spacer implantation is the restoration of the heights of the intervertebral space and foramina, ensuring decompression of the nerve roots. Furthermore, the lordosis of the cervical spine is modified in an anatomical manner. This is significantly proven in a study by Bartels et al.[19] Another issue is the assessment of the osseous fusion after the ventral operation and cage implantation. Most authors consider the segment to be fused as soon as there is no detectable loosening of the implant during function tests. The presence of osseous bridges between adjacent vertebrae and the absence of bright lines at the interface between the implant and vertebral body serve as further criteria. Osseous fusion within the cage cannot be detected by radiographic imaging of the cervical spine. Levi et al.[29] looked at titanium and carbonium spacers with tantalum markings in the cervical spine and found that titanium elements are better examined using CT, whereas tantalum produces fewer artifacts in images produced by MRI.

Outcome

Eighty-five percent of our patients showed an improvement in their symptoms 1 year after the operation.

These results are confirmed in a review article by Grote et al.[30], in which an improvement rate of 60% to 94% is cited. The operations were carried out by four operators with comparable experience. Lunsford et al.[31] looked for correlations between outcomes and individual operators, but they could not find any significant differences. In a systematic literature survey, van Limbeek et al.[20] arrived at the conclusion that none of the existing operating methods can be defined as a gold standard. We agree with this finding in the sense that the method of operation has to be chosen according to the symptoms, radiologic findings, and surgical experience of the operating physician. When using an implant, however, the implant properties and economic factors are among the criteria to be considered.

CONCLUSIONS

The spacer offered by Weber features a large support surface and good intraoperative handling, but the lordosis angle is not always sufficient. Without an HAC coating, the compact implant does not allow sufficient bone fusion; the optimum achievable in this way is a ventral or dorsal osseous enclosure. Without a biocompatible coating, however, this spacer represents a cost-efficient solution. The version of the Weber cage with an HAC coating may be expensive, but it is an extremely biocompatible and osteotropic spacer.

The spacer supplied by Intromed has a large enough support surface and offers good intraoperative handling as well as a sufficient lordosis angle. This spacer represents the best cost/performance ratio of all the interponates that we evaluated. Its downside, however, is the relatively sharp edges of the implant, which is probably one of the reasons for the excessive incidence of penetration into the base and/or end plates of the adjacent vertebral bodies.

The AcroMed spacer was the only carbonium cage evaluated by us. It was primarily offered as a monoimplant, with its filling up with spongiosa said to be unnecessary. This spacer showed good intraoperative handling and a physiologic lordosis angle. Its drawbacks are a small support surface causing penetration of the base and/or end plates of the neighboring vertebral bodies, insufficient radiographic contrast during implantation (especially in the lower cervical spine), and its high purchase price. Because of these disadvantages, we would not currently use the AcroMed cage for spondylodesis of the cervical spine.

The Cespace by Aesculap features a sufficient support area and a physiologic lordosis angle, satisfactory intraoperative handling, and the lowest tendency toward calcification of all the spacers that we examined. The Cespace is the only one among the spacers that we evaluated to feature a titanium ring for fastening the cage to the base and cover plates of the adjacent vertebrae. This may make it slightly more difficult to get used to its intraoperative handling, but it prevents any dislocation or luxation of the implant. These positive application features and its moderate price currently make the Cespace our spacer of choice.

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