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Vertebral body replacement system Synex in unstable burst fractures of the thoracic and lumbar spine

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Abstract A prospective longitudinal study was performed to evaluate the vertebral body replacement system Synex associated with posterior fixation in unstable burst fractures of the lumbar and thoracic spine. Within 24 months, we treated 28 patients (average age, 41 years; range, 22–64 years; 14 women, 14 men) with acute unstable burst fractures without osteoporosis of the thoracolumbar region (n=16) and the thoracic (n=3) as well as the lumbar (n=9) spine in two stages (primary dorsal transpedicular stabilization and secondary vertebral body replacement). The complications were analyzed and the postoperative follow-up result was evaluated regarding stability, bone fusion, correction loss, pain and neurological status. One patient showed a transient irritation of the lumbosacral plexus and one patient had a superficial wound infection (complication rate, 7.1%). At the follow-up examination (mean follow-up, 13 months) only in two cases a minimal loss of correction (<5°) was measured. Radiologically, 27 patients showed secure bone fusions and all patients had stability of the osteosynthesis. Most of the patients stated no or just slight pain at follow-up. Only two patients with pain to a medium degree had to take painkillers. The vertebral body replacement system Synex seems to be a good alternative for vertebral body replacement in unstable burst fractures of the thoracic and lumbar spine since at present follow-up it shows a high rate of bone fusion and minimal loss of correction.

Key words Unstable burst fractures · Thoracic spine · Lumbar spine · Vertebral body replacement

Introduction

Unstable vertebral fractures, especially complete and incomplete burst fractures of the thoracic and lumbar spine without neurological deficits, can be treated in various ways. The treatment concepts range from conservative therapy via dorsal stabilization with only an internal fixator to complex dorsal and ventral combinatory surgical treatments [1–9]. Because of the intrusion of disc tissue into the fracture gap in most burst fractures, the injury of the disc tissue and the loss of height of the vertebral body, I favor a two-step treatment concept. In this treatment concept, the burst fracture is first stabilized transpedicularly. The vertebral body is then replaced with the Synex vertebral body replacement system. Synex is a titanium implant designed for the reconstruction of the anterior column in cases of vertebral body destruction (e.g. post-traumatic kyphosis, tumor, spondylitis) [10, 11]. The biomechanical properties of this vertebral body replacement system have been subjected to comprehensive testing [10]. Clinical investigations, especially radiologi-

cal investigations on the treatment of burst fractures of the thoracic and lumbar spine, have been performed retrospectively on a heterogeneous group of patients, some of whom had additional ventrolateral stabilization [11]. In the present study, the efficiency of this vertebral body replacement system and the occurrence of associated complications were investigated prospectively in a group of consecutive patients.

Patients and methods

The study enrolled consecutive patients older than 20 years with acute traumatic burst fractures of a single vertebra. Specifically, they had unstable complete and incomplete burst fractures of the thoracic (T5-T11) or thoracolumbar (T12-L1) region or lumbar spine (L2-L5) (Magerl A 3.1 and more complex injury pattern or Magerl B or C injuries in combination with burst fractures). Patients were excluded if they had bone metabolism deficiencies, especially osteoporosis. Over a 24-month period, 28 patients (14 women) of mean age 41 years (range, 22–68 years) were enrolled.

Surgical technique and characteristics of the device

The vertebral body replacement system Synex (Synthes, Umkirch, Germany) is a pre-assembled, distractible vertebral replacement made of titanium with a locking mechanism (Fig. 1a, b). It is available in different sizes (different sectional diameters and distraction lengths) and with different inclination angles. The vertebral replacement is introduced in a neutral state and is then extended (Fig. 1c). If the result is not satisfactory, the extended implant can be reset to the neutral state with an unlocking instrument. The endplates of the implant must completely touch the endplates of the adjacent vertebrae. Before implantation, the hollow cylinder is filled with autologous bone graft from the resected vertebral body and after extension the resulting hollow space is again filled with bone graft material.

In this study, bone from the resected vertebral body was used. We attached additional autologous bone graft from the resected vertebral body lateral to the vertebral body replacement to ensure secure bone fusion. Operations were carried out in two stages. First, a dorsal stabilization with an internal fixator was performed. After a period of 7–10 days, complete or incomplete corporectomy was carried out. The vertebral body was then replaced from ventral (retroperitoneal, combination retroperitoneal-transthoracic or transthoracic depending on the spine section) in a minimally invasive procedure using the Synframe system (Synthes, Umkirch, Germany). A dorsal decompression of the spinal channel was performed on three patients using hemilaminectomy and on one patient using laminectomy.

Examination methods

All patients were examined radiologically and clinically. The fracture type according to a modified Magerl classification [12] was determined by plain radiography and computed tomography (CT). Neurological status was documented preoperatively, postoperatively, and in follow-up examinations according to the classification system of the American Spinal Injury Association (ASIA) [13]. On this scale, grade A indicates sensorimotor paraplegia, grade B refers to retained sensory function, in grade C some motor function is retained, in grade D motor function and practical use are retained, and grade E indicates normal function. Stability, bone structure (lateral and ventral bone clasp between base plate and cover plate), and correction loss were analyzed using radiographs and X-ray movement pictures. The kyphosis angle was measured on lateral radiographs in the neutral position before and after stabilization and at the time of the follow-up examination. The kyphosis angle (Cobb angle) was

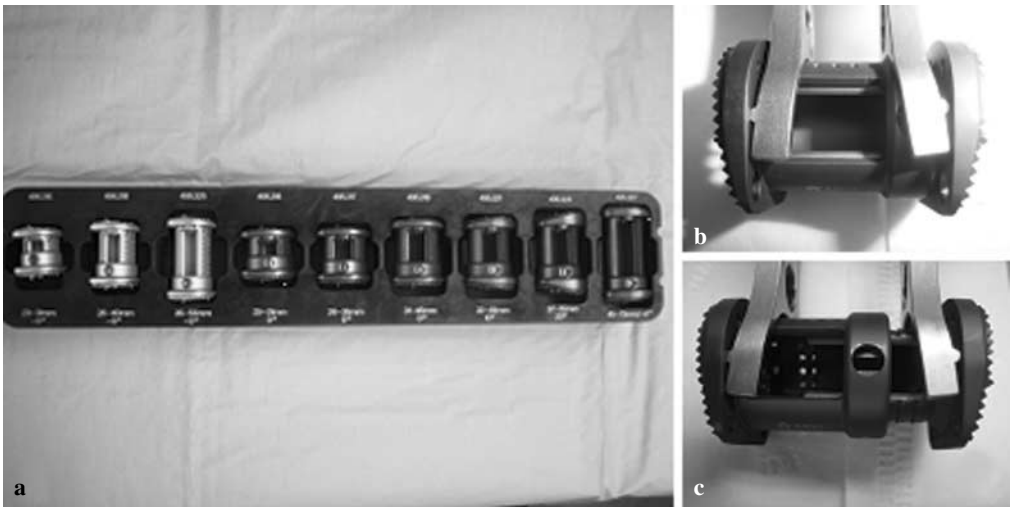

Fig. 1a-c *Synex vertebral body replacement system (Synthes, Umkirch, Germany).* **a** Operating kit with different sizes. **b** Close-up of the neutral state. **c** Extended state

Table 1 Clinical characteristics of 28 patients with vertebral fractures, before and after vertebral body replacement and at last follow-up

Patient	Age, years	Sex	Fracture level	Magerl type	ASIA grade		Kyphosis, degrees			Complications	Follow-up, months	Pain score[a]	BF	LC
					Pre	Follow-up	Pre	Post	Follow-up					
1	53	M	L 1	A 3.3	C	D	10	3	7	No	24	2	Yes	Yes
2	68	M	T 12	A 3.3	C	C	5	3	3	No	14	1	Yes	No
3	23	F	L 3	A 3.3	C	C	0	-6	-6	No	12	0	Yes	No
4	35	M	T 12	A 3.2	E	E	15	3	3	No	18	0	Yes	No
5	43	F	L 5	B 3.3	C	C	-20	-22	-22	Plexus irritation	17	0	Yes	No
6	39	M	T 6	B 3.2	E	E	10	9	9	Superficial wound infection	12	0	Yes	No
7	64	F	T 12	A 3.3	E	E	10	3	3	No	20	1	Yes	No
8	45	F	L 3	A 3.3	E	E	0	-8	-8	No	16	0	Yes	No
9	24	M	L 1	A 3.3	E	E	5	0	0	No	10	0	Yes	No
10	53	M	L 3	C 3.2	E	E	5	-5	-5	No	10	1	Yes	No
11	22	M	L 4	A 3.2	E	E	5	-10	-10	No	12	0	Yes	No
12	57	F	T 12	B 2.3	E	E	25	5	15	No	10	0	Yes	No
13	34	M	L 2	A 3.1	E	E	0	-2	-2	No	10	0	Yes	No
14	42	M	L 2	A 3.2	E	E	10	5	5	No	12	1	Yes	No
15	40	M	L 1	A 3.2	E	E	15	5	5	No	12	0	Yes	No
16	65	M	T 12	A 3.3	A	A	8	5	5	No	12	0	Yes	No
17	33	M	T 8	C 3.2	A	A	18	10	10	No	18	0	Yes	No
18	42	M	L 1	A 3.3	C	D	8	8	13	No	19	2	Yes	Yes
19	20	F	L 2	A 3.2	E	E	3	-4	-4	No	12	0	Yes	No
20	47	F	L 1	A 3.2	E	E	10	5	5	No	16	1	Yes	No
21	39	F	L 1	A 3.3	C	D	5	2	2	No	10	0	Yes	No
22	65	F	L 1	A 3.3	D	D	15	4	4	No	12	1	Yes	No
23	22	F	L 1	A 3.2	E	E	5	0	0	No	12	0	Yes	No
24	32	F	L 1	A 3.2	E	E	7	3	3	No	12	1	Yes	No
25	47	M	T 12	A 3.1	E	E	5	0	0	No	12	1	Yes	No
26	40	F	L 2	A 3.3	D	E	2	0	0	No	12	0	Yes	No
27	44	F	T 9	C 3.2	E	E	7	5	5	No	8	0	No	No
28	22	F	L 1	A 2.3	E	E	10	3	3	No	10	0	Yes	No

Pre, pre-operative; *Post*, postoperative; *BF*, bone fusion; *LC*, loss of correction, [a]On a 4-point verbal rating scale

measured from the superior endplate of the superior adjacent vertebral body to the inferior endplate of the inferior adjacent vertebral body [7, 14, 15]. Fusion was investigated on CT scans with biplanar reconstruction. A bone bridge in the cage or a lateral or ventral continuous bone clasp was assumed to be a secure bone fusion. Pain intensity was documented using the 4-point verbal rating scale (VRS-4) as follows: grade 0, no pain; grade 1, minimal pain, pain only during intensive physical exercise; grade 2, medium pain, pain during easy exercise; and grade 3, permanent pain [16]. Complications of the vertebral body replacement operation were also analyzed.

Results

The study enrolled 28 consecutive patients with unstable complete or incomplete burst fractures of a single vertebra (Table 1). Altogether, there were 16 fractures of the thoracolumbar spine, 3 fractures of the thoracic spine, and 9 fractures of the lumbar spine (Table 1). According to the modified Magerl classification, the fractures were classified as follows:

- Fracture type A, *n*=22 (type A 3.1, *n*=2; type A 3.2, *n*=8; type A 3.3, *n*=12)
- Fracture type B in combination with a burst fracture, *n*=3
- Fracture type C in combination with a burst fracture, *n*=3

At study entry, 18 patients had no neurological deficits (ASIA grade E), eight patients had incomplete paraplegia (grades C and D) and two had complete paraplegia (grade A).

There were no instances of hardware failure of the vertebral body replacement system. The average time between operation and follow-up examination was 13 months (range, 8–24 months). An average correction loss under 1° was found. In only two cases was a minimal loss of correction (<5°) measured. At the follow-up examination, secure bone fusions were demonstrated radiologically in 27 patients (96%). Lateral and ventral clasp formation visible on plain radiographs was taken to indicate bone fusion (Fig. 2). Alternative indications were a continuous bone structure in the cage or lateral or ventral clasp formation visible on CT. For all patients, functional images in both flexed and extended positions showed the region to be stable. Most of the patients reported no or only slight pain at follow-up. Only two patients with pain to a medium degree had to take analgesics. The remaining patients were free of pain or felt only minor pain during or after hard physical exercise. Two patients (7.1%) had complications: one patient developed a superficial wound infection and the other developed an irritation of the lumbosacral plexus. Neurological losses were not observed at the follow-up examination.

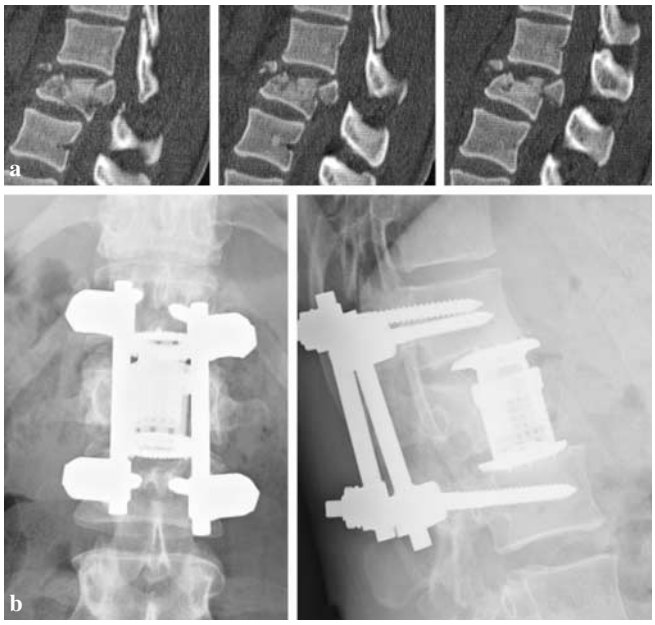

Fig. 2 Preoperative CT scan reconstruction of a 39-year-old woman (case 21) with an unstable burst fracture at L1 with incomplete paraplegia. (**a**) Postoperative anteroposterior (*left*) and lateral (*right*) radiographs after vertebral body replacement with synex and transpedicular stabilization with USS internal fizator (Synthes Umkirch, Germany) (**b**)

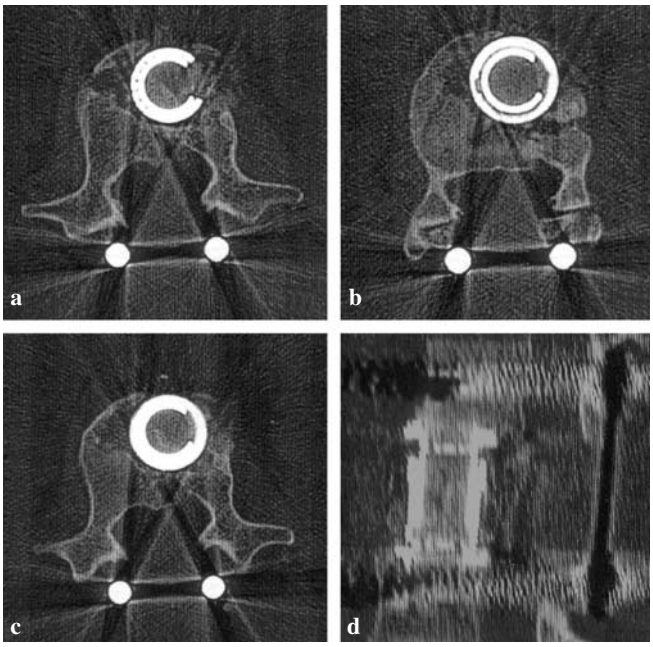

Fig. 3 Continuous bone structure in the cage visible on computed tomography scans (**a-c**) and reconstructions (**d**)

Discussion

A number of methods of replacing the resected vertebral body have been described. The goal in all cases is to cre-

ate a solid and stable substitute that restores the alignment of the spine. Different materials and design variations can be considered for vertebral body replacement. Autologous bone graft (pelvic, tibial, fibular, rib or femoral bone), ceramics, carbon fiber, plastics, and metals have all been used for vertebral body replacements [1, 9, 11, 15, 17–19]. The most common and versatile material for vertebral body replacement has been polymethylmetacrylate (PMMA). However, problems encountered with PMMA vertebral body replacements include displacement of the implant and primary inhibition of bone fusion.

The Polster-Brinkmann screw, which is made of implant steel and can be extended by means of a thread, is easy to incorporate into the defect after corporectomy. It allows the straightening of the ventral spine [20]. A disadvantage of this system is that it can only be used with PMMA and not with bone. Furthermore, the load-carrying surface is small, resulting in lower primary stability of the spine.

The design of Gerdinger and Hipp's vertebral body replacement was similar [21]. The risk of migration into adjacent vertebral bodies was decreased by the use of broader base plates and cover plates. The Harms cage (titanium mesh cylinder) represents a combination of bone and metallic support. It is made of titanium, has a broad load-carrying surface, and can be adapted to the height of the defect [22, 30]. The cavity is commonly filled with bone or more rarely with PMMA. However it offers no opportunity for ventral straightening. A design was therefore required which could be extended in situ and filled with bone. The Synex vertebral body replacement system presented in this paper can be adapted to the spine and can be filled with autologous bone. This distractible implant can be used for primary or secondary tumors of the thoracic and lumbar spine, fractures of thoracic and lumbar vertebral bodies, and for degenerative or infectious diseases that require the resection of a vertebral body. The biomechanical studies of Knop et al. [10] indicated good stability in combination with an internal fixator. The stability of this system was better than that of the combination of a Harms cage and an internal fixator. In addition, further biomechanical studies on other distractible vertebral body replacement systems revealed that the stretching of the cage or vertebral body device after implantation positively influenced the primary stability. The application of a distraction force had the same effect [10, 23].

Based on these biomechanical studies, a good postoperative radiological result was expected with a small postoperative correction loss or more rarely a loosening of the implant. Clinical results, and especially radiological results, have not yet been analyzed with respect to bone fusion rates. The treatment results observed between 8 and 24 months after the implantation of the Synex showed that these vertebral body replacements allow good bone fusion. Secure bone fusion, as indicated by lateral and ventral clasp formation or a definite fusion of the cavity of the distraction element, was ascertained from radiographs and computed tomograms. At follow-up, fusion had occurred in 96% of patients. This fusion rate is comparable to the values reported in the literature, which lie between 67% and 99%, and is considered to be good [24]. The opportunities for comparison with results reported in the literature are limited owing to the use of different follow-up examination techniques and criteria for bone fusion. A direct comparison of fusion rates is therefore not possible. According to the definition given by McAfee [19], bone fusion can only be said to have occurred if there is a radiologically proven continuous bone bridge from end-plate to end-plate inside the cage, or bone around the implant (Fig. 3). These criteria were used in this study. The radiological results are also reflected in good clinical results, especially the absence of pain. The majority of the patients was totally or mostly pain free. This was judged to be a good treatment result overall.

In summary, the average correction loss in most patients was under 1°. This is better than many of the results reported in the literature. For example, a correction loss of 3.6°–11° was found after dorsal transpedicular stabilization with an internal fixator and posterior intercorporal fusion [18, 25–27]. For anterior stabilization alone, correction losses between 5° and 7° have been reported [1, 3, 8, 9, 26]. McDonough et al. [7] reported a median loss of correction of 2° after anterior corpectomy and Z-plate fixation. Especially in cases involving the anterior column, the question of how these fractures should be approached and stabilized (anteriorly, posteriorly, or combined anteroposteriorly) is controversial. To date, the dorsal transpedicular stabilization of unstable fractures of the thoracic or lumbar spine with an internal fixator system is still the standard method for surgical treatment [18, 26]. One argument in favor of the solely dorsal approach is the single-operation, one-side procedure, which is less invasive. However, there are currently many authors who favor solely ventral or combined dorsoventral approaches for the treatment of complete and incomplete burst fractures [1, 3, 6, 8]. These approaches enable the anterior spine to bear weight immediately while remaining stable and ensure secure fusion without correction loss [10]. They are associated with longer operation times, greater stress for the patient, and higher complication rates for the operation. However, they afford better treatment results in terms of a lower rate of pseudarthrosis, a higher fusion rate, lower correction losses, and better clinical postoperative treatment results, e.g. freedom from pain [18]. The positive clinical and radiological results of the present work confirm this. Only two patients complained of permanent pain (grade 2, medium pain). The remaining patients were either

free from pain or experienced pain only during or after hard physical exercise. The treatment result can thus be regarded as positive with respect to quality of life. The complication rate among the patients was 7.1%. One patient developed a superficial wound infection, and the other had irritation of the lumbosacral plexus. Neurological breakdowns were not found at the time of the follow-up examination. Compared with findings in the literature, the complication rate is similar or better. Complication rates reported in the literature for ventral approaches are between 14% and 38% [1, 4, 9, 18, 28, 29]. With reference to the article of Knop et al. [10] from 2002, the complication rate is good, although a one-institute series cannot be subjected to detailed comparison with a prospective multi-center study. Knop et al. [10] reported an overall complication rate of 14% (complications requiring revision, 8.1%; complications not requiring revision, 5.6%). In conclusion, the vertebral body replacement system Synex seems to be suitable for the treatment of unstable burst fractures of the thoracic and lumbar spine. Both clinical and radiological results are positive and the occurrence of secondary dislocation and correction loss is minimal.

References

1. Been HO (1991) Anterior decompression and stabilization of thoracolumbar burst fractures by the use of the Slot-Zielke device. Spine 16:70–77
2. Esses SI, Botsford DJ, Kostuik JP (1990) Evaluation of surgical treatment for burst fractures. Spine 15:667–673
3. Feil J, Wörsdorfer O (1990) Ventral Stabilisation of the thoracic and lumbar spine. Chirurg 63:856–865 (in German)
4. Fountain S (1979) A single-stage combined surgical approach for vertebral resection. J Bone Joint Surg Am 61:1011–1017
5. Haas N, Blauth M, Tscherne H (1996) Anterior plating in thoracolumbar spine unstable burst fractures in the absence of neurological deficits. Spine 21:620–625
6. Kaneda K, Taneichi H, Abumi K, Hashimoto T (1997) Anterior decompression and stabilization with the Kaneda device for thoracolumbar fractures associated with neurological deficits. J Bone Joint Surg Am 79:69–83
7. McDonough PW, Davis R, Tribus C, Zdelblick TA (2004) The management of acute thoracolumbar burst fractures with anterior corpectomy and Z-plate fixation. Spine 29:1901–1909
8. Miyakoshi N, Abe E, Shimada Y et al (1999) Anterior decompression with single segmental spinal interbody fusion for lumbar burst fracture. Spine 24:67–73
9. Van Loon JLM, Slot GH, Pavlov PW (1996) Anterior instrumentation of the spine in thoracic and thoracolumbar fractures. Spine 21:734–739
10. Knop C, Lange U, Bastian L, Blauth M (2000) Three-dimensional motion analysis with Synex. Comparative biomechanical test series with a new vertebral body replacement for the thoracolumbar spine. Eur Spine J 9:472–485
11. Vieweg U, Sölch O, Kalff R (2003) Vertebral body replacement system Synex in unstable burst fractures of the thoracic and lumbar spine – a retrospective study on 30 cases. Zentralbl Neurochir 64:58–64 (in German)
12. Magerl F, Aebi M, Gertzbein SD et al (1994) A comprehensive classification of thoracic and lumbar injuries. Eur Spine J 3:184–201
13. Stover LS, Apple DF, Donovan WH, Ditunno JF (1992) Standards for neurological and functional classification of spinal injuries. American Spinal Injury Association (ASIA), New York
14. Okuyama K, Abe E, Chiba M et al (1996) Outcome of anterior decompression and stabilization for thoracolumbar unstable burst fractures in the absence of neurologic deficits. Spine 21:620–625
15. Vieweg U, Kaden B, Schramm J (1996) Vertebral body replacement with a rib segment bloc in transthoracic procedures. Zentralbl Neurochir 57:136–142 (in German)
16. Downie WW, Leatham PLA, Rhind VM, Wright V (1978) Studies with pain rating scales. Ann Rheum Dis 37:378–381
17. Harrington KD (1981) The use of methylmethacrylate for vertebral body replacement and anterior stabilization of pathological fracture dislocations of the spine due to metastatic malignant disease. J Bone Joint Surg Am 63:36–46
18. Knop C, Bastian L, Lange et al (2002) Complications in surgical treatment of thoracolumbar injuries. Eur Spine J 11:214–226
19. McAfee PC (1991) Interbody fusion cages in reconstructive operations on the spine. J Bone Joint Surg Am 81:190–191
20. Polster J, Brinkmann P (1977) A vertebral body implant for use in palliative surgery of spinal tumors. Z Orthop 115:118–122 (in German)
21. Plötz W, Wicke-Wittenius S, Göbel WE et al (1995) Vertebral body replacement in palliative tumor treatment. Fortschr Med 113:437–440 (in German)
22. Rauzzino M, Shaffrey CI, Nockels RP et al (1999) Anterior lumbar fusion with titanium threated and interbody cages. Neurosurg Focus 7: article 7
22. McLain RF, Benson DR, Gertzbein GD (1999) Urgent surgical stabilization of spinal fractures in polytrauma patients. Spine 24:1646–1652
23. Kanziora F, Schnake KJ, Klostermann CK, Hass NP (2004) Vertebral body replacement in spine surgery. Unfallchirurg 107:354–371 (in German)
24. Thomsen K, Christensen FB, Eiskjaer SP et al (1999) The effect of pedicle screw instrumentation on functional outcome and fusion rates in posterolateral lumbar spinal fusion: a prospective, randomized clinical study. Spine 22:2813–2822

25. Aebi M, Etter C, Kehl T, Thalgott J (1987) Stabilization of the lower thoracic and lumbar spine with the internal spinal skeletal fixation system. Indications, techniques and first results of treatment. Spine 12:544–555
26. Knop C, Blauth M, Bastian L et al (1997) Fractures of the thoracolumbar spine. Late results of dorsal instrumentation and its consequences. Unfallchirurg 100:630–639 (in German)
27. Leferink VJM, Zimmerman KW, Veldhuis EFM et al (2001) Thoracolumbar spinal fractures - radiological results of transpedicular fixation combined with transpedicular cancellous bone graft and posterior fusion in 183 patients. Eur Spine J 10:517–523
28. Feil J, Wörsdorfer O (1992) Complications in surgical management of spinal injuries. Langenbecks Arch Chir Suppl Kongressbd 87:304–310 (in German)
29. McAfee PC, Bohlmann HH, Ducker T, Eismont FJ (1986) Failure of stabilization of the spine with methylmethacrylate - A retrospective analysis of twenty-four cases. J Bone Joint Surg Am 68:1145–1157
30. Bhat AL, Lowery GL, Sei A (1999) The use of titanium surgical mesh-bone graft composite in the anterior thoracic or lumbar spine after complete or partial corpectomy. Eur Spine J 8:304–309