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Vertebral body replacement with a bioglass-polyurethane composite in spine metastases – clinical, radiological and biomechanical results

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Abstract Metastatic spine lesions frequently require corpectomy in order to achieve decompression of the spinal cord and restoration of spinal stability. A variety of systems have been developed for vertebral body replacement. In patients with prolonged life expectancy due to an improvement of both systemic and local therapy, treatment results can be impaired by a loosening at the implant-bone interface or mechanical failure. Furthermore, early detection of a metastatic recurrence using sensitive imaging modalities like computed tomography (CT) and magnetic resonance imaging (MRI) is possible in these patients without artefact interference. The aim of our pilot study was to evaluate the clinical applicability and results of a new radiolucent system for vertebral body replacement in the lumbar spine. The system consists of bone-integrating biocompatible materials – a polyetherurethane/bioglass composite (PU-C) replacement body and an integrated plate of carbon-fibre rein-

forced polyetheretherketone (CF-PEEK) – and provides high primary stability with anterior instrumentation alone. In a current prospective study, five patients with metastatic lesions of the lumbar spine were treated by corpectomy and reconstruction using this new system. Good primary stability was achieved in all cases. Follow-up (median 15 months) using CT and MRI revealed progressive osseous integration of the PU-C spacer in four patients surviving more than 6 months. Results obtained from imaging methods were confirmed following autopsy by biomechanical investigation of an explanted device. From these data, it can be concluded that implantation of the new radiolucent system provides sufficient long-term stability for the requirements of selected tumour patients with improved prognosis.

Key words Lumbar spine · Metastases · Corpectomy · Vertebral body replacement · Biomechanics

Introduction

Since advances in tumour treatment have improved the prognosis of cancer patients, the incidence of clinically apparent metastatic disease has increased [8]. Carcinomas of the breast, prostate, lung, thyroid gland and kidney account for 80% of all osseous metastatic manifestations [5]. The highest incidence of skeletal secondaries is ob-

served in the spine, reported in one post-mortem study to be 36% [24]. Spinal metastases are primarily located in the vertebral body and in the peridural space; dorsal localisation is a rare finding [8]. Stability of the spine is impaired once the dorsal cortex of the vertebral body or the roots of the vertebral arch show signs of destruction. Local tumour progression may cause vertebral body collapse, deteriorating stability, pain and neurological symptoms. Spinal fractures may result in a kyphotic deformity

that leads to a compression or distraction of the spinal cord. In the cervical and the upper thoracic spine, where mechanical demands are lower than in other parts of the axial skeleton, pain frequently is less indicative than radicular neurologic symptoms. Metastases occurring in segments of the spine that have to withstand major forces frequently cause acute onset paraplegia. With few exceptions, any kind of treatment for metastatic disease that is available today remains palliative by definition, so surgery has to strive for maximum palliative effect with a minimum of operative morbidity and mortality. Therefore, radical tumour removal generally is not the ultimate goal of treatment. Instead, primary therapeutic goals are reduction of pain, and to secure or restore function and stability of the locomotor apparatus. Nevertheless, recent studies have shown the benefit of a more radical removal of metastatic spine lesions in selected patients with intermediate or good prognosis [1, 21, 22]. In these patients, reconstruction of the vertebral body following corpectomy must provide sufficient long-term stability.

Various systems with different levels of primary and long-term stability have been developed for vertebral body restoration [2, 7, 9, 10, 12, 13, 15, 16, 19]. Recurrent instability can be caused by mechanical failure, by a loosening at the interface between implant and bone [6, 14, 16, 20], or by a metastatic relapse [18]. Furthermore, metallic implants that were used in the past frequently disturbed postoperative computed tomography (CT) or magnetic resonance imaging (MRI) due to artefacts, and interfered with the planning and administration of radiotherapy.

The aim of our pilot study was to evaluate the clinical applicability and results of a new radiolucent system for vertebral body replacement in the lumbar spine, which consists of bone-integrating biocompatible material and provides high primary stability with an anterior instrumentation exclusively.

Materials and methods

Implant device

A newly developed vertebral body replacement from polyetherurethane and bioglass composite (PU-C, Biovision, Illmenau, Germany), fixed by an integrated plate of carbon-fibre reinforced polyetheretherketone (CF-PEEK) was used [3]. Stability was achieved by a total of six CF-PEEK screws securing the plate to both the replacement body and the adjacent unaffected vertebral segments (Fig. 1). Two oblique lag screws were inserted through the plate and a prefabricated hole in the vertebral replacement into the adjacent bone proximal and distal, providing a high compression force across both segments. Additional four-point fixation was achieved by a pair of horizontal, convergent screws at each end. The vertebral body replacement was slotted to mate with the plate; graft and plate were thus constrained against relative movement when the oblique screws applied compression. As a compromise of biomechanical requirements and surgical practicability, the plate was located at the left anterolateral aspect of the vertebral body replacement, in order to enable a retroperitoneal approach for

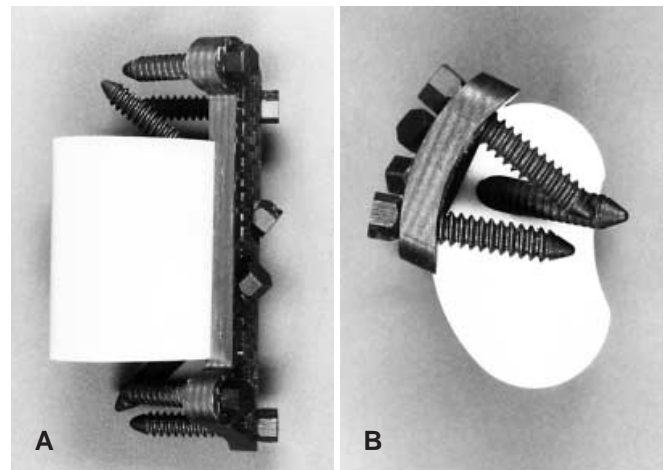


Fig. 1 Polyetherurethane/bioglass composite (PU-C) vertebral replacement: **A** side view, and **B** top view

anterior instrumentation and to protect the large vessels in front of the lumbar spine. Components of the system were available in various sizes to allow individual reconstruction of each defect.

Patients

From July 1995 to December 1996, five patients with spine metastases who were eligible for the study were operated on using the new device. Study inclusion criteria comprised indication for corpectomy, defined as:

1. Removal of the vertebral body, and
2. All of the following conditions: tumour localisation in the lumbar spine (L1-L4), monosegmental lesion, destruction of the vertebral body with intact posterior structures, and low-risk metastasis defined as metastatic disease with good or intermediate prognosis, e.g. in patients with receptor-positive breast cancer, differentiated thyroid cancer, or renal cell carcinoma.

Surgical treatment of spinal metastases was performed in patients with unstable pathologic fracture, impending fracture, spinal cord compression with or without neurological symptoms, and solitary lesions.

All patients gave written informed consent concerning participation in the study. Before decease, patient 2 agreed to an autopsy and removal of the implanted system for biomechanical and histologic investigations.

Application of the new system was indicated and planned in seven patients. Due to intraoperative complications, the intended procedure could not be performed in two patients: in a 48-year-old woman with breast cancer metastasis, L4 implantation of the PU-C spacer led to a fracture of the L5 upper plate, necessitating the use of a MOSS spacer. Though preoperative tumour embolisation was performed, profuse bleeding after removal of a solitary L4 teratoma metastasis required defect reconstruction with a MOSS spacer and polymethylmethacrylate in a 30-year-old man.

Table 1 shows data of the five patients who were treated using the new PU-C vertebral body replacement. Three patients were suffering from receptor-positive breast carcinoma with skeletal metastases exclusively, two patients from secondaries of a renal cell carcinoma. All patients had a metachronous dissemination with an interval from the first cancer diagnosis of 2.5 years at a minimum. Indication for surgical intervention resulted from a collapse of the vertebral body in four patients (Fig. 2), and a solitary metastasis without fracture in one patient (patient 2).

Table 1 Data of five patients with PU-C vertebral body replacement (*ADM* alive with metastases, *DD* died of disease, *D* died of unrelated cause)

Patient no.	ID	Sex	Age	Segment	Primary tumour	Frankel grade (preop./postop.)	Follow-up (months)	Status	Operating time (min)	Blood loss (ml)
1	HM	F	75	L3	Breast	E/E	9	DD	260	4000
2	HW	M	66	L2	Kidney	E/E	15	D	225	3000
3	HZ	F	51	L3	Breast	E/E	39	DD	195	2400
4	WJ	M	46	L3	Kidney	E/D	5	DD	210	2300
5	HS	F	36	L3	Breast	D/E	29	ADM	140	3500

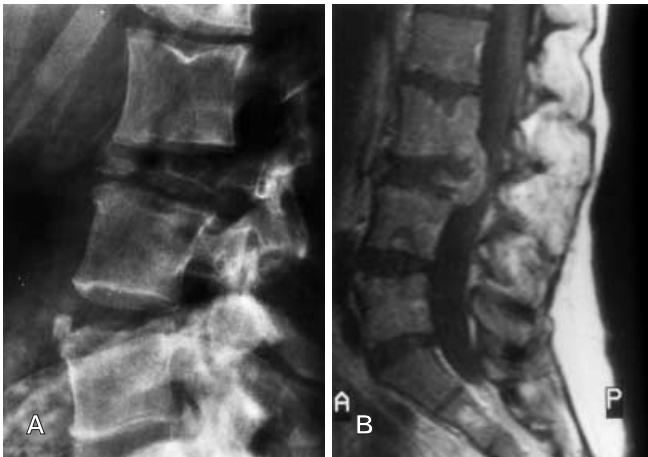


Fig. 2A, B A 36-year-old woman (patient 5) with L3 vertebral body collapse due to a breast cancer metastasis and mild paraparesis. **A** Lateral view conventional radiograph displays a vertebra plana resulting in a kyphotic deformity. **B** T1-weighted sagittal magnetic resonance (MR) image reveals a compression of the cauda equina

In order to analyse local tumour extension, all patients underwent MRI examination prior to surgery. Three-dimensional calculation of the resulting defect following corpectomy was performed preoperatively by spiral CT with two-dimensional reconstructions. In patients with pathologic fracture, dimensions of the vertebral body that had to be replaced were estimated using data acquired from the adjacent vertebrae. Based on these imaging data, the PU-C spacer was provided custom-made, enabling precise reconstitution of the original distance of the adjacent vertebral segments.

All patients underwent digital subtraction angiography and intra-arterial selective tumour embolisation, using ethibloc, immediately before surgical removal of the affected vertebral body. Operations were performed with the patient in lateral decubitus position, using an oblique lumbar extraperitoneal approach. All metastases were resected intralesionally without leaving macroscopic residual tumour. The procedure included complete removal of both adjacent discs and the anterior longitudinal ligament.

Neurological status was investigated preoperatively and again following surgical procedure, and classified according to Frankel [4]. Postoperative follow-up examinations, with intervals of 6 months, comprised evaluation of clinical performance, plain radiography, CT and MRI.

One patient received radiotherapy (45 Gy) prior to surgery, postoperative irradiation at the same dose was applied to three patients. Tamoxifen was administered pre- and postoperatively in the three patients with receptor-positive breast cancer.



Fig. 3 Biomechanical investigation on an explanted specimen (patient 2, T12-L4) using a universal spine tester. L2 corpectomy and implantation of the PU-C vertebral replacement had been performed 15 months previously. Resulting three-dimensional displacements were measured between all adjacent segments with an ultrasound motion measurement system

Biomechanical testing

Patient 2 had agreed to an autopsy and removal of the implanted system for biomechanical and histologic investigations. This patient who underwent spine surgery for a solitary metastasis of a renal cell carcinoma received a combined immunochemotherapy after CT diagnosis of clinically asymptomatic lung metastases, and died 15 months postoperatively without further tumour progression, due to therapy-related cardiac toxicity. It was possible to remove the vertebral body replacement together with the adjacent lumbar segments (T11-L3) at autopsy, and the device therefore was available for in vitro radiographic, biomechanical, and histologic examination.

In previous biomechanical testing, the new device was compared with several marketed systems [3]. Six normal donor human specimens were tested, intact and after corpectomy of L1, with several stabilization systems as well as with the new device, to compare the primary stability parameters range of motion (ROM) and neutral zone (NZ) of the stabilized spine in a common spine tester [3]. In order to compare the results of this study with the biomechanical testing from 1.5 years earlier, the explanted specimen testing was performed identically [3]. In preparation, surrounding soft tissue and muscles were dissected with care to preserve bone, discs and spinal ligaments. T12 and L4 were potted in polymethylmethacrylate (Technovit 3040, Heraeus Kulzer GmbH, Wehrheim/Ts, Germany) for fixation in the custom spine tester [23]. During testing, the specimens were kept moist with saline. Biomechanical testing was performed in a spine tester (Fig. 3) that provides controlled moment loading in one plane and unconstrained motion in free space [23]. Pure moments from -3.75 Nm to $+3.75$ Nm were applied in flexion/extension ($\pm M_x$), right/left axial rotation ($\pm M_y$) and right/left lateral bending ($\pm M_z$) at a constant rate of $1.7^\circ/s$ without axial preload. Resulting three-dimensional displacements were measured between all adjacent segments with an ultrasound motion measurement system (Cmstrao 1.0, Zebris, Isny, Germany). Data were recorded on the third cycle. From the load-deformation curves, ROM and NZ [17] were determined for the angles α , β , γ around the x , y , z axes between L1 and L3, for comparison with the initial identically performed biomechanical study [3].

Histological analysis

Histological investigation following autopsy was performed in patient 2. The implant-bone interfaces of the endplates were designated for undecalcified bone histological evaluation.

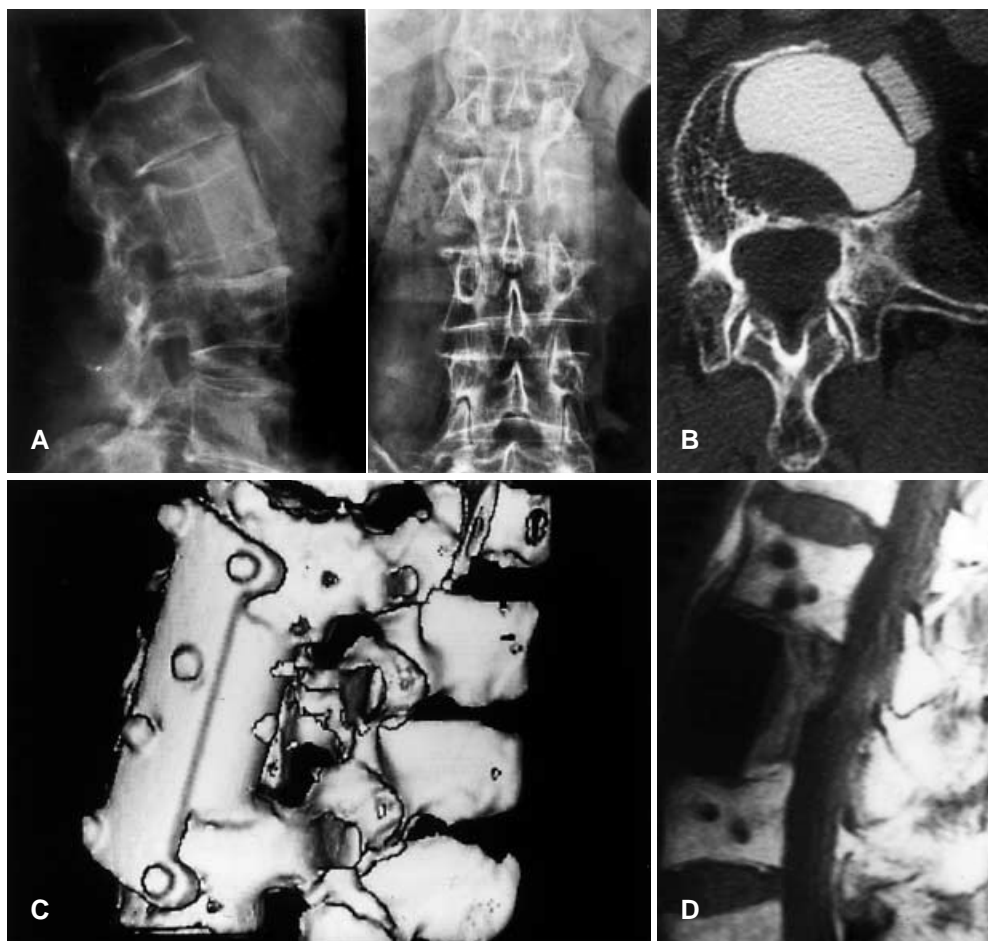
The whole specimen was sawed into 1-cm slices. After embedding in methacrylate, a $70\text{-}\mu\text{m}$ slice was cut and surface-stained with paragon. Using light microscopy (Axiophot, Zeiss, Oberkochen, Germany), the bone-implant interface was examined. Qualitative aspects of the interface, such as cancellous bone, bone marrow and fibrous tissue, were noted, and especially presence or absence of inflammation.

Results

Clinical follow-up

From the selected surgical approach, implantation of the PU-C spacer after corpectomy and instrumentation using the CF-PEEK plate was uncomplicated in all five patients. To achieve a sufficient primary stability, in one case (patient 3) additional reinforcement of screw anchorage using polymethylmethacrylate (Palacos, Merck Biomate-

Fig. 4 Imaging performed 5 months postoperatively in patient 2 using plain radiography (A), spiral CT (B) with three-dimensional reconstruction (C), and contrast-enhanced T1-weighted sagittal MRI (D). The implant and the surrounding tissue is visualised without artefacts. A new-formed bony rim anterior to the implant can be recognised on the transversal CT scan (B)



rials, Merck KGaA, Germany) was necessary. No intra- or postoperative complications, such as bleeding from the resection area, damage to neighbouring vessels or neural structures, or disturbances of wound healing were registered. Neurological deficits classified according to Frankel [4] were observed preoperatively in one patient (patient 5) with a vertebra plana L3 (Fig. 2). While the weakness of the lower extremities was improved by the operative procedure in this case, a patient with pathologic fracture of L3 (patient 4) developed mild paraplegia with maintained walking ability following operation. Stability, which was achieved primarily in all cases, enabled an unrestricted postoperative mobilisation without need for external support. No patient required additional posterior instrumentation. Administration of analgesic drugs was ended after 3 weeks at the latest.

In our series, median time of follow-up was 15 months (Table 1). During the observation period, no patient developed a neurological or functional deterioration correlated to the lumbar spine. CT and MR imaging, which could be performed artefact free, focused on early detection of metastatic recurrence and implant failure, and facilitated postoperative radiotherapy (Fig. 4). Conventional radiographs and CT scans revealed progressive osteointe-

gration of the PU-C spacer, first detectable after 6 months in all four surviving patients (Fig. 4). There were no radiographic signs of implant loosening or dislocation; MRI revealed no evidence of a local relapse. Four patients succumbed to their progressive disease after 5, 9, 15, and 35 months, respectively. Follow-up period in patient 5,

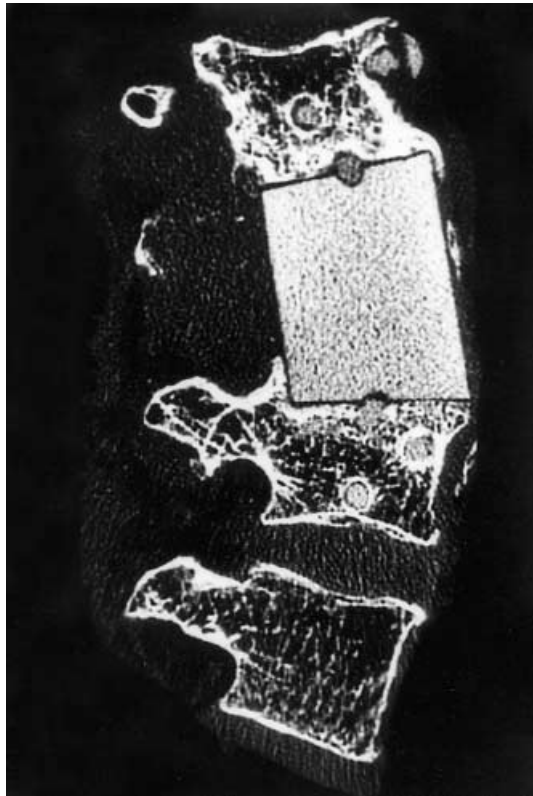


Fig. 5 Spiral CT with sagittal reconstruction of the explanted specimen from patient 2, demonstrating a partial integration of the PU-C spacer into the adjacent vertebral bodies

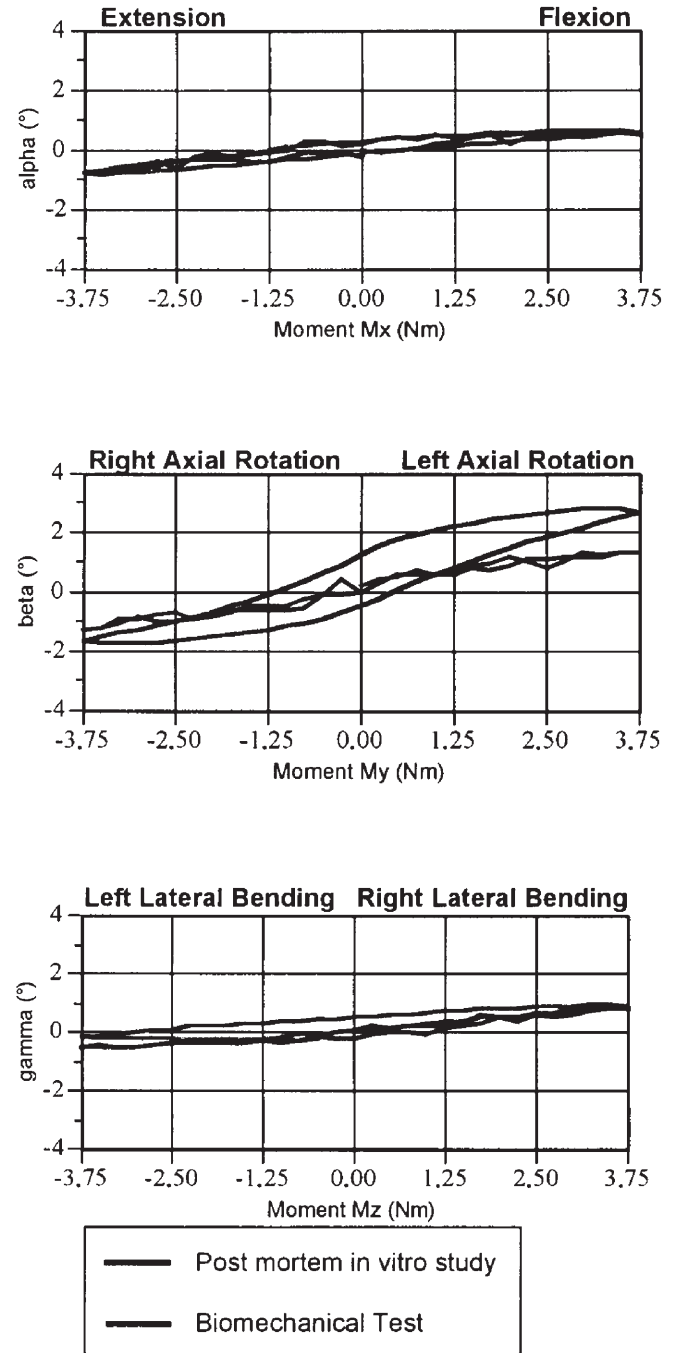


Fig. 6 Load-deformation curves of the overbridged segments in the three primary directions; comparison of the explanted specimen in the present study with the results of previous biomechanical investigations [3] on primary stability of the implant in vitro

with receptor-positive breast carcinoma and complete remission of multiple skeletal metastases, is 39 months so far.

Following autopsy in patient 2, plain radiography and CT of the resected specimen confirmed the *in vivo* diagnosis of osteointegration of the PU-C spacer (Fig. 5).

Biomechanical testing

The load-deformation curves of the explanted specimen demonstrated nearly linear behaviour under cyclic loading (Fig. 6).

In flexion/extension, total ROM was 1.25° (+ROM 0.5° ; -ROM 0.75°) and total NZ 0.31° (+NZ 0.19° ; -NZ 0.12°).

For axial rotation over the range of moments -3.75 Nm to 3.75 Nm, the implant produced a total ROM of 2.59° (+ROM 1.3° ; -ROM 1.29°) and a total NZ of 0.13° (+NZ 0.12° ; -NZ 0.01°).

For lateral bending over the range of moments -3.75 Nm to 3.75 Nm, total ROM was 1.3° (+ROM 0.8° ; -ROM 0.5°) and total NZ 0.29° (+NZ 0.1° ; -NZ 0.19°) (Fig. 6). ROM and NZ were comparable to values reported in the initial comparative biomechanical testing of this device [3].

Histological analysis

Histological examination of the specimen of patient 2 was complicated due to different material properties, which made preparation and fixation of the cuts more difficult. Therefore, not all areas of the endplate-bone interface were available for microscopic examination.

In the remaining slices, no signs of inflammation, such as macrophages, giant cells or lymphocytes were observed.

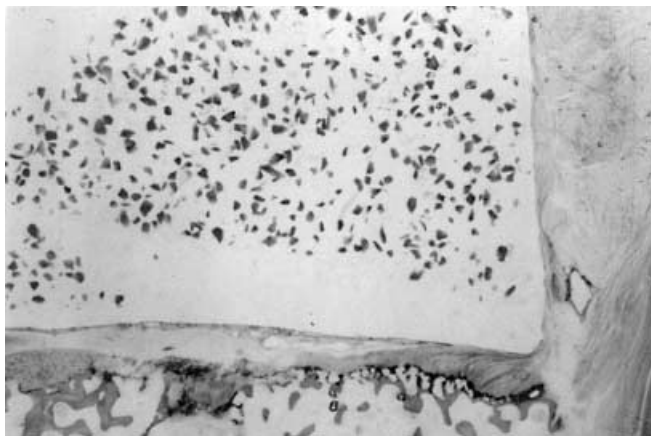


Fig. 7 Polyurethane/bioglass composite-endplate interface 15 months after implantation

Areas of direct contact between bone and implant were rarely observed; mostly a small line of fibrous connective tissue was between the PU-C replacement body and the adjacent bone (Fig. 7). Tooth-like ingrowth (arrows) had not occurred 15 months after implantation [11].

Discussion

In vitro stability of a new radiolucent system for vertebral body replacement, consisting of a composite bioglass-polyurethane body and a polymeric fastening hardware, has been shown to be superior to currently used systems [3], providing a significantly higher restraint of motion. We therefore investigated its *in vivo* application in a small series of selected patients with low-risk metastatic disease involving the spine.

While good primary stability was achieved in four patients, in one patient, a 51-year-old woman, reinforcement of the implanted screws using polymethylmethacrylate was required due to a pre-existing osteoporosis, in order to obtain sufficient fixation of the PU-C spacer. Restoration of spinal stability permitted immediate remobilization of all patients without the need for posterior instrumentation. During follow-up, no loosening, dislocation or breakage of the implant was observed.

Investigation of the biomechanical performance of the explanted vertebral segments revealed excellent stability, which was comparable or superior to the stability achieved in the initial biomechanical testing, which included ventral systems such as Ventrofix, the USIS system and a compression plate system [3]. In flexion/extension, the specimen of patient 2, in whom the device had been implanted 1.5 years earlier, demonstrated values of ROM and NZ identical with the former biomechanical study [3]. Lateral bending ROM of the implanted device and NZ were equal or even better than the results of previous testing [3]. The total ROM and NZ in axial rotation indicated considerably enhanced ROM and NZ in comparison to the biomechanical investigation [3]. Overall, this demonstrated excellent long-term stability of the implanted device over the course of 1.5 years, and even improved stability due to increased mechanical interlocking by bony build-round through heterotopic ossification and the beginnings of osteointegration at the bone-endplate interface.

We used the Zebris ultrasound three-dimensional measurement system in this biomechanical testing, instead of the six-degrees-of-freedom goniometer systems of the previous study [3], because of its higher accuracy. The earlier biomechanical series was performed on T12-L2 specimens with a corpectomy at L2. The current, explanted specimen was T11-L3, with a corpectomy at L1. The biomechanical properties of these two slightly differing spinal segments do not deviate substantially from one another; thus, the comparison between the two sets of data is warranted without detailed qualification. Furthermore, the

specimen of this study corresponds in age (66 years) with the mean of the previous series (64 years).

Biocompatibility of the used material in comparison to titanium has been investigated in vivo in long-term experiments in sheep, revealing an osseous integration of the new composite that was similar for short application times and significantly superior after an implantation period of 2 years [11]. Inter-individual variability was high in the earlier time period, but settled down at 24 months, at which time a well-structured, tooth-like apposition could also be observed [11].

After 16 months ingrowth time in our study, mostly a small fibrous connective tissue was observed at the bone-implant interface. Based on the results of the animal study, a time-dependent increase could be expected after 2 years, which demonstrates a higher interfacial shear strength in comparison to titanium. CT scan comparison demonstrated bony build-round by heterotopic ossification of the PU-C spacer macroscopically during the follow-up in four patients. Therefore, for reasons of biomechanical properties and biocompatibility, an adequate long-term stability and bony incorporation of the PU-C spacer can be expected.

Inflammatory reactions were not seen macroscopically or microscopically, due to good biocompatibility of the PU-C material.

The new device was shown to enable undisturbed MRI and CT investigation, and therefore to facilitate postoperative radiotherapy. In irradiated patients, MRI is essentially for distinguishing local tumour relapse and irradiation-induced transverse myelitis [8]. No postoperative complications related to the surgical approach, tumour resection, or kind of restoration of spinal stability was observed in our series. However, in comparison to vertebral body replacement using polymethylmethacrylate, the system does not provide a haemostatic effect on the surrounding tissue. Therefore, angiography, which outlines the vascular supply of the lesion and represents the basis for selective embolisation, should be mandatory, if application of the PU-C spacer is intended. From our experience, in patients with osteoporosis, reduced stability of the endplates of the adjacent vertebral bodies must be regarded as a limitation for the use of the new system providing a high compression force against these anatomical structures.

For spinal metastases, a ventral approach is generally considered more appropriate, because they are located mostly in the vertebral body and the roots of the vertebral arches. However, factors such as age, general health status, operative risks and the pattern of metastatic spread have to be taken into consideration before deciding on the optimal approach in the individual patient. The PU-C spacer, which was used in our series, can be recommended in patients with neoplastic lesions limited to the vertebral body, with unaffected adjacent segments or solitary lesions, and with an expected longer time of survival. Due to size and configuration of the developed system, its application is limited to the lumbar spine. Additionally, since the sacral anatomy does not permit anterolateral instrumentation, treatment of L5 metastases had to be excluded from this procedure. It must be regarded as a disadvantage of a custom-made device that the intraoperative flexibility regarding resection and defect reconstruction is much lower in comparison to a modular reconstruction system without defined connection of the vertebral body replacement and the fixating device.

Conclusion

Surgical treatment of metastatic disease of the lumbar spine using a radiolucent vertebral body replacement from polyetherurethane and bioglass composite (PU-C) fixed by an integrated plate of carbon-fibre reinforced polyetheretherketone was successful in five patients, with encouraging results regarding spinal stability. While a high primary stability was achieved because of the biomechanical properties, the fixation of the PU-C spacer was improved by a progressive osseous integration due to the biocompatibility of the device. In spite of the limited number of cases in our series, we conclude from our data that, with the employed material and fixation device, sufficient long-term results in restoration of spinal stability in selected patients with metastatic lesions as well as primary bone tumours can be expected. Further studies with modified implants are necessary to evaluate the use of the PU-C system for treatment of neoplastic lesions of the thoracic spine.

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