Cervical spine disc prosthesis: radiographic, biomechanical and morphological post mortal findings 12 weeks after implantation. A retrieval example

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Abstract There is a gap between in vitro and clinical studies concerning performance of spinal disc prosthesis. Retrieval studies may help to bridge this gap by providing more detailed information about motion characteristics, wear properties and osseous integration. Here, we report on the radiographic, mechanical, histological properties of a cervical spine segment treated with a cervical spine disc prosthesis (Prodisc C, Synthes Spine, Paoli, USA) for 3 months. A 48-year-old male received the device due to symptomatic degenerative disc disease within C5–C6. The patient recovered completely from his symptoms. Twelve weeks later, he died from a subarachnoid hemorrhage. During routine autopsy, C3–T1 was removed with all attached muscles and ligaments and subjected to plain X-rays and computed tomography, three dimensional flexibility tests, shear test as well as histological and electronic microscopic investigations. We detected radiolucencies mainly at the cranial interface between bone and implant. The flexibility of the segment under pure bending moments of ± 2.5 Nm applied in flexion/extension, axial rotation and lateral bending was pre-

served, with, however, reduced lateral bending and enlarged neutral zone compared to the adjacent segments C4–C5, and C6–C7. Stepwise increase of loading in flexion/extension up to ± 9.5 Nm did not result in segmental destruction. A postero-anterior force of 146 N was necessary to detach the lower half of the prosthesis from the vertebra. At the polyethylene (PE) core, signs of wear were observed compared to an unused core using electronic microscopy. Metal and PE debris without signs of severe inflammatory reaction was found within the surrounding soft tissue shell of the segment. A thin layer of soft connective tissue covered the major part of the implant endplate. Despite the limits of such a case report, the results show: that such implants are able to preserve at least a certain degree of segmental flexibility, that direct bone implant contact is probably rare, and that debris may be found after 12 weeks.

Keywords Spine · Implants · Disc replacement · Biomechanics · Case report

Introduction

Cervical spine disc replacement [1, 2, 5, 13] seems to be a promising alternative to anterior cervical fusion [14], thought to prevent adjacent level disease [6]. Clinical as well as in vitro results have been reported to be favourable [1–3, 5, 8, 10, 13]. However, there is still paucity of information how these implants behave like within the human cervical spine under in vivo conditions. Post mortal findings using cervical spine specimens from patients who underwent surgery during their lifetime may help to bridge this gap.

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A cervical spine disc prosthesis (Prodisc C, Synthes Spine, Paoli, USA) had been inserted into the disc space C5–C6 of a 48-year-old male due to symptomatic degenerative disc disease, resulting in right sided C6 radiculopathy (Fig. 1). The patient was enrolled into a prospective study, performed to measure segmental motion following cervical spine disc replacement using Roentgen Stereophotogrammatic Analysis (RSA). For this, the patient was placed with the head in extension—right sided rotation—bending within the RSA-equipment. Flexibility within the segment C5–C6 was analysed immediately and 6 weeks after surgery. Thus, tantalum markers have been inserted within the adjacent vertebral bodies C5 and C6. C5–C6 flexibility immediately after surgery was 5.4° in extension, 4.6° in right sided axial rotation and 3.2° in right sided lateral bending. Six weeks later, C5–C6 flexibility was measured to be 4.2° in extension, 3.9° in right sided axial rotation and 2.8° in right sided lateral bending. Twelve weeks after surgery, the patient died from a sub-arachnoid haemorrhage. An informed consent about removing the cervical spine within routine autopsy and analysing anatomical, mechanical and histological details of the treated and adjacent segments was received by his relatives. The current report is about our findings and results from these investigations.

Fig. 1 X-ray of the cervical spine after surgery, lateral projection. Please note, that tantalum markers have been inserted into the vertebral bodies of C5 and C6 according to the study the patient was included (see above)

Material and methods

We received written consent from the patient's relatives to remove and investigate his cervical spine. During routine autopsy, the cervical spine from C3 to T1 was removed with all attached muscles and ligaments via anterior approach. Care was taken not to harm the anterior longitudinal ligament as well as the anterior aspects of the discs. The specimen was wrapped in double plastic bags and frozen at -20°C .

The specimen was first visually checked at its anterior aspect for any abnormalities. Next, a standard anterior-posterior and lateral X-ray was taken as well as a high resolution computed tomography including three-dimensional reconstruction (CT Twin, Philips, Calimotion 1.5 mm, slice thickness 1.7 mm, pitch 1.5). This was done to investigate the specimen with respect to major defects around the implant or within the vertebral bodies adjacent to the implant as a possible complication of the surgical procedure. Bone density was determined for each vertebral body using quantitative computed tomography (qCT, Stratec XCT 960 A, Birkenfeld, Germany). The attached muscles were removed and soft tissue taken around the segment C5–C6 was preserved for histological analysis with respect to metal and/or polyethylene (PE) debris.

All soft tissue was stripped from the caudal aspect of the vertebra T1 and the cranial aspect of C3. Within these parts of the specimen, commercially available wood screws were drilled and then embedded into polymethylmethacrylat (Technovit 3040, HeraeusKulzer, Hanau, Germany). A motion analyzing system was attached to each vertebra (Zebris, WinBiomechanics, Isny, Germany). The specimen was fixed into a custom spine tester [15] and pure bending moments of ± 2.5 Nm were applied to the top vertebra in the three motions planes. Range of motion (ROM) and neutral zone (NZ) in flexion/extension, right/left lateral bending and left/right axial rotation were recorded for C4 versus C5, C5 versus C6, and C6 versus C7, respectively. We also analysed all coupled motions with special respect to lateral bending measured during axial rotation and axial rotation during lateral bending. Next, pure bending moments in flexion–extension were increased stepwise by 1 Nm up to a load limit of ± 9.5 Nm. Again, ROM and NZ were determined.

The segment C5–C6 which was harbouring the disc prosthesis was opened by dissecting all intervertebral ligaments. The lower part of the specimen was used for push-out testing of the metal endplate of the prosthesis from the surrounding bone: in a material testing machine, a postero-anterior shear force was applied to the implant at a rate of 1 mm/min while the vertebra C5

Fig. 2 Bar graph, giving ROM (black plus grey) NZ (black) for C4–C5, C5–C6, and C6–C7 in flexion–extension, axial rotation, and lateral bending. Please note enlarged NZ within C5–C6 with respect to adjacent segments as well as reduced ROM in lateral bending within C5–C6

was rigidly fixed. From the force-deformation curve, the maximum push-out force was determined. The upper part was decalcified and embedded into polyester resin and used for histological investigation. Soft tissues around the segment were checked for PE as well as metal debris. Finally, the core of the implant consisting of PE was looked at with respect to damages at its surface using electronic microscopy. Moreover, the core was compared to the core of an unused prosthesis.

Results

Macroscopically, the anterior aspect of the implant was completely covered by tissue which was slightly

discoloured compared to the anterior longitudinal ligament of the adjacent levels. Signs of radiolucency were seen by X-ray within the ap-view, which were more pronounced at the C5 vertebral body. No defects were seen within the vertebral bodies of C5 and C6 as documented by X-ray as well as computed tomography. Bone mineral density was 497 mg/ccm at C5 and 376 mg/ccm at C6 but lower at C4 (255 mg/ccm) and C7 (251 mg/ccm).

NZ/ROM in flexion plus extension were 10.9°/12.2° for C5–C6, 8.1°/10.9° for C4–C5, and 9.2°/13.2° for C6–C7. NZ/ROM in axial rotation were 3.9°/6.1° for C5–C6, 1.4°/5.2° for C4–C5, and 3.0°/8.4° for C6–C7. In lateral bending, however, NZ / ROM were 1.6°/2.3° for C5–C6, 11.9°/15.6° for C4–C5, and 5.3°/7.7° for C6–C7 (Fig. 2). Coupled lateral bending (NZ/ROM) under loading of the specimen using ± 2.5 Nm in axial rotation were as follows: 0.1°/1.8° for C5–C6, 8.8°/12.4° for C4–C5, and 2.5°/2.5° for C6–C7 (Fig. 3), while coupled axial rotation in lateral bending was similar in the treated and both adjacent segments. Stepwise increase of loading the specimen in flexion–extension resulted in an increase of NZ/ROM up to the load limit of ± 9.5 Nm (Fig. 4).

During destructive biomechanical tests, a postero-anterior force of 146 N was necessary to detach the lower half of the prosthesis from the vertebra C6 (Fig. 5).

Histologically, we detected debris from both PE (Fig. 6) and metal within the surrounding tissues removed from the spinal segment. However, there was no severe inflammatory reaction around. The anterior longitudinal ligament showed a normal ligamentous structure except for some regions, where scar tissue formation was observed. Signs of bony incorporation were seen between the vertebral body of C5 and the lateral aspects of the fixation petal (Fig. 7). The major part of the metal endplate, however, was covered by fibrous tissue.

Electronic microscopic investigation of the core of the implant detected signs of superficial damage and wear of the PE when compared to an unused device (Fig. 8).

Fig. 3 Bar graph, giving ROM (black plus grey) and NZ (black) of coupled motion (lateral bending) under application of ± 2.5 Nm in axial rotation

Fig. 4 Bar graph, giving ROM (black plus grey) and NZ (black) of segment C5–6 with implant for stepwise increased bending moments in flexion–extension

Fig. 5 Force–displacement graph for push-out test to the lower plate of the device. A maximum force of 146 N could be applied

Fig. 6 Microscopic section through soft tissue surrounding the disc space. Polyethylene (PE) particles and macrophages are visible

Discussion

In this patient, the cervical spine disc prosthesis was in place and worked well within 3 months after surgery. Also, the patient felt well and even free of any complaints related to the cervical spine until he died from

Fig. 7 Microscopic section through the upper endplate of the device and the adjacent vertebral body (C5). An area of bone formation in contact to the metal endplate can be seen close to the lateral aspects of the fixation petal. The borders of this area are indicated by black arrows

reasons unrelated to the procedure. Therefore, these results are of special interest: they enable us to look at the “post surgical” anatomy and mechanics in a more detailed way compared to radiological examinations usually performed after surgery. Results as these may help us to bridge the current gap between in vitro studies and clinical studies.

Preservation of segmental flexibility is the most important aim in cervical spine disc replacement. Here, detailed flexibility tests of both treated segment and adjacent segments, including coupled motions, were possible in a standardized manner. A slightly greater NZ when compared to adjacent segments was seen, which may be an effect of the design of the prosthesis, being a ball-socket design. We noticed restricted ROM in lateral bending also when coupled with axial rotation. This is somewhat surprising facing the completely unconstrained ball to socket design of the device. Comparable data come from our in vivo results in this patient. Six weeks after surgery, extension and right lateral bending represented approximately 50% of the

Fig. 8 Electronic microscopy (factor of magnification: 50) of the PE core of both a new, unused device (*left*) versus the core from the prosthesis explanted after 3 months (*right*). Please note the scratches on the latter one

ROM as measured within the in vitro experiment, but right lateral bending was reduced, too. Former in vitro investigation by DiAngelo [3] resulted in flexibility in lateral bending very close to that of the intact segment. Facing these results, our findings may be partially due to slight degeneration of this segment. Such a comparison of the treated segment with its two adjacent segments as baseline only makes sense if the adjacent segments are healthy and not degenerated. From the radiographs no severe degeneration could be seen. Yet, some minor changes cannot be excluded. Therefore, an additional comparison with the flexibility data reported in the literature is important [4, 10].

Destructive tests illuminated that pure bending moments up to ± 9.5 Nm applied in flexion–extension did not destroy segmental integrity. No signs of ligamentous destruction were visible when the segment finally was dissected. Removal of the lower metal plate of the prosthesis required application of 146 N in posterior-anterior direction. This force seems to be relatively small when compared to pullout forces necessary for removal of cervical spine screws, which are around 400–550 N [11, 12], or to these of cages (130–945 N) [4]. Finally, it may be suspected, that much better fixation may occur as a result of an ongoing bony ingrowth with time. A significant ingrowth of bone in the titanium shells of another type of disc replacement has been described before [7] and may be expected with the type of prosthesis used here.

Recently, Kurtz et al. [9] described local inflammatory reaction within the vertebral bodies as a possible complication induced by PE wear. Local inflammatory reaction as induced by PE particles is discussed to be a risk for implant loosening and migration. Three months after surgery, we detected parts of PE and metal debris within the dissected soft tissue or bone, and first signs of destruction at the surface of the core when compared to a new core. However, strong inflammatory reactions could not yet be observed. Yet, similar effects as mentioned above may be expected

also for cervical spine prostheses after a period of time longer than 12 weeks.

Post mortal investigation includes the possibility to look at forces, necessary to destroy a spine segment or to cause implant failure as well as for damages to the implant and related effects to the surrounding tissues. This part of the current investigation is considered to be one of its major advantages. However, it must be taken into account that the findings just come from one specimen. Moreover, we report findings of an in vitro study, which do not necessarily reflect the behaviour of the spine under in vivo conditions: the influence of neck muscles, for example, has been neglected here. Finally, please note that these results just represent short time findings 3 months after insertion. It is necessary to look at these limitations, if reflecting the results.

Conclusions

Three months after insertion of a cervical spine disc prosthesis, segmental motility is preserved with, however, reduced lateral bending. Push-out force for the lower endplate was 146 N, the upper endplate was covered with both bone in contact to the plate and fibrous tissue. Both PE and metal debris were found within the surrounding tissue.

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