Eur Spine J
DOI 10.1007/s00586-016-4473-9

IDEAS AND TECHNICAL INNOVATIONS

Surgical planning, manufacturing and implantation of an individualized cervical fusion titanium cage using patient-specific data

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Received: 31 July 2015 / Revised: 18 February 2016 / Accepted: 19 February 2016

Abstract
Background Most cervical fusion cages imperfectly mimic the anatomy of the intervertebral disc space. The production of individualized cages might be the next step to further improve spinal implants due to their enhanced load-bearing surface.
Objective To evaluate the planning, manufacturing, and implantation of an individualized cervical cage in co-operation with EIT and 3D Systems.
Methods A digital 3D model of the patient's cervical spine was rendered from the patients CT data. It was then possible to correct degenerative deformities by digitally repositioning the vertebrae and virtually resecting the osteophytes. The implantation of the cage can be simulated to check the accuracy of the fit. The cage is made of trabecular titanium and manufactured by Direct Metal Printing.
Results The pilot project for the implantation of the first individualized cervical cage ever, resulted in a highly accurate fit. During surgery, the cage self-located into the correct position after suspending distraction due to the implants unique end plate design. Furthermore, it was impossible to move the cage in any direction with the inserting instrument after suspending distraction for the same reason. Thus, it can be assumed that an individualized cervical implant provides excellent primary stability.
Conclusion Preconditions for the manufacturing of individualized cervical fusion cages using specific patient data are given. The implantation is uncomplicated. The improved load-bearing surface will lower the rate of implant dislocation and subsidence. The production of individualized cages at a reasonable price has to be evaluated by spine surgeons and the industry.

Keywords Titanium cage · Cervical spine · Fusion · Patient data · Computer-aided design · 3D modeling · Manufacturing

Introduction

The implantation of intervertebral fusion cages made of polyether-etherketone or titanium with or without anterior plating has been the standard surgical therapy for the treatment of spondylotic cervical myelopathy and/or radiculopathy for many years [1–4].

The numerous cervical cages offered by the industry mimic the anatomy of the intervertebral disc space more or less whereat size and design of the cages are adapted to average shapes and sizes of intervertebral discs.

For the reconstruction of several bony defects in the human body such as skull defects individualized implants based on the patient's CT data have been used on a routine base for many years [5–8]. Thus, it was a logical step to evaluate the technical possibilities for the manufacturing of individualized fusion implants for the cervical spine together with our industrial partners EIT (Emerging Implant Technologies GmbH, Tuttlingen, Germany) and 3D Systems (Rock Hill, SC, USA).

Electronic supplementary material The online version of this article (doi:10.1007/s00586-016-4473-9) contains supplementary material, which is available to authorized users.

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Published online: 01 March 2016

This development aims to create an implant that perfectly fits to the endplates of the adjacent vertebral bodies to avoid fusion complications such as secondary dislocation or subsidence of the cage into the bone [9–11].

Methods

Surgical planning

Using a DICOM CT dataset, a 3D model of the patient's cervical spine is rendered ('as-scanned anatomy', Fig. 1).

After analyzing the 3D model with emphasis on deformities such as kyphosis, it is possible to virtually correct these deformities by repositioning vertebrae. By this procedure, the individualized cage obtains the ideal lordotic angle for restoring the sagittal balance of the cervical spine.

The next planning step is the virtual resection of osteophytes ('resected anatomy', Fig. 2). The resection of posterior osteophytes is often necessary for the decompression of the spinal cord and nerve roots. The resection of anterior osteophytes should be considered if they obstruct the entrance into the disc space or in case of symptomatic dysphagia.

Afterwards the cage implantation can be simulated to check the implanís accuracy of fit ('implant placement', Fig. 3). The determination of the optimum height of the implant takes the height and facet joint orientation of adjacent levels into consideration. The planning starts with the data of an EIT standard titanium cage which is modified according to the patienís individual anatomy.

After the rendering of an implant that matches the individual shape of the patients endplate anatomy, it is possible to simulate different implant heights (Fig. 4). Beside the height of the intervertebral disc space as determined in the 3D CT model the design and manufacturing process includes the production of two more cages with a height that is lower by 0.5 and 1.0 mm, respectively, than the original height to have two more options during surgery (Fig. 4).

Manufacturing

The EIT titanium cages are manufactured slice by slice using the modern additive production process DMP (direct metal printing). During this process, a very thin powder layer of the titanium alloy Ti6AL 4V is applied to a base plate. The titanium alloy powder is completely melted by a laser beam and makes up a tight layer after consolidation. After this process, the base plate is lowered by 30–50 μm, and the next layer is applied. This procedure is repeated until all layers are completed and the cage reached its final shape.

The guidance of the laser beam is carried out by a 3D CAD software that divides the device into several layers and calculates the lanes of the laser.

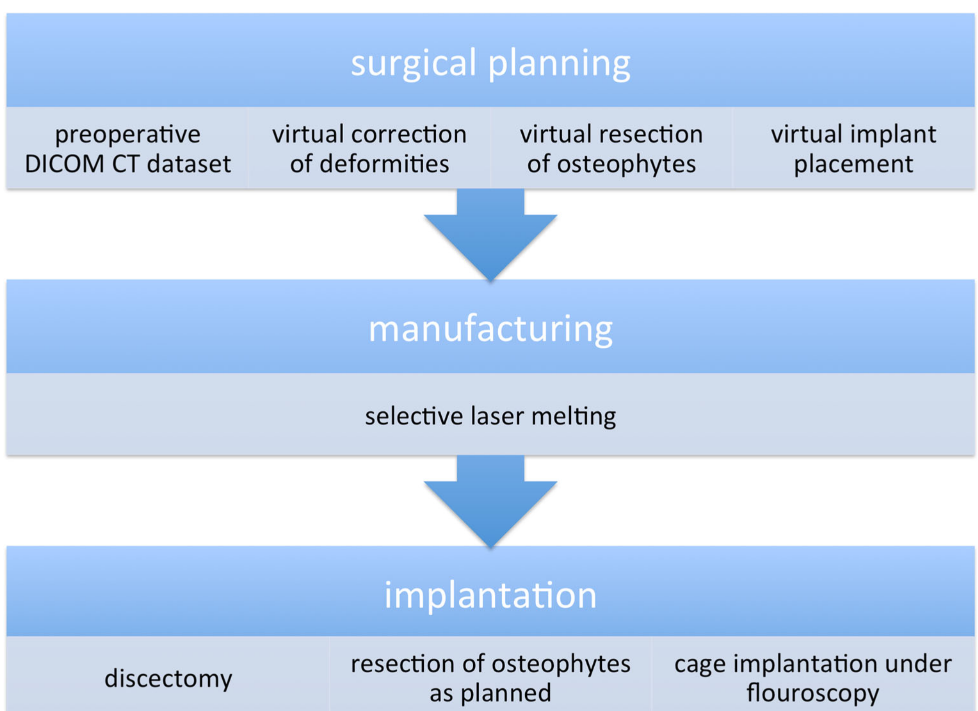

Fig. 1 *Flow diagram* showing the process from planning to implantation

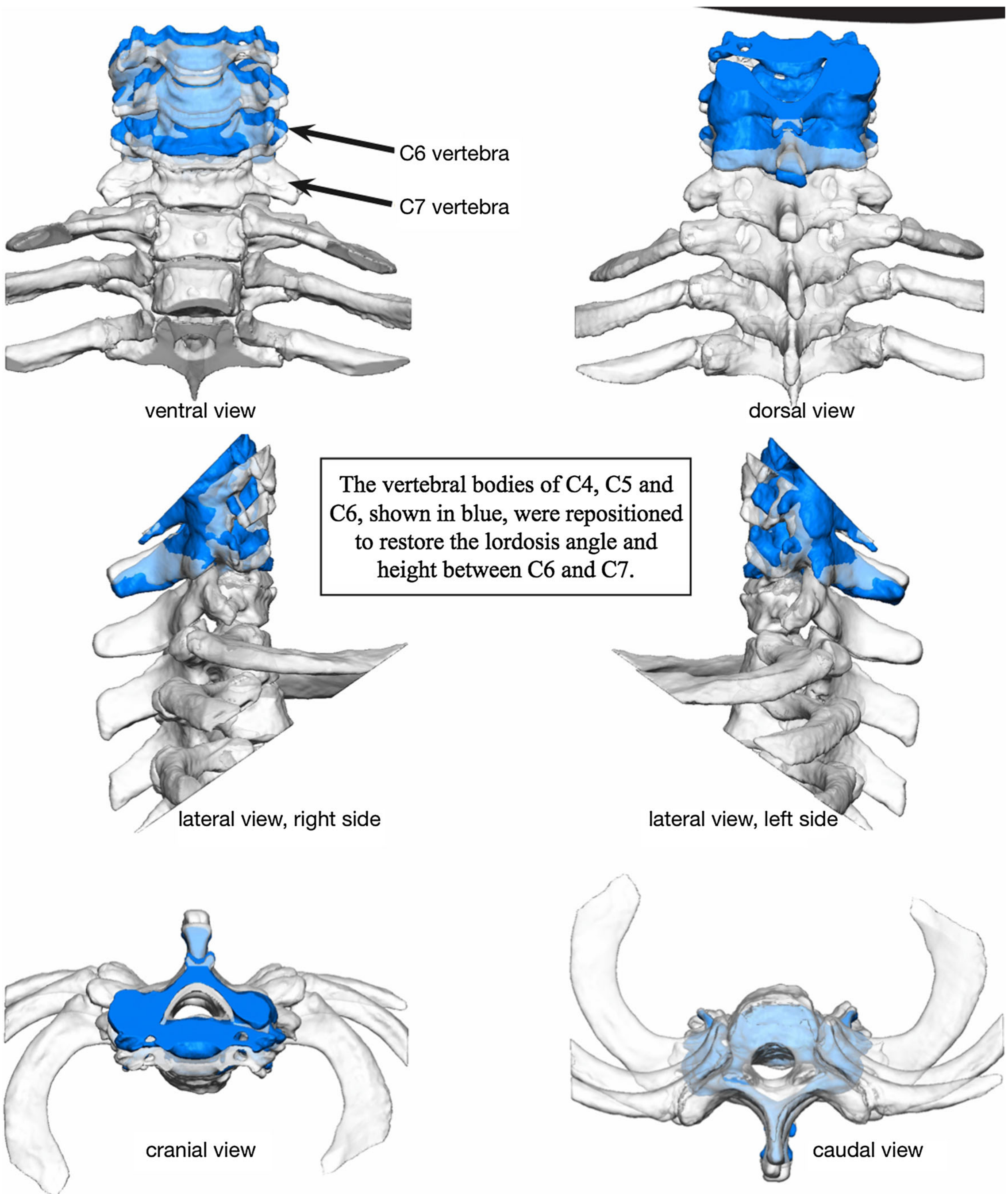

Fig. 2 Repositioned anatomy with a virtual correction of the patient's spondylotic kyphosis

This additive production process influences many industrial sectors such as designing, architecture, aircraft construction, and medical engineering because it eliminates many limitations of product design. Furthermore, it enables the design of complex three-dimensional structures and free forms that cannot be manufactured by the usual production processes. For example, it is possible to mimic the trabecular structure of bone inside of a titanium fusion cage (Fig. 5). Thus, DMP offers the potential of producing individual spinal implants.

Implantation

For the anterior discectomy and decompression with cervical fusion (ACDF), the authors use the anterolateral standard approach to the cervical spine.

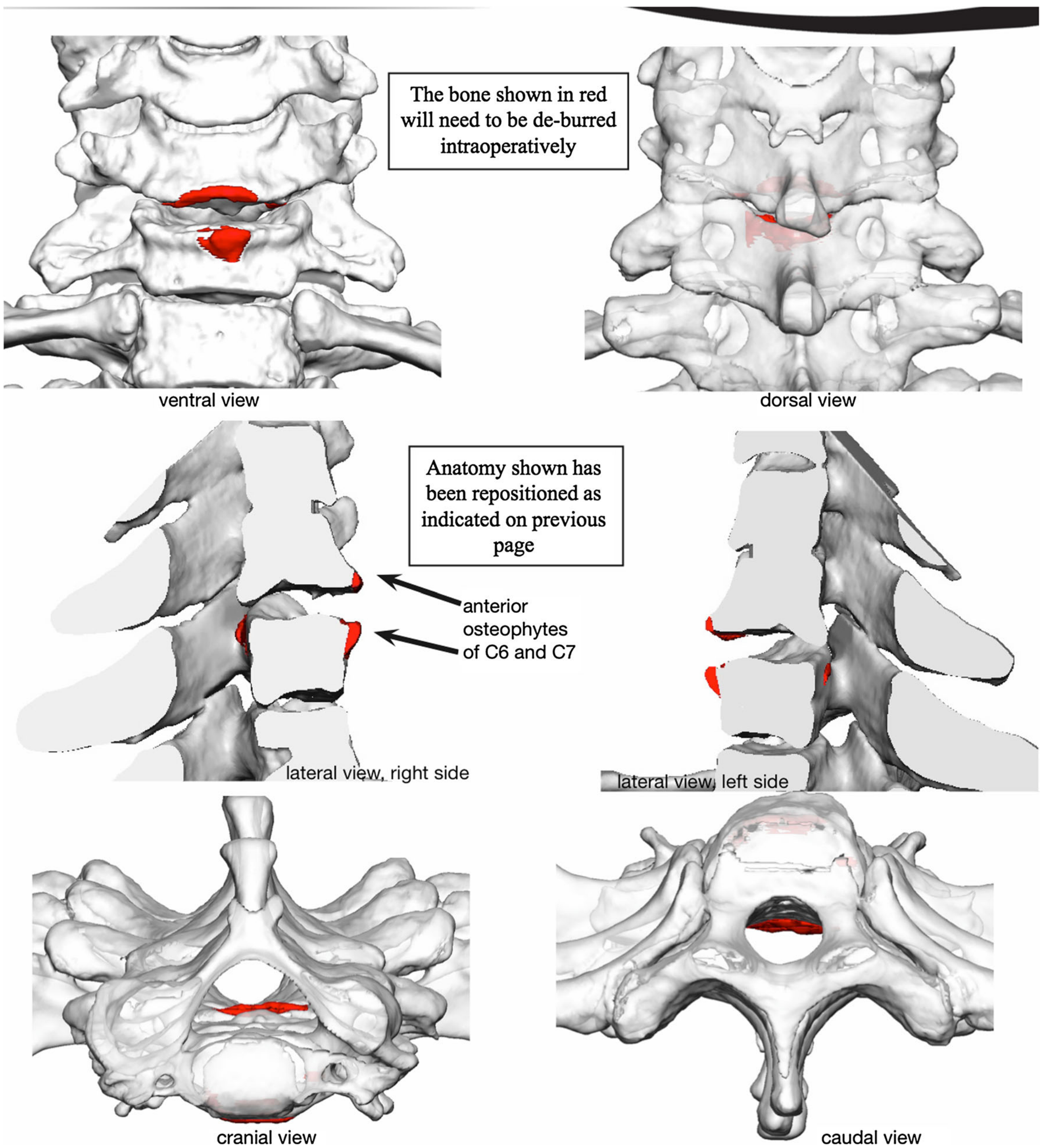

Fig. 3 Resected anatomy showing the osteophytes that need to be resected during surgery

After incision of the anterior longitudinal ligament, the discectomy is performed using a forceps and a curette (Fig. 6a, b). It is crucial to avoid damaging of the bony endplates of the adjacent vertebral bodies to prevent cage subsidence.

Posterior osteophytes that narrow the spinal canal are selectively removed with a 4 mm high-speed diamond drill or a 2 mm Kerrison punch (Fig. 6c, d). For an adequate decompression, it is necessary to resect the posterior longitudinal ligament as well.

As mentioned above, the resection of anterior osteophytes can be indicated (Fig. 6e, f).

The final step is the cage implantation with the use of intraoperative flouroscopy (Fig. 6g, h). The Caspar distractor is put under slight distraction. The surgeon can chose between three different cage heights in 0.5 mm steps depending on the intraoperative situation. For the implantation, the inserter of EIT standard cages can be used. The final position of the cage is checked by fluoroscopy after removal of the Caspar distractor and pins. At the first day after surgery, the postoperative result is documented by anteriorposterior and lateral X-ray (Fig. 8).

The whole procedure is shown in the supplemental video.

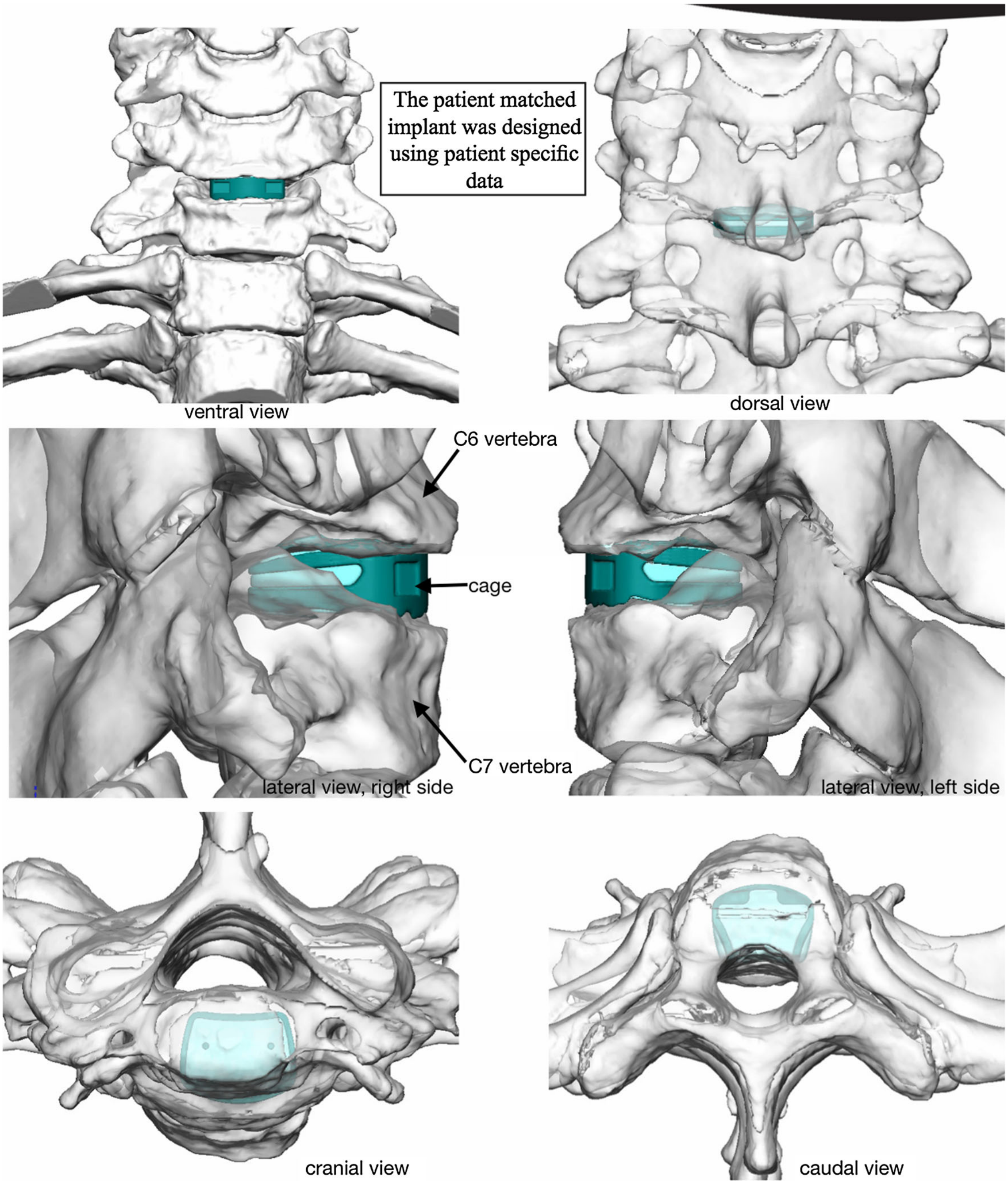

Fig. 4 Virtual design of the implant according to the patient's individual anatomy

Results

The pilot project of the first implantation of an individualized cervical titatium cage ever resulted in a highly accurate fit of the implant (Fig. 7). During surgery the cage self-located into the correct position after suspending distraction due to the implants unique endplate design (Fig. 5).

Furthermore, it was impossible to move the cage in any direction with the inserting instrument after suspending distraction for the same reason. Thus, it can be assumed that an individualized cervical implant provides excellent primary stability.

The cage is made of EIT cellular titanium™ with an eighty percent porosity and a pore size of 0.65 mm that provides good preconditions for secondary bony

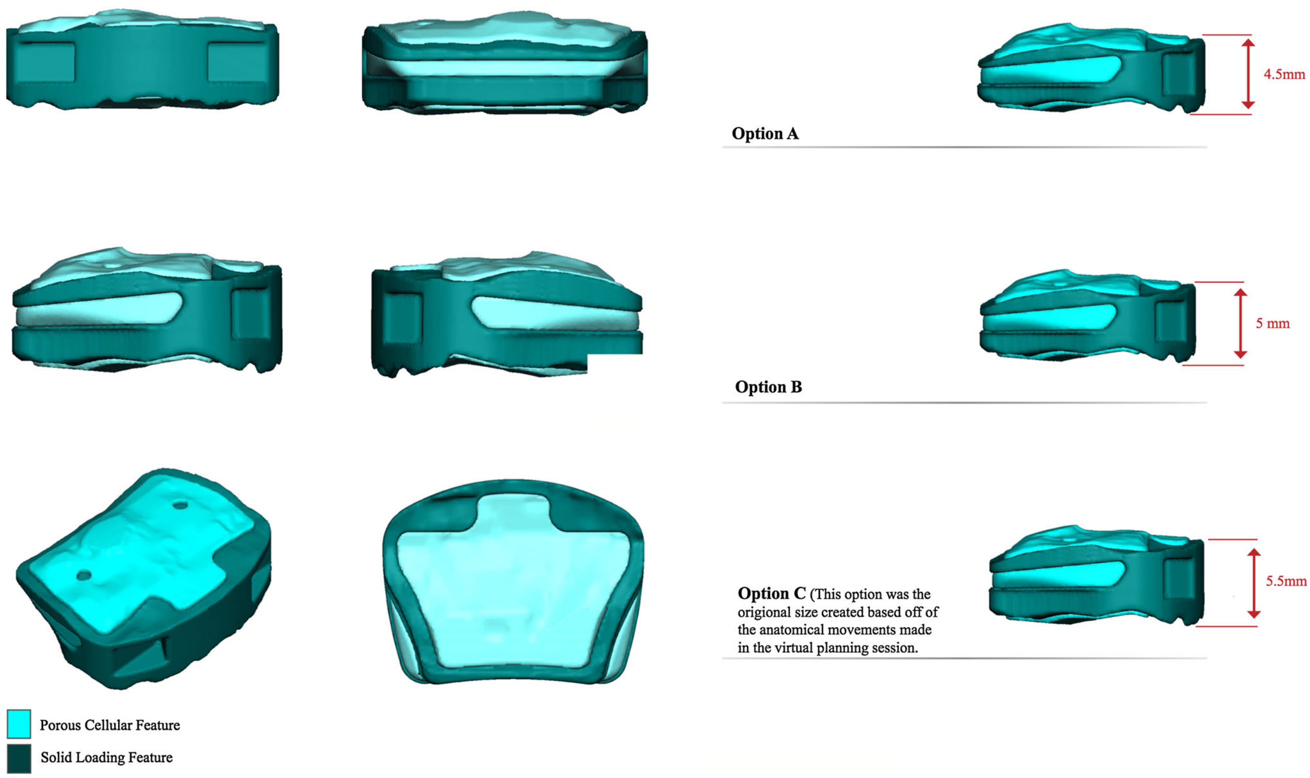

Fig. 5 Finished design of the individual implant with three different heights in 0.5 mm steps

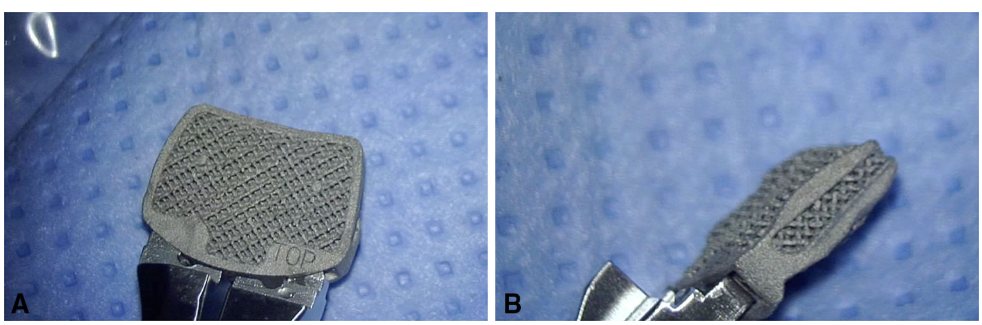

Fig. 6 The actual implant with a macro- and microcellular trabecular structure for improved osseointegration. Cranial endplate (**a**) and lateral view (**b**)

fusion without an additional synthetic bone graft (Fig. 5).

Discussion

Individualized cages for cervical fusion for the surgical treatment of spondylotic cervical myelopathy and/or radiculopathy have the potential to be the next step in the development of up-to-date spinal implants [1, 2]. Especially in neurosurgery there is an analogy to computer-aided design cranial implants for the reconstruction of skull defects [5–8].

Nevertheless, the manufacturing process of individualized spinal implants is much more complex because of the spine's contour and function. Thus, the production process takes much more time, effort, and costs compared to a standard cage especially when considering the planning and manufacturing procedures. Beside these disadvantages,

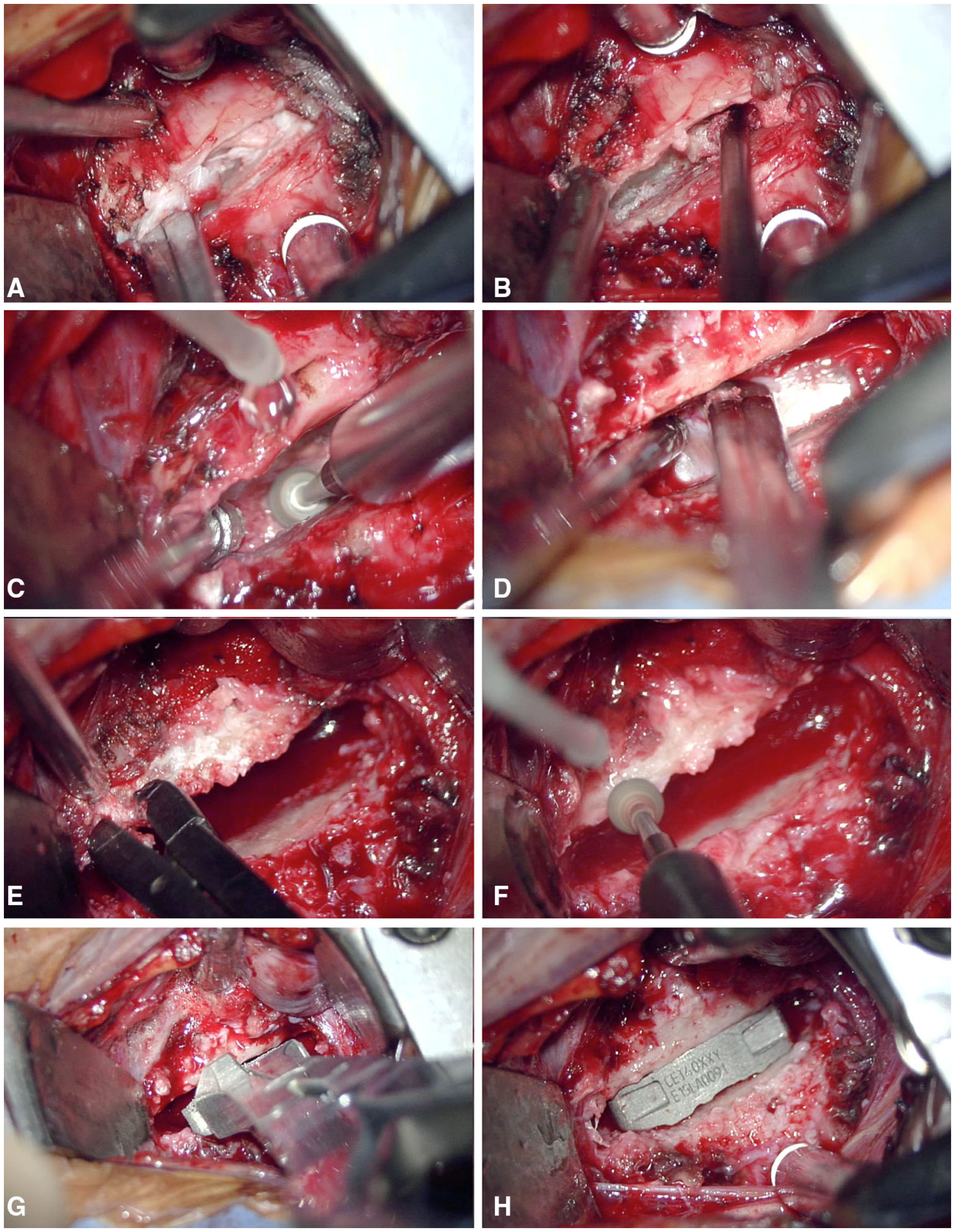

Fig. 7 Surgical steps of the implantation. Discectomy (**a**) with removal of the cartilage attached to the bony endplates (**b**). Selective removal of posterior osteophytes using a diamond drill (**c**). Resection of the thickened posterior longitudinal ligament (**d**). Removal of anterior osteophytes (**e**, **f**). Checking the height of the disc space to estimate the appropriate height for the final implant (**g**). Individualized titanium cage in situ (**h**)

there are some potential advantages in avoiding implant-related complications: a better load-bearing surface, and a lower rate of implant dislocation and cage subsidence into the bony endplates of adjacent vertebral bodies. As a result of this, there will be a lower rate of revision surgeries.

It is likely that the production of a higher number of individualized cages will lower the implant costs. The biggest challenge will be the process optimization to minimize the additional cost.

Conclusion

The technical preconditions for the planning and manufacturing of individualized cervical fusion cages using specific patient data are given. The implantation of these cages is as uncomplicated as the implantation of standard cages. The improved load-bearing surface will be probably able to reduce the rate of implant dislocation and cage subsidence. If it will be possible to produce such

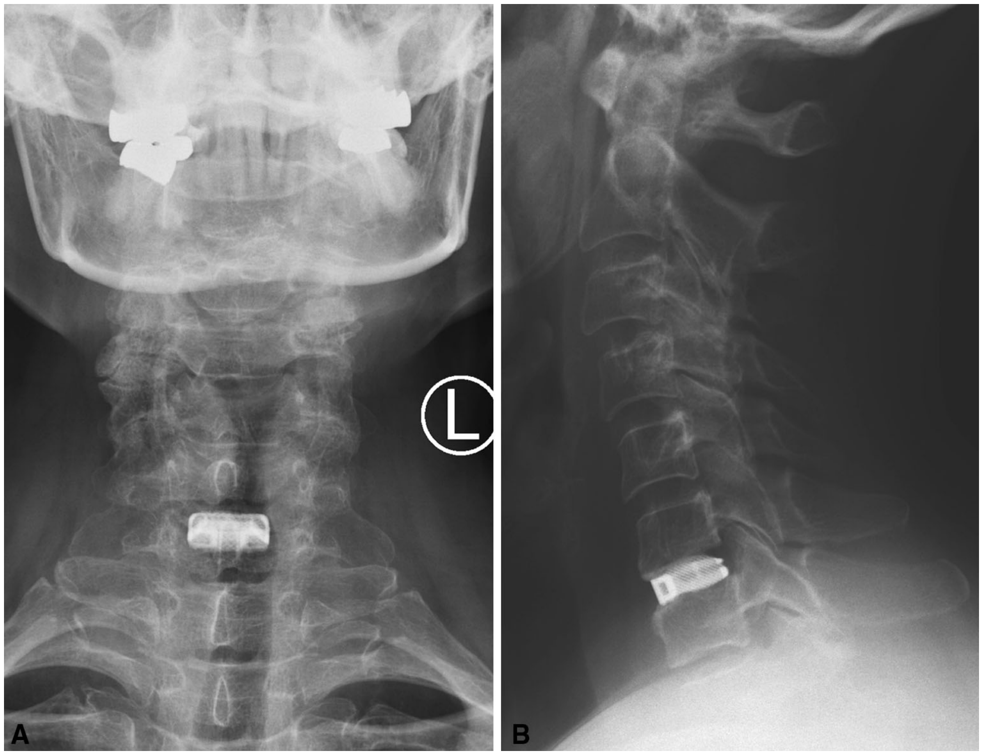

Fig. 8 Postoperative result of an ACDF with an individualized titanium cage. Anteriorposterior (**a**) and lateral (**b**) X-ray images

individualized cages at a reasonable price has to be evaluated by a collaboration of spine surgeons and the industry.

Compliance with ethical standards

Conflict of interest The authors have no personal financial or institutional interest in any of the materials, or devices described in this article.

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