Fusion behaviour of different cervical interbody devices -
Comparison of the cages available on the market

HuT-P02-11
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Abstrakt


Abstract

The treatment of degenerative cervical spine disorders has gone through constant development in recent decades. The solutions available on the market differ with reference to materials and design. Each of them has one or more specific central issues, such as the biomechanical load-bearing capacity, biocompatibility, fusion performance or translucency on X-ray or MRT images. It has not been possible to achieve an overall satisfactory solution for the implants that have been developed. In the following, a newly approved cervical cage produced by HumanTech will be presented that complies with all the required specifications.

1. Introduction

Degenerative cervical spine disorders are often a symptom of the degenerative process that advances with age. Overuse, traumas, inflammations or tumorous lesions can promote or accelerate these changes. These processes can result in compensatory hypertrophy of the ligaments or adjacent bony structures (Voorhies, 2001). A distinction is made between soft and hard disc herniation, ossification of the posterior longitudinal ligament and cervical spondylogenic myelopathy. Surgical treatment in the form of a discectomy with or without fusion is required if neurological deficits occur or in cases of progressive cervical myopathy (Grote et al, 1991).

The performance of discectomy alone results in a significant decrease in the stability of the cervical spine, as has become sufficiently clear in the past. The loss of height in the intervertebral space causes a kyphotic malposition of the affected segment of the spine. Disadvantages are protracted bony consolidation, lower fusion rates and the possibility of post-operative recurrence of
the pre-operative pain symptoms (Goel et al, 1998).

Due to these problems, the approach was changed in practice and the cervical discectomy was carried out with simultaneous fusion (Heidecke et al, 2000).

The spinal fusion agent serves as a structural support, in order to re-establish the physiological lordosis in the cervical spine and make solid fusion possible.

High fusion rates are achieved through maintenance of the foraminal height and the development of kyphotic deformities is generally prevented through preservation of spinal alignment, axial dislocations are avoided and simultaneous regression of the symptoms is achieved in the patients treated in this way (Watters et al, 1994).

Initially, the anterior cervical discectomy was carried out with cylindrical dowel-shaped bone plugs, following Cloward’s method or, as described by Howard-Robinson, through the use of a tricortical, horseshoe-shaped autologous bone graft taken from the iliac crest. Complications occurring during these interventions were dowel breakage, dislocation or pseudarthrosis at the site of the implant. Complications at the site from which the transplant was taken included post-operative pain, small numbers of infections, haematomas, deformation of the iliac crest, injuries to nerves, fractures, peritoneal injuries and high blood loss (Lindsey et al, 1978). Against this, there is the advantage that autologous bone has osteoconductive, osteo-inductive and osteogenic properties. There is also no risk of disease transmission or biological rejection reactions (Anderson et al, 2002).

The option of using an allograft was considered in order to avoid the negative consequences of using an autograft (Young et al, 1993). However, the risk of transmissible diseases and the fact that allografts are very expensive means their use is questionable. A further negative factor associated with the stand-alone use of autografts or allografts is the common occurrence of vertebral body end plate deformations and the resultant loss of height.

In recent years, based on the sometimes negative experiences with discectomy and the risks posed by the use of autografts and allografts, we have seen the development of a trend towards the use of cages. These have several advantages over the classical method of bone fusion (Zevgaridis et al, 2002).

Recent years have seen the development of implants for the cervical spine region that are made of titanium, tantalum, hydroxylapatite ceramics, carbon, polymethylacrylate (PMMA), PEEK and surface-coated PEEK cages.

The design of these cages is either solid, their shape is cubical, cubic-cylindrical or helical (cylindrical) and they have no, one, or several pores for the uptake of bony material and other compounds.

The cages must comply with the following requirements to fulfil their function:

- no taking of an autograft
- no use of allografts
- maintenance or restoration of foraminal height
- restoration of the cervical lordosis
- high biomechanical load-bearing capacity
- prevention of dislocations
- no sintering (subsidence)
- no migration of the implant
- no hindrance to post-operative X-ray, CT and MRI follow-ups
- facilitation of a solid fusion (through osteo-integration, osteoconduction and, if appropriate, osteo-induction)

The following analysis of the alternatives available on the market takes into consideration the requirements that the cages need to fulfil. Coating with growth factors is not considered in this analysis.

2. Advantages and disadvantages of different cage materials

2.1. Titanium

Most of the CIDs available on the market are made of titanium alloys. Compared to other materials, these biocompatible alloys have the advantage that they have a high biomechanical load-bearing capacity. The question arises as to whether such an increase in biomechanical load-bearing capacity needs to be guaranteed in the cervical region. With reference to its material properties, titanium is 10 times more rigid than bone, which can result in an imbalance in the weight distribution between the implant and the bone, the consequences of which can be loosening and sintering of the implant. Based on biocompatibility, it can be assumed that there are no concerns over the titanium alloys that are used. A serious defect with reference to this group of cages are the artefacts that complicate radiological evaluation, as well as that of CT and MRI images. Osteo-integration is dependent on the surface structure of the titanium.

2.2. Tantalum

The trabecular metal cages made of the expensive heavy metal tantalum have the advantage that they are osteoconductive and osteo-integrative due to their high porosity and the affinity of osteocytes to the material tantalum. Counter to the expectation that these implants exhibit a high fusion rate similar to that for autologous bone, a study conducted by Löfgren (Löfgren et al, 2010) did, indeed, determine a higher fusion rate than for carbon cages, but, at 69% after 2 years, this was still considerably lower than for an autograft, with a fusion rate of 92%. Due to the properties of the lateral surfaces of these cages, introduction causing minimal trauma to the tissue is substantially complicated. These implants also have the disadvantage of producing artefacts as the CID is metallic.

2.3. Carbon, hydroxylapatite ceramics, PMMA and PEEK

Alternative materials that do not have the disadvantage of producing artefacts, are cages made of carbon, hydroxylapatite ceramics, PMMA and PEEK. However, complete translucency on X-ray images is as little use in the evaluation of X-ray, MRI and CT examinations to assess the outcome of treatment as a cage produced from pure titanium or a titanium alloy. This disadvantage can be countered through the use of X-ray-positive parts (pins). These cages are inferior to the metallic cages in terms of their biomechanical qualities. In addition, both PMMA and PEEK do not form a
substrate that bone cells can attach to. The cages are not integrated into the bony substance, but can allow bony growth around them and, if pores are available, bony consolidation can take place.

2.3.1. Carbon

With reference to their material properties, cages made of carbon fibre are almost as elastic as the cortical substance of bone. This results in better weight distribution and force transmission. However, there is the risk of abrasion of carbon fibres with subsequent inflammatory and foreign body reactions (Parsons et al, 1985). The fusion rate for carbon cages was given as 86% in a study conducted by Vavruch (Vavruch et al, 2002).

2.3.2. Hydroxylapatite ceramics

CIDs made of hydroxylapatite ceramics are characterized by the problem that they become brittle due to the high temperatures required during manufacture and that extrusions and breaks can then occur. The advantage of hydroxylapatite is that it possesses both osteoconductive and osteo-integrative properties. In spite of the characteristics attributed to these materials, the bony consolidation process is slow, which means that they should be used in combination with a plate and screw system (Montazem et al, 1994).

2.3.3. PMMA

PMMA cages are only used occasionally as they are often associated with the development of necroses and there have been multiple cases of implant breakages and dislocations (Schröder et al, 2001).

2.3.4. PEEK

Cages made of PEEK have only become available on the market in recent years. The material exhibits high biocompatibility and is characterized by an elasticity that is more similar to that of bone than is the case for titanium or carbon. Table 1 summarizes the advantages and disadvantages of the different materials used in the manufacture of cages.
A combination of the materials with the best properties should therefore be used to produce a cage that fulfils all requirements. Appropriate combinations appear to be PEEK cages with a titanium or tantalum coating. The fusion rates are given in Table 2.

The implant surfaces are structured differently. To date, rough, toothed or serrated structures are known and these accelerate bonding and growth in the region of the base and upper plates of the vertebral bodies and are considered to improve primary stability.

A further characteristic that is focused on with reference to cages is porosity. A distinction is made between cages without pores, with one pore, or with several pores. Kandziora (Kandziora, 2003) concluded from his experiments that biological mechanical qualities, like the size of the largest pore in a cage, correlated positively with implant healing behaviour. In his studies, Kanayama (Kanayama et al, 2000) provided evidence in support of the following hypothesis: 'The greater the size of the largest pore in the contact surface of a cage, the lower the stress shielding effect on the incorporated spongiosa and the more favourable the healing behaviour of the cage.' However, the stability of the implant is reduced with increasing pore size and there is a greater risk of the implant collapsing into the vertebral body as the forces are being spread over a smaller contact area.

Another disadvantage of the pores is that they must be filled with bone or a bone replacement substance to enable bony consolidation. The risks and disadvantages of this have already been described above.

### Table 1: Summary overview

<table>
<thead>
<tr>
<th>Material</th>
<th>No artefacts</th>
<th>Biomech. load-bearing capacity</th>
<th>Biocompatibility</th>
<th>Fusion behaviour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Titanium</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Tantalum</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Carbon</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HA ceramics</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>PMMA</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>PEEK</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

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A combination of the materials with the best properties should therefore be used to produce a cage that fulfils all requirements. Appropriate combinations appear to be PEEK cages with a titanium or tantalum coating. The fusion rates are given in Table 2.

### Table 2: Radiological analysis of the outcomes for fusion (Abel-latif, 2005)

<table>
<thead>
<tr>
<th>Interponent</th>
<th>Solid implant healing</th>
<th>Non-solid fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone graft</td>
<td>69.2%</td>
<td>30.8%</td>
</tr>
<tr>
<td>PEEK cage</td>
<td>95.2%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Titanium cage</td>
<td>80.0%</td>
<td>20.0%</td>
</tr>
</tbody>
</table>

3. Advantages and disadvantages of different cage shapes

A study conducted by Fürderer (Fürderer et al, 2002) demonstrated that cages with a cubical or cubic-cylindrical contact surface exhibited a lower sintering tendency than implants with a cylindrical design. In addition, sintering increased with increasing depth of the structures cut into the cage.

Another disadvantage of the pores is that they must be filled with bone or a bone replacement substance to enable bony consolidation. The risks and disadvantages of this have already been described above.

4. Summary

In summary, we can state that the optimal cage is cubic in shape, adapts to the anatomical shape of the adjacent vertebral surfaces and has no pores.
The surface should have no deep structures in it, but should still guarantee high primary stability. The material should not produce any artefacts on images produced with imaging techniques, it should exhibit a high biomechanical load-bearing capacity, be biocompatible and exhibit positive fusion behaviour. Furthermore, a cost-effective production of the cage is desirable.

In order to comply with these requirements, the company HumanTech has developed a PEEK Cage with surfaces coated with titanium plasma spray.

Image 1: Frontal X-ray, Tristan PEEK-Ti-coated

Image 2: Lateral X-ray, Tristan PEEK-Ti-coated

The PEEK Ti-coated TRISTAN Cage is a cervical cage that is visible on X-ray images that:

- produces no scatter effects (no artefacts),
- can be introduced causing little tissue trauma,
- is optimally adapted to the anatomical shapes of the adjacent vertebral surfaces,
- does not collapse into the end plates,
- optimally cushions jarring movements without dislocation and exhibits optimum elasticity,
- can also be individually adapted to the different heights of the intervertebral spaces and the surfaces of the vertebral bodies with minimal finishing work and at minimal cost.
5. Technical data for Tristan

Winkel=Angle; Höhe=Height; Tiefe=Depth; Breite=Width

Image 3: Design Tristan

Image 4: Fibrin network on the surface of the implant

Image 5: HENIAPORE-K surface on Tristan

Image 6: Formation of a bone-specific extracellular matrix (collagen) on the surface of the implant.
References:


Schröder, J., und Wassmann, H. (Schröder et al, 2001): “Polymethylmethacrylate (PMMA) in


