On the development of an artificial intervertebral disc
Eijkelkamp, Marcus Franciscus

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version
Publisher's PDF, also known as Version of record

Publication date:
2002

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):
Chapter 6    Improving the fixation of an artificial intervertebral disc

M.F. Eijkelkamp, J. Hayen, A.G. Veldhuizen, J.R. van Horn, G.J. Verkerke

Abstract
The fixation of an artificial intervertebral disc has been studied especially with respect to the dimensions, the convexity of the endplates and the size of the fixation elements. From literature and cadaveric vertebrae, the dimensions and shape of the lumbar vertebral endplates were determined and the dimensions of fixation ribs for the artificial intervertebral disc were calculated. To withstand shear forces and prevent dislocation, two sagittal ribs, each 3.5 mm in height and at least 20 mm in length and four transversal ribs, each 1.5 mm in height and with a total length of 60 mm are sufficient. A range of five different sagittal diameters was selected as sufficient for all patients. At least 72.6 % of the endplate of the vertebrae is covered. A convexity with a radius of 140 mm limits the gap to 0.62 mm.( Int J Artif Organs 2002; 25: 327-33)
Chapter 6: Improving the fixation of an artificial intervertebral disc

6.1. Introduction

Patients with degenerative lumbar disc disease or hernia can be treated by implanting an artificial intervertebral disc (AID). Only a few AIDs have been applied clinically (1-3). The Fernström AID (1) is composed of a stainless steel ball. The Charité AID (3) is composed of two cobalt-chromium endplates, sliding on a polyethylene core. Both AIDs had problems with the fixation of the AID to the adjacent vertebrae. Ray (4) replaces only the function of the nucleus pulposus of the IVD, by implanting two hydrogel capsules into the intervertebral disc. The annulus fibrosus is damaged during the implantation.

Migration of the AID into the vertebrae is one of the risks of an AID, especially when only the center of cancellous bone of the vertebrae supports it. The designers of the Charité disc encountered this problem in their first design and therefore developed larger endplates for their AID, but these are still not as large as the endplate of the vertebra and not supported by the cortical shell (3).

Another risk is dislocation of the AID after implantation. The AID has to be fixated firmly to the vertebra immediately after implantation. To achieve this, pins or nails are placed on top of the endplates. Penetration of these fixation elements into the vertebral body should ensure a firm fixation. However, adequacy of these elements could be doubtful.

To overcome these risks, a suggestion for a new AID endplate has been developed with the potential of an optimal fixation, both immediately after the operation and on the long-term to withstand both compressive and shear forces. It is assumed that the AID consists of two endplates and a core element and that the AID will be introduced in one piece.

To withstand compressive forces the vertebrae have to support over their entire surface to avoid bone damage or resorption due to overloading or unloading the bone.

The size of the AID endplate should therefore be close to the size of the adjacent vertebra. When the endplates of the AID are larger, damage to vital structures like spinal cord and aorta are possible. When the endplates are smaller, subsidence into the vertebral body could occur.
By applying a porous surface bone ingrowth should occur to ensure optimal fixation. To withstand shear forces the AID endplates have to be provided by a series of pins, nails or ribs. We assume that the initial fixation of the AID can only be done with some large ribs to achieve enough surface to withstand the shear forces. To insert the endplate with the large ribs, the vertebrae have to be pre-conditioned. The grooves for the large ribs can be cut in the vertebra with a small mill or with laser cutting.

The curvature of the vertebral endplate should be followed as close as possible. A gap between the vertebra and the AID of 1 mm result in a better fixation than a gap of 2 mm when hydroxyapatite was used (5).

The range in disc size of patients will be too large for a one-size-fits-all concept. To make the AID suitable for every patient, the AID can be custom-made for each patient or can be chosen from a limited number of AIDs in different sizes. The first option gives the best fit of the prosthesis to the patient, the last option is preferred, because of the simplicity of operation preparation and logistics.

First goal of this paper is to determine whether it is possible to have only five AID endplates with different sizes and shapes. Second goal of this paper is to determine the optimal size of these elements that ensures optimal fixation and still allows easy introduction, bearing in mind that the new fixation should:
- be suitable for all lumbar levels for all persons,
- be biocompatible,
- not damage the spinal ligaments and muscles during insertion,
- have minimal thickness,
- not overstretch the ligaments during insertion,
- not have elements protruding out of the intervertebral disc space

**6.2. Material and Methods**

A literature survey was performed to determine the sagittal and transversal diameter, shape and curvature of the endplates of lumbar vertebrae. In addition, measurements using a caliper on cadaveric lumbar vertebrae from six healthy adult spines were performed to retrieve the form of the vertebrae. From these data, the relation between transverse and sagittal diameter, the range in transverse and sagittal diameter, shapes and curvatures of the disc endplate were calculated. We checked whether five different endplates with regard to shape, size and curvature are sufficient to have a support area of at least 70 % and a gap of at most 1 mm.
The design of the endplate, used for the calculation of the height of the fixation elements is shown in Figure 6-1. At first, two sagittal ribs (A) and four transversal ribs (B) are proposed.

\[ A = \text{sagittal fixation ribs}, \quad B = \text{transversal fixation ribs}. \]

To determine the minimum size and number of fixation elements like pins, nails or ribs, maximal forces on a lumbar motion segment of 8 kN in compression, 3 kN in sagittal shear and 2 kN in lateral shear are assumed (6).

The relevant material properties of cortical and cancellous bone are given in Table 6-1. For our calculations, the minimum values are used. The material properties of cancellous bone are assumed to be 1/10 th of the properties of cortical bone (7, 8).

<table>
<thead>
<tr>
<th>Table 6-1: Relevant mechanical properties (in MPa) of cortical and cancellous bone (7, 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cortical bone</strong></td>
</tr>
<tr>
<td>Compr. strength</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

It is assumed that a rib rests for 1/9th in cortical bone and 8/9th in cancellous bone. The maximum height of the fixation elements has been determined by analyzing the maximum increase in length for the spinal ligaments when inserting the AID.

The minimum required contact area of one endplate and for the sagittal and transversal ribs that prevent dislocation of the AID have been calculated. The formulas used are given in the appendix. Also the formulas to calculate the preferred radii of curvature for the endplate of the disc are given in the appendix.
6.3. Results

The size of the vertebral endplates has been derived from studies by Aharinejad (CT and MRI scans) (9) Amonoo (10), Gilad (11) (transversal radiographs), Panjabi (12) (radiographs), Berry (13) and Linton (14) (cadaveric material) and summarized in Table 6-2 and Table 6-3. Data measured from cadaveric vertebrae give larger transversal/sagittal diameter quotients (Linton: 1.51, Berry: 1.50) than data from radiographic studies (Aharinejad: 1.38, Panjabi: 1.32).

Table 6-2: Average sagittal diameters of the lumbar vertebrae (in mm)

<table>
<thead>
<tr>
<th></th>
<th>Aharinejad (9)</th>
<th>Amonoo (10)</th>
<th>Berry (13)</th>
<th>Linton (14)</th>
<th>Panjabi (12)</th>
<th>Gilad (11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1</td>
<td>29.0</td>
<td>39.8</td>
<td>32.3</td>
<td>28.1</td>
<td>35.3</td>
<td>34.1</td>
</tr>
<tr>
<td>L2</td>
<td>31.1</td>
<td>41.1</td>
<td>33.4</td>
<td>34.9</td>
<td>34.7</td>
<td></td>
</tr>
<tr>
<td>L3</td>
<td>34.6</td>
<td>41.8</td>
<td>34.2</td>
<td>31.2</td>
<td>34.8</td>
<td>34.6</td>
</tr>
<tr>
<td>L4</td>
<td>38.0</td>
<td>42.4</td>
<td>35.6</td>
<td></td>
<td>33.9</td>
<td>34.9</td>
</tr>
<tr>
<td>L5</td>
<td>37.6</td>
<td>41.0</td>
<td>34.5</td>
<td>33.0</td>
<td>33.2</td>
<td>33.9</td>
</tr>
<tr>
<td>Patients</td>
<td>359</td>
<td>600</td>
<td>30</td>
<td>50</td>
<td>12</td>
<td>157</td>
</tr>
</tbody>
</table>

In Table 6-4 the result of our cadaveric measurements are given. In radiographic studies the sagittal size is mostly measured from the ultimate anterior to ultimate posterior point, without the indent (from the kidney shape) at the posterior side, which is the decisive measure for an AID. Mean value from our measurements is 1.50 with a standard deviation of 0.03. The quotient of sagittal and transversal diameter appeared to be rather independent from level and patient.

Table 6-3: Average transverse diameters (in mm) of the lumbar vertebrae.

<table>
<thead>
<tr>
<th></th>
<th>Aharinejad (9)</th>
<th>Berry (13)</th>
<th>Linton (14)</th>
<th>Panjabi (12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1</td>
<td>39.7</td>
<td>49.1</td>
<td>41.55</td>
<td>43.3</td>
</tr>
<tr>
<td>L2</td>
<td>41.6</td>
<td>54.8</td>
<td>45.5</td>
<td></td>
</tr>
<tr>
<td>L3</td>
<td>47.7</td>
<td>53.8</td>
<td>45.95</td>
<td>48.0</td>
</tr>
<tr>
<td>L4</td>
<td>52.5</td>
<td>50.9</td>
<td>49.5</td>
<td></td>
</tr>
<tr>
<td>L5</td>
<td>54.5</td>
<td>52.7</td>
<td>50.75</td>
<td>49.4</td>
</tr>
<tr>
<td>Patients</td>
<td>359</td>
<td>30</td>
<td>50</td>
<td>12</td>
</tr>
</tbody>
</table>
From these ranges, the sizes of the 5 AID endplates are derived (Table V). For each endplate the increase in sagittal diameter is 2.9 mm, the increase in transversal diameter is 4.5 mm.

A representative graph of the shape of the vertebral endplates of the studied cadaveric lumbar vertebrae is shown in Figure 6-3: Shape of the endplates of the lumbar vertebrae and the fit of an ellipse shaped prosthesis (Gray) on the lumbar vertebrae. In the upper lumbar segment, the vertebral body is kidney shaped, in the lower lumbar segments this shape turns to an ellipse. From Figure III can be seen that an ellipse-shaped endplate offers a very good fit for the vertebrae. If the ellipse shaped AID endplate would be custom made, a support area of at least 87 % would be achieved. When considering the right size of the 5 proposed AID endplates from Table 6-5, at least 72.5% of the vertebral endplate was covered.

To prevent migration of the disc into the vertebrae, the surface area of the AID has to be at least 702 mm$^2$ (equation 1). Even the smallest endplates, with a surface area of 990.8 mm$^2$ have a 1.4 times higher area than necessary for an 8 kN compression force, assuming only cancellous bone support.

Chazal (15) found that the maximal deformation of the ligaments without damage ranged between 3.2 and 7.4 mm. Therefore, the height of a fixation element should not exceed 1.5 mm.

The side area of the sagittal ribs has to be at least 131.6 mm$^2$ according to equation 2 to prevent damage to the cancellous bone, the side area of the transversal ribs (equation (3)) has to be at least 87.7 mm$^2$. If the rib height is 1.5 mm, the total length of the sagittal ribs has to be at least 87.7 mm. The total length of the transversal ribs has to be at least 58.5 mm. For the smallest size of the endplate, with a rib length of 20 mm, at least 5 sagittal ribs and 3 transversal ribs are required to ensure a good fixation of the prosthesis. When the height of the sagittal ribs is enlarged to 3.3 mm, two sagittal ribs are sufficient. The prosthesis can be inserted from the side, after cutting grooves into the vertebrae. Therefore, a sagittal rib height of 3.3 mm is suggested. The transversal ribs cannot be enlarged, therefore it is suggested to apply...
three ribs with a total length of 60 mm. The larger sizes of the AID can be supplied with longer ribs and therefore lower and less ribs.

The radius of curvature was calculated from the data of Aharinejad (9). These are listed in Table 6-6. The sagittal radius of convexity calculated with equation 4 ranges from 98.8 mm for L1-L2 to 140.6 mm for L4-L5. When a radius of curvature of 141 mm is chosen for each endplate, the maximal gap between the AID endplate and the vertebra with the smallest curvature, is 0.62 mm. When the AID was given a flat endplate, the distance could be up to 2.05 mm.

6.4. Discussion

The data found in literature resulted from measurements with different techniques. The various imaging techniques that are used in hospitals have influence on the results. The viewing direction relative to the measured object influences the outcome of the measurement. Also, the scanplane or viewing plane is not always perpendicular to the required direction. With X-ray, one has to cope with the magnification that occurs during the making of the image. Also it is difficult to measure the distance from the anterior side of the vertebrae to the indent at the posterior side. The result of this is that there will be an error in the outcome of the measurements, performed with different techniques. These errors do not occur when measuring cadaveric material.

Table 6-4: Average values for a, b, r1, r2 (in mm), averaged from 6 cadaveric lumbar spines
(for explanation, see Figure II).

<table>
<thead>
<tr>
<th>Level</th>
<th>a</th>
<th>b</th>
<th>r1</th>
<th>r2</th>
<th>Quotient a/b</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1-L2</td>
<td>48.89</td>
<td>33.10</td>
<td>14.42</td>
<td>26.82</td>
<td>1.48</td>
</tr>
<tr>
<td>L2-L3</td>
<td>50.64</td>
<td>33.90</td>
<td>16.07</td>
<td>32.12</td>
<td>1.50</td>
</tr>
<tr>
<td>L3-L4</td>
<td>53.25</td>
<td>35.70</td>
<td>17.40</td>
<td>52.57</td>
<td>1.49</td>
</tr>
<tr>
<td>L4-L5</td>
<td>54.86</td>
<td>36.63</td>
<td>ellipse shaped flat</td>
<td>1.50</td>
<td></td>
</tr>
<tr>
<td>L5-S1</td>
<td>55.96</td>
<td>37.03</td>
<td>ellipse shaped -</td>
<td>1.51</td>
<td></td>
</tr>
<tr>
<td>average</td>
<td>52.72</td>
<td>35.27</td>
<td>15.96</td>
<td>37.17</td>
<td>1.50</td>
</tr>
<tr>
<td>SD</td>
<td>3.78</td>
<td>2.42</td>
<td>1.68</td>
<td>11.99</td>
<td>0.03</td>
</tr>
</tbody>
</table>

From Table 6-2 to Table 6-4 can be seen that there is also a difference in results between different studies using the same technique. This can be due to an systematic error (for example, how to define the reference points) or by differences in subjects that were studied.

When implanting an artificial intervertebral disc, as less damage as possible should be caused to the vertebral column. The spinal ligaments must not be damaged due to the implantation of the disc, because they play a crucial role in maintaining the stability of the vertebral column. Also the vertebrae should be damaged as little as possible. With
the suggested endplate, it is possible to slide it in from the side, without chance of damage to major blood vessels and spinal ligaments.

From the calculation of the size of the endplate area of the AID, it appears that the contact area of the AID with the vertebra is more than adequate to prevent migration. Due to surface irregularities on the vertebral endplates, the contact area will be smaller at first, but it is to be expected that the high-loaded peaks will disappear thus enlarging the contact area to its maximum.

Table 6-5: Sagittal and transverse diameter, sagittal and transversal rib lengths and surface area for the 5 different sizes of lumbar Artificial Intervertebral Disc (AID) endplates.

<table>
<thead>
<tr>
<th>Size</th>
<th>Sagittal diameter (mm)</th>
<th>Transv. diameter (mm)</th>
<th>Sagittal rib length (mm)</th>
<th>Sagittal rib height (mm)</th>
<th>Transv. rib length (mm)</th>
<th>Transv. rib height (mm)</th>
<th># transv. ribs</th>
<th>Surface area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>29.0</td>
<td>43.5</td>
<td>20.0</td>
<td>3.3</td>
<td>20.0</td>
<td>3</td>
<td>990.8</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>31.9</td>
<td>47.9</td>
<td>24.4</td>
<td>2.7</td>
<td>22.9</td>
<td>3</td>
<td>1198.8</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>34.8</td>
<td>52.2</td>
<td>28.8</td>
<td>2.3</td>
<td>25.8</td>
<td>3</td>
<td>1426.7</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>37.7</td>
<td>56.6</td>
<td>33.2</td>
<td>2.0</td>
<td>28.7</td>
<td>2</td>
<td>1674.4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>40.6</td>
<td>60.9</td>
<td>37.6</td>
<td>1.8</td>
<td>31.6</td>
<td>2</td>
<td>1941.9</td>
<td></td>
</tr>
</tbody>
</table>

The size of the endplates has to be well chosen. When the size of the endplate is too small, the cortical shell of the vertebra stays unloaded and high compressive stresses on the cancellous bone could result in subsidence of the AID into the vertebrae.

The maximum increase in sagittal diameter is small enough to ensure loading of the cortical shell because the cortical shell of the IVD about 2 to 3 mm thick. If the AID is placed as far as possible to the anterior side of the vertebra, the highest compressive forces in flexion could be supported by the anterior cortical shell. The sagittal diameter of the proper size of the prosthesis is always smaller than the diameter of the vertebrae to avoid damage. The transversal diameter of the AID endplate may be 1-2 mm larger than the diameter of the vertebral endplates. There is hardly any chance for damage, and the cortical shell of the vertebrae will be covered maximally.

The long-term fixation of the AID endplate can be improved by applying a coating, e.g. hydroxyapatite. Fast ingrowth of bone decreases the chance of dislocation of the AID. The ingrowth of bone decreases the chance of stress concentrations on the bone on the edges of the fixation, because the stress is dispersed over a larger area. The proposed rib elements are large enough to prevent movement, even without bone ingrowth. This is necessary since movement of the AID in relation with the vertebrae will prohibit bone ingrowth into the endplates of the AID. Moreover, the position of the ribs prevents damage to the ligaments, in contrast to fixation of the disc with screws to the side of the vertebra. The proposed fixation elements of the AID cut
mostly into the cancellous bone instead of the cortical bone. Even then, the strength of the fixation is sufficient.

The shear forces on the AID are very high, up to 3000 N. Not all this load has to be transferred through the AID and the endplates, because the facet joints of the vertebrae are able to bear part of the shear load (16). But very often, the facet joints of the motion segment are degenerated when the disc has to be replaced. Therefore, to unload the facet joints, it would be better to construct a relatively stiff artificial disc. Before the facet joints make contact, more load is transferred by the AID. The downside of this solution is a larger load on the fixation of the AID (17).

The convexity of the endplate decreases the size of the gap between the surface of the AID endplate and the vertebra. The ingrowth of bone will be faster when the gap between the bone and the prosthesis is smaller thereby decreasing the chance of dislocation of the AID (5, 18).

In conclusion, the 5 proposed endplates with ribs will adequately support the vertebrae. Dislocation of the prosthesis is prevented, minimizing the chance of damage to the spinal cord and major blood vessels. The chance of AID subsidence into the body is prevented by making the contact area as large as possible. The close fit to the vertebrae in combination with the large fixation elements will facilitate fast ingrowth of bone in a porous coating.

<table>
<thead>
<tr>
<th>Level</th>
<th>y1</th>
<th>y2</th>
<th>y3</th>
<th>x</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1-L2</td>
<td>4.98</td>
<td>3.79</td>
<td>4.03</td>
<td>14.5</td>
<td>98.8</td>
</tr>
<tr>
<td>L2-L3</td>
<td>5.17</td>
<td>4.11</td>
<td>4.09</td>
<td>15.55</td>
<td>113.5</td>
</tr>
<tr>
<td>L3-L4</td>
<td>5.49</td>
<td>4.32</td>
<td>4.32</td>
<td>17.3</td>
<td>112.5</td>
</tr>
<tr>
<td>L4-L5</td>
<td>5.81</td>
<td>4.54</td>
<td>4.51</td>
<td>19</td>
<td>140.6</td>
</tr>
<tr>
<td>L5-S1</td>
<td>6.1</td>
<td>4.71</td>
<td>4.7</td>
<td>18.8</td>
<td>126.9</td>
</tr>
</tbody>
</table>
6.5. Appendix

6.5.1. Size contact area with vertebrae

The contact areas are estimated for a situation in which the endplate is supported by for 1/9 by cortical bone and for 8/9 by cancellous bone. The stress on the bone can be calculated using:

\[ \sigma = \frac{F_c}{A_{cont}} \leq \sigma_{res} \implies A_{cont} \geq \frac{F_c}{\sigma_{res}} \]  

(1)

\[ F_c = 8 \text{ kN} = \text{compression Force} \]

\[ \sigma_{res} = f_{cort} \cdot \sigma_{cort} + f_{canc} \cdot \sigma_{canc} \]

(2)

\[ f_{cort} = \text{fraction supported by cortical bone} = 1/9 \]

\[ f_{canc} = \text{fraction supported by cancellous bone} = 8/9 \]

\[ \sigma_{cort} = 114 \text{ Mpa} = \text{compressive strength cortical bone} \]

\[ \sigma_{canc} = 11.4 \text{ Mpa} = \text{compressive strength cancellous bone} \]

6.5.2. Sagittal rib area

The minimum required area of the sagittal ribs has been calculated using:

\[ \sigma_{sag} = \frac{F_s}{A_{sag}} \leq \sigma_{res} \text{ with } A_{sag} = h_{sag} \cdot l_{sag} \]

(3)

with

\[ F_s = \text{Sagittal shear force} = 3 \text{ kN} \]

\[ \sigma_{res} = \text{as above} \]

\[ h_{sag} = \text{height sagittal ribs, } l_{sag} = \text{length sagittal ribs} \]

6.5.3. Transversal rib area

The minimum required area of a transversal rib has been calculated using:

\[ \sigma_{trans} = \frac{F_s}{A_{trans}} \leq \sigma_{res} \text{ with } A_{trans} = h_{trans} \cdot l_{trans} \]

(4)

\[ h_{trans} = \text{height transversal ribs, } l_{trans} = \text{length transversal ribs} \]

\[ F_s = 2 \text{ kN} = \text{transversal shear force} \]

The friction force between the AID and the vertebrae is neglected.

The radius of curvature of the concavity of a vertebra was calculated using:

\[ r = \sqrt{x^2 + \left( y_3 - \frac{x^2 + y_2^2 - y_1^2}{2(y_2 - y_1)} \right)^2} \]

(5)

with
\[ x = \frac{1}{2} \times \text{the sagittal diameter} \]
\[ y_1 = \frac{1}{2} \times \text{middle height of the intervertebral disc} \]
\[ y_2 = \frac{1}{2} \times \text{anterior height of the intervertebral disc} \]
\[ y_3 = \frac{1}{2} \times \text{posterior height of the intervertebral disc} \]

From these radii, the largest one was chosen for the AID, and the maximum gap between the AID and the vertebrae was calculated.

### 6.6. References

10. Amonoo KH. Morphometric changes in the heights and anteroposterior diameters of the lumbar intervertebral discs with age. J Anat 1991; 175: 159-68.