On the development of an artificial intervertebral disc

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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):

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Chapter 2    Requirements for an artificial intervertebral disc

M.F. Eijkelkamp, C.C. van Donkelaar, A.G. Veldhuizen, J.R. van Horn, J.M. Huyghe, G. J. Verkerke

Abstract
Intervertebral disc degeneration is an important social and economical problem. Presently available artificial intervertebral discs (AIDs) are insufficient and the main surgical intervention is still spinal fusion. The objective of the present study is to present a list of requirements for the development of an AID which could replace the human lumbar intervertebral disc and restores its function. The list addresses geometry, stiffness, range of motion, strength, facet joint function, center of rotation, fixation, failsafety and implantation technique. Date are obtained from literature, quantified where possible and checked for consistency. Existing AIDs are evaluated according to the presented list of requirements. Endplate size is a weak point in existing AIDs. These should be large and fit vertebral bodies to prevent migration. Disc height and wedge angle should be restored, unless this would overstretch ligaments. Finally, stiffness and range of motion in all directions should equal those of the healthy disc, except for the axial rotation to relieve the facet joints. (Int J Artif Organs 2001; 24: 311-21)
Chapter 2: Requirements for an artificial intervertebral disc

2.1. Introduction

The intervertebral disc (IVD) consists of a gelatinous nucleus pulposus, surrounded by a fibrous annulus fibrosus. This particular construction can withstand the high loads acting on the spine during everyday life (1,2), while giving the vertebral column its mobility. IVD degeneration is a frequently occurring pathology with important social and economic consequences, as it is a major cause of occupational disability. In the case of symptomatic IVD degeneration, surgical intervention is necessary. Unless the pathology is limited and localised, total IVD replacement is inevitable.

The vertebral column consists of 24 separate vertebrae and the sacrum, connected by intervertebral discs, ligaments and muscles. Replacing one part of the vertebral column with a mechanically different part could affect the whole system negatively. As an example, a frequently practiced surgical solution is fixation of the intervertebral joint. Besides loss of mobility, extra loading or movement of the adjacent discs could result in increased disc degeneration at these levels (3,4). An artificial intervertebral disc (AID) mimicks the mechanical properties of the IVD, meaning that mechanics around the spinal column are unchanged and stability is unaffected, while motion between vertebral bodies is still possible.

The aim of the present paper is to provide directions for improvement of existing AIDs and their future development. Therefore, a list of specifications for the development of an AID has been derived from an extended literature survey of IVD properties. Existing clinically used AIDs, i.e. the Fernström (5), the Acroflex (6,7) and the Charité AID (8), are judged according to this list regarding functioning and cause of failure.

The following requirements have been selected as critical items in the development of an AID:

1. Geometry
2. Stiffness
3. Range
4. Strength
5. Center of rotation
6. Fixation to the adjacent vertebra
7. Function of the facet joints
8. Failsafety
9. Surgical procedure

Where possible, these variables are quantified using literature data. Qualitative adjustment is suggested whenever applicable.
2.2. Materials and Methods

An extensive literature study was performed to retrieve data for the requirements an artificial intervertebral disc has to satisfy. All data were checked on consistency and for each of the requirements, properties were given which are applicable to an artificial intervertebral disc. Artificial discs that have been used clinically were evaluated with these results. Guidelines for the development of new or for the improvement of existing AIDs are given.

2.3. Results

2.3.1. Geometry

Boundaries for the AID geometry are determined by the endplates of the adjacent vertebral bodies and the IVD space. Fixation of the AID to the endplates is most critical for successful intervention. For maximum grip between the AID and the bones, the shape of the AID endplates should be complementary to the surface of the adjacent bones. The size of the vertebral body endplates has been studied extensively, using radiographs (9-12), cadaveric specimens (13,14), CT and MRI scans (15). The results of these studies are comparable. The size of the vertebrae increases ~15 % from T12 to S1. The caudal lumbar vertebrae are ellipse shaped whereas the cranial lumbar vertebrae are kidney shaped. The vertebral endplates are slightly concave, but this has not been quantified in the literature, through it has been shown that concavity increases with age (16).

To restore the mechanics of the spine, the AID should fully restore height and wedge angle of the healthy situation. The height of human lumbar IVD’s has been studied extensively using lateral radiographs (10, 16-18), and MRI and CT scans (15) (Table 2-1). The small variation in average measured IVD height between studies is probably due to radiographical magnification bias. Also, in radiographs, the measured distance is mostly the largest lateral diameter of the vertebrae. However, the distance to the indent of the "kidney" is important for the fit of the AID.

During disc unloading (e.g. during bedrest), the disc attracts water and swells, while during loading of the disc, the water is expelled again. This diurnal volume variation (on the average 20 % in L3-L4 to L5-S1) (19), is accounted for by IVD height

| Table 2-1: Range and average values for lateral and sagittal diameter, disc height and wedge angle of lumbar intervertebral discs (T12/L1 – L5/S1) (9, 15) |
|-----------------|-----------------|-----------------|
| Range          | Average         |                 |
| Lateral diameter (mm) | 35 – 63         | 50              |
| Sagittal diameter (mm) | 27 – 45         | 35              |
| Height* (mm)    | 6 – 14          | 10              |
| Wedge angle (degrees) | 6 – 14          | Tables II and III |

*: Height in the middle of the intervertebral disc
rather than by disc diameter. As a result, distance between the transverse processi before and and after bedrest varies 1.7 mm (L1-L2 to L3-L4) (20).

From measurements of anterior and posterior disc height in combination with the anterior-posterior diameter (9, 10, 15-18), the IVD wedge angle could be calculated (Table II). Chen (21) studied differences in wedge angle between upright standing and 60º flexion. The total lumbar disc angle decreased with 42º for men and 46º for women.

Table 2-2: Intervertebral disc wedge angle (in degrees), calculated from anterior, posterior disc heights and anterior-posterior diameters (9, 15, 18, 70)

<table>
<thead>
<tr>
<th>Level</th>
<th>Tibrewall</th>
<th>Nissan</th>
<th>Aharinejad</th>
<th>Amonoo Kuofi Males</th>
<th>Amonoo Kuofi Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>L1-L2</td>
<td>6.7</td>
<td>3.7</td>
<td>-1.0</td>
<td>10.4</td>
<td>11.3</td>
</tr>
<tr>
<td>L2-L3</td>
<td>10.8</td>
<td>5.1</td>
<td>0.1</td>
<td>11.0</td>
<td>9.9</td>
</tr>
<tr>
<td>L3-L4</td>
<td>13.6</td>
<td>5.5</td>
<td>0.0</td>
<td>10.3</td>
<td>12.1</td>
</tr>
<tr>
<td>L4-L5</td>
<td>14.4</td>
<td>10.9</td>
<td>0.1</td>
<td>10.4</td>
<td>12.4</td>
</tr>
<tr>
<td>L5-S1</td>
<td>15.3</td>
<td>15.4</td>
<td>0.0</td>
<td>12.2</td>
<td>14.2</td>
</tr>
</tbody>
</table>

Mean values are calculated from all papers except Aharinejad (15)

According to most studies, the IVD is wedge shaped in neutral position with the anterior height larger than the posterior height (9, 10, 18). The wedge angle increases from T12 to S1 (Table 2-2) and with age (Table 2-3). Aharinejad (15) found wedge angles less than 1 degree, which distinctly differs from the numerous other findings on this topic.

Table 2-3: Average wedge angles (in degrees) for all levels of lumbar intervertebral discs

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Wedge angle males</th>
<th>Wedge angle females</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-20</td>
<td>8.1</td>
<td>8.0</td>
</tr>
<tr>
<td>20-30</td>
<td>8.2</td>
<td>8.7</td>
</tr>
<tr>
<td>30-40</td>
<td>9.6</td>
<td>11.7</td>
</tr>
<tr>
<td>40-50</td>
<td>12.8</td>
<td>13.6</td>
</tr>
<tr>
<td>50+</td>
<td>15.8</td>
<td>17.0</td>
</tr>
</tbody>
</table>

2.3.2. Stiffness

IVD stiffness (Table 2-4) is important for the shock absorbing ability of the vertebral column, which is largely accounted for by the IVD mechanical properties (22). The stiffness of the IVD has been studied in vitro (23, 24). Data that roughly describe the relationship between stiffness and compression are 800 N/mm at loads up to 1000 N, and 2000 N/mm at loads over 4000 N (25). This non-linear progressive stiffness of the IVD and ligaments facilitates small movements around the neutral situation, and restricts larger movements. Unfortunately, a comprehensive description of the relationship between stiffness and compression has not been found in the literature.
Probably the most important reason for discrepancies between the aforementioned studies is that test circumstances varied with respect to the time and rate of disc loading, and with respect to the final load applied on the disc. Because the disc exhibits visco-elastic mechanical behavior, time-dependency is an important variable when determining IVD stiffness.

For appropriate deformation of the spinal column and therewith appropriate loading of surrounding soft tissues, the stiffness of the AID and the IVD should be comparable.

### 2.3.3. Range of Motion

The range of motion (ROM) of the IVD was studied in vitro (26) and in vivo using lateral radiographs (21, 27, 28) and skin markers (27). The results are comparable. Kapandji (29) showed that the ROM decreases to 60% in 70 years old males. ROM data obtained from White and Panjabi’s review (22) and from Pearcy (30, 31), who distinguished flexion and extension, are given in Table V. An AID should allow for the same range of motion as the natural IVD, to restore full functionality of the spine. However, it should be noticed that an overly flexible motion segment may increase the chance of spinal instability.

Data are obtained from a review by White (46). Data from Pearcy (30, 31) are presented separately to distinguish flexion from extension.

### 2.3.4. Strength

One should distinguish loads that frequently occur during everyday life, such as walking and lifting small weights, from rare extreme loads, i.e. those that occur while lifting heavy objects or falling. The first type of load determines the AID fatigue

<table>
<thead>
<tr>
<th>Force/Moment</th>
<th>Stiffness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tension</td>
<td>770N/mm</td>
</tr>
<tr>
<td>Compression</td>
<td>2000 (700-2500) N/mm</td>
</tr>
<tr>
<td>Anterior shear</td>
<td>121N/mm</td>
</tr>
<tr>
<td>Posterior shear</td>
<td>170N/mm</td>
</tr>
<tr>
<td>Lateral shear</td>
<td>145N/mm</td>
</tr>
<tr>
<td>Flexion</td>
<td>1.36 (0.8-2.5) Nm/deg</td>
</tr>
<tr>
<td>Extension</td>
<td>2.08Nm/deg</td>
</tr>
<tr>
<td>Lateral bending</td>
<td>1.75Nm/deg</td>
</tr>
<tr>
<td>Axial rotation</td>
<td>5.00 (2.0-9.6) Nm/deg</td>
</tr>
</tbody>
</table>

Table 2-5: Range of motion (ROM) and its range in degrees for lumbar intervertebral discs

<table>
<thead>
<tr>
<th>Author</th>
<th>Motion</th>
<th>L1-L2 (°)</th>
<th>L2-L3 (°)</th>
<th>L3-L4 (°)</th>
<th>L4-L5 (°)</th>
<th>L5-S1 (°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>Axial rot.</td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
<td>1 (1-3)</td>
</tr>
<tr>
<td>White</td>
<td>Lat. bending</td>
<td>6 (3-8)</td>
<td>6 (3-10)</td>
<td>8 (4-12)</td>
<td>6 (3-9)</td>
<td>2 (2-6)</td>
</tr>
<tr>
<td>White</td>
<td>Flex. +Ext.</td>
<td>12 (5-16)</td>
<td>14 (8-18)</td>
<td>15 (6-17)</td>
<td>16 (9-21)</td>
<td>17 (10-24)</td>
</tr>
<tr>
<td>Pearcy</td>
<td>Flexion</td>
<td>8 (5)</td>
<td>10 (2)</td>
<td>12 (1)</td>
<td>13 (4)</td>
<td>9 (6)</td>
</tr>
<tr>
<td>Pearcy</td>
<td>Extension</td>
<td>5 (2)</td>
<td>3 (2)</td>
<td>1 (1)</td>
<td>2 (1)</td>
<td>5 (4)</td>
</tr>
</tbody>
</table>
strength, whereas the second determines the maximum strength of the AID, both of which are important failure criteria. The maximum strength of the AID has been studied in several ways:

Measurement of the load on the IVD in vivo (1, 2).
Measurement of the failure load of the IVD in vitro (23, 32, 33).
Measurement of the failure load of the vertebra in vitro (34).

**Table 2-6: Fatigue test loads for walking and lifting activities and maximum test load for the lumbar artificial disc**

<table>
<thead>
<tr>
<th></th>
<th>Fatigue Strength Walking</th>
<th>Fatigue Strength Lifting</th>
<th>Minimum Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression</td>
<td>200 – 2250 N</td>
<td>150 – 1250 N</td>
<td>8 kN</td>
</tr>
<tr>
<td>Lateral shear</td>
<td>-100 – 100 N</td>
<td>-450 – 450 N</td>
<td></td>
</tr>
<tr>
<td>Sagittal shear</td>
<td>-100 – 100 N</td>
<td>-450 – 450 N</td>
<td></td>
</tr>
<tr>
<td>Flexion</td>
<td>0 – 2˚ (*)</td>
<td>0 – 4˚ (*)</td>
<td>14˚</td>
</tr>
<tr>
<td>Extension</td>
<td>0 – 1˚ (*)</td>
<td>0 – 2˚ (*)</td>
<td>5˚</td>
</tr>
<tr>
<td>Lateral bending</td>
<td>0 – 1˚ (*)</td>
<td>0 – 2˚ (*)</td>
<td>6˚</td>
</tr>
<tr>
<td>Rotation</td>
<td>0 – 1˚ (*)</td>
<td>0 – 1˚ (*)</td>
<td>3˚</td>
</tr>
<tr>
<td># of cycles</td>
<td>80 million</td>
<td>5 million</td>
<td>20</td>
</tr>
</tbody>
</table>

Data marked with (*) are estimations, the others are retrieved from the literature.

Calculation of the load on the IVD with mathematical models (25, 35, 36).
In vivo intradiscal pressure on L3-L4 is approximately 1000 N in a standing position, increasing to 3000 N in a sitting, leaning forward position or carrying 20 Kg (1, 2). Wilke (2) found an increase in intradiscal pressure during sleep up to 240 % at the end of the sleep period, presumably because of rehydration.

Failure load according to Brown (23) is 5700 N, which is in agreement with the range found by Adams: 6400 ± 2450 N in compression (33) and 33 ± 12.8 Nm in flexion(32). Both studies show rupture of the endplates prior to IVD failure.

The maximum strength is needed for an AID is also determined by the failure load of adjacent vertebral bodies. Although White (22) concluded that the strength of the vertebrae is lower than that of the IVD (Table 2-5), Jäger (34) determined that the maximum failure load of the lumbar vertebrae equals 8000 N, which exceeds the 6400 N disc failure load as found by Adams (33).

Global forces that act on the IVD can also be estimated with numerical models in which the structures of the spine are represented by springs and dashpots. The results of these studies vary due to different assumptions, such as working distance of muscles, stiffness of the ligaments, speed of lifting and way of lifting. Despite these assumptions, the highest loads that were reported from these computations are 7500 N in compression (37), 3000 N in anterior posterior and 2000 N in lateral shear (38).
These values are in close agreement with the failure loads of Jäger (34). Therefore, not taking a safety factor into account, assuming a minimum failure load for the AID of 8000 N in compression, 3000 N in anterior posterior shear and 45 Nm in anteflexion, is reasonable (Table 2-6). Maximum and minimum peak compression loads on L5-S1 while walking are 2.07 and 0.2 times bodyweight, respectively (39), maximum peak shear load is 0.63 times bodyweight. Ambrosio (40) used the load on the IVD while lying supine (200 N) and lifting a weight of 20 kg (2250 N) (1) for fatigue testing of an AID. For average fatigue torques and rotations of the IVD, no data were found in the literature.

The number of walking cycles is ~2*10^6 per year, and the number of lifting cycles is ~125*10^3 per year (41). Therefore, in a fatigue test, an AID should be loaded with 80*10^6 sinusoidal cyclic loads (2 Hz) between 150 and 1250 N (= 0.2 - 1.8 * 70 kg) in compression and between -450 and +450 N of shear load to represent 40 years of walking, followed by 5*10^6 sinusoidal 0.5 Hz cyclic loads between 200 and 2250 N in compression to simulate lifting weights (Table VI).

2.3.5. Center of rotation
In flexion, the center of rotation moves to the anterior side of the vertebral column, in extension to the posterior side, and during lateral bending and axial rotation, the center of rotation moves to the opposite side of the spinal column (22). The advantage of the movement of the center of rotation is that the working distance of the spinal muscles and ligaments increases during these actions. Therefore, loads are reduced (42-45). For this reason, and to minimize kinematic changes of the spine, the center of rotation of the AID preferably mimicks this behavior.

2.3.6. Fixation
Dislocation of a disc may result in serious damage to vital systems such as the spinal cord and large veins and arteries. Directly after implantation, a firm initial fixation is required, which must last for at least 20 years. Long term fixation can probably be improved by stimulation of bone ingrowth, using specific coatings. Similar techniques are widely used in other orthopedic implants.

2.3.7. Facet joints
Facet joints are small, stabilizing articulations between the vertebral bodies, located at the latero-posterior sides of the nerve root. The orientation of the joint surface, and therewith the direction in which movements are enabled, differs with position in the spinal column. In the lumbar spine, the orientation of the facets limits axial rotation, posterior-anterior shear and extension. Flexion and lateral bending are less restricted (22).
In neutral position, facet joints account for 15% of the total load, whereas in extension and axial rotation, this increases to 40% (46). Disc space narrowing, which is seen in degenerated discs, increases facet joint loading (47).

In degenerated discs, the facet joints are often arthritic and joint contact is painful. Therefore, the ideal AID would account for the function of degenerated facet joints (48), thus relieving these joints.

### 2.3.8. Surgical procedure

The surgical replacement procedure must exclude the chance of possible damage to surrounding tissues such as the spinal cord and large vessels, and limit interaction with nearby muscles and ligaments. A less obvious, but important consideration, is to prevent spinal ligaments from overstretching during insertion of the AID, which predisposes ligament ossification in the long run.

The operating procedure should further minimize the chance of misaligning the lower and the upper AID fixation in relation to the vertebrae. Since only a small operating space is available to the surgeon, positioning is difficult. As disc positioning as well as initial fixation is of ultimate concern for successful replacement, repositioning must be avoided. Therefore, the insertion must be unambiguous.

### 2.4. Evaluation of the clinically used AIDs

#### 2.4.1. Fernström

The Fernström AID is a stainless steel ball with a diameter of 10 to 16 mm. The ball, sized to the height of the IVD, is inserted between the vertebrae after partial dissection of the IVD. The geometrical aspect of this prosthesis is good with regard to disc height, wedge angle and shape. However, the contact area with the vertebral bodies, is small. The prosthesis is stiff in compression and shear but very compliant in rotation, while it does not limit the ROM of the motion segment. This may negatively affect the stability of the spine, at the same time overloading the facet joints. The center of rotation is fixed in the middle of the prosthesis. Both initial- and long-term fixation depend on the contact force between the AID and the vertebrae. Bone ingrowth would affect the ROM.

After a follow up time of 10 to more than 20 years (average 17 years), 103 patients who underwent Fernström IVD replacement were examined (49). In total, 155 prostheses were implanted. General results of surgery were graded excellent or good in 79%, whereas only one of 155 prosthesis had to be removed. In spite of these results, migration of the AID into the vertebrae was the reason for abandoning the Fernström AID (50). Possibly, migration had to do with the small contact area.
between the AID and the vertebral bodies, in combination with the press-fit fixation of the prosthesis.

2.4.2. Acroflex

The custom-made Acroflex AID consists of a hexene-based polyolefin rubber core between two parallel titanium endplates. On top of the endplates, cone shaped posts are placed to ensure firm initial fixation. The surface of the titanium endplates is sintered with titanium beads to allow bone ingrowth for long-term fixation. Maximum rotation during anteflexion is determined by compression of the rubber core. The center of rotation of the AID depends on the load on the AID. The prosthesis was successfully tested with a cyclic compressive force between 0 and 445 N at 2 Hz for 11.5 million cycles. A small tear developed at 4 million cycles but did not propagate up to 11.5 million cycles. In total, six prostheses were implanted. One prosthesis, implanted to correct scoliosis, failed (6). Eventually, the disc was abandoned because the rubber core was found to be carcinogenic.

2.4.3. Charité

The Charité AID is commercially available and currently used in several clinics. It consists of two cobalt chromium endplates, sliding on a polyethylene core. Six small pins on top of the endplates ensure initial fixation. In the three subsequent types of the Charité AID, the size of the endplates increased, whereas the endplate became convex to adapt to the concavity of the vertebrae. The design of the polyethylene core was not changed. The endplates of the Charité type III AID are presently available in different sizes to adapt to the size of the vertebrae. Wedged endplates are available to adapt the AID to the L5-S1 wedge angle. The prosthesis is inserted from the anterior side of the vertebral column, the annulus fibrosus is cut and held to the side while the nucleus pulposus is being removed. After insertion of the AID, the annulus is repositioned and sutured around the prosthesis.

The Charité AID adapts automatically to the desired wedge shape. The stiffness of the Charité disc is high in compression but lower in bending and axial rotation compared to the healthy IVD. The ROM is limited to 14 degrees flexion and lateral bending. However, the ROM in axial rotation is unlimited. The center of rotation of the AID is not fixed. The motion of the parts of the AID determine the kinematics of the disc.

The core of the Charité AID is available in different heights. It deforms irreversibly with loads above 6 kN, which approximates the maximum expected peak load. Height reduces 10 % at 10.5 kN load. The endplates have been tested up to 19.5 kN successfully (51). Further, a load of 4.2 kN was applied repetetively to check for permanent deformation. In successful fatigue tests, the disc was loaded once a week with a load of 8.0 kN and several loads of intermediate magnitude, on top of a preload of 0.7 kN, to a total of 20 million cycles. This is equivalent to 20 years use (8).
Three studies that addressed the clinical performance of the Charité disc (52-54) concluded that the prosthesis is successful in approximately 70% of the cases. Mechanical malfunction did not occur, malfunction was a result of malpositioning of the prosthesis. Some prosthesis migrated into the vertebra due to a prosthesis chosen too small (53).

The evaluation of the AIDs is summarized in Table 2-7. Other efforts to design an AID during the past decade have been abandoned (55-57), whereas a number of AIDs are still in a pre-clinical stage (41, 58-65). Discussing these prosthesis in detail is beyond the scope of the present study.

### Table 2-7: Clinically used AIDs evaluated using the present list of requirements

<table>
<thead>
<tr>
<th></th>
<th>Fernström</th>
<th>Acroflex</th>
<th>Charité</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Geometry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>+</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Contact area</td>
<td>--</td>
<td>++</td>
<td>(type I) 0 (type III)</td>
</tr>
<tr>
<td>Convex area</td>
<td>+</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Wedge angle</td>
<td>+</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td><strong>Stiffness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bending and torsion</td>
<td>-</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Shear/compression</td>
<td>+</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td>Range of motion #</td>
<td>+</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td>Strength*</td>
<td>+</td>
<td></td>
<td>0 (shear)</td>
</tr>
<tr>
<td>Center of rotation</td>
<td>Fixed, center</td>
<td>Moving</td>
<td>Fixed, center</td>
</tr>
<tr>
<td>Facets</td>
<td>-</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Fixation*</td>
<td>-</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Failsafe*</td>
<td>+</td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

*The following symbols are used to indicate appropriateness to the opinion of the authors.*

*) ++: good, +: above average 0: average, -: below average, --: bad
#) +: exceeding the IVD 0: similar to the IVD (±20 %), -: less than the IVD

### 2.5. Discussion

#### 2.5.1. Geometry of the AID

Since fixation of the AID is critical for the success of the disc replacement, endplates are of particular importance. The size of the endplates has to be large enough to prevent migration, without the chance of coming into contact with surrounding vital tissues. Migration obviously happened with the Fernström and first types of the Charité AID. Since the size and shape of the IVD is different for each patient, custom-made prostheses will probably give the best results. In practice, providing a number of different sized AIDs will be sufficient. In that case, the thickness of the load bearing
cortical shell of the vertebrae should be taken into account. Therefore, size increments in sagittal and lateral diameter should not exceed 4 millimeters.

Apart from the proper size, the endplates must ensure tight fixation. Optimally, their shape matches the concavity of the vertebrae to load the full area of the vertebral body. It is anticipated that this will prevent bone loss in unsupported areas, while preventing the chance of dislocation. Furthermore, the ingrowth of bone is faster with smaller space between the bone and the endplate (66). Although adaptation of the AID surface to the surface of the vertebral body is preferred, a feasible alternative is to adjust the bone surface to the AID. In this way, anatomical variations are leveled off, thus enabling a closer fit between AID and bone.

Regarding disc height and wedge angle, the AID should aim at restoring the height and wedge angle of the original IVD-space, to unload the facet joints and to restore the range of motion. However, degenerated IVD’s are generally lower than IVD’s (17), and the vertebral column may have adapted to the degenerated disc height. Therefore, restoring healthy disc height can incidentally be in contradiction with preventing overstretching of surrounding structures, in particular of spinal ligaments. It has already been mentioned that ossification of the ligaments can result (67), which could be a major cause of long-term implant failure. Given the fact that spinal ligaments can be elongated approximately 3.2 mm without damaging them (68), it is advised not to enlarge the height of a degenerated disc more than 2 mm. It should be noticed however, that a too low AID may lead to excessive loading of the facet joints, loosening of the ligaments, and instability of the spinal column.

2.5.2. Stiffness of the AID

A suitable stiffness for the AID is a matter of balance between stability, ROM, and loading of surrounding structures, including fixation. In general, low stiffness in either direction results in spinal instability. Low stiffness in compression decreases the ROM and results in overloading of the facet joints, whereas high compression stiffness of the AID decreases its shock absorbing capacity. Steffee noticed that the high shear stiffness of the Charité AID was probably a reason for failure of the Charité AID (7), as a result of peak loads on the fixation. Further, low bending stiffness could increase wear of the AID, or damage spinal ligaments. High bending stiffness may lead to excessive bending of adjacent motion segments, resulting in additional damage at these levels as is being observed after full fixation of a spinal segment (3).

The relative importance of stiffness also depends on the quality of spinal ligaments and muscles. In full flexion, a healthy lumbar IVD accounts for only 29 % of the motion segment stiffness (69), and therefore, a small difference in disc stiffness does not change the mechanics of the vertebral column.
2.5.3. Range of motion of the AID
Theoretically, when the ROM of the AID exceeds the ROM of the IVD, there is a risk of ligament overloading and instability of the spinal column. However, limiting the ROM in an AID would load its fixation, which is critical. Furthermore, adjacent discs are expected to degenerate faster with stiffer implants, as is seen after rigid fixation of a motion segment. Therefore, taken into account that limitation of the ROM in the normal situation is more affected by spinal ligaments than by the IVD itself (69), it is advisable to allow for abundant ROM in the design of an AID, and let ligaments and muscles limit it. This is an additional reason to prevent damage to the spinal ligaments and muscles during surgery.

It is suggested that criteria for AID function in rotation are better determined by its ROM in angles than by stiffness, because of the attribution of other structures to the stiffness of the motion segment.

2.5.4. Strength of the AID
Failure loads of IVD (23, 33) and vertebral bodies (34) do not agree with the finding of White that the maximum failure load of the discs exceeds that lumbar vertebrae (22). Yet, the failure load for vertebral bodies is within the range of failure loads of IVD as found by Adams (33). Furthermore, the actual values may depend on the exact setup of the experiment. Therefore it is proposed that maximum failure load of an AID should exceed that of the maximum failure load found, which is the failure load of a vertebral body (8000 N) (34). Although computations of IVD loading with analytical models depend on numerous assumptions regarding mechanical properties and geometric relations, results agree with this proposed failure load.

The shear stiffness of an IVD is only 120-170 N/mm, while shear loads can reach 2000-3000 N. Facet joints significantly contribute in bearing this load, especially in anterior shear, but their contribution cannot be quantified from the literature. Yet, when designing an AID that incorporates facet joint function, this must be considered.

2.5.5. Center of rotation of the AID
It has been argued that during rotation, the center of rotation of an AID should follow that of the healthy IVD. However, from the clinically used prostheses, only the Acroflex, which behaved moderately with respect to the other mechanical considerations, had a moving center of rotation. The center of rotation of the Charité AID was also able to move, but only when the upper vertebra translates in relation to the lower vertebra and decreasing the ROM of the vertebrae at the same time. During future development of AIDs, this point should be given more attention. The added decrease of freedom could decrease the load on AID and fixation.
2.5.6. Facet joints
Taking over the function of facet joints in the design of an AID is delicate. This can principally be achieved for the lumbar AID by increasing stiffness in extension and axial rotation, by limiting the ROM in these directions, by increasing disc height, or by decreasing the wedge angle. Yet, because the contribution of the IVD to the stiffness of the motion segment is less than that of the ligaments, the effect of increased stiffness in facet joint loading will be limited. Further, it has previously been argued that limiting the range of motion in extension and axial rotation results in unwanted loading of the fixation. Finally, increasing disc height or changing the wedge angle may lead to overloading and subsequent ossification of spinal ligaments. In the final AID design, these discrepancies must be considered thoroughly.

2.5.7. Surgical procedure
Ligament ossification is a major concern for the long term beneficial effect of disc replacement. This obviously can be in contradiction with our goal to fully restore healthy disc height. In this contradiction, the negative effects of ossification are considered more important than the beneficial effect of regaining the full disc height. Therefore, in incidence cases, it is proposed to restrict revision of the disc height to such an extend that the spinal ligaments are not overstretched. Removal of the spinal ligaments during implantation is not advised, seeing the essential role they play.

For proper placement of the AID, a positioning device that assists in determining its exact position and helps to insert the disc in that particular place could be valuable.

2.5.8. Failsafety
The possibility of failure of an AID cannot be fully excluded. A possible way in which an AID fails should not irreversibly damage vital organs or otherwise cause severe harm. Moreover, it has to be taken into account that an AID may need replacement in the long term. These facts as well must be considered when designing an AID.

2.6. Conclusions
Based on the assumption that an AID should mimick the regular mechanical IVD behavior, feasible suggestions for the design of an AID are presented, as well as suggesting means to prevent AID failure. These suggestions include geometry, stiffness, ROM, strength, center of rotation, fixation, facet joint function, failsafety and surgical procedure. Failure of clinically used prostheses is apparent when judged according to this list. The following criteria and proposals are noteworthy:
For optimum fixation, the AID should closely fit the vertebral endplates (Table I), whereas the AID needs support from the cortical shell to prevent it from migration. Therefore, AID diameter increments should be less than 4 mm.
The AID should restore loss of disc height (Table I) only if that does not increase disc height by more than 2 mm, to prevent spinal ligament overstretching. Stiffness (Table IV) in flexion, extension and lateral bending is less critical than in compression, because of the contributions of ligaments and muscles. For this reason, rotation in these directions should not be limited by stiffness or ROM of the AID. Thus the chance of overloading of the fixation is decreased (Tables V and VI). Minimum AID failure strength in compression is 8 kN (vertebral body collapse), in lateral and sagittal shear 2 and 3 kN, respectively. Requirements for strength and fatigue testing are provided in Table VI.

The center of rotation of the AID should move with rotation of the motion segment similar to the natural disc, to increase muscle working distance and consequently decrease disc loading. The Charité prosthesis does not call for this criterion. Ultimately, an AID incorporates facet joint function. Possible means are discussed, but these principally interfere with prior requirements.
Chapter 2

References

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