On the development of an artificial intervertebral disc
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Chapter 7  Discussion

Low back pain is an extensive social and medical problem. The resulting occupational
disability is very expensive for society. The cause of low back pain remains unclear in
many patients, but due to the fact that pain receptors are located in the intervertebral
disc degeneration of the intervertebral disc could play an important role.

In the future an ultimate treatment by restoring the natural disc using tissue
engineering techniques could become feasible. Up to now, cartilage for joint repair is
studied experimentally. Bone tissue can already be produced on small scale. For the
time being, the implantation of an artificial intervertebral disc is an attractive
treatment, because it restores the mechanical properties of the spine and thus
decreases complications, caused by a change in spinal stiffness or mobility.

Existing artificial intervertebral discs are not used on a routine base like hip and knee
prostheses. The limited reliability caused by the relatively large chance of failure of
those existing implants due to malpositioning or mechanical malfunction is the main
cause that surgeons are discouraged. Development of a more satisfactory artificial
intervertebral disc is possible, because existing devices lack to comply with essential
requirements, like a proper and long-term fixation as is described in this thesis.

The requirements for a good function of the artificial disc are given in Chapter 2.
They can be differentiated in existing requirements found in the literature and in
requirements that were found after research.

7.1. Requirements found in the literature

7.1.1. Range of motion
The range of motion of the artificial disc is very important. As described in Chapter 2
the range of motion preferably should exceed the range of motion of the total motion
segment to prevent large loads on the fixation of the artificial disc when very large
rotations occur. Not damaging the surrounding structures during the insertion of the
disc (the design of the fixation of the disc, described in Chapter 6, allows introduction
with minimal damage) is favourable for the stability of the motion segment.

7.1.2. Center of rotation
According to White, in the natural disc the center of rotation in flexion is located at
the anterior side. This is the best place, from a biomechanical point of view, because
the forces of the spinal muscles needed to withstand the large moments in flexion are
smallest and therefore the compressive forces on the artificial disc are also smaller.
Kostuik proposed to place the center of rotation in flexion as far back as possible in
the artificial disc. The rotation point of the Prodisc artificial disc, however, is located just inferior of the artificial disc.

A center of rotation located 20 mm below the center of the prosthesis results in a forward translation of up to 3.5 mm when the vertebra rotates 10 degrees, which could be enough to damage the spinal cord. Therefore, the center of rotation has to be located inside the artificial disc. For flexion, the best place for the center of rotation is the front side of the disc. For lateral bending, the center of rotation should move to the side the person is leaning to.

7.1.3. Strength

The strength of the artificial disc as described in Chapter 2 was retrieved from the literature. More precise information of the exact loads that occur in the vertebral column can be retrieved when better models of the vertebral column are developed. For the development of an artificial intervertebral disc, the loads given in Chapter 2 of this thesis can be used, because they are a safe estimation of the maximal loads that will occur.

7.1.4. Facet joint function

The facet joints are very important for the stability of the vertebral column. They also guide the possible motions of the vertebral column. In most cases, when the intervertebral disc is degenerated the facet joints are degenerated too. Therefore, preferably the function of the facet joints has to be incorporated in the artificial disc. The load bearing capacity of the facet joints could be solved with a slightly stiffer artificial disc, especially on the posterior side of the artificial disc. Also the disc could be made stiffer in anterior shear to mimic the restriction of the motion in anterior shear by the facet joints.

The downside of an artificial disc with built-in facet joints is that the fixation of the artificial disc will be much more loaded than in the healthy situation. Therefore, the fixation of the artificial disc with built-in facet joint function has to withstand larger loads than an artificial disc without this function.

7.2. Requirements found after research

An important requirement for successful intervertebral disc replacement is replacing the intervertebral disc with a well-sized intervertebral disc prosthesis. Important dimensions for the artificial disc are the size, shape and convexity of the endplates, and the height and the wedge angle of the artificial disc. Since data found in the literature are missing (concavity, shape, fixation) or conflicting (wedge angle, stiffness), they were studied.
7.2.1. Size of the endplates

The size of the endplates has to be chosen as large as possible, without protruding out of the disc space. The first types of the Charité prosthesis had endplates that were too small and the migration of the prosthesis into the vertebra gave the Charité prosthesis a bad reputation. The third type of this prosthesis had much larger endplates, which gave improved results. The endplates of a prosthesis have the largest contact area with the vertebrae when the endplates have the same shape as the natural disc both in the transverse plane and in convexity. In Chapter 6 the relation between the lateral and sagittal diameter of the endplates was calculated. This is the most important geometric property of the artificial disc. Because the variety in sizes between patients and between vertebral levels is high, a range of different endplates are required to decrease the chance of a size mismatch. A range of 6 different sizes will be enough for most patients and vertebral levels. The largest size that does not protrude out of the disc space will minimize the chance of subsidence of the prosthesis into the vertebra.

7.2.2. The convexity of the intervertebral disc

The ingrowth of bone in the endplate will be encouraged if the distance between the endplates of the artificial disc and the endplate of a vertebra is small, so a close match between both endplates is required. When convexity of the endplate of the artificial disc is too large, initially only the spongious bone will be loaded. This bone is not strong enough to bear the entire load on the vertebral motion segment when the spine is fully loaded, so the AID will migrate into the vertebrae, until the rim of the artificial disc will come in contact with the cortical bone of the vertebra. The advantage is that the bone of the vertebra will be in close contact with the artificial disc, and that bone will be pushed very close to the ribs of the artificial disc. This will ensure a fast growth of bone to the artificial disc surface. The downside of this method is that fixation depends on a proper reaction of the bone and initial fixation could be poor.

When the convexity of the artificial disc is not large enough, the ingrowth of bone will be slowed down, because the gap between disc and vertebra will be large. A convexity that is too large is better, because it offers a better chance on a proper fixation than when the convexity is too small.

7.2.3. Height of the intervertebral disc

Since the difference in height between patients is large, the artificial disc has to be custom-made for each patient or has to be delivered in height increments of 2 mm at most. Larger increments can result in damage to the spinal ligaments when inserting the AID. During the insertion of the artificial disc, the intervertebral disc space has to be enlarged to make it possible to insert the disc. The ligaments will therefore be stretched during the implantation of the prosthesis, which can result in overstretching and damage of the ligaments when the height of the prosthesis does not match the
original disc height. The design of the endplate discussed in Chapter 6 makes it possible to insert a disc with large fixation entities in the direction where the largest shear forces occur, but without the need to distract the vertebrae very far when inserting a disc with those large endplates.

Another possibility for inserting a disc with large fixation ribs is the method used as with the implantation of the Charité prosthesis. First the two endplates are placed in the vertebrae, then the core of the artificial disc is pushed between the two endplates. However, realising a proper fixation of the flexible core to the endplate is very difficult.

### 7.2.4. Wedge angle of the intervertebral disc

For artificial discs like the Charité prosthesis and the Prodisc, the initial wedge angle is not important, because the bending stiffness of these discs is very low due to their construction. The fact that these discs are delivered with two wedge angles is only because the wedge angle of L5-S1 is so large that the range of motion of the artificial disc would be endangered. For the artificial disc that is subject of this study a correct initial wedge angle of the intervertebral disc is more important because the bending stiffness aims at resembling the natural one. The wedge angle of an artificial intervertebral disc should be 6 degrees for levels L1-L2 to L3-L4. For L4-L5 a prosthesis with a wedge angle of 9 degrees is sufficient, for L5-S1 a prosthesis with a wedge angle of 13 degrees is advisable.

### 7.2.5. Stiffness of the intervertebral disc

In the experiments in Chapter 4 the contribution of the various structures to the stiffness of the torso was studied. It was found that for the lumbar levels, the ribs do not have a clear influence on the compliance. The flexion compliance of the thoracic spine, however, is about ten times smaller in comparison with the total torso due to the presence of the ribs and the soft tissues in front of the spine, which are compressed by the rib cage. The rib cage has a direct effect on the thoracic flexion compliance making it smaller than the lumbar one. The influence of the rib cage on axial and lateral compliance is limited, because the ribs are connected to the vertebral column via joints. The axial and lateral compliance is more influenced by the orientation of the facet joints.

A clear influence of the muscles and ligaments on the compliance of the torso was not found. In axial rotation the compliance decreased. In lateral bending the compliance is lowest with the muscles dissected, but largest when the ligaments and muscles were dissected. The spinal ligaments and the spinal muscles are more important for the stability of the spinal column than the intervertebral disc, except for stability under shear forces and compression. Therefore, the first important stiffness of the artificial disc is the lateral stiffness and the second one is the compression stiffness. 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.

The bending stiffness of the artificial disc has to be the same or lower as the natural disc, because the mobility of the vertebral column will be ensured and also the fixation of the disc to the vertebral column will be less loaded. In full flexion, a healthy lumbar IVD accounts for only 29% of the motion segment stiffness and therefore, a small difference in disc stiffness does not change the mechanics of the vertebral column.

7.2.6. Muscles of the spine

For the test of an artificial disc, numerical models are the first to be used, followed by in vitro physical models and animal experiments. Both for the numerical and in vitro models, the exact locations of all spinal muscles are essential. The insertion point of the spinal muscles on the sacrum and the spinous processus are very helpful in determining the line of action of the spinal muscles. For the situation in full flexion or other positions of the vertebral column, additional measurements need to be done to measure the line of action in full flexion. But because the place of insertion is known from the measurements made in Chapter 3 the line of action can be reconstructed from X-ray measurements.

7.2.7. Design of the endplate

The design of the endplates is very important for the function of an artificial disc. The most important function of the endplate is the fixation to the adjacent vertebra. A loss of fixation could result in very bad injuries, paralysis or even death. If the surface of the disc makes ingrowth of bone possible, in time a good fixation will occur. But before bone ingrowth is possible, the disc has to be firmly attached to the vertebrae. Even without the ingrowth of bone into the vertebrae, the artificial disc has to be fixated very firmly to the vertebrae. Normally the patient is advised to avoid large loads on the spinal column, but some movements of the spine load the spinal column with very high forces, which could make the artificial disc dislocate.

This initial fixation can be realised via fixation elements like screws, spikes or ribs. According to the calculations made in Chapter 6, the fixation elements of the Charité prosthesis are too small. The fixation of the Prodisc artificial disc only secures in the lateral direction, while the largest forces on the AID occur in the anterior posterior direction. Therefore an improved fixation of the artificial disc to the vertebrae was designed using six ribs, two large ones and four smaller ones. The downside of an artificial disc with large ribs to prevent dislocation is that the vertebrae have to be prepared for the artificial disc before implantation. For the endplate proposed in Chapter 6, two lateral grooves have to be milled into the vertebra.
The maximum shear load that could be exerted onto the artificial disc in the body is very high. This value resulted from the biomechanical model of Marras 2. From other models, for example of Jäger and Luttmann 1, the sagittal shear was 950 N and the lateral shear 300 N. This will result in much smaller fixation ribs for a good fixation. Very likely, the in-vivo forces in life will be smaller than from the Marras model, due to misassumptions made by the developers of the model, but for a worst-case scenario these values are useful.

7.3. General conclusion

With the demands, as determined in this thesis, the chance of realising a proper functioning artificial intervertebral discs is increased. Lack of a good overview of those requirements are the main reason for failure of existing artificial intervertebral discs.

Based on the set of requirements, a new endplate was designed. Both the initial and the long-term fixation with the adjacent vertebra are improved due to a closer match with the vertebral geometry and increased strength of the initial fixation elements.

References