Chapter 1    Introduction

Low back pain is a severe medical problem with important social and economic consequences, as it is a major cause of occupational disability. It has been established that the problems of backache alone costs the Dutch society already over 4 billion dollars per year (8). Although the cause of low back pain remains unclear in many patients, it is generally accepted that degeneration of the intervertebral disc plays an important part in the causes of the complaints (10).

When surgical removal of the degenerated disc is necessary, reconstruction could be performed using an artificial intervertebral disc. Because existing artificial intervertebral discs have several shortcomings, a project was started to develop a new artificial intervertebral disc.

1.1. Goal of the research

The goal of the research, described in this thesis, is to define requirements for the development of an artificial disc that has to replace the whole natural intervertebral disc and to realise a suitable endplate for the artificial disc.

1.2. Anatomy of the vertebral column

For the development of the artificial disc, first a clear view of the relevant anatomy of the vertebral column is required. The three basic functions of the vertebral column are to transmit load, allow movement, and protect the spinal cord. The vertebral column (Figure 1-1) is a strong flexible rod carrying the weight of the head, chest, abdomen and its contents and arms. It is the central support for the upper body, it makes it possible to walk upright and serves as a point of attachment for the ribs. The human vertebral column is build out of 33 vertebrae. The 24 mobile vertebrae are separated by intervertebral discs. The column is divided into five sections: the cervical section (seven mobile vertebrae, C1-C7), the thoracic section (twelve mobile vertebrae, T1-T12), lumbar section (five mobile vertebrae, L1-L5), sacral section (five fused vertebrae) and coccygeal section (three to four fused vertebrae).

The combined intervertebral discs account for one-fourth of the total length of the column above the sacrum. In the lumbar section the discs account for one-third, in the thoracic section for one-fifth and in the cervical section for two-fifth of the total length of the section.

When looking at the spine in the frontal plane, it appears straight and symmetrical. In the sagittal plane there are four normal curves, convex anteriorly (lordosis) at the cervical and lumbar levels, and convex posteriorly (kyphosis) at the thoracic and sacroccygeal levels. In the cervical and lumbar section, the curve is due to the shape of the intervertebral discs, in the thoracic section due to the shape of the vertebrae.
These curves give the spine increased flexibility, and allow load bearing and shock-absorption.

1.2.1. Anatomy of the vertebrae

A vertebra consists of an anterior block of bone, the body, and a posterior bony ring, the neural arch, containing articular, transverse and spinous processes (Figure 1-2). The transverse and spinous processes serve as points for attachment of the spinal muscles and ligaments. The two superior and the two inferior articular processes articulate with the adjacent vertebra and are also called articular facets. The body is a roughly cylindrical mass of cancellous bone with a shell of cortical bone. Its superior and inferior surfaces, slightly concave, are the vertebral endplates. The thoracic vertebrae have articular facets for the ribs. The size of the vertebrae is increasing from cervical to lumbar.

The movements of the spine depend on the shape and position of the articulating processes. The orientation and geometry of the facet joints are different for the different sections, see Figure 1-3. The orientation of the joints is only approximate.

The exact orientation varies in the sections and also varies in different persons.
1.2.2. Anatomy of the Intervertebral Disc

The intervertebral disc (Figure 1-4) is composed of the nucleus pulposus, the annulus fibrosus and two cortical endplates. The total water content of the intervertebral disc ranges from 70 to 90%. It is highest at birth and tends to decrease with age.

The nucleus pulposus is located in the center of the disc. It is composed of a loose network of collagen fibers that lie in a mucoprotein gel containing proteoglycans (PG). The PG retain the water in the disc. In an adult, the water content of the nucleus pulposus is 80-85%. The PG-content is 60-65% dry weight, the collagen content is 30% dry weight. In lumbar and cervical section the size (about 30 to 50% of the total size of the intervertebral disc) and the swell capacity is higher than in the thoracic section.

The annulus fibrosus forms the outer boundary of the disc. It is composed of collagen fibers in concentric laminated bands. The fibers run in the same directions (30° to the disc plane) in a given band but in the opposite direction in the adjacent bands. The fibers are attached to the cartilaginous endplates in the inner zones and to the osseous tissue of the vertebral body in the peripheral zone (Sharpey’s fibers). The water content of the annulus fibrosus is 60-70%, the PG-content 20% dry weight and the collagen content is 50-60% dry weight.

In general, in a healthy intervertebral disc the water- and PG-content are decreasing while the collagen content is increasing from center to border.

The cartilaginous endplates are composed of hyaline cartilage. The water content is 55%, the collagen content 75-80% dry weight and the PG-content 10-15%.
1.2.3. Nutrition of the intervertebral disc

While the outer annulus lamellae receive some small arterial branches, the intervertebral disc has no major feeding arteries. Consequently, the intervertebral disc is dependent on diffusion for its nutrition. This diffusion takes place from the arteries in the outer annulus and the arteries in the vertebral bodies. Because the lumbar intervertebral discs are the largest, the nutrition of these is the most difficult. The in- and outflow of fluids during loading and unloading of the discs facilitate the diffusion of nutrition.

1.2.4. Anatomy of the ligaments

The ligaments are uniaxial structures. There are seven ligaments of the spine (Figure 1-5):

The anterior longitudinal ligament (ALL) is attached to all anterior surfaces of the vertebrae, but not firmly attached to the intervertebral discs. The posterior longitudinal ligament (PLL) is attached to all posterior surfaces of the vertebrae and the intervertebral discs. Both ligaments extend over the whole length of the spinal column. The intertransverse ligaments (ITL) are attached to the transverse processes. The capsular ligaments (CL) are attached just beyond the margins of the adjacent articular processes. The ligamenta flava (LF) connect the lamina. They have a large amount of elastic fibers. The interspinous ligaments (ISL) connect adjacent spines from the root to the apex of the spines. The supraspinous ligaments (SSL) connect the tips of the processes spinoi. Several ligaments, namely the ALL, PLL, CL, ISL and SSL are highly innervated and therefore potential sites of back pain.

1.2.5. Function of the ligaments

The ligaments are most effective in carrying tensile loads along the direction in which the fibers run. The functions of the ligaments are:

They allow adequate motion and fixed postural attitudes among vertebrae.
When stretched, the surrounding muscles are relieved.
They protect the spinal cord by restricting the motions within well-defined limits, thus keeping the spine stable.
They protect the spinal cord in traumatic situations where high loads are applied at high speeds. In this situation the ligaments absorb large amounts of energy.
1.2.6. Anatomy of the muscles

The muscles of the spine can be divided into two groups: postvertebral and prevertebral. The postvertebral muscles can be divided into three groups:

The deep muscles are short muscles that connect adjacent spinous processes, musculi interspinales, adjacent transverse processes, musculi intertransversarii, transverse processes below to laminae above, musculi rotatores, and in the thoracic region, transverse processes to the ribs, musculi levatores costarum.

The intermediate muscles arise from the transverse processes of each vertebrae and attach to the spinous processes of the vertebrae above. In the lumbar region they are called the multifidus. According to the other regions they are called the semispinalis thoracis and semispinalis cervicis.

The superficial muscles, the iliocostalis (most laterally placed), the longissimus and the spinalis (most medially placed), are collectively called the erector spinae.

The prevertebral muscles are the four abdominal muscles. The external oblique, the internal oblique, the transversus abdominis encircle the abdominal region. The rectus abdominis is located at the midline.

1.2.7. Function of the muscles

Without the muscles, the spine is extremely unstable. For example, a fresh cadaver spine with ligaments but without muscles can only carry a load of 20 N placed centrally at T1 (11). The muscles give the spine stability and can produce motions of the spine. Another function of the muscles is protecting the spine during a trauma. They can also absorb energy.

1.3. Degenerative disc disease

Unlike the muscles in the back, the discs does not have a blood supply of its own and therefore cannot heal itself very fast, so the painful symptoms of degenerative disc disease can become chronic. Disc degeneration is part of the natural process of aging and does not necessarily lead to low back pain, so not all degenerative discs are pain generators. There is no consensus about the pathogenesis of discus degeneration, but diminished nutrition is probably the most important factor (4). There is an increase in the ratio of keratan sulfate, and the proteoglycans lose their association with the disc collagen. The disc loses also its water-binding capacity and the water content decreases from 90 to 70%, resulting in a stiffer disc (9). This is very often combined with a loss of intervertebral disc height. As a result the most important function of the intervertebral disc, the absorption of mechanical load on the spine, diminishes.

With more advanced degeneration, compact disorganized fibrous tissue replaces the normal fibrocartilaginous structure of the nucleus pulposus and makes it impossible to
distinguish between the nucleus and annulus fibrosus. Development of annular tears weakens the annulus and allows the nucleus to engrave into the defect. Tears that extend through the outer annulus produce ingrowth of granulation tissue and accelerate the degenerative process. Advanced degeneration can lead to gas formation or calcification within the disc. Also, fissures develop in the cartilaginous endplates and granulation tissue forms in the area.

1.4. Treatment Of Degenerative Discs

The traditional treatment consists of a removal of (parts of) the intervertebral disc (discectomy) and fusion of the two adjacent discs. Fusion is supported by the application of a cage that fills up the space between the two vertebrae. The formation of bone between the two vertebrae is induced by filling the cage with bone grafts, usually taken from the pelvis during surgery. Although discectomy and fusion produce a relatively good short-term clinical result in relieving pain, they alter the biomechanics of the spine, because the mobility of the vertebral column is reduced. This may lead to further degeneration of the surrounding tissues and the discs at adjacent levels.

An alternative treatment is the use of an artificial intervertebral disc. The advantage of an artificial intervertebral disc is that the mobility of the vertebral column will be restored, so the discs at adjacent levels will be saved.

1.5. Existing artificial intervertebral discs

Over the past 40 years a large effort has been made to develop an artificial intervertebral disc to replace the degenerative disc. A schematic design of an artificial disc is given in Figure 1-6.

An artificial disc consists of two endplates with in between a body. The properties of the body of the artificial disc makes it possible that the endplates of the artificial disc can rotate. Only a few designs were tested clinically. Fernström (5) made the first attempt. General results of surgery were graded excellent or good in 79 percent of the cases. Only one of 155 prostheses had to be removed. In spite of these results, the migration of the disc into the vertebrae was one of the reasons to abandon the Fernström artificial intervertebral disc.

The second disc that has been tested clinically was the Acroflex disc (2, 7). In total six prostheses have been implanted. The prosthesis was custom-made for each patient. In
1990, the developers stopped clinical trials because a chemical, used for the vulcanization of the rubber core, was found to be carcinogenic in rats. Two designs are used clinically at the moment. The Charité prosthesis (Figure 1-7) is commercially available in Europe (1). General results show that the disc is successful in approximately 70 % of the cases. Until 1997 it was implanted in about 1300 patients. The current design has two concave endplates made of cobalt-chromemolybdenum alloy. The plates have spikes or teeth for connecting them without bone cement to the vertebral body. A biconvex polyethylene core with contours that match the endplates is placed in between.

The Prodisc has been implanted between 1990 and 1993 in 64 (6). A new type of the Prodisc has been used since September 1999, and 27 patients are treated with the new type. Just like the Charité intervertebral disc, the Prodisc consists of two metal endplates with a polyethylene core fitted in the inferior endplate. The core is available in three heights, with a resulting height of the prosthesis of 10, 12 or 14 mm. The endplates are available in two sizes. Rabb (5) reported a success rate of 90% in 62 of the patients of the first series at more than eight years of follow-up.

The two existing artificial intervertebral discs are only used by a limited number of surgeons, because the long-term results are not optimal. Therefore it was decided to develop a new artificial intervertebral disc

1.6. Development of a new artificial intervertebral disc

In cooperation with the Technical University of Eindhoven a project is started to develop an artificial intervertebral disc. The artificial disc will be designed for lumbar intervertebral disc replacement. Indications for replacement are:
- Painful disc, minimally flexible, highly degenerated,
- Painful disc, nearly collapsed, inflexible, severely degenerated.

The apophyseal joints of the vertebrae (facets) are very often degenerated when the intervertebral disc is replaced. Therefore, the function of the facet joints must be integrated in the artificial disc. The ligaments of the motion segment and the two vertebrae are supposed to be intact. The prosthesis has to be developed for all lumbar intervertebral levels. If necessary, different sizes (anterior-posterior diameter, lateral diameter, height, height difference anterior/posterior etc.) of the prosthesis have to be developed.
The new artificial intervertebral disc is based on a new core that was developed at the Technical University of Eindhoven and is made from hydrogel, reinforced with nylon filaments. The core can be given the same mechanical properties as the natural intervertebral disc to prevent different mechanical properties of the vertebral column.

The body of the prosthesis will be developed further at the Technical University of Eindhoven with the use of the requirements reported in this thesis. The design of the endplates of the prosthesis was performed at the University of Groningen and will be discussed in this thesis.

1.7. Overview of This Thesis

In Chapter 2 requirements for the development of an artificial disc retrieved from literature are given. To find values for missing requirements studies are performed and reported in Chapter 3-7. In Chapter 3 the study on wedge angle, height of the artificial disc and the depth of the endplates of the vertebrae is described. Chapter 4 deals with a study on the insertio and origin of several muscles of the spine. In Chapter 5 a study on the compliance of the human torso is reported. In Chapter 6 a design for the endplate and its fixation to the vertebrae is presented, including its geometry based on the variety in geometries of the vertebrae. A general discussion is given in Chapter 7 and the summary is given in the Chapters 8 and 9.
References
