Fiber reinforced intervertebral disc prosthesis

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Abstract

Intervertebral disc failure (discus hernia) is an important social and economic problem. The techniques and surgical procedures they use at the moment are temporary solutions and in most of the cases they will lead to new problems like discus hernia in the surrounding discs and calcification of ligaments. Our hypothesis is that a normal mechanical environment for surrounding tissue reduces these problems. A fiber reinforced hydrogel is developed as a start of making a disc prosthesis. The fibers were wounded around the gel. Tests have shown that the stiffness of this material is still to small.

In this study we tried to improve the strengt and stiffness by making a fiber reinforced hydrogel with chopped fibers. The stress-displacement curves show that the stress level reached is 2 times as high the level reached with the wounded fibers, but the level of strain still needs to be reduced.
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Chapter 1

Introduction

An intervertebral disc is the tissue connecting the vertebrae. It damps forces and motions in the spine and facilitates spinal mobility. It consists of fibrous cartilage. The constituents of fibrous cartilage are collagen fibres, proteoglycan molecules, cells and interstitial fluid with dissolved ions. The disc is built of an outer firm annulus fibrosus and a soft gel-like core, the nucleus pulposus. The annulus fibrosus primarily consists of collagen fibers. The nucleus pulposus mainly consists of proteoglycans, large molecules containing negatively charged side groups, which cause an osmotic pressure in the disc, in the order of 1.1 MPa. [1]

![Figure 1.1: Schematic representation of an intervertebral disc](image)

Due to the swelling pressure of the nucleus pulposus, the annulus fibrosus is continuously under tension. Due to ageing the core looses its swelling pressure, which can lead to a decrease in size of the core. The annulus fibrosus therefore looses its tensile tension. As ageing progresses, the osmotic pressuring weakens and the collagen network of the disc is exposed to compressive stresses. During this transition ruptures of the collagen may occur. This enables osteoblasts to enter, which eventually leads to mineralization of different parts of the disc.

A pulposus hernia (discus hernia) occurs when damage causes the gel-like core to be squeezed into the spinal cord. This endangers the spinal cord and the roots of spinal nerves. In case of complete rupture of the annulus fibrosus a hernia leads to a discus prolaps (nucleus prolaps). These damages eventually lead to displacement of several vertebrae.
The currently available intervertebral disc prosthesis has secondary problems after implementation [2], like for example calcification of ligaments. Besides that the surgical procedure is difficult. In previous research [4] the following requirements have been selected as critical items in the development of an artificial intervertebral disc (AID): Geometry, stiffness, range, strength, center of rotation, fixation to the adjacent vertebrae, function of the facet joints, failsafety and surgical procedure. To design an AID, Brouwers [2] formulated the hypothesis that an intervertebral disc prosthesis, which mimics the natural disc, leads to a normal mechanical environment for surrounding tissues, and therefore reduces secondary problems after implementation.

For this AID she used a hydrogel (pHEMA-NaMA), which swells up to 260% under a salt concentration of 0.15 M (the same concentration as in the human body)[5]. This property can be used when the AID is placed in the body; The AID is small when it is put into the body and it will swell when placed in the right position. To improve the stiffness and strength of the hydrogel she used a fiber, which she wound around the hydrogel sample. The design criteria for stiffness[2] range from 750 to 2500 N/mm, with a maximum force of 8 kN. Brouwers obtained the minimum stiffness level of 750 N/mm but only at strain level of over 0.5, which suggests that stiffness for small strains might be too small.

The aim of the research for this report is to find out if the strength and stiffness can be improved by making a hydrogel with chopped fibers. The materials and methods used for making the hydrogel are mainly the same as the ones that were used in Brouwers’ experiment, the fiber reinforcement is done differently.

First I describe the differences in the methods and materials. Then I will discuss the experiments that were carried out, which shows the effects of different fiber reinforcement and changes in rate of NaMA and crosslinker. Finally, in the discussion, the results of the experiments are analyzed and compared with the results of Brouwers’ experiments and I will give suggestions on how to improve the AID.
Chapter 2

Material and Methods

2.1 Hydrogel

Hydrogels are formed by a polymerization of a mixture that consists of water (oxygen free distilled water), monomer, crosslinking agent and initiator. In this study two monomers are used: 2-Hydroxyethyl Methacrylate (HEMA) (Aldrich, Steinheim Germany) and Sodium Methacrylate (NaMA) (Aldrich, Steinheim Germany). The standard molar ratio between HEMA and NaMA is 18:2, because with this ratio the density of the sample is similar to the natural disc density. When the NaMA level is increased the osmotic pressure increases, so the sample swells more. The crosslinks form a tight and stiff network within the hydrogel. In this case polyethylene glycol dimethacrylate (Aldrich, Milwaukee USA) is used as crosslinking agent, because it functions well in combination with HEMA. When the amount of crosslinker is increased, its network becomes tighter and therefore stiffer. This reduces the swelling capacity.

The initiator is a free radical initiator 2,2-Azobis(2-methylpropionamidine) dihydrochloride (Aldrich, Milwaukee USA). The initiator stimulates the polymerization, when it is heated. The standard composition of the gel mixture is:

\[ 18 \text{HEMA} + 2 \text{NaMA} + 79.93 \text{H}_2\text{O} + 0.04 \text{crosslinker} + 0.03 \text{initiator} \rightarrow \text{hydrogel} \] (2.1)

The procedure for making the mixture is described in appendix A; Three different mixtures are compared, the standard mixture, a mixture without NaMA and 10 times the amount of Crosslinker (the hydrogel will lose it’s swelling ability) and a mixture with 0.5 times the amount of NaMA and 5 times the amount of crosslinker.

2.2 Fiber reinforcement

In an attempt to improve the strength and stiffness of the hydrogel, chopped fibers were prepared from Lycra elastine fiber. The Lycra fiber was wound onto a small bar with a preload and then cut off the bar in small pieces of between 3 and 10 mm.

The samples were prepared by weighing the mixture and the test tube that was going to be used. Then about 10 mm of mixture was poured into the tube, followed by as much fibers as the mixture could contain. Because the fibers absorb the mixture they merge with the gel. Then the tube was weighed, and the procedure was repeated several times. When several 10 mm layers of mixture saturated with fibers were superimposed and weighed, the Erlenmeyer
with the remaining mixture was also weighed. The mass-percentage of fibers in the tube was
determined. To make sure there would be no air left in the tube, it was placed into a vacuum
oven. When the tube came out of the oven it was placed overnight into a hot water bath of
45 degrees. At this temperature the polymerization process works best. When the gel had
cured, the glass of the tube was removed, and the hydrogel was put in a salt solution of 0.15
M. To get good testing samples of 8 mm thick the best parts of the gel are cut by fitting the
bar of gel into a metal tub, which was placed in the spinning head of a lathe. The knife was
slowly moved through the hydrogel, while being lubricated with water. It was not possible to
get flat surfaces because the random fibers in the gel.

2.3 Compression tests

The hydrogel sample was then tested in a Zwick Z010 testing machine. The Zwick Z010 has
a force range of 10 kN. For the compression test the computer program testXpert is used.
All results were processed in Matlab.

Because the sample had to stay in the salt solution, the measurements were made in wet
conditions. The sample was lying in a cup (Figure 2.1). The stamp was placed 1 mm above
the sample, and the sample was pressed down until a certain force level was reached.

![Figure 2.1: The compression test](image)

The test was done with series of increasing force applied without a preload. After each
compression the level of damage on the sample was checked. The normal range of a test lies
between 100 N and 400 N. The amount of damage was also checked after a force of 1 kN. To
see what happened with the material after applying the same load a few times in different
periods after each other, a test was done by applying 100 N a few times with different resting
periods between the loads.
Chapter 3

Results

When the hydrogel bar was laid in a 0.15 M salt bath, the bar did not swell equally. This was because the fibers were not equally spread, which means the mass-percentage fiber is a mean over the bar. 10 Bars were made with mean mass-percentages between 28.5 mass % and 34.8 mass %.

3.1 Compression tests

In Figure 3.1 the compressive stress is plotted, under the assumption of isovolumetric deformation, against the impression or displacement of the stamp. The results shown are all from samples at 0.15 M, since this molarity equals the natural conditions in the body. The three figures shown are those of the original hydrogel, the hydrogel with no NaMA and 10 times the normal amount of crosslinker and the gel with times the normal amount of NaMA and 5 times the normal amount of crosslinker.

The vertical displacement is very large (Figure 3.1). This means the stiffness of the gel is not high enough. Figure 3.3 demonstrates the displacement during the test. Before the load was put on the sample its height was about 8 mm. During the load the sample’s height became 2 mm and after unloading it returned almost to the initial height. The diameter of the sample increased during the test.

After the level of 200 N was reached minute cracks developed. Along the test the cracks grew larger but the material never fell apart. As can be seen in Figure 3.3 the damage caused to a sample of the standard mixture was much more severe then damage caused to a sample with no NaMA.

Figure 3.1: loading curves of a) normal hydrogel, b) without NaMA and 10 crosslinker, c) 0.5 × crosslinker (relative to normal hydrogel)
The samples with half the amount of NaMA and five times the amount of crosslinker, showed similar damage to the ones without NaMA, but they were much stronger.

During the first few compressions the material behavior exhibited creep. When we looked at the material behaviour by putting seven times a load of 100 N on the sample the figure shows that the creep time was relatively long compared to the time an intervertebral disc normally gets to rest between different loads (Figure 3.2).

With 5, 10 and 15 minutes between the compressions total creep did not occur, but the figure shows that a longer time period will bring the material close to the original state. The material behavior may instead be characterized as visco-plastic.

3.2 Analysis

If these results are compared with Brouwers’ results, a few comments on the differences in strength and stiffness can be made. The stiffness of the reinforced sample by wounded fibers is higher than that of the sample with chopped fibers, so instead of increasing the stiffness, it caused a small decrease in stiffness.

When the strength is considered the main difference is that there is no real failure point. After the cutting of a sample the surface is very rough, minute cracks originate from this process. During the compression they grow bigger but the material stays together. So the moment of failure was not really there. This is a probable reason why the maximum stress reached is higher then the stress reached in Brouwers’ experiments (max of 4.5 MPa against 2 MPa). It must also be noticed that Brouwers’ experiments were not in wet conditions, she took the samples out of the salt solution before compressing them.

Figure 3.2: after the first 3 compressions (the fist 3 curves on the left) there was a resting period of 5 min, after the next 2 a period of 10 min and between the 6th and the last compression were 15 min.
Figure 3.3: A compressed sample

Figure 3.4: a) Standard mixture, after a 400 N and after a 1 kN load, b) Mixture no NaMA, without load, after a 400 N and after a 1 kN load, c) a side view of b
Chapter 4

Discussion

A HEMA-hydrogel reinforced by chopped fibers is used to try to improve the strength and stiffness reached by a HEMA-hydrogel reinforced by chopped fibers. This to eventually use it as intervertebral disc prosthesis.

The mass-percentage fibers was tried to compute, but because the fibers were not evenly spread through the bar it could not be calculated how much it was in each sample.

When the toughness is considered you can say the chopped fibers were an improvement on the model with the wounded fibers. The maximum stress, which could be tolerated by the sample, was 2.25 times as high as the one reached with the wounded fibers but the cracks that develop in the sample are not acceptable. Because a hydrogel bar with fibers in it is cut there are fibers in the cut plane who cause miner cracks. This problem may be improved by making a sample straight away instead of a bar, so the cutting process doesn’t have to take place. Also the mass-percentage fibers will be easier to compute.

The stiffness is a bigger problem, when the hydrogel is going to be used as disc prosthesis, it may have a distortion of about 1 ore 2 mm at most. In these experiments it was about 6 mm and that is absolutely unacceptable. With the wounded fibers the distortion was little less than 6 mm but still to big. Something has to be found to improve the stiffness a lot. A possibility would be to knit a cover around the chopped fiber reinforced hydrogel. This cover needs to have a certain size which makes it fit around the swollen hydrogel tightly, so that it will give stiffness and strength to the prosthesis. However, the advantage of the swelling after placing the prosthesis in the body, should still be there.
Bibliography


Appendix A

Preparing a hydrogel

Preparing the mixture A number of different mixtures have been made, which are described here: The solution is obtained by weighing the different parts of the hydrogel and then mixing them together. For a standard composition (100 grams) the following ingredients are used: 35.785 grams H2O 5.374 grams Sodium Methacrylate (Aldrich) 58.247 grams 2-Hydroxy ethyl methacrylate (Aldrich) 0.547 grams Polyethylene glycerol dimethacrylate (Aldrich) 0.0472 grams 2,2-Azobis((2-methylpropionamidine), dihydrochloride) (Aldrich) The distilled water has to be free of oxygen. This is obtained by putting the Erlenmeyer with water in an ultrasonic bath. This hydrogel consists of nearly 80 mol percent water. The water serves as a heat conductor, since the reaction is exothermic. Water also increases the distance between the polymer chains while polymerizing. This is assumed to result in a homogeneous porous material.

Water forms the basis of the solution. The other parts are added in order of solubility. First, NaMA is added, since this is also polar. The solution is stirred until the grains are dissolved. Then HEMA is added. HEMA contains an apolar as well as a polar side. Again, the solution is stirred until it is clear. The apolar crosslinker is then added and dissolved. The initiator is added as the last part, to prevent it from decomposing early. When the mixture is complete, it is stirred for an hour to ensure complete solving. During stirring, parafilm is applied onto the Erlenmeyer flask to keep oxygen out of the mixture.

Curing Hydrogel samples are produced by preparing a hydrogel bar, which is cut to the appropriate sizes. This bar is obtained by filling a glass tube with the mixture and the fibers, weighting it to know the concentration fibers, sealing it with a plug and letting it cure in a vertical position overnight in a bath at a temperature of 45C. This temperature is about the minimum temperature for the initiator to decompose and therefore allowing a slow reaction. The water bath allows better heat exchange than using warm air in an oven. The heat exchange also enables the reaction to remain slow. This prevents the appearance of discontinuations, such as gas bubbles.

Several different types of hydrogel are made: - With a different indicator, which didn’t work out because the polymerization process didn’t get going in the 45C bath. - With no NaMA and ten times as much crosslinker. - With half a much NaMA and five times as much crosslinker.

After the samples were made they were put into a 0.15 M salt bath.