Porous polymeric elastomers for repair and replacement of the knee joint meniscus

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Chapter 6

PREPARATION OF POROUS 50/50 COPOLY(L-LACTIDE/-CAPROLACTONE) WITH HIGH COMPRESSION MODULI. MENISCAL PROSTHESIS WITH DIFFERENT COMPRESSION MODULI IMPLANTED INTO KNEES OF GOATS

Summary

A technique was developed to prepare stiff porous materials of a high molecular weight 50/50 copoly(ɛ-caprolactone/L-lactide). Porous microspheres (50-250 μm) were agglutinated in the presence of NaCl crystals (250-300 μm). The microspheres were mixed with solid solvent in order to obtain a homogeneous distribution of solvent over the spheres. By changing the amount of solvent and crystals, the density and thus the compression modulus could be varied over a range of 0.07 gram/ml to 0.5 gram/dl and 40 kPa to 1100 kPa respectively. Three series of copolymer prostheses with compression moduli of 150, 400 and 650 kPa were implanted into knee joints of goats. By comparison, an aliphatic PU prosthesis series with a compression modulus of 150 kPa was implanted. Goats appeared to be rather unsuitable as test animal for this application. Due to the high degradation rate of the copolymer, fibrocartilage formation was not observed. Since the high degradation rate caused excellent adhesive properties, which is essential for the healing of meniscal lesions, porous copolymer described in this paper are probably very appropriate materials for meniscal reconstruction.

Introduction

Menisci are very important structures in the knee joint. Lesions of the knee joint meniscus are, due to the increase of sporting activities, among the most frequent orthopaedic affections. Since the increasing awareness of the consequences of total meniscectomy, partial meniscectomy or meniscus suturing are nowadays the methods of choice. But although the results do improve, osteoarthritus is not prevented.

Repair of the meniscus may be the best option since all the meniscal tissue can be preserved. Healing by simple suturing is only possible for lesions situated in the outer, vascularized part of the meniscus. For lesions situated in the central part of the meniscus no reliable methods exist, although new techniques are being developed.

Basic principle for healing in the avascular part of the meniscus is the improvement of the vascularity. It has been shown that implantation of porous biodegradable polyurethanes do result in healing of a meniscal lesion in a substantial number of cases. The porous material act as a scaffold for the ingrowth tissue. Repair tissue inside the implant initially consisted of vascular fibrous tissue. It appeared that the implant guided vascular tissue from the periphery.
towards the lesion resulting in healing of the tear. After fibrocartilage had formed, vascularity decreased and was completely absent in mature fibrocartilage.

When a meniscus is too severely damaged to be treated by partial meniscectomy or meniscal repair, total meniscectomy or replacement of the meniscus by a prosthesis are two options. As the results of total meniscectomy rather are poor, replacement is an attractive alternative. In previous study we implanted porous prostheses of an aliphatic polyurethane network\textsuperscript{17}. The prosthesis turned out to induce fibrocartilage and after 18 weeks the prostheses contained fibrocartilage only. Articular cartilage degeneration decreased compared to meniscectomy.

In the early studies, an aromatic polyurethane based upon 4,4’-diphenylmethane diisocyanate was used for meniscal reconstruction\textsuperscript{12-15}. Owing to the carcinogenic degradation product of this polymer, methylenedianiline, an linear aliphatic PU, based upon trans-cyclohexane diisocyanate, was used in later studies\textsuperscript{16,17}. For meniscal prosthesis, an aliphatic PU network, based upon trans-cyclohexane diisocyanate was used. Although the degradation product of aliphatic PU’s, aliphatic diamines, are less toxic than aromatic diamines\textsuperscript{18}, a polymer that releases only non-toxic degradation products was preferred.

Therefore, in a previous study we used a high molecular weight 50/50 copolymer of L-lactide and \(\gamma\)-caprolactone for meniscal reconstruction\textsuperscript{19}. This copolymer appeared to be an elastomer with mechanical properties comparable to segmented polyurethanes due to a highly entangled polymer chains and the presence of crystallizable L-lactide sequences\textsuperscript{20}. Degradation the polymer will yield L-lactic acid and \(\gamma\)-hydroxy hexanoic acid as the degradation products. The copolymer implants showed better healing of the meniscal lesions than aliphatic PU implants due to a better adhesion of implant to meniscal tissue. This was a result of a higher degradation rate. Upon degradation a larger number carboxylic groups are formed which are able to adhere to the meniscal tissue.

Fibrocartilage formation in copolymer implants was affected by the compression modulus of the material. Implants with a compression modulus of 40 kPa never showed ingrowth of fibrocartilage whether the implants with compression moduli of 100 kPa showed maximal 50-70 % fibrocartilage after 10-25 weeks of implantation. Aliphatic PU implants with a compression modulus of 150 kPa showed maximal 100 % fibrocartilage. To improve the implantation results of copolymer implants, the compression modulus should be enhanced. However, due to the high molecular weight of the polymer, increasing of the compression modulus of the materials using the freeze-drying/salt-leaching technique, was not possible.
The aim of this study was to increase the compression modulus of the porous copolymer materials and explore the influence of these material as a meniscal prosthesis. With an adapted freeze-drying/salt-leaching method, materials with an compression modulus of 150 kPa could be made. One prosthesis of this material was implanted into a knee joint of a dog. For further increasing of the compression modulus, materials were prepared by agglutinate copolymer microspheres in presence of NaCl crystals 250-300?m. Three series of copolymer prostheses with compression moduli of 150, 400 and 650 kPa were implanted into knee joints of goats to study the effect of fibrocartilage formation as a function of compression modulus. By comparison, an aliphatic PU prosthesis series with a compression modulus of 150 kPa was also implanted.

Experimental

Materials
L-lactide (CCA/Purac Biochem, the Netherlands) was purified by recrystallization from dry toluene. ?-caprolactone (Jansen Chimica, Belgium) was purified by drying over CaH₂ and distillation under a reduced nitrogen atmosphere. The catalyst, stannous octoate, was used directly from the supplier without further purification.

Polymerization
Polymerization was carried out in silanized ampoules. Monomers were mixed and an amount of 10⁻⁵ mole catalyst per mole of monomer was added. Under reduced pressure (1 - 0.5 Pa), the ampoules were heat sealed. After homogenization at 110°C, polymerization was continued for 10 days.

Preparation porous materials 1
Polymer solution in 1,4-dioxane (5 wt.-%) was mixed with saccharose crystals, wetting agent (water, 2-methyl-2-butanol or 2,2-dimethyl-1-propanol) and non-solvent (c-hexane). The melting point of the solvent/non-solvent mixture decreased to -11.1°C. The polymer solution/crystal mixture was cooled to -20°C until the solution was frozen. The mixture was freeze-dried under reduced pressure (0.05 mmHg) until the polymer concentration was 10%. Then the mixture was cut into pieces in frozen state and poured into a mould.
homogenizing the pieces at 45°C, the mixture was frozen and solvent was removed under reduced pressure and crystals were removed with water leaving behind the polymer as a foam.

_Microspheres_

Microspheres were prepared using the solvent evaporation method. The polymer was dissolved in dichloromethane to a concentration of 2 wt.-%. The solution was slowly added to a fivefold excess of a 2 wt.-% solution of polyvinylalcohol in water under stirring (250 rpm) at 30°C. The dichloromethane was then evaporated at atmospheric pressure for 7 hours. When evaporation was complete, the microspheres were sieved into a fraction >50 µm and washed with water and ethanol. Then the microspheres were dried in a vacuum stove at 37°C. The yield under these conditions was 80% and size of the spheres 50 - 250 µm.

In order to prepare porous microspheres, the polymer solution in dichloromethane was mixed with paraffin oil. The ratio polymer and paraffin oil was 1:1. After preparation as described above, the paraffin oil was removed by washing with hexane.

_Preparation porous materials 2_

Porous materials were made by agglutinate copolymer microspheres in presence of NaCl crystals 250-300 µm. Agglutination of the microspheres was achieved by 3 methods. a: By sintering at 130°C at nitrogen atmosphere for 16 hours, using paraffin oil as conduction agent; b: by mixing the microspheres with a 25/75 wt.-% 1,4-dioxane/c-hexane mixture at room temperature; c: by mixing the microspheres with solid 1,4-dioxane. In order to obtain small solid 1,4-dioxane particles, 1,4-dioxane was mixed with liquid nitrogen and pulverized. Non-solvent and solid solvent were used to obtain a homogeneous distribution distribution of the microspheres and solvent.

_Characterization_

The effectiveness of paraffin oil removal was determined by 300 MHz ¹H NMR.

Characterisations of microspheres and pore structure in the materials was performed using an ISI-DS scanning electron microscope.

Stress-strain and compression curves were determined at room temperature using an Instron (4301) tensile tester equipped with a 10N or 100N load-cell at a cross-head speed of 12 mm/min.
Tensile strength as function of agglutination time was determined. Rectangular test samples of 5 x 3 x 25 mm$^3$ were subjected to tensile testing.

For compression, cylindrical specimens with a diameter of 10 mm and a length of about 8 mm were cut out of the foams by cooling them with liquid nitrogen.

![Figure 1. Total porous meniscal prosthesis](image1)

![Figure 2. Operative procedure of the meniscal prosthesis](image2)

Preparation prostheses

Preparation of aliphatic polyurethane prostheses (series 1) was described elsewhere$^{17}$. The compression modulus was 100 kPa at 20% compression and 150 kPa at 0% compression.
One copolymer prosthesis was prepared by an adapted freeze-drying/salt-leaching technique. A 5 wt.-% copolymer solution in 1,4-dioxane and c-hexane (90/10) was mixed with 30 wt.-% saccharose crystals (200-400 μm). After freezing the mixture at -30 °C, freeze-drying of solvent/non-solvent was performed until the percentage polymer was 10%. Then the mixture was homogenized at 40°C, again frozen at 30°C and freeze-dried until all the solvent and non-solvent was removed. Afterwards the crystals were removed with water. With this method materials with a compression modulus of 150 kPa could be made reproducibly. This meniscal prosthesis was implanted into a knee of a dog.

In the case of copolymer prostheses series, 20 gram porous microspheres (50-250 μm) containing 20 gram paraffin oil, were agglutinated in presence of NaCl crystals with solid 1,4-dioxane. The density and the compression modulus of the porous material were changed using different amounts of NaCl crystals and 1,4-dioxane. The respective crystals and solvent amounts for series 2, 3 and 4 were 35 gram and 35 gram, 22,5 gram and 32 gram and 12 gram and 30 gram, respectively. The respective compression moduli were 100, 300, 550 at 20% compression and 150, 350 and 650 at 0% compression.

Meniscal prostheses, shown in figure 1, were cut out of porous materials after cooling with liquid nitrogen.

**Surgery**

The operative procedure for meniscal prostheses is shown in figure 2. The meniscus was separated from its anterior and posterior attachments. Two drill holes were made in the lateral aspect of the proximal tibia, ending in the anterior and posterior area of the intercondylar eminence. Two sutures were attached to the prosthesis and were pulled through the drill holes. Sutures were attached to both prosthesis horn. Additionally sutures were applied longitudinally through the entire prosthesis. The remains of the meniscal attachments were sutured to the appropriate meniscal horn. The prosthesis' periphery was sutured to the perimeniscal capsular and synovial tissues.

Sixteen prostheses of each series were implanted in the lateral position of knee-joints of goats. Follow-up periods were 5 and 7 months.

**Histology**

The prosthesis were cut into transverse slices, covering anterior, anteromedial, medial, medioposterior and posterior regions. From each regions, adjacent slices were taken for routine histology. For histology, slices were washed in ethanol, infiltrated in glycol
methacrylate and embedded at 4 °C. They were cut into 2 mm sections and stained with toluidine blue.

**Results and discussion**

In a previous study, a porous 50/50 copolymer of L-lactide and \( \text{\text{-caprolactone} \) was used for meniscal reconstruction\textsuperscript{19}. The materials were prepared using a combination of freeze-drying and salt leaching. The polymer was dissolved in 1,4-dioxane and mixed with saccharose crystals of 200-400 \( \mu \text{m} \) and non-solvent. After freezing of the mixture, sublimating of solvent/non-solvent and washing out the crystals, a porous structure was obtained. Macropores due to the casting material were dispersed in a matrix of micropores (<50 \( \mu \text{m} \) as a result of the freeze-drying process. The macropores have proven to be very important for the formation of fibrocartilaginous tissue\textsuperscript{13,21}.

Due to high molecular weight of the polymer, the maximal concentration of the polymer solution to which saccharose crystals could be added homogeneously was only 5\%, which resulted in a compression modulus of 40 kPa. To obtain a higher compression modulus \( E_t \), the density \( \rho_f \) of the porous material should be increased since they, theoretically, are related by\textsuperscript{22,23}:

\[
E_t \approx (\rho_f)^2
\]

Therefore, after mixing the polymer solution with the crystals, the polymer concentration was increased by controlled evaporation of the solvent. The maximal compression modulus of porous copolymer using this technique was 100 kPa. This compression modulus, however, was too low to achieve 100\% fibrocartilage ingrowth. When the materials are implanted as meniscal prosthesis, a higher compression modulus is necessary to protect the articular cartilage.

**Porous materials 1**

In order to increase the polymer concentration, a 5 wt.-\% copolymer solution in 1,4-dioxane and \( \text{c-hexane (90/10) was mixed with 30 wt.-\% saccharose crystals (200-400 \( \mu \text{m}. \))}

After freezing the mixture at -30 °C, freeze-drying of solvent/non-solvent was performed until
the percentage polymer was 10%. Then the mixture was homogenized at 40°C, again frozen at
-30°C and freeze-dried until all the solvent and non-solvent was removed. Afterwards the
crystals were washed out with water. With this method materials with a compression modulus
of 150 kPa could be made reproducibly.

One prosthesis of this material was implanted into a knee of a dog. After 22 weeks the
prosthesis was still in place and ingrowth of tissue was complete but formation of
fibrocartilage was not observed. For the preparation of stiffer materials, an other technique is
required.

An option is to agglutinate small copolymer particles in the presence of crystals. However,
due to the low glass transition of the polymer and the high toughness of the polymer at
temperatures below the transition temperature, mechanically grinding was impossible.
Therefore, microspheres were produced.

**Microspheres**

To prepare microspheres, the solvent evaporation method was used. Biodegradable
polyester microspheres made by this technique were first described by Beck, Cowsar et al.\(^{24}\).
The polymer is dissolved in a volatile solvent and suspended in water with appropriate
emulsifying agent. After removing the solvent under reduced pressure and by heating,
microspheres can be filtrated. The polymer concentration, stirring rate during emulsifying,
concentration and kind of emulsifying agent and temperature affects the morphology of
microspheres.

In this study, the copolymer was dissolved in dichloromethane to a concentration of 2 wt.-%.
The solution was slowly added to a fivefold excess of a 2 wt.-% solution of polyvinylalcohol in water under stirring at 30°C. The dichloromethane was then evaporated at
atmospheric pressure. The microspheres were sieved into a fraction >50 μm and washed with
water and ethanol. Then the microspheres were dried in a vacuum stove at 37°C. The yield
under these conditions was 80% and size of the spheres 50 - 250 μm. Figure 3 shows a
scanning electron micrograph of the microspheres.
Figure 3. Scanning electron micrograph of copolymer microspheres prepared by the solvent evaporation method.

Porous materials

The microspheres were agglutinate in presence of NaCl crystals with sizes of 150-300 μm using different methods of agglutination. Afterwards the crystals were washed out with water.

First the microspheres were sintered at 130 °C using paraffin oil as conduction agent. The porous material is shown in figure 4. Due to the temperature gradient as a result of the poor conductivity of polymer, the materials were inhomogeneous. At the outside of the material, the microspheres were melted together, contrary to the inside, where disconnected microspheres were visible. At longer sintering times, at the outside the polymer degraded while at the inside loose spheres were still visible.

Agglutinate with solvent, 1,4-dioxane, was difficult because homogeneous dispersion of the solvent was impossible due to the quick agglutination. Therefore, the solubility was decreased by adding 65 wt.-% non-solvent, c-hexane, to the solvent. After agglutination of the microspheres in the presence of NaCl crystals, the solvent/non-solvent mixture was removed by freeze-drying. The porous structure is shown in figure 5. The shape of the spheres is still visible due to the poor solubility of the polymer in the solvent/non-solvent mixture. The interconnectivity pores, which is essential for quick ingrowth of tissue should be improved.
Therefore, porous microspheres were prepared by mixing the polymer solution in dichloromethane with paraffin oil. The ratio polymer and paraffin oil was 1:1. During evaporation of solvent, liquid-solid phase separation between paraffin and polymer occurred. The paraffin oil was totally removed, according to \(^1\)H-NMR experiments, by washing the microspheres with n-hexane. The porosity of the spheres was 45%. Figure 6a shows a scanning electron micrograph of porous microspheres and figure 6b shows a detail of a porous microsphere.

An other method to decrease the solubility of the polymer during mixing, is to freeze the solvent. 1,4-dioxane was frozen with liquid nitrogen and pulverized. Then the solid dioxane was mixed with porous copolymer microspheres and NaCl crystals. At room temperature the spheres were allowed to agglutinate. Afterwards the solvent was removed by freeze-drying and the crystals were washed out with water. The resulting porous structure is shown in figure 7. Noteworthy is the skin formation of the porous microspheres.

In order to prevent skin formation, hexane was removed after agglutination, freeze-drying and washing out the crystals. The resulting porous structure is shown in figure 8. The spheres
Figure 6. Scanning electron micrograph of porous copolymer microspheres made by solvent evaporation combined by adding 50 wt.-% paraffin oil to the polymer solution (a). A detail of a microspheres is shown in b.

Figure 7. Scanning electron micrograph of porous copolymer made by mixing porous microspheres with solid solvent (1,4-dioxane) and NaCl crystals (250-300 µm). After agglutination of the spheres at room temperature, dioxane was removed by freeze-drying and crystals were washed out with water.

Figure 8. Scanning electron micrograph of porous copolymer. Material was prepared using porous microspheres in which the paraffin oil was still present. After agglutination, freeze-drying and washing out of the crystals, paraffin oil was removed.
are not visible anymore. The macrospheres due to the casting material, are dispersed in a
matrix of micropores smaller than ??? m. This method appeared to be an excellent method to
reproducibly prepare porous copolymer.

By varying the crystal concentration, the compression modulus could be varied. As was
mentioned before, the Young’s modulus of open-cell porous materials the density are
theoretically related by$^{22,23}$,

$$\frac{E_f}{E_s} = \left(\frac{?_f}{?_s}\right)^2$$

Where $E_f$ and $E_s$ are the Young's modulus porous and solid materials, respectively, and $?_f$ and
$?_s$ are the respective densities. The compressive stress-strain curves of the materials exhibit
linear elasticity at low stresses. It was followed by a collapse plateau, due to buckling of the
walls, which is truncated by a regime of densification in which the stress rises steeply. As the
porous material, used as meniscal prosthesis, are highly stressed, the modulus at this collapse
plateau, which is positioned at 10-25% compression, is very important. The relationship
between the collapse stress and the density is more complicated because the densification has
to be taken into account$^{25}$. Although the fit is rather better with a more refined equation, data
of different open-cell foams are fitted approximately by the simple equation (1).
Figure 10. Relationship between the logarithm of the compression at 20% compression and the logarithm of the relative density.

Figure 11. The tensile strength of porous copolymer, made by agglutination of microspheres, as function of agglutination time.
Figure 9 shows the compression modulus at 20% compression as function of relative density of the porous materials. The logarithm of the compression modulus at 20% compression is plotted against the logarithm of the relative density in figure 10, and fall on a linear curve with a slope of 1.8, approaching the theoretically value of 2. Thus, with this technique material over a wide range of densities, from 40 kPa to 1100 kPa can be made reproducibly.

Figure 11 shows the tensile strength of porous copolymer, with a porosity of 75%, as function of agglutination time. Materials with maximal tensile strength, which are obtained after two days agglutination, are used for meniscal prosthesis.

*Meniscal prosthesis*

Three copolymer series with compression moduli of 150, 350 and 650 kPa at 20% compression were implanted as meniscal prosthesis in knee of goats as is shown in figure 2. A control PU series, which have already been implanted as meniscal prosthesis in dogs, was also implanted. The follow-up time was 5 and 7 months. The data of the different prosthesis series are presented in table 1. The Young’s modulus as well as the compression modulus at 20% compression are presented.

Figure 12 shows the compression behavior of the meniscal prosthesis and meniscal tissue of dogs. The compression modulus goats of meniscal tissue was not determined but is expected to be lower than the modulus of dogs meniscal tissue\(^\text{26}\).

Of series 1, 10 of the 16 prosthesis dislocated, leaving six prosthesis for histological examination. The percentage dislocation was much higher than in a previous study when these prosthesis were implanted into knees of dogs. Then, only one of 11 prosthesis dislocated.

After 5 months of implantation, ingrowth of tissue was not complete. 70-90 percent of the ingrown tissue consisted of vascular fibrous tissue. 10-30 percent consisted of fibrocartilage tissue. In the cartilaginous areas, chondrocytes could be observed and vascularity was completely absent. After 7 months the percentage fibrocartilage increased to 40%. The ingrowth of tissue was, however, still not complete. The central part, containing 20% percent of the prosthesis, remained empty. When these prosthesis were implanted in knee joints of dogs, ingrowth was complete after 18 weeks of implantation. Additionally, all the tissue in the prosthesis appeared to be fibrocartilaginous tissue.
## Summary

<table>
<thead>
<tr>
<th></th>
<th>series 1</th>
<th>series 2</th>
<th>series 3</th>
<th>series 4</th>
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</thead>
<tbody>
<tr>
<td><strong>Polymer</strong></td>
<td>aliphatic PU</td>
<td>copolymer</td>
<td>copolymer</td>
<td>copolymer</td>
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<td>82 %</td>
<td>76 %</td>
<td>64 %</td>
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<td>70 %</td>
<td>78 %</td>
<td>87 %</td>
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<tr>
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<td>&lt;30 ?m</td>
<td>&lt;30 ?m</td>
<td>&lt;30 ?m</td>
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<td>30 %</td>
<td>22 %</td>
<td>13 %</td>
</tr>
<tr>
<td></td>
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<td>250-300 ?m</td>
<td>250-300 ?m</td>
<td>250-300 ?m</td>
</tr>
<tr>
<td><strong>Compression modulus</strong></td>
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<td>150 kPa (0%)</td>
<td>350 kPa (0%)</td>
<td>650 kPa (0%)</td>
</tr>
<tr>
<td></td>
<td>100 kPa (20%)</td>
<td>100 kPa (20%)</td>
<td>300 kPa (20%)</td>
<td>550 kPa (20%)</td>
</tr>
</tbody>
</table>

All the prosthesis of series 2 dislocated or disappeared, contrary to the prosthesis that was implanted in a dog. Here, the prosthesis was still in place after 22 weeks. The dislocated prosthesis were completely filled with vascular fibrous tissue only. The prostheses were highly deformed, while the PU implants had still their initial shape after 7 months.

In the case of series 3, eight of sixteen prosthesis dislocated. The prosthesis had a deformed appearance. All the prosthesis were completely filled with fibrous tissue and fibrocartilage was never observed. This tissue was highly vascularized and strongly resembles the tissue of a partially regenerated rim observed in a 7 month meniscectomy control knee.

Of series 4, eight of sixteen prosthesis had dislocated. Like prosthesis series 2 and 3, the prostheses were highly deformed and fibrocartilage was never observed.

The high degradation rate of the copolymer, which causes the excellent adhesion properties in the case of meniscal reconstruction, seem to limit the ingrowth of fibrocartilaginous tissue in the case of meniscal prostheses. The implantation results are also affected by the sort of test animal. PU prostheses were more successful in dogs than in goats. Less dislocation occurred and more fibrocartilage was formed. Additionally, in the case of dogs, ingrowth was complete after 18 weeks while in goats ingrowth was not even complete after 7 months. The fact that goats cannot unload the operated leg is probably the reason for these negative results.

The copolymer is less suitable for the use as meniscal prosthesis in goats but it may be proper materials for prostheses in dogs. In addition it is quite possible that these materials are very appropriate for the use as meniscal reconstruction material. The copolymer posses good adhesive properties, which are essential for healing of meniscal lesions. In a previous study, synthesis of materials with a high compression modulus was not possible and 100% fibrocartilage could not be accomplished. However, with the technique described in this paper, materials with high compression moduli can reproducibly be made which make them attractive as meniscal reconstruction material.
Conclusions

Agglutination of porous microspheres in the presence of NaCl crystal has proven to be an excellent method to prepare stiff porous materials of a polymer with a high molecular weight. By mixing microspheres with solvent in the solid state, premature adhesion could be prevented and the solvent could be homogeneous distributed. With technique, porous copolymer materials could be prepared reproducibly over a wide range of densities and moduli.

The high degradation rate of the copolymer inhibited the formation of fibrocartilage in mensical prostheses. Therefore, no correlation of compression modulus as a function of fibrocartilage could be observed.

For testing meniscal prosthesis, the choice of test animal seems to be crucial. PU prosthesis were more successful implanted in dogs than in goats. Only nine percent of the prosthesis dislocated in dogs against 60 percent in goats. In dogs, hundred percent fibrocartilage was formed while in goats maximal 40% fibrocartilage was formed. Additionally, tissue ingrowth

Figure 12. Compression behavior of mensical prosthesis and mensical tissue of dogs; a: meniscal prosthesis series 1 (PU) and 2 (copolymer), b: mensical copolymer prosthesis series 3, c: meniscal copolymer prosthesis series 4 and d: mensical tissue of dogs.
in goats’ prosthesis was not complete after 7 months whereas the ingrowth in dogs was already complete after 18 weeks. The fact that goats cannot unload the operated leg might be the reason for the different results.

The high degradation rate of the copolymer caused deformation of the prosthesis when implanted in goats. Porous copolymer may, however, be a proper materials for prosthesis in dogs. The high degradation rate of the copolymer causes excellent adhesive properties in the case of meniscal reconstruction. The adhesion has found to essential for the healing of meniscal lesions. To accomplish 100% fibrocartilage formation, materials with high compression moduli are needed. Therefore, the porous copolymer described in this paper are probably very appropriate materials for meniscal reconstruction.

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