Development and Coating of Porous Ultra High Molecular Weight Polyethylene Plates

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Porous implants having interconnecting channels allow ingrowth of host connective tissue. Complete implant vascularization reduces the risk of infection, extrusion, and other complications associated with nonintegrated implants. We developed 60% and 70% porous Ultra High Molecular Weight Polyethylene (UHMWPE) plates and blocks using Sodium Chloride as channeling agent, which when dissolved in boiling water leaves behind the interconnecting channels. The average diameter of the pores of 60% and 70% porous plates was found to be approx. 170μm and 210μm respectively. Various mechanical characterizations of the plates were also done. Average Modulus Of Elasticity of 60% and 70% porous plates were found to be 153.802 MPa and 114.579 MPa respectively. The corresponding Ultimate Strengths were 6.21 MPa and 3.9 MPa respectively. This material was also found to be hemocompatible with the human blood. Subsequently these porous plates were dip coated with a solution mixture of Sodium Carboxy Methyl Cellulose (SCMC)/ Polyvinyl Alcohol (PVA)/ Hydroxyapatite (HA) which showed hemocompatibility.

Introduction

All biomaterialists and surgeons are familiar with porous implants (Couldwell WT et al, 1994). These implants have become the implant of choice during various surgical procedures. Porous implants having interconnecting channels allow ingrowth of host connective tissue and thereby helps in keeping the implant in it’s place ie it reduces the migration of the implant after implantation. Complete implant vascularization reduces the risk of infection, extrusion and other complications associated with nonintegrated implants. Porous polyethylene (PE) is available in dozens of prefabricated shapes or plain blocks for individualized intraoperative customizing. The material is firm but malleable and allows direct suturing of muscles to implant without wrapping or extra-steps. Additionally the smooth surface is less abrasive and irritating than other materials used for similar purposes. Porous polyethylene is manufactured in such a way as to produce interconnecting channels that occupy about 60-70% of the volume. Channels are of about 200μm in diameter and will allow host tissue vascularization (Larry M. Wolford et al, 1999). While firm to touch, it can be easily sculpted with a surgical blade or scissors and custom-molded by simply heating in warm saline. Sutures can be directly attached with surgical needles, and the material can be easily fixated with Titanium screws, mesh or plates. Porous polyethylene fulfills several criteria for successful implant, including little propensity to migrate and restoration of defect in an anatomic fashion; it is readily available, cost-effective and can easily modified or custom-fit for each defect. The coating of the porous polyethylene with the Hydroxyapatite (HA) will enhance soft tissue growth (Cottrell DA et al, 1998) over it.

Materials and Methods

Preparation of porous plates

Accurately weighed Ultra High Molecular Weight Polyethylene (UHMWPE) powder (Piliane ultra 2504 manufactured by NOCIL) and dried Sodium Chloride (channeling agent, Gonzalez-
such that the weight percentage of the Sodium Chloride in the mixture is equal to the percent porosity of the plate. Then the powders were mixed thoroughly in a planetary mixer for 24hrs. The mixture was poured into a stainless steel flat bed mould (previously coated with Magnesium Stearate) and was leveled with a level indicator. After that the mould was closed with a top plate and the temperature of the mould was increased slowly to 145-150°C using an embedded heating element with a controller and was maintained for 2hrs. Then the mould was cooled to room temperature and the composite of UHMWPE-Sodium Chloride was obtained in the form of plate.

**Determination of Sodium Chloride present in the plate**

In two beakers 100ml of double distilled water was taken. The first one was kept as blank and in the second one a block of the porous plate was kept. Then both the beakers were kept in the incubator for 24hrs to promote leaching of Sodium Chloride into the water. Then the salinity of water in each of the beakers was checked using a salinity tester (Hanna Salinity Tester model no. W100-9820).

**Determination of pore size of the porous plates**

Assuming membrane pores, (Dembczynski R. et al, 2001), to be circular, straight with uniform cross-section, viscous flow of fluids through the capillary may be estimated from the Poiseuille's equation, [http://landau1.phys.virginia.edu/classes/241L/poise/poise.htm](http://landau1.phys.virginia.edu/classes/241L/poise/poise.htm), expressed as follows:

\[
J_v = \varepsilon \frac{d^2}{12} (\Delta P / T \cdot \eta) = A \frac{d^2}{12} \Delta P
\]

Where,

- \(J_v\) = permeate flux (ml/sec-cm²) through the membrane
- \(\varepsilon\) = Porosity
- \(d\) = Pore diameter (cm)
- \(\Delta P\) = Transmembrane Pressure (kg/cm²)
- \(T\) = Thickness of the membrane (cm)
- \(\eta\) = Fluid viscosity (Poise)
- \(A\) = Membrane constant involving porosity, tortuosity factor, active membrane thickness, fluid viscosity etc which are known for standard membrane and supplied by the manufacturer.

Distilled water was taken inside the vessel of the test-cell (200ml). Sample (to be tested) was placed on a porous metallic plate and clamped to the fluid vessel by rotating the fixer. Nitrogen gas from the gas cylinder was introduced (through a precision pressure gauge) inside the fluid vessel. Permeate flux through the membrane (under steady state conditions) was recorded by measuring volumetric flow of the permeate and time taken. Then the pore size was determined by the following formula:
\[ d^2 = \frac{128 \times V \times T \times \eta}{t \times \pi \times D^2 \times \varepsilon \times \Delta P} \]

where,

- \( V \) = volume of fluid collected, ml
- \( t \) = time taken to collect the fluid, sec.
- \( D \) = diameter of the circular plate, mm

Then the test was performed and the load deformation diagram was recorded on the connected recorder. The recorder parameters were set using main console. Then from the record, Modulus of Elasticity and Ultimate Strength, Callister Jr. WD 2003, were calculated, using the appropriate scales for load and deformation, which were preset, before the start of loading.

**Coating of the porous polyethylene plates of Sodium Carboxy Methyl Cellulose /Polyvinyl Alcohol/Hydroxyapatite membrane:**

A solution of Sodium Carboxy Methyl Cellulose (SCMC) (2\%) in water was prepared with constant stirring to avoid the formation of the lumps. Simultaneously a 30\% solution of Polyvinyl Alcohol (PVA) was made by keeping the mixture of PVA and water in the autoclave (120°C, 15psi) for one and half hour. These two solutions were mixed, the PVA solution being added slowly to the constantly stirring SCMC solution. This was followed by the addition of HA powder to the solution mixture. The stirring was done until a homogenous mixture was formed. Then the solution was kept for 24 hrs. for removing any entrapped bubbles, if any. Then the porous polyethylene plates were dip coated, (Radhakrishnan S. et al, 1997), with the above mixture.

**Mechanical characterization of the porous plates**

For carrying out the tensile tests, (Stein H.L. et al, 1999), the samples were first cut into dog-bone shapes. Then the sample holding grips of the Instron were changed to accommodate tensile specimens, (Callister Jr. WD, 2003). Then the thickness and the width were measured thrice and the average value was taken. After switching on the testing machine (Instron model no.: 4204), the following parameters were set:

1. Max. load range = 500N
2. Load rate = 1mm/min.
3. Displacement range of loading = As per the specimen geometry

**Development of Sodium Carboxy Methyl Cellulose/Polyvinyl Alcohol/Hydroxyapatite membrane:**

A membrane was casted, (Yoshikazu Miyake et al, 1993), on a glass plate using the above mixture of SCMC/PVA/HA. Another membrane...
was also casted without HA ie it contained only SCMS and PVA. Then the membranes were sterilized by autoclaving.

**Mechanical characterization of the membranes:**

The tensile tests of the above membranes were done in the same way like that of the UHMWPE plates.

**Surface roughness studies of the polymer plates:**

The surface roughness, (Bennet J.M. et al, 1989), (Ra in micrometer) of the HA coated polymer surface samples were measured using the Handysurf E-30A surface roughness measuring equipment. The Ra value is obtained by the sampling the evaluation length $L$ from the average curve to the centre line, then calculating the arithmetic mean of the absolute value of the differences between the centre line of the evaluation length and the roughness curve.

$$Ra = \frac{1}{L} \int_{0}^{L} |f(x)| \, dx$$

Where, $Ra$=average roughness of the central line

The higher the roughness value of the HA coated polymer surface, the greater is the bonding of the soft tissue to the bioactive coated polymer implant. The coating with lower Ra values have better adherence to the polymer surface which may be due to the proper fusion and settling of the coating material to the polymer surface.

**Estimation of haemocompatibility of porous plates by hemolysis studies, (Ravaglioli et al 1991)**

Fresh human blood, collected in a beaker, containing Sodium Citrate (3.8gm%, 10:1) was diluted with normal saline solution (8ml blood+10ml normal saline). For checking hemolysis, 0.2ml of the diluted blood was added to 10ml of 0.1% Sodium Carbonate solution and optical density measured at 545nm in a UV-spectrophotometer. Take a 5mmX5mm sample without sharp edges in a standard tube containing 10ml of normal saline kept in an incubator at 37°C for 30min providing temperature equilibration. Add 0.2ml of the diluted blood to the test-tube, mix gently and incubate for 60min.

For positive control, 0.2ml of diluted blood was taken in 10ml of 0.1% Sodium Carbonate solution and for negative control, 0.2ml of diluted blood was taken in 10ml of normal saline and incubated for 60min at 37°C. In a similar manner, material sample was incubated for 60min at 37°C. After 60mins of incubation, all the test-tubes were centrifuged for 5mins at 3000rpm and the supernatant was carefully removed and transferred to the cuvette for spectroscopic analysis at 545nm wavelength and percentage hemolysis was calculated.

$$\text{Percentage hemolysis} = \frac{[\text{OD(test)} - \text{OD(negative control)}] \times 100}{\text{[OD (positive control) – OD (negative control)]}}$$

Where,

- OD= optical density at 545nm

Percentage hemolysis was calculated based on average of two replicates.
1. Highly hemocompatible
   (<5% hemolysis)
2. Hemocompatible
   (within 10% hemolysis) and
3. Non-hemocompatible
   (>20% hemolysis)

**Results and Discussion**

**Determination of the porosity**

The 60% porous UHMWPE plate was actually found to be 59.99% porous, and the 70% porous UHMWPE plate was actually found to be 70% porous.

**Determination of Sodium Chloride present in the plate**

The observations showed that the porous samples do not leach any Sodium Chloride.

**Determination of pore size of the porous plates**

![Figure 7. Comparison of pore diameters of 60% and 70% porous plates](image)

**Mechanical characterization of porous UHMWPE plates**

![Figure 10. Comparison of Modulus of Elasticity of 60% and 70% porous plates](image)
Comparison of Roughness measurements

Figure 12. Comparison of Roughness measurements

Estimation of hemocompatibility of porous plates by hemolysis studies

We can infer from table 1 that the porous plates developed by us are compatible with the RBCs (which is one of the most sensitive connective tissue of our body).

Conclusion

This method of developing a porous implant is a cost effective one as we can reuse the Sodium Chloride time and again. The most important factor is that the porous plates are hemocompatible. The size of the pores varies from 160-220\(\mu\)m, which helps in soft-tissue ingrowth into the implant. Almost whole of the Sodium Chloride is removed from the plates, so the chances of leaching of Sodium Chloride is minimized.

Acknowledgement

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Table 1. Haemocompatibility test of the samples prepared:

<table>
<thead>
<tr>
<th>Samples</th>
<th>O.D. at</th>
<th>% Hemolysis</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ve control</td>
<td>0.397</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-ve control</td>
<td>0.066</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60% porous UHMWPE plate</td>
<td>0.087</td>
<td>6.34</td>
<td>Haemocompatible</td>
</tr>
<tr>
<td>70% porous UHMWPE plate</td>
<td>0.087</td>
<td>6.34</td>
<td>Haemocompatible</td>
</tr>
<tr>
<td>Sod.CMC/PVA/HA/Ciprofloxacin</td>
<td>0.070</td>
<td>1.21</td>
<td>Highly Haemocompatible</td>
</tr>
<tr>
<td>Coated porous plates</td>
<td>0.079</td>
<td>3.92</td>
<td>Highly Haemocompatible</td>
</tr>
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References