Development of a setup to study vascular prostheses

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Abstract

One of the factors thought responsible for the failure of small-diameter vascular prostheses is the haemodynamic influence of the difference in compliance between the artery and the prosthesis. Therefore, an experimental setup is built to measure the mechanical behaviour of these prostheses. Quasi-static tests have been performed on elastic tubes of latex and silicone, a small-diameter prosthesis of Corvita and a small-diameter prosthesis of Gore. The porosity problem of the Corvita prosthesis is overcome by mounting the much more compliant, but water-tight silicone rubber tube inside the prosthesis. Pressure is measured by a mercury manometer and the diameter is measured optically by a cathetometer. Highly anisotropic material behaviour was found for the Gore prosthesis. The Corvita prosthesis behaves anisotropic as well. Furthermore, the stiffness of this prosthesis seems to increase at higher strains.
Samenvatting

Eén van de mogelijke oorzaken voor het faalgedrag van vaatprothesen met een kleine diameter is de invloed die de compliantie heeft op het stromingsgedrag van het bloed. Daarom is er een experimentele opstelling gebouwd, om de compliantie van deze prothesen te kunnen meten. Quasi-statische tests zijn hiermee uitgevoerd aan elastische latex en siliconen buizen, een kleine diameter prothese van Corvita en een kleine diameter prothese van Gore. Het poreus zijn van de Corvita prothese is opgelost door de waterdichte siliconen rubber buis, die veel complianter is, in de Corvita prothese aan te brengen. Druk is hierbij gemeten met een kwik-manometer en de diameter is optisch gemeten met een cathetometer. Sterk anisotroop gedrag is hierbij gevonden voor de Gore prothese en in mindere mate voor de Corvita prothese. Verder blijkt bij toenemende rek, ook de stijfheid van deze prothese toe te nemen.
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Chapter 1

Introduction

1.1 Vascular prostheses

Vascular prostheses have already been used for over 40 years to replace occluded arteries. The use of vascular prostheses has become almost a routine and generally successful operation. Vascular prostheses can be divided into textile (woven, knitted or velour) and non-textile designs. The first kind is usually made of polyethylene terephthalate (PETP, Dacron) or polytetrafluorethylene (PTFE, Teflon). The second kind is based on the use of polyurethanes and for example manufactured by extrusion under high pressure into tubes.

Vascular prostheses perform satisfactorily when they are used for the replacement of large arteries where blood velocities are high. However, when the diameter of the artery is small (less than 6 mm), and blood velocities are low, success rates are much lower [1]. Causes of this failure are multifactoral and complex and the exact mechanisms are not yet understood. Most failures occur by thrombosis which can result in occlusion of the prosthesis. Responsible factors for this occlusion can be divided into those related to the material (such as difference in compliance between the artery and prosthesis, change of material behaviour with time and the surface characteristics of the prosthesis) and those related to the host (such as the conditions of the inflow and outflow vessels and the progression of atherosclerosis). Because of the lack of good small-diameter prostheses, autologous veins are considered to be the best grafts for the reconstruction of small peripheral arteries. However, suitable autologous veins are not always available and small-diameter prostheses have to be used.

Several authors have listed the principal requirements that must be met to design a small-diameter arterial prosthesis [1].

Some important characteristics for a successful small-diameter prosthesis, are:

**Non-thrombogenic surface:** In order to obtain a surface which is less thrombogenic than the base material, prostheses are porous. The concept of a porous prosthesis is that it acts as a skeleton, in which blood clots and becomes entrapped. The thrombus is then transformed into a compact fibrin lining and forms a less thrombogenic surface than the base material.

The distribution of the pore sizes is known to play an important role in the tissue response to the vascular prosthesis. It is possible to control the tissue response and the compliance of the prosthesis, by selecting the structure having the appropriate pore distribution. When the pore size is greater than 45 \( \mu m \), the prosthesis becomes
infiltrated with fibrous tissue (type I collagen). When the pore size is less than 45 \(\mu m\) the wall is penetrated by fibroblasts and type III collagen is formed. Although a new intimal layer is formed, the flow surface of the prosthesis should be smooth. Not only because a rough surface increases the flow resistance, but also because at a rough surface local flow separation can occur, and the risk of thrombosis increases.

**Haemodynamic behaviour:** The vascular graft must have sufficient strength to withstand the highest blood pressures, and this strength should be maintained over the lifetime of the prosthesis. Since the prosthesis undergoes cyclic deformations, fatigue properties are very important. Furthermore, the material must withstand the aggressive environment and can be affected by biochemical degradation. The compliance of the implant should be as close as possible to that of the artery of the host for optimal haemodynamic performance. Discontinuity in elastic properties of the wall also causes a reflection of the blood pressure wave and thus a reflection of energy. This reflection of energy can be minimized by matching the compliances. Not only discontinuity in elastic properties, but also discontinuity in the cross-sectional area causes reflection of the blood pressure wave. Furthermore, a discontinuity in the cross-sectional area will influence the haemodynamics and can lead to flow separation and turbulence, and abnormally high and low shear stresses. The geometry of the prosthesis should therefore have no sudden changes in cross-sectional area and be similar to the diameter of the prosthesis.

It is often pointed out, that since the arteries that are being bypassed or replaced, are diseased and calcified, it is no use to equalize the compliance of the graft to that of the artery, since these vessels do not have the same compliance as normal healthy arteries. However, Langewouters [2] has compared the compliance of mildly diseased and severely atherosclerotic aortas and did not find differences in compliance over the physiologic pressure range.

Nowadays, one of the directions of research to develop more successful small-diameter vascular prostheses, is to seed endothelial cells on to currently available prostheses in order to obtain a less thrombogenic surface. Université Paris XII - Val de Marne has developed a ‘biological’ prosthesis, in which the inner wall is covered with endothelial cells. To be able to calculate the velocity of the pressure wave propagation, reflection and transmission, the (dynamic) compliance of this (and other) prostheses should be measured. One extra problem however is to define the effect of porosity on the dynamic behaviour of the prosthesis. Recently, several experiments were performed to test the properties of tubes under pressure [3]. Also experiments specially focussed on the flow through deformable tubes are reported in recent literature [4].

This report only considers the design and assembly of an experimental setup to measure the static and dynamic compliance of small-diameter vascular prostheses. In chapter 2 a description is given of an experimental setup built at the Laboratoire de Mécanique Physique of Université Paris XII - Val de Marne. Methods to measure material characteristics are described as well. The results of tests on several specimens are presented in chapter 3, and will be discussed in chapter 4. Finally, in chapter 5 conclusions are drawn and recommendations for future research are presented.
Chapter 2

Experimental setup

2.1 Theory

An experimental setup is built to measure the pressure diameter relations of small-diameter tubes. With this relation, one can calculate the compliance of the tested specimen. The compliance $C$ of a cylindrical tube is defined as:

$$C(p) = \left. \frac{\partial A}{\partial p} \right|_{\omega=0} \quad [m^4/N]$$

(2.1)

in which $A = \pi R^2$ is the cross-sectional area of the tube and $p$ the transmural pressure.

In dynamic situations, the compliance can be a function of the frequency and one has to calculate the dynamic compliance:

$$C(p, \omega) = \frac{\partial A}{\partial p} \quad [m^4/N]$$

(2.2)

When performing tests, one also has to deal with the pressure wave propagation, transition and reflection. These parameters depend on the amount of the dynamic compliance and the geometry of the setup and specimen.

2.2 Experiments

The tested specimen is suspended in a rectangular PMMA reservoir and fixed at its ends to a PMMA tube, and a PMMA cylinder (figure 2.1). The fixation of the specimen takes place by mounting the specimen at its ends over the tube and cylinder with slightly larger diameters. Over the specimen ends, small pieces of a thick walled silicone tube are mounted, which are swelled in cyclohexane. After mounting the pieces of the silicone tube, they soon get their normal proportions and the ends of the specimen are fastened. The other end of the PMMA tube, with 6mm inner diameter, is connected to a closed tank. Furthermore this tank is connected to a syringe, to pressurise the specimen, and a mercury or water manometer, to measure the pressure. The tank is fixed with screws to a bottom plate, thus providing to regulate the length of the tube in the reservoir. The PMMA cylinder is connected to a micrometer. In combination with regulation of the length of the tube in the reservoir, this provides the setup to be used to test tube varying in length between 1 and 35 centimeters.
Figure 2.1: experimental setup
Experimental setup

Syringe, tank, tube and specimen are filled with water to pressurise the specimen. The reservoir is filled with water as well, to avoid influence of gravity on the experiments. Water-tight closing of the reservoir at the outlets of the tube and cylinder is obtained by means of a small-diameter rubber tube.

A cathetometer is placed in the horizontal plane of the specimen, at a right angle to the axis of the setup. A cathetometer is a telescope to magnify the image of objects at a relatively small distance to the cathetometer ($O(1 \text{ m})$). An optical measuring-stick provides the possibility of diameter-measurements.

Quasi-static tests are performed on a thick walled latex tube, a thin walled silicone tube, a (knitted) Corvita prosthesis with a silicone tube inside and a Gore prosthesis. The pressure is measured by a mercury or water manometer and the diameter by a cathetometer. The first protocol to test the specimen is to pressurise the tube by means of the syringe and to measure the pressure and diameter. In the second protocol the tube is axially elongated and the diameter is measured at a constant pressure. Both protocols can be performed at different temperatures.

Dynamic tests were not performed. Though the setup that has been built is suitable to perform dynamic tests, several instruments as pressure and diameter measuring instruments were not yet available. Because of quick changes with time in dynamic tests, data acquisition must take place automatically.
Chapter 3

Results

3.1 Latex tube

First the setup was tested using a latex tube of 9.0 mm outer diameter, a wall thickness of 1.7 mm and a length of 200 mm. In figure 3.1 the influence of prestrain on the pressure-diameter relation is shown. Figure 3.2 shows the results of measurements at different temperatures. Notice that this specimen is pressurized far beyond the physiologic pressure range (80 mmHg ≈ 10 kPa - 150 mmHg ≈ 20 kPa) in order to test the setup.

Latex can be considered to be an isotropic, homogeneous, linear elastic tube. An appropriate constitutive relationship for the description of such materials, is commonly referred to as Neo-Hookean. The relationship between the pressure and outer radius for

![Graph showing the influence of prestrain on latex tube](image)

Figure 3.1: Latex: influence of prestrain: o : \( \lambda_z = 1 \), + : \( \lambda_z = 1.05 \)
Results

Figure 3.2: Latex: influence of temperature: o : 20°C, + : 35°C

A uniform, thick walled latex tube exposed to a transmural pressure reads [5]:

\[ p = \frac{\mu}{4\lambda_2} \left\{ \ln \frac{Ro_0^2 \left( Ro^2 + \frac{Ri_0^2 - Ro_0^2}{\lambda_2} \right)}{Ro^2 Ri_0^2} + \frac{(Ro^2 - \frac{Ro_0^2}{\lambda_2})(Ro_0^2 - Ri_0^2)}{\lambda_2 Ro^2 \left( Ro^2 + \frac{Ri_0^2 - Ro_0^2}{\lambda_2} \right)} \right\} \]  \hspace{1cm} (3.1)

with \( p \) the transmural pressure, \( \mu \) a material parameter, \( \lambda_2 \) the axial elongation factor, \( Ro_0 \) and \( Ri_0 \) the outer and inner radius in reference situation and \( Ro \) the actual outer radius.

A fit of relation 3.1 to the experimental results is shown in figure 3.3. This leads to a Young's modulus of \( E = 1.09 \text{ MPa} \) with a standard deviation of 0.14 MPa (figure 3.3). This result corresponds to the Young's modulus for latex found in uni-axial tests (appendix B.1).

Figure 3.4 shows an axial elongation – diameter relation at different constant pressures. If incompressibility and isotropic material behaviour is assumed, this relation should be:

\[ Ro = \frac{Ro(p)|_{\lambda_2=1}}{\sqrt{\lambda_2}} \]  \hspace{1cm} (3.2)

These curves are shown in figure 3.4 as well. The measurements in figure 3.4 however, do not evidently show this relation. This is possibly due to the fact that the chosen reference situation does not completely correspond with the exact reference situation. In this case, the radius \( Ro \) should be constant until the real reference situation is reached and from this point behave as described in equation 3.2.
Figure 3.3: Latex: experimental results and fitted curve at $\lambda_z = 1$

Figure 3.4: Latex: elongation diameter relation at: $\circ = 13.3 \, kPa$, $\ast = 53.2 \, kPa$ and $\ast = 66.5 \, kPa$
Results

3.2 Silicone tube

Next a silicone tube is tested. The manufacturing of this tube is described in appendix A. The dimensions of this tube are 6.5 mm outer diameter, 0.25 mm wall thickness and 90 mm length. In figure 3.5 the influence of prestrain on the pressure-diameter relation is shown.

The silicone tube can be considered to be a thin walled tube and the material behaviour can be described with a Neo-Hookean constitutive relation. The relation between the transmural pressure and the radius now reads [6]:

\[
p = \frac{1}{3} E \frac{h_0}{\lambda_z R_0} \left( 1 - \frac{1}{\lambda_z^2} \left( \frac{R_0}{R_0} \right)^4 \right)
\]  

(3.3)

with \( h_0 \) and \( R_0 \) the wall thickness and radius in reference situation. A Young's modulus of \( E = 0.500 \, MPa \) with a standard deviation of 0.011 \( MPa \) was obtained, when equation 3.3 was fitted to the experimental results (figure 3.6).

3.3 Corvita prosthesis

The following specimen tested is the Corvita Compliant Vascular Graft. However, because this prosthesis is porous, the silicone tube (see §3.2) is mounted inside the prosthesis before quasi-static tests are performed. The dimensions of the Corvita prosthesis are: outer diameter: 8.0 mm, wall thickness: 0.80 mm and length: 90 mm. Pressure-diameter measurements at 20°C and at 35°C are shown in figure 3.7 for \( \lambda_z = 1 \). No difference is seen in the physiologic pressure range (up to 20 kPa ≈ 150 mmHg) between the curves for the different temperatures within the accuracy of these measurements (see chapter
Corvita prosthesis

Figure 3.6: Silicone: experimental results and fitted curve at $\lambda_s = 1$

Figure 3.7: Corvita: influence of temperature: $\circ: 20^\circ C$ and $+: 35^\circ C$
4.1. From the graph it can be concluded that the material does not behave linearly elastic, but becomes stiffer at higher radial strains. The compliance of the Corvita prosthesis (equation 2.1) at a pressure of $13.3 \text{kPa}$ is $8.3 \cdot 10^{-10} \text{m}^4/\text{N}$. At the same strain, for the silicone tube a compliance of $6.2 \cdot 10^{-9} \text{m}^4/\text{N}$ is found.

3.4 Gore prosthesis

The Gore prosthesis behaves very different from the above mentioned tubes. A specimen of $6.0 \text{mm}$ outer diameter, $0.50 \text{mm}$ wall thickness and $48 \text{mm}$ length is tested at a low pressure range, at which quasi-static tests can be done fairly well due to the low porosity of the prosthesis. As we see in figure 3.8 and 3.9 the diameter does not change much in this pressure range, but the prosthesis gets much longer.

![Figure 3.8: Gore: pressure-diameter relation](image-url)
Figure 3.9: Gore: pressure axial elongation relation
Chapter 4

Discussion

4.1 Quasi-static experiments

Quasi-static tests are performed on elastic tubes of latex and silicone, a Corvita Compliant Vascular Graft (Corvita prosthesis) and a small-diameter Gore prosthesis. The experimental setup, built at Université Paris XII, gives results that are reasonably accurate and, within this accuracy, repeatable. The accuracy of the measuring instruments is for the mercury manometer ±1 mm Hg which corresponds to ±0.13 kPa and the accuracy of the cathetometer is ±0.05 mm. The influence on the mechanical behaviour of several parameters can be measured:

- The influence of prestrain is shown in the smaller diameter (for incompressible isotropic materials: \( d \sim \frac{1}{\sqrt{\lambda}} \)). The stiffness of the tube decreases as well, as is seen in the tests of the silicone tube.

- Influence of temperature is not measured for the latex tube, where theory predicts a Young's modulus \( E \sim T \) with \( T \) the absolute temperature \([7]\). However, notice that temperature variation is small: \( 293K \ (20^\circ C) - 308K \ (35^\circ C) \). The stiffness of the Corvita prosthesis is also not dependent on this temperature variation.

- Tube length does not seem to influence the stiffness in the lengths used. No critical value for tube length has yet been determined, beneath which the mounting ends do have a significant influence on the pressure-diameter relation.

4.2 Constitutive behaviour

As expected for latex and silicone, results for the pressure-diameter relation were obtained that reflect linear elastic material behaviour. Probably due to mounting problems or bad definition of the reference situation, the diameter-axial elongation relation differs from the theoretically predicted curve.

The Corvita prosthesis is a prosthesis with a knitted wrapping. This prosthesis becomes stiffer at higher strains and is not linear elastic. The porosity problem of this prosthesis was overcome by mounting the more compliant, but water-tight silicone tube inside the prosthesis. The compliance of this silicone tube at 13.3 kPa is 7 times higher than the compliance of the Corvita prosthesis with the silicone tube. The influence of the silicone tube on the mechanical behaviour of the Corvita prosthesis is therefore not negligible.
Moreover, the silicone tube could influence the axial behaviour of the Corvita prosthesis when it is pressurized.

The Gore prosthesis does not change in diameter with transmural pressure. Though there is no axial force acting on the tube, there is only axial elongation when pressurising the tube. Highly anisotropic behaviour is therefore expected, which is confirmed by uni-axial tests (see appendix B.4). Problem is the low porosity of the prosthesis, which makes it impossible to perform measurements at a really constant pressure. The influence of the water flowing through the wall on the mechanical behaviour is not known as well.

For further study of the mechanical behaviour of these prostheses, it is interesting to measure the axial force, that acts on the mounting ends.

The influence of the forming of collagen in the porous prosthesis, as mentioned in the introduction, on the mechanical behaviour is not studied in this setup. It is likely that the forming of collagen will stiffen the prosthesis.
Chapter 5

Conclusion and recommendations

5.1 Conclusion

The quasi-static experiments performed on tubes of latex and silicone, a Corvita Compliant Vascular Graft (Corvita prosthesis) and a small-diameter Gore prosthesis, show that the experimental setup built at Université Paris XII offers the possibility to study the mechanical behaviour of small-diameter vascular prostheses: It gives results that are reasonably accurate and, within this accuracy, repeatable. Influence of prestrain, temperature and tube length can be measured as well. Because of the porosity of some prostheses, a compliant silicone tube is mounted inside the prosthesis. This tube is easy to make. However, the compliance of this tube will influence the measurements and the real compliance of the prosthesis is not measured.

5.2 Recommendations

For further study of the behaviour of small-diameter vascular prostheses, it is interesting to perform the tests described in chapter 2 with a measuring instrument, capable to measure the axial force. Furthermore, the influence of the mounting ends on the behaviour of the specimen should be studied as well as the influence of the forming of collagen on the mechanical behaviour of the prostheses. To overcome the porosity problem of the prostheses, one could use a high molecular fluid to pressurise the specimens, that cannot flow through the porous prosthesis. In this way, no influence of other tubes on the mechanical behaviour of the prosthesis is measured. Dynamic experiments are interesting also to understand the mechanical characteristics of vascular prostheses, especially for calculation of the reflection coefficient and the pressure wave propagation velocity. However, not only an extra axial force measuring instrument is needed. Pressure should be measured inside the specimen and the diameter of the specimen should be measured optically. It could be recommended not to measure the diameter, but the deformation of the diameter, which should be more accurate in our study. Data acquisition must take place automatically and results of pressure, diameter and axial force should be measured simultaneously.
Bibliography


Appendix A

Silicone tube

A thin walled silicone tube is made of the material Silicone RTV 71556, produced by Rhône Poulenc. After mixing the two products, that form the silicone, with cyclohexan to catalyse the reaction, a high viscous gel is obtained, that can be used for further processing. A tube is made by rolling a tube of glass with a certain diameter at constant speed through the liquid. After drying, an elastic, water-tight tube is formed by the thin film that sticks to the glass tube.
Appendix B

Uni-axial tests

B.1 Latex tube

Uni-axial tests on prepared pieces of the latex tube give the following results for pieces of axial and radial orientation. In figure B.1 the Cauchy stress is shown against the axial elongation for a specimen in longitudinal and a specimen in radial direction of the tube. In figure B.2 the Cauchy stress $\sigma$ is shown against $\frac{1}{2}(\lambda - \frac{1}{\nu})$. This relation represents a Neo-Hookean constitutive relation. Fitting a linear material function to the test data yields for the two directions:

$$E_{\text{axial}} = 1.01 \, MPa$$
$$E_{\text{radial}} = 1.04 \, MPa$$
Figure B.2: Determination of the Young's modulus of latex

Figure B.3: Uni-axial test on a axial specimen of silicone
B.2 Silicone tube

Figure B.3 shows the results for uni-axial tests on a longitudinal specimen of the silicone tube. The relation between the Cauchy stress and the axial elongation factor seems to be linear with:

axial : $E = 0.57 \, MPa$

B.3 Corvita prosthesis

In figure B.4 the uni-axial test results for the Corvita prosthesis are presented. It is clear that this material does not behave linear elastic. The begin and end elastic moduli in these graph are:

axial : $E_{\text{begin}} = 0.80 \, MPa; \, E_{\text{end}} = 8.71 \, MPa$
radial : $E_{\text{begin}} = 1.83 \, MPa; \, E_{\text{end}} = 13.1 \, MPa$

From the difference in elastic moduli, it is clear that the material behaves anisotropic.

B.4 Gore prosthesis

The elastic behaviour of the Gore prosthesis is non linear as is shown in figure B.5 for an axial an radial specimen. It is clear that this material is highly anisotropic. The begin and end elastic moduli in these graphs are:

axial : $E_{\text{begin}} = 0.63 \, MPa; \, E_{\text{end}} = 35.3 \, MPa$
radial : $E_{\text{begin}} = 2.91 \, MPa; \, E_{\text{end}} = 23.6 \, MPa$
Figure B.5: Uni-axial test on a axial (−) and radial (−−) specimen of the Gore prosthesis