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Mechanical Behavior of a Porous, Sub-total Meniscus Implant Based on Poly(trimethylene carbonate): a Pilot Study in the Knee

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Abstract - Meniscus tears often occur in the avascular inner part of the meniscus and therefore do not heal spontaneously. Current treatments such as meniscectomy and the implantation of allografts are insufficient. In this study we prepared a designed, sub-total, porous meniscus implant from functionalized poly(trimethylene carbonate) by stereolithography, and investigated its mechanical behavior in a human cadaveric knee. The sub-total meniscus implant was sutured to the peripheral rim of the meniscus and placed in the medial compartment of the knee. To determine the peak- and mean pressures and the contact area pressure distribution, measurements were made and compared to those of the native meniscus-, meniscectomy- and allograft implant situations. Compared to the native meniscus, meniscectomy results in considerably higher peak- and mean pressures. Compared to meniscectomy, the allograft and PTMC implants show a limited decrease in peak pressures and a much lower mean pressure. The mean pressures are close to those of the native meniscus. Both the allograft and the PTMC implant show improved mechanical behavior compared to meniscectomy. It can be expected that the mechanical function of the PTMC implant will improve upon the formation of tissue in the pores of the implant after implantation in patients.

Keywords - mechanical properties, meniscus implant, poly(trimethylene carbonate), stereolithography

1. INTRODUCTION

In young patients meniscus injuries frequently occur as a result of twisting motions [1]. Meniscus tears are then often located in the avascular inner part of the meniscus, and therefore do not heal spontaneously [2]. In the USA, of the 650,000 meniscus related surgeries which are conducted annually, most involve (partial) meniscectomy [3]. However, 50 % of the meniscectomized patients develop osteoarthritis in the long-term [4]. Currently, the only treatment option for these patients is meniscal allograft transplantation [5]. While allograft transplantation results in short-term improvement of the knee function, issues such as implant shrinkage and structural remodelling may compromise its function in the long-term. Furthermore, the availability is allografts is restricted.

Recently, we prepared a designed, porous, and biodegradable goat meniscus implant with mechanical properties close to those of the natural meniscus by stereolithography using resins based on poly(trimethylene carbonate) macromers [6]. Here, we prepared a designed, subtotal (without the peripheral rim), porous, human meniscus implant in a corresponding manner and investigated the mechanical behavior of the implant in a human cadaveric knee.

2. MATERIAL AND METHODS

Meniscus implant preparation

A sub-total, porous, human meniscus implant with gyroid pore architecture was prepared by stereolithography using a resin based on a photo-crosslinkable, methacrylate functionalized poly(trimethylene carbonate) macromer with a molecular weight of 20.0 kg/mol (PTMC-tMA) and subsequent extraction of the diluent and drying. The experimental details of the design process, resin composition, implant preparation and extraction have previously been described [6].

Knee Preparation

A cadaveric knee was obtained from the department of Anatomy of the Radboud university medical center, and it was evaluated based on anteroposterior and lateral radiographs as previously described [5]. Briefly, the medial meniscus length and width were estimated to make sure the dimensions did not deviate more than 10 % from the dimensions of the implant.

Pressure distribution measurements on the medial tibial condyle with the native meniscus in place were performed using a K-Scan 4010N sensor placed under the native meniscus (Figure 1A) after the circumferential meniscus attachment was released. The knee was then mounted in the compression testing rig in the full extension position (Figure 1B).



FIGURE 1 Specimen preparation. A) Pressure sensor is placed under the meniscus. B) Knee in test setup.

To measure the pressure distribution after an allograft transplantation, the natural meniscus was sutured to the knee by a standard allograft fixation procedure. To measure the pressure distribution with the implant, the implant was sutured to the meniscus rim: five sutures were placed with the knots pointing upwards to prevent artefacts in the pressure measurements. The fixation of the implant to the knee was subsequently realized in a similar manner as the allograft. See Figure 2.



A) THE PTMC IMPLANT IS SUTURED TO THE PREIPHERAL RIM OF A MENISCUS. B) THE IMPLANT FIXED IN THE MEDIAL COMPARTMENT OF THE KNEE.

Pressure distribution measurements

After the knee was mounted in the compression testing rig, the knee was preconditioned by applying 5 loading cycles of 1000 N for 50 s. During the 6th loading cycle, pressure distribution measurements were taken to determine the peak pressure, mean pressure and contact area.

3. RESULTS

Meniscus implant

A porous, subtotal meniscus implant with gyroid pore architecture with a porosity of 68 % and a pore size of 660 μ m was designed to obtain an implant with optimal mechanical properties, as described previously [6]. After building by stereolithography and extraction, a sub-total porous human meniscus implant with gyroid pore architecture and a porosity of 50 % was obtained. Figure 3 shows the resulting sub-total implant after extraction and drying.



A designed sub-total porous human meniscus implant with a gyroid pore architecture after extraction and drying. Scale bar is $1\ {\rm Cm}.$

The suturing of the implant to the peripheral rim of the meniscus could be done easily.

Pressure distribution

The pressure measurements were taken during the 6th loading cycle with 1000 N. The results are presented in Table 1 and Figure 4.

From Table 1 and Figure 4 it is clear that with a native meniscus the contact area is large and the pressure is evenly distributed across the tibial condyle. As can be expected, the peak pressure was low, 1.20 MPa [3]. The obtained mean pressure of the native meniscus was 0.47 MPa.

	TABLE I		
PEAK PRESSURES, MEAN PRES	SSURE AND CONTAC	T AREAS ON THE MEDIAL	
TIBIAL CONDYLE OF A CADAVE	ERIC KNEE FOR A NA	TIVE MENISCUS, AFTER	
MENISCECTOMY, ALLOGRAFT	FRANSPLANTATION	AND A PTMC IMPLANT	
TRANSPLANTATION.			
		ä	

	Peak	Mean	Contact
	Pressure	Pressure	Area
	(MPa)	(MPa)	(mm^2)
Native Meniscus	1.20	0.47	575
Meniscectomy	2.33	0.78	362
Allograft	2.15	0.58	395
PTMC implant	2.30	0.54	318

Figure 4 shows that after meniscectomy, the pressure is concentrated in the middle of the tibial condyle, with a much higher peak pressure of 2.33 MPa and a reduced contact area as can be seen in Table 1. Furthermore, the mean pressure was increased to 0.78 MPa.

With use of the allograft and the PTMC implant, the pressure areas on the middle of the tibial condyle decrease. See Figure 4. Part of these pressures are now located on the outside of the condyle. The contact areas of both the allograft and the PTMC implant remain much lower than in the case of the

native meniscus. Compared to the meniscectomy case, both the allograft and the PTMC implant show decreased peak pressures of respectively 2.15 and 2.30 MPa. This decrease is limited and both peak pressures are still considerably higher than the peak pressure of the native meniscus. (Note: the high pressure points in the left bottom corner of both the allograft and the PTMC implant are artifacts and are therefore excluded when determining the peak pressures.) Both the allograft and the PTMC implant result in much lower mean pressures of respectively 0.58 and 0.54 MPa. These values are much closer to the mean pressure of the native meniscus.



FROM LEFT TO RIGHT: THE PRESSURE SENSOR OUTPUT MEASURED IN THE KNEE WITH A NATIVE MENISCUS, AFTER MENISCECTOMY, AN ALLOGRAFT AND A PTMC IMPLANT. (NOTE: THE HIGH PRESSURE POINTS IN THE LEFT BOTTOM CORNER OF BOTH THE ALLOGRAFT AND THE PTMC IMPLANT IMAGES ARE ARTIFACTS AND ARE THEREFORE EXCLUDED WHEN DETERMINING THE PEAK PRESSURES).

From these results it follows that the use of an allograft as well as a PTMC implant is an improvement when compared to the meniscectomy case. It can be expected that the mechanical function of the porous PTMC implant will further improve upon tissue formation within the porous implant upon implantation in patients.

4. CONCLUSIONS

A porous, sub-total, human meniscus implant with gyroid pore architecture was prepared by stereolithography using PTMC-based resins. The implant could readily be sutured to the peripheral rim of a natural meniscus.

Subsequent pressure measurements showed that compared to meniscectomy, an allograft and the PTMC implant reduced the mean on the tibial condyle. Although the contact area remained lower than that of the native meniscus and the decrease in the peak pressures was limited, the use of an allograft as well as a PTMC implant is an improvement over the meniscectomy case.

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