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Biomechanical characteristics of different artificial substitutes for rabbit medial meniscus and effect of prosthesis size on knee cartilage

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Summary

Large and small Dacron prostheses were implanted as substitute for the medial rabbit meniscus to investigate whether prosthesis size influences the biomechanical and clinical results. Both prostheses had a higher compression compliance and higher energy storage than the normal meniscus. Knees with sham-operation and meniscus resection were used as controls. Both prostheses led to similar osteophyte formation and synovitis after a 3-month implantation period. Ingrowth to the periphery of the prostheses was found in all cases. Knees with prostheses, no matter what size, had a higher compression compliance than sham-operated knees, but energy storage was similar to normal. Knees with prostheses had a similar cartilage status to sham-operated knees, and had less cartilage degeneration on the tibia than knees with resected menisci. Overall, prosthesis size had no influence on the outcome. Three new prostheses made of coated and uncoated Teflon and Dacron were developed to find a substitute with properties closer to the normal meniscus. Only the uncoated Teflon prosthesis showed similar compression compliance to normal, and had energy storage closer to normal than the other prostheses. These material properties could lead to improved results after implantation.

Relevance

Slightly inappropriate sizing of an artificial prosthesis may not adversely influence the clinical outcome. However, the selection of an artificial meniscus with material characteristics as close to the normal meniscus as possible seems more important. Therefore, the use of an uncoated Teflon meniscus prosthesis may improve the results after implantation.

Key words: Meniscus prostheses, size, biomechanics, ingrowth, cartilage, synovitis

Introduction

In experiments, the load transmitting and absorbing function of the meniscus has been shown[1–6] as well as its participation in lubrication[7] and stabilization of the knee joint[4,6,8]. To restore these important functions after meniscus removal, different types of meniscus substitutes have been tested in animal experiments[9–14].

The authors initially studied a Dacron meniscus prosthesis with polyurethane coating in a rabbit experiment[12]. At 3 months, good prosthesis fixation and cartilage protection on the tibia in contrast to meniscectomy were noted. However, the load–relaxation characteristics of the knee following prosthesis implantation were similar to a knee after meniscus resection. The chosen prosthesis was too large, had a higher compression compliance, and stored more energy than the normal medial meniscus. Osteophyte formation on the medial femoral margin, and bulging and thickening of the medial collateral ligament indicated that the inappropriate size of the prosthesis might have had a more deteriorating effect than its inferior biomechanics alone. Therefore, a smaller prosthesis with similar biomechanics to the former was developed.

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In the present experiment the large and small Dacron prostheses were studied in a paired fashion in a 3-month rabbit experiment to test if osteophyte formation and synovitis could be avoided by use of a smaller, more appropriately sized prosthesis. Furthermore, three new designs were introduced to find a meniscus substitute with characteristics closer to the normal meniscus.

Methods

Large (n = 10), small (n = 10) Dacron medial meniscus prostheses for the knee joint of skeletally mature New Zealand white rabbits were tested biomechanically with load–compression–relaxation tests. Biomechanical data of eight medial menisci from eight adult New Zealand white rabbits served as controls. The prostheses were made of low-porosity woven Dacron sheets coated with polyurethane on both the upper and lower articulating surfaces, leaving the peripheral margin uncoated (D1,D2). Both prostheses were then implanted in paired fashion in 10 skeletally mature rabbits for a 3-month period. After sacrifice the knee joints were evaluated biomechanically with load–compression–relaxation tests and with gross inspection. Synovial samples for histology were taken in all specimens. The results were compared to rabbit knees with sham-operation (n = 10) and meniscus removal (n = 12) of a previous experiment[12]. Six of the implanted large prostheses were submitted to biomechanical testing (D1/3m). Finally, three new prostheses were tested with load–compression–relaxation tests. One prosthesis was made of Dacron felt with polyurethane coating on only the upper articulating surface, leaving the peripheral margin uncoated (D3, n = 10). The second was made of Teflon felt with polyurethane coating on only the upper articulating surface (T1, n = 6). The third prosthesis was made of Teflon felt without coating (T2, n = 10).

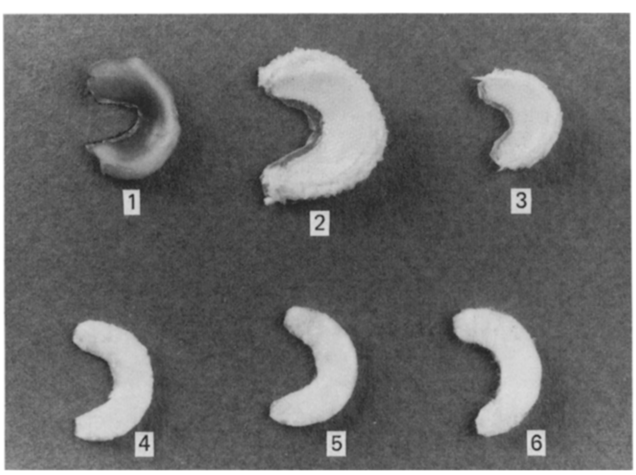

Figure 1. Normal rabbit meniscus and the different prostheses. From left to right: (1) normal meniscus; (2) D1 prosthesis; (3) D2 prosthesis; (4) D3 prosthesis; (5) T1 prosthesis; (6) T2 prosthesis.

Table 1. Size of prostheses and menisci

Group	Thickness mm (SD)	Diameter mm (SD)	Width mm (SD)
D1(n=10)	2.20 (0.26)*	9.65 (0.47)*	4.45 (0.40)*
D1/3m(n=6)	2.17 (0.17)*	10.23 (0.41)*	4.68 (0.37)*
D2(n=10)	1.95 (0.30)*	7.15 (0.27)*	3.48 (0.19)*
D3(n=10)	1.19 (0.10)*	8.12 (0.17)	2.93 (0.15)*
T1(n=6)	1.26 (0.11)	8.38 (0.21)	2.87 (0.23)
T2(n=10)	1.32 (0.11)	8.28 (0.37)	2.87 (0.05)
NM(n=8)	1.37 (0.21)	8.19 (0.37)	2.69 (0.33)

D1, Dacron coated large; D1/3m, Dacron large after 3 months implantation; D2, Dacron coated small; D3, Dacron coated on upper surface; T1, Teflon coated; T2, Teflon uncoated; NM, normal meniscus.
*Significant difference $P<0.01$ from normal meniscus.

All prostheses had non-resorbable sutures attached to the horns and the middle third of the periphery. The prostheses were manufactured by Stryker BV, Uden, The Netherlands. The different prostheses without sutures are shown in Figure 1. The thickness, diameter, and width of the prostheses and normal menisci were measured with a caliper (Table 1).

Biomechanical testing of prostheses

All prostheses had been stored in physiological saline solution at 20°C for 2 days prior to testing. In group D1/3m, synovial tissue as well as sutures were removed from the meniscus periphery.

All specimens were placed in a fixture of 10-mm diameter at the base of the material testing machine (Alwetron, Lorentzon and Wettre, Sweden). A ball-shaped metal plunger of 10-mm diameter, which had been designed to fit the normal medial meniscus, was mounted at the cross-head of the testing machine. The cross-head with the plunger was then lowered until it touched the meniscus (Figure 2).

The meniscus was first cycled five times with a maximum load of 40 N at a speed of 1.5 mm min^{-1}. The sixth cycle (Speed: 0.5 mm min^{-1}) was followed by 2 min relaxation. After 2 min recovery, a second load–relaxation cycle was performed. Data for compliance were gathered during the last cycle, and data for relaxation during both cycles. The compression curves were linear in semilogarithmic plots (mm log N^{-1}) with correlation coefficients of 0.99. Meniscus compliance was defined as the slope coefficient of this curve. The relaxation curves became linear in semilogarithmic plots (N log s^{-1}), after an initial drop during the first 12 s, with correlation coefficients of 0.99. To characterize relaxation, the dissipated energy at 12 s and the slope coefficients for the linear part of the relaxation were calculated. The ratio of the dissipated energy at 12 s (Ed) to the input energy (Ei) was calculated during the first relaxation cycle. The decrease in relaxation at 120 s of the second load–relaxation cycle compared to the first cycle was calculated, and was called the decrease in energy dissipation after recovery (Ed/rec).

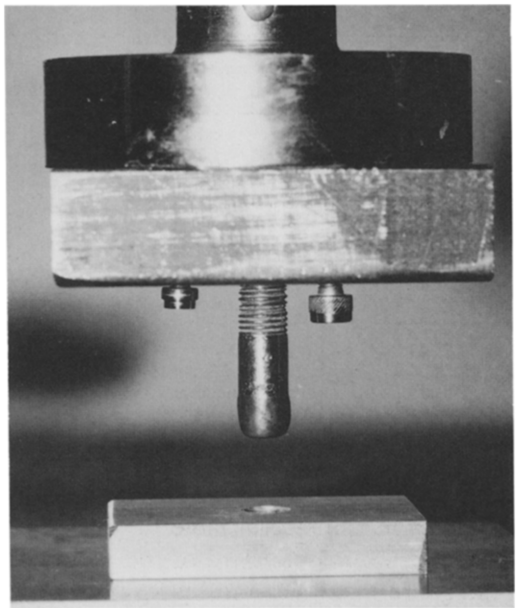

Figure 2. The ball-shaped metal plunger at the cross-head of the testing machine and the fixture containing the prosthesis at the foot.

Rabbit experiment

Surgical procedure

By sterile technique, both knee joints were opened anterior and posterior to the medial collateral ligament (MCL) and both medial menisci were resected. Two 1-mm drill-holes were placed 1 mm apart anterior to the tibial portion of the MCL, and aimed at the anterior and posterior intra-articular tibial attachment of the meniscus. The meniscus prosthesis was implanted using anchoring sutures through the drill-holes, and sutured to the MCL and anterior and posterior capsule (Figure 3). For sham-operation the knee joint was opened anterior and posterior to the MCL without damage to any other structures. In knees with meniscectomy the medial meniscus was removed using an anterior and posterior arthrotomy.

All surgical procedures were performed under intravenous general anaesthesia using a ketamine-Xylazin chloride combination (15 mg kg^{-1} and 1.5 mg kg^{-1} respectively).

The postoperative treatment consisted of free cage activity (0.5 m^2) without immobilization of the joint. Antibiotics were added to the drinking water for 1 week. All animals were sacrificed 3 months after the surgical procedure. The hind limbs were disarticulated in the hip joint and stored at −20° C until testing.

Biomechanical testing of knee joint

The specimens were thawed overnight at 4°C and then at room temperature on the testing day. All muscles were removed, leaving the joint capsule and ligaments intact. The femur and tibia were cut 40 mm from the joint line. The specimen was fixed in the material testing machine. Both the tibial and femoral fixture incorporated a 35° angle in the parasagittal plane between the axis of the femur and tibia and the cross-head movement with the load axis perpendicular to the joint plane.

For knee joint testing, similar test protocols and calculations were used as described for meniscal testing. The compression curves were linear with correlation coefficients above 0.95 in all specimens. Therefore, the results were expressed as millimetres, compression N^{-1}. Similar to the menisci and prostheses, the relaxation curves of the knee joints were linear in semilogarithmic plots (N log s^{-1}) after an initial drop.

Gross inspection

After the compression compliance and relaxation testing, the joint was opened laterally and rinsed. For histological evaluation, synovial tissue samples were collected from the suprapatellar pouch. Fibrous tissue ingrowth into the prosthesis was graded as: (1) the total, the whole prosthesis periphery showed ingrowth of tissue; (2) partial one-third or more of the periphery showed ingrowth; and (3) no ingrowth, less than one-third ingrowth up to a loose prosthesis. Signs of macroscopic wear were documented. The appearance of the articular cartilage was examined, including the presence and size of osteophytes. The degree of osteoarthritis was classified under light-microscopy (4 × magnification) using a modification of Mankins[15] histological classification: grade 0, normal; grade 1, fibrillation and surface irregularities; grade 2, pannus and surface irregularities; grade 3, superficial cleft formation; grade 4, deep but localized clefts down to

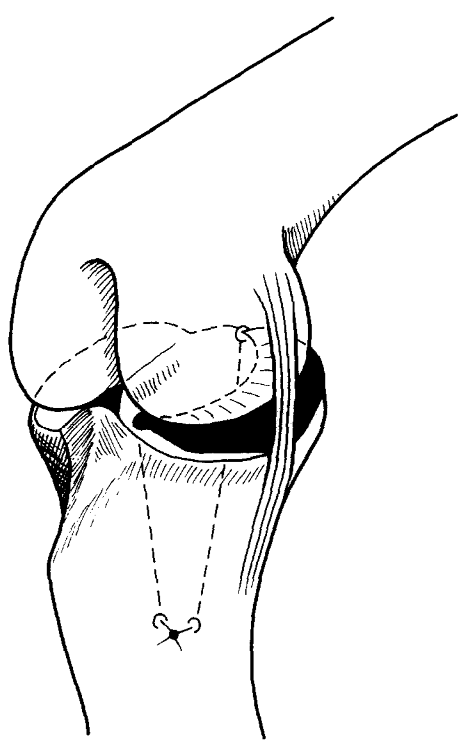

Figure 3. Surgical procedure: implantation and fixation of the prosthesis with the help of two tibial tunnels. The prosthesis is additionally fixed to the medial collateral ligament.

bone; grade 5, larger surface defects down to bone; grade 6, complete loss of cartilage on the load-bearing surface.

Synovial histology
The synovial biopsies were embedded and stained with haematoxylin and eosin and examined under light-microscopy (10 × and 40 × magnification). Conditions of the synovia and underlying tissues were quantitatively classified according to severity and extent: grade 0, normal synovia and underlying tissue; grade 1, mild or focal synovitis limited to the surface, or mild fibrosis of subsynovial tissue without synovial infiltration; grade 2, moderate synovitis with start of fibrosis of subsynovial tissue; and grade 3, severe synovitis with moderate to severe fibrosis of the underlying tissue[12].

Statistics

For intra-animal comparisons, the paired Student's t-test was used for continuous data, and the Wilcoxon signed rank test for categorical data (significance level: $P<0.05$). For interanimal comparisons, a multi-comparison test analysis type ANOVA was performed first. The P level of the following t-test (continuous data) or Mann–Whitney U-test (categorical data) was adjusted downwards by a factor of two (two comparisons) to compensate for the increased probability of type I error during multiple comparisons. A P-level of $<0.05/2 = 0.025$ was regarded as significant. Differences between prostheses and the normal meniscus were evaluated with Student's t-test on a significance level of $P<0.05$.

Results

Knee joints with different sized prostheses did not differ in compression compliance and load–relaxation behaviour. Both were more compliant than sham-operated knees and knees with previous meniscus resection (Table 2, Figure 4). Energy storage after prosthesis implantation was similar to sham-operation. Furthermore, knees with a small prosthesis (D2) stored more energy than knees with meniscus resection. Knees with a large prosthesis (D1) showed no difference in energy storage to meniscectomized knees (Table 2, Figure 5).

Table 2. Biomechanical data of the joints: animal experiment

Group	*Compliance mm* N^{-1} *(SD) (×* 10^{-2}*)*	*Relaxation (Slope coeff.) N/log* s^{-1} *(SD) (×* 10^{-3}*)*	*Ratio Ed/Ei(%)*	*Ed/rec N (SD)*
Dacron large	0.45* (0.09)	2.9 (0.9)	25	3 (3)
Dacron small	0.45* (0.10)	2.3** (0.4)	22.5	2 (3)
Sham-op	0.31 (0.21)	3.1 (1.4)	27.5	4 (5)
ME	0.24 (0.17)	3.8 (1.7)	27.5	4 (4)

Slope coeff., slope coefficient for the linear part of the relaxation curve in semilogarithmic plots (N log s^{-1}); Ed/Ei, Dissipated energy at 12 s to input energy; Ed/rec, Decrease in energy dissipation after recovery; ME, Meniscectomy. * Significant difference from sham-op and meniscectomy, $P<0.05$; ** significant difference, $P<0.05$, from meniscectomy.

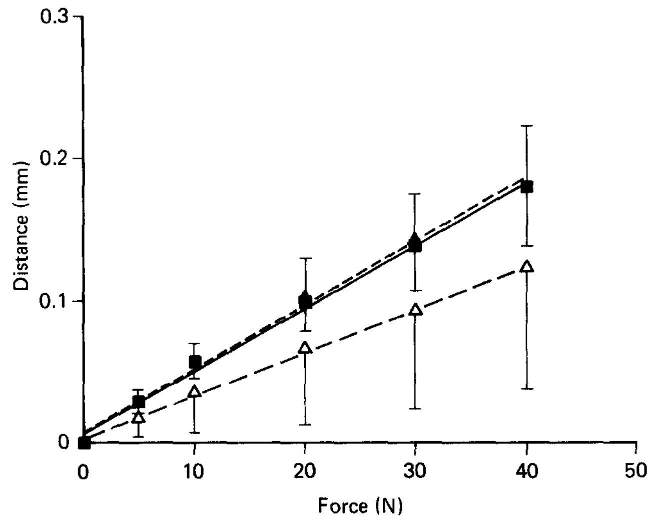

Figure 4. Compression compliance of knee joints (mm N) with (■——■) implanted large and (▲------▲) small Dacron prostheses in comparison to (△---△) sham operation. Implantation of both prostheses led to a higher joint compliance than sham-operation.

Large-sized Dacron menisci (D1) usually exhibited a slight medial subluxation due to oversize (Figure 6), and a thickening and bulging of the MCL. D2 menisci did not cover the anterior and posterior horn areas due to the small diameter; the MCL seemed to be unaffected (Figure 7). Partial or total ingrowth of tissue into the prosthesis periphery was present in all knees for both large and small prostheses.

The frequency of cartilage changes on the femur and tibia was similar for both prostheses groups (Table 3). There was no significant difference to sham-operated knees which were free from changes. On the femoral condyles, osteoarthritis was more frequent for meniscectomized than for sham-operated knees. Between knees with prosthesis or meniscus resection, the differences in femoral cartilage degeneration were not significant. On the tibia, sham-operated knees as well as knees with implanted prostheses had fewer changes than meniscectomized knees. The frequency and size of osteophytes were similar for knees with prostheses and meniscus removal in contrast to sham-operated knees which were free from osteophytes.

In most cases, implantation of both prostheses types (D1,D2) was followed by chronic synovitis, but no specific foreign-body reaction or Dacron wear particles were found. The incidence of synovitis and subsynovial affection was higher and more severe than in sham-operated or meniscectomized knees.

Only the Teflon prostheses had a compression compliance similar to the normal meniscus. All other prostheses were more compliant. After implantation, the large Dacron prostheses (D1/3m) had similar values to non-implanted prostheses of the same type

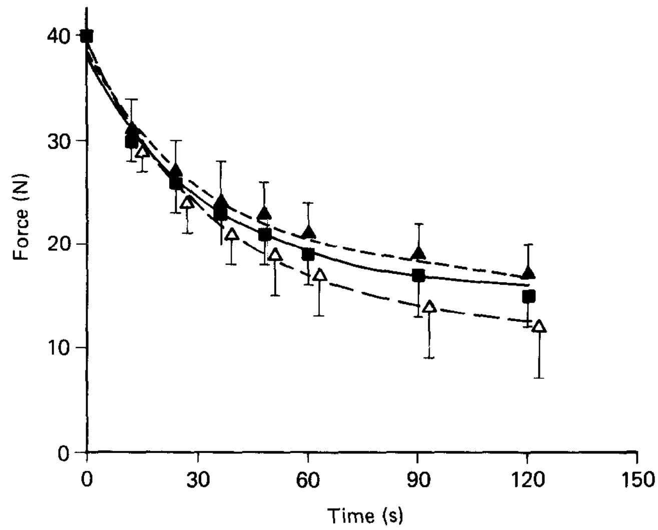

Figure 5. Relaxation characteristics (N s^{-1}) of knees with (■——■) implanted large and (▲----▲) small prostheses in comparison to (△——△) meniscectomy. Knees with a small prosthesis stored more energy than knees with meniscectomy.

(D1) (Figure 8 a,b). None of the prostheses had load–relaxation characteristics similar to the normal meniscus (Figure 9). The ratio of dissipated to input energy at 12 s and the slope coefficients for the linear part of the curves were very high for normal menisci. D1 and D2 prostheses had a negligible amount of dissipated energy during relaxation. D1/3m prostheses showed a higher dissipated energy at 12 s relaxation after implantation than before, but the slope coefficient of the relaxation from 12 to 120s was similar to that before implantation. Furthermore, the values were still far from normal. The Teflon prostheses showed a higher ratio of dissipated to input energy during relaxation compared to the other prostheses, but this ratio was still below normal. All prostheses showed a negligible amount of dissipated energy during recovery.

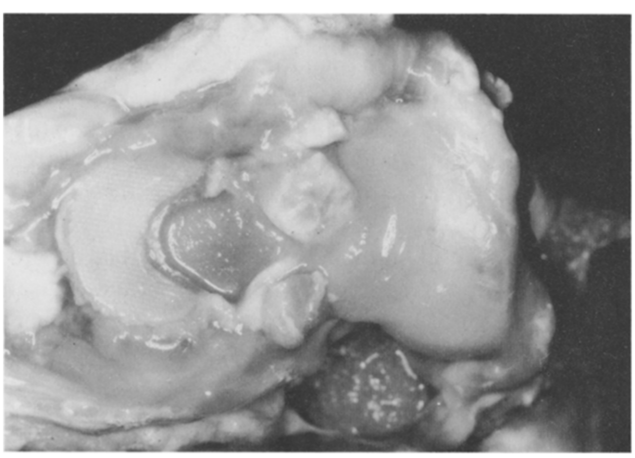

Figure 6. Gross inspection. Right rabbit knee with a prosthesis type D1 in place. Note the medial subluxation of the implant due to oversize and the surface irregularities of the tibial plateau.

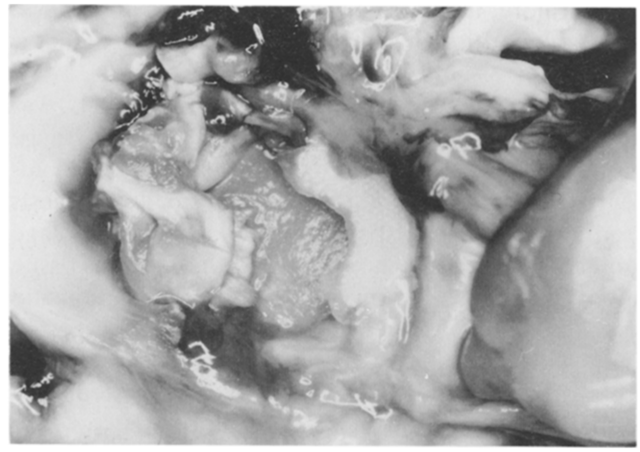

Figure 7. Gross inspection. Left rabbit knee with a prosthesis type D2 in place. The prosthesis does not cover the area of both horns due to undersize. Note the surface irregularities of the tibial plateau.

In fact, both relaxation cycles did not differ significantly. In contrast, the normal meniscus showed a significant increase of energy storage at the second relaxation cycle compared to the first cycle.

Discussion

The normal meniscus is composed of a porous matrix reinforced with collagen fibres and contains water up to 75% of its weight[16,17]. The material properties of the meniscus vary in compliance and tensile strength at different locations due to different water content of the matrix[18]. The healing process after a radial intrasubstance rupture was followed by scar tissue formation. Such a meniscus has been found to be biomechanically similar to meniscectomy[19].

Because of the structural and functional complexity of the meniscus, its replacement with a substitute poses high demands on the implant. For meniscal replacement, three concepts are possible: Replacement with autologous tissue[10,11], a biodegradable matrix[13], or a prosthesis. The demands on a meniscus prosthesis are higher than on biodegradable implants. From the beginning, the prosthesis has to be as close in shape and material properties to the normal meniscus as possible.

Table 3. Osteoarthritis and osteophytes

Group	*OA med femur (Median*	*OA med tibia (range))*	*No OA (%)*	*Knees with Osteoph.(n/%)*
Dacron large	0(0–5)	0(0–1)	50	8/80
Dacron small	0(0–1)	0(0–1)	70	8/80
Sham-op	0(0)	0(0)	100	0/0
Meniscectomy	1(0–4)*	1(0–5)**	8	8/67

OA, osteoarthritis grade 1–6; Osteoph, osteophytes.
*Significant difference from sham-op ($P<0.05$); **significant difference from sham-op and prosthesis implantation ($P<0.01$) and prosthesis implantation ($P<0.01$).

Furthermore, it must keep these properties during use, and stable fixation by ingrowth of surrounding tissues is required.

We have shown that the Dacron prosthesis was properly fixed by ingrowth and that it had a cartilage protecting effect[12] similar to that observed with biodegradable substitutes[10,11,13,14]. The small prosthesis used in the present experiment had a similar cartilage protecting effect and showed ingrowth of fibrous tissue into its periphery. However, osteophyte formation and synovitis were observed despite the smaller size. In knees with a small prosthesis a bulging or thickening of the MCL was not observed. Therefore, osteophyte formation may no longer be interpreted as the consequence of abnormal stress on this ligament. Furthermore, meniscectomy showed osteophyte formation at the same sites. According to these findings, prosthesis size within the limits of the rabbit knee joint seemed to have no influence on osteophyte formation or synovitis. Osteophyte formation and synovitis have been often discussed as the consequence of disturbed joint kinematics[21,22]. The increase in compression compliance of the joint after prosthesis implantation as well as the abnormal low compliance after meniscectomy demonstrated that joint mechanics were changed after meniscus manipulation[12,20]. The abnormal biomechanics of the prosthesis, and the lost spacer effect and increased stress development on the tibia after meniscus removal[5], could have created abnormal motion patterns, and these were probably responsible for the cartilage changes and osteophytes.

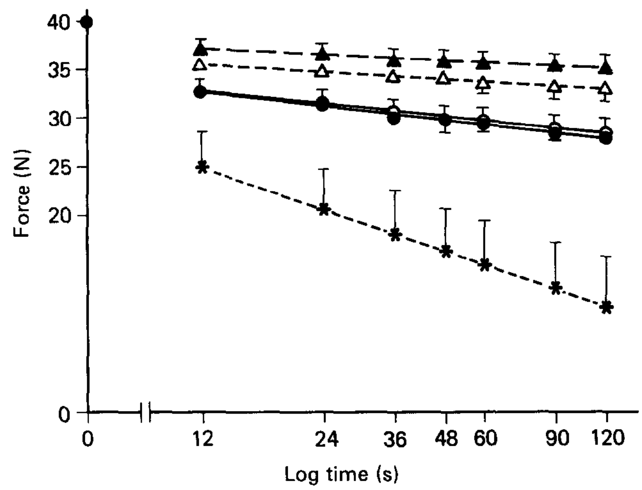

Figure 9. Relaxation characteristics of the different prostheses and the normal meniscus (▲---▲ D1; △----△ D1/3m, ○—○ T1; ●—● T2; and *—* normal meniscus). Note the initial drop and the following linearity of the curve in semilogarithmic plots (N log s^{-1}).

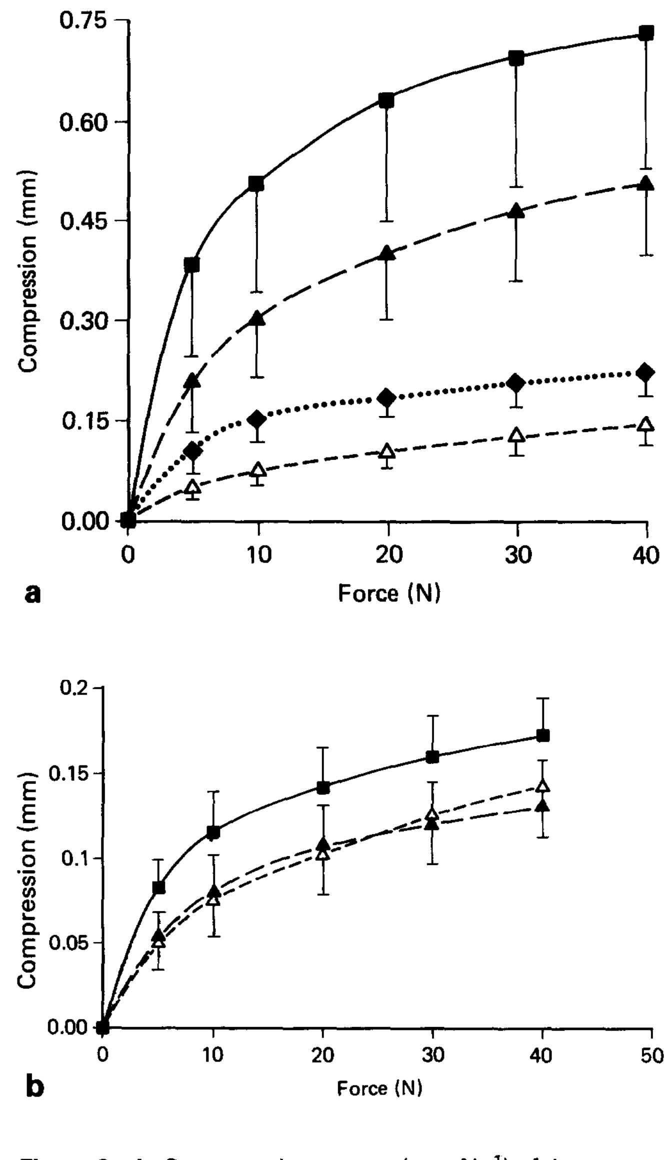

Figure 8 a,b. Compression curves (mm N^{-1}) of the prostheses and normal meniscus. ■—■ D1; ▲---▲ D2; ◆·····◆ D3; △-----△ normal meniscus. Only T2 prostheses had a similar compression compliance to the normal meniscus. ■—■ T1; ▲---▲ T2; △-----△ normal meniscus.

The size of the test fixture (10-mm diameter) may have had a constraining effect especially on the large-sized prostheses, which could have falsely decreased the values for compression compliance and increased energy storage. However, in the same test design the same prostheses showed decreased energy storage after implantation. Since the smaller prostheses had a lower compression compliance than the others, less constraint of the larger prostheses would have increased the noted difference. Therefore, the authors believed that the test design was sensitive enough to measure the large differences between artificial materials and the normal meniscus. The slightly improved stress–relaxation characteristics after implantation was probably due to water absorption into the prosthesis matrix under use. Only the uncoated version of the Teflon prosthesis had compression compliance values similar to normal but energy storage was still much too high. The development of a prosthesis with normal biomechanics was not possible with the available materials.

In this study, only a static load was used, but the results indicate that the function of the prostheses may be worse in situations with impulse loading due to the low energy dissipation. Furthermore it may be impossible to achieve the variations in composition in different areas of the meniscus and the complex movements of the meniscus during knee motion.

Nevertheless, implantation of a biomechanically insufficient prosthesis showed an improvement in comparison to meniscus removal. This emphasizes that a biomechanically improved prosthesis design, as for example the Teflon prosthesis, could improve the results further, even if the implant still has abnormal biomechanics.

Conclusions

1. Stable fixation by fibrous tissue ingrowth and protection of the tibial cartilage was provided using a large and small coated Dacron prosthesis.
2. Non-normal biomechanics of a large and small Dacron prosthesis led to altered joint mechanics, osteophyte formation, and synovitis.
3. The uncoated version of the Teflon prosthesis had similar compliance to the normal meniscus. All other prostheses were more compliant.
4. None of the prostheses could match the stress-relaxation of the normal meniscus, but the Teflon prostheses showed values closer to normal than the Dacron prostheses.

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