Biologic anchorage of cruciate ligament prosthesis

Bone ingrowth and fixation of the Gore-Tex® ligament in sheep

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The biologic fixation and strength of fixation of the polytetrafluoroethylene (PTFE) Gore-Tex® ligament prosthesis was investigated in sheep knees. The device was inserted to replace the anterior cruciate ligament according to the recommended technique. Histological bone tunnel evaluation together with mechanical tensile studies were done at 6, 12, and 18 months.

Already at 6 months the pull-out load of the prosthesis exceeded that of the normal ligament, and this finding persisted up to 18 months postoperatively. At 6 months there was marked fibrous tissue ingrowth into the prosthesis, and at 12 months trabecular bone had replaced the fibrous tissue between the interstices of the filaments; at 18 months bone even penetrated into the individual porous fibers of the prosthesis.The intra-articular part of the prosthesis was surrounded and partly invaded by undifferentiated connective tissue, with no recognizable macrophages or other inflammatory cells.

In this experiment, the biocompatibility and porosity of the Gore-Tex® prosthesis seemed optimal to permit ingrowth from surrounding fibrous and osseous tissues and firm anchorage into the bone tunnels.

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Gore-Tex® (W.L. Gore and Associates, Inc., Flagstaff, AZ, U.S.A.) is a true prosthetic substitute designed for permanent replacement of a torn or absent cruciate ligament without any associated autogenous tissue transplantations or reconstructions. It is made of a single expanded polytetrafluoroethylene (PTFE) fiber that is formed into a braided configuration (Bolton and Bruchman 1985). The material itself is biocompatible and porous; the fiber structure is designed to facilitate tissue ingrowth and thus contains 75 percent air by volume. The microstructure is characterized by fibrils averaging at least 60 μm in length (Bolton and Bruchman 1985).

The tensile strength of the anterior cruciate ligament prosthesis is 5300 Newtons, which greatly exceeds that of the human ligament (Noyes et al. 1974, Noyes and Grood 1976). The primary fixation is very rigid. With permanent prostheses, however, a prerequisite for a long implant time is incorporation of the substitute into bone tunnels after rigid fixation (Kennedy et al. 1980).

Bone ingrowth into the prosthesis in different parts of the tunnels has been poorly documented thus far, despite the fact that more than 1,000 reconstructions have been done in humans (Benedetto 1984, Collins 1985, Ahlfeld et al. 1987, Friedman 1988, Indelicato et al. 1989, Dahlstedt et al. 1990). We examined the histology and strength of fixation of the Gore-Tex® as an anterior cruciate ligament prosthesis.

Material and methods

Operation technique

15 adult, female Finnish sheep weighing 22–48 kg underwent a left knee arthrotomy under general anesthesia, the incision extending laterally from the distal femur medially to the proximal tibia. The joint was exposed medially and the anterior cruciate ligament was sharply excised. The reconstruction was done using the prosthesis Gore-Tex®, 14 cm long and of the same structure as those used in humans (specially fabricated for this study by W.L. Gore & Associates, Inc.). The prosthesis was placed intraarticularly using the over-the-top technique as recommended by the manufacturer (Friedman 1988).

The initial fixation was obtained by using bicortical AO/ASIF cortical screws through the washers. Bone tunnels were carefully prepared smoothing sharp bone edges and a notchplasty was routinely performed. Special attention was paid to the apex of the notch to pre-

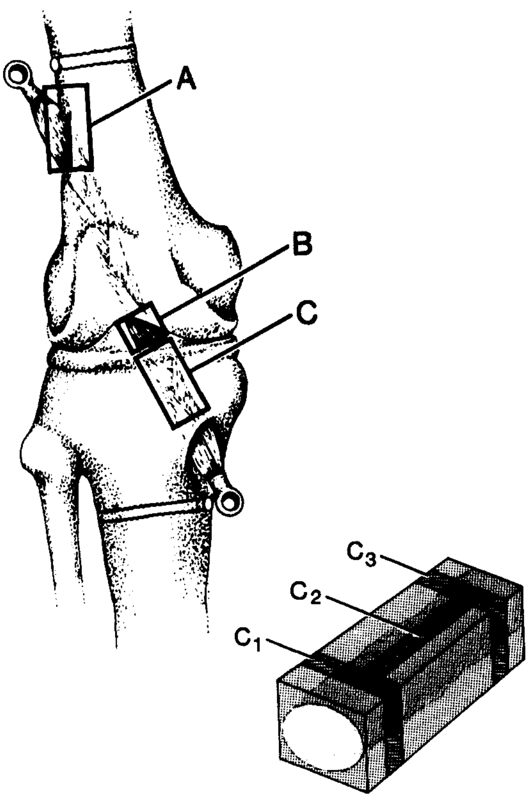

Figure 1. A diagram showing the specimens taken for further histological analysis. Section A contained the femoral bone tunnel plus the periosteal area nearby B, that contained the intra-articular portion of the prosthesis, and section C contained the tibial bony channel. Details of the tibial bone tunnel block, which was further divided into 3 specimens; C1 and C3 transversely and C2 longitudinally (shaded areas).

vent impingement against the condyles when the knee is extended. Tightening of the prosthesis was done manually with the knee in 10° of flexion without any tension device, and an extension-flexion maneuver was carried out to rule out condylar notch impingement (Friedman 1988, Indelicato et al. 1989). After the operation, knee stability was tested manually using anterior drawer and Lachman tests; all the knees were considered to be stable. The right knee served as an unoperated control.

No immobilization was used postoperatively. The animals were allowed to move freely in 3 × 5 m pens with a cement floor and straw. The animals were quite active with only a moderate limp for 2 weeks. They were divided into 3 groups of 5 animals each, and were killed at 6, 12, and 18 months postoperatively.

Tensile load displacement testing was done for 3 animals in the 6- and 12-month groups and for 4 animals in the 18-month group. The intact specimens were reserved for histological analysis (Figure 1). Samples for histology were also taken from the bone tunnels exposed to tensile loading.

Mechanical testing

The maximum tensile load of the prosthesis and control cruciate ligaments was tested on an Instron device (mode 1185) in the Technical Research Center of Finland. The fixation screws were removed before testing and other ligamentous structures around the knees were cut. Testing was performed in an adjustable jig with the femur-anterior cruciate ligament-tibia complex orientated to allow a vertical line of pull in the testing machine. The ligament and adjacent tissue were left moist. Testing was performed using a 2 kN traction scale recording simultaneously with a constant linear displacement rate of 50 mm/min.

Earlier pilot studies had shown that the maximum load of the ligament prosthesis after 6 months exceeded the holding capacity of the metal pins, which were 8 mm wide and had been placed transversely through the bones. Therefore a specially designed metal basket net was constructed around the femoral condyles so that the traction force could be withstood. The load-displacement history was recorded as the cross-head movement on an X–Y drawer, and the ultimate level was measured from the deformation curve. Due to the fact that the reconstruction was done over-the-top and that the actual displacement history of the prosthesis itself was not monitored, stiffness of the implant could not be accurately recorded.

Statistics

The multivariate analysis of variance (one-way ANOVA with repeated measures) was done to determine whether any difference existed between any of the test groups. The repeated measures model with one between-subject variable (follow-up time) and one within-subject variable (pull-out strength of Gore-Tex® vs control) was used. Hypotheses consisting only of one type of factor are tested assuming that there is no interaction between the two types of factors and no higher order interaction of the within-factors, including the effects to be tested.

Wilcoxon's rank sum test was used to test the differences between the pull-out strength of the specimens from Gore-Tex® or control knees. $P < 0.05$ was considered significant.

Histology

6 samples were taken from each operated knee for further investigation of intra-articular behavior and bone ingrowth (Figure 1). First, the intra-articular section of the prosthesis was dissected; then both the femoral and tibial bony channels of the knees were sawed open, and longitudinal as well as transverse sections were taken from the middle part of each channel. Similarly, one section from the periosteal area near the proximal opening of the femoral tunnel was taken. All specimens were embedded into methylmetacrylate, and sections 5 microns thick were stained with Goldner's trichrome.

Results

Manual testing did not reveal any signs of instability or breakage of the prosthesis; however, at 18 months a few individual filaments of the implants were broken at the femoral bone-implant margin. The intra-articular part of the implant was surrounded by scar tissue and synovium, but there were no macroscopic signs of synovitis and the appearance of the synovial fluid was normal.

At all follow-up times the maximum loads of the prosthetic reconstructions were greater than that of the contralateral unoperated ligament (Table 1). At 6 months all 3 prostheses failed from the tibial side by pulling out of the tibial tunnel without any signs of real bony anchorage. On the contrary, at 12 and 18 months there was no evidence of the device migrating out of the bone canal. The biologic fixation of the prosthesis to bone tunnels was so strong that individual filaments of the device started to break intra-articularly, and the bone round the femoral over-the-top area fractured in every case.

There was no interaction between the operated vs. non-operated legs and the postoperative follow-up time. Therefore the conclusion can be drawn from the main effect (i.e., pull-out strength). The pull-out strength of the implant exceeded that of the control ligament ($P < 0.001$); but there was no dependence on the follow-up time.

Wilcoxon's rank sum test of the pooled values revealed no significant differences in pull-out strength between implant and control knees at 6, 12, and 18 months (*P* 0.005).

Because of the small sample size of only 3 or 4 animals at each time point, the statistical power of the test was weak; possible differences concerning the follow-up time can therefore be overlooked (ß-error).

Table 1. Mechanical findings

Follow-up	Ultimate tensile load (kN)	
	Gore-Tex®	Normal ligament
6 months	1.27	0.54
	2.74	0.67
	1.63	0.92
mean *SD*	1.88 *0.77*	0.71 *0.19*
12 months	1.30	1.00
	1.15	0.24
	1.75	1.15
mean *SD*	1.40 *0.31*	0.80 *0.49*
18 months	1.75	1.17
	1.74	0.86
	1.89	0.76
	1.97	0.71
mean *SD*	1.84 *0.11*	0.88 *0.21*

The one-way ANOVA with repeated measures revealed a difference ($P < 0.001$) between the pull-out strength of the specimens from the Gore-Tex® or control knees, without any time-dependence. Wilcoxon's rank sum test was not significant for paired values at 6, 12, and 18 months, but *P* 0.005 when all the values from 6 to 18 months were pooled together.

Histology

At 6 months the individual fibers of the prosthesis in the bone tunnels were surrounded by dense fibrous tissue; no foreign body reaction was observed. Bone ingrowth was already seen in some of the fibers at the periphery of the implant bundle (Figure 2). At 12 months the tunnels were partly filled with osteoid and bone invading the individual fibers. Undifferentiated connective and fat tissue could be noticed between the fibers. The ossifying process continued, and at 18 months bone filled the fibers throughout the transverse sections of the bone tunnels (Figures 3 and 4). The intra-articular part of the implant was surrounded and partly invaded by undifferentiated connective tissue with no recognizable macrophages or other inflammatory cells (Figure 5). Similarly, the adaptation towards the periosteum near the outer ends of the bone tunnels was free of any specific reaction.

Discussion

In our study the primary fixation with screws was strong enough to minimize the strain within the bone tunnel to such an extent that tissue ingrowth into the device was possible. Already at 6 months, the holding capacity (maximum load) of the implant was stronger than that of the control ligament.

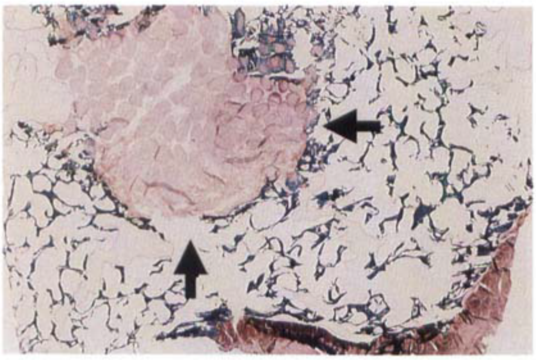

Figure 2. A. Cross-section of a Gore-Tex® ligament within a tibial bone tunnel at 6 months (arrows), Goldner stain, ×10.

Figure 2. B. A close-up of the bundle with ingrowth of fibrous tissue into the periphery of single Gore-Tex® fibers where intimate contact with bone is established (arrow), ×150.

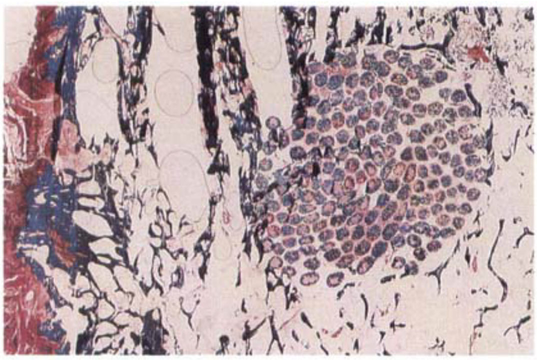

Figure 3. A. Cross-section of a Gore-Tex® ligament within a tibial bone tunnel at 18 months. Goldner stain, ×10.

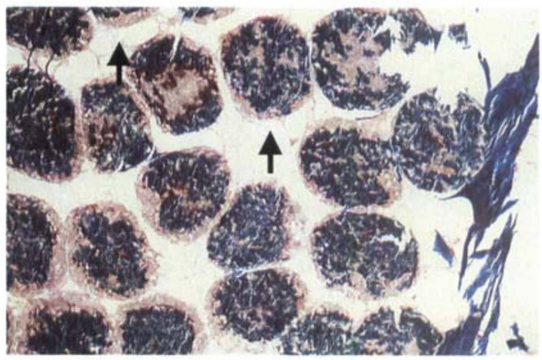

Figure 3. B. A close-up of the bundle with ingrowth of bone into single Gore-Tex® fibers (arrows), ×150.

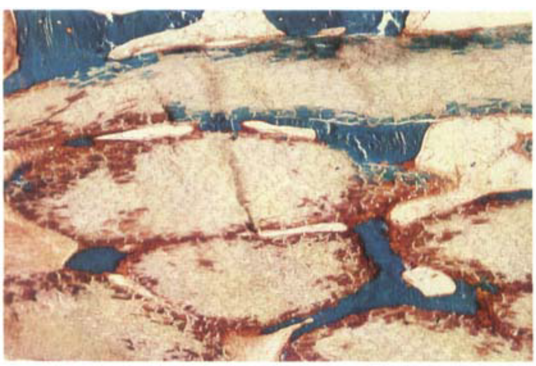

Figure 4. Longitudinal section of a Gore-Tex® ligament in a tibial bone tunnel at 18 months with firm anchorage of the filaments in the surrounding bone without any excess of fibrous tissue. Goldner stain, ×60.

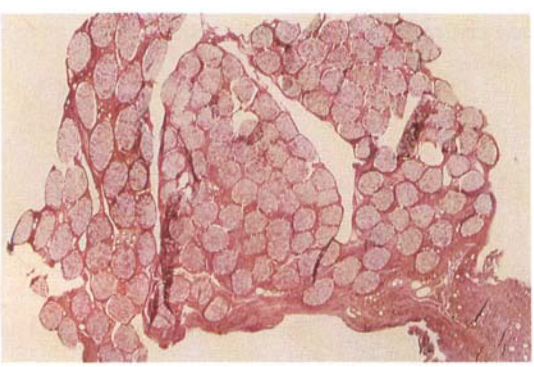

Figure 5. A. Cross-section of a Gore-Tex® ligament from the intraarticular portion at 18 months. Goldner stain, ×30.

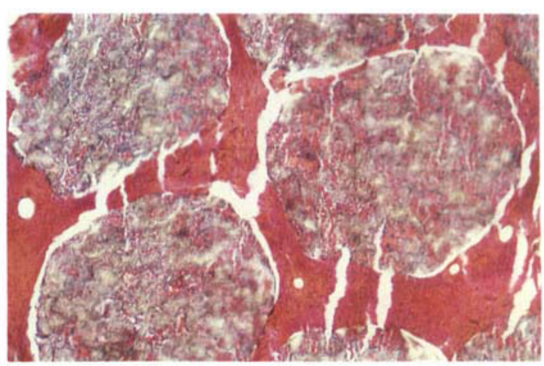

Figure 5. B. A close-up with connective tissue bundles between and some ingrowth of loose fibrous tissue into individual filaments without any signs of foreign-body reaction, ×150.

The many interstices present within the fibers of the prosthesis, i.e., 75 percent air by volume, permitted progressive bone ingrowth into these devices; even the individual fibers of the Gore-Tex® bundle were gradually invaded by bone. This is in close accordance with the findings described by Bolton and Bruchman (1985) with a similar loaded experiment on sheep and by Arnoczky et al. (1988), who used an unstressed, extra-articular location in the dog.

Because we were especially interested in the pull-out behavior of the specimens, and because the tensile strength of the Gore-Tex® is so high that it was impossible to break it in the middle part, an exceptionally slow displacement rate (50 mm/min) was used in this experiment. This is naturally far from that encountered in the acute trauma episode. It is therefore logical to assume that the slow displacement rate used in the present study may explain the comparatively low pull-out values for both implant and control ligaments. This may also reflect the different technical details (i.e., over-the-top at the femoral side, length of material within the bone tunnel, and the experimental animal used), and the viscoelastic nature of the ligaments. Accordingly, the range of the pull-out load for the normal ovine cruciate ligament reported in those few studies which can be found in the literature is wide; 1912 ± 487 N at a rate of 500 mm/min (Bolton and Bruchman 1985) to 568 ± 176 N 100 mm/min (Claes et al. 1987).

Our earlier studies with the braided carbon fiber ligament prosthesis have shown that bone ingrowth is inhibited if the device is coated with autogenous tissue, e.g., fascia lata (Mäkisalo et al. 1988). Although in this study the bone matrix in the Gore-Tex® increased rapidly towards the center of the transverse sections of the prosthesis, it is not clear that this implication can be made regarding the degree of bony ingrowth into the depth of the prosthesis in the longitudinal sections (cf. Figures 1 and 4). The creeping distance to be crossed over into the core of the prosthesis—seen in the longitudinal sections—is longer and takes more time. This was reflected by scarcer bone ingrowth within the fibers, seen in the longitudinal sections taken from the femoral and tibial tunnels during the follow-up. On the transverse sections at 18 months, however, bone had even invaded the individual fibers, despite functional implantation and continuous micro-strain within the bone tunnels.

The intra-articular segment was invaded by synovial and fibrous tissue, with a lack of synovial irritation and the absence of any significant foreign body reaction or other inflammatory response. This means that the basic principle of Gore-Tex®—a true permanent prosthetic substitute of ACL without any associated autogenous tissue transplantation or augmentation—seems to be realistic. In contrast to some other synthetic materials, Gore-Tex® has no unrealistic goals of intra-articular induction of connective tissue or formation of any scaffolding neotendon (Alexander et al. 1981, Kramer and King 1983, Woods 1985, Mäkisalo et al. 1988).

At 18 months of follow-up intra-articularly a few individual filaments of the implant were broken. This reflects the major problem encountered with most prosthetic devices; although they satisfy the strength requirements, they are too stiff to reproduce the force-deformation curve of the ligament. That is why alignment of the bone channel with respect to the prosthesis is of prime importance (Drouin 1986). It is evident that the most critical site of the reconstruction is inside the joint—the intercondylar notch being the most vulnerable site of the prosthesis. Whether the careful preparation of bone edges and notchplasty can prevent bone impingement and save the prosthesis permanently from breakage is unknown (Kennedy et al. 1980, Friedman 1988, Mäkisalo et al. 1988, Indelicato et al. 1989). With time, however, all artificial ligament replacement devices will tend to form wear particles to a variable degree in the knee, with an increasing risk of synovitis and arthritis (Olson et al. 1988, Dahlstedt et al. 1990).

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