

**Evaluation of Cruciate Ligament Prostheses :
Criticism of the Current Concepts and Procedures**

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1. INTRODUCTION

An extremely important number of studies have been published on ligament replacements since the beginning of this century. A lot of research groups have emitted very contradictory opinions about this problem. To this day, none of the current reconstruction procedure proved a good long term behavior. And even if some of the techniques seem to show promising results, a lot of questions still remain concerning the material to be used, the structure and the reconstruction technique. Surgeons disagree even on the type of procedure to be used (autograft or synthetic ligament) .

Understanding the failures and success of previous grafts and studying the surgical techniques and prosthetic designs which show promising results permits now to elaborate a certain number of hypotheses concerning the ligament replacement. These hypotheses should lead to further studies in this field, hoping that these will find a solution to the problem.

The importance of the cruciate ligaments of the knee joint is well understood. Failure of the anterior cruciate ligament (ACL) leads to instability and excessive joint mobility that, if left untreated, leads to osteoarthritis. Since the beginning of this century, a growing interest has been focused on knee ligament reconstructions. The basic alternatives for replacing the ACL are autografts, allografts, and synthetic ligaments.

Ligaments are now recognized to play both mechanical and neurological functions in the biomechanics of the knee (see chapters I.1. and I.2.). Ligaments as a control system of a healthy knee-joint supported by the muscular system are responsible for the rolling and gliding motion of the femoral condyles on the tibial plateau. The presence of mechanoreceptors in the human cruciate

ligaments has been confirmed only in recent years. The first histological demonstration of mechanoreceptors in the human ACL was reported by Schultz et al. in 1984 [37]. In 1986, Zimny et al [46] identified by using a modification of Gairn's gold chloride stain, the presence of Ruffini's end organs, Golgi tendon organs and Pacini corpuscles. In 1992, we confirmed the presence of Ruffini's and Pacini's corpuscles and free nerve endings in canine cruciate ligaments [44, 45]. The development of prosthetic materials to replace ligaments has stimulated interest in the contribution of mechanoreceptors activity in the cruciate ligaments to the stability in the knee joint. The specificity of the gold chloride technique was demonstrated by using immunohistochemical methods [34]. Using this highly specific method, we demonstrated recently the presence of the same mechanoreceptors in human cruciate ligaments [35] (Figures 1, 2 and 3). It is therefore accepted now that the knee joint ligaments contain Ruffini, Pacinian, Golgi tendon-like organs, and free-nerve endings with different capabilities of providing the central nervous system with information about movement and position as well as noxious events [21, 42]. The mechanoreceptors in the knee joint ligaments are suggested to play a key role in the joint stiffness and the functional joint stability [39].

Most of the presently used treatments for injured ligaments are based on the view that the ligaments primarily act as static, mechanical stabilizers of the joint. Consequently, a lot of efforts have been devoted to find, for instance, substitution materials and structures which have mechanical properties comparable to those of the natural ligaments. However, at the light of the clinical results, following ligament reconstruction, it becomes evident that the restoration of the neuroproprioceptive as well as the mechanical functions of the cruciate ligaments is needed (see chapters I.5 and I.1). In fact, impaired proprioception of the joint has been demonstrated in patients with a severely damaged or ruptured ACL [3].

Problems associated with the use of autografts are mainly the necrosis which occurs during the early postoperative period during revascularization and the loss of normal structures which contribute to the normal function of the knee joint. The use of the bone-tendon-bone graft already causes further damage of the neuro-muscular balance impaired by the loss of the ACL including its receptors. In addition, the still existing receptors of the ligamentous stumps can be destroyed by big tunnels.

Although autografts and allografts have been reported to yield positive results in short-term follow-up studies, long-term results are not as promising. The present concern about the transmission of viral disease also has not been fully resolved. It appears that this risk is very small with proper handling of the graft, but sterilization by irradiation affects the physical properties of the graft and has been implicated in the failure of grafts [41].

For these reasons, synthetic ligaments presented themselves to be used for the cruciate ligament replacements. The prosthetic ligament is biomechanically stronger which allows for earlier range of motion of the knee, weight-bearing, and return to full activities. Its use for reconstruction avoids moreover proprioceptive disturbance due to the harvest of autologous tissues.

Prosthetic ligaments are generally classified into three types : permanent ligaments, stents, or scaffolds. Permanent ligaments include the Gore-Tex and the Stryker-Dacron ligaments and are presumably designed with high strength and increased resistance to fatigue failure. The second type is a temporary prosthetic ligament used as a stent such as the LAD or Trevira. The third type of prosthetic ligament is the scaffold device, which allows ingrowth of tissue. These ligaments depend on autogenous tissue ingrowth. The collagen tissue may grow into the existing graft, as in the Leeds-Keio ligament and the LARS.

2. FAILURE ANALYSIS OF THE FDA-APPROVED DEVICES

Many synthetic ligaments were introduced for human clinical trials, including the carbon fiber, Kennedy LAD, Leeds-Keio, Gore-Tex, and Stryker Dacron ligaments (see chapter II.2). Gore-Tex, Stryker and LAD have been approved by the FDA for use as a replacement for the ACL, but with restrictions.

The FDA gave approval in 1986 for the general use of Gore-Tex (Expanded polytetrafluoroethylene PTFE, WL Gore, Flagstaff, Arizona) and in 1989 for Stryker-Dacron (Polyester fabric, Meadox Medical, Oakland, New Jersey) artificial ligaments, but restricted their use to patients with failed intra-articular reconstructions. The Kennedy Ligament Augmentation Device (LAD, diamond-braided poly(propylene, 3M, St Paul, Minnesota) was also approved in 1986 to augment the autogenous graft used in the Marshall-Macintosh procedure, i.e. the quadriceps tendon-patellar tissue-patellar tendon autograft [38]. In 1991, the LAD was also approved as an augmentation for the iliotibial band, the semi tendinous tendon, and portions of the patellar tendon used for ACL replacement.

The Gore-Tex ligament was predicted to have a life to rupture of 4×10^9 cycles and less than 4% elongation at 3×10^8 cycles [5]. Assuming an average of 4.2×10^6 cycles per year, the ligament should have a life expectancy of 950 years prior to rupture and 70 years prior to 4% elongation [13]. This has not been seen in actual clinical application, and the ligament has failed both because of rupture and elongation. Despite the encouraging preliminary results of Gore-Tex ligament reconstruction, the results of 4- to 5-year follow-ups of many studies have demonstrated an apparent deterioration in both subjective and objective results [30].

The Stryker-Dacron ligament was initially designed to be used as an augmentation device with the iliotibial band in ACL reconstructions, but the high strength of the ligament has led to its use as a permanent prosthesis. Fatigue testing showed the ability to withstand 134, 000 fatigue cycles at 1730 Newtons. This amount of force would presumably disrupt a normal ACL after a single cycle. The estimated *in vivo* life expectancy from the fatigue testing data is 8.5 years. Recent studies demonstrate a significant failure rate at 5 years.

The LAD prosthesis is a permanent, non-absorbable augmentation device made of woven polypropylene. *In vitro* testing demonstrates a cyclic elongation of 4% after 1 million cycles between 50 N and 500 N, resulting in a 9% strength loss. Bending fatigue parameters after 10 million cycles of 150 N to 300 N, with flexion between 15 and 40 degrees, yielded 4.5% cyclic elongation and 23% strength loss [30].

Many clinical studies have demonstrated early success but, as far as we know, no long-term investigations have shown convincingly that these constructs remain intact or that they replace the function of the ACL effectively. Very limited use of these prostheses in the United States has been disappointing. The life-span of the existing prostheses remains short. Fatigue, fretting, and wear have resulted in an unacceptably high rate of failure.

As a consequence, enthusiasm for the use of synthetic ligaments has been tempered by poor long-term results and replacement of the cruciate ligaments seems impossible with today's techniques. The FDA adopted a low profile regarding this high rate of failure and the bone-patellar tendon-bone appears as the "golden standard" solution and the best alternative to synthetic ligaments in North America. Although it is more appropriate to consider this solution as a "best available to date" [12].

Outside the United States, several polyester prosthetic ligaments have been developed without the control of the FDA. However, recently, the synthetic cruciate ligaments are also subjected to some limitations in France. It is permitted to implant artificial ligament prostheses as either stents or replacements but severe restrictions have been imposed by the French health care system [26]. However, no scientific argument has been given.

One of the better known investigational polyester prosthesis in United States is the Leeds-Keio implant, while in Canada LARS^R and Trevira Hochfest^R are gaining some popularity.

In England, the Leeds-Keio^R ligament was presented as a scaffold to ease the growth of a neoligament, but up to 1988 the clinical data did not provide the expected success [32]. Clinical trials for the Leeds-Keio prosthesis began in the United States in 1990. As far as we know, it is not yet approved.

Another polyester ACL prosthesis, the Ligastic implant, was introduced mainly in France. The particularity of this artificial ligament is its knitted structure, in which all the fibers are oriented longitudinally at their maximal length [8]. This first generation was very sensitive to the surgical technique and a high rate of failure was reported recently by Cazenave et al [7]. This is surprising and contradictory to the previous results published by the same authors. Cazenave et al. [7] did not provide any scientific explanation for this difference.

Based on Ligastic experience, a new design using mechanically and biologically selected polyester has been introduced recently by LARS [25]. The Ligament Advanced Reinforcement System

(LARS) has two different parts : (1) The intra-osseous part is made of longitudinal fibers that are united by a transverse knitted structure which, unlike a woven structure, prevents elongation over time. (2) The intra-articular part is built only of longitudinal and parallel fibers which are pre-twisted. This architecture is based on a biomimetical approach and showed a higher performance compared to the Ligastic first generation [12, 23].

In Germany, Trevira hochfest, a woven prosthetic ligament made out of polyethylene terephthalate (PET), has been used since 1986. Clinical results revealed an incidence of prosthesis tearing or loosening of 5.15 per cent after an implantation time of up to four years [22]. In case of salvage procedures, about 18% ruptures after 4 years follow up have been stated. No synovial reaction could be observed [27]

The surgical techniques using LARS^R and Trevira^R ligament are both trying to save the mechanoreceptors present in the ruptured ACL and to minimize any further sensory damage. The Trevira^R ligament has bony tunnels of small diameter, which avoids excessive tissue harvest and the LARS^R is inserted by preserving the stumps of the broken ligament. Surgeons [Laboureau, personal communication] believe that this technique preserves the mechanoreceptors which are present in the stumps. These could therefore pass on information to the central nervous system on the position of the joint surfaces. In fact, damages to the innervation of the ACL leads to inadequate motor control of the joint and can give rise to disturbances in the synchronization of movements. This loss of control may result in uneven joint loading, leading to repetitive microtrauma and could be involved in premature fatigue of artificial ligaments.

In the case of the Leeds-Keio ligament, the harvest of the remnant of the original ligament may explain the absence of mechanoreceptors in the ligament stated by Denti et al. [11].

If we look at the ligament augmentation device (LAD), which is an augmentation of an autologous structure for the repair of the ACL, Ruffini, Pacini and free nerve endings were found. In this case, the synthetic augmentation device is completely surrounded with autologous structures.

Regarding the remarks made above, following clinical consequence has been stated by Metak et al [31]: "*...the evidence of nervous structures in cruciate ligament stumps up to 7 years after the injury renders the resection of these stumps obsolete. Regardless of the time of operative care, cruciate ligament stumps should be integrated in the reconstruction*". It is however not evident whether the preservation of the stumps has an influence on the life time of artificial ligaments. Further research on retrieved ligaments is therefore needed in order to confirm this hypothesis.

3. UNFORESEEN FAILURE OF PROSTHETIC LIGAMENTS

The poor clinical results observed with the ligaments developed in the USA under FDA control are surprising since *in vitro* evaluation of the implants has been performed following the FDA guidelines. Why do therefore artificial ligaments fail ?

Considering that most of the devices involved have been subjected to rigorous premarket testing in compliance with the current guidelines, a number of questions are raised. Were the evaluations properly conducted? Was the simulation of product usage conditions inadequate? Or is there something fundamentally inadequate in the current approach?

To begin to develop answers to these questions, one must compare current practices in biomechanical and biocompatibility testings with the state of the art in analytical science. In doing so, the assumptions inherent in the current recommended tests need to be identified and their limitations questioned.

Since these synthetic ligaments have been approved by the FDA, they are supposed to have fulfilled the FDA biomechanical requirements. It is still our opinion that the concepts used in the old designs and the procedures used for their evaluation are inadequate for the cruciate ligaments [41, 44]. In 1984, we have been the first Laboratory to suspect that the FDA guidelines were not appropriate (we will see later in details why the guidelines of the FDA are not appropriate) [18]. Among the weaknesses raised the loading mode (combined loading versus single load; displacement-controlled versus force-controlled), the tunnel angulation, and the lengthening were identified as very critical for the prostheses life-span [16].

However, FDA was led by a school of thoughts that rejected our innovative approach without discussion. In 1988, we had difficulties to publish our work showing the twisting of the collagen fibers in the natural ACL and PCL [42].

Prejudice against artificial ligaments is also caused by problems frequently associated with the development of any new product or method. The results of previous generation ligaments were poor because of a lack of technical expertise. In essence, synthetic ligament reconstruction offers the surgeon a logical solution by creating no new damage to the knee [12].

To elucidate the reasons of the failure we have to understand also the success. Konrad Lorenz, the renowned philosopher, physician and ethnologist, advocates that much more can be learned from trial and success than from trial and error [28]. By studying only random clinical (retrieved "failed") implants, Jonathan Black, father of modern biomaterials, advised that we are making the same mistake as certain penologists, who, wishing to know about crime, study only failed criminals, those convicted and incarcerated [4]. It is therefore interesting to look at European devices, which showed better clinical results.

4. MECHANICAL TESTING OF PROSTHETIC LIGAMENT : THE STATE OF THE ART [19]

4.1. Current practices: requirements according to the FDA guidelines

Standard test methods are needed to predict the clinical performance of new biomedical devices, however, there are many problems associated with the current standards. This is made evident by the recent clinical failures of ligament prostheses. The test standards for the ligament prostheses are based on specific forces; clinical failures can be due to many factors, including the surface finish and the surgical technique. A device assessment should provide a lifetime prediction for the device, similar to the manner in which airplanes have been designed for decades; materials, component and system testing is required to determine device performance.

Given the extensive recommendations offered by the FDA guidelines, and the impressive body of scientific experience on which they are based, there is a strong temptation to follow the guidelines without actively considering their possible limitations or how the individual device being tested may

require additional, more extensive testing. But recent and well-publicized failures of medical devices (ligament prostheses) suggest that these recommendations must be subjected to constant questioning, and that, depending on the device and its application, testing protocols may need to go beyond the current guidelines to ensure the safety of the device.

It is clear that most of the *in vitro* testings do not reproduce the *in vivo* loading of the ligament prostheses. Moreover, the biological variability among the individuals and the large number of different surgical techniques result in varying *in vivo* loading of the prostheses. This knowledge led us to develop tools for the *in vitro* testing of artificial ligaments in more physiological conditions (torsion, tension, bending testing machine, TTF, [15]) and to adapt these tests to each procedure (see chapter II.3)

4.1.1. Displacement controlled versus load controlled procedure.

A ligament prosthesis is loaded by a 3D displacement and rotation of its bony attachments. Usually, a load controlled procedure is chosen, loading the ligament between predetermined values F_{min} and F_{max} . The load-elongation curves, irreversible changes in shape and the lifetimes of different prostheses can be compared and conclusions for the service lives under physiological conditions are drawn. However, the minimum load state of the prosthesis is not given by a lower load as in the standard test but by the position in the knee when it is unloaded. Recently, a new version of our fatigue machine allowing load and position controlled cyclic testing is under development. The elongation of the prosthesis is load controlled in the upper loading period and the machine can be switched to position control when, during the unloading phase, a certain level has been reached. Thus, at zero load the actuator moves to the same position in all cycles. The consequence is that the residual elongation of the ligament which could be detected in the purely load controlled test, causes

buckling in this arrangement. This buckling occurs in a strongly concentrated area and the prosthesis can be damaged there. As a consequence, the cycling test itself or a tear test after cycling, reveals a distinct weakening of the prosthesis in this region. To avoid the influence of the residual elongation on the fatigue strength by buckling and on the destabilization of the joint, it is therefore suggested to include this test into routine methods. This tests would in fact provide a better idea of the fatigue life *in vivo* of the prosthesis.

4.1.2. Fatigue concept : combined load versus single load

The fatigue strength of ligament prostheses should be tested under physiological load conditions, i.e. test under normal gait conditions. To this day, no knee joint simulator exists. The most difficult problem of the *in vitro* fatigue test of ligament prosthesis is the lack of knowledge regarding the biomechanics, i.e. the *in vivo* load conditions. Fatigue-abrasion which occurs *in vivo* certainly has the most deleterious effect on implant survival. Nevertheless, its pattern is difficult to reproduce *in vitro*.

In order to ensure the biomechanical reliability of ligament prostheses during several years service time, laboratory tests are required which allow for the prediction of the mechanical long time behavior. Methods have been suggested in the FDA-guidelines for tensile and bending fatigue testings [19]. Nothing is mentioned regarding torsion tests, or fatigue under realistic conditions, i.e. combined loading.

Most of the ligament prostheses approved by the FDA have been tested following their guidelines. A comparison of this approach to the state of the art suggests a significant shortcoming : these tests

only provide data for non physiological conditions. That is, current practices do not determine the fatigue resistance under service loading conditions such as the combined tension-torsion-bending loadings to which the ACL is subjected. Consequently, ligaments that have been tested to 40 million cycles in the laboratory, rupture at 6 months in the human knee [17].

Using a Tension - Torsion - Flexion fatigue testing machine (TTF) developed in our Laboratory, we have shown that the fatigue lifetime of ACL prostheses decreased dramatically compared to standard tensile fatigue testings used by most investigators [15].

To our best knowledge, among the different manufacturers, only LARS performed similar fatigue tests which are beyond the protocols and provided fatigue lifetime data by using combined tension - flexion -torsion tests [25]. By cycling at 2 Hz frequency under 110 N tension, 30 deg. flexion, 10 deg. torsion, the LARS prosthesis resisted to 22 millions of cycles without complete rupture and with 50% of their initial resistance [Laboureau, personal communication]. The permanent lengthening was found to be 5.1% corresponding to a laxity of about 1.5 mm. This is a first attempt to test a prosthesis under such conditions. However these data are hypothetical, and tools are needed to measure the range of parameters *in vivo* (torsion, flexion and tension). Further efforts must therefore be made to insure that the loads and displacements are near to those which will occur *in vivo* (adapt the test to the surgical procedure and the patient's anatomy).

4.2. Boundary conditions

It should be recognized that data on forces in the ACL during specific activities are needed to aid in the design of prostheses and to establish proper reconstructive techniques. The direct measurement

of ligament forces at the knee *in vivo* is impracticable. As a result, most investigators have used the data estimated by Chen and Black [9]. In daily life, the ACL is supposed to be subjected to loads which vary from 70 N in climbing stairs, 210 N in walking, 485 N in descending an incline, and 630 N in jogging. These characteristics appear to leave a significant margin of safety for ACL protection with routine activities. The validity of these data is now questioned by the high rate of failure of ACL prostheses. In addition, loads for athletic activities not yet well known are significantly greater.

4.2.1. Service loading conditions

The mechanical function of the ligament is to limit movement between femur and tibia. From this arises the concept that ligaments are loaded by bone displacement which demonstrate a three dimensional movement. The corresponding force levels imposed by 3D kinematics on ACL prostheses depend on their mechanical properties; i.e. their stiffness. However, most authors have used the tensile forces estimated for natural ligaments by Chen [9] while artificial ligaments are much stiffer [10]. As a result, for the same range of movement, the prostheses undergo much higher stresses in service. In addition, the surgical technique determines the angle of torsion and bending and the strains and stresses to which the synthetic ligament is submitted. These stresses are different from those existing in natural ligaments on which mechanical evaluations are often based.

4.2.2. Influence of the direction of the drill-holes

The relative motion of the ligament insertions (loaded by displacement) give the boundary conditions for the deformations of the ligament when no other interaction of the ligament with other

ligaments or with bones occur. Most authors considered only a single mode of deformation, i.e. the longitudinal deformation. The torsional deformation of the cruciate ligaments, which has been previously addressed in a qualitative sense by Palmer [33] and in a quantitative sense by our laboratory [14, 18], was often overlooked. The reported global torsions from Gely et al [18] for six different femoral and seven different tibial anchoring channels for the prosthetic ACL ranged from 36 to 86 degrees. The surgical technique is then important in order to obtain some initial torsion in the artificial ligament, when the knee is in extension, so that all fibers are arranged properly for the functional joint positions when the maximum strength of the artificial ligament is required.

During every knee flexion, the prosthesis is bent at the drill-hole entrances. At the same time, the prosthesis is subjected to torsional stress. The changes of the bending angles at the drill-hole entrances of tibia and femur and the torsion angle of the intra-articular part of the prosthesis depend on the direction of the drill-canals.

We have investigated the influence of different localizations of these drill-hole outlets on the torsion of ligament prosthesis and on the bending angle of the prosthesis in relation to the axis of the drill-hole [14, 18]. The torsion angle depends on the combination of lateral femoral and anteromedial tibial drill-hole entrance. At the femur, bending of the prosthesis in the anterior direction predominates; at the tibia, the ligament is mostly bent posteriorly. The bending angle of the prostheses is generally bigger at the femur than at the tibia. Stress concentrations occur at the outlets of the drill-canals at the tibial plateau and at the femoral condyle. With every flexion of the knee the prosthesis is bent around the edge of the drill-hole under a simultaneous torque. This combined bending-torque stress is superposed by a tensile force; which depends on the flexion angle. The resulting stress depends on the properties of the prostheses itself, the implantation technique and its integration inside the joint.

Claes et al. [10] showed that the bending radius has a very important influence on the fatigue of ligament prostheses. To achieve long-term endurance of the prostheses this requires a large bending radius at the drill-tunnel entrance. However, the realization of this requirement is limited by the anatomical circumstances inside the joint. Fatigue tests using larger bending radii do not correspond to the clinical conditions and reveal too high fatigue results.

4.2.3. Effect of the method of implantation

The method of implantation has also an important effect on the loading conditions, to which the prosthetic ligament will be submitted. Some important aspects are highlighted here.

As mentioned above, the preservation of the innervation in the joint (by minimizing the bony tunnels and avoiding the harvest of autologous structures) will have an influence on the loads on the prosthesis.

The tightness of the reconstruction (pretension) depends usually on the surgeon's "judgment". The optimum amount of pretensioning load is still subject for debate. It may vary between 20 to 70 N according to the literature. Witzel showed that a pretensioning of 70 N resulted in tolerable loosening of the prosthesis for the larger knee flexions (chapter II.5).

It is important to note that small changes in the tightness of an implant cause significant differences in stability and range of movement [2]. The optimum tightness will allow the knee to be extended

fully, but with a "springy" feeling caused by a high implant tension, since weight-bearing will compress the joint and relax the implant a little. The implant, whether "isometric" or not, should not be under tension continuously since this will predispose it to creep.

Isometry, when applied to an ACL reconstruction, is defined as following : the distance between the femoral and tibial attachments of the reconstruction remains constant as the knee is moved in flexion/extension [2]. This definition makes no reference to the position of the reconstruction. The definition of isometry means that the femoral attachment is constrained to travel approximately in an arc centered at the tibial attachment, when viewed in the sagittal plan. Because of the 3D nature of the ACL, the femoral attachment should be described as moving in a spherical locus centered at the tibial attachment, relative to the tibia. Isometry should be measured by using a suture passed along the ligament fibers, linked to a displacement transducer or "isometer". It is interesting to note that isometry is dependent on the range of movement of the knee. Hefzy et al [20] showed how an increase in the range of movement over which isometry is desired reduces the attachment area available with a given length change tolerance. Cazenave and Laboureau [8] took radiographs of pins in five cadaveric ACL-damaged knee joints at 0° and 90° knee flexion. They concluded that the center of the circular arc of the posterior part of the lateral femoral condyle, connected with the anatomical center of the tibial attachment, was nearly isometric, finding a length change less than 2 mm between those two positions. This does not mean that there was no length change at the other positions of knee flexion.

Isometry is normally aspired to because this type of reconstruction avoids excessive length changes of the prosthesis (permanent stretching) during knee function.

Cruciate ligament tissue fails if it is extended of approximately 20%. A review of the literature shows that the ACL has a mean reported length of 32 mm, therefore an elongation of 7 mm (22%) could be expected to cause rupture. A more significant limit, however, is the viscoelastic nature of the tissue: this means that cyclic elongation of only 6% has been reported to cause permanent stretching of grafts, and that represents an elongation of only 2 mm.

Since the extension to failure of the natural ligament corresponds to a force of 1725 N to 2200 N, it seems likely that the normal motion forces will be approximately up to 600 N. At a load of 500 N some artificial implants (the Gore-Tex band and the Trevira) stretched of 2% to 3%. In that case, with the implant much stiffer than the natural ligament, the length change will be only about 1 mm.

A rigid ACL replacement would impose knee motion that would not be physiological. Thus, rather than pursuing isometry by checking on reconstructions, a more logical approach would be to know how to recreate the behavior of the ACL-intact knee. It seems logical to suggest that what is needed is an approach that allows the surgeon to identify the isometric spot that would have been found when the knee was intact, and then to base the reconstruction on that location. Even with this approach, normality could only be restored if the graft were a reasonable facsimile of the mechanical properties of the natural ACL [1]. Witzel et al. showed in fact that a nearly isometric behavior is obtained when the tunnel is placed dorsomedially of the native insertion point (Chapter II.5).

The presence of a ligament torque during axial loading has implications in the design and selection of a ligament substitute. Based on this natural design, LARS^R and Trevira hochfest^R developed a design to minimize the torsion stresses. In the case of the LARS ligament, the design and architecture of the fibers were arranged in parallel to avoid the interfibers abrasion that occurs with woven or braided structures. In both cases, the intra-articular fibrous part of the prosthesis is implanted under a pre-rotation to the left or to the right similar to natural ligaments. This structure avoids shearing forces between the fibers during the combined tension, torsion and flexion and minimizes the torsion angle.

These polyethylene-terephthalate devices allow tissue ingrowth in the intraarticular part. This ingrowth of connective tissue into the structure of the prosthesis is a great biomechanical advantage [10]. Soft tissue between the ligament fibers acts as a viscoelastic element and protects the ligament fibers against friction relative to the drill-canal as well as against friction among the fibers itself. The friction of fibers among themselves contributes to wear of ligament prostheses.

The natural ligaments originate from relatively large areas of bone, therefore it is impossible for most of the fibers to be isometric; for example, those anterior to the axis must stretch during flexion [1]. Multi-bundled implant structures will provide a closer approach to normal knee behavior, with their structure acting in a manner analogous to the fiber bundles.

A prosthesis being implanted isometrically, does not change its length during flexion and performs no relative movements in relation to drill-canal and deflection points. Isometric implantation would be useful for endurance and stress of a prosthesis since a constant tensile loads would be generated during pure flexion movement and wear at the insertion spots could be minimized. A look at natural ligaments shows that this aim of isometric implantation can never be achieved. Even natural

ligaments are subjected to strain of up to 4% during pure flexion, corresponding to a change in length of up to 1.2 mm for an average length of 30 mm for the ACL [10].

4.3.3. Loads in prostheses: a redundant biomechanical problem

We have seen that a redundant problem related to synthetic ligaments is to know precisely the loads, which are applied in service conditions on the prostheses. These forces depend on the surgical procedure, the material and the design of the prosthesis.

We have recently developed tools to predict prosthetic ligament deformations occurring *in vivo* (chapter II.3). This program is based on our previous work to analyze prosthetic ligament deformation for optimal insertion orientation. A software permitting to measure and visualize personalized knee kinematics *in vivo* was developed. The system consists of a mechanical system, equipped with magnetic position tracking sensors, which clamps onto the knee non-invasively to obtain accurate *in vivo* knee kinematics. Personalized knee geometry is obtained using 3D medical imagery, and incorporated into an interactive 3D graphics environment. This system was found to be sufficiently accurate to calculate prosthetic ligament deformations *in vivo* [36]. These deformations which are more realistic can then be introduced in the TTF fatigue testing system .

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Figure captions

Figure 1: NFP- immunoreactive Ruffini nerve ending in human anterior cruciate ligament (arrowhead) x390

Figure 2: Pacinian's corpuscle immunoreactivity to S-100 protein in human ACL showing the inner core and the lamellar system (arrows, x 125)

Figure 3: S-100 immunoreactive peri-insertion nerves and Pacinian-like corpuscle in human anterior cruciate ligament (arrows, x125)



Fig 1.

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Fig. 2

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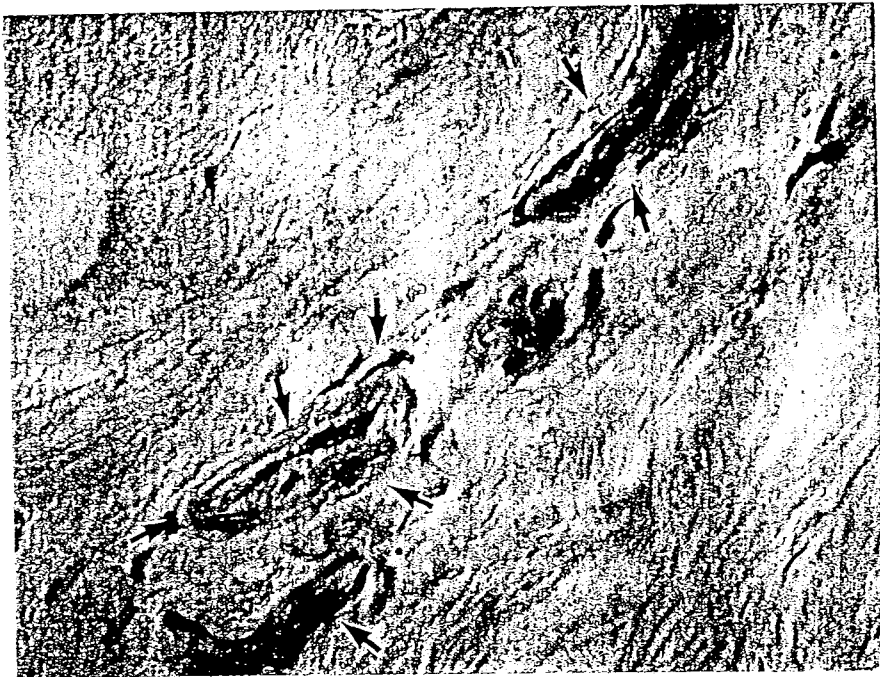


fig 3

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