

Anterior cruciate ligament reconstruction with synthetic grafts. A review of literature

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Received: 21 November 2009 / Revised: 2 January 2010 / Accepted: 13 January 2010 / Published online: 16 February 2010
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Abstract Anterior cruciate ligament (ACL) rupture, one of the most common knee injuries in sports, results in anteroposterior laxity, which often leads to an unstable knee. Traditional ACL reconstruction is performed with autograft; disadvantages of this technique are donor site morbidity and a long rehabilitation period. In the 1980s, artificial ligaments became an attractive alternative to biological grafts. The initial enthusiasm surrounding their introduction stemmed from their lack of donor morbidity, their abundant supply and significant strength, immediate loading and reduced postoperative rehabilitation. Synthetic grafts made of different materials such as carbon fibers, polypropylene, Dacron and polyester have been utilised either as a prosthesis or as an augmentation for a biological ACL graft substitute. Nevertheless, every material presented serious drawbacks: cross-infections, immunological responses, breakage, debris dispersion leading to synovitis, chronic effusions, recurrent instability and knee osteoarthritis. Recently, a resurgence of interest in the use of synthetic prostheses has occurred

and studies regarding new artificial grafts have been reported. Although many experimental studies have been made and much effort has been put forth, currently no ideal prosthesis mimicking natural human tissue has been found.

Introduction

Anterior cruciate ligament (ACL) reconstruction is commonly performed to restore knee stability after ACL rupture. Several methods have been proposed for the treatment of ACL deficient knee, but controversy exists about the best procedure. For intra-articular reconstruction the patellar tendon [1–3], the iliotibial tract [4] and the hamstring tendons [5] are commonly used. However, autologous grafts have some well-recognised drawbacks related to donor site morbidity and delayed return to sports [6, 7]. Allograft tendons are reported to have excellent clinical results, but these grafts bring the risk of infection and disease transmission and sterilisation could cause a weakening of the tissue in comparison to the native ACL. For these reasons their use has been confined to ACL revision surgery [8, 9]. In order to overcome such inconveniences, the use of synthetic ligaments for ACL reconstruction became popular in the 1980s and early 1990s. The initial enthusiasm about the introduction of artificial ligaments stemmed from their lack of harvest site pathology, their abundant supply and significant strength, the technically easier surgical technique and the accelerated rehabilitation period. Different procedures and various materials have been employed throughout the years and contributed to the diffusion of artificial ligaments as a therapeutic option in knee surgery.

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Artificial materials

The beginning: carbon fibres

The advent of artificial ligaments dates back to the beginning of the 20th century, when silver and stainless wires, nylon and silk strings and various synthetic fibres were used to create artificial grafts [10]. However, the unsatisfactory results and the high rate of early ruptures confined these initial attempts to the stage of animal experiments, and these materials were never adopted in clinical trials.

In the 1970s the interest for synthetic grafts led to their introduction as substitutes for biological human tissue. The increased appeal of these supports resulted in the commercialization of products such as Proplast ligaments (Vitex-Inc, Houston, TX, USA) made of Teflon and carbon and Polyflex (Richard, Memphis, TN, USA) made of polypropylene. Results were scarce for both methods which had to be withdrawn from the market due to their high rupture rate and inflammatory reaction in the surrounding tissues. Experimental studies conducted on these materials showed their unsuitable mechanical properties.

In 1977, Jenkins et al. [11] developed an artificial ligament made of carbon fibre (Intergraft, Osteonics Biomaterials, Livermore, CA, USA). After being initially employed for tendon sutures, its use was then extended to ligament reconstruction in the knee and other joints.

In 1981, Dandy et al. first implanted a carbon-fibre reinforced substitute for ACL with an arthroscopic procedure [12].

However, after preliminary encouraging results, serious sequelae were observed during clinical application. It has been demonstrated that the poor resistance to torsion forces caused an early rupture of the fibres leading to carbon deposits in the liver and inflammatory synovitis in the knee joint [13].

Neither the subsequent attempt to combine this material with autologous tissue nor the association with bio-adsorbable polymers on the ligament surface could prevent the significant side effects associated with these grafts. For this reason these materials were completely abandoned.

Gore-Tex

As carbon fibres were overtaken and surgeons increasingly performed ACL reconstruction arthroscopically, new materials came in.

In 1986, ligaments made by expanded polytetrafluoroethylene (PTFE) (Gore-Tex, W.L.Gore, Flagstaff, AR, USA), a material already adopted in vascular surgery, were approved in the United States by the Food and Drug Administration (FDA) for the use in patients with previously failed autologous ACL reconstructions.

The Gore-Tex ligament is made by a single strand of PTFE wounded into multiple loops. It was designed as a true prosthesis and implanted to permanently replace the natural ACL [14]. It was supposed to promote immediate fixation and early load-bearing capacity. These grafts have an ultimate tensile strength of 5300 N, higher than any other commercial artificial ligament [15]. It should be noted that a natural ACL has a tensile strength of 630 N in adults [16] and 1730 N in the young population [17] (Table 1). In addition, its stiffness of 322 N/mm and its ultimate strain of 9% confer to the graft an excellent postoperative stability immediately and an early load-bearing capacity; thus explaining their initial spread as first reports in 1983 documented their encouraging short-term results.

Ahlfeld et al. [18] followed 30 patients with a Gore-Tex ACL graft, and two years after the implant documented only one prosthetic breakage. Glousman et al. [19] reported a prospective study on the implant of 82 PTFE ligaments with an 18 month follow-up (range 12–30), noticing an immediate improvement of objective and subjective parameters. Complications included four ruptures, seven major complications (8%) and 14 revision operations (17%). Similar results were reported by Woods et al. [20] in a two-year follow-up on 33 patients. After preliminary good results, they observed a worsening in knee stability. Ahlfeld et al. [21] followed up 30 patients with a Gore-Tex ACL graft and two years after the implant observed only one prosthetic breakage. Similarly, Friedman [22] reported the results of 103 Gore-Tex ACL ligaments with a follow-up of 16 months documenting only three ruptures. Using the same graft material, Ferkel et al. [23] performed 21 second look arthroscopies 11 months after surgery and found the ligament partially damaged in six knees and completely ruptured in four cases.

Soon, mechanical properties of these grafts were recognised as unsuitable, as failures were related to mechanical fatigue due to the lack of tissue ingrowth and to the presence of wear debris.

With a two-year follow-up after the implantation of 41 Gore-Tex ligaments, Indelicato et al. [24] stressed the possibility that these devices were susceptible to breakage and correlated the findings of synovial reaction found in nine patients to the presence of PTFE particles. Paulos et al. [25] noted an improvement of subjective and objective criteria in less than 50% of the 188 patients followed-up for four years, reporting a total complication rate of 76% in patients that had already previously undergone ACL reconstruction. Sledge et al. [26] reported a rupture rate of 29% in their five-year follow-up and discouraged future implantation of these devices. Two cases of tunnel osteolysis were described by Seemann and Steadman [27] with the finding of a progressive tunnel enlargement leading to late failure. Wilson et al. [28] described an inguinal lymphadenopathy in two patients after Gore-Tex

Table 1 Mechanical properties of synthetic grafts compared to natural ligaments

Properties	Natural ligament	Carbon fibre	Gore-Tex	Dacron	Kennedy-LAD	Trevira	Leeds-Keio
Ultimate tensile strength (N)	1730	660	5300	3631	1500	1866	2000
Stiffness (N/mm)	182	230×10 ⁹	322	420	280	68.3	270

ligament implantation in the knee joint. Microbiological and histological examinations demonstrated the presence of PTFE particles in the lymph node, proving the occurrence of complications in sites distant from the knee.

The Gore-Tex graft was withdrawn from the market in 1993 as well as the Gore-Tex CD, the second-generation ligament. Since then the use of this material has been completely abandoned in knee instability surgery.

Dacron

A different approach in the development was adopted for the Dacron ligament (Meadox Medicals, Oakland, NJ, USA; Stryker Corp., Kalamazoo, MI, USA), initially employed in acromio-clavicular joint injuries and in tendon reconstructions. This ligament, approved in 1989 in the United States by the FDA, is made of polyester and is designed to replace the ACL permanently. The graft is composed of an 8-mm diameter sleeve of loosely woven velour with a central core made of four tightly woven tapes. It has a mean ultimate tensile strength of 3,631 N and a mean ultimate elongation of 18.7% [15, 29] (Table 1).

Initial reports have shown encouraging results in the short term. A study by Lukianov et al. [29] reported the results at a mean follow-up of 28 months in 41 patients who underwent ACL reconstruction with a Stryker Dacron ligament prosthesis. In 75% of the patients Lachman, anterior drawer, and pivot shift tests were found negative.

However, in 1991, Arnauw et al. [30] studied 57 patients with an ACL Dacron prosthesis and observed a rupture rate of 40% 18 months after surgery.

Wilk and Richmond [31] described the five-year results after the implantation of 84 Dacron ligaments in which the failure rate was 35.7%. This represented a dramatic increase compared to the 20% failure rate reported at the two-year follow-up. With the same artificial ligaments, Gillquist and Odensten [32] reported a five-year follow-up of 69 patients. They noticed only two cases of mild synovitis, but a high percentage of revisions (34%) and a high level of anteroposterior (AP) laxity. In 1997, presenting their long-term results, they described an increased rupture rate with 29% of the patients who underwent revision surgery. Eighty-three percent of the patients had documented radiographic degenerative osteoarthritis and only 14% had an acceptable stability and functional outcome. Noble [33] presented the results of 110 patients after having implanted a Dacron ACL graft with

a follow-up of two to five years. He noticed a complication rate of 30%, with 12 ruptures and 19 cases of significant synovitis. Barrett et al. [34] reviewed 40 patients after implantation of Dacron prostheses, reporting a rupture rate of 60%, and found the suitability of the material unfavourable. In their paper, Maletius and Gillquist [35] evaluated the osteoarthritis grading in 52 patients nine years after the implantation of Dacron ligaments and detected a narrowing of the joint space greater than 50% (grade II according to Ahlbäck classification) in 40% of the patients.

This product was withdrawn from the market by Striker in 1994.

Kennedy LAD and the “augmentation” concept

The introduction of the Kennedy Ligament Augmentation Device (LAD; 3M, St. Paul, MN, USA) in 1975 by Dr. John Kennedy, made an important change in the history of artificial grafts.

It consisted of an 8-mm diameter ribbon of polypropylene woven with an ultimate tensile strength of 1,730 and a stiffness of 56 N/mm [15]. It was implanted in knee ligament surgery in addition to an autologous ACL reconstruction or after ACL primary repair and was designed to provide protection to the healing ACL or autologous graft. In fact its mechanical profile, much inferior to other artificial ligaments, was conceived to transfer loads during initial healing process and to protect the autologous implant during its early phase of vascularisation and collagen maturation.

In this surgical procedure (the so-called “augmentation”), the role of the autologous component can be played by several tissues, such as bone-patellar-tendon-bone graft (BPTB), hamstrings, and ilio-tibial tract.

By creating a composite structure, the artificial component plays the role of a load-carrier while it progressively transfers load to the healing neo-ligament, protecting the biological transplant from potentially damaging precocious loads.

Roth et al. [36] presented the results of a Marshall-MacIntosh technique reinforced with LAD and documented significant improvements in terms of stability and functional outcome. Del Pizzo [37], in his three-year follow-up paper on patients who underwent ACL reconstruction with LAD, documented negativity to Pivot-shift test in 95% of the patients and AP laxity less than 3 mm in 72%. The rupture rate was 1.4%.

All studies stress the importance of the biocompatibility of the material, but its use as an ACL substitute has not been recommended.

Polyester

Apart from polypropylene, the only materials implanted in recent years were polyester composites, like Proflex (Protek Ltd, Bern, Switzerland) and Trevira-hochfest (Telos, SARL, Marburg, Germany), the latter being the most long-lived in terms of use by orthopaedic surgeons.

Proflex was conceived by Mansat [38] in France in 1985 and implanted for chronic knee instability with an “over the top” technique. According to this procedure already reported by Kennedy, a free transplant of the central third of the patellar tendon is introduced into the femoral tunnel, while the artificial ligament is fixed proximally to the external femoral cortex by a staple. Both components are then introduced and fixed in the tibial tunnel. The implantation through the “over the top” technique demonstrated a reduction of tunnel abrasion and consequently less wear particles in the joint cavity. Nevertheless, follow-ups demonstrated several complications including arthrosynovites, early breakage, and tunnel osteolysis.

The Trevira ligament has been implanted since 1980. It has good mechanical properties (ultimate tensile strength of 1,866 N, stiffness 68,3 N/mm [39]) and a reduced water adsorption capacity (<0.04 vol %) (Table 1). Its first use was in the cervical spine for stabilisation procedures. Subsequently adapted as a ligament for the knee joint, it has been used as a prosthesis or as an augmentation together with an autologous transplant.

Both animal and clinical trials showed a reduced breakage rate and minor inflammatory responses compared to other materials.

In 1988 in Milan, a small ligament (30-mm long and 10-mm thick) made of polyethylene terephthalate was developed; it was called Pro-Pivot and implanted as an augment to a BPBT graft with an “over the top” technique [40]. The study conducted in 1991 by Lanzetta et al. on 130 sportsmen who underwent ACL Pro-Pivot replacement showed good results in terms of joint stability. Second-look arthroscopies at six, 12 and 24 months after surgery demonstrated a process of integration of the artificial ligament that appeared complete two years after its implantation [40].

Showing the results eight years after the implantation of 160 artificial Trevira-hochfest devices using an over the top technique, Krudwig [41] demonstrated good results in terms of patient satisfaction and AP stability (only 16% of the patients showed an anterior sub-luxation >5 mm). Radiographic signs of osteoarthritis were found only in patients with previous history of meniscal surgery. The author suggested that synthetic prostheses do not invariably induce knee arthritis.

In the 1980s the marketing system led to a wide diffusion of polyester grafts and many synthetic ligaments were produced in Europe, including Ligastic (Orthomed, Marsannay La Côte, France) and SEM (Science et Médecine, Montrouge, France). The early failures of these prostheses, together with many other prototypes, were microscopically analysed in a retrospective study by Guidoin et al. [42]. The authors report that failure was related to inadequate resistance to abrasion and torsion forces, together with structural changes of the grafts due to unpredictable tissue infiltration.

After analysing 33 ruptured ABC grafts (Surgicraft Ltd, Redditch, UK) with scanning electron microscopy, Mowbray et al. correlated the high incidence of early prosthetic ligament failures to the abrasion of the ligament at the tibial tunnel exit. The authors found that artificial implants are particularly vulnerable to rupture if an impingement occurs [43].

Similarly, Amis and Kempson reported the failure mechanisms of Apex ligaments (DePuy International, Leeds, UK) and confirmed the hypothesis that bone impingement at the tibial tunnel exit leads to synthetic fibre damage [44].

Leeds-Keio: promoting tissue ingrowth

The Leeds-Keio (LK) ligament (Neoligaments Ltd, Leeds, UK) was developed in 1982 from the collaboration between the University of Leeds (UK) and the Keio University (Japan) [45]. It is made by woven polyester fibers constituting a tubular bundle measuring 10 mm in diameter. It has been used for ACL reconstruction and in other types of reconstructive surgery. Over 50,000 LK grafts have been implanted worldwide.

The LK ligament is a “scaffold” type of prosthesis, as it acts as an inducer for tissue ingrowth; porous coating allows the induction of biological tissue and promotes the formation of a neo-ligament on the intra-articular portion [46]. Without rehabilitation, its tensile strength is approximately 850 N; by the developing of tissue ingrowth, a maximum tensile strength of 2000 N has been demonstrated; its stiffness has been measured as 270 N/mm, which is similar to a natural ligament [45] (Table 1).

Denti et al. [47] reported their results after an average period of 33 months from the implantation of LK ligaments on 26 patients. They noticed an improvement in subjective and objective parameters and two cases of rupture. Fujikawa [45] reviewed 152 patients after a follow-up of more than four years: 90.1% had a negative Lachman test and 82.2% a negative anterior drawer sign; no major complications were noticed. Second-look arthroscopies performed three and six months after surgery reported a good coverage of the implanted ligament; ruptures occurred only in 3.3% of cases. Rading and Peterson [48] reported the results of 24 cases treated with a LK artificial ligament

two years after implantation; only eight patients had a subjectively stable knee and 37.5% were objectively unstable. Engstrom et al. [49] compared LK to autologous patellar tendon graft (TR) in a prospective randomised study including 26 TR and 29 LK after an average follow-up of 28 months; the authors noticed in the LK group an increased anterior laxity and positivity to pivot-shift test. Murray and Macnicol [50] reported long-term follow-up results ten to 16 years after LK ACL reconstruction. Twenty-eight percent were found to have ruptured their ligament and all postoperative knees had increased degenerative changes compared with their opposite joint. The authors found that LK ligaments do not give satisfactory guarantees in ACL reconstruction.

Artificial ligaments as an iatrogenic model of osteoarthritis in the human knee

The 1990s were characterised by a loss of trust by orthopaedic surgeons in artificial ligaments implantation. The findings of complications during the first decade of use of these materials (breakage, wear debris, synovitis, recurrent instability, osteolysis and chronic effusions) forced the abandonment of synthetic grafts [27, 29, 32, 34, 35].

The effect of wear debris has been studied using animal models at Pittsburgh University. Olson et al. reported the *in vivo* and *in vitro* behaviour of seven artificial ligaments on synovial cells; the foreign-body reaction induced by the synthetic particles led to giant cell aggregation and synovial hypertrophy close to the wear debris [51]. All grafts were associated with increased expression of cytokines such as interleukin-1 (IL-1) and various metalloproteinases (MMPs), including gelatinases and collagenases. These MMPs are involved in the unbalanced matrix degradation process that initiates cartilage degeneration in osteoarthritis [52]. Studies demonstrate that the inflammatory reaction caused by wear particles of a foreign body leads to peculiar modification in the composition of the synovial fluid: the protein concentration within the synovial fluid increases in response to synovitis signalling reactions [53]. The depletion of cartilage matrix that follows is responsible for the development of osteoarthritis.

In their paper Olson et al. first suggested the possibility that artificial ligaments could induce osteoarthritis in the knee joint instead of preventing it [51].

In 1992, when analysing the results four years after the implantation of 55 Dacron ligaments, Klein and Jensen [54] noted that this material can act as an inducer in the development of osteoarthritis in the knee joint and that artificial grafts are essentially “an iatrogenic model of degenerative arthritis in the human knee”. The authors recommended the orthopaedic community not use any artificial support in ACL surgery.

Recently, Ventura et al. [55] evaluated prospectively the outcome of ACL reconstruction using polyethylene terephthalate (PET) artificial ligaments in sportsmen, with a follow-up extending to 19 years. They reported a high rate of degenerative osteoarthritis in all patients and suggested that artificial ligaments could contribute to the establishment of the degenerative osteoarthritic process.

Synthetic grafts in the year 2000: LARS artificial ligaments

Despite the discouraging results and loss of confidence by the scientific community in the use of synthetic materials, recently a resurgence of interest in the use of artificial ligaments has occurred since some studies indicate that, under particular conditions, artificial ACL reconstruction can be successful [56, 57].

Lavoie et al. [56] reported their results after the implantation of LARS ligaments (Ligament Advanced Reinforcement System, Surgical Implants and Devices, Arc-sur-Tille, France). These ligaments are made of polyethylene terephthalate and their structure allows tissue ingrowth in the intra-articular part.

The follow-up made on 47 patients, eight to 45 months after implantation, showed good average results according to subjective parameters (average KOOS score 93), and a satisfying Tegner activity level. A subsequent study from the same scientific group compares two-year results after LARS ligament ACL reconstruction with the BPTB graft technique [57]. Their findings were that the LARS ligament gave better subjective and objective outcomes during the initial years, while no difference with the autologous procedure could be found 24 months after surgery.

In a retrospective study, Liu et al. compared LARS artificial ligaments to four-strand hamstring tendon autografts four years after implantation. They observed excellent functional outcomes, with a higher knee stability in the LARS group [58].

Studies advocate that LARS ligament reconstruction could lead to an early return to high activity levels, although long-term results are still required.

Conclusions and future directions

The study and analysis of failures in artificial ligament history has put the basis for future research and studies on finding a synthetic substitute with the best physical and chemical properties [59].

Research in the field of artificial ligaments demonstrates that the ultimate characteristic required for these materials is biocompatibility (chemical stability, degree of polymerization, absence of soluble additives, scarce water adsorption, presence of pores for fibroblasts ingrowth); on the other

hand, mechanical characteristics (traction resistance, stiffness, elongation, torsion and abrasion resistance) should be as similar as possible to those of the natural ligament.

In order to succeed, tissue engineering should provide a functional and biologically valid ACL, able to promote a continuous tissue remodelling.

Despite much effort and many experimental studies, every material has been found to have several drawbacks, and research to find the ideal substitute, mimicking the natural human tissue, is still ongoing.

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