Synthetic grafts for anterior cruciate ligament rupture: 19-year outcome study

Alberto Ventura a,*, Clara Terzaghi b, Claudio Legnani b, Enrico Borgo a, Walter Albisetti b

a I Divisione, Istituto Ortopedico G. Pini, Milano, Italy
b I Scuola di Specializzazione in Ortopedia e Traumatologia, Università degli Studi di Milano, Milano, Italy

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ABSTRACT

Artificial ligaments for ACL replacement have been widely used in the 1980s and early 1990s in orthopaedic surgery. Synthetic devices have been utilized either as a prosthetic material or as an augmentation for a biological ACL graft substitute. The initial enthusiasm surrounding the introduction of synthetic graft materials stemmed from their lack of donor morbidity, their abundant supply and significant strength of these devices. The disadvantages in long-term follow-up were found to be cross-infections, immunological responses, tunnels osteolysis, femoral and tibial fractures, foreign-body synovitis and knee osteoarthritis.

A total of 126 patients were treated with artificial ACL substitution with polyethylene terephthalate (PET) synthetic ligaments in our Institute between 1986 and 1990. Of the original group, 51 sportsmen aged 15 to 40 were followed-up at a mean of 19 years (range 17.5 to 20.6 years) after surgery. Assessment was made with KOOS and IKDC score, Tegner activity scale, clinical examination, KT-1000 arthrometer, and X-ray evaluation. Of the 51 patients followed-up, 27.5% were found to have ruptured their PET ligaments and 100% presented degenerative osteoarthritis at the X-ray evaluation according to Ahlbäck radiological classification of arthritis. The objective evaluation showed functional impairment in 29.4% with an average reduction of 3 points in the Tegner activity scale. The osteoarthritis observed in all patients prompted us to avoid the diffusion of this surgical technique. Although in theory well-conceived, studies have yet to substantiate the function of these augmentation devices or to show clinical better results than those achieved with isolated autograft or allograft ACL substitutes.

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1. Introduction

Anterior cruciate ligament (ACL) is essential for maintaining stability in the knee joint. While in young and active population with an ACL tear surgery is often the best therapeutic option, controversy exists about the best treatment. For intra-articular reconstruction the patellar tendon [1–3], the iliotibial tract [4] and the hamstring tendons [5] are commonly used. Autologous grafts, however, have some well-recognized drawbacks since the harvesting of the graft may lead to problems such as local tenderness, patellar crepitus and pain and weakness of the extensor mechanism [6–8]. In order to overcome such inconveniences, synthetic ligaments for ACL reconstruction have been widely used in the 1980s and early 1990s. The initial enthusiasm about the introduction of synthetic graft materials stemmed from their lack of donor morbidity, their abundant supply and their significant strength [9,10]. In long-term follow-up, however, cross-infections from allogenic material, an immunological response against the artificial ACL, tunnel osteolysis, femoral and tibial fractures near the tunnels, foreign-body synovitis and knee osteoarthritis were reported [11–14]. Therefore, the implant of artificial ligament substitutes for ACL reconstruction has declined. Recently, a resurgence of interest in the use of these synthetic prostheses has occurred since some studies indicate that, under particular conditions, artificial ACL reconstruction can be successful [15,16].

With this prospective study we report long-term results after artificial ligaments implantations in the knee. We analyzed subjective and objective data, diagnostic images, arthroscopic and bioptic examinations to evaluate the efficiency of these materials in the surgery of ACL.

2. Materials and methods

2.1. Recruitment of the patients

Between 1986 and 1990, 126 patients underwent ACL reconstruction using artificial ligaments at the Sport Traumatology Center of our Institute. Only 90 sportsmen aged 15 to 40 years old were included in this study: 64 were male and 26 were female. Mean age at surgery was 27.4 years. Pre-operative standard radiographs showed 84 patients with no radiological signs of arthritis corresponding to grade 0 according to Ahlbäck radiological classification of arthritis (Table 1); six patients were considered grade I; five of them underwent previous meniscectomies.

The stabilization was carried out using three different synthetic grafts: Trevira-hochfest (Telos, SARL, Marburg, Germany), Proflex...
implanted as a prosthesis, by mini-arthrotomy using an ultrahydrophilic polyethylene terephthalate (PET).

The ligaments used in this study were all made of polyethylene terephthalate (PET).

Twenty-seven patients had chronic tears and the ligament was reconstructed using a synthetic graft. Moreover, five medial meniscectomies, one lateral meniscectomy and three meniscal sutures were performed.

Fifty-one patients (56.6% of the original group) were contacted after an average time of 18.75 years (17.5 to 20.6 years) from surgery. There were 42 men and nine women. Mean age at the evaluation was 43.39 years, mean age at surgery was 24.85. All the patients underwent artificial ACL reconstruction using an “over the top” technique: in 11 patients the graft was implanted as a prosthesis; in 40 cases it was augmented together with a BPTB graft.

In addition to the ACL damage, two patients had a complete rupture of the medial collateral ligament (MCL), conservatively treated; one patient showed a rupture of the posterior cruciate ligament (PCL), reconstructed using a synthetic graft. Moreover, five medial meniscectomies, one lateral meniscectomy and three meniscal sutures were performed.

Activity level was graded according to Tegner activity scale (Table 2).

Four patients out of the 51 recalled had undergone medial meniscectomies during first surgery. Afterwards, eight medial and two lateral meniscectomies were performed in nine patients. All together, at the 19-years follow-up the patients who had a (partial or complete) meniscectomy were 13. Patients with concomitant lesion of the ligaments (collateral or posterior cruciate ligaments) were not considered.

Assessment was made by the Knee Osteoarthritis Outcome Score (KOOS) for patient subjective statement [18], an International Knee Documentation Committee (IKDC) scoring system for clinical knee stability [19], and the Tegner activity scale for patient activity level [20]. Objective evaluation was carried out with a standard manual knee examination, including thigh size measurement, range of motion (R.O.M.), patellofemoral crepitus, Lachman test in 20° of flexion and Anterior Drawer test in 90° of flexion. In this study, Lachman test and Anterior Drawer sign were considered as either negative (0 mm

Table 1
Ahlbäck classification criteria.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 0</td>
<td>No radiographic sign of arthritis</td>
</tr>
<tr>
<td>Stage I</td>
<td>Narrowing of the joint space (JSN) (with or without subchondral sclerosis). JSN is defined by a space inferior to 3 mm or inferior to the half of the space in the other compartment</td>
</tr>
<tr>
<td>Stage II</td>
<td>Obliteration of the joint space</td>
</tr>
<tr>
<td>Stage III</td>
<td>Bone defect/loss &lt; 5 mm</td>
</tr>
<tr>
<td>Stage IV</td>
<td>Bone defect/loss between 5 and 10 mm</td>
</tr>
<tr>
<td>Stage V</td>
<td>Bone defect/loss &gt; 10 mm, often with subluxation and arthritis of the other compartment</td>
</tr>
</tbody>
</table>

Table 2
Tegner activity scale.

<table>
<thead>
<tr>
<th>Level</th>
<th>Competitive sports: soccer, football, rugby (national elite)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 9</td>
<td>Competitive sports: soccer, football, rugby (lower divisions), ice hockey, wrestling, gymnastics, basketball</td>
</tr>
<tr>
<td>Level 8</td>
<td>Competitive sports: tennis, running, motorcars speedway, handball</td>
</tr>
<tr>
<td>Level 7</td>
<td>Recreational sports: tennis, football, squash, badminton, track and field athletics (jumping, etc.), down-hill skiing</td>
</tr>
<tr>
<td>Level 6</td>
<td>Recreational sports: tennis and badminton, handball, racquetball, down-hill skiing, jogging at least 5 times per week</td>
</tr>
<tr>
<td>Level 5</td>
<td>Work: heavy labor (construction, etc.)</td>
</tr>
<tr>
<td>Level 4</td>
<td>Work: moderately heavy labor (e.g. truck driving, etc.)</td>
</tr>
<tr>
<td>Level 3</td>
<td>Work: light labor (nursing, etc.)</td>
</tr>
<tr>
<td>Level 2</td>
<td>Work: light labor</td>
</tr>
<tr>
<td>Level 1</td>
<td>Work: sedentary (secretarial, etc.)</td>
</tr>
<tr>
<td>Level 0</td>
<td>Sick leave or disability pension because of knee problems</td>
</tr>
</tbody>
</table>

Fig. 1. KOOS subjective statement: in the histogram are shown the number of patients and their category. In the right graph are inserted the percentage values.
displacement) or positive. An instrumented laxity tester (KT1000 arthrometer, MEDmetric Corporation, San Diego, CA) was used to document antero-posterior (AP) displacement of the tibia at 67 N, 89 N and 134 N load at 20° flexion.

Standard AP and lateral radiographs were taken and degenerative changes were graded according to Ahlbäck radiologic classification of arthritis [21].

2.2. Revision surgery and prosthesis removal

Fourteen out of the 51 followed-up patients were diagnosed to have an artificial ACL rupture; revision surgery was considered the treatment of choice. The procedure included a first surgical step to remove the artificial graft and the staples, followed by autologous ACL reconstruction six months later.

ACL reconstruction was performed either with hamstring tendons or BPTB, in local anaesthesia. In the first case tendons were harvested through a short vertical incision medial to the anterior tibial tuberosity. The tendons were then tightened and tied-up together. Tibial and femoral tunnels were drilled using guide wires of the RIGID-FIX equipment (Mitek, Johnson & Johnson, Norwood MA). The proximal end of the graft was introduced through the femoral tunnel and fixed with two transcondylar pins. The fixation of the distal end was achieved using a BioRCI interference screw (Smith & Nephew, London England). In the case of BPTB reconstruction, the medial third of the patellar tendon was harvested and then fixed along extremities with transcondylar pins and a bioadsorbable interference screw.

2.3. Statistical analysis

Data were analyzed using the program SPSS Version 14.0 (SPSS Inc., Chicago, IL). Paired t-test (two sided test and \( \alpha = 0.05 \)) was utilized to compare the difference in the level of activity and of osteoarthritis before injury and after surgery. Differences with a \( p \) value < 0.05 were considered statistically significant.

| Table 3 | Mean value of AP displacement as assessed with KT1000 (134 N). |
|-----------------|---------------------------|---------------------------|
|                | Before operation (mm)    | 18 years (mm)            |
| Injured limb    | 9.5                       | 8.3                      |
| Uninjured limb  | 5.6                       | 5.7                      |
| Difference inj/unijn | 3.9                      | 2.6                      |

3. Results

The subjective assessment made on 51 patients showed a mean KOOS score of 81.91 (standard deviation (SD) 16.04) (Fig. 1). The IKDC grades were slightly worse, due to the fact that this evaluation method includes both subjective and objective parameters: only one patient scored A; 11 patients reached a B score; 25 patients’ grade was sufficient (C); finally, 14 patients scored D, indicating an important impairment of everyday function, which is a concern in this relatively young population (Fig. 2).

The mean Tegner activity rating significantly worsened (\( p<0.001 \)) from a pre-operative average of 7 (range 3 to 9) to 4 (range 1 to 9).

The physical examination was performed on 51 patients. Thigh size measurement comparison between injured and uninjured limbs showed a mean difference of 1.09 cm (SD: 0.82). The subjects with full range R.O.M. were 36 (70.6%); three had a slight flexion impairment (between 10° and 20°), two had an important impairment in motion (flexion deficit >20° and 10° extension deficit in two patients). Patellofemoral pain was reported in 11 cases (21.6%). Lachman test resulted positive in 38 (74.5%) patients, as well as the anterior drawer test. Three patients showed positivity to Lachman test in the healthy knee. The AP displacement at the arthrometric evaluation increased to 8.3 mm in the injured knee and 5.7 mm in the uninjured knee (see Table 3).

Standard radiographs were conducted in 51 patients and evaluated in accordance with Ahlbäck radiological classification of arthritis, based on the narrowing of the joint space (see Table 4). In the follow-up, all the patients had pre-operative standard radiographs documenting 84 patients with grade 0 according to Ahlbäck and six with grade I: five of them underwent previous meniscectomies.

Osteoarthritis was detected in all patients: none was considered stage 0; seven were grade I, 12 were grade II, the majority (20) were grade III, seven were grade IV and five patients were found to be grade V (Fig. 3). The differences between the level of osteoarthritis before injury and at the follow-up resulted to be statistically significant (\( p<0.001 \)).

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Pathologic changes documented with radiological examination at the long-term follow-up.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology</td>
<td>No. of patients</td>
</tr>
<tr>
<td>Degenerative osteoarthritis</td>
<td>51</td>
</tr>
<tr>
<td>Chondrocalcinosis</td>
<td>18</td>
</tr>
<tr>
<td>Patellofemoral pain</td>
<td>8</td>
</tr>
<tr>
<td>Porosis</td>
<td>4</td>
</tr>
<tr>
<td>Pellegrini-Stieda syndrome</td>
<td>1</td>
</tr>
<tr>
<td>Prominence of the proximal staple</td>
<td>1</td>
</tr>
</tbody>
</table>
Artificial reconstruction of the ACL with the use of various materials was recommended in the 1980s. Although outcomes were satisfactory in the short-term, little is known about the long-term results in artificial ligament implantation.

In our study, standard radiographs conducted in the long-term follow-up documented increasing of osteoarthritis in all the patients without differences between patients who underwent previous meniscectomies and those who did not. Similar findings were also reported by other authors [22–23].

The rate of osteoarthritis observed in the long-term follow-up was higher than the one previously described after primary repair, with most patients having grade III (bone defect less than 5 mm at the radiograph). These findings did not match the satisfactory subjective outcomes observed with KOOS and IKDC scores.

We are aware that the development of osteoarthritis is a complex process influenced by multiple factors. Several studies have focused attention on the correlation between foreign-body inflammatory reaction to wear particles on the knee joint and the development of degenerative osteoarthritis [24,25]. In 2004 Murray and Macnicol [13] demonstrated degenerative osteoarthritis in 18 patients 16 years after the implantation of Leeds–Keio artificial ligaments. In their paper Maletius and Gillquist [26] evaluated the osteoarthritis grading in 52 patients nine years after the implantation of Dacron ligaments and detected a narrowing of the joint space superior to 50% (grade II according to Ahlbäck classification) in 40% of the patients. Showing the results eight years after the implantation of 160 artificial Trevira-hochfest devices, Krudwig [27] suggested that synthetic prostheses do not invariably induce knee arthritis. With a 2-years follow-up after the implantation of 41 Gore-Tex ligaments, Indelicato et al. [28] stressed the possibility that these devices are subjected to breakage and correlated the findings of synovial reaction to the presence of PTFE debris. Noble [29] presented the results of 110 patients having implanted a Dacron ACL graft with a follow-up of 2–5 years. He noticed a complication rate of 30%, 12 ruptures and 19 cases of significant synovitis. With the same artificial ligaments, Gillquist and Odensten [14] reported a 5-years follow-up on 69 patients. They noticed only two cases of mild synovitis, but a high percentage of reoperations (34%) and a high level of AP instability. By testing inflammatory reaction to injected wear particle in animal joints, Olson et al. [11] stated the possibility that artificial ligaments could induce degenerative arthritis instead of preventing it. Analyzing the results four years after the implants of 55 Dacron ligaments, Klein and Jensen [12] suggest that this ligament can act as inducer in the development of osteoarthritis in the knee joint.

Another factor that could possibly induce the early-onset of osteoarthritis of the knee might be the release of wear particle debris into the knee joint because of the breakage of the artificial ligament.

Some authors observed that the prosthesis broke close to the tibial tunnel exit, where the ligament is more subjected to flexion and torsion forces, and they correlated the breakage to the mechanical stress of the fibers [14,30].

In our experience all patients undergoing reoperation were found to have their ligaments ruptured in the central intra-articular portion. In our opinion such a high rupture rate is due to the unsuitable mechanical properties of the artificial ligaments which are not as capable to adjust to the loading as the natural ligaments. Even though ruptures can be related to operative technique and ligament position [31,32], it is noteworthy that in our study all operations were performed by the same senior surgeon and attention was given in reproducing the correct anatomy of the natural ACL, by placing tunnels in straight alignment with the over-the-top point [17]. Indeed, in case of incorrect positioning the graft is expected to break close to tunnel exits. Our ruptures were found to be in a site where flexural–torsional fatigue is generally considered low. In addition, in all cases no tunnel enlargement could be observed, thus excluding any “windscreen wiper” effect due to malplacement.

We also studied local and systemic biocompatibility of the artificial grafts. It is generally known that the knee joint reacts to the implantation of a foreign material with an inflammatory infiltration caused by wear particles, thus leading to changes in the synovial fluid.

4. Discussion

Radiological signs of osteoarthritis (grade V according to Ahlbäck) in a patient 18 years after the implant of a Trevira-hochfest artificial ligament.
Therefore, a high rupture rate has been related to the loss of strength due to foreign-body reaction with increased permeability of the ligament to synovial liquid [34], loss of wear particles leading to inflammatory reaction that inhibits the ligamentization process [35,36], and incapacity to reproduce an implant mimicking the correct anatomy of the natural ACL [37].

The subjective outcome assessed with the KOOS 18.75 years after surgery documented satisfactory average results, both in patients undergoing re-surgery and in those with remaining synthetic ligaments. The mean IKDC score showed a moderate degree of impairment, due to the objective parameters considered in this scoring system. In addition, it should be recalled that IKDC scoring is more sensitive than the KOOS as the lowest grade is the discriminating factor for the whole outcome. The relatively satisfactory subjective outcome observed can be explained with their lower demands on the knee joints. Indeed, mean Tegner activity level decreased from a pre-operative average value of 7.47 to 4.56 in the long-term follow-up. At 19 years, 22 (43.1%) of the patients evaluated were in the lowest activity levels (0–3), and three of them had low subjective and objective scores, indicating unsatisfactory compensation for their problems.

Synthetic grafts were developed to overcome problems related to autogenous graft implantation. Artificial ligaments gave satisfactory results in the short-term. Glousman et al. [38] reported a prospective study on the implant of 82 Gore-Tex ligaments with 18 months follow-up, noticing an immediate improvement of the subjective and objective parameters. The complications included four ruptures, seven major complications (8%) and 14 reoperations (17%). Similar results were reported by Woods et al. [39] on a 2-year follow-up on 33 patients. After preliminary good results, they observed a worsening of the patients’ knee stability. Ahfeld et al. [40] followed 30 patients with a Gore-Tex ACL graft and two years after the implant documented only one prosthetic breakdown. Similarly Friedman [41] reported the results of 103 Gore-Tex ACL ligaments with a follow-up of 16 months and documented only three ruptures. Using the same graft material, Ferkel et al. [42] performed 21 second look arthroscopies 11 months after surgery and found the ligament partially damaged in six knees and completely ruptured in four cases.

Despite their possible advantages (such as minimal morbidity from the operation allowing an early return to unrestricted sports activity), the use of artificial ACL has almost universally been recognized as unsuitable. In fact, artificial implants implicate a risk of structural failures, adverse host reactions and reactive synovitis as a result of wear particles.

Olson et al. [11] and Klein and Jensen [12] observed that the damage induced by the synthetic particles is essentially “an iatrogenic model for degenerative arthritis in the human knee” and that artificial ligaments, used to prevent osteoarthritis, are mainly responsible in the induction of this process.

5. Conclusions

The purpose of this study was to evaluate prospectively the outcome of ACL reconstruction using PET artificial ligaments in sportsmen, with a follow-up extending to 19 years.

The follow-up documented a high rate of degenerative osteoarthritis in all patients, suggesting the involvement of the synthetic graft prosthesis in the establishment of the degenerative process.

Surprisingly, subjective evaluation in the long-term follow-up showed satisfactory average results, thus indicating that subjective outcome does not correlate with objective parameters such as radiographic evaluation, while it is influenced by the activity level of the subject.

Multiple factors are responsible for the development of knee osteoarthritis and artificial ligaments could contribute to the establishment of the degenerative osteoarthritic process.

6. Conflict of interest

Each author discloses any financial and personal relationships (e.g., employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, grants or other funding) that might pose a conflict of interest in connection with the submitted article.

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