A prospective study was performed to determine the effect of a ligament augmentation device (LAD) on the replacement of the anterior cruciate ligament (ACL) using tendon allografts. Twenty-five patients were followed for 66 to 98 months after tendon allograft replacement with LAD reinforcement for ACL rupture. The evaluation was done using the form of the International Knee Documentation Committee (IKDC), the Lysholm score and the Tegner scale. Two patients sustained a rerupture after major injury. Three other multiply-injured patients scored poorly because of associated injuries and fractures (IKDC grade D). Four patients scored normal (grade A), 12 patients nearly normal (grade B), and 5 patients abnormal (grade C). The Lysholm score showed 14 excellent (average 96), 5 good (average 86) and 4 fair results (average 76). Three patients with excellent results were IKDC grade C, solely because the x-rays showed slight narrowing of the medial joint line, which might indeed indicate future problems. On the Tegner scale, the sports level decreased by an average of 1.4 points (from 7.25 to 5.83). Only five patients showed an anteroposterior displacement of more than 3 mm, of which only one was in the grade C group.

**Keywords** : anterior cruciate ligament ; ligament augmentation device ; joint instability ; tendon allograft ; knee injury ; chronic instability.

**Mots-clés** : ligament croisé antérieur ; renforcement ligamentaire ; instabilité articulaire ; allogreffe tendineuse ; laxité chronique.

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**INTRODUCTION**

Acute ACL rupture is most commonly associated with injury to other ligaments of the knee, the menisci, or both. When combined with collateral ligament ruptures it has been found to further compromise stability (7, 13, 28, 32).

Consequently, a direct correlation has been suggested between the complexity of the injuries associated with ACL rupture and the need for surgical repair or replacement. Likewise, patients without associated ligamentous or meniscal injuries (those having isolated ACL ruptures) are assumed to have a better prognosis. Autogenous and allogeneic grafts that have been used to reconstruct ACL-deficient knees undergo a precipitous drop in strength in the early postoperative period due to tissue necrosis, revascularization, and remodeling (1, 3, 4, 5, 8, 14, 16, 24, 26). In an effort to protect a healing autogenous patellar-ligament reconstruction in the early postoperative period, Kennedy et al. proposed the use of a ligament augmentation device made of polypropylene braid (3 M, St. Paul, Minn.).

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USA) in 1980. They hypothesized that load-shear- ing between the ligament augmentation device and the biological graft would protect the graft during the period of degeneration and weakening, after which so-called collagenization would eventually occur. Van Kampen et al. (30) later supported this hypothesis by postulating that the load would be gradually transferred from the synthetic device to the autogenous graft, over time, as the biological graft remodeled and became inherently stronger. These authors suggested that the outcome of a reconstruction with an augmented graft would depend on the amount of load that was carried by the biological tissue; they believed that the tissue must carry a sufficient amount of load to allow the graft to mature. Kennedy et al. stated (15, 16) that the polypropylene braided device for ligament augmentation had adequate tensile strength, fatigue, and creep properties for it to be used as an adjunct to reconstructions with autogenous patellar ligaments. Sheep, dog and goat models demonstrated that the augmentation of biological grafts with the device resulted in less anteroposterior displacement than when the graft was used alone (8) and that the device did not affect the remodeling process of the biological graft. Encouraged by early reports of success in animal models (8) and in an effort to increase the success rate of the allograft reconstructions in our patients, we initiated a small prospective study of the combined use of the ligament augmentation device and the allograft in knees with a torn ACL. In our department we have been using fresh-frozen tendon allografts since November 1988 (2, 31).

**MATERIALS**

Between July 1990 and August 1994, 25 consecutive operations for chronic ACL rupture were performed by the senior author (RV), using a tendon allograft with an augmentation device. Twenty male and five female patients were evaluated at an average of 74 months after their operation (66 to 98 months). The mean age at the time of follow-up was 37 years (range: 23 to 55 years). All cases were traumatic in origin. Twenty (80%) had injured the knee during sports activities (table I). Prior to the ACL reconstruction, 10 patients had already undergone one or more surgical interventions, mainly meniscal procedures but no ligament reconstructions (table II).

The indications were as follows: In young patients, anterolateral rotatory instability (ALRI) (pivot+) was an indication for a combined intra-articular and extra-articular reconstruction, if they complained of instability during activities of daily living or expressed a strong wish to continue contact or pivot sports. Combined ALRI and anteromedial rotatory instability (AMRI) was treated with an intra-articular and a lateral extra-articular procedure, augmented with suture of the MCL or reefing of the posterior oblique ligament (POL). This is a protocol designed for treatment of ligamentous lesions in our department. Only one patient required medial collateral ligament reefing, one patient had a partial medial meniscectomy and another patient had a suture of the medial meniscus. None of the other patients had any associated ligamentous injuries (table III). All patients were operated on for chronic ligament instability, at least 8 weeks after injury.

**METHODS**

Under sterile conditions, the allografts are harvested in the operating room within 12 hours of death from general organ donors, screened for transmittable diseases.
After microbial culture, the tendon is stored at minus 80°C for a minimum of 14 days and a maximum of 6 months. We use only tibialis anterior and posterior tendons. We normally use an LAD of 8-mm width and 15 cm in length. This is placed inside the transplant, which is closed in a cylinder along its entire length by a seam of resorbable sutures. The LAD is then fixed to the transplant by 3 or 4 resorbable sutures. The graft is implanted through a limited arthrotomy (double-incision technique). The LAD enters the joint from the medial side through a predrilled tibial bone hole just over the pes anserinus attachment, to a point slightly anterior and medial to the center of the ACL anatomic attachment. A heavy suture is threaded through the eye of a curved passer, which is driven into the joint cavity via the medial entry portal. The passer is brought through the intercondylar notch over-the-top of the lateral condyle. After opening the iliotibial band and elevating the vastus lateralis, the heavy leading suture is pulled through a 3- to 4-cm skin incision on the distal third of the thigh. The opposite end is passed from the joint cavity to the medial side of the tibia via the osseous tunnel, with the help of a hook. The graft is secured proximally with a staple. The distal end of the synthetic band is also fixed with a staple after preloading with the knee joint in 30° flexion. As shown in table III, a number of patients were also treated for associated meniscal damage. Because the load in full extension is supported by the LAD during the early postoperative period, the LAD in double-end fixation is supposed to permit early postoperative functional treatment. Stress shield prevents the allograft structure of the ACL reconstruction from being overloaded. Full weightbearing of the operated knee joint was permitted immediately after the operation, if there were no additional intra-articular lesions. Every patient had a custom-made brace with an extension lag of 30° for a period of six weeks. Because the ligament is taut and fixed at 30° of flexion, there is a postoperative limitation of extension. Rehabilitation aimed at correcting this flexion will lead to stretching and possible rupture of the transplant. The use of the brace was initiated because we believed that elongation of the graft should occur within limits for optimal healing and “ligamentization”. In case of a combined intra-articular and extra-articular ligamentoplasty, immediate mobilization was initiated using continuous passive motion between 20° and 90° of flexion. Progressive dynamic rehabilitation and proprioceptive training were prescribed for 6 months. Return to sports was discouraged within the first 6 months. Pivot and contact sports were not allowed within the first year.

RESULTS

Short-term

Two complications were noted in the early postoperative course. For a persistent flexion lag, one patient required manipulation under anesthesia 6 months after the operation. In one patient the tibial staples had to be removed after 6 months because of irritation. There was no clinical evidence of allograft rejection, deep infection, thrombosis or persistent effusion. The average flexion was 128°. One patient had an extension lag of 20°.

Medium-term

If an intra-articular lesion was suspected, a repeat arthroscopy was performed (4 patients). Two ruptures of the reconstructed ligament were noted. They all occurred after a major injury (1 sports, 1 traffic) between 2 and 6 years postoperatively. The other 2 patients showed an intact reconstructed ACL, and in both cases a partial medial meniscectomy was performed.

EVALUATION

Knee performance was evaluated using the form of the International Knee Documentation Committee (IKDC), the Lysholm score and the Tegner scale. The reruptures were excluded.

Lysholm score

Fourteen patients had an excellent result (average 96). Five patients scored good (average 86) and four patients poor (average 76).

Tegner scale

The mean level for sporting activities was 7.25 preoperatively and 5.83 at evaluation. The Tegner scale should be used with caution in the interpretation of medium-term results. Most of the patients, being more than 40 years of age at evaluation, did not wish to return to their preinjury sports level. The mean decrease of professional activities was 0.5.
Range of motion and laxity testing

Laxity testing was performed using the KT-1000 arthrometer, using a force of 90 Newton (N) (34). The average range of flexion was 131°. There were no patients with an extension lag. Satisfactory results were obtained on clinical mediolateral laxity evaluation. The results are shown in table IV.

Table IV. — Laxity testing with the KT-1000 arthrometer using a force of 90 N

<table>
<thead>
<tr>
<th>&lt; 3 mm</th>
<th>&gt; 3mm</th>
<th>&lt; 5 mm</th>
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</thead>
<tbody>
<tr>
<td>AP neutral</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Lachmann</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Pivot</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>med laxity</td>
<td>0</td>
<td>0</td>
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<tr>
<td>lat laxity</td>
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IKDC form

Four patients scored normal (grade A), twelve patients nearly normal (grade B), five patients abnormal (grade C) and two severely abnormal (grade D).

DISCUSSION

Allografts can be used for revisions and multiple reconstructions if insufficient or no autografts can be harvested. This results in a shorter operating time, a smaller incision with arthroscopic techniques, and reduced postoperative donor site morbidity (14, 19, 21).

Synovitis is a serious problem associated with artificial ligaments (9, 27). Tolerance of the Kennedy LAD was satisfactory, since there were no cases of acute or chronic synovitis and no clinical or radiological signs of iatrogenic disease associated with the synthetic reinforcement. It is possible that some had a mild synovitis that was not diagnosed because they did not pay attention to it. Reports have been made of increasing effusion rates over time using artificial ligaments (23).

The comparison of our results with those of studies in which no reinforcements were used (6, 11, 18, 29, 33) is difficult because of differences in the study groups, the condition of the menisci, and the time elapsed between accident and intervention. Noyes and Barber (22) studied the effect of the ligament augmentation device on reconstructions using bone-patellar ligament-bone allografts. The patients were followed for a mean of 34 months, and the failure rate was found to be 29% in knees that were not augmented and 27% in the augmented group. They concluded that the addition of the ligament augmentation device did not improve the results of allograft reconstruction. Our results show a failure rate of 12%. An anteroposterior displacement on laxity testing of more than 3 mm was considered a failure. We had two complications. The reruptures occurred after major trauma and are therefore not regarded as complications. Our rehabilitation program was designed to maximize the possible protective effect of the augmentation device. Fixation of the device at both ends should reduce the load on the graft by approximately one third (12).

We used the IKDC scoring system because it is widely employed to report data in the current orthopedic literature. The IKDC scoring system was designed in 1991 and modified 2 years later by 11 members of the AOSSM and 10 members of the European Society for Knee Surgery and Arthroscopy (ESKA). There are eight categories of assessment, each of which has four grades: normal, nearly normal, abnormal and severely abnormal. The worst grade determines the final evaluation. Only the first four categories’ grades for subjective assessment count toward the final evaluation in patients with chronic ACL rupture. However, the lowest score in any of the groups will determine the final score and may not reflect knee function accurately. Therefore we believed that the Lysholm score, despite its subjective and optimistic nature, added crucial information to the final evaluation.

The patients in this series had good results on the Lysholm score. Four scored poorly, most probably because of their associated injuries. The results on the Tegner scale were good, when corrected for age by asking the patients for the sports level they actually desired to achieve.
The results of laxity testing are acceptable. The reruptures were caused by new severe trauma in patients with a good score at evaluation before the ACL rupture. The scorings on the IKDC form are debatable. The patients scoring severely abnormal (grade D) also had poor Lysholm scores. One was a multiply-injured patient with several associated lesions. Another one showed marked degenerative changes on x-rays. Three patients scored abnormal (grade C), because of a slight (1-mm) narrowing of the medial compartment on x-rays. Nevertheless, they had an excellent Lysholm score. This narrowing was probably caused by a medial meniscectomy in two of these patients (10, 20, 24).

Since the device is fixed at both ends and may thus function as a prosthesis, stress protection may have occurred. This could lead to increased laxity when the ligament augmentation device eventually breaks. If it is taking most of the load during our rehabilitation program, we feel that breakage would probably have occurred before the two-year review.

CONCLUSION

Previous and current studies place us in a dilemma with regard to the use of allografts in knees with a chronic ACL rupture. All studies show a highly significant improvement in the subjective ratings of symptoms, function, and activity levels, but the arthrometric data are not satisfactory either for the knees that have been treated with an allograft alone or for those that have been treated with the allograft and the augmentation device.

Our results are in the same range as those of the longest follow-up studies of allografts with an augmentation device (17, 22, 25). Augmentation did not give better results than when no augmentation was performed (2, 17, 31). Although the strict IKDC scoring suggests average results of the allograft reconstruction technique, satisfactory results are achieved on the Lysholm and Tegner scale, and on clinical examination after 6 years. Although the LAD has been shown to be effective in augmenting hamstring or the medial quadriceps-periosteum autografts or allografts, which are inherently weaker than the bone-tendon-bone autograft, there is no evidence to prove the usefulness of the LAD with better techniques of graft selection and isometric graft positioning (17).

Nevertheless, we found it to be a valuable alternative to reconstruction with autografts, especially for knees with multiple ligament lesions and for revision cases (31).

We currently no longer perform this operation through an arthrotomy, but instead we perform it arthroscopically. We have abandoned the over-the-top technique because it fails to provide adequate isometry for graft placement (25).

Implantation of allograft ligament material with an augmentation device as a substitute for the ACL has not induced clinically detectable rejection in this medium-term evaluation or, at the time of writing, transmission of disease.

REFERENCES


SAMENVATTING

F. STEENBRUGGE, R. VERDONK, P. VORLAT, F. MORTIER, K. VERSTRAETE. Plastie van chronische scheuren van de voorste kruisband met behulp van pees-allogreffes en een peesverstevigingsapparaat.

We hebben een prospectieve studie gedaan om het effect te beoordelen van een peesverstevigingsapparaat (ligament augmentation device – LAD) op de plastie van chronische voorste kruisband (VKB) scheuren met peesallogreffes. Vijf en twintig patiënten werden gevolgd gedurende 6 jaar (gemiddeld 74 maanden) na plastie van de VKB met een peesallogreffe en LAD. De evaluatie gebeurde aan de hand van het document van de International Knee Documentation Committee (IKDC), de Lysholm score en de Tegner score. Twee patiënten hadden een herruptuur van hun hersteld ligament na een nieuw ernstig trauma. Drie andere patiënten die multiple letselesc hadden, scoorden slecht omwille van hun geassocieerde letselesc (IKDC graad D). Vier patiënten scoorden normaal (graad A), twaalf patiënten bijna normaal (graad B), en vijf patiënten abnormaal (graad C). De Lysholm score toonde 14 (gemiddeld 96) uitstekende resultaten, 5 goede (gemiddeld 86) en 4 behoorlijke resultaten (gemiddeld 76). Drie van de uitstekende resultaten waren IKDC-graad C, enkel omdat de radiografische opnames een kleine vernauwing toonden van het mediale kraakbeen wat op toekomstige problemen kan wijzen. Op de Tegnerschaal was het sportniveau gedaald met een gemiddelde van 1.4 punten (van 7.25 tot 5.83). Slechts 5 patiënten toonden een voorachterwaartse verplaatsing van meer dan 3 mm, waarvan er enkel een in groep C was.

RÉSUMÉ

F. STEENBRUGGE, R. VERDONK, P. VORLAT, F. MORTIER, K. VERSTRAETE. Ligamentoplastie pour rupture chronique du ligament croisé antérieur par allogreffe et renfort synthétique.

Nous avons conduit une étude sur l’effet d’un renforcement ligamentaire synthétique (ligament augmentation device – LAD) sur le résultat des plasties du ligament croisé antérieur (LCA) par allogreffe. Vingt-cinq patients ont été suivis pendant 66 à 98 mois (moyenne : 74 mois) après plastie du LCA par allogreffe et LAD. L’évaluation a été faite avec le formulaire de l’International Knee Documentation Committee (IKDC), le score de Lysholm, et le score de Tegner. Deux patients ont eu une rerupture de leur ligamentoplastie après un nouveau traumatisme important. Trois patients qui présentaient des lésions multiples, avaient un mauvais score en raison des lésions et fractures associées (IKDC grade D). Quatre patients avaient un score normal (grade A), douze patients un score presque normal (grade B), et cinq patients un score anormal (grade C). Le score de Lysholm montrait 14 résultats excellents (score moyen : 96), 5 résultats bons (score moyen : 86) et 4 résultats passables (score moyen : 76). Trois des résultats excellents étaient IKDC-grade C, uniquement parce que les radiographies montraient un petit pincement de l’interligne médial, ce qui peut faire présumer de problèmes dans l’avenir. Le score de Tegner montrait que le niveau sportif était diminué en moyenne de 1.4 points (de 7.25 à 5.83). Cinq patients seulement avaient un déplacement antéropostérieur de plus de 3 mm, dont seulement un était dans le groupe C.