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Prodromos

The Anterior Cruciate Ligament

Reconstruction and Basic Science

Andrews • Brown • Fu • Georgoulis
Gobbi • Noyes • Shelbourne

ELSEVIER

- Any cartilage or meniscal pathology should be addressed initially after the ACL is débrided. This will allow for ease in visualization.
- If the posteromedial femoral ACL tunnel is too posterior, an over-the-top reconstruction can be used for the AM bundle. This will avoid fracture or posterior wall blowout.
- After the tibial guide pins are passed, the PL guide pin should be more vertical as it emerges from the anteromedial tibial incision. If this is not the case, the surgeon should be very cautious to make sure the tibial tunnels do not intersect after reaming.
- The tibial tunnels should be separated by about 1 cm when viewed arthroscopically. Having the tunnels closer to each other risks fracture or tunnel convergence.

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39 Augmented Grafts: Synthetic/Allograft/Autograft

Lars Peterson, MD, PhD, Christian Ernest, RPT, BSc

INTRODUCTION

The anterior cruciate ligament (ACL) is the primary and most important stabilizer of the knee joint. Rupture of the ACL is the most common serious ligament injury, and untreated or in spite of conservative treatment, it may progress into posttraumatic osteoarthritis accelerated by strenuous sports like football, long-distance running, and so on. After surgical treatment with acute repair alone of ACL ruptures,^{1–3} and after chronic instability with late ACL reconstruction (iliotibial band),⁴ most actual techniques using autografts like the central third of the patellar tendon or multiple loops of the hamstring tendons, iliotibial band, quadriceps tendon, and so on still result in many patients having unsatisfactory short- or long-term outcomes. Remaining rotatory instability and progressive anterior laxity and clinical instability, along with pain and donor site morbidity, an increasing number of re-ruptures, and meniscus and articular cartilage lesions, have caused reoperations in 30% of cases and late posttraumatic osteoarthritis in football players in 50% of cases.⁵ These insufficient treatments have resulted in a continued search for better surgical treatments to reproduce the anatomic functional structure of ACL and improve the mechanical properties and strength of the graft materials. Looking for new ways has led to the use of autografts, allografts, and synthetic materials historically as an augmentation in acute repair of ACL, and as an augmentation or as a prosthesis in early or late reconstructions of ACL.

AUTOGRAFT AUGMENTATION OF ACUTE REPAIR OF ANTERIOR CRUCIATE LIGAMENT

Palmer¹ in his 1938 thesis and O'Donoghue² recommended acute repair in the treatment of ACL, and for a period this was done all over the world but with about 30%–50% unacceptable results according to Feagin,³ Lysholm and Gillquist,⁶ and Odensten et al.⁷

Augmentation of the acute repair was mostly done with a fascia lata strip, iliotibial tract, semitendinosus, gracilis tendons, or medial longitudinal retinaculum to provide increased strength and protection during healing.^{3,7–10} They reported improved long-term results in up to 90% of cases. Shelbourne et al.^{11,12} found less arthrofibrosis and stiffness, and better range of motion and muscle function with training in the acute phase instead of performing acute repair. He thus advocated the use of delayed primary ACL reconstruction at 6–8 weeks as a planned elective procedure, making it also easier to plan the surgical program and gain OR time as well as improved results.

AUTOGRAFTS, ALLOGRAFTS, AND SYNTHETICS FOR ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

The most common autografts used in early and late ACL reconstructions by arthroscopic techniques are the central third of the patellar tendon with adjacent bone included, multiple loops of the hamstrings tendons, iliotibial tract, and the quadriceps tendon. These avascular grafts are all undergoing necrosis followed by revascularization, cellular invasion, resorption with phagocytosis of necrotic tissue, and migrating fibroblasts for matrix production with type I collagen to restore the ligament structures and the mechanical properties like strength and elasticity. This ligamentization process takes about 12 months to reach maturation and restored functional capacity.¹³ However, the reconstruction of the functional anatomic structures of ACL by using single-bundle grafts has not been achieved, as no actual autografts or allografts are restoring the structure of a normal ACL, and neither has going from single bundle to double bundles (anteromedial and posterolateral). Precise positioning of the graft fixation in anatomical footprints in the bone is still not achieved,¹⁴ but perhaps a triple-bundle design including the intermediate bundle could come closer to anatomic function. The augmentation of

autografts and allografts using nondegradable synthetic devices as well as nondegradable synthetic prosthesis has been researched and tried over 100 years with disappointing results (silver wire, silk sutures, ligament augmentation device (LAD), Gore-Tex, Leeds Keio, Dacron, ligament advanced reinforcement system (LARS) carbon fiber) and high complication rates.¹⁵ However, so far neither techniques nor synthetic designs have come close to the normal anatomy to adequately restore the lifetime function of the ACL. Consequently most of the nondegradable synthetic devices have been taken off the market (see Chapter 18).

NONDEGRADABLE BIOLOGIC GRAFT (XENOGRAFT)

Xenograft from a bovine foot extensor tendon with stabilization of the collagens by paraldehyde was used as a permanent prosthesis, not undergoing any remodeling with short-term promising results, but only 50% had an acceptable end result. However, over time re-ruptures due to fatigue and fragmentation caused serious inflammation; synovial thickening and instability were frequent and required reoperations. Thus xenograft should not be used.¹⁶

DEGRADABLE SYNTHETIC DEVICES FOR ANTERIOR CRUCIATE LIGAMENT AUGMENTATION OR PROSTHESIS

The high failure rate of nondegradable augmentation devices and prostheses has increased the interest in degradable materials. For tissue repair and tissue regeneration in the musculoskeletal system, the use of degradable-resorbable devices for temporary support of the tissue repair area over time is necessary until functional tissue healing has been achieved. Besides being a mechanical support, the device should be porous to allow revascularization and cellular ingrowth. Devices being slowly degradable will allow tensional forces to act on the cellular production of the matrix, adapting to the increasing loading of the graft over the healing period to mature tissue. This may be achieved if the device is able to recapture its original length after loading, being more elastic and not too stiff in mimicking the biomechanical characteristics of the human ACL.

POLYDIOXANONE

Among the first synthetic materials used for degradable devices was polydioxanone (PDS). It was used as an augmentation to support the acute repair of ACL or the autograft ACL. The high stiffness of the PDS led to stress-shielding phenomena by unloading the autograft from tensional stimulation of the fibroblasts. The degradation/resorption of the PDS band is achieved by hydrolysis, and the time to reduce its strength by 50% is 2 months. This time period is too short to protect the healing phase of the repair or the graft over the rehabilitation phase and during return to sport.

ARTELON (POLYURETHANE-UREA)

In the research for a better solution, the polyurethane class of polymers well tolerated in the human body was used as a chemical base for the synthesis of a by hydrolysis slowly degradable polymer, ending up in a polyurethane-urea (PUUR) solution. By wet spinning, the PUUR solution was extruded through a spinneret with 60 holes, with a diameter of 80 μm and secondly drawn 400%–600%. The fibers were then collected by textile technology into bundles and synthetic ligaments, and they were tested in a biomechanical laboratory for ultimate load and cyclic tests. The mechanical properties could be changed by using different textile techniques as well as adjusting the porosity of the ligament, and different products like strips, meshes, and bands for different indications were designed. The ACL augmentation device is a woven polycaprolactone-based polyurethane urea. The degradation by

hydrolysis results in a resorbable and nonresorbable fraction. The resorbable fraction is eliminated through the Krebs cycle (citric acid cycle), primarily as carbon dioxide and in the urine. The nonresorbable fraction of microfragments is incorporated in the surrounding host tissue without any inflammatory or foreign body response. The Artelon augmentation device was approved by the US Food and Drug Administration in 1993. The Artelon device was tested in a pilot study of 23 patients with ACL bone–patellar tendon–bone (BPTB) grafts and augmentation, and followed with biopsies showing vascularization with fibroblast ingrowth and matrix production with collagen Type I.¹⁷ Artelon was tested in a randomized multicenter study¹⁸ with a BPTB group ($n = 105$) and a BPTB augmented with Artelon group ($n = 96$), with follow-ups at 4 and 12 years. No significant differences could be found in the subjective (Knee Injury and Osteoarthritis Outcome Score, Tegner activity evaluation score) or objective (KT-1000) results. Four controls had re-ruptures, and six of the augmented patients had insufficient screw fixation in the femur, five after new trauma early in the study. Those six with screw loosening and four devices with residual swelling were explanted. The survival rate was 89%.

De Pamphilis et al.¹⁹ reported in 2012 on 22 ACL reconstructions with a double semitendinosus or gracilis tendon augmented with an Artelon Tissue Reinforcement (ATR) band sutured to the autograft. Single tunnels were used. For fixation on the femoral side, a ZipLoop device was used, and on the tibial side a resorbable Bio-INTRAFIX System screw was implemented (DePuy, Mitek). Accelerated rehabilitation and early return to sport at 6.5 months was possible. Subjective and objective results were promising at 12 months. No side effects were observed. A longer follow-up is ongoing.

COMMENTS AND FUTURE DIRECTIONS

We are faced with a great challenge when discerning how to proceed in the future to improve the ACL repair and reconstructive surgical technique, how to optimize the anatomic design, and how to find the graft materials that allow tissue ingrowth and ligamentization, incorporated in the normal tissue turnover to maintain durability over the course of a lifetime.

ACUTE REPAIR OF ANTERIOR CRUCIATE LIGAMENT

In instances of acute ruptures of ACL in adolescent and young athletes, the injury can be located in the midsubstance, with disruption of the ligament and its vascular supply. More often, however, there will be avulsion ruptures at the bony insertion in the femur, and in growing individuals often with a bony fragment avulsion from the femoral or tibial ligament insertions. In those last conditions the ligamentous anatomy is not seriously damaged, and an acute repair offers the best opportunity for restoring or preserving the anatomy by reinsertion of the ACL and augmentation. Using autologous tissue will add mechanic support and even provide revascularization in the case of using the medial longitudinal retinaculum with preserved base fixation to the bone. This augmentation has also been successfully used in acute repair of ACL substance ruptures.²⁰

A second option to support the acute repair of ACL could be to use a synthetic degradable augmentation device allowing tissue ingrowth and with a degradation time of at least 2 years, such as polycaprolacton (PCL), polyglycolic acid (PGA), poly-L-lactic acid (PLLA), or polyurethane-urea (PUUR, Artelon). This would help avoid donor site morbidity.

ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING AUTOGRAFTS AND ALLOGRAFTS

The weakness of autografts and allografts is the avascularity resulting in tissue necrosis, eliciting the inflammatory response with

revascularization, resorption by cellular phagocytosis, and cellular ingrowth of fibroblasts for matrix production and maturation ending up in ligamentization, a process taking about 12 months or more to complete.¹³ The structures of the grafts are weakened and vulnerable for stretching during this period, and they need a mechanic support for at least this period or longer during rehabilitation and return to sport. Rading and Peterson designed a more anatomic graft using the medial third of the patellar tendon and the medial longitudinal retinaculum en bloc, preserving the vascular supply from the anastomosis of the medial and lateral inferior genicular arteries and sending a branch running up the fibrous space between the patellar tendon and the retinaculum to the patella. The patellar graft was anchored in a posterolateral bundle position, the medial longitudinal retinaculum in an anteromedial bundle position, and the connecting fibrous tissue carrying the vascular supply in an intermediate bundle position. A PDS band was added to the retinaculum. Results of 51 patients at 2-years follow-up showed International Knee Documentation Committee scores at normal/nearly normal in over 90% of cases. Pivot shift tests were negative in all patients. Autologous augmentation, which could provide circulation and contribute to revascularization and decrease necrosis, would be preferable but may add donor site morbidity.

ANTERIOR CRUCIATE LIGAMENT PROSTHESES (PERMANENT DEVICES)

The future device preferred may be a slowly degradable synthetic prosthesis with a textile design mimicking the ACL anatomy in its substance with anteromedial, intermediate, and posterolateral bundles building up a total functional unit for stability. The combination of porosity and degradation will over time leave space, allowing tissue ingrowth and maturation ending in ligamentization. The temporary mechanic fixation should gradually allow biologic healing of the ligament into the anatomic footprints of the tibial and femoral bones. The degradation time of the prosthesis to 50% of its strength should be at least 2 years.

New ways should be evaluated, such as adding cultured autologous fibroblasts, grown in the prosthetic device in biochambers and sustained to adequate physical stimuli to promote ligamentization before implanting, or directly adding aspirated and concentrated autologous mesenchymal stem cells to the device at surgery. The effect of adding plasma rich proteins to the cells or the construct should be studied.

CONCLUSIONS

Permanently replacing the ACL with an identical, functional lifelong substitute is the focus of ongoing research, while also considering whether it should be biologic or nonbiologic. So far it seems that nondegradable materials in permanent replacements or augmentations have not been successful. They have problems of biocompatibility with inflammation, synovitis with hydrops and thickening, material fatigue failures, re-ruptures,

tunnel widening, loosening bone fixations, fragmentations causing inflammation and foreign body reactions, remaining laxity and instability, and secondary osteoarthritis. Consequently most of the nondegradable devices have been taken off the market.

The future will be degradable materials by hydrolysis, with a slow degradation of 1–2 years at least to get down to 50% of their strength. These should have adequate stiffness and elasticity, not being too stiff but allowing physical stimulation of the ingrowing cells and fibroblasts.

Degradable synthetic augmentation seems to fill a need for temporary support, progressive degradation, and tissue ingrowth incorporated to the autograft or allograft ACL, but may also have a place in acute repair of ACL in growing and young athletes to preserve the original ligament.

Degradable temporary prosthesis needs biocompatibility, an optimal anatomic structure with adequate mechanical properties mimicking the ACL to allow tissue ingrowth and ligamentization over the whole maturation and rehabilitation time, and incorporation in the normal tissue turnover for a lifetime.

The great challenge for orthopaedic surgeons today and tomorrow will be to participate in interdisciplinary work with researchers in basic sciences, biomaterials, biomechanics, cell biology, and other fields to arrive at sustainable solutions using tissue regeneration to replace ligaments like ACL while also advancing regeneration of other tissues in the musculoskeletal system, such as tendons, bone, cartilage, meniscus, and muscles.

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