

Anterior Cruciate Ligament Reconstruction With LARS Artificial Ligament: A Multicenter Study With 3- to 5-Year Follow-up

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Purpose: The aim of this multicenter study was to evaluate the clinical outcome of anterior cruciate ligament (ACL) reconstruction by use of the Ligament Advanced Reinforcement System (LARS) artificial ligament (Surgical Implants and Devices, Arc-sur-Tille, France) with 3- to 5-year follow-up. **Methods:** From August 2004 to July 2006, 159 patients with ACL rupture underwent arthroscopic ACL reconstruction with LARS artificial ligament at 4 orthopaedic sports medicine centers in China. They were retrospectively followed up for 50 ± 6 months (range, 36 to 62 months). Outcome assessment included physical examination, KT-1000 arthrometer testing (MEDmetric, San Diego, CA), magnetic resonance imaging, radiography, Lysholm score, Tegner score, International Knee Documentation Committee score, and subjective satisfaction rate. Quadriceps and hamstring isokinetic strength was evaluated in 68 patients. **Results:** The side-to-side difference in anterior translation (injured side – uninjured side) measured by KT-1000 arthrometer was 1.5 ± 1.6 mm (range, –1 to 7 mm) postoperatively, and knee stability was significantly improved compared with preoperative data ($P < .0001$). Quadriceps and hamstring isokinetic peak torque of the injured limb expressed as a percentage of the contralateral limb was 93.6 ± 10.7 and 95.8 ± 12.0 , respectively. The Lysholm score improved from 65.1 ± 12.3 points (range, 30 to 95 points) preoperatively to 94.5 ± 7.0 points (range, 65 to 100 points) postoperatively ($P < .0001$). The Tegner score improved from 3.1 ± 1.6 (range, 0 to 6) preoperatively to 6.1 ± 1.5 (range, 1 to 9) postoperatively ($P < .0001$). According to the International Knee Documentation Committee score, 94% of patients were graded A or B at last follow-up. Ninety-three percent of patients were very satisfied or satisfied with their outcome. LARS artificial ligament rupture occurred in 3 patients; knee synovitis developed in 1 of these patients. **Conclusions:** ACL reconstruction with LARS artificial ligament used in patients with the ACL stump preserved in the acute and chronic phases has a very good outcome at mean of 50 months' follow-up. The overall complication rate for ACL reconstruction with LARS artificial ligament is 5.7%, and knee synovitis developed in only 1 case. **Level of Evidence:** Level IV, therapeutic case series.

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Orthopaedic surgeons in the United States still remember vividly and fear the severe synovitis of the knee and implant rupture caused by the misuse of artificial ligament for anterior cruciate ligament (ACL) reconstruction in the last century. Artificial ligament seems to have disappeared in the United States, and people reject its use for ACL reconstruction without giving it a second thought. Autograft and allograft are the predominant materials currently used for ACL reconstruction.¹⁻³ Bone–patellar tendon–bone (BPTB) autograft and hamstring tendon (HT) autograft or allograft are most frequently used for ACL reconstruction, and the excellent clinical results of those techniques have been shown.¹⁻³ However, autograft harvest for ACL reconstruction may lead to donor-site morbidity, such as anterior knee pain and knee extensor strength deficits, after BPTB autograft harvest.⁴ Both deficits in knee flexor strength and

internal tibial rotation strength after HT autograft harvest for ACL reconstruction have been reported.^{5,6} In addition, the supply of autograft is insufficient for multiple ligament reconstructions and ACL revision surgery. The use of allograft eliminates donor-site morbidity, but the shortage of available tissue banks limits the use of this technique in ACL reconstruction in China and some other Asian countries. Furthermore, the use of allograft may result in disease transmission and immunologic rejection response. However, in China with its large population, artificial ligament is being used once again for ACL reconstruction. Accordingly, the efficacy and safety of using artificial ligament for ACL reconstruction have become the focus of attention by orthopaedic sports medicine surgeons, and people are waiting for the results.

In the 1980s artificial ligament was initially used for ACL reconstruction to avoid the drawbacks of autograft and allograft ACL reconstruction. The short-term clinical results of ACL reconstruction with artificial ligament were appealing,^{7,8} but subsequent follow-up showed a very high failure rate.⁹⁻¹² The major mechanisms of artificial ligament failure included very poor biomechanics of resisting flexion and torsion load of the ligaments,¹³ insufficient autologous tissue coverage, and growth into the artificial ligament scaffold; thus neoligament with good function could not be formed.⁹ These factors resulted in fatigue rupture or elongation of the artificial ligament and severe synovitis of the knee caused by wearing particles of artificial ligament fibers.^{10,14} After that, artificial ligament was rarely used for ACL reconstruction, especially in the United States.

With the advancement in research on anatomy and biomechanics of the ACL and the improvement of ACL reconstruction surgical technique, a novel artificial ligament scaffold—the Ligament Advanced Reinforcement System (LARS; Surgical Implants and Devices, Arc-sur-Tille, France)—has been developed.¹⁵ LARS artificial ligament is a biomimic scaffold of artificial ligament made of polyester (polyethylene terephthalate [PET]) fibers. The intra-articular portion of LARS artificial ligament is composed of longitudinal external rotation fibers, and the left knee and right knee are separately designed, as clockwise or counterclockwise, respectively (Fig 1). The biomechanics of resisting tension, flexion, and torsion load of LARS artificial ligament are good.^{15,16} In vitro cell culture indicated that fibroblasts could adhere to and encapsulate LARS artificial ligament well,¹⁷ and in vivo

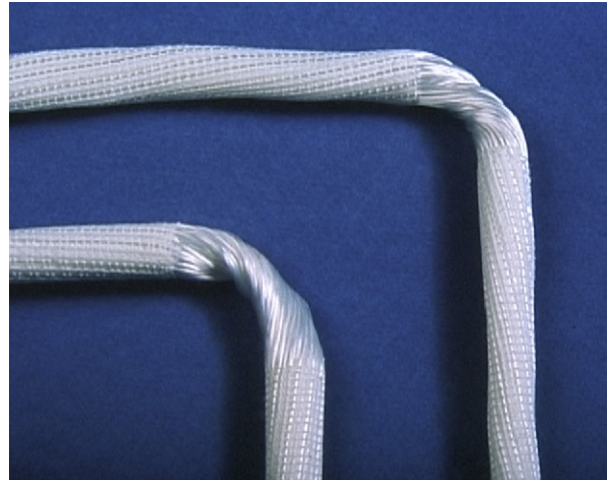


FIGURE 1. Torsion of free fibers of LARS artificial ligament mimicking native ACL (top, left graft; bottom, right graft).

LARS artificial ligament could induce the growth of autologous collagen tissue and neoligament formation.¹⁸ Recently, a few clinical studies of ACL reconstruction using LARS artificial ligament have shown good short-term results with a low failure rate and a very low rate of knee synovitis.^{15,19-26} However, in all previous studies, the number of cases available for midterm follow-up was none or very small.^{15,19-26} The midterm and long-term clinical results of ACL reconstruction using LARS artificial ligament are still unknown.

Since the State Food and Drug Administration of China approved the use of LARS artificial ligament for ACL reconstruction on March 18, 2004, more than 4,000 patients with ACL or posterior cruciate ligament (PCL) injury have undergone cruciate ligament reconstruction with LARS artificial ligament in China. Consequently, some experience with this technique was gained.

The aim of this multicenter study was to evaluate the clinical outcome of ACL reconstruction using LARS artificial ligament with 3 to 5 years' follow-up. We hypothesized that the use of LARS artificial ligament for ACL reconstruction was effective and safe with a lower failure rate and low incidence of synovitis in cases in which it was properly indicated. To test our hypothesis, we retrospectively evaluated 159 patients who underwent ACL reconstruction with LARS artificial ligament at 4 large orthopaedic sports medicine centers affiliated with university hospitals in China.

METHODS

Patients

Between August 2004 and July 2006, 235 patients underwent arthroscopic ACL reconstruction with LARS artificial ligament at 4 representative orthopaedic sports medicine centers affiliated with different university hospitals and a military hospital from Southern to Northern China, and all operations were performed by 4 experienced arthroscopy orthopaedic sports medicine surgeons trained in the United States. All patients had a history of knee injury with a diagnosis of ACL rupture according to clinical examination and magnetic resonance imaging (MRI). A duration between injury and reconstruction within 3 months was defined as acute injury, and a duration over 3 months was defined as chronic injury. The sole indication for ACL reconstruction with LARS artificial ligament was arthroscopic findings showing that enough ACL stump was remaining for passage of LARS artificial ligament through the stump. Patients were also offered the choice to undergo other procedures for ACL reconstruction using either BPTB autograft or HT autograft or allograft, rather than LARS artificial ligament, during this period. All patients were carefully informed about the potential risks and benefits of ACL reconstruction with artificial ligament. The use of LARS artificial ligament for ACL reconstruction was based on the decision of the patients. In the same period, ACL reconstruction was performed by use of 82 BPTB autografts, 269 HT autografts, and 45 HT allografts. Fifty-three patients underwent conservative treatments during this period. The protocol was approved by the institutional review board of each participating center, and informed consent was obtained from all patients.

Inclusion criteria included age of 18 years or older, unilateral ACL rupture with a normal contralateral knee, visible ACL remnant on MRI, and primary ACL reconstruction. We excluded 61 patients: bilateral ACL injury ($n = 5$), PCL injury ($n = 20$), medial collateral ligament injury ($n = 16$), lateral collateral ligament injury ($n = 4$), meniscus transplantation ($n = 2$), articular cartilage transplantation ($n = 4$), and chondral lesion classified as higher than grade 2 according to the Outerbridge classification ($n = 10$). A total of 174 patients who met the criteria were included and were retrospectively evaluated in this study. Of these patients, 159 were available for a minimum of 3 years' follow-up after surgery, including 95 acute injury cases and 64 chronic cases. The mean follow-up time was 50 ± 6 months (range, 36 to

TABLE 1. Demographic Data

	Data
No. of patients	159
Male/female	105/54
Reason for injury (sports/traffic accident)	147/12
Age at operation [mean (range)] (yr)	30 ± 7 (18-55)
Time between injury and operation [mean (range)]	5.0 ± 10.1 mo (5 d to 96 mo)
Meniscus operation (partial meniscectomy/repair)	74/8
Follow-up period [mean (range)] (mo)	50 ± 6 (36-62)

62 months). Fifteen patients were lost to follow-up because they moved to other cities or abroad. We contacted the patients who were lost to follow-up by telephone and e-mail, and all patients were very satisfied with the results of surgery but they could not return for examination. The follow-up rate was 91%. The demographic data are shown in Table 1. Concomitant surgeries included partial medial meniscectomy in 29 cases, partial lateral meniscectomy in 36 cases, partial medial and lateral meniscectomy in 7 cases, lateral meniscus repair in 7 cases, and medial meniscus repair in 1 case.

Surgical Technique

The procedures were performed with an arthroscopic technique. A thorough arthroscopic examination was routinely performed to determine whether ACL injury was present and to evaluate concomitant injuries of the knee. Partial meniscectomy or meniscal repair was carried out for meniscus injuries before ACL reconstruction. Notchplasty was performed with a motorized bur if there were notch osteophytes or a narrow notch.

ACL reconstruction with LARS was performed according to the isometric reconstruction surgical principles described previously by Dericks,¹⁵ and ACL remnant was routinely preserved. Left or right LARS artificial ligament with 120 fibers (double-bundle, AC 120 2BL/2BR) was used for ACL reconstruction in the left or right knee. The diameters of the tibial tunnel and femoral tunnel were identical (7.5 mm) in all patients.

The femoral and tibial tunnels were made by use of the customized drill guide in all cases. The LARS drill guide was introduced through an anteromedial approach for drilling of the tibial tunnel. The intra-articular point of the tibial tunnel was positioned at the center of the ACL stump in the tibial insertion. A Kirschner wire was passed through the center of the ACL stump, and then the tibial tunnel was drilled with a 7.5-mm-diameter drill bit. The femoral tunnel was

placed by the transtibial technique at the 11-o'clock to 10:30 position on the right knee (1:00-o'clock to 1:30 position on the left knee). The Kirschner wire was drilled upward, penetrated through the femur, and emerged from the skin of the anterolateral thigh, and a 3-cm incision was made at the point of the wire emerging. With the soft tissue of the thigh protected by a series of tubes, the 7.5-mm-diameter drill bit guided by the Kirschner wire was drilled into the femur from the anterolateral thigh and into the knee joint.

The artificial ligament was mounted and fixed. A wire was introduced into the knee joint from the extra-articular exit of the femoral tunnel, was passed through the tibial tunnel, and emerged from the extra-articular opening of the tibial tunnel. LARS artificial ligament was introduced into the knee joint from the extra-articular exit of the tibial tunnel after the ligament setting on the wire, and the ligament was passed upward through the ACL remnant (Fig 2). LARS artificial ligament was pulled upward to make the longitudinal free fibers of the graft entering the femoral tunnel about 1 mm, and then the longitudinal free fibers were adjusted to a position of slight external rotation. Titanium interference fit screws with blunt thread edges (Surgical Implants and Devices) were used for fixation of both ends of LARS artificial ligament, and the diameter of the screw was 8 mm on the femoral side and 9 mm on the tibial side. The tibial

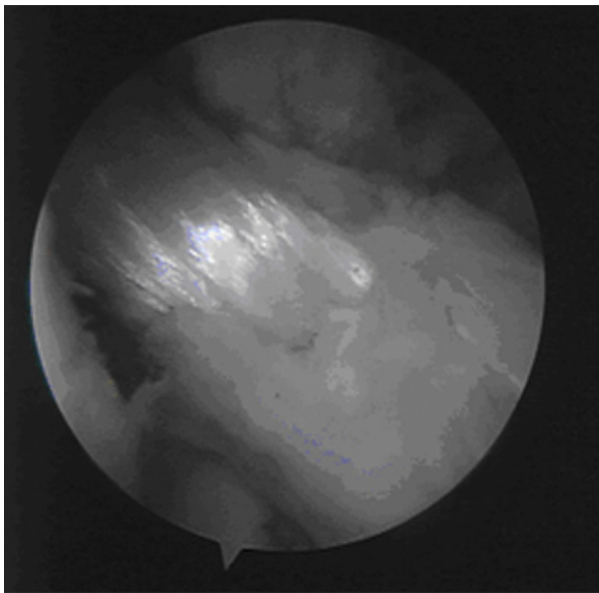


FIGURE 2. Arthroscopic view showing LARS artificial ligament enveloped by ACL remnant.

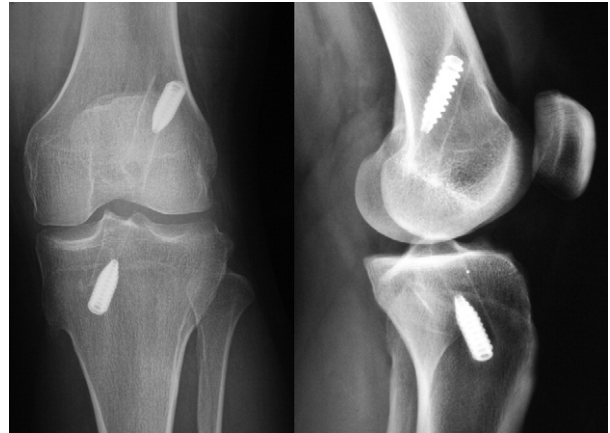


FIGURE 3. Postoperative radiograph of ACL reconstruction with LARS artificial ligament.

end of the graft was pulled, and the tension of the ligament was adjusted by moving the knee through 20 cycles of the full range of knee motion, with the surgeon ensuring that the full range of knee motion was achieved and there was no impingement between LARS artificial ligament, the notch, and the PCL. At knee flexion of 20° to 30°, the tibia was pushed backward and the tibial end of the ligament was fixed with an interference screw (Fig 3). The redundant ligament of both ends of LARS artificial ligament was cut, and the portals were closed.

Rehabilitation

The same rehabilitation protocol was used at all 4 centers. No braces were used postoperatively. Quadriceps contraction started from the first day after surgery, and the patients walked with crutches with partial weight bearing from the second day after surgery for 2 weeks and gradually progressed to full weight bearing at 4 weeks postoperatively. Range of motion of the knee from 0° to 90° of knee flexion was achieved during the first week postoperatively and 120° of knee flexion during the second week postoperatively. Activities of daily living were restored from 4 weeks to 2 months postoperatively, jogging started from the third month postoperatively, and patients were allowed to return to unrestricted sports 6 months after surgery.

Clinical Assessment

Effusion of the knee was assessed by the floating patella test at follow-up. MRI and radiography were used to assess whether there was synovitis and bone

TABLE 2. Preoperative and Postoperative KT-1000 Data

Side-to-Side Difference	Preoperative (n = 156)	Postoperative (n = 156)	P Value
<3 mm	0	121	<.0001
3-5 mm	42	31	
>5 mm	114	4	

tunnel malpositioning. Knee stability evaluation included the Lachman test, pivot-shift test, and KT-1000 arthrometer laxity measurement (MEDmetric, San Diego, CA) at 25° of knee flexion with an anterior drawer force of 134 N. Clinical failure of LARS artificial ligament was defined as a KT-1000 side-to-side difference of more than 5 mm. Lysholm score,²⁷ Tegner activity score,²⁷ and International Knee Documentation Committee (IKDC) score²⁸ were used to evaluate functional outcome. Patients' degree of subjective satisfaction with the surgical results was evaluated as follows: very satisfied, satisfied, unsatisfied, or very unsatisfied. At final follow-up, quadriceps and hamstring isokinetic peak torque was evaluated in 68 patients at a velocity of 60°/s with a Biodex III dynamometer (Biodex, Shirley, NY) at 2 of our centers. Results of isokinetic peak torque of the injured limb were reported as a percentage of the contralateral limb.

Statistical Analysis

The follow-up data were compared with preoperative data. The Kolmogorov-Smirnov test was used to test whether the data showed normal distribution. Continuous variables with normal distribution were analyzed by paired *t* test, and continuous variables with non-normal distribution were analyzed by Wilcoxon signed rank test. Categorical variables were analyzed with the χ^2 test. Statistical analysis was performed with SPSS software (version 11.0; SPSS, Chicago, IL). *P* < .05 was considered statistically significant.

RESULTS

The follow-up time was 50 ± 6 months (range, 36 to 62 months) after ACL reconstruction with LARS artificial ligament. Recurrent instability occurred in the operative knee in 3 patients, caused by sports trauma within 1 to 2 years postoperatively, and second-look arthroscopy was performed in those cases. Of the 3 patients, 1 had partial rupture and laxity of LARS artificial ligament and the other 2 had complete

rupture of LARS artificial ligament. ACL revision surgery was performed by use of autograft or allograft in those 3 patients. At final follow-up, 156 patients with LARS artificial ligament still in the knee were followed up more than 3 years after reconstruction.

Knee Stability

At final follow-up, the side-to-side difference in anterior translation (injured side – uninjured side) measured with KT-1000 arthrometer was 1.5 ± 1.6 mm (range, –1 to 7 mm), which was significantly decreased compared with the preoperative value of 5.8 ± 1.1 mm (range, 4 to 11 mm) (*P* < .0001) (Table 2). Postoperatively, 4 patients (3%) had a side-to-side difference of more than 5 mm.

The Lachman test showed 1+ laxity in 17 patients and 2+ laxity in 4 patients postoperatively; 49 patients had 1+ laxity and 107 patients had 2+ laxity preoperatively, indicating a significant difference (*P* < .0001) (Table 3). The pivot-shift test showed a 1+ grade in 14 patients and 2+ grade in 4 patients postoperatively; 61 patients had a 1+ grade and 95 patients had a 2+ grade preoperatively, also indicating a significant difference (*P* < .0001) (Table 3).

Isokinetic Strength

Sixty-eight patients underwent isokinetic strength testing at 60°/s at 2 of the involved centers at the final follow-up. Quadriceps and hamstring isokinetic peak torque of the injured limb, expressed as a percentage of the contralateral limb, was 93.6 ± 10.7 and 95.8 ± 12.0, respectively.

Range of Motion

Two cases had a 3° extension deficit, and four had a 6° to 10° flexion deficit. All the other patients had normal range of motion of the knee.

TABLE 3. Preoperative and Postoperative Physical Examination

	0	1+	2+	3+	P Value
Lachman test					<.0001
Preoperative	0	49	107	0	
Postoperative	135	17	4	0	
Pivot-shift test					<.0001
Preoperative	0	61	95	0	
Postoperative	138	14	4	0	

TABLE 4. Preoperative and Postoperative IKDC Score

IKDC Score	Preoperative (n = 156)	Postoperative (n = 156)	P Value
A	0	81	<.0001
B	0	65	
C	126	9	
D	30	1	

Knee Function Scores

The mean Lysholm score significantly improved from 65.1 ± 12.3 points (range, 30 to 95 points) preoperatively to 94.5 ± 7.0 points (range, 65 to 100) postoperatively ($P < .0001$). The Tegner activity level significantly improved from 3.1 ± 1.6 (range, 0 to 6) preoperatively to 6.1 ± 1.5 (range, 1 to 9) postoperatively ($P < .0001$). All patients returned to their preinjury activity level from 6 to 18 months postoperatively, and at final follow-up, 54% patients still had an equal or higher Tegner activity level in comparison with the preinjury level. The IKDC final evaluation showed grade A or B in 94% patients (146 of 156) and C or D in 6% patients (10 of 156) postoperatively, indicating a significant difference between postoperative and preoperative IKDC scores ($P < .0001$) (Table 4).

Patient Satisfaction

Of the patients, 81% (127 of 156) described subjectively feeling very satisfied, 12% (18 of 156) were satisfied, 4% (7 of 156) were unsatisfied, and 3% (4 of 156) were very unsatisfied.

Complications

The overall complication rate of ACL reconstruction with LARS artificial ligament is 5.7% (9 of 159). The cases in which reoperation was performed are shown in Table 5. One patient had superficial infection of the tibial incision during the first week postoperatively, and it soon healed after antibiotic treat-

ment. Femoral screw loosening out of the femoral contour occurred in 2 patients at 8 months and 10 months after surgery, respectively, and tibial screw loosening in 1 patient at 19 months after surgery. The screws partially exited from the extra-articular portion of the bone tunnels and caused regional pain on soft-tissue stimulation, but the knee stability was not influenced. The screws were readjusted and advanced into the bone tunnel again, after which the pain disappeared. One patient had pain on the thigh caused by residual artificial ligament outside the femoral tunnel, and the pain soon resolved after the residual artificial ligament was removed. One patient had patellar dislocation caused by sports trauma at 7 months after surgery, and second-look arthroscopy showed that LARS artificial ligament was fully covered by synovium and the ligament had good tension without a visible injury appearance. Three patients had recurrent knee instability caused by sports accidents at 16 months, 18 months, and 21 months after surgery, respectively. The 3 patients were identified as having rupture and loosening of LARS artificial ligament confirmed by second-look arthroscopy. Before revision surgery, both the tibial tunnel and femoral tunnel were found to be too anterior in 2 patients, and the tibial tunnel was too anterior in another patient (Fig 4). Second-look arthroscopy showed that LARS artificial ligament partially ruptured in 1 patient and completely ruptured in 2 patients. Of these, 1 patient showed obvious synovitis of the knee. The patient had persistent effusion and a positive floating patella test before second-look arthroscopy. There was no evidence of synovitis in all other patients by clinical examination and/or MRI at follow-up. The ruptured LARS artificial ligaments were removed and proper bone tunnels created. Two patients underwent quadruple HT autograft reconstruction, and the other patient underwent HT allograft revision surgery. The intra-articular portion of LARS artificial ligament covered by some autologous tissue was found in these 3 failed

TABLE 5. Cases Undergoing Second Operation

Reason	No. of Patients	Treatment
Femoral screw loosening	2	Femoral screw readjustment
Tibial screw loosening	1	Tibial screw readjustment
Traumatic patellar dislocation	1	Medial retinaculum suture
Artificial ligament rupture caused by tunnel malpositioning	3	HT autograft or allograft revision
Pain caused by residual artificial ligament outside femoral tunnel	1	Residual artificial ligament removal

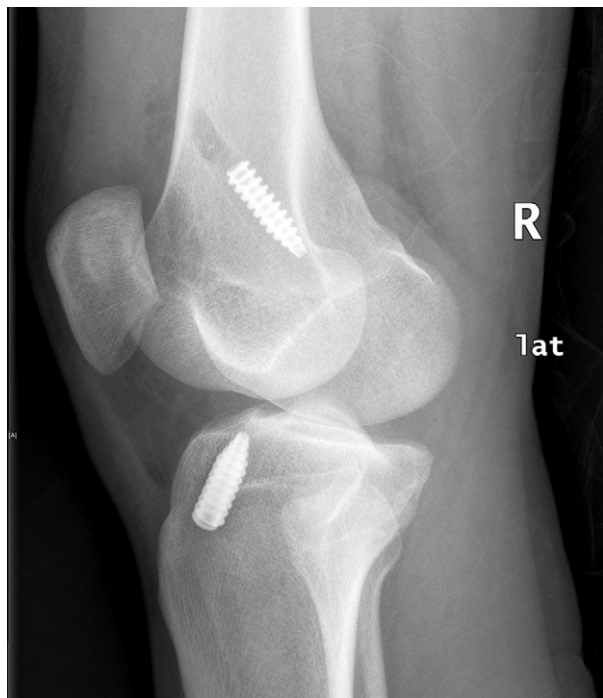


FIGURE 4. Radiograph of a patient who had graft rupture. The tibial tunnel was at the anterior of the extended line of the Blumensaat line in the knee extension position.

cases, and the connective tissue between LARS artificial ligament and bone tunnel was fibrous tissue.

DISCUSSION

This study evaluated the clinical results of ACL reconstruction with LARS artificial ligament with 50 months (range, 36 to 62 months) of follow-up after surgery and showed the effectiveness and safety of the procedure. Three patients had LARS artificial ligament rupture caused by accident; among them, only 1 patient presented with knee synovitis. At final follow-up, the failure rate of LARS artificial ligament was 4.4% (7 of 159). There was a low complication rate for ACL reconstruction with LARS artificial ligament.

This study showed that the result of LARS artificial ligament ACL reconstruction was similar to results in previous reports.^{15,19-21} Nau et al.¹⁹ reported a randomized clinical trial comparing LARS artificial ligament and BPTB autograft ACL reconstruction in patients with chronic ACL deficiency, and they reported that there was no synovitis in the 26 patients who underwent ACL reconstruction with LARS artificial ligament and there was no difference regarding the failure rate between the 2 groups at 24 months⁷

follow-up. Lavoie et al.²⁰ reported on 47 cases of ACL reconstruction using LARS artificial ligament with 8 to 45 months of follow-up after surgery, and good short-term results were obtained without symptoms or signs of synovitis or implant failure. Dericks¹⁵ reported that the failure rate was 4% in 220 cases receiving ACL reconstruction with LARS artificial ligament after a mean follow-up time of 2.5 years (range, 4 months to 4.5 years). More than half of those patients had chronic ACL injury (>6 months).

In this study 3 cases had fixation screw loosening and required reoperation to secure the screws. Nau et al.¹⁹ reported that 1 patient had recurrent knee instability caused by femoral fixation screw loosening 6 months after surgery and required reoperation and revision of the femoral fixation screw to stabilize the knee. In addition, Lavoie et al.²⁰ reported that 3 patients had failure of implant fixation and required reoperation to secure anchorage in bone. Dericks¹⁵ reported that 9 cases had graft rupture, and most cases of rupture occurred within 6 months, but the radiographs of the failure cases were not presented. In this study 3 patients had rupture of LARS artificial ligament proved by second-look arthroscopy. Although the ruptures of the 3 LARS artificial ligaments were directly caused by sports trauma, the fundamental failure reason was placement of the tibial tunnel and/or femoral tunnel too anterior. Because the tibial tunnel was at the anterior of the extended line of the Blumensaat line in the knee extension position (Fig 4), the graft would impinge with the notch in the knee extension position and cause graft rupture. Of the 4 patients with a 2+ pivot shift, 2 had malpositioning of the femoral tunnel and tibial tunnel. The correct tibial tunnel should be placed at 43% of the anterior-posterior length of the tibia on the lateral view. The second-look arthroscopy showed that the connective tissue between LARS artificial ligament and the bone tunnel was fibrous tissue, which was consistent with the literature about the healing between PET polyester artificial ligament and the bone tunnel.²⁹ Future studies should be focused on how to promote the bone integration between artificial ligament and the bone tunnel to improve therapeutic effect.

In this study the majority of cases had acute ACL injury and chronic ACL injury with a shorter history of injury, and all patients had available ACL stump. We preserved the stump of the ACL during ACL reconstruction with LARS artificial ligament to facilitate the growth of the fibroblasts of the ACL stump into LARS artificial ligament. There was no significant difference between acute cases and chronic cases

with regard to subjective and objective clinical results. In addition, meniscus injury did not affect the clinical outcome. Second-look arthroscopy showed that LARS artificial ligament of all patients was fully covered by autologous tissues except the 3 patients who had a ruptured LARS artificial ligament. Furthermore, the free fibers of the intra-articular portion of LARS artificial ligament entered the bone tunnel about 1 mm, and this design was used so that the abrasion of artificial ligament against the bone could be eliminated. The abrasion can cause liberation of particle debris of artificial ligament fibers, synovitis of the knee, and artificial ligament failure.³⁰ LARS artificial ligament overcomes the drawbacks of previous artificial ligament to some degree.

Although the initial tension strength of some previous prosthetic artificial ligaments was high, their capabilities of resisting flexion and torsion load were poor. The knee joint was subjected to various kinds of loads during the activities of daily living after ACL reconstruction, and abrasion of the prosthetic artificial ligament against the bone would lead to failure of permanent prosthetic ligaments.^{30,31} So the longevity of prosthetic artificial ligament was transient with a high failure rate.¹¹

Therefore artificial ligament scaffolds with an open-weave structure were developed.³¹ The scaffolds were expected to promote the ingrowth of autologous collagen fibrous tissue to improve the strength of artificial ligament and to avoid the abrasion and fatigue rupture of artificial ligament.³¹ In vivo, when fibrous tissue grew into the Leeds-Keio ligament and aligned along the lines of load, the ultimate strength of the Leeds-Keio artificial ligament increased to 2,000 N from 840 N.³¹ However, the majority of studies reported a high failure rate for artificial ligament scaffolds,^{12,32,33} and the failure was also caused by poor mechanics of resisting flexion and torsion load¹³ and insufficient growth into artificial ligament scaffolds of autologous tissue.⁹

Zaffagnini et al.³⁴ recently reported a histologic and ultrastructural study of an intact Leeds-Keio ligament 20 years after implantation. Their results showed that the Leeds-Keio ligament was fully covered by autologous tissue, and the histologic evaluation showed collagen fibril orientation very close to the structure of the normal ACL.³⁴ This study showed that when artificial ligament scaffold made of PET polyester was implanted into the knee, the ligament, as a nondegradable scaffold, could induce the fibroblast migration and regeneration of collagen tissue. Then, the tissue could remodel under physiologic load, and neoligament with good function could be obtained; thus good long-term clinical results were ensured.^{34,35} This is

consistent with the theory of tissue engineering ligament to some extent.

We do not want to compare superiority and inferiority between LARS artificial ligament and Leeds-Keio ligament. These 2 types of artificial ligaments are both made of PET polyester, so their biocompatibility may be similar. After ACL reconstruction, the condition of autologous tissue growth into these 2 types of artificial ligaments may be very similar.

Recently, Yu et al.¹⁸ reported the histology and ultrastructure of LARS artificial ligament after implantation for ACL reconstruction in rabbits. In 1 group LARS artificial ligament was used for ACL reconstruction, and the ACL remnant was preserved; in another group only LARS artificial ligament was used for ACL reconstruction, and ACL remnant was not preserved. In the group with ACL remnant preserved, it was shown that LARS artificial ligament was covered starting from 1 month after implantation and was fully covered from 3 to 6 months postoperatively, with progressive ligamentization by means of autologous collagen tissue growth into LARS artificial ligament.¹⁸ However, in the group with ACL remnant not preserved, LARS artificial ligament was not covered by anything up to 6 months after implantation, and no ligamentization was found.¹⁸ This study proved that LARS artificial ligament as a nondegradable scaffold in vivo could induce the growth of autologous collagen tissue and neoligament formation, which would increase the strength of LARS artificial ligament, avoid the abrasion of ligament fibers, and extend the longevity of the ligament.

Our study showed that LARS artificial ligament use is indicated for ACL reconstruction in patients with the ACL stump preserved, whether the injury is acute or chronic. The clinical results were good within 3- to 5-year follow-up with a low failure rate and complication rate. These results of ACL reconstruction using LARS artificial ligament are comparable to the results of autograft and allograft ACL reconstruction.^{1,2} We consider LARS artificial ligament to be an alternative graft for ACL reconstruction, especially for patients who are not willing to undergo autograft or allograft ACL reconstruction, multiple ligament reconstructions, and ACL revision surgery.

Limitations of this study were that it was a retrospective study and no control group was evaluated. The other limitation is that our mean follow-up time was 4 years (range, 3 to 5 years), and longer-term follow-up should be carried out to determine the mid-term clinical results of ACL reconstruction with LARS artificial ligament.

CONCLUSIONS

ACL reconstruction with LARS artificial ligament used in the patients with the ACL stump preserved in the acute and chronic phases has a very good outcome at a mean of 50 months' follow-up. The overall complication rate of ACL reconstruction with LARS artificial ligament is 5.7%, and knee synovitis developed in only 1 case.

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