The aim of this study was to evaluate the clinical results of anterior cruciate ligament (ACL) reconstruction with an artificial ligament of the Ligament Augmentation and Reconstruction System (LARS) via an 8–15-year follow-up. Between January 1996 and January 2003, 38 patients received arthroscopic anterior cruciate reconstruction with the LARS artificial ligament at the Show Chwan Memorial Hospital, Changhua, Taiwan. Among them, 28 cases were included in this study. Excluding two failure cases, 26 cases were involved in the statistical analysis of various clinical assessments. The mean follow-up period after reconstruction was 11.4 ± 1.9 years. Assessment of clinical results included physical examination, magnetic resonance imaging, radiography, KT-1000 arthrometer test for knee stability, range of motion measurement, Lysholm score, and Tegner scale activity evaluations. The outcomes showed that among these 28 follow-up patients, there were two failure cases. The survival rate of LARS ligament reconstruction in this long-term follow-up was 92.9%. Among the 26 clinical assessed cases, the stability of the knee joint was improved as the anterior translation displacement measured by arthrometer reduced from 7.0 ± 3.1 mm (range: 4–17 mm) pre-operatively to 1.7 ± 1.7 mm (range: 0–6 mm) post-operatively. The Lysholm score improved from 39.7 ± 11.5 pre-operatively to 85.9 ± 19.6 post-operatively. Tegner activity scale improved from 3.2 ± 1.5 pre-operatively to 5.4 ± 2.4 post-operatively. All three improvements have statistic significance as the p-values were less than 0.05. In conclusion, ruptured ACL reconstruction with LARS artificial ligament has a survival rate of 92.9% and complication rate of 28.6% in this 8–15-year follow-up.

Keywords: ACL reconstruction; LARS artificial ligament; Lysholm score; Tegner scale.

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1. Introduction

The reconstruction of the anterior cruciate ligament (ACL) of the knee joint can be achieved by allograft, autograft, and synthetic ligament replacement. Aside from the shortage in the tissue bank, allografts suffer the risks of disease transmission, immunological rejection, and early graft failure or laxity. Autologous tendon grafts were reported to have a satisfactory result in up to 90% cases in a 5–9-year follow-up. Nonetheless, several morbidities were reported and early physical rehabilitation after reconstruction was also influenced by this procedure. ACL reconstruction with a synthetic ligament is an alternative procedure to prevent the above complications. Unfortunately in the past, poor results in long-term follow-up studies hindered the usage of artificial ligaments. To address the past defects of the artificial ligament, new materials and design were developed for improvements. The LARS (Ligament Augmentation and Reconstruction System, Dijon, France) artificial ligament may offer better results. The fibers of this artificial ligament are arranged in a spiral configuration to mimic the native orientation of the ACL fibers and with unknotted free bundles of fibers in the middle segment to relief torsion load and reduce yarn-to-yarn abrasion. The short-term and mid-term clinical results of ACL reconstruction with the LARS artificial ligament have been reported with good outcomes. Orthopedic surgeons can expect to know the results of long-term follow-ups after reconstruction. However, there are few long-term retrospective studies present in the current literature.

We retrospectively evaluated 26 cases who received anterior cruciate ligament reconstruction using LARS artificial ligament at the Show Chwan Memorial Hospital in Changhua, Taiwan. The aim of this study was to evaluate the clinical results of anterior cruciate reconstruction with the LARS artificial ligament in an 8–15-year follow-up.

2. Patients and Methods

2.1. Patients

Between January 1996 and January 2003, 38 patients received arthroscopic anterior cruciate reconstruction with the LARS artificial ligament at the Show Chwan Memorial Hospital. Ten cases were lost to follow-up; the follow-up rate was 73.7%. Two cases suffered from complete or partial rupture of the LARS artificial ligament and were revised with autograft and total knee arthroplasty procedures respectively. Due to the explant of the LARS artificial ligament, these two patients were counted as failure cases and were not included in the statistical analysis of clinical assessments. In total, 26 patients (11 males and 15 females), were included in the clinical evaluation of the long-term surgical outcome. The mean age at the time of reconstruction was $36.1 \pm 12.5$ years old ($18–51$ years old). Clinical diagnosis of the ACL rupture was based on clinical examination, magnetic resonance imaging, and arthroscopic examination. Injury causes included motor vehicle accidents.
(20 cases), sport injuries (three cases), and through falling down (three cases). All surgical procedures were performed by the same orthopedic surgeon, Dr. Ming-Chou Ku, one of the authors. All patients were first informed about the benefits and risks of autografts for reconstruction and then those of ACL reconstruction with the LARS artificial ligament. The final method of reconstruction for the ruptured ACL was according to the patient’s decision. The average time between injury and operation was 1.7 ± 2.1 months with the reconstruction procedure of 19 acute cases within three months after injury, and nine chronic cases after 3 months. Concomitant surgeries were also performed: partial lateral meniscectomy in six cases, partial medial meniscectomy in two cases, lateral meniscus repair in three cases, and medial meniscus repair in one case. The mean follow-up period after reconstruction was 11.4 ± 1.9 years (8–15 years). The detailed demographic data are summarized in Table 1.

2.2. Operative procedure

The femoral isometric point was identified by preoperative radiography and the entire operative procedure was performed with an arthroscopy and C-arm fluoroscopy. Internal derangement of the knee was examined. The meniscectomy or repair of meniscus was performed if necessary. The knee was flexed about 110°. A Kirschner guide wire was drilled from the intercondylar notch of the lateral femoral condyle through the isometric point until it exited above the lateral femoral condyle. This procedure was assisted by the LARS ACL guide and C-arm fluoroscopy. The guide wire was progressively drilled through the center of the ACL remnants until it exited on the anteromedial face of the tibia. The femoral and tibia tunnels were enlarged with a cannulated reamer along with the Kirschner wire. The diameter of the drill hole was 7 mm for both the femoral and tibia tunnels. We

| Table 1. Demographic data of patients who underwent clinical assessment. |
|-----------------------------|------------------|
| Factor                      | Value            |
| No. of patients             | 26               |
| Male/female                 | 11/15            |
| Age of operation            | 36.1 ± 12.5 (18–51) |
| Reason for injury           |                  |
| Traffic accident            | 20               |
| Sports injury               | 3                |
| Falling down                | 3                |
| Time between injury and operation (mean) | 1.7 ± 2.1 months |
| Meniscus operation          |                  |
| Partial lateral meniscectomy| 6                |
| Partial medial meniscectomy | 2                |
| Repair of lateral meniscus  | 3                |
| Repair of medial meniscus   | 1                |
| Follow-up period (mean)     | 11.4 ± 1.9 years |
ensured that the longitudinal free fiber of the LARS artificial ligament remained intra-articular. The distal stumps of the LARS artificial ligament were fixed by interference titanium screws of 8 mm in diameter after adjusting the adequate tension of the implanted artificial ligament.

2.3. Post-operative care and rehabilitation

Anti-inflammatory medication was prescribed for five post-operative days. Quadriceps contraction training started on the first three post-operative days. On the following days, patients were encouraged to walk with partial bearing using bilateral axillary crutches for two to four weeks. Four weeks later, patients were encouraged to walk without using crutches and gradually went back to daily life activities. Patients were allowed to return to pre-operative sports (if any) after six months.

2.4. Clinical assessment

We followed and examined all patients, including factors such as symptoms and signs, stability of the knee, life and sports activities, as well as the range of motion of the knee in the outpatient department (OPD). Effusion of the knee and unstable knee were evaluated with magnetic resonance imaging and radiography to determine whether there was synovitis, loosening of the interference-fit titanium screws, or other abnormal findings. The Lysholm knee function score was used to assess the everyday activity limitation. The Tegner activity scale was used to evaluate the specific activities.\textsuperscript{15}

Standard postero-anterior weight-bearing radiographs were taken with the knee joint in 30° of flexion.\textsuperscript{16} To estimate the minimum joint space width in the medial tibiofemoral compartment, the knee radiographs were digitized with a laser film digitizer and the radiographic magnification corrected with a computer software. The joint space was graded as normal, narrowing but greater than 4 mm, 2–4 mm, and less than 2 mm.

2.5. Statistics

All measurements were expressed as mean and standard deviation. Paired $t$-test for paired data, before and after surgery, was used for statistical analysis. A probability level of $p$-value less than 0.05 was considered to be statistically significant.

3. Results

All 26 patients were followed for 8–15 post-operative years, average 11.4 ± 1.9 years, after ACL reconstruction with the LARS artificial ligament. There were four patients where instability of the operated knees occurred. Case 3 experienced distal end loosening of the artificial ligament due to a loosening screw in the tibia bone seven months after the reconstruction procedure. The loosening screw was replaced
by one with a larger diameter. A staple was used to fix the artificial ligament at the exterior eight months after the ACL reconstructive procedure (Table 2). Case 4 experienced loosening of the artificial ligament due to strenuous exercise three years after the reconstruction procedure. One case experienced synovitis two months after the reconstruction procedure. The patient received medical treatment and conservative treatment, and symptoms improved two weeks later. Another case suffered from severe synovitis 10 years after the reconstruction procedure. The patient underwent arthrocentesis to relieve the pain and swelling of the knee joint, and also received medical treatment and symptoms were alleviated one month later. There were two cases which experienced stiffness of the knee joint six weeks after the reconstruction procedure. These patients received manual manipulation under intravenous anesthesia to improve the range of motion.

Degenerative changes were found in 53.8% (14 out of 26 cases) of the reconstructed knees (Fig. 1).

<table>
<thead>
<tr>
<th>Joint space</th>
<th>No. of subjects ($n = 26$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>normal</td>
<td>12</td>
</tr>
<tr>
<td>&gt;4 mm</td>
<td>12</td>
</tr>
<tr>
<td>2–4 mm</td>
<td>2</td>
</tr>
<tr>
<td>&lt;2 mm</td>
<td>0</td>
</tr>
</tbody>
</table>

Fig. 1. Number of cases of normal and degenerative changes. To estimate the minimum joint space width in the medial tibiofemoral compartment of the knee, knee radiographs were digitized with a laser film digitizer and the radiographic magnification corrected with a computer software.
3.1. **Knee stability**

Pre-operative and post-operative distances of the anterior translation of the knee were measured with a KT1000 arthrometer. The average preoperative value of anterior translation was 7.0 ± 3.1 mm (range: 4–17 mm). The average post-operative value of anterior translation was 1.7 ± 1.7 mm (range: 0–6 mm). A comparison between preoperative and post-operative distances of anterior translation of 26 patients revealed significant improvements ($p < 0.05$) (Table 3).

3.2. **Range of motion**

One case had a 4° extension and 110° flexion deficit, and two cases had a 6° and 10° extension deficit respectively. The rest of the cases had a normal range of motion, and comparing to a 13- to 74-year-old group of normal subjects: extension 0° to 1.6°; flexion 131° to 150°.17–19

3.3. **Knee function scores**

The Lysholm score improved from 39.7 ± 11.5 points pre-operatively to 85.9 ± 19.6 points post-operatively ($p < 0.05$) (Fig. 2). This improvement was statistically significant.

![Fig. 2. Mean Lysholm Scores. Preoperative (left) and post-operative (right) follow-up after mean 11.4-year follow-up.](image-url)
The Tegner activity scale improved from 3.2 ± 1.5 preoperatively to 5.4 ± 2.4 post-operatively \((p < 0.05)\) (Fig. 3). This improvement was also statistically significant.

4. Discussion

One of post-operative cases (No. 1) suffered from complete rupture of the LARS artificial ligament (diagnosed by arthroscopic diagnosis) and received the bone-patellar tendon-bone (BPTB) autograft to resolve this complication. Case 2 developed severe instability of the operative knee due to partial rupture of the LARS artificial ligament (Fig. 4). The patient agreed to excise the implanted LARS artificial ligament and total knee arthroplasty was performed because she was afflicted with severe osteoarthritis of the knee. The explanted LARS ligament received mechanical analysis with mechanical test systems (MTS 858 Mini Bionix, MTS Systems Corp., MN) and an examination by scanning electron microscopy (JEOL JSM-6390LV). Both above cases were not involved this follow-up study.

Gao et al. reported that the Lysholm score improved from 65.1 ± 12.3 points pre-operatively to 94.5 ± 12.0 points post-operatively with 3- to 5-year mid-term follow-up in 159 patients. In their study, the Tegner score improved from 3.1 ± 1.6 pre-operatively to 6.1 ± 1.5 points post-operatively. In our study, the results of the Lyshom scores improved from 39.7 ± 11.5 points pre-operatively to 85.9 ± 19.6 points post-operatively. The Tegner score improved from 3.2 ± 1.5 points pre-operatively to 5.4 ± 2.4 points post-operatively. Also here, the outcome of the assessment of life and sports activity with a mean 11.4-year follow-up in 26 cases maintained good results. Ruiz et al. reported that there was no significant difference of post-operative osteoarthritis of the knee after different reconstructive procedures.
of ruptured ACL between BPTB and LARS artificial ligaments. Clinical results of this study were similar to the previous study. In other words, it showed the effectiveness of reconstructing the ACL with a LARS artificial ligament with a mean 11.4-year follow-up. Early reconstruction of the ruptured ACL is believed to improve the function of the knee and decrease the osteoarthritis incidence of the knee.

Furthermore, Lavoie et al. reported that there was no synovitis after reconstruction with the LARS artificial ligament with 8–45 months of follow-up after surgery. Gao et al., on the other hand, reported one case from 159 cases which developed knee synovitis. Although Trieb et al. reported the PET (polyethylene terephthalate) of the LARS artificial ligament had good biocompatibility, and two patients experienced synovitis in this study.

Although tissue ingrowths of the implanted LARS artificial ligament was expected to enhance strength, Kock et al. reported increasing tissue infiltration of the PET artificial ligament prostheses 3–12 months after implantation under investigation by scanning electron microscopy. In this explanted LARS artificial ligament (Case 2), the tissue infiltration was also noted, but it was scant (Fig. 5). There does not seem to be any supporting function. Kock et al. also reported foreign body cells and round cells were found in the vicinity of the PET fibers. In our early study, the buried PET fibers in the subcutaneous tissue of pigs were surrounded by foreign body cells in 12.2% of the fibers and the ultimate strength decreased by 23.53%. Marchant et al. demonstrated that phagocytes would destroy the material by acid phosphatase. In this mechanical study of the explanted LARS artificial ligament (Case 2), we showed the reduction of the ultimate tension strength to 1,264 N from original 4,720 N. The length of the unknotted middle part of the explanted LARS artificial ligament elongated to 58 mm from the original 27 mm (Fig. 6).
The main limitation of this study was similar to other retrospective studies in long-term follow-up — losing 10 cases (27.8%). It is essential to evaluate more clinical cases on a long-term basis before concluding the benefits of LARS artificial ligament reconstruction.

Fig. 5. Scanning electron microscopy of the explanted LARS artificial ligament showing scant soft tissue adhered to the surface of PET fibers of the artificial ligament (magnification: × 500).

The main limitation of this study was similar to other retrospective studies in long-term follow-up — losing 10 cases (27.8%). It is essential to evaluate more clinical cases on a long-term basis before concluding the benefits of LARS artificial ligament reconstruction.

Fig. 6. Tension testing of partial rupture of the explanted LARS artificial ligament revealed the ultimate tension strength decreasing to 1,264 N. The length of the unknotted middle part elongated to 58 mm.
5. Conclusion

Ruptured ACL reconstruction with LARS artificial ligament was demonstrated to have good results in improving life function and activity according to assessment via the Lysholm score and Tegner activity scores of at least eight years of follow-up and a mean of 11.4 years.

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References


