Clinical and functional outcome after anterior cruciate ligament reconstruction using the LARS™ system at a minimum follow-up of 10 years

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A B S T R A C T

Background: Since the 1980’s several artificial ligaments were used for reconstruction of the anterior cruciate ligament (ACL) serving different complications. The aim of this study was to assess the clinical and functional outcomes of primary ACL reconstruction using the Ligament Augmentation Reconstruction System (LARS™) with a minimum follow-up of 10-years. The LARS™ presents a synthetic material consisting of non-absorbing polyethylene terephthalate fibres used for ligament reconstruction.

Methods: Outcomes of 18 patients who underwent arthroscopic ACL reconstruction using the LARS™ system between 2000 and 2004 with a minimum follow-up of 10-years were observed. The International Knee Documentation Committee score (IKDC), Visual Analog Scale (VAS), Lysholm score, and Tegner Activity Scale were assessed. Clinical assessment was performed by Lachman testing, assessment of side-to-side difference on KT-2000 testing and plain radiography evaluation of osteoarthritis.

Results: There were seven males and 11 females, mean age 29 years (range, 18 to 44 years) and a mean follow-up of 151.5 months. Five patients (27.8%) sustained a re-rupture of the LARS™ system and underwent revision surgery after a mean time of 23 months and four patients (22.2%) presented with a re-rupture. The average IKDC score was 76.60 ± 18.18, the average Lysholm score was 88.00 ± 10.07 and the average Tegner activity score was five at final follow-up.

Conclusion: Our results indicate that the LARS™ system should currently not be suggested as a potential graft for primary reconstruction of the ACL in special cases, however, the LARS™ system can serve as an alternative graft. Level of evidence: Level IV, retrospective study.

1. Introduction

Since the 1980s several artificial ligaments (Carbone fibre®, Dacron®, Gore-tex®) have been developed to serve as an alternative to biological grafts for reconstruction of the anterior cruciate ligament (ACL) [1]. Artificial ligaments became highly attractive for orthopaedic surgeons at that time due to the lack of donor side morbidity and the ability of early return to sport activities [2]. Accelerated rehabilitation, immediate knee stability and full weight bearing following surgery were feasible compared to biological grafts [3] thus leading to encouraging results in the short-term [4,5]. Despite the initial enthusiasm, clinical research revealed a high percentage of complications in the long-term such as mechanical failures (prosthetic components breakage, fixation loss), synovial complications (foreign body synovitis), chronic effusions, recurrent instability and early knee osteoarthritis [6,7]. According to these serious drawbacks, the use of artificial ligaments has decreased over the past two decades [7].

Nevertheless, as a result to the development of new biomaterials, improved understanding in design and more accurate surgical procedures, the interest in artificial grafts for reconstruction of the ACL has gained popularity again [8]. Although the use of artificial ligaments has been discussed critically in the literature [7,9], LARS™ ligaments (Ligament Advanced Reinforcement System, Surgical Implants and Devices, Arc-sur-Tille, France) has been reported to be a suitable material for ACL reconstruction [3,5,9–12]. As if history would repeat itself, clinical results in the long-term are again lacking in the literature to confirm the safety and effectiveness of the LARS™ system as a suitable graft for the reconstruction of the ACL.

Therefore the purpose of this study was to evaluate the functional outcome, safety and effectiveness of the LARS™ ligament following primary, isolated ACL reconstruction at a single institution with a minimum follow-up of 10-years.

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2. Material and methods

This study was a retrospective analysis of prospective collected data of all patients who had undergone primary, isolated ACL reconstruction using the LARS™ system from a single institution between 2000 and 2004. All patients demand a quick return to full knee stability and quick return to sport activity and therefore were treated with the LARS™ system (Fig. 1.).

Exclusion criteria were as follows: (1) age younger than 18 years; (2) multiple ligament injuries; (3) chondral lesions greater than grade 3 according to the Outerbridge classification [13], (4) additional injuries to the collateral ligaments greater than grade 2 and (5) clinical follow-up of less than 10 years. Outcome measures at final follow-up included validated objective and subjective assessment scores such as the Lysholm score, Tegner Activity Score, Visual Analog Scale (VAS) and International Knee Documentation Committee (IKDC) score; clinical assessments such as measuring the range of motion (ROM), Lachman testing and side-to-side difference using a knee laxity testing device (KT-2000; MEDmetric, San Diego, USA). A side-to-side difference of five millimetres, compared to the contralateral, non-injured knee was defined as clinically unstable (clinical re-ruptured). Patients treated secondarily with a bone tendon bone implant were classified as LARS™ ligament failure (re-rupture). Extension weight-bearing anterior–posterior (AP) and lateral radiography were performed to grade the osteoarthritic status of knee according to the Kellgren–Lawrence grade [14]. All patients underwent a standardized rehabilitation programme at this department starting directly after the surgery and all patients were able to return to sport activity (pivoting sports) after a mean of four months. Finally patients were divided into three groups: (1) intact LARS™ ligament, (2) re-ruptured LARS™ ligament that was treated non-operatively and (3) re-ruptured LARS™ ligament that was treated operatively with an autologous graft. ACL reconstruction was performed as previously described with a trans-tibial technique [15] by experienced knee surgeons. Interference screws were used as fixation methods. All patients signed informed consent prior to participation. Institutional review board approval was obtained for this study.

2.1. Statistical analysis

Descriptive data (mean, median, range, proportions) are reported for the entire patient cohort. Differences between means and proportions were tested with the Chi-square test for categorical variables and the unpaired t-test for continuous variables. A probability value of \( p \leq 0.05 \) is considered statistically significant. All calculations were made using Microsoft Excel® and SPSS® software (Version 21.0, SPSS Inc., Chicago, IL, USA).

3. Results

A total of 26 patients underwent primary, isolated ACL reconstruction utilizing the LARS™ system of which 18 (70%) patients were available for long-term follow-up (minimum 10 years). There were seven males (38.8%) and 11 females (61.2%) with a mean age of 29 years (median, 29 years; range, 18 to 44 years). The mean follow-up was 151 months (median, 151 months; range, 120 to 165 months). None of the patients received surgical intervention of the operated knee prior to ACL reconstruction. Time between injury and surgery was in mean 10 days (median, seven days; range three to 60 days). In two patients a partial meniscectomy was performed. All patients were able to return to sport activity (pivoting sports) after a mean of four months (median, 3.5 months; range, 2.5 to 5.0 months).

According to the criteria mentioned in the Material and methods section patients were divided into three groups presenting a significant difference regarding the groups in evaluated scores (IKDC, Lysholm, Tegner Activity Score) according to patient’s outcome; details are presented in Table 1.

All but six patients were evaluated by the KT-2000 testing device at final follow-up revealing in four patients a side-to-side difference of \( \geq 5 \) mm leading to the assumption of a re-rupture of the LARS ligament. A mean side-to-side difference of 1.3 mm (range: 0 mm to four millimetres) was assessed in the group of ‘revision LARS’. In the ‘intact LARS’ group the mean side-to-side difference was 1.5 mm (range: 0 mm to three millimetres). The ‘stable LARS’ group presented with a mean side-to-side difference of 5.3 mm (range: 0 mm to nine millimetres).

There was a significant difference between KT-2000 measurements; showing significant higher measurements in unstable LARS™ compared to intact LARS™ (\( p = 0.0113 \)); intact LARS™ versus re-operated LARS™ and intact LARS™ against re-operated LARS™ revealed no significant difference (\( p = 0.1217, p = 0.1324 \)); although the re-operated group presented with significant lower scores according to the outcome as presented in Table 1.

ROM significantly improved over time to a ROM at latest follow-up with a mean of 0–140°. There was no significant side-to-side difference or difference according to evaluated groups.

Complications were observed in 10 patients (56%). One patient sustained a superficial surgical site infection, which was treated with oral antibiotics (Cefuroxim 1.5 g three times a day) after a wound-healing disturbance. Two patients revealed a delayed deep surgical site infection after 19 and 25 months. In one patient the LARS ligament had to be removed followed by the implementation of a suction and irrigation system until the infection parameter decreased. Finally a bone tendon bone graft was used for secondary stabilisation. The second patient underwent multiple revisions (n = 7) due to persisting effusions and infections. The LARS ligament was also removed followed by a secondary stabilisation using a bone tendon bone graft. Both patients, however, remained clinically unstable at final follow-up. In one patient the interference screw had to be removed due to persisting pain. A total of five graft breakages (27.8%) occurred during the follow-up period. In three patients a new trauma during sport activity was the reason for graft re-rupture, while an infection was lead to the removal of the graft in the other two patients. In all two cases a bone tendon bone graft was used and in one patient the semitendinosus tendon was used during the revision procedure. Four patients (22%), who denied a new knee surgery, presented with an unstable knee, positive Lachman testing and a side-to-side difference of \( \geq 5 \) mm, thus revealing an insufficiency of the LARS ligament.

In 11 (61%) patients anterior–posterior and lateral radiograph views were available at final follow-up and were compared to the radiographic views taken prior to primary ACL reconstruction. The remaining patients refused to undergo radiographic evaluation of the knee due to personal reasons.

Of this cohort, seven patients showed radiological signs of osteoarthritis. Kellgren–Lawrence Score increased from one (0 to two) to two (0 to four) in mean at latest follow-up. In seven patients the Kellgren–Lawrence Score decreased between primary X-ray and final follow-up X-ray (Table 2). In five patients a Kellgren–Lawrence Score of two, in one patient a score of four, in one patient a score of three, in one patient a score of one and in three patients a score of 0 was detected at final follow-up.

Almost one half of the patients (eight patients, 44.4%) were subjectively not satisfied with the surgical result following primary LARS™ implantation.

4. Discussion

The most important finding of the present study was that nearly half of the patients revealed a graft failure at a minimum follow-up of 10 years following ACL reconstruction using the LARS™ system and that seven out of 11 patients showed radiographic signs of early osteoarthritis compared to the radiographs taken prior to primary ACL reconstruction. Overall 40% were not satisfied with the clinical and functional outcome following LARS™ reconstruction. However, these findings are not consistent with the results published so far.
In 1995 Dericks et al. [15] presented the first clinical report on 220 patients that were treated with the LARS™ augmentation. At a mean follow-up of 2.5 years none of the patients showed any signs of synovitis or serious complications. Newman et al. [16], in their review article, reported an overall complication rate of 2.5% (n = 675) at short- and midterm follow-up which is comparable to the failure rate achieved in autologous hamstring ACL reconstruction. Complications such as surgical side infections or interference screw-related issues were reported infrequently [16]. This low complication rate is in contrast to the present study where nearly half of the patients showed complications and a graft failure at final follow-up. This contrast has one potential theory: the range of follow-up plays a crucial role in determining the clinical and functional outcome following ACL reconstruction. While a two years follow-up period is required as a minimal follow-up for most journals, clinical and functional outcome in the long-term such as five and 10 years postoperatively is of utmost importance, especially when artificial grafts were used for reconstruction.

In order to avoid this drawback, we have searched for all papers reporting the functional and clinical outcome using the LARS™ system for ACL reconstruction at a minimum follow-up of five years. Only two articles were available with a total of 51 patients included. Parchi P. et al. [5] presented in their study with a mean follow-up of 95.3 months 16 optimal results and eight good results, with a fast functional recovery and a high knee stability. In only one patient a graft failure occurred after 58 months and in two patients the stability of the ACL reconstructed knee was described as poor using the Rollimeter Aircast™. Global poor results were reported in two cases, but no major complication (e.g. infection, knee synovitis) was reported [5]. Cerulli et al. [17] presented in their study with a mean follow-up of nine years good results in 95% of the ACL reconstructed patients. There was no graft failure or case of knee arthritis presented. Patients in this study presented with an average age of 46 years, which is higher, compared to our collective (mean 32 years) and the current literature [9–11]. Therefore this collective may not represent the typical ACL reconstruction patient. Older patients may have different expectations and functional goals and therefore might report lower rates of different complications. We cannot conclude this encouraging results found in literature concerning long-term outcome of these two papers after using LARS™ system as reconstruction method for the ACL [5,10,18] as it is also concluded by Savarese et al. [6]. Our complication and re-rupture rate is quite high compared to previous presented long-term follow-up studies [5,6]. Therefore others might underestimate the high complication rate of artificial ligaments according to a selection bias.

Nevertheless, there are special indications described in literature for the use of the LARS™ system. Hamido F. et al. [11] presented the potential use of LARS™ as ligament support for undersized hamstrings, reporting good outcome after a mean follow-up of 45.2 months. In addition, the LARS™ system might be considered in a patient who needs fast recovery and understand all the possible complications and the high long-term failure rate [2]. Despite these findings the autologous graft remains still the “gold standard” of ACL reconstruction, with a lower rate of complications and re-ruptures, especially in younger patients [19].

Nevertheless readers have to be aware of the limitations of this study including its retrospective design, the use of the trans-tibial technique, investigating patients over a time period of four years and the small patient number. However, to the best of our knowledge, this is the first study investigating LARS™ system for ACL reconstruction at a long-term follow-up of minimum 10 years.

5. Conclusion

Our results indicate that the LARS™ system should currently not be suggested as a potential graft for the primary reconstruction of the ACL. However, we should keep in mind that high-quality controlled studies with long-term follow-up should determine whether artificial ligaments have become an effective and safe graft option and, most importantly, do no harm patients.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgments

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References


Table 1
Mean evaluated scores (IKDC, Lysholm, Tegner Activity Score, VAS) according to the three groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>IKDC</th>
<th>Lysholm</th>
<th>Tegner Activity Score</th>
<th>Number of patients</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>86.07</td>
<td>93.43</td>
<td>6</td>
<td>8</td>
<td>0.0015*, 0.0153**</td>
</tr>
<tr>
<td>2</td>
<td>85.54</td>
<td>90.60</td>
<td>5</td>
<td>5</td>
<td>0.0033*, 0.0146**</td>
</tr>
<tr>
<td>3</td>
<td>54.20</td>
<td>77.80</td>
<td>4</td>
<td>4</td>
<td>0.0063*</td>
</tr>
</tbody>
</table>

Values are presented in means.

Table 2
Detailed overview of evaluated Kellgren Lawrence Scores.

<table>
<thead>
<tr>
<th>Pat. number</th>
<th>Primary X-ray RKL</th>
<th>X-ray at latest FUP RKL</th>
<th>Age at latest X-ray</th>
<th>Revision surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>n.a.</td>
<td>–</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>n.a.</td>
<td>–</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>2</td>
<td>40.93</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>3</td>
<td>31.10</td>
<td>Yes/multiple</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>1</td>
<td>42.12</td>
<td>None</td>
</tr>
<tr>
<td>6</td>
<td>0</td>
<td>n.a.</td>
<td>–</td>
<td>None</td>
</tr>
<tr>
<td>7</td>
<td>0</td>
<td>2</td>
<td>38.19</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>0</td>
<td>n.a.</td>
<td>–</td>
<td>None</td>
</tr>
<tr>
<td>9</td>
<td>0</td>
<td>0</td>
<td>50.46</td>
<td>None</td>
</tr>
<tr>
<td>10</td>
<td>0</td>
<td>n.a.</td>
<td>–</td>
<td>None</td>
</tr>
<tr>
<td>11</td>
<td>0</td>
<td>2</td>
<td>51.68</td>
<td>None</td>
</tr>
<tr>
<td>12</td>
<td>1</td>
<td>2</td>
<td>45.73</td>
<td>Yes/multiple</td>
</tr>
<tr>
<td>13</td>
<td>0</td>
<td>2</td>
<td>38.67</td>
<td>Yes/multiple</td>
</tr>
<tr>
<td>14</td>
<td>0</td>
<td>0</td>
<td>48.76</td>
<td>None</td>
</tr>
<tr>
<td>15</td>
<td>2</td>
<td>4</td>
<td>56.24</td>
<td>None</td>
</tr>
<tr>
<td>16</td>
<td>0</td>
<td>0</td>
<td>31.62</td>
<td>None</td>
</tr>
<tr>
<td>17</td>
<td>0</td>
<td>n.a.</td>
<td>–</td>
<td>Yes/multiple</td>
</tr>
<tr>
<td>18</td>
<td>0</td>
<td>n.a.</td>
<td>–</td>
<td>Yes/multiple</td>
</tr>
</tbody>
</table>

FUP — follow-up; RKL — Kellgren-Lawrence Score; n.a. — not available; Pat — patient.


