My experience with the LARS ACL device at minimum 5 year follow up

Cameron J Norsworthy, MB.BS., FRACS (Australia)

Co-authors: Scott J Tulloch, Brian M Devitt, Tabitha J Porter, Taylor R Hartwig, Haydn J Klemm

2017 ISAKOS Congress

15:50, Wednesday June 7

Background

The early synthetic ligament devices, first introduced in the 1970s, yielded poor clinical results. High failure rates were reported in the literature from many countries, including USA, UK, Sweden, Spain, Germany, Belgium, and Netherlands. [1-15] The main problems associated with these designs included the accumulation of debris material within the knee, the development of synovitis or sterile effusions, and mechanical failure of the ligament whether by creep, fatigue, or traumatic rupture. The use of these synthetic ligament devices was ceased by the early 1990s.

A decade later, there was renewed interest and enthusiasm for the use of synthetic devices to treat the anterior cruciate ligament (ACL) injured knee, particularly in certain centres around the world. The most popular of these devices was the Ligament Augmentation and Reconstruction System (LARS ®), developed in France. The specific intention of this design was to allow "healing" of the acutely or sub-acutely injured ACL through a process of soft tissue internal fixation. This method was promoted as allowing a more rapid return to activity than traditional ACL reconstruction, whilst eliminating the need for autogenous tissue harvest. The technique for its use was first described in 1995[16].

Purpose

The main purpose of this study was to determine the clinical and functional outcome of an entire single surgeon cohort of patients who underwent primary LARS surgery to treat their ACL injured knee, at a minimum 5 years post-surgery. Of particular interest was the rate of complications, specifically failure of the LARS ACL construct, and the development of synovitis or sterile effusions.

Study design

Cohort study; Level of evidence, 3

Methods

The study cohort consisted of 54 patients who underwent LARS ACL surgery by a single surgeon between the dates of 9/7/2007 and 16/5/2012. This represents the entire group of patients in whom this technique was used. To put this in perspective, a further 305 patients underwent primary ACL reconstruction using autogenous tissue grafts by the surgeon during the same period. Therefore, the LARS device was used in 15% (54/359) of the surgeon's primary ACL operations during the time period in question.

The LARS option was offered only to those patients who specifically requested the technique, or those who required a rapid return to activity without the use of allograft tissue. The described surgical technique[16] was followed in all cases, with particular attention to stump preservation, attempted suture repair, and "outside-in"

tunnel drilling and screw fixation. Importantly, if a patient was found intra-operatively to have a poor quality ACL stump, the LARS technique was abandoned. In this situation, autogenous hamstring tissue was used, and a traditional ACL reconstruction performed. Such patients are therefore not included in this study.

Follow-up of the cohort commenced in October of 2016, and was completed in May 2017. 17 patients had a failure of the LARS ACL construct confirmed by subsequent surgery either before, or at the time of their follow-up evaluation. All information pertaining to the failure of the LARS ACL construct was collected, including histological specimens in a number of cases. A further 32 patients presented for an independent clinical assessment (range of motion, KT-1000, hop test) and completed patient reported outcome measure surveys (IKDC and SF-36). 5 patients were not available for follow-up.

Results

The total cohort of 54 patients consisted of 32 males and 22 females, with a mean age of 36.5 years (19 - 58 years) at the time of the LARS ACL surgery. The mean delay between sustaining the ACL injury and undergoing the LARS ACL surgery was 85.6 days (4 - 421 days). The overall follow-up rate was 90.7% (49/54).

17 patients (31.2%) had suffered a confirmed failure of the LARS ACL construct. In all cases, confirmation of failure was made at the time of further surgery: 16 at an arthroscopic procedure, 1 at total knee arthroplasty (TKA). 15 of these cases were treated by the same surgeon, 2 by different surgeons. In all cases the operative record of the subsequent surgery was reviewed along with histological findings, where obtained.

On inspection of the failed LARS ACL construct in these 17 patients, none had more than approximately 50% native tissue coverage of the LARS device, indicating poor incorporation of the synthetic material, and a failure to achieve ACL “healing”. Furthermore, of these 17 failures, 7 had visible evidence of synovitis at the time of their subsequent surgery, with biopsies taken. In all 7 the histology showed chronic synovitis with a giant cell foreign body reaction (mild in 5, moderate in 2). The removed LARS material was also assessed histologically, with varying amounts of hypocellular collagen infiltrate demonstrated around the fibres of the LARS device. 11 patients underwent revision ACL reconstructive surgery (4 in a single stage, 7 as a 2 stage procedure), 1 underwent TKA, and the remaining 5 had arthroscopic surgery to remove the failed LARS device but not reconstruct the ACL.

The remaining 32 patients (59.3%) did not have a surgically confirmed failure of the LARS ACL construct, and were reviewed at a mean of 7.9 years after the index LARS ACL surgery (6.0 - 9.4 years). The mean IKDC score for the cohort was 86.2 (24.7 - 100). The mean SF-36 scores for each domain were: Physical functioning 90.3, Role limitations due to physical health 98.5, Role limitations due to emotional problems 88.5, Energy / fatigue 63.7, Emotional well - being 78.6, Social functioning 92.2, Pain 85.2, General health 77.8.

Range of motion was tested, with no statistically significant side-to-side difference in all measurements (standing knee flexion range, supine active flexion range, supine passive flexion range, extension range).

The mean side-to-side difference in anterior laxity (measured at 30lbs, KT-1000) was 1.0mm, which was not statistically significant. 2 of the 32 patients recorded a side-to-side difference of greater than 5mm (6mm for each). With these 2 results removed, the mean side-to-side difference in anterior laxity becomes 0.7mm for the remaining 30 patients.

In addition, 4 of the 32 patients had undergone a subsequent arthroscopic procedure between their index LARS ACL surgery and the cohort follow-up. All 4 arthroscopic procedures were performed by the same surgeon, at a mean of 953 days (308 - 1930 days) or 2.6 years (0.8 - 5.3 years) after the index LARS ACL surgery. The indications

for the subsequent arthroscopic procedures were LM tear in 2, MM tear in 1, and debridement of a cyclops lesion in 1. In each case the knee was stable when examined under anaesthetic, and in each the LARS ACL construct was intact at arthroscopy, but the degree of fibrous tissue incorporation was variable. In only 1 patient was complete incorporation of the LARS device demonstrated. There was mild, but visible synovitis in 2 of these patients with histological confirmation in 1, but no biopsy performed in the other.

When the entire cohort is considered together, 21 have undergone further surgery subsequent to the index LARS ACL procedure. Given 5 patients were unable for follow-up, the rate of reoperation was therefore 42.9% (21/49). Of these 21 re-operated patients, 9 had visible or histologically proven synovitis, at a rate of 18.4% (9/49)

Conclusion

The primary purpose of this study was to accurately define the failure rate of the LARS ACL construct in a cohort of patients who underwent this surgery using the designing surgeon's operative technique. We have demonstrated a confirmed failure rate of 31.2%. It has been described previously that a side to side difference in KT-1000 measurement between the operated knee and the contralateral, non-operated knee of greater than 5mm is indicative of ACL deficiency[17]. Using this criteria, 2 of the 32 patients examined qualify based on their results, and when added to the 17 confirmed LARS ACL construct failures, the total cohort failure rate becomes 19/54 (35.2%)

Furthermore, this study provided the opportunity to review the findings of "second look" surgeries, with all 17 of the confirmed failures, and 4 of the remaining patients, undergoing operations at a time subsequent to their index LARS ACL surgery. It was demonstrated that the process of native ACL and fibrous tissue incorporation with the LARS device is variable, being seen in only 1 of the 21 patients. Chronic synovitis, with a giant cell foreign body reaction, was seen in 9 of the 21 patients.

The rates of LARS ACL construct failure (35.2%) and synovitis (18.4%) are both considerably higher than those published previously[18-25]. When compared to the well established clinical and functional outcomes of autologous tissue ACL reconstructions[26-27], we find the LARS device to be inferior in treating the ACL injured knee.

References

1. **Funk J.** Synthetic Ligaments – Current Status. *Clin Orthop 1987; 219: 107-111*
2. **James SL, Woods GW, Homsey CA, Prewitt JM, Slocum DB.** Cruciate ligament stents in reconstruction of the unstable knee. A preliminary report. *Clin Orthop 1979; 143: 90*
3. **Arnauw G, Verdonk R, Harth A, Moerman J, Vorlat P, Bataillie F, Claessens H.** Prosthetic versus tendon allograft replacement of ACL-deficient knees. *Acta Orthop Belg 1991;57-Suppl 2:67-74.*
4. **Strum G, Larson RL.** Clinical experience and early results of carbon fiber augmentation of anterior cruciate ligament reconstruction of the knee. *Clin Orthop 1985; 196: 124*
5. **Weiss AB, Blazina ME, Goldstein AR, Alexander H.** Ligament replacement with an absorbable copolymer carbon fiber scaffold. Early clinical experience. *Clin Orthop 1985; 196: 77*
6. **McPherson GK, Mendenhall HV, Gibbins DF, Plenk H, Rottman W, Sanford JB, Kennedy JC, Roth JH.** Experimental mechanical and histologic evaluation of the Kennedy ligament augmentation device. *Clin Orthop 1985; 196: 186*
7. **Noble CA.** The Stryker Dacron Ligament in Chronic Anterior Cruciate Ligament Tears. *Am J Sports Med 1989; 17-5: 723*
8. **Macnicol M, Penny I, Sheppard L.** Early results of the Leeds-Keio anterior cruciate ligament replacement. *J Bone and Joint Surg 1991;73-B:377-80.*
9. **Wilk RM, Richmond JC.** Dacron ligament reconstruction for chronic ACL insufficiency. *Am J Sports Med 1993;21-3:374-9.*
10. **Barrett GR, Lawrence LL, Shelton WR, Manning JO, Phelps R.** The Dacron ligament prosthesis in anterior cruciate ligament reconstruction. A four year review. *Am J Sports Med 1993;21-3:367-73.*
11. **Denti M, Bigoni M, Dodaro G, Monteleone M, Arosio A.** Long-term results of the Leeds-Keio anterior cruciate ligament reconstruction. *Knee surgery, Sports Traum., Arthroscopy 1995;3-2:75-7.*
12. **Rading J, Peterson L.** Clinical Experience with the Leeds-Keio Artificial Ligament in the Anterior Cruciate Ligament Reconstruction. *Am J Sports Med 1995;23-3:316-9.*

13. **Maletius W, Gillquist J.** Long-term results of anterior cruciate ligament reconstruction with a dacron prosthesis. The frequency of osteoarthritis after seven to eleven years. *Am J Sports 1997;25-3:288-93.*
14. **Murray AW, Macnicol MF.** 10-16 year results of Leeds-Keio anterior cruciate ligament reconstruction. *The Knee 2004;11-1:9-14.*
15. **Ventura A, Terzaghi C, Legnani C, Borgo E, Albisetti W.** Synthetic grafts for anterior cruciate ligament rupture: 19-year outcome study. *The Knee 2010;17-2:108-13.*
16. **Dericks G.** Ligament advanced reinforcement system anterior cruciate ligament reconstruction. *Oper Tech Sports Med*. 1995;3(3):187–205.
17. **Tiefenboeck T, Thurmaier E, Tiefenboeck M, et al.** Clinical and functional outcome after anterior cruciate ligament reconstruction using the LARS™ system at a minimum follow-up of 10 years. *The Knee 2015; (22): 565-568*
18. **Lavoie P, Fletcher J, Duval N.** Patient satisfaction needs as related to knee stability and objective findings after ACL reconstruction using the LARS artificial ligament. *Knee 2000; 1(7): 157-63*
19. **Nau T, Lavoie P, Duval N.** A new generation of artificial ligaments in reconstruction of the anterior cruciate ligament. Two-year follow-up of a randomized trial. *J Bone Joint Surg Br. 2002; 84(3): 356-60*
20. **Zhong-tang Liu, Xian-long Zhang, Yao Jiang, Bing-Fang Zeng.** Four-strand hamstring tendon autograft versus LARS artificial ligament for anterior cruciate ligament reconstruction. *Int Orthop (SICOT) 2009; 10: 264-9*
21. **Huang Jian-ming, Wang Qian, Shen Feng, Wang Zi-min, Kang Yi-fan.** Cruciate ligament reconstruction using LARS artificial ligament under arthroscopy: 81 cases report. *Chin Med J 2010; 123 (2): 160-164*
22. **Legnani C, Ventura A, Terzaghi C, Borgo E, Albisetti W.** Anterior cruciate ligament reconstruction with synthetic grafts. A review of literature. *International Orthopaedics 2010;34-4:465-71.*
23. **Bernardino S.** ACL prosthesis: any promise for the future? *Knee Surgery, Sports Traumatology,* 18**.** *Arthroscopy 2010;18-6:797-804.*
24. **Parchi P, Gianluca C, Dolfi L, et al.** Anterior cruciate ligament reconstruction with LARS™ artificial ligament results at a mean follow-up of eight years. *International Orthopaedics (SICOT). 2013;37(8):1567–1574.*
25. **Zhenyu J, Chenchen X, Wei W et al.** Clinical outcomes of anterior cruciate ligament reconstruction using LARS artificial graft with an at least 7-year follow-up. *Medicine Open (2017) 96:14 (e6568)*
26. **Roe J, Pincewski L, Russell V et al.** A 7-Year Follow-up of Patellar Tendon and Hamstring Tendon Grafts for Arthroscopic Anterior Cruciate Ligament Reconstruction. *AJSM 2005; 33 (9): 1337-1345*
27. **Yasen S, Borton Z, Eyre-Brook A et al.** Clinical outcomes of anatomic, all inside, anterior cruciate ligament (ACL) reconstruction. *The Knee 2017; (24): 55-62*