

# Anterior cruciate ligament reconstruction with LARS™ artificial ligament results at a mean follow-up of eight years

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## Abstract

**Purpose** The aim of this study was to review patients that underwent ACL reconstruction with the LARS™ ligament in the First Orthopaedic Division of Pisa University during the period between January 2003 and December 2005.

**Methods** Twenty-six patients were reviewed with an average follow-up of 95.3 months (7.9 years). The review protocol was articulated in three phases: (1) a subjective evaluation using three grading scales: VAS, KOOS and the Cincinnati knee rating scale, (2) a clinical and objective evaluation, and (3) a biomechanical evaluation of the knee stability.

**Results** A global positive result was obtained in 92.3 % of the patients (16 optimal results and eight good results), with a fast functional recovery and a high knee stability. A global poor result was reported in two cases. In our series we did not record cases of infection or knee synovitis. We recorded only one case of mechanical graft failure. The results obtained from our study are encouraging and similar to those in the literature.

**Conclusions** We conclude that the LARS™ ligament can be considered a suitable option for ACL reconstruction in carefully selected cases, especially for older patients needing a fast functional recovery.

## Introduction

The anterior cruciate ligament (ACL) is one of the most commonly injured structures of the knee. Several different methods have been suggested for the treatment of the unstable anterior cruciate ligament deficient knee. These methods differ in the surgical techniques (open, arthroscopic or both combined) and in the type of graft used (autograft, allograft,

synthetic). Four-strand-semitendinosus-tendon autograft (4SHG) and bone-patellar-tendon-bone (BPTB) are the most commonly used autograft and actually they represent the gold standards for ACL reconstruction [1, 2]. The main complications of using autografts are related to the harvesting of the graft and to the donor site morbidity [3].

In the 1980s many synthetic materials were proposed for ACL synthetic replacement (carbon fibre, Dacron, Gore-tex) and biological tissue augmentation (Leed-Keio and Kennedy augmentation device). The use of synthetic graft was abandoned following a high percentage of long-term complications, such as mechanical failures (prosthetic components breakage, fixation loss, etc.), synovial complications (synovitis) due to material debridement and development of an early knee arthrosis [4]. During the last 15 years, as a result of the development of new biomaterials and more accurate surgical techniques, interest in the possibility of using synthetic grafts for the reconstruction of the ACL has reappeared. The Ligament Augmentation & Reconstruction System (LARS™) has recently been reported to be a suitable material for ACL reconstruction [5].

The aim of this study was to review the patients that underwent an ACL reconstruction with the LARS™ in the First Orthopaedic Division of Pisa University between January 2003 and December 2005 to evaluate the safety and efficacy of the treatment at a medium-term follow-up.

## Materials and methods

From January 2003 to June 2012 at the First Orthopaedic Division of Pisa University 146 surgical procedures of ACL reconstruction with the LARS™ ligament were performed. These operations were carried out in patients older than 30 years of age with symptomatic ACL lesions. All patients were strongly motivated by work or sport requirements and needed a fast functional recovery. Before the surgery, the use of a synthetic graft was proposed by the surgeon to the

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patients older than 30 years old as a possible alternative to the use of an autograft, explaining advantages and disadvantages of each technique. The patient gave written consent before the surgical procedure.

The LARS™ ligament is manufactured in polyethylene terephthalate (PET) and consists of two different parts: the intraosseous part is made of longitudinal fibres bound together by a transverse knitted structure, while the intra-articular part comprises only longitudinal parallel fibres which are pretwisted at 90 degrees. We used two types of LARS ligament: the AC50DB with a strength of 2300 Newton and a diameter of five millimetres and the AC40DB with a strength of 1700 Newton and a diameter of five millimetres. The choice of the LARS ligament type is related to the patients' weight (over 80 kg the AC50DB) and to the surgeon's preference based on intra-operative findings.

All the operations were performed by the same surgeon (FC) under regional anaesthesia and the aid of a pneumo-ischæmic tourniquet. Once the diagnosis of ACL deficiency had been made, an arthroscopic inspection of the knee and treatment of any meniscal and/or cartilaginous lesions encountered (85 % meniscal lesions and 40 % low grade chondritis) was carried out. The ACL stumps were always preserved and the LARS™ ligament was inserted through it towards the residents' ACL ridge. The tibial tunnel was created using a cannulated reamer matching the diameter of the graft (7.5 mm for the AC40DB and 8 mm for the AC50DB). Regardless of the device used, the angle between the tibial tunnel and the horizontal arm of the guide should always be set at 55°. This produces best guide pin orientation to allow drilling the femoral tunnel through the tibial tunnel; if the tunnel is placed too anteriorly it could cause graft impingement within the intercondylar notch. The femoral reamer was introduced through the tibial tunnel with the knee flexed at 90°, and the femoral half tunnel was reamed under arthroscopic control reaching a depth of 35–40 mm. The LARS™ ligament was then introduced and fixed at the femoral level using the Arthrex Titanium TransFix® cross pin fixation technique at the tibial level using a metal cannulated interference screw. As reported in an *in vitro* study published by Trieb in 2004 the ACL stumps are fundamental to promote the tissue ingrowths into the artificial ligament and to obtain the ligament synovial cover [6]; preserving the ACL stumps is also important to protect the graft against friction at the opening of the bony tunnels and between the fibres themselves and sometimes it could be useful to guide for the surgeon to reproduce the native ACL position.

The rehabilitation protocol began from the first post-operative day with the execution of active and passive mobilisation. The patients were discharged on the second post-operative day with a partial weight bearing on the limb for 15 days. After two weeks the patients progressively

began to increase the load and were allowed to part with crutches four weeks after the surgical procedure.

From January 2003 to December 2005 at the first Orthopaedic Division of Pisa University 29 surgical procedures of ACL reconstruction using the LARS™ ligament were performed. It was possible to review only 26 of the 29 patients because three were lost in the follow-up. The 26 patients reviewed were six women and 20 men; the mean age was 38.5 years old (range 32–52). The dominant limb was involved in 18 cases. The mean follow-up was 95.3 months (range 85–110). All patients gave informed consent prior to being included into the study; the study was authorised by the internal revision board and was performed in accordance with the Ethical standards of the 1964 Declaration of Helsinki as revised in 2000.

The review protocol was articulated in three phases:

1. Subjective evaluation using three grading scales: VAS (visual analogue scale), KOOS (knee injury and osteoarthritis outcome score) and Cincinnati knee rating scales. The VAS is used to quantify the pain perceived by the patient on the affected limb. The KOOS is a graded evaluation scale to assess several subjective parameters of the knee [7]. The Cincinnati knee rating scales evaluates eight subjective parameters (pain, swelling and stability, level of total activity, climbing stairs, jumping and running) to assess the patient's functional recovery. This scale has great reproducibility [8].
2. Clinical and objective evaluations: This was done by an accurate anamnesis with detailed attention to the moment of the trauma, the time elapsed between the trauma and the surgery, the early postoperative period, the rehabilitation and the return at the working activities and sport. Tests for meniscal evaluation and for the antero-posterior (AP) and varus-valgus knee stability were also executed.
3. Biomechanical evaluation of the knee stability: For the evaluation of knee stability the Rollimeter Aircast™ knee tester was used. Schuster et al. [9] have demonstrated that the Rollimeter is as reproducible and reliable as the KT-1000 arthrometer and it offers a valid method for the measurement of anteroposterior translation of the knee. The tests performed were the anterior drawer test and the Lachmann test. Both tests were carried out three times to improve the accuracy of the evaluation and the value was recorded. These measurements were made on both knees. Our attention was focused on the differences between the values obtained on the affected knee and the contralateral side in order to be aware of constitutional laxity. Based on these values, we have subdivided the results into three groups: optimal (difference between operated knee and contralateral less than two millimetres), good (difference between operated

knee and controlateral comprised between two and four millimetres) and bad (difference between operated knee and controlateral over four millimetres).

## Results

Most of the patients declared a good level of satisfaction for the reconstruction of the anterior cruciate ligament with LARS™. The patient was asked to mark the level of satisfaction on a scale graded from 0 to 10. The mean value obtained was to 8.1. The patients returned to sports and work activities at the level experienced before surgery in an average period of four months (range 1.5–7).

The VAS grading scale was completed by all the examined subjects. The mean value of the VAS was 2.1; 16 (61.5 %) of the patients showed values between 0 and 2, eight patients (30.8 %) expressed an appraisal between 3 and 5, while two patients (7.7 %) gave an appraisal between 6 and 8.

The analysis of the KOOS grading scale has shown a mean score of 84 with 11 (42.3 %) optimal results, 13 good results (50 %) and two bad results (7.7 %). More detailed results are found in Table 1.

The Cincinnati knee rating scale has shown a mean score of 89.1 points (range 22–100) with 16 optimal results (61.5 %), eight good results (30.8 %) and two bad results (7.7 %).

From the clinical point of view, we found a slight swelling only in two patients. The ROM of the affected knee did not differ from the contralateral in 61.5 % of the cases, was slightly reduced in 30.8 % (difference less than 10°) and moderately reduced in 7.7 % (difference between 10° and 15°). There were no cases of reactive knee synovitis or knee infection. Only one patient reported, episodes of instability of the knee and moderate pain.

The results obtained from the evaluation of the knee stability performed using the Rollimeter Aircast™ knee tester were optimal in 16 patients (61.5 %), good in eight patients (30.8 %) and bad in two patients (7.7 %).

A global positive result was obtained in 92.3 % of the patients (16 optimal results and eight good results) with a

fast functional recovery and a high knee stability. A global poor result was reported in two cases. In our series, we have not found any major complications, such as infection and knee synovitis, while in some cases there was only a transient knee haematoma that resolved spontaneously with conservative treatment. From the clinical point of view, we did not find any signs of synovitis, which is one main drawback associated with the use of the earlier synthetic ligaments. The ligament stability was good in 92.3 % (24/26) of the patients. We recorded only one case of mechanical graft failure after 58 months from the surgical procedure; the graft's rupture occurred during a high level sporting activity in a patient with an optimal outcome after the first ACL reconstruction using LARS.

## Discussion

During recent years, as a result of the development of new biomaterials and more accurate surgical techniques, the interest in the possibility of using synthetic grafts for the reconstruction of the ACL has resurfaced. The main advantages of the use of a synthetic ligament in ACL reconstruction are: the immediate recovery of the stability, the early rehabilitation and avoidance of sacrifice of autologous structures. The first attempts of ACL reconstruction with synthetic graft were performed by Corner in 1914 who used a metallic filament; afterwards in 1918, Alwin-Smith executed ACL reconstruction using a silk ligament and reported complete failure of the system after about three months. After those first pioneering experiences, the use of synthetic materials for ACL reconstruction ceased until the 1970s, when the technological progress offered materials that were more suitable for medical requirements. However, because of the high systems failure rate (reactive synovitis and mechanical breakdown), the concept of ACL artificial substitutes lost credibility and in the 1990s there was a decline in the use of synthetic grafts [4].

During the last 15 years, the development of mainly biocompatible materials and a better understanding of the knee's kinematics has led to the development of a new generation of synthetic graft [5, 10].

**Table 1** KOOS grading scale

KOOS	Results			
	Mean	Optimal > 90	Good 70–89	Bad < 69
Pain	89 (14–100)	53.7 % (15/26)	38.6 % (9/26)	7.7 % (2/26)
Symptoms	82 (25–100)	30.8 % (8/26)	61.5 % (16/26)	7.7 % (2/26)
Functions of daily life	93 (13–100)	76.9 % (20/26)	15.4 % (4/26)	7.7 % (2/26)
Sport and recreation function	81 (0–100)	46.2 % (12/26)	38.4 % (10/26)	15.4 % (4/26)
Quality of life	75 (0–100)	23.1 % (6/26)	61.5 % (16/26)	15.4 % (4/26)
Global	84 (10–100)	42.3 % (11/26)	50 % (13/26)	7.7 % (2/26)

**Table 2** Summary of the literature

Author	Publication	Database	Availability	Number of cases	Average age (years)	Follow-up	Graft	Rupture	Synovitis
Dericks	1995 Oper Tech Sport Med	Pubmed, Google Scholar, Scopus	Full text	220	33.4	4-48 months	LARS (220pz)	9	0
Lavoie et al.	2000 Knee	Pubmed, Google Scholar, Scopus	Full text	47	31.6	8-45 months	LARS (47pz)	0	0
Nau et al.	2002 J Bone Joint Surg [Br]	Pubmed, Google Scholar, Scopus	Full text	53	30.6	24 months	LARS (26pz) vs BPBT (27pz)	0	0
Talbot et al. <sup>a</sup>	2004 J Can Chir	Pubmed, Google Scholar, Scopus	Full text	20	28.5	27.4 months	LARS (20pz)	0	0
Brunet P et al. <sup>a</sup>	2005 Rev Chir Orthop	Pubmed, Google Scholar, Scopus	Full text	14	27	10-88 months	LARS (14pz)	0	0
Wu YL et al.	2007 Journal of Practical Orthopedics	Google Scholar	Abstract only	18	—	6-24 months	LARS (18pz)	0	0
Wu YL et al. <sup>b</sup>	2007 J Clin Rehab Tissue Eng Res	Google Scholar, Scopus, Embase	Abstract only	15	—	6-24 months	LARS (15pz)	0	0
Chen SY et al.	2007 China Medical Engineering	Google Scholar, Scopus	Abstract only	42	—	9-15 months	LARS (23pz) vs 4SHG (19pz)	0	0
Shang P et al. <sup>b</sup>	2007 J Clin Rehab Tissue Eng Res	Embase	Abstract only	6	—	10.2 months	LARS (6pz)	0	0
Dong Q et al. <sup>b</sup>	2007 Jiangu Medical Journal	Google Scholar	Abstract only	7	—	1.5-5 months	LARS (7pz)	0	0
Jing Xin et al. <sup>b</sup>	2008 Journal of Clinical Orthopedics	Google Scholar	Abstract only	7	—	5-25 months	LARS (7pz)	0	0
Chen, M. et al.	2008 J Clin Rehab Tissue Eng Res	Scopus, Embase	Abstract only	32	21	24 months	LARS (32pz)	0	0
Fu, P.-L. et al.	2008 J Clin Rehab Tissue Eng Res	Scopus, Embase	Abstract only	28	—	20 months	LARS (28pz)	0	0
Fan et al.	2008 Chinese Journal of Reparative and Reconstructive Surgery	Pubmed, Google Scholar, Scopus, Embase	Abstract only	42	17-40	24 months	LARS (15pz) vs 4SHG (27pz)	0	0
Huang H.-Y et al.	2008 Journal of Clinical Rehabilitative Tissue Engineering Research	Google Scholar, Scopus	Abstract only	42	—	12-24 months	LARS (42pz)	0	0

**Table 2** (continued)

Author	Publication	Database	Availability	Number of cases	Average age (years)	Follow-up	Graft	Rupture	Synovitis
Huang H.-Y et al.	2008 J Clin Rehab Tissue Eng Res	Embase	Abstract only	11	—	—	LARS (11pz)	0	0
Xu Y et al. <sup>b</sup>	2008 Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi	Pubmed, Google Scholar	Abstract only	9	23-49	8-16 months	LARS (9pz)	0	0
Zhang Y et al.	2009 Journal of Clinical Orthopedics	Google Scholar	Abstract only	12	—	3-11 months	LARS (12pz)	0	0
Xu Y et al. <sup>c</sup>	2009 Journal of Orthopedics Practical	Google Scholar	Abstract only	16	—	3-30 months	LARS (16pz)	0	0
Li B. et al. <sup>b</sup>	2009 Int Orthop	Pubmed, Google Scholar, Embase	Full text	54	18-47	24-36 months	LARS (21pz) vs 4SHG (15pz)	0	0
Zhang, J.-L.	2010 J Clin Rehab Tissue Eng Res	Scopus, Embase	Abstract only	23	21-54	11.2 months	LARS (23pz)	0	0
Liu Z.-T et al.	2010 Int Orthop	Pubmed, Google Scholar, Scopus, Embase	Full text	60	36	48-52 months	LARS (28pz) vs 4SHG (32pz)	0	0
Gao et al.	2010 Arthroscopy	Pubmed, Google Scholar, Scopus, Embase	Full text	159	30	50 months	LARS (159pz)	3	1
Huang et al. <sup>d</sup>	2010 Chin Med J	Pubmed, Google Scholar, Scopus	Full text	81	27,5	29,4 months	LARS (81pz)	0	0
Li Q et al.	2010 Zhongguo Gu Shang	Pubmed, Google Scholar, Google Embase	No abstract	—	—	—	—	—	—
Guo L et al.	2011 Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi	Pubmed, Google Scholar, Scopus	Abstract only	80	29,2	16,8 months	LARS (80pz)	0	0
Hamido et al. <sup>d</sup>	2011 Knee	Pubmed, Google Scholar, Scopus, Embase	Full text	112	26	5 years	LARS (112pz)	0	0
Cerulli et al.	2011 GIOT	Google Scholar, Scopus	Full text	25	46,2	9 years	LARS (25pz)	0	0
Ranger et al. <sup>a</sup>	2011 Int. Orthop	Pubmed, Google Scholar, Scopus, Embase	Full text	71	38,5	54 months	LARS (71 pz reviewed of 140)	0	0
Glezos et al.	2012 AJSM	Pubmed, Google Scholar, Scopus, Embase	Full text	1	33	6-9 months	LARS (1pz)	0	1
Li H et al.	2012 J Arthr Rel Surg	Pubmed, Google Scholar, Scopus, Embase	Full text	1	26	3 years	LARS (1pz)	0	1
Shen G et al. <sup>b</sup>	2012 J Surg Res	Pubmed, Google Scholar, Scopus, Embase	Full text	41	34	44 months	LARS (41 pz)	0	0

**Table 2** (continued)

Author	Publication	Database	Availability	Number of cases	Average age (years)	Follow-up	Graft	Rupture	Synovitis
Li Y et al.	2012 Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi	Pubmed, Google Scholar, Scopus	Abstract only	50		2–3 years	LARS (24) vs BPBT (26pz)	0	0
Chen CP et al. <sup>a,b</sup>	2012 Orthopaedics	Pubmed, Google Scholar, Scopus, Embase	Full text	38	32.6	37 months	LARS (38pz)	0	0
Pan X et al.	2012 European Journal of Orthopaedic Surgery and Traumatology	Scopus, Embase (Article in press)	Abstract only	62	—	4 years	LARS (32) vs BPBT (30pz)	0	0
Total							1245	12	3

<sup>a</sup> Knee dislocation<sup>b</sup> PCL reconstruction<sup>c</sup> ACL + PCL<sup>d</sup> ACL augmentation

The LARS™ ligament consists of fibres made of polyethylene terephthalate (PET) composed of two parts: an intra-osseous segment composed of longitudinal fibres bound together by a transverse knitted structure and an intra-articular segment composed of parallel longitudinal free fibres twisted at 90°. The PET fibres of the intra-articular segment are designed to encourage tissue ingrowth due to the porosity of the material, allowing ingrowth from the surrounding bony tunnels as shown from in-vitro and in vivo study [6, 11]. As suggested from the authors ideally, such tissue ingrowth between the ligament fibres would contribute to the viscoelasticity of the graft and protect against friction at the opening of the bony tunnels and between the fibres themselves.

The first clinical report on the use of LARS™ in ACL reconstruction was made by Dericks in 1995 [12]. He reported encouraging results in 220 cases with a mean follow-up of 2.5 years, without any case of knee synovitis.

After this first experience several papers related to the use of LARS™ ligament for knee ligament reconstruction have been published. We reviewed all the papers that reported clinical results of the LARS™ ligament for knee ligament reconstruction (ACL, PCL, ACL + PCL and knee dislocation), searching in four different databases (Pubmed, Scopus, Embase and Google Scholar) (Table 2). We found 35 papers (16 were full text, 18 were abstract and one was not available in any format) for a total number of 1,245 cases with a follow-up ranging from three months to nine years [13–33]. We focused our attention on the number of graft ruptures and the number of cases of knee synovitis that were complications historically related to the use of artificial ligaments. We recorded 12 graft ruptures (0.96 %) and three cases of knee synovitis (0.24 %) of which two are case reports.

In five of the 16 papers available as full-text, the LARS™ ligament was compared to autografts (two BPBT and three 4SHG) [17, 19, 20, 31, 33]. The results showed that there were no significant differences between the two groups and that the patients treated with LARS™ had a faster recovery and return to sport activities without complications, such as synovitis.

Only one study, published by Cerulli et al., reported the results obtained with the use of LARS™ ligament in ACL reconstruction in a group of 25 patients at a long-term follow-up (nine years) [26]. The authors reported positive results in over 95 % of the cases without any case of knee synovitis.

A study published in 2012 evaluated the changes in the bone tunnel following ACL reconstruction using the LARS™ ligament in 43 patients at three years of follow-up [34]. Grade 1 femoral bone tunnel enlargement was observed in three of the 43 patients six months after surgery. Forty cases were evaluated as grade 0. The



average tibial and femoral tunnel enlargements at the last follow-up were (0.8±0.3) and (1.1±0.3) mm, respectively. The authors concluded that bone tunnel enlargement was not marked following ACL reconstruction surgery with the LARS artificial ligament, and bone tunnel change was not significantly correlated with clinical efficacy.

The data obtained from the assessment forms showed global positive results in 92.3 % of the patients at a mean follow-up of 95.3 months. In most of the cases the use of the LARS™ ligament was also associated with a high patient satisfaction in absence of mechanical and synovial complications (no cases of synovitis was observed in our series).

As reported in literature, even if the results using LARS™ have been encouraging, the autologous transplants remain the golden standard in ACL reconstruction, especially in young people [35]. We conclude that the LARS™ ligament can be considered a suitable option for ACL reconstruction in carefully selected cases, especially for older patients needing a fast functional recovery.

**Conflict of interest** The authors have no conflict of interest.

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