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Medial patellofemoral ligament reconstruction with bioactive synthetic ligament is an option. A 3-year follow-up study

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Abstract
Purpose The purpose of this study was to evaluate mid-term follow-up results of medial patellofemoral ligament (MPFL) reconstruction using a bioactive synthetic ligament in the treatment of objective patellofemoral (PF) instability.
Methods Sixteen patients (18 knees) presenting with objective PF instability underwent a MPFL reconstruction, isolated or associated with other surgical procedures for PF stabilization. All patients were clinically evaluated at a minimum follow-up of 3 years. Kujala, subjective IKDC and KOOS scores were used to assess clinical outcome. Pre-operative and post-operative pain was quantified with VAS scale and the overall satisfaction graded according to Insall and Crosby. Although none of the patients in this series were involved in high-level sports activity because of patellofemoral instability, activity level pre-operatively and at follow-up were evaluated according to Tegner scale.
Results No recurrence of dislocation was observed in this series. The overall satisfaction rate was 88.8 %. Kujala score improved significantly from 57 ± 8.4 to 84.3 ± 10.2 points ($p < .01$). Both subjective IKDC (42.4 ± 7.13 to 70.1 ± 3.9) and KOOS (62.7 ± 4.34 to 82.8 ± 8.8) significantly improved from pre-operative evaluation ($p < .01$). VAS decreased from a mean pre-operative value of 2.5 ± 1.6 to 1.4 ± 1.5 at 3 years follow-up. Only one patient required revision debridement surgery for persistent medial epicondylar pain.
Conclusions Isolated or associated MPFL reconstruction with bioactive synthetic ligament is a valid option in surgical treatment of objective PF instability, with results at mid-term follow-up comparable to autologous graft, thus minimizing donor-site morbidity and associated complications.
Level of evidence IV.

Keywords Patellar instability · Medial patellofemoral ligament · Reconstruction · Synthetic graft

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Introduction

Medial patellofemoral ligament (MPFL) is the primary passive restraint to patellar lateralization between 0° and 30° of flexion [23, 32, 40]. Studies have shown that the MPFL is always ruptured or deficient after a dislocation or in cases of chronic patellofemoral (PF) instability [6, 29]. These findings opened the field to description and evaluation of MPFL surgical reconstruction, introducing a new subject in surgical treatment of patellofemoral instability. MPFL reconstruction is now routinely performed for instability alone or in association with other procedures such as medial and/or distal ATT transfer or trochleoplasty.

A number of techniques have been described for MPFL reconstruction, with options for both patellar and femoral fixation, as well as the choice of the graft: autograft, allograft or synthetic [5, 10, 18–21, 30, 36]. The purpose of this article is to test the reliability at a mid-term follow-up of a bioactive synthetic ligament (R6×400 Ligament

Augmentation and Reconstruction System—LARS, Arc sur Tille, France) graft in MPFL reconstruction for surgical treatment of objective patellofemoral instability.

Materials and methods

Sixteen patients (18 knees) were prospectively enrolled in the study starting from April 2009. Exclusion criteria included previous ipsilateral surgery for PF instability or pain, associated menisci tears or ACL deficiency. Nine patients were males and seven females. Mean age at the time of surgery was 19 ± 6.5 (range 15–43). Indications for surgery were confirmed by history, clinical evaluation, plain radiographs (including axial views), MRI and CT scan [2]. All patients underwent standard pre-operative protocol and clinical evaluation and were reviewed at 3, 6, 12 and 36 months with Kujala score [16], subjective IKDC score [14] and KOOS score [28]. Pain was assessed using the VAS scale, and the overall clinical outcome was rated according to Insall and Crosby [4]. Pre-operative and post-operative level of activity was evaluated with Tegner activity scale [38]. All data were collected prospectively, and bilateral knees were scored separately.

Indications

Indication of surgical treatment of objective PF instability was given in presence of two or more episodes of documented patellar dislocation and a positive apprehension sign, defined as a subjective discomfort reported by the patient during passive patellar lateralization. All patients underwent MPFL reconstruction using a biosynthetic second-generation LARS R6×400 graft. In case of pathologic patellar height (Caton-Deschamps Index > 1.2 measured on sagittal X-rays) [1], found in eight patients, a distalization of the anterior tibial tuberosity (ATT) was performed. Five patients presented a TT-TG distance >20 mm on the CT scan [12] and underwent a medialization of the ATT according to Elmslie–Trillat [3, 39]. Isolated MPFL reconstruction was performed in five patients presenting a true objective PF instability with mild anatomical abnormalities. The need of an associated lateral retinaculum release was assessed pre-operatively evaluating the lateral patellar tilt test [35] and performed in 16 cases. All procedures were performed by the same fully trained orthopaedic surgeon using the same surgical technique.

Surgical technique

MPFL reconstruction can be performed in an isolated fashion or in association with other procedures such as medial and/or distal ATT transfer and lateral release. Lateral release was performed through the same incision used for the MPFL reconstruction. The MPFL reconstruction was performed as the final part of the surgical correction of PF instability. Two guidewires were inserted into the proximal 2/3 of the patella with a slight divergent direction from medial to lateral, reproducing the anatomical MPFL insertion on the medial side of the patella. The ideal distance between the tunnels is 20 mm, similar to the 22 mm described by Kang et al. [15]. as the native anatomical footprint. This distance should be sufficient to maintain a bone bridge between the tunnels at the moment of drilling. LARS R6×400 ligament was prepared with absorbable suture (no. 2 Vicryl, Ethicon, Somerville, NJ) Krackow stitches on the free end. The guidewire position was then checked with fluoroscopy and tunnels performed with a 3.2-mm cannulated drill (Fig. 1). The graft was passed through the tunnels using a shuttle suture from medial to lateral and then back from lateral to medial, making a loop around the proximal third of the patella (Fig. 2). The lateral part of the looped graft was whip stitched on the lateral side of the patella with absorbable sutures in order to prevent the risk of post-operative micromotion and loosening. Lateral patellar mobility and tilt correction were evaluated by tractioning on the free ends of the graft. After performing a 2-cm skin incision between medial epicondyle and adductor tubercle, the femoral insertion point was identified according to Schottle et al. [31] under fluoroscopy guide. A guidewire with an eyelet was then drilled through the femur. The graft was then carefully passed through the second layer of the medial retinaculum. The free ends of the graft were rolled around the k-wire, in order to check the isometric positioning of the femoral tunnel by doing several cycles of flexion–extension. The femoral tunnel was made using a 7-mm cannulated drill to a depth of 40 mm. The length of the free ends of the graft that needs to be introduced in the tunnel was then measured. The excess was cut and the two free ends sutured together using absorbable suture with Krackow stitches on the terminal 35–40 mm that would be introduced into the tunnel. The graft was then tractioned into the tunnel using the transfemoral guidewire. Having free ends of the suture on the lateral side blocked by a Kocher, tension of the graft and patellar medial to lateral mobility could be evaluated before and after several cycles of flexion–extension. Patellar translation in full extension and 30° of flexion was checked by feeling for a firm endpoint. Fixation was then performed at 90° of flexion using a 7 × 25 mm Biorci (Smith & Nephew, Mansfield MA) resorbable interference screw (Fig. 3).

Post-operative management and rehabilitation protocol

Progressive partial weight-bearing with crutches was immediately allowed. The rehabilitation protocol consisted

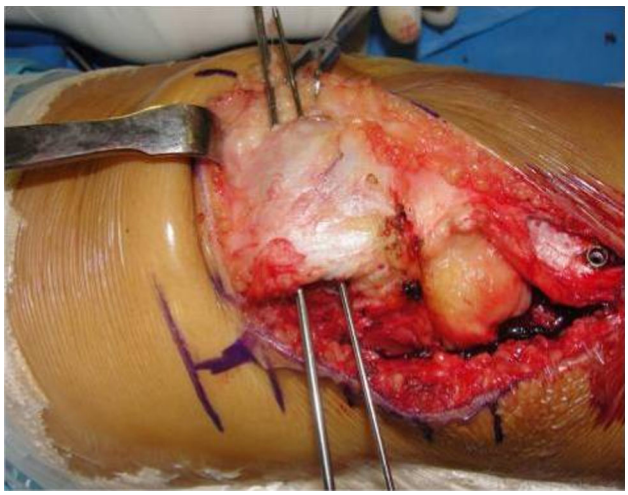

Fig. 1 Two Kirschner wires are positioned in the patella from medial to lateral with a slightly divergent orientation. This patient underwent a distalization of anterior tibial tuberosity and an open lateral release before MPFL reconstruction

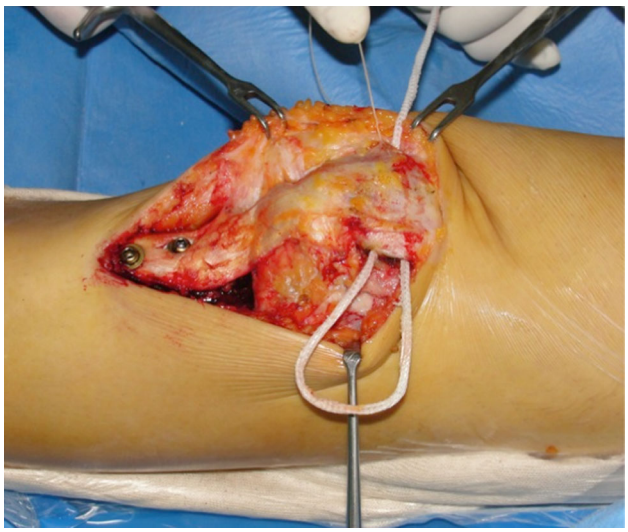

Fig. 2 LARS ligament is looped trough patellar tunnels

of continuous passive motion and quadriceps isometric exercises, beginning immediately post-operatively. We emphasize complete recovery of range of motion and quadriceps control also by the means of assisted water exercises after suture removal. The primary end point of the rehabilitation protocol was defined as maintaining complete extension and reaching 90° of flexion in the first 4 weeks. After 6 weeks, if quadriceps control was regained, full weight-bearing and closed kinetic chain exercises were allowed. Complete recovery and return to sports can be obtained after going through a progressive rehabilitation programme lasting at least 6 months after surgery.

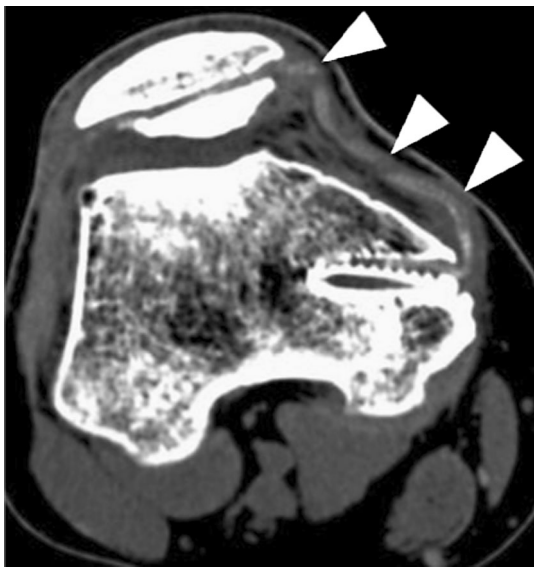

Fig. 3 LARS ligament in a post-operative CT scan

This study was performed in accordance with the ethical standards of 1964 Declaration of Helsinki and approved by G.Pini Institute Ethical Committee (WA-28725). All patients gave their informed consent prior to their inclusion in the study.

Statistical analysis

Descriptive statistics were calculated on all 18 knees. Comparisons of pre- and post-treatment VAS scale, Kujala, IKDC and KOOS scores were calculated using paired Student's *t* tests. Pre-operative and post-operative Tegner scale values were evaluated using Wilcoxon's test for significatively. Analysis was carried out using SPSS 14.0 Student Version (SPSS, an IBM company, Chicago, IL). Significance level was set at ≤ 0.05 throughout.

Results

All patients were available for follow-up. Mean follow-up was 40.6 ± 3.3 months (range 36–48). Mean VAS score decreased from a mean pre-operative value of 2.5 ± 1.6 (0–8) to 1.4 ± 1.5 (0–6) at the last follow-up, showing a rapidly decreasing trend in the early post-operative period (2.6 ± 1.4 range 0–7 at 3 months follow-up). Kujala score improved significantly ($p < 0.01$) from 57 ± 8.4 (44–73) pre-operatively to 84.3 ± 10.2 (62–100). Mean subjective IKDC at the last follow-up was 70.1 ± 3.9 (41.4–85.1) with a significative improvement ($p < 0.01$) from 42.4 ± 7.1 (28.7–50.6). KOOS score also improved significantly from 62.7 ± 4.3 (55.4–69) to 82.8 ± 8.8

(58.3–92.3) at the last follow-up ($p < 0.01$). No major complications (patellar fracture, recurrence of instability or subluxation) were observed in this series. One patient suffered persistent pain on the medial femoral tunnel region at 8 months follow-up. A CT scan showed a calcific/fibrotic neoformation near femoral insertion of the MPFL (Fig. 4). Surgical debridement resulted in complete resolution of symptoms. ATT screws removal was necessary for local discomfort in seven patients who underwent ATT transfer. 88 % of patients were either very satisfied (55 %) or satisfied (33 %) with the surgical outcome. One patient with complaints of persistent pain during squatting and kneeling rated the outcome as "partially satisfied", and another patient complained for a persistent subjective instability without any evidence of recurrence of dislocation (negative apprehension sign). According to Insall and Crosby, nine patients were graded excellent, 7 good and 2 fair. No patient was graded poor in this series. Median Tegner activity scale at the last follow-up improved significantly ($p < 0.01$) from 3.9 (3–5) pre-operatively to 5.7 (3–7). All patients stated that they would undergo the surgical therapy again.

Fig. 4 CT scan at 8 months of follow-up showed in this patient a calcific fibrotic neoformation near to the femoral insertion of reconstructed MPFL

Discussion

The most important finding of this study is that biosynthetic ligament can be a valid option in isolated or associated MPFL reconstruction for surgical treatment of objective PF instability. Use of this type of artificial graft gives good clinical results, comparable to other analogous series' in literature, thus sparing the patient of the need of tendon harvesting, minimizing donor-site morbidity and post-operative pain (Table 1).

For more than 20 years, synthetic scaffolds have been developed for tendon and ligament repair surgery. Ellera Gomes pioneered MPFL reconstruction in 1992 using a synthetic graft for his procedure, starting his series with a Leeds Keio (LK) (Neoligaments, Leeds, UK) ligament, then replaced by an Artrolig (Engimplan-Engenharia De Implante E Com, Brazil) 8 mm tubular polyester graft [8]. Nomura et al. reported 96 % of good/excellent results on 27 MPFL reconstructions performed with a mesh type LK polyester ligament at an average follow-up of 5.9 years [21, 22]. In two successive studies, Nomura et al. performed an ultrastructural analysis of the extra-articular portion of the LK ligament at 6 and 8 years follow-up finding a ligament-like tissue that continued to grow in the face of prolonged periods of mechanical stress [24, 25]. LARS was introduced in 1992 designed to provide a scaffold for natural tissue ingrowth with woven fibres offering strength to elongation in ACL reconstruction [11]. The poor biomechanics of resisting flexion and torsion load of the ligaments, insufficient autologous tissue coverage and growth into the artificial ligament scaffold were the

Table 1 Comparison between different series of MPFL reconstruction performed with autologous hamstrings grafts

Study	Number of knees	Mean follow-up (months)	Clinical outcomes	Operative procedures
Panni et al. [27]	51	33	Kujala score increased from 56.7 to 86.8	Isolated reconstruction (divergent patellar two-tunnel technique)
Schottle et al. [30]	15	47	Kujala score increased from 53.3 to 85.7	Isolated reconstruction or associated with ATT mediatisation ($n = 8$) MPFL reconstruction.
Drez et al. [7]	15	31	Post-operative Kujala score: 88	MPFL and MPTL simultaneous reconstruction
Slenker et al. [34]	35	21	Kujala score improved from 49 to 89.5	Reconstruction performed with allograft ($n = 23$) or autograft ($n = 12$) with comparable outcomes
Song et al. [37]	20	34	Kujala score improved from 52 to 90.9	Patellar fixation with suture anchors

main mechanisms of high failure of first ACL reconstructions using early generation synthetic ligaments [17]. The LARS R6 model has a complete transverse knitted structure, different than ACL-specific designed LARS ligament. No study, as far as we know, examined directly the mechanical influence of LARS tissue ingrowth on the extra-articular structure (as R6) of the synthetic ligament. The most recent study on biocompatibility and mechanical property of LARS analysed only the unknotted region of LARS for ACL reconstruction in subcutaneous conditions [11]. The results showed that fibroblasts and collagen fibres had grown into the ligament; however, 12.2 % of fibres were surrounded by foreign body giant cells. LARS R6 ligament ultimate tensile strength is set to 4,000 N, and stiffness was measured at 400 N/mm (Native MPFL stiffness is quantified at 16 N/mm) [17]. One may say that an increased stiffness of the graft could increase medial pressures on the PF joint, leading to a so-called medial hyperpression syndrome. This was not encountered in this series, with no clinical evidence of persistent medial patellofemoral pain, swelling or limitation of range of motion. Restoring the native insertion on the femoral side and avoiding over tensioning of the ligament may prevent the occurrence of this kind of complication, being more related to surgical technique than to the characteristics of the graft. The mechanical characteristics of the graft can justify the conservation of the firm endpoint feeling when performing passive patellar lateralization observed in all patients even at the last follow-up. It has to be acknowledged that, despite this very promising results at mid-term follow-up, the characteristics of the graft, its resistance to traction and biocompatibility should be evaluated at a longer follow-up. The reason for choosing a double transpatellar tunnel fixation technique, despite the relatively higher risk of patellar fracture associated with this procedure [33], was to maintain good control on patellar medial and lateral translation. Although the presence of the two tunnels potentially weakens the resistance against direct traumas, there were no instances of patellar fractures in our series at the last follow-up. The incidence of fracture may be dramatically decreased if the tunnels are drilled in the proximal 2/3 of the patella, taking care to preserve a bony bridge of at least 20–22 mm on the medial side. To avoid the theoretical risk of fracture associated with this technique, alternative patellar fixation with suture anchors may be used with comparable results as shown by Hapa et al. [13] and, more recently, by Song et al. [37]. The use of anchors with a biosynthetic graft is currently being investigated at our institution. There has been only one case report of MPFL reconstruction using R6×400 ligament, with excellent results at 24 months follow-up [26]. This article reports the first case series evaluating mid-term results of MPFL reconstruction with R6×400 in objective patellofemoral instability. One of the main limitations of this study is the small number of patients enrolled, although comparable to analogous series in literature. This results discuss an heterogeneous group of surgically treated patients; our therapeutic algorithm is based on the so-called Menu á la Carte described by Lyon's School, and we believe that MPFL reconstruction should be associated to every other surgical procedure in order to correct predisposing factors, as well as to restore stability, and checkrein function of the ligament to prevent recurrence. Comparing our results to analogous series in literature in which the MPFL reconstruction was performed with autologous grafts, we found similar clinical outcomes (Table 1) [36]. Schiavone-Panni et al. [27] found a significative increase in the Kujala score, going from 56.7 ± 17.7 (2 × SD) preoperatively to 86.8 ± 14.4 at an average follow-up of 33 months in a series of patients undergoing an isolated reconstruction of the MPFL. Schottle et al. [30] reported a significant increase in the same score from 53.3 to 85.7 at 47 months, associating MPFL to medialization of the ATT in patients presenting a pathological TT-TG distance; they did not observe any significant difference in clinical outcome between the two groups of patients (isolated and associated reconstruction). Despite using a different technique which involves also an associated reconstruction of the medial patello–tibial ligament (MPTL), Drez et al. [7] found a mean Kujala score of 88.6 (57–100) at a mean follow-up of 31.5 months on 15 patients. A similar value of 89.5 was also observed by Slenker et al. [34] in a consecutive series of 35 patients undergoing MPFL reconstruction performed with allograft or autologous hamstrings evaluated at mean follow-up of 21 months. At a longer follow-up, Ellera Gomes et al. [9] observed good/excellent outcomes in 15 on 16 knees of their series using the Crosby–Insall score. The clinical relevance of using a LARS ligament instead of an autograft is about avoiding the need of tendon harvest, preserving it for an eventual ligament surgery, reducing donor-site morbidity and operating time, thus achieving comparable results in treatment of recurrent patellar dislocation. We acknowledge that further studies with a longer follow-up are necessary for comparing results with biosynthetic ligament to autograft in MPFL reconstruction.

Conclusions

Biosynthetic LARS ligament represents a valid option as a graft in isolated or associated MPFL reconstruction in treatment of objective PF instability. The use of this technique minimizes donor-site morbidity and post-operative pain if compared to the use of an autologous graft thus maintaining mid-term follow-up comparable results. The

outcomes of this series show an overall patient satisfaction rate of 88 % with no recurrence of dislocation and/or graft failure.

Conflict of interest The authors declare that they have no conflict of interest.

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