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Minimally Invasive Medial Patellofemoral Ligament Reconstruction For Patellar Instability Using An Artificial Ligament: A 2 Year Follow-Up

Running Title

Minimally Invasive MPFL Reconstruction

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None

Ethical Review Committee Statement

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Statement of Location

• The study was undertaken at Associate Professors M. Al Muderis's clinics, situated at Norwest Private Hospital

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Key Words

• Medial patellofemoral ligament; Reconstruction; Artificial Ligament; No Bracing

Abstract

Introduction

Recurrence of acute patellar dislocation affects approximately 30% of individuals, and up to 75% of those with grade IV instability. The medial patellofemoral ligament (MPFL) is considered to be critical for patella stabilisation. MPFL reconstruction with allografts has been proposed to reduce risk of recurrence, but there is limited evidence about the safety and effectiveness of techniques using synthetic allografts.

Method

We present a retrospective case series of 29 individuals who underwent a MPFL reconstruction between 2009 and 2012, using an artificial ligament for patellar

instability by a single surgeon. Clinical, radiological and functional outcomes were measured at a minimum of 24 months.

Results

31 knees (29 individuals) were followed up for a median of 43 (range: 24 – 68) months. Using the Crosby and Insall grading system, 21 (68%) were graded as excellent, 9 (29%) were good, 1 (3%) as fair and none as worse at 24 months. The mean improvement in Lysholm knee score for knee instability was 68 points (standard deviation 10). Ligamentous laxity was seen in 17 (55%) of individuals. In this subset, 12 were graded as excellent, 4 as good and 1 as fair. The mean improvement in patellar height was 11% at 3 months follow-up. All knees had a stable graft fixation with one re-dislocation following trauma.

Conclusions

We propose a minimally invasive technique to reconstruct the MPFL using an artificial ligament allowing early mobilization without bracing. This study indicates the procedure is safe, with a low risk of re-dislocation in all grades of instability.

Word Count – 249

Keywords

Patella; Medial patellofemoral ligament; Reconstruction; Artificial Ligament; No Bracing

1 1. Introduction

3 Acute patellar dislocation frequently leads to recurrence. A systematic review of trials of reconstruction techniques versus conservative rehabilitation reported the rate of 4 re-dislocation after a conservatively managed primary patellar dislocation ranged 5 6 from 19 - 54 % (5 trials, 339 patients) [1]. This risk is higher in patients with ligamentous laxity, with one retrospective single centre series of 104 individuals 7 treated for patellar dislocation reporting an overall recurrence after an acute 8 dislocation of 30 %, and 75 % in the subgroup (n = 66) who had ligamentous laxity 9 and abnormal patella position [2]. 10

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Various surgical methods have been described in the literature to treat lateral patella 12 dislocation [3-8]. Surgical procedures used in Europe have been founded on strict 13 radiographic guidelines, that is, "le menu a `la carte", where all the instability factors 14 are individually corrected [9]. However, the importance of correcting each of these 15 16 instability factors, alone or in combination is uncertain [9]. There is also uncertainty about the safety and effectiveness of current standard procedures. The above 17 mentioned systematic review comparing surgical repair with conservative 18 rehabilitation in a total of 339 patients with dislocation found no robust evidence of 19 20 improved clinical (pain, range of motion) or functional (Kujala scores) outcomes in individuals managed with surgical repair [1]. Apart from recurrent dislocation, 21 22 common post-operative complications reported in the literature are persistent patellofemoral instability, patellofemoral osteoarthritis, loss of flexion, medial 23 24 subluxation, stiffness and chronic knee pain [1, 3, 7, 8, 10].

25

The importance of the medial patellofemoral ligament (MPFL) was first described in 26 the late 1950's [11]. A cadaveric study on 25 specimens determined that, 27 biomechanically the MPFL provides 53 % of the lateral stabilizing force [12]. It is 28 consequently the most important medial soft-tissue restraint and has been shown to 29 be consistently injured after a patellar dislocation [4]. Brückner was the first to 30 present a technique of transferring the medial part of the patellar ligament to the 31 medial epicondyle to stabilize the patella [13]. But only recently with the evolution of 32 shoulder surgery there has been an increased focus on reconstruction of the MPFL. 33

Several techniques have been described to reduce the high incidence of recurrentdislocation with encouraging clinical results [8].

36

Numerous sources have been used to reconstruct the MPFL including 37 38 semitendinosus, semimembranosus, gracilis, quadriceps, vastus medialis retinaculum, or artificial tendons [3, 8, 14-16]. In 1992, Ellera was the first to describe 39 MPFL reconstruction with an artificial polyester ligament in 30 patients fixed by tunnel 40 fixation on the patella and sub-fascially to the medial femoral condyle [17]. At a 41 minimum of 24 month follow-up, 25 (83%) patients showed improvement with a 42 Crosby and Insall grade of good-excellent [17]. The use of synthetic material is 43 appealing to avoid the morbidity associated with other allograft choices [16]. 44 However, there have been very few other articles describing techniques using 45 synthetic allografts. Nomura et al (2000) have recently reported a 5 year follow-up 46 study of 27 patients treated with MPFL reconstruction with an artificial polyester 47 ligament with staple fixation at the femoral condyle, with 26 (96 %) reporting good to 48 excellent outcomes using the Crosby and Insall grading system[5]. But other cohort 49 studies reporting on the use of the artificial ligament question its safety in view of late 50 graft failure, risk of late infection, stiffness, inflammation and cost effectiveness 51 subsequent to use of synthetic allografts [15, 16]. 52

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54 The purpose of our study is:

- To describe a minimally invasive arthroscopically assisted technique to
 reconstruct the MPFL using a synthetic allograft.
- 2. To describe our post-operative rehabilitation protocol.
- 3. To present data on safety and benefits of the surgical procedure in patellar
 instability especially in patients with predisposing factors.

60 2. Patient & Methods

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62 2.1 Study Design & Setting

We retrospectively reviewed all individuals who underwent a MPFL reconstruction using an artificial ligament (LARS Ligament, CORIN Ltd, Mersilene Tape MT, or AchilloCord^{PLUS} Ligament, Neoligaments Ltd) for patellar instability by a single surgeon between 2009 and 2012 who had completed 24-month follow-up. Each case
was treated at a specialized orthopaedic knee clinic run by the investigators. The
University Human Research Ethics Committee and hospitals where the study was
conducted approved the study.

71

72 All individuals underwent a screening interview and examination to determine their eligibility using the criteria listed in Table 1. Pre-operative assessment included a 73 thorough history, physical examination and radiological evaluation. Patients were 74 assessed for passive patellar hypermobility, mal-tracking, apprehension, knee range 75 of motion and a Clarke test as a part of the physical examination [18]. Generalized 76 77 ligamentous laxity was scored using the Wynn Davies criteria [19] and classified using the method established by Runow et al [2]. The Lysholm knee scoring scale 78 79 was administered to assess the functional impairment due to clinical instability and evaluate the outcomes of knee ligament surgery [20, 21]. Plain x-ray (antero-80 81 posterior, lateral & skyline view) examinations and Magnetic Resonant Imaging (MRI) scans were performed to assess the integrity of the MPFL, chondral damage, internal 82 derangement and the position of the tibial tuberosity. The procedure was 83 recommended for individuals with a torn/attenuated MPFL who had symptoms such 84 as giving way, instability, & mal-tracking that did not ameliorate after 3 months of 85 conservative therapy including quadriceps muscle strengthening (Table 1). 86

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Table 1 – Inclusion /	Exclusion	Criteria
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Inclusion Criteria	Exclusion Criteria
Torn/Attenuated Medial Patello-femoral	Intact Medial Patello-femoral
Ligament	Ligament
Recurrent Patellar Dislocation Refractory to	Instability in Presence of Moderate-
Conservative Treatment > 3 months	Severe Patello-femoral Arthritis
Pathological Ligamentous Laxity	History of Previous Surgery

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90 2.2 Outcome Measures

92 Clinical outcomes included pain level, knee range of motion, passive patellar 93 hypermobility, mal-tracking & apprehension at follow up [3]. Plain x-rays were used to 94 measure the sulcus angles & the patellar height (Insall-Salvati index) at baseline & 3-95 month follow up [3]. X-Rays were also performed at 6, 12 months and yearly follow-96 up to assess the integrity of the fixation (alignment, positioning) and other 97 complications (arthritis, fracture). Adverse events including re-dislocation,
98 prominence of the graft, and knee stiffness were monitored. All outcomes were
99 measured by a single investigator and confirmed by a senior surgeon.

100

Functional outcomes were assessed using the Lysholm knee scoring scale to measure symptoms in the knee at baseline and yearly follow-up [20]. The Crosby and Insall grading system was used to assess outcomes following ligament reconstruction. Using this system, outcomes were classified into four categories (Excellent, Good, Fair to Poor & Worse) [22].

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107 **2.3 Surgical Technique**

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A two-step surgical procedure was performed including a knee arthroscopy followedby reconstruction of the MPFL using an artificial ligament.

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Patients underwent general anaesthesia. Prophylactic intravenous antibiotics using 1 112 gram of Cephazolin was administered. Positioning and draping was similar to a 113 standard knee arthroscopy. The knee was first examined & the tightness of the 114 lateral structures was assessed. Following this a knee arthroscopy was performed 115 using standard antero-medial & antero-lateral portals to visualize the knee, remove 116 any loose bodies and deal with any other intra-articular pathology (e.g. chondroplasty 117 for chondral wear). The lateral retinaculum was released arthroscopically using 118 thermal ablation in all patients. 119

120

121 The Through Tunnel Technique was used to achieve fixation for the artificial ligament [23]. A 2 - 3 cm vertical skin incision was made over the lateral upper half of the 122 patella. Under image intensifier a 3.2 mm tunnel was drilled over a guide wire 123 through the junction of the upper third and the lower two thirds of the patella (Figure 124 1). A wire was then passed through the patellar drill hole. A 1 cm incision was made 125 over the medial condule at the natural attachment of the MPFL through which the 126 wire was pulled medially using long forceps in the middle layer of the soft tissues, just 127 superficial to the capsule. Through the same incision, a second 3.2 mm tunnel was 128 made at the isometric insertion site of the MPFL (1 mm anterior to the extension line 129 of the posterior cortex and just proximal and behind the attachment of the superficial 130

part of the medial collateral ligament), along the epicondylar axis of the femur [3, 24]. 131 For skeletally immature patients, the tunnel was accurately positioned in the 132 epiphysis to avoid injury to the growth plate [3]. The artificial ligament was then 133 prepared by folding it over itself and passing an endobutton at one end to secure the 134 fixation at the lateral border of the patella. A wire passer was utilized to thread the 135 ligament through the patella and the femur. The ligament was now tensioned with the 136 leg in full extension. Subsequently, the knee was positioned in full flexion, without 137 engaging the ligament at the lateral femoral cortex. Femoral fixation was then 138 achieved using a 7 mm interference peek screw, which was inserted through the 139 lateral incision (Figure 2, 3). This avoided over loosening or over tightening of the 140 artificial ligament. The knee was then taken through a range of motion to check 141 tracking and patellar stability. 142

143

The tibial tuberosity - trochlear groove (TT-TG) distance was measured using 144 145 superimposition of axial slices on MRI [25] for all the patients and if the distance was more than 15 mm and patella mal-tracking persisted after the MPFL reconstruction, a 146 medialization procedure for the tibial tuberosity was performed. This involved a 147 separate 2 - 3 cm vertical incision centering over the tibial tuberosity. Under image 148 intensifier guidance an osteotome was used to elevate the tibial tuberosity and 149 realign it. Fixation was attained by use of 2 standard AO screws under image 150 intensifier guidance. Final x-rays were then taken and the wound was closed in 151 layers. No knee immobilizer was used post-operatively. 152

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Figure 1 – Patellar Tunnel a. Clinical Image b. X-ray Image



157	
158	Figure 2 – Graft Construct
159	a. Artificial Ligament, b. Endobutton, c. Interference Screw, d. Through Tunnel
160	Technique
	AB



Figure 3 – Final Graft Position



2.4 Post-operative Management

Immediately after surgery no brace was applied. Patients had an overnight hospital stay. The post-operative protocol is shown in Table 2. Quadriceps rehabilitation was started on the first post-operative day with the knee in extension and the patients were allowed to mobilize weight bearing as tolerated using crutches. They were discharged on oral analgesics. The passive knee range of motion was started in the 1st week by a physiotherapist. At one week, the wounds were checked and the

integrity of fixation was formally confirmed using plain x-rays (Figure 4). Jogging and
 non-impact sports activities were permitted at 8 weeks and full sports activities at 12
 weeks.





Table 2 – Post Operative Protocol

Timeline	Intervention
1 st Day	No Brace/ Knee Immobilizer Used
	Quadriceps Sets, Calf raises initiated
	Mobilize weight bearing as tolerated with two crutches
1 st Week	Passive knee range of motion initiated
	Continue Quadriceps Sets, Calf raises advanced
2 nd Week	Progress to single crutch as tolerated
	Continue Quadriceps Sets, Calf raises
	Continue knee range of motion
3 rd - 6 th Week	Full knee range of motion
	Stationary bike with minimal resistance and then progress as tolerated
	Closed-chain double-leg strengthening exercises as tolerated
6 th - 12 th Week	Start running when capable
	May progress to closed-chain single-leg strengthening as tolerated
	May begin functional exercises as tolerated
12 th - 16 th Week	Gradual return to sport

2.5 Statistical Analysis

The frequency of clinical outcome events were summarised using percentages. Functional outcomes were summarised by calculating the group mean and standard deviation for baseline and follow-up measurements. The differences between followup and baseline values for each knee were calculated in measurement units and the
difference in patella height was calculated as a percentage of the baseline value. A
2-tailed paired t test was used to test for a statistical difference in baseline versus
follow-up measures. A p-value <0.05 was considered statistically significant.
Analyses were conducted using SPSS statistical software.

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194 **3. Results**

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196 **3.1 Participants**

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Our study reviewed 29 individuals (31 knees) with a median follow-up of 43 months 198 (24 – 68 months). Patient characteristics and baseline clinical findings are 199 summarised in Table 3. The mean patient age at the time of the procedure was 25 200 (9-44) years. The average duration of instability before the procedure was 1 (0.25 – 201 10) year. More than 50 % of the study population had an element of generalized 202 ligamentous laxity. 52 % of the individuals had Grade IV Instability (Table 4). The age 203 of onset of dislocation and the amount of trauma required to cause dislocation was 204 found to be consistently lower in this subset of individuals (Table 4). Dysplastic 205 changes were evident on x-ray and MRI examinations in more than half the study 206 population. There was no evidence of patella-femoral arthritis in any of the 207 individuals. 208

209 210

Table 3 – Patient Characteristics, Baseline Clinical Findings, & Surgical Details

Characteristic	N (%)	Mean (SD)			
Patient Characteristics, 29 patients					
Gender		-			
male	11 (38)				
female	18 (62)	-			
Age (years)	-	25 (9)			
Side		-			
left	16 (55)				
right	15 (52)	-			
bilateral	2 (7)	-			
Baseline Clinical and Imaging Findings, 31 knees					
Maltracking	31 (100)	-			
Apprehension	29 (94)	-			

Ligamentous Laxity	17 (55)	-			
Wynn Davies Scale		3 (1)			
Duration of Symptoms (Months)	-	13 (14)			
Surgical Technique, 31 knees					
Procedure		-			
MPFL	29 (94)				
MPFL + Tibial Tubercle Osteotomy	2 (6)	-			
Ligament					
LARS	5 (16)				
Merselene Tape	17 (55)				
Neoligament	9 (29)	-			

Abbreviations: SD = Standard Deviation ; LARS = Ligament Augment Reconstruction System ; MPFL = Medial Patello-Femoral
 Ligament

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24.4

214

215 Table 4 Baseline Classification of Patellar Instability, N=31 knees

Instability Grade	Joint Laxity	Insall-Salvati Index > 1.3	n (%)	Age at Onset, years	Bilateral Dislocations	Moderate Trauma ¹
				Mean (range)	n	n (%)
I	-	-	7 (23)	26 (18 - 44)	0	6 (86)
II	+	-	1 (3)	11 (7 - 16)	0	0 (0)
III	-	+	7 (23)	25 (15 - 42)	0	3 (43)
IV	+	+	16 (52)	14 (8 - 25)	2	6 (38)

216 1. Moderate: Direct force against the patella or indirect forces associated with athletics

217

Surgical details are summarised in Table 3. The LARS Ligament was used in the first 5 knees. We shifted to use of Mersilene Tape (17 knees) and subsequently to use AchilloCord^{PLUS} Ligament. A tibial tubercle osteotomy to medialize the tibial tuberosity was performed in 2 cases (TT-TG distance > 15 mm with persistent maltracking after MPFL reconstruction).

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225

3.2 Clinical Outcomes

Using the Crosby and Insall grading [22], 21 knees (68%) were graded as excellent, 9 knees (29%) were good, 1 knee (3%) as fair to poor and none as worse at the last follow-up assessment. At 1 week, all patients had started knee bending and could achieve $70 - 90^{\circ}$ of flexion. 30 knees had full range of motion of more than 150 ° while 1 knee had a slight loss of flexion 20 ° at their last follow up. Passive patellar hypermobility with the knee extended and flexed at 20 ° and mal-tracking was present in all knees pre-operatively. At follow-up, 2 knees were judged to have mild hypermobility and none had severe hypermobility or mal-tracking. The apprehension test was positive in 96 % of the knees pre-operatively (Table 3) and was found positive at the follow-up only in 1 knee (2%). Generalized ligamentous laxity was seen in 15 patients (17 knees – 55 %) with a mean score of 3 (3 – 5) (Table 3). In this subset 12 knees were graded as excellent, 4 knees as good and 1 knee as fair to poor according to the grading by Crosby and Insall.

239

Graft fixation was stable in all patients at 12-month follow up. One patient had a redislocation 9 months after surgery. Four patients had prominence of the ligament over the medial femoral condyle. Three patients presented with anterior knee pain at their 24-month follow up. No other major complications were reported. The sulcus angle was 137 (range 128 - 159) ° pre-operatively. The mean patellar height was 1.5 (s.d. 0.4) pre-operatively, and showed a statistically significant improvement to 1.4 (s.d. 0.3) at follow-up (p < 0.001) (Table 5).

247 248

3.3 Functional Outcomes

All patients improved at their 24 month follow-up for the Lysholm knee score (score
mean improvement 67, s.d. 10, range 18 – 87, p-value < 0.001, paired t test) (Table
5). These outcomes remained consistent at their final follow up.

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253

	Baseline	Follow Up	Mean difference between baseline and follow up	
	Mean (SD)	Mean (SD)		P - Value
Lysholm Knee Score	20 (19)	87 (9)	67 (10)	< 0.001
Insall-Salvati Index	1.5 (0.4)	1.4 (0.3)	0.1 (0.1)	< 0.001

Table 5 – Functional outcomes at 24 months

254 SD=standard deviation

255 **4. Discussion**

256

Over the last two decades, the MPFL has been accepted as the primary restraint amongst the structures stabilizing the patella from cadaveric and biomechanical studies [24, 26]. Our study makes an important contribution to the evidence about the safety and effectiveness of a minimally invasive technique to reconstruct the MPFL using an artificial ligament. We report on the surgical and rehabilitation protocol and provide descriptive information about the clinical benefits and safety in a broad population of patients with all grades of patellar instability, including those with ligamentous laxity and patella alta. This is the first published report of an MPFL reconstruction procedure we are aware of that does not use a knee immobilizer post operatively.

267

The ideal characteristics directing graft choice for ligament reconstruction have been 268 previously described as: similarity to the natural ligament structure and 269 biomechanics, allowing secure fixation, speedy integration, and reduced donor site 270 271 morbidity [27]. Artificial ligaments have been widely used in cruciate ligament surgery from the 1980's secondary to their easy availability and reduced donor site morbidity 272 273 [28]. Our findings contribute to the growing body of evidence that their use for MPFL reconstruction substantially reduces the risk of patella re-dislocation. Overall, we 274 observed excellent to good clinical outcomes (Crosby and Insall grading system), 275 statistically significant improvement in functional (Lysholm score) and radiological 276 277 (Insall – Salvati Index) outcomes in 98 % of our study population.

278

Our positive findings are consistent with the favourable results reported for artificial 279 ligaments in extra-articular ligament reconstruction (Medial Collateral Ligament, 280 Postero-lateral Corner and MPFL) by others [5, 17, 29-31]. Most recently, a three 281 year follow-up study of 18 knees by Berutto et al (2014) presenting with objective 282 patellofemoral instability that underwent a MPFL reconstruction with a bioactive 283 artificial ligament, reported an overall satisfaction rate (88.8%), improvement in 284 Kujala score (57 - 84.3) and IKDC scores (42.4 - 70.1), with one patient requiring 285 revision surgery [30]. Studies of MPFL reconstruction using allografts like the gracilis 286 or the semitendinosis have reported similar functional outcomes. However, one 287 288 recent study has reported a higher incidence of revisions at 6-49 months follow-up (n=8 of 87 patients, 90 reconstructions) due to stiffness or re-dislocation in addition to 289 290 donor site morbidity [32].

291

The operative technique in our study involved arthroscopy and minimal incisions, thereby not violating the extensor mechanism compared to standard open surgical techniques that have been previously assessed, which involve extensive surgery [8].

The potential advantages for patients include reduced postoperative swelling, 295 reduced pain, reduced risk of complications, and improved recovery times. 296 Importantly in this study, we demonstrate that our approach also allowed post-297 operative rehabilitation without a knee immobilizer. Various techniques including 298 patellar drill holes, sutures, suture anchors and interference screws at the femoral 299 condyle have been used for graft fixation during MPFL reconstruction. Mountney et al 300 replicated MPFL reconstructions techniques using sutures +/- bone anchors, blind 301 tunnel tendon graft and a through tunnel tendon graft in a cadaveric study and 302 suggested that the latter technique provided comparable strength to the native 303 ligament (195 N) [33]. A recent systematic review on the safety of MPFL 304 305 reconstruction techniques (25 studies) reported 164 complications in 629 knees [34]. The findings suggest a trend of higher overall complications with tunnel techniques 306 307 (29.8%, including redislocation 3.3%, patellar fractures 2.4%) compared to suture techniques (21.6%, 4.8 % re-dislocation, patellar fracture 0 %) [34]. Anatomical 308 309 replication of the native MPFL in our study using an artificial ligament with no complications associated with the tunnel technique suggests good safety. 310

311

Safety concerns for artificial ligaments include rupture, synovitis, chronic effusions, 312 cross-infections, and osteolysis [35]. A case series of 126 patients using polyethylene 313 ligaments with a long term follow up of 19 years showed re-ruptures (27.5%) and 314 osteoarthritis (100 %) as complications in addition to functional impairment (29.4 %) 315 [35]. Shah et al in their systematic review concluded that MPFL reconstruction is a 316 successful procedure, however, the complication rate of 26.1% associated with this 317 procedure was not inconsequential [34]. At a median follow-up of over 2 years, we 318 observed no serious adverse events in any individuals receiving this technique at our 319 centre and graft fixation was stable for all but one individual. The re-dislocation 320 occurred in one knee with grade IV instability secondary to a significant fall 9 months 321 322 after surgery. The MPFL was revised with a tibial tuberosity osteotomy within a week after the fall and the graft was intact intra-operatively. This knee was graded as fair to 323 poor at follow up as per the Insall & Crosby Grading System [22]. The other adverse 324 events included prominence of the ligament over the medial condyle and anterior 325 326 knee pain in 4 and 3 knees respectively. The prominence was noted in the first few knees (n = 2), attributed to the bulkiness of the LARS, hence we discontinued its use 327 328 but managed these knees conservatively. Mersiline tape was used as an alternative

to LARS. In 17 patients, 2 suffered from a similar complication as seen with the 329 LARS. This was attributed to the rough texture of the tape. Therefore we shifted to 330 AchilloCord^{PLUS} Ligament, which is a densely woven polymer and smooth in texture. 331 An MRI was repeated for patients with anterior knee pain and they were 332 subsequently treated with another arthroscopy and chondroplasty (n = 3). Together 333 with data reported on artificial ligament use by Nomura et al (n = 27) and Berruto et al 334 (n = 18), there are now more than 75 cases of isolated MPFL reconstruction for 335 patella-femoral instability reported [29, 30]. The complication rate including the re-336 dislocation rate has been extremely low (n = 1), with low persistence of apprehension 337 (n = 4) in our study. Altogether, we believe our favourable results and acceptable 338 339 incidence of minor complications can be attributed to careful patient selection, the minimally invasive technique, anatomical placement of the femoral insertion, 340 341 accurate tunnel placement, absence of morbidity associated with hamstring or quadriceps allografts and a strong post operative rehabilitation regime. 342

343

An important feature of our study is that the majority of our study population had 344 ligamentous laxity with 55 % (n = 17) of the individuals classified as grade IV 345 instability (Table 4). Similar to the findings of Runow et al (1983) [2], we observed 346 that this subgroup appeared to have a lower age of onset and a history of minimal 347 trauma. In the past, severe instability has been treated with a combination of soft 348 tissue and bony realignment procedures [3, 6, 36]. There has been insufficient 349 evidence to date to demonstrate the role of only MPFL reconstruction with or without 350 lateral release in this subpopulation. A subgroup analysis conducted in patients with 351 severe instability in our study showed improvement in clinical and functional 352 outcomes for all 17 knees (16 (99%) - Excellent & Good, and mean increase in 353 Lysholm score by 68 points). These favourable results indicate the procedure is 354 suitable for individuals with ligamentous laxity and patella alta. 355

356

As a case series, the main weakness of our study is that it does not allow a direct comparison with conservative treatment or other reconstruction techniques to estimate the magnitude of the clinical benefits using our approach. Nevertheless, based on historical comparison with the outcomes of conservative treatment reported in the literature, in particular for re-dislocation rates, we believe the highly favourable outcomes we observed indicate true benefits for the use of a minimally invasive technique and artificial MPFL graft, and are unlikely to be due to chance or thefavourable selection of patients alone.

365

Another limitation of our study is the lack of long-term follow-up. Given the good 366 outcomes, achieving on going follow-up of this patient group will be challenging, but 367 essential to report long-term results. There is a need for other centres to report their 368 results to build the evidence base on long-term benefits and harms, and to define 369 which patient groups with acute patellar dislocation are most likely to benefit versus 370 conservative management. If other centres report similar findings to the present 371 study and clinical equipoise is lost, it may not be feasible to recruit patients to a 372 373 rigorous randomised controlled trial to compare this approach versus conservative treatment. However, trials comparing this procedure with alternative allograft 374 375 techniques are warranted.

376 **5. Conclusion**

377

These mid-term results demonstrate the clinical and functional benefits of this minimally invasive surgical technique using an artificial ligament, and suggest these benefits are achieved with a low risk of complications, with a minimal damage to the extensor mechanism, including in those with severe instability.

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Legends

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