First-Time Patellar Dislocation: Surgery or Conservative Treatment?

Petri J. Sillanpää, MD, PhD and Heikki M. Mäenpää, MD, PhD

Abstract: Primary patellar dislocation injures the medial patellofemoral ligament (MPFL), the major soft-tissue stabilizer of the patella, which may lead to recurrent patellar instability. Recurrent patellar dislocation are common and may require surgical intervention. The variation in location of injury of the MPFL and the presence of an osteochondral fracture produces challenges in clinical decision making between nonoperative and operative treatment, including the surgical modality, to repair or reconstruct the MPFL. Current evidence suggests that not all primary dislocations should undergo the same treatment. MPFL reconstruction may theoretically be more reliable than repair, but the optimal time to perform additional bony corrections is not known. A normal or minor dysplastic patellofemoral joint may be suitable for nonoperative treatment, whereas a higher grade of trochlear dysplasia or other significant abnormalities may benefit from surgical treatment. In this paper, we present a treatment algorithm for primary patellar dislocation.

Key Words: patella, medial patellofemoral ligament, dislocation, injury, knee, magnetic resonance imaging


First-time (primary) patellar dislocation commonly occurs in the young physically active population and is associated with a high rate of recurrent patellar instability. Depending on the patient cohort, 44% to 70% patients sustain recurrent dislocations. With a complete dislocation of the patella, the primary stabilizer, the medial patellofemoral ligament (MPFL), is frequently torn. A total or partial MPFL disruption can be observed by magnetic resonance imaging (MRI). Biomechanical studies reveal that the MPFL is the major ligamentous restraint against lateral patellar dislocation. The MPFL extends from the medial margin of the patella and attaches firmly to the femur between the adductor tubercle and the medial epicondyle. The MPFL is estimated to contribute 50% to 60% of the restraining force against lateral patellar displacement.

Patellar dislocation and MPFL injury can be diagnosed using MRI. A variable amount of anatomic abnormalities may be involved in patients with primary patellar dislocation. Primary dislocation might thus be related to trochlear dysplasia, patella alta, or malalignment, whereas primary dislocation can occur in a normal patellofemoral joint if extensive external forces twist or rotate the knee in certain way. Primary patellar dislocations quite often involve an osteochondral fracture that may require surgical fixation. Therefore the significant variation in the injury pattern and other associated factors such as alignment, dysplasia, and osteochondral injury can make treatment challenging. The majority of primary dislocations can be managed nonsurgically, although occasionally surgery is warranted and a thorough evaluation of each case is required. The optimal strategy is not yet established.

The aim of this paper is to review the evidence in the treatment of primary patellar dislocation. Surgical techniques for acute MPFL injuries and additional injuries are also discussed. A treatment algorithm for primary patellar dislocation, based on the evidence from current literature, is presented.

ETOLOGY AND RISK FACTORS FOR PRIMARY DISLOCATION

When the patella dislocates laterally, the medial patellar restraints are injured, particularly the MPFL. The patella may spontaneously relocate back to the femoral trochlear groove. The force required to dislocate the patella most likely depends on the individual patellofemoral morphology. When the femur rotates internally and the tibia externally, with the foot fixed on the ground, the patella may dislocate without any pathologic structures in the patellofemoral joint. Quite often, however, patellar dislocation occurs in a knee that has predisposing anatomic features for patellar instability. These include trochlear dysplasia, patella alta, increased femoral antetorsion, increased external tibial torsion, and valgus alignment of the lower limb. Rarely, ligamentous laxity can be present.

The incidence of primary patellar dislocation is reported to range from 6 to 112 per 100,000 persons depending on the age of the population. In a study of military conscripts, the calculated incidence of acute traumatic primary patellar dislocation was 77.4 per 100,000 persons per year; in females 104.6 per 100,000 persons per year. In that study, 63% of the injuries occurred during sports activities and 37% occurred during military training, indicating that injury was related to physical activity. The mechanism of injury is reported to be knee valgus stress and internal rotation of the femur with the foot fixed on the ground. The risk factors for primary patellar dislocation are tall height and excess weight (Table 1).

The risk factors for recurrent patellar instability are well described and include anatomic predisposing factors; trochlear dysplasia, patella alta, variations of limb alignment, connective tissue laxity, and insufficiency of previously injured medial restraints.

DIAGNOSIS OF PRIMARY PATELLAR DISLOCATION

Patellar dislocation is usually diagnosed on the basis of the clinical findings and the patient may describe “knee was out of place.” Clinical findings include tenderness of the
medial restraints. A medial hematoma may be observed. The patella may be lateraled, and an apprehension test positive. The knee is acutely swollen and hemarthrosis can be aspirated for pain relief. The patella is usually spontaneously reduced, and is quite rarely still dislocated when the patient arrives at the hospital. Children and adults may have quite different symptoms. Children can have a relatively atraumatic dislocation with slight or no effusion, indicating dysplasia in the patellofemoral joint, which allows the patella to dislocate without extensive soft-tissue damage. The primary dislocation can then be an atraumatic primary dislocation, because of patellofemoral joint laxity. This situation is nearly impossible in mature skeletons. In adults who sustain a primary dislocation without prior knee complaints, soft-tissue damage and medial restraint injury with acute hemarthrosis occur. Additional injuries such as osteochondral fractures are more frequent in traumatic primary dislocations. Traumatic dislocation means a twisting, bending, rotating, or valgusing movement of the lower limb, and that tissue damage has occurred. Both conditions, atraumatic dislocation in young children and traumatic dislocation in young adults, can sometimes be difficult to diagnose, because of the lack of clinical findings or painfully swollen knee. Radiographs are therefore always needed to confirm the diagnosis.

**TABLE 1. Risk Factors for Acute Traumatic Primary Patellar Dislocations Among Military Conscripts (Median and SD)**

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Acute Traumatic Primary Patellar Dislocation (n = 75)</th>
<th>Healthy Controls (n = 130,421)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>73</td>
<td>128,642</td>
<td>0.283</td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>1992</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>19.8 (0.8)</td>
<td>20.0 (1.3)</td>
<td>0.287</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>180.3 (7.2)</td>
<td>178.5 (6.7)</td>
<td>0.031*</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>77.2 (4.3)</td>
<td>73.2 (12.7)</td>
<td>0.014*</td>
</tr>
<tr>
<td>Muscle strength</td>
<td>16.4 (3.5)</td>
<td>16.4 (3.6)</td>
<td>0.960</td>
</tr>
<tr>
<td>Run test (m)</td>
<td>2500 (371)</td>
<td>2520 (355)</td>
<td>0.703</td>
</tr>
<tr>
<td>Body mass index</td>
<td>23.7 (3.8)</td>
<td>22.9 (3.5)</td>
<td>0.105</td>
</tr>
</tbody>
</table>

*Considered significant with P-value < 0.05.
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**FIGURE 1.** Axial Merchant radiographic view after primary patellar dislocation. Right side (R) has been dislocated and the patella is abnormally lateraled. Left side (L) is normal.

**IMAGING**

Imaging of the patellofemoral joint is described more thoroughly in another chapter in this issue. Primary patellar dislocation has certain important signs that affect decision making between surgical and nonsurgical methods. First, plain radiographs are always needed to evaluate patellar position and assess osteochondral fractures. Sagittal and anteroposterior views with axial Merchant view are essential. Axial views are particularly important, and both patellae should be included in this view. The patella may be lateraled if compared with the contralateral side (Fig. 1), and fragmentation of the medial patella, a defect of the patellar articular surface, or a loose osteochondral fragment may be observed (Fig. 2). MRI is recommended to assess the cartilage more precisely. MPFL injury location can be assessed reliably by MRI. MPFL injuries are classified in 3 categories based on location: at the level of the MPFL patellar insertion, at the midsubstance of the MPFL and medial retinaculum, and at the femoral origin of the MPFL (Table 2). Therefore, MRI is recommended in cases of primary dislocation to verify the diagnosis, evaluate additional injuries, and, importantly, describe the anatomic factors of the patellofemoral joint. Because of the high prevalence of osteochondral fractures, MRI should be performed quite soon after the injury.

**REVIEW OF THE CURRENT CLINICAL EVIDENCE**

A recent Cochrane Review concluded that there was insufficient evidence to confirm a significant difference in the outcome between surgical or nonsurgical initial management in those who have sustained a primary patellar dislocation. A meta-analysis regarding nonsurgical and surgical care of acute primary patellar dislocation concluded that surgery was not better than nonsurgical treatment. Below, we discuss prospective studies that include primary patellar dislocation and factors affecting clinical decision making between surgical and nonsurgical treatment.

Generally, prospective studies report variable results after surgical treatment for patellar dislocation. Studies initiated > 10 years ago mainly utilized surgical techniques that were nonanatomic and are no longer used. Therefore, those results are considered less reliable than modern surgical techniques. MPFL repair by sutures is not better than nonsurgical treatment, and does not decrease recurrent instability rate in skeletally immature children and do not improve subjective results in adults. Acute arthroscopic MPFL repair is also not superior to nonsurgical management. Arthroscopic repair is likely an insufficient method to approach the MPFL injury locations. Delayed repair is usually not targeted to the previous injury location and is therefore not useful.

Two prospective randomized studies described better patellar stability after MPFL repair compared with conservative treatment. However, only 1 study described clinically significant improvement in subjective outcome. An older study included a suture repair technique and a recent study included a suture repair technique.
A study included MPFL reinsertion with anchors, showing more favorable results with surgical treatment. The more recent the prospective randomized study, the more favorable the result toward operative treatment. All of the prospective randomized studies utilized different kinds of MPFL repair. To date, no study has compared MPFL reconstruction to nonoperative treatment in a prospective and randomized study setting.

The clinical importance of an MPFL injury location was evaluated in a study. In that study, MPFL disruption at the femoral attachment was related to more frequent subsequent instability than patellar or midsubstance MPFL injuries. The study is limited by its retrospective nature and the use of only male subjects. MPFL patellar attachment injury was recently reported to be at least as common as femoral attachment injury. Midsubstance MPFL disruption as an independent injury location is less common. Partial tears or wavy features of the midsubstance MPFL structure are commonly seen in cases of patellar or femoral attachment MPFL disruption. Patellar MPFL injury may include an osteochondral avulsion fracture, in which the MPFL structure is relatively intact and attached to the avulsed bone from the medial margin of the patella. In some cases, articular cartilage involvement is seen.

On the basis of these previous findings, MPFL repair may be considered more unreliable than MPFL reconstruction, in terms of providing sufficient medial soft-tissue stability.

Studies of the long-term clinical outcome of primary patellar dislocation regarding the injury location are limited to retrospective studies and are insufficient to prove any clear benefits of certain treatment modalities.

### PRINCIPLES OF NONSURGICAL MANAGEMENT FOR PRIMARY DISLOCATION

Conservative treatment has been historically suggested for patients with primary patellar dislocation. A short immobilization period is used for patient comfort and is followed by formal physiotherapy. A recent systematic review regarding the clinical outcomes of rehabilitation for patients after lateral patellar dislocation concluded that no randomized controlled clinical trials had been published that assessed different physiotherapy interventions. Therefore, the optimal conservative management has yet to be established.

Acute primary patellar dislocation is painful. Hemarthrosis can be aspirated for pain relief, after which clinical examination is controlled and the patient undergoes diagnostic imaging studies. There is no clear evidence that the knee should be immobilized after primary dislocation. Studies have poorly described the primary and recurrent nature of the patellar dislocation and the immobilization period has varied widely between 0 to 6 weeks. A recent report of preliminary results of a prospective randomized study in which immediate mobilization was compared with flexion restriction with a patellar brace found no difference at 2 years. The study is ongoing and will provide additional information in a few years. A feasibility study for a pragmatic randomized controlled trial comparing cast immobilization versus no immobilization for patients after first-time patellar dislocation suggested better short-term functional result for those not immobilized, but the reported preliminary sample was too small to make any conclusions.

The aims of physiotherapy are to restore knee range of motion, and to strengthen the quadriceps muscles to restore the dynamic part of the patellar soft-tissue stabilizers. Patients should be encouraged to activate the quadriceps as tolerated by pain and after a few weeks, strenuous exercises should be started aimed at normalizing quadriceps strength and control. At 4 to 6 weeks, by which point walking and knee range of motion have been normalized, exercises continue with more extensive extension raises, proprioceptive activities, and core stability training. Return to full activity can be suggested at 3 months. Avoiding chronic muscle weakness and imbalance is the main rehabilitation goal.

### FIGURE 2
Medial osteochondral avulsion fracture with articular surface involvement (at the patellar insertion of the medial patellofemoral ligament). Axial proton-density magnetic resonance image.

### TABLE 2
Classification on MPFL Injuries Based on Injury Location and Reported Incidence in the Literature

<table>
<thead>
<tr>
<th>MPFL Injury Classification</th>
<th>Anatomic Description</th>
<th>Proportion in Primary Dislocations</th>
<th>Mean Reported Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patellar</td>
<td>MPFL patellar attachment</td>
<td>13%-76%</td>
<td>54</td>
</tr>
<tr>
<td>Midsubstance</td>
<td>MPFL midsubstance (region between patellar and femoral attachments)</td>
<td>0%-30%</td>
<td>12</td>
</tr>
<tr>
<td>Femoral</td>
<td>MPFL femoral attachment</td>
<td>12%-66%</td>
<td>34</td>
</tr>
</tbody>
</table>

MPFL indicates medial patellofemoral ligament.
A variety of different clinical outcomes have been reported in patients after physiotherapy management after a lateral patellar dislocation. The results are discussed more thoroughly in another chapter in this issue.

In conclusion, because of the lack of clinical evidence, it is not possible to determine the optimal nonsurgical schema after primary patellar dislocation. Most likely physiotherapy treatments are recommended for patients after primary patellar dislocation, because quadriceps control and strength can be compromised, thereby affecting long-term clinical outcome. No evidence is available as to whether quadriceps weakness and especially vastus medialis oblique (VMO) muscle inactivity are an acquired clinical situation after primary patellar dislocation or present before the injury. Because of the nature of the primary dislocation, which is usually a sport-related injury or related to other physical activities, muscle weaknesses or imbalances are perhaps subsequent side effects of the injury resulting from medial capsular disruption, potential neural injuries, and loss of proprioceptive control.

**SURGICAL OPTIONS FOR PRIMARY DISLOCATION**

As described earlier, in primary patellar dislocation, MPFL injury location can be diagnosed by MRI. Secondary dislocation may not have a clear MPFL disruption due to prior MPFL laxity, and MRI is less useful in secondary dislocations if surgery is not planned. MPFL injury location should not be assessed surgically because it requires a large incision and involves dissecting the medial capsular structures including VMO fascia, which can potentially produce comorbidity to muscle function and saphenous nerve branches.

In primary patellar dislocation, the MPFL is the injured part of the patellar stability complex, whereas limb alignment and patellofemoral joint morphology are individual persistent factors. Theoretically, repair of the injured part of this complex structure should be the primary surgical option. Surgical stabilization of the patella can be performed with MPFL repair or reconstruction. Surgical repair can be performed if the injury location is known. Some patients, however, may have remarkable underlying pathology that critically affects patellar stability, although there is no evidence available when osseous abnormalities should be addressed in addition to restoring the MPFL. Additional procedures involving osseous anatomy should be performed on an individual basis and are generally not considered necessary as a first-line treatment after primary patellar dislocation.

MPFL patellar or femoral attachment injury can be surgically reinserted with satisfying results and may lead to a better outcome than nonsurgical treatment, although some controversy exists in the results of prospective studies. MPFL midsubstance injuries seem to benefit from acute repairs. MPFL injury at the femoral or patellar attachment can be repaired with sutures or suture anchors (Fig. 3). Midsubstance MPFL injury is difficult to repair adequately and is not recommended. Midsubstance MPFL injury should be repaired only in rare cases with extensive VMO fascial disruption in a high-energy dislocation (Fig. 4). In such cases, the VMO detaches from the medial patellar capsule (Fig. 4), and the quadriceps pull vector may be significantly lateralized, therefore the patella dislocates in extension when the quadriceps is activated.

Patellar attachment MPFL injury can be classified as a ligamentous or bony avulsion from the medial margin of the patella. A third type includes an osteochondral fragment with articular cartilage involvement from the medial patella (Fig. 2). According to a retrospective study, ligamentous patellar MPFL avulsion is not associated with an increased rate of recurrent instability compared with femoral MPFL avulsion injury with similar nonsurgical management. Articular cartilage involvement can be considered an indication for surgery, and cartilage defects should be repaired by reduction and fixation of the fragment (Fig. 5). In particular, fractures located in a high-pressure area, central or lateral patellar cartilage, or lateral trochlear wall, should be repaired if possible. A fragment size > 5 x 10 mm can be fixed, and based on the experience of the authors, large fragments heal well if fixation is performed within 1 week of the injury. Fixation is performed with bioabsorbable nails, pins, small screws, or sutures. Small osteochondral fractures can be managed nonsurgically, especially in cases when the fracture is located in a low-pressure area, the distal lateral margin in the lateral condyle of the femur, which normally does not carry weight or articulate with the patella. In such cases, a small fracture may be arthroscopically removed if it acts as a loose body and produces symptoms. Symptoms usually persist > 4 weeks in cases of loose body formation.
and disappear in cases of fracture incorporation with the synovial tissue, indicating no need for fragment removal.

In some cases, the MPFL may be injured in 2 locations.6 Most likely, MPFL patellar or femoral attachment disruption can be accompanied by a midsubstance total or partial tear. Therefore, MPFL reconstruction may be more reliable surgical method than MPFL repair. MPFL reconstruction cannot be safely performed at the time of injury if there is a medial patellar margin MPFL avulsion fracture (Fig. 2).28 MPFL reconstruction requires experience in patellofemoral surgery and is considered technically more demanding than repair. MPFL reconstruction produces good stability in the majority of cases with few complications, as described in many studies.41 MPFL reconstruction techniques are described in another chapter of this issue. Current evidence for MPFL repair is, however, very limited compared with that for MPFL reconstruction. MPFL repair cannot be performed without MRI verification of the injury location and repair is inappropriate if performed later in cases of chronic patellar instability.32 Repair is perhaps best indicated in acute cases with MRI-verified patellar or femoral attachment MPFL disruption within a few weeks of the injury. An additional indication could be an osteochondral fragment from the medial patella with simultaneous patellar attachment MPFL avulsion (Fig. 2).

To summarize, if surgical treatment has been chosen, primary dislocation in adults without any prior knee complaints requires only MPFL reconstruction in most cases. MPFL repair can be performed at the patellar or femoral attachment, but may be more unreliable than reconstruction. Skeletally immature patients and adolescents with primary dislocation quite often have severe trochlear dysplasia or alignment abnormalities that may need to be addressed if surgery is performed after primary dislocation. The vast majority of the primary dislocations belong to this group. It might be that repair alone is especially insufficient in anatomically abnormal population, based on the high probability of recurrent patellar instability, which is reported to be as high as 70%, especially in a very young population.23

A treatment algorithm, based on current evidence in the literature and the experience of the authors, is shown in Figure 6.

AFTER MANAGEMENT OF PRIMARY PATELLAR DISLOCATION

After initial surgical or nonsurgical treatment for primary patellar dislocation, the knee is usually immobilized for a short period to relieve pain. If MPFL reconstruction is performed, immobilization is usually not needed. Additional surgical procedures may require their own specific aftercare, which are discussed in other chapters of this issue. During the first few weeks to 3 months, patients undergo physiotherapy to recover any muscle atrophy or joint range of motion restrictions related to the injury. Patients are then encouraged to return to physical activity after 3 months and to sports when quadriceps strength and proprioceptive control are regained. The return to preinjury levels of physical activity vary between 44% to 60% after primary patellar dislocation, regardless of treatment modality.5,12,28,35

RECURRENT DISLOCATIONS

After primary dislocation, patients tend to have a 2-year period before the risk of recurrence increases.23 This may be partly because of the inability to participate in physical activities for a long time after injury. Many studies have assessed the frequency of recurrent patellar dislocation after primary dislocation. The findings indicate that 33% (range, 6% to 100%) of patients experience patellar instability after primary dislocation.4,22 Reoperation rate after primary dislocation varies between 10% and 55%.4

FIGURE 4. Extensive, combined medial patellofemoral ligament patellar attachment (small arrow) and midsubstance injury with vastus medialis obliquus muscular detachment (large arrow) from the medial patellar capsule. Only skin and subcutaneous have been incised before photography. All parts of the medial stabilizing structures of the patella (P) have been injured and the patella does not stay its place when medial and lateral part of the quadriceps muscle pulls patella cranially.

FIGURE 5. Acute osteochondral fracture (size, 10 × 18 mm) involving the medial facet and central articular surface of the patella (A). The defect should be repaired by reduction and fixation of the fragment (B).
Recurrent dislocations are exceptionally common in skeletally immature patients, as reported by Palmu et al23 and Nikku et al21 (study included, but was not restricted to, children), that 70% of their cohort presented with recurrent patellar instability after rehabilitation.

**DISCUSSION**

Primary patellar dislocation leads to MPFL injury. Some studies advocate surgical management for primary patellar dislocation whereas others recommend nonsurgical treatment.21,23,31 Because of the insufficient amount of

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**FIGURE 6.** A treatment algorithm for primary patellar dislocation. MPFL indicates medial patellofemoral ligament; MRI, magnetic resonance imaging.
The complexity of patellar instability leads to challenges in decision making between different treatment modalities. Most cases are suitable for initial nonsurgical management with physiotherapy, although recurrent instability is very common. Osteochondral fragments amenable for surgical fixation are an indication for surgery, and MPFL reconstruction may be a more reliable method of stabilizing the patella than MPFL repair, which has limitations related to the MPFL injury location. Osseous surgery is usually not needed if surgery is planned after primary dislocation, but corrections are needed in cases with severe bony abnormalities.

The MPFL injury location can be reliably assessed by MRI. Several recent studies advocate MRI after acute patellar dislocation, as the acutely injured knee usually shows hemarthrosis as a sign of tissue damage and clinical diagnosis can sometimes be difficult. MRI can be used to diagnose the signs of acute patellar dislocation and associated injuries, such as osteochondral fractures and meniscal or ligament injuries. Previous randomized studies of primary patellar dislocations concluded that surgery is not superior to nonsurgical treatment if all the patients with different types of MPFL injuries are treated similarly.

In contrast, a recent prospective randomized study in which nonsurgical treatment was compared with surgical reinsertion in either femoral or patellar attachment, surgery resulted in better stability than nonoperative treatment. Because of the high, 44% to 70%, redislocation rate after primary dislocation some cases might benefit from initial surgery, and surgery should definitely be considered for cases with a high risk of failure after nonsurgical treatment. Patients with patellar MPFL avulsion fracture and femoral attachment MPFL disruption may be at greater risk of subsequent dislocation. In these patients, restoring the integrity of the MPFL might be necessary to ensure better stability. Ruptures at the MPFL midsubstance or patellar insertion regions are generally not related to significant subsequent patellar instability. We therefore suggest that rupture of the MPFL at its midsubstance or near the patellar attachment should be treated nonsurgically.

The clinical outcome of various MPFL injuries, however, remains highly uncertain with regard to the well-known factors that predispose a patient to patellar instability, such as trochlear dysplasia, axial and torsional lower-limb alignment abnormalities, and MPFL injuries. Most likely, the more dysplastic the trochlear shape, the more devastating the injury to the MPFL is to patellar stability. Surgical treatment needs to be tailored individually, based on the MRI findings of the MPFL injury and osseous anatomy, although nonoperative treatment is still preferred in most cases.

In conclusion, primary patellar dislocation leads to MPFL injury. MPFL injuries can occur in different locations and may be combined with an osteochondral avulsion fracture of the mediolateral patellar margin or an impact fracture, which should be treated with initial fixation of the fragment. MRI is recommended for assessment of the MPFL injury and the exclusion of additional injuries. Current evidence supports nonoperative management for primary patellar dislocation in majority of the cases. Surgery should probably be considered for MPFL patellar or femoral attachment disruptions in cases with 1 or more dysplastic features, especially if patella is highly unstable after dislocation. In some cases, osseous corrections may be needed, but the majority will stabilize with MPFL reconstruction alone. Because of the complex nature of patellar instability, treatment of primary patellar dislocation is challenging. The optimal treatment has not yet been established and further prospective randomized studies are required.

REFERENCES