Correction of Patellar Bone Deviation on the Range of Motion after Total Knee Arthroplasty

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Abstract

Introduction: This study aimed to compare the improvement of the activity content and pain reduction in patients with patella displacement after total knee arthroplasty surgery with and without correction.

Methods: This study was conducted on all patients over 18 years of age refer to Baqiyatallah Hospital suffering from patella displacement, on patellar view radiography, were candidates for knee joint replacement, and underwent joint replacement. Thirty-five patients with deviation and required removal of the patella bone, whose problem was corrected after total knee joint replacement, with 35 patients whose deviation and displacement of the patellar bone was not restored after total knee joint replacement. Reducing the VAS and improve the range of motion (ROM) was assessed in the follow-up periods of 1, 2, and 4 months postoperative. Evaluation of the presence of deviation and displacement of the patella and its correction was done based on the radiograph of the patella view at an angle of 90 degrees.

Results: In examining the range of motion, the results showed that the patients in the cases and control before surgery had no significant difference in the range of motion (P=0.001). This is while a statistically significant difference was reported in the patient’s range of motion between the two groups at one month, two months, and four months after surgery (P=0.001). The average pain before surgery was similar in the two groups (P=0.953). The average pain in one, two, and four months after surgery in the modified group was lower than in the non-modified group (P=0.001).

Conclusion: This study showed that the range of motion in the modified group was higher one month, two months, and four months after surgery. Also, the average pain one, two, and four months after surgery in the modified group was lower than in the unmodified group.

Keywords: Patellar bone deviation; Range of motion; Total Knee Arthroplasty.

Introduction

Patellar deformity1 or deviation and displacement of the patella occurs due to an imbalance in the dynamic relationship between the patella and the trochlea, often secondary to an underlying structural abnormality. In total knee arthroplasty2 (TKA), most of the complications related to the extensor mechanism are due to patellar deformity or instability1,2. The malposition of components and limb misalignment, prosthetic design, improper patellar preparation, or soft tissue imbalance may cause patellar deformation. Patellofemoral instability is more likely to result from internal malrotation of femoral or tibial components. Although patellofemoral radiographs may show lateral subluxation of the patella, only a CT scan can determine rotational malalignment of the femur or tibia. Non-surgical treatment is usually unsuccessful. The significant component malformation is best managed by implant correction. In the absence of component malposition, proximal repositioning or tibial tubercle transfer has been used. Surgery on the patellar tendon may risk tearing the extensor mechanism1,3.

Anterior knee pain remains a significant problem in patellar deviation and displacement following TKA2, 3.
Patellar deviation and displacement after TKA can lead to anterior knee pain, increased component wear, increased risk of component loosening, patellar fracture, instability, and poor clinical outcomes. Surgeons have tried to reduce the incidence of tilting and symptomatic subluxation of the patella by modifying their surgical method, including using the technique of preserving the quadriceps muscles, preventing internal rotation of the femur and tibia components, medialization of the patellar component, and releasing the muscle. However, moving the patella is sometimes a challenge. Identifying and correcting patella deformity during surgery may reduce anterior knee pain and other patella complications and prevent the need for revision surgery. Although the most widely accepted belief is that anterior knee pain is often associated with patellofemoral causes, there is no consensus on etiology or treatment. Previous studies have addressed this issue to some extent, and they have stated that medial or lateral release will correct the displacement of the patella. Still, the design of this study in the form that we will have in the future has yet to be done in Iran or the world. In this study, we addressed the issue of how effective, under similar conditions, the correction or non-displacement of the patella would be in improving the range of motion and reducing pain.

Risk factors for patellar complications include valgus, obesity, the lateral release of the retina, and a thin patella before and after surgery, and the choice of patellar implant is critical: the artificial trochlea should ensure good patellar tracking and fit with TKA without resurfacing. To be selected, and in primary TKA, the patellar implant must conform well to the design of the artificial trochlea.

Considering the increase in the prevalence of TKA surgery and the fact that some patients have knee deformity and patella displacement before surgery if there is a significant relationship between the pain reduction of the patients and also the improvement of the ROM after the operation with the amount correction of patella displacement can help perform surgical procedures, this study aims to compare the amount of improvement in range of motion and pain reduction in corrected and uncorrected patients with patellar displacement after TKA surgery, which is significant or not explains its correction to the surgeon during surgery.

**Methods**

This study is a prospective cohort study and was conducted on all patients over 18 years of age who were referred to Baqiyatallah Hospital with patella displacement, who were proved by radiography of the patellar view, were candidates for knee joint replacement, and underwent joint replacement. After obtaining the necessary permissions from the Orthopedic Department of Baqiyatallah Hospital and the Ethics Committee of Baqiyatallah University of Medical Sciences, the procedure of conducting the study was as follows: 35 patients with patellar bone deviation and displacement, whose problem was corrected after total knee joint replacement with 35 patients whose patella bone deviation and displacement were not corrected after total knee replacement, to reduce pain (using VAS criteria) and improve ROM in the follow-up periods of 1, 2, and 4 months after surgery. Evaluation of the presence of deviation and displacement of the patella and its correction was done based on the radiograph of the patella view at an angle of 90 degrees. Figure 1 shows the patient's position in taking the radiograph and the leg angle between 45 and 90 degrees.

Figure 1: Position of the patient in taking a radiograph of the foot angle between 45 and 90 degrees.
It is worth mentioning that upon the arrival of the participants in the study, the demographic information of the patients was recorded and included in separate and pre-prepared checklists. This information includes things such as age, gender, height, weight, and underlying disease. Further, other information, such as radiological findings and surgical complications, was also recorded from the patients. By using the Tibial Tuberosity-Trochlear Groove (TT-TG) criterion by calculating the transverse length between the Trochlear groove on the femur and the tibial tuberosity in the axial images, it is possible to move around using the distance from the tibial groove to the trochlear groove (TT-TG distance). Measurements are used to quantify patellar disability. Values less than 20 mm were considered normal, and values above 20 mm were considered abnormal. As shown in Figure 2, the contours used to calculate lateralization of the tibial tubercle using CT. The line on the superimposed image is drawn between the posterior margins of the femoral condyles (AB). Two perpendicular lines are drawn, a femoral trochlear groove (CD) and an anterior tibial tuberosity through the selected point at the center of the patellar tendon insertion (EF). The distance between these two lines (GH) is measured in millimeters (Fig 2). Also, the congruence angle, which measures the relationship of the patellar joint prominence with the groove between the condyles, was used to measure the congruence of the patellofemoral joint 9 (Fig 3).

Figure 2: Tibial Tuberosity-Trochlear Groove (TT-TG) criterion: lines used to calculate lateralization of the tibial tubercle using CT. The line on the superimposed image is drawn between the posterior margins of the femoral condyles (AB). Two perpendicular lines are drawn, a femoral trochlear groove (CD) and an anterior tibial tuberosity through the selected point at the center of the patellar tendon insertion (EF). The distance between these two lines (GH) is measured in millimeters. 

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Impact of the Correction of Patellar Bone Deviation

Figure 3: Measurement of Patellofemoral Conformity F, Facet; L, lateral condyle; M, medial condyle; P, patellar ridge; S, sulcus. (Mean, 137 degrees, standard deviation, 6 degrees). Line SO is the angle of the groove that bisects the zero reference line. The PSO angle is the concordance angle (mean, -8 degrees, standard deviation, 6 degrees). The PF line (lateral aspect) and the ML line form the patellofemoral angle, which should diverge laterally.

**Inclusion criteria**
1. Patients over 18 years old are candidates for TKA surgery with confirmed patellar maltracking
2. Surgery with a medial parapatellar approach

**Exclusion criteria**
1. Death of the patient during surgery or during the study
2. Non-referral of patients for follow-up in months 1, 2 and 4
3. Complicated surgery such as infection after infection, tendon rupture
4. Performing other surgeries at the same time as TKA
5. Suffering from rheumatic and inflammatory diseases in participants such as lupus, rheumatoid arthritis, etc.
6. The patient's unwillingness to participate or continue the study.

**Data Collection tools:**
Based on the VAS questionnaire, the patient's pain level will be measured, and the ROM level will be measured in the examination, and one month after the surgery, the radiograph of the patellar view will be taken again to evaluate the correction or non-correction of the displacement and deviation of the patella bone. Then 35 modified and 35 non-modified people will be randomly selected, and again in the first, second, and fourth months after the operation, the VAS questionnaire and ROM examination were performed, and the two groups were compared with each other.

**Factors to be measured:**

The follow-up period of patients was 1, 2, and 4 months after TKA surgery.

VAS was used to compare pain scores before and after surgery. The VAS is a pain measurement tool that attempts to change the attitude that believes continuous numbers are not easily measurable.

Various methods have been described to measure VAS. The simplest VAS is a straight horizontal line with a constant length of 100 mm, the end of which is considered the final limit of the parameter. Suggested points in VAS measurement are as follows: no pain (0-4 mm), mild pain (5-44 mm), moderate pain (45-74 mm), and severe pain (75-100 mm). In order to compare the amount of ROM, a degree scale was used, which varies from 0 to 110 degrees.
and is measured by a special protractor. The information collected from the patients was done by obtaining consent from them and by, maintaining ethical principles, and respecting the confidentiality of the patients, and each patient can freely refuse to cooperate in filling out the questionnaire form by the doctor, and this matter did not interfere with his treatment in any way. Personal information remains confidential with the administrators. All information was recorded and collected confidentially and anonymously with a special code.

After collecting the data, including age, sex, disease stage, need for chemotherapy, the number of sessions, the presence or absence of metastasis, the survival rate, etc. All information was stored in the Spss software database version 20 and then analyzed. Mean, standard deviation, median, range, frequency, and percentage were used to describe the data. The normality of the data will be measured using the Shapiro-Wilk test, and if the data is not normal, the non-parametric t-test and ANOVA, including Mann-Whitney, will be used. Chi-square is also used to measure the relationship between the above-mentioned classified variables. The significance level of all tests is considered 0.05.

Results
In this study, the number of 70 patients with patella dislocation, who were proved by radiography of the patellar view, were candidates for knee joint replacement and underwent joint replacement, referred to Baqiyatollah Hospital, were included in the study.

The number of 35 patients with deviation and displacement of the patella bone whose problem was corrected after total knee replacement was compared with 35 patients whose deviation and displacement of the patella bone were not corrected after total knee replacement.

The average age of the patients was 61.41 ± 6.19. The average age in the modified group was 61.41±6.19 and in the unmodified group was 60.22±6.34 days (P=0.68).

The gender distribution of the patients was also similar in the two groups and 75% of the patients were female (P=0.894).

The average range of motion before surgery was 100.30±12.37 in the modified group and 100.85±12.80 in the unmodified group (P=0.857). The average range of motion four months after surgery was 124.71±9.31 in the modified group and 106.28±12.20 in the unmodified group (P=0.001).

In examining the range of motion, the results showed that the patients before surgery did not have a significant difference in the range of motion (P=0.001). This is while a significant statistical difference was reported in the range of motion of the patients between the two groups at one month, two months, and four months after surgery (P=0.001) (Table 1).

There was a significant statistical difference in the range of motion of patients before and after treatment in one month, two months, and four months in the modified group (P=0.001). But in the unmodified group before and after treatment in one month, two months, and four months, it was not present in the modified group (P=0.817) (Table 1).

The average pain before surgery was similar in the two modified groups and in the non-modified group (P=0.953).

The average pain at one, two, and four months after surgery in the modified group was lower than the non-modified group (P=0.001) (Table 2).

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<th>Corrected (35)</th>
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<td>Preoperation</td>
<td>100.85±12.80</td>
<td>100.30±12.37</td>
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<td>One month</td>
<td>98.48±11.12</td>
<td>114.65±10.45</td>
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<td>Two month</td>
<td>104.28±12.20</td>
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<td>Four month</td>
<td>106.28±12.20</td>
<td>124.71±9.31</td>
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Table 2: Average pain in consecutive time periods in two groups.

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<th>Uncorrected (35)</th>
<th>Corrected (35)</th>
<th>P-value</th>
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<tr>
<td>Preoperation</td>
<td>9.87±0.76</td>
<td>9.94±0.50</td>
<td>0.953</td>
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<tr>
<td>One month</td>
<td>4.87±1.06</td>
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<td>Two month</td>
<td>4.15±1.11</td>
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<tr>
<td>Four month</td>
<td>3.61±1.09</td>
<td>1.42±0.86</td>
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Discussion
Deviation and displacement of the patella are often one of the causes of TKA failure. The reasons for this instability must be determined precisely before treatment, including possible errors in implanting the prosthesis, such as an abnormal femoral and/or tibial internal rotation component, re-exfoliation, etc.)13-16. Among the various surgical options for the treatment of patellar instability, the optimal method should be selected according to the primary surgical error and secondary pathology. Despite the decreasing frequency of patellar instability due to advances in implant design and surgical technique, this adverse complication still accounts for approximately 10% of all TKA complications.17 Several technical factors influence patellofemoral instability after TKA, including internal rotation of the femoral or tibial components, lateral adjustment of the patellar segment, low patellar resection, and use of a large femoral component.18-19

The results of the present study showed that there was a statistically significant difference in the range of motion of the patients between the two groups at one month, two months, and four months after surgery, and the range of motion of the patients in the modified group was higher than the unmodified group. Also, the average pain at one, two, and four months after surgery in the modified group was less than in the non-modified group. Wang et al. showed that displacement and deviation of the patella after total knee arthroplasty can cause disabling symptoms such as pain, weakness, limitation of range of motion, delay in extension, and difficulty going up or down stairs.13 Total knee arthroplasty is a common procedure for treating patients with end-stage osteoarthritis of the knee. There are several complications that may require revision of implants. Patellar-related complications are difficult to treat, and their consequences affect the longevity of the implanted joint and functional outcomes.20 Complications related to the patella can be classified into bony or soft tissue complications and include bone loss, aseptic loosening, periprosthetic fractures, patellar fractures, patellar clunk syndrome, patellofemoral instability, extensor mechanism complications, mal tracking, patella Baja and rotation. Patellar complications are common in total knee arthroplasty and have significant implications for the functional outcome of total knee arthroplasty. A high index of suspicion must be maintained to avoid them. Improper implant placement and other forms of intraoperative technical error are the main cause of these complications, and therefore early prevention is very important.17-19 Patellar resurfacing has many complications that are difficult to treat. Therefore, patellar reconstruction has been controversial for several years.20-24 Some support routine reconstruction, while others recommend it in cases with specific factors.24-27

Angelos et al. (2019) suggested that patellar complications following TKA have a significant impact on functional outcomes. Careful pre-TKA planning may reduce their incidence. Any patellar complication can be managed in a variety of ways, and there is much debate about the effectiveness of each approach. When revision surgery is necessary, the knee must be approached carefully to avoid further complications. Conservative management remains valuable in dealing with a significant number of patellar complications. Moving forward, innovations in prosthetic technology may help prevent patellar complications and new surgical techniques may be needed to effectively treat them.14

Patellar denervation has been suggested to prevent pain if there is no patellar resurfacing. However, the effects seem to diminish over time. Sercillo et al. found that patellar (osteophyte removal) was better than simple denervation (29-30). Patellar resurfacing may appear to be an attractive option in patients with persistent anterior knee pain, particularly when serial radiographs show progressive narrowing of the patellofemoral joint line and lateral bone sclerosis. In a review of 15 studies on secondary patellar reconstruction, Jovenbergh et al. found that only 64% of patients were satisfied, and complication rates were 2.2% for infection, 2.2% for wound healing problems, and 1.5% for fracture.31 Bhattee et al. recommend looking for
rotational malalignment before re-examining the secondary patellar surface (32). In patients with more than 3 degrees of internal rotation of femoral components, simple secondary exfoliation was associated with poor clinical outcomes in their experience. Persistent anterior knee pain should prompt evaluation for patellar causes listed above. However, and most importantly, other causes of pain must be ruled out. The decision to undergo surgical correction for patellar pain should not be made without an extensive workup. It should be noted that investigations do not identify the source of pain in 10–15% of cases, a situation that does not indicate surgical revision 33.

Altay et al. (2012) investigated patellar denervation in TKA without patellar resurfacing in a prospective, randomized, controlled study. The clinical and radiological outcomes of 35 patients with one-stage bilateral TKA (70 knees; 26 women, nine men; mean age, 68 years [range, 58 to 77 years]) were evaluated. In addition to the removal of all osteophytes, denervation of the patella with electrocautery on one patella, as well as debridement alone, removal of all osteophytes, was performed on the contralateral patella as a control. KSS and VAS scores were used to evaluate anterior knee pain before and after surgery. The average follow-up of patients was 36 months (24 to 60 months). No surgery or reoperation was performed. There were no patellar fractures. In all parameters (KSS score, range of motion, and VAS), there was a statistically significant difference before and after the operation in favor of the denervation group. Finally, the authors stated that denervation of the patella with electrocautery could reduce anterior knee pain, and in addition, it is associated with satisfactory clinical and radiological results in TKA without patella resurfacing 5.

Carlson et al. (2017) conducted a study to evaluate changes in patellar bone displacement patterns in female patients with patellofemoral pain during puberty (mid to late adolescence). In the course of conducting this longitudinal cohort study, the researchers evaluated the information related to patellar-femoral movements by dynamic MRI in 6 girls (10 knees) with knee pain and with an average age of 14 years. In the second stage, patients at an average age of 18.5 years were re-evaluated for follow-up in terms of dynamic MRI, pain level, and ROM level. The results of the study showed that all parameters indicate the improvement of patellofemoral pain symptoms in patients in the follow-up. Of these, one patient reported complete recovery. However, compared to the initial visit, no difference in patellar maltracking was observed. Also, reducing the duration of physical activities was effective in improving all the evaluated parameters in the follow-up 5. Merkow et al. reported that the incidence of patellar complications after total knee replacement ranges from 5% to 30%. Patellar dislocation is rare but can cause debilitating symptoms 29.

Kelly (2001) stated in his study that patellofemoral complications following TKA are largely avoided by proper surgical technique. A variety of surgical exposures, including the midvastus and subcutaneous approaches, have resulted in good clinical success. It is important to maintain the integrity of the extensor mechanism. The surgeon must be prepared to use specific surgical techniques to help reveal knee stiffness and prevent damage to the patellar tendon. These techniques may include transection of the quadriceps muscle, V-Y repositioning of the quadriceps, and osteotomy of the tibial tubercle. When osteotomy of the tibial tubercle is necessary, the Whiteside method using wire fixation of the osteotomy is preferred. Choosing the right size of femoral components is important. In general, the surgeon should avoid selecting an excessively large femoral component and overfilling the patellofemoral area. Similarly, the surgeon should restore the patellar-implant composite to the original thickness of the patella, or slightly less if possible. The placement of femoral components is critical for proper patellofemoral tracking. The rotation of the femoral components should be in line with the Trans epicondylar axis of the femur. The anteroposterior axis of the femur, as described by Whiteside and Arima, is a useful secondary landmark to ensure the correct positioning of the femoral components. A slightly lateral position of the femoral components is preferred if possible to further facilitate proper tracking of the patella. Correct rotation of the tibial component is important. A variety of surgical techniques and anatomic landmarks may be used to achieve proper rotation of the tibial components. The surgeon must avoid internal rotation of the tibia, which leads to an increase in the quadriceps angle and lateral malalignment of the patella. Patellar osteotomy may be performed using a calibrated cutting system or the eyeball technique. The surgeon should avoid an oblique osteotomy that places the patella on the lateral facet. An all-cement polyethylene component placed in an intermediate position to improve patellar adhesion is preferred. Adequate soft tissue traction may require lateral retinacular release in a small percentage of cases. The superior lateral geniculate artery is preserved by release if possible. Adequate patellar femoral tracking should be performed at the time of primary TKA. Diagnosis and treatment of frequent extensor mechanism complications following TKA are discussed. Although
these complications may be successfully treated, they may be largely preventable with proper surgical technique and design of prosthetic components.

Chia et al. (2009) studied radiographic features predictive of patellar displacement during TKA. The results showed that the only radiographic parameter that was independently associated with patellar displacement was patellar inclination. The median preoperative patellar lateral shift in patients with mal tracking was 4.1 mm compared to 0.0 mm in patients without maltracking. Patients with patellar displacement greater than 3.0 mm were at a high probability of mal tracking, with positive and negative predictive values estimated at 78 and 95%, respectively.

Finally, they stated that preoperative patellar displacement might be clinically relevant to identify patients with osteoarthritis who are more likely to have patellar displacement during TKA.

Van Gennip et al. (2014), in a case series study, between 2007 and 2010, nine patients (9 knees) with anterior knee pain and symptomatic patellar luxation after primary or revised TKA with MPFL reconstruction in combination with Lateral release were treated, investigated. In two cases, an additional tibial tuberosity transfer was performed due to insufficient postoperative correction. The preoperative workup included a CT scan to rule out malrotation of the patella before and after the operation, and the inclination of the lateral patella were measured in the axial radiograph. Clinical outcome was evaluated using satisfaction, VAS pain, dislocation rate, and Patella Bartlett score. The results showed that the mean displacement of the patella improved from 29 mm (0-44) to 0 mm (0-9) after the operation. The median lateral patellar tilt before the operation was 45 (62-23) and changed to 15 (-3 to 21) after the operation. Median VAS satisfaction was 8 (5-9), and only one patient reported feeling subluxated afterward. Patlay Bartlett's score presented a diverse picture. The authors concluded that patellar dislocation after primary or revision TKA without malrotation could be effectively treated with MPFL reconstruction in combination with the lateral release. Only in limited cases is additional tibial tuberosity transfer required.

Heller et al. (2016) reviewed the causes of patellar instability listed separately and the importance of clinical diagnosis and imaging as well as preventive strategies in a review study. The findings showed that in addition to the disharmony of extensor genu valgum mechanisms after surgery, other risk factors for patellar malformation are insufficiency, inner retina, weakening of the broad middle muscle, contraction of the quadriceps muscle or tracts iliobilial, residual detial valgus deformity, femur deformity or Tibia as well as improper positioning of the patella, improper design of the prosthesis and asymmetric removal of the patella. Causes of component misalignment, defective patellar preparation, tibial misalignment, poor prosthetic design, and soft tissue imbalances must be identified to address the problem in a targeted manner. The preferred procedure for patellofemoral instability after total knee replacement is usually surgery. However, the cause of the instability must be identified and corrected prior to surgery. Without an identified cause, surgical procedures are worthless and almost invariably lead to an unsatisfactory outcome. Finally, the conclusion of patella displacement after TKA is multi-factorial and needs careful clarification. Surgical revision is recommended only in cases where there are obvious causes of pain or specific reasons for the patellar deformity.

Noh et al. (2021) investigated pre- and postoperative variables that significantly influence patellar tracking after cruciate-retaining TKA in a study. They studied 142 knee joints in patients who underwent TKA. Knees were divided into two groups based on patellar tracking after the operation, which was checked in the horizon line of the patella, axial radiographs: group 1, normal patellar tracking (Lateral tilt ≤ 10° and displacement ≤3mm) and group 2, patella displacement (lateral tilt >10° or displacement >3mm). Demographic information of patients and clinical and radiographic measurements before and after surgery were compared between the two groups. The results showed that the displacement of the lateral patella before the operation was higher (4.1 ± 2.6 mm vs. 6.0 ± 3.5 mm), as well as the frequency of release of the medial collateral ligament (MCL) (67/3 vs. 75/24) in group 2 compared to group 2. It was 1p more, < 0.001 and p < 0.001 respectively. The distal femur in group 1 was cut to a greater degree of valgus than in group 2. Complete MCL release during surgery was associated with patellar dislocation after primary or revision TKA without malrotation could be effectively treated with MPFL reconstruction in combination with the lateral release.

Decisions to perform revision surgery for patellofemoral complications must be convincingly documented by identifying the cause of the complication. When no cause is
identified, non-surgical treatment is the best option, given the uncertain results of the various surgical procedures available. Thus, of the 361 TKA recurrences for extensor apparatus complications studied by Cooney et al., 23% required repeat surgical revision procedures, 33% of which were related to patellofemoral complications. A recent study demonstrated that associated pathways and related genes be considered intelligent targets for treating pain in trauma injuries. Also, biological compounds have recently been applied for well-repair types of trauma. It suggests that related genes and biological compounds be considered intelligent targets for treating orthopedic patients.

Conclusion

The results of this study showed that the range of motion in one month, two months, and four months after surgery was higher in the modified group, and also the average pain in one, two, and four months after surgery in the modified group was lower than in the unmodified group.

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Conflict of Interest Disclosures

This is no any conflict of interest.

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Authors’ Contributions

Concepts: Hossein Pirmohammadi, Mohamad Kazem Emami Maybodi, Alireza Shakerisefat; Data gathering: Hossein Pirmohammadi, Mohamad Kazem Emami Maybodi, Alireza Shakerisefat; Writhing: Hossein Pirmohammadi, Mohamad Kazem Emami Maybodi, Alireza Shakerisefat

Ethical Statement

The ethical committee of Baqiyatallah University of medical sciences confirmed the protocol of this study (Cod: IR.BMSU.BAQ.REC.1401.106)

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