# ORIGINAL ARTICLE

# Periprosthetic knee fractures. A review of epidemiology, risk factors, diagnosis, management and outcome

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Summary. Background and aim of the work: Periprosthetic knee fractures incidence is gradually raising due to aging of population and increasing of total knee arthroplasties. Management of this complication represents a challenge for the orthopaedic surgeon. Aim of the present study is to critically review the recent literature about epidemiology, risk factors, diagnosis, management and outcome of periprosthetic knee fractures. Methods: A systematic search of Embase, Medline and Pubmed was performed by two reviewers who selected the eligible papers favoring studies published in the last ten years. Epidemiology, risk factors, diagnostic features, clinical management and outcome of different techniques were all reviewed. Results: 52 studies including reviews, meta-analysis, clinical and biomechanical studies were selected. Conclusions: Correct clinical management requires adequate diagnosis and evaluation of risk factors. Conservative treatment is rarely indicated. Locking plate fixation, intramedullary nailing and revision arthroplasty are all valuable treatment methods. Surgical technique should be chosen considering age and functional demand, comorbidities, fracture morphology and location, bone quality and stability of the implant. Given the correct indication all surgical treatment can lead to satisfactory clinical and radiographic results despite a relevant complication rate. (www.actabiomedica.it)

Key words: periprosthetic knee fractures, TKA, complications, management, supracondylar, patella, tibia

## Introduction

In recent years periprosthetic knee fractures became a growing problem due to aging of general population and to the increase in total knee arthroplasty (TKA) implants. Distal femur is involved in most cases, much less common is the involvement of tibia and patella. Advanced age and comorbidities often characterizing periprosthetic knee fracture patients add to the intrinsic technical difficulty in treating these fractures. Therefore, clinical and surgical management of these lesions can be a challenge for the orthopaedic surgeon. Aim of treatment should be early functional recovery minimizing the risk of complications.

#### Methods

Two reviewers (RF and GC) independently identified studies by a systematic search of Embase, Medline and Pubmed from inception of the database to 28 February 2017, using various combinations of the terms "periprosthetic, knee", "knee arthroplasty, fracture", "periprosthetic, fracture", "knee arthroplasty, complication", "TKA, fracture", "tibial fracture in TKA", "patella fracture in TKA". Aim of this review is to report a summary of literature evidence about epidemiology, risk factors, diagnosis, management and outcome of periprosthetic knee fractures. The two reviewers screened the titles and abstracts of the cita-

tions identified independently and in duplicate, and acquired the full text of any article that either judged potentially eligible, favoring studies published in the last ten years. Epidemiology, risk factors, diagnostic features, clinical management and outcome of different techniques were all reviewed. We resolved disagreements by discussion

### Results

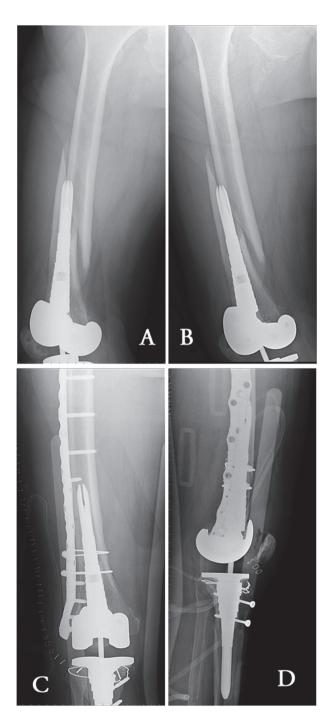
The two reviewers selected 52 studies including reviews, meta-analysis, clinical series and biomechanical studies. Case reports and small case series reporting about complications and very uncommon events as patellar periprosthetic fractures were also included [9; 10; 13; 21-26; 29; 30; 37; 51; 53; 55; 56].

### Discussion

# **Epidemiology**

Knee periprosthetic fractures are defined as fractures of the femur or tibia occurring within 15 cm from the joint line or 5 cm from the endomedullary stem if present (1, 2). Patella fractures in presence of a TKA are also considered as periprosthetic fractures (1, 2). These fractures became a growing problem in recent years, with a reported incidence in the USA of about 300.000 events per year (3). The reasons of this trend probably reside both in aging of the general population, with several comorbidities including osteoporosis and higher risk of fall to the ground, and in the growing number of TKAs. Indeed, in Italy the number of TKA implants grew from 26.787 in 2001 to 62.886 in 2014, with a rate increase of 6.8% per year (4).

Distal femur is most frequently involved, with an incidence of 0.3 to 2.5% of all knee implants (5-7). The incidence may raise up to 38% of cases in revision implants (6, 7) (fig. 1). Much less common is the involvement of tibia, with a reported incidence of 0.4 to 1.7% of cases (8, 9), and even less common of patella. The reported incidence of periprosthetic patella fractures varies widely depending on the eventual patellar resurfacing, which raises the incidence of fracture to



**Figure 1.** a, b) AP and Lateral x-rays showing a periprosthetic distal femur fracture in a 70 yrs old patient occurring on a long stemmed hinged revision knee prosthesis implanted 3 years before. c, d) AP and Lateral x-rays obtained after open reduction and internal locking plate fixation

0.2-21% of cases (6, 10). In unresurfaced patella the incidence is reported to be 0.05% of cases (6, 11).

The causative event of these fractures in most commonly (94% of cases) a low energy trauma, especially in elderly patients (12, 13). In some cases, especially for patella fractures, the causative event may be inappropriate and repeated mechanical strains, due to technical errors in resurfacing or to residual malalignment (10, 14, 15). Indeed, traumatic periprosthetic patella fractures occur in as low as 11% of cases, and may be diagnosed in routine radiographic exams in paucisymptomatic or asymptomatic patients (10).

The time interval from TKA implant to periprosthetic fracture is widely variable, depending on patients' characteristics and fracture location. As far as distal femur fractures are concerned, Gondalia et al (16) report a mean time interval of 25.5 months. On the other hand, Hoffmann et al (17) report for the same fracture location a much longer time interval (70 months). In patella fracture setting, time interval seems to be meanly shorter. Ortiguera et al (13) report 46% of patella periprosthetic fractures occurring in the first year after surgery, 68% within 2 years and 82% within 3 years.

# Diagnosis

In most cases periprosthetic knee fractures diagnosis is straightforward, based on clinical suspicion that should always arise in case of trauma occurring to a prosthetic joint. Standard orthogonal radiographic views of the knee are sufficient in most cases. Merchant views should be added to radiographic exam if a patellar fracture is suspected. A CT scan is usually diagnostic in doubt cases and might be useful for preop planning.

#### Risk Factors

Risk factors can be divided in patient related and implant related.

The main patient related risk factor for periprosthetic knee fracture is advanced age, particularly because of its association with higher risk of fall to the ground and with osteoporosis, which may both be considered as independent risk factors. Nonetheless, in the last years mean age of periprosthetic fracture patients notably raised, with a reported mean age of 78 years in 2010, resulting notably higher than the reported mean age in 1986 (66.7 years) (16). Medical conditions associated to ambulation instability and/or to higher risk of fall as cardiac and neurologic pathologies may all be considered as risk factors. Chronic use of osteopenia inducing drugs such as corticosteroids or any other medical condition affecting bone quality may also be identified as risk factors. Moreover, bone quality is a critical factor to be considered for surgical treatment, especially when internal fixation of the fracture is indicated (12, 15).

Other medical conditions as diabetes may act both as risk factor for fracture and as factors negatively affecting outcome. Diabetic patients may indeed be considered at risk for periprosthetic fracture because of risk of fall. Moreover, the same patients may be at risk for unfavorable outcome and complications because of vascular and neurologic peripheral compromise. In a population of 22 patients treated for periprosthetic knee fracture with internal locking plate fixation, Ricci et al (18) reported 2 cases of infected non-union and 1 case of aseptic non-union, all occurring in obese (BMI >30) diabetic insulin-dependent patients presenting disease progression associated conditions (peripheral neuropathy, vascular ulcers). Nonetheless, elevated BMI has been reported to be associated to periprosthetic fractures. In a case serie of 36 periprosthetic knee fractures in 35 patients Hoffmann et al (16) report a mean BMI of 32.4.

Another factor associated to these fractures has been identified by Meek et al (19) in female gender. Other authors confirmed the latter finding, reporting an 80% incidence of tibia and femur fractures in TKA in female patients (10). On the other hand, the same authors found a higher incidence of patella fractures in men, probably due to the higher mechanical forces exerted on patella by the extensor apparatus in male patients 10.

The presence of a revision TKA is the first implant related risk factor to consider, particularly on the femoral side where the incidence raises up to 38% of cases (5-7, 15). Periprosthetic osteolysis due to implant components wear leads to localized osteopenia and eventual implant loosening, both recognized as

risk factors for periprosthetic fracture. Malalignment can also lead to higher risk of fracture. In particular, varus malalignment has been reported to be associated with tibia periprosthetic fracture, especially with older TKA designs (6, 20, 21). The introduction of keeled and short stemmed tibial components seems to have partially solved this problem, reducing shear and torsional stresses on proximal tibia (6).

On the femoral side, anterior femoral notching has been widely discussed in the literature. Biomechanical studies on cadaveric specimens and biomechanical models have demonstrated a role for femoral notching in potentially causing periprosthetic fracture (22, 23). The rationale resides in a weakening of anterior femoral cortex causing a reduced resistance to flection and torsional forces. Results of clinical studies remain controversial indeed. In a study conducted by Lesh et al (21) on 164 periprosthetic distal femur fractures an association with femoral notching was found in 30% of cases. Nonetheless, many patients in their population presented other relevant risk factors. More recently Ritter et al (24) and Guiarathi et al (25) could not find any correlation between femoral notching and distal femur periprosthetic fracture in two large retrospective case series. On the other hand, Hoffmann et al (16) reported a statistically significant association of anterior femoral notching with more distal location of fracture (average distance of the fracture from the anterior femoral flange of 3.2 mm vs 39 mm) and with implant to fracture time (average 37.5 months in the anterior femoral notching group vs 80.3 months).

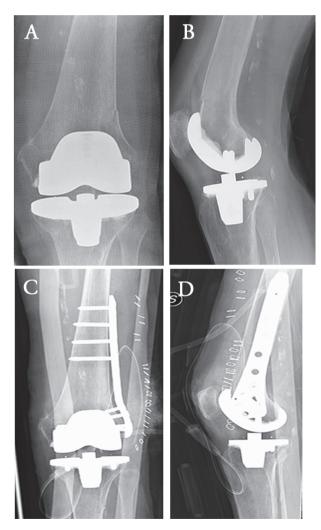
As far as patella fractures are concerned, association with patellar resurfacing in nearly exclusive. A previous literature review (10) revealed that 99% of fractures occur in resurfaced patellas. Several technical features have been identified to be associated with fracture after resurfacing, including excessive (26) or insufficient resection (13), the use of PMMA (10) and osteonecrosis (10, 13).

The latter feature has been found to be associated to supero-lateral geniculate artery damage during lateral release procedures (10). Anyway, the association between lateral release and resurfaced patella fracture has been questioned by the literature, with extremely divergent reports going from 51.2% (10) to 0% of cases (27). The explanation probably resides in surgical tech-

nique, with more aggressive releases potentially leading to arterial damage and consequent osteonecrosis.

# Classification

Several classification systems have been purposed for periprosthetic knee fractures. Distal femur fractures are more commonly classified with Lewis and Rorabeck (28) and with Su (29) classifications. According to Lewis and Rorabeck (27) distal femur periprosthetic fractures are divided in three types. In type I the fracture is undisplaced and the implant stable (fig. 2), in type II the fracture is displaced and the



**Figure 2.** a, b) AP and Lateral x-rays of an undisplaced periprosthetic knee fracture of the distal femur (Rorabeck type I) in a 78yrs old female patient. c,d) AP and Lateral x-rays obtained after internal locking plate fixation

implant stable and in type III the implant in loosened. Although this classification is widely used it does not consider fracture location, which is also determinant in the choice of treatment (17). On this basys Su and associates (28) develop a classification system which recognizes three fracture types according to the distance from the femoral prosthetic component (fig. 3). In type I the fracture is located proximal to anterior femoral flange. In type II the fracture extends cranially into the diaphysis starting from the anterior flange level. In type III the fracture line begins at the level of the anterior flange and extends distally into the epiphysis.

Tibial periprosthetic fractures are classified according to Felix et al (30) in four fracture types. In type I the fracture involves the tibial plateau and is normally associated to a malaligned or loosened tibial component. In type II the fracture in located in proximity to the tibial stem, commonly in a tibial osteolysis setting. Type III fractures occur distally to the tibial component, and Type IV involve the tibial tubercle. The four fracture types are furtherly divided in type A or B if the implant is respectively stable or loosened.

Finally, patella fractures are classified according to Goldberg (31) on the basys of extensor apparatus continuity and stability of patella resurfacing. In type I fracture the extensor apparatus is not interrupted ant the patellar component stable. In type II one of the two aspects is compromised. In Type III the distal patellar pole is fractured, and subtypes A and B are iden-



Figure 3. Radiographic lateral view of 3 different cases of Rorabeck type II distal femur periprosthetic knee fracture. These fractures can be differently classified according to Su et al. a) Su Type I: the fracture is located proximal to anterior femoral flange. b) Su Type II: the fracture extends cranially into the diaphysis starting from the anterior flange level. c) Su Type III: the fracture line begins at the level of the anterior flange and extends distally into the epiphysis

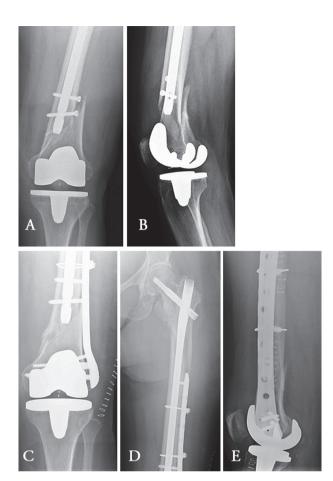
tified on the basys of extensor apparatus integrity (subtype A) or compromise (subtype B). In case a patellar dislocation results associated to the fracture a type IV lesion is identified.

#### Treatment

Correct indication for treatment of these complex lesions can differ case by case. The variables influencing the decisional process are general health status and functional demand of the patient, fracture location and morphology, bone quality, type of knee implant and eventual loosening of prosthetic components. Surgical experience of the treating surgeon should also be considered (15, 18). Aim of surgical treatment should be functional recovery with respect to pre-injury activity level, minimizing complications. Healing is generally considered when the patient recovers full weight bearing without pain, associated with radiographic healing (8, 32, 33).

Treatment modalities for distal femur periprosthetic fractures range from conservative treatment to internal fixation with retrograde intramedullary nail or locking compression plate and revision arthroplasty. In case of non-displaced fractures conservative treatment may be indicated, given a stable implant and patients clinical conditions that might lead to a clinical outcome as favorable as that of surgical treatment (7). Conversely, in displaced periprosthetic fractures conservative treatment may be indicated in non-walking patients or in the presence of severe comorbidities (7). In these cases closed reduction and immobilization in an above knee cast or hinged brace for 4-6 weeks without weight bearing may be an appropriate indication (14). Clinical and radiographic evaluation every week or every two weeks should be carried out (12, 14). Any fracture displacement observed during the follow-up period may be an indication for surgical treatment to avoid total displacement or malunion. Herrera et al (11) reported a 12% nonunion incidence in periprosthetic fractures treated conservatively, with 18% of patients who subsequently underwent surgery. Moran et al (34) reported good results in patients with nondisplaced periprosthetic fractures whereas in displaced fractures clinical and radiographic outcomes compared negatively with surgical treatment. In summary, the long period of immobilization, struggle to maintain fracture reduction, loss of knee range of motion, malalignment and risk of non-union make conservative treatment for displaced periprosthetic fracture scarcely appealing (12).

When surgical treatment is indicated, the choice of internal fixation or implant revision depends on several factors. Internal fixation is generally preferred in all cases in which it results technically feasible. Bone quality, fracture morphology including number of fragments, distance of the fracture from the implant and type and stability of knee arthroplasty implant are all to be considered. Conventional plates have gradually been abandoned for this fractures treatment because of high failure and complication rates compared to locking compression plates and intramedullary nails, which represent the implants of choice. Numerous clinical and radiographic studies have reported locking compression plates to have better clinical outcomes and lower complication rates compared to conventional plates (7, 11, 12, 14, 35-37). Advantages of locking compression plates in knee periprosthetic fracture setting are minimal invasiveness, strength of fixation in osteoporotic bone and the possibility of monocortical fixation eventually coupled with metal cerclage in proximity to the prosthetic implant (1, 7, 12, 16, 17). The latter becomes even more useful in presence of other endomedullary devices, such as nails or hip prosthesis. In this scenario the fracture occurs between the two implants with a double incidence with respect to other locations (38). Obtaining stable fixation in these fractures is even more difficult and monocortical fixation alone or coupled with metal cerclages becomes paramount (fig. 4). In order to avoid stress raisers potentially leading to new fractures the bone segment must be fully stabilized using a plate long enough to overlap with all intramedullary devices (fig. 5). After surgical intervention locking plate fixation allows early active mobilization and full weight bearing after average 6-8 weeks depending on radiographic healing (7). Early full weight bearing has also been purposed by some authors (39) with good results in terms of functional recovery and absence of complications. Clinical results of locking plate fixation of periprosthetic knee fractures are generally satisfactory (7, 11, 17, 34, 40) despite a relevant incidence of delayed union and non-



**Figure 4.** a, b) AP and lateral x-rays showing a distal femur periprosthetic knee fracture in a 80yrs old female patient treated 3 months before with a long cephalo-medullary nail for a subtrocantheric fracture. c, d, e) Radiographs obtained after open reduction internal locking plate fixation. A monocortical proximal screw, metal cerclages locked on the plate and bicortical screws inserted thorough the locking nail holes were all used to obtain stable fixation

union. Henderson et al (41) published a meta-analysis in which nonunion rate was reported to be 0-19%. Hoffmann et al (16) found in surgical invasiveness a possible risk factors, with nonunion occurring with significantly lower incidence in patients treated with minimally invasive osteosynthesis with respect to open reduction techniques. Moreover, other risk factors should not be neglected when evaluating treatment failure. In fact, Ricci et al (17) report a 13.6% nonunion rate for locking plate fixation, with all complications occurring in insulin-dependent diabetic obese patients.

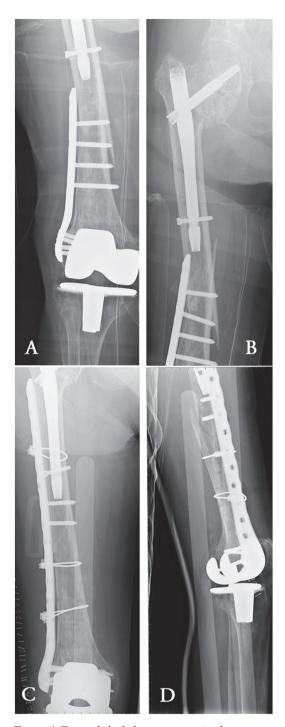


Figure 5. Femoral shaft fracture occurring between a too short locking plate implanted to treat a periprosthetic knee fracture and a previously implanted trocantheric nail in a 82 yrs old female patient. a, b) Radiographs showing the diaphyseal fracture between the two implants. c, d) AP and lateral x-rays obtained after plate removal, open reduction and new internal fixation with a longer locking plate sufficiently overlapping with the intramedullary nail to avoid stress raisers

The other most commonly used surgical technique for periprosthetic distal femur fracture fixation is retrograde endomedullary nailing. The advantages are minimally invasiveness on fracture site with full periosteal preservation, reduced blood loss and short surgical time in most cases. Ideal indications are metaphyseal and diaphyseal fractures occurring above femoral implant in presence of an adequate bone stock. Clinical result are generally satisfactory, with nearly 100% union rate at 12-16 weeks in several studies (42, 43, 44, 45). On the other hand, some limitations of this technique have to considered. First of all retrograde nailing is not applicable to all prosthetic implants. Femoral notch diameter and morphology may not allow the passage of the nail especially in posterior stabilized knee implants. Thompson et al (46) published a very useful paper which resumes the characteristics of several knee implants in order to determine their compatibility with retrograde nailing and the maximum diameter allowed to be implanted. In doubt cases or when the prosthetic model is unknown an intraoperative notch view can be resolving. Fracture location and morphology are also limiting factors for endomedullary nailing. In fractures occurring in proximity to femoral component retrograde nailing is not recommended (1, 6). Fixation stability is strictly dependent on blocking screws in the distal fragment, thus at least two bicortical screws are required. Consequently, different nail designs may allow to treat more or less distal fractures depending on blocking modalities. Anyway, fractures located distally to the prosthetic anterior flange are generally poorly stabilized by the nail, with higher risk of nonunion (32). In cases of severe osteoporosis, locking plate fixation may guarantee more stable fixation with respect to nailing (1, 6). Finally, retrograde nailing is contraindicated in patients with throcanteric nails or hip arthroplasty in order to avoid stress raisers between the two implants potentially leading to new fractures (12). After surgery retrograde nailing allows early active mobilization and full weight bearing after average 4-6 weeks depending on radiographic healing (7). Retrograde nailing is commonly associated to some degree of malunion, especially in valgus and recurvatum. The possible explanation is related to the presence of the femoral prosthetic implant which may alter entry point identification and guide wire orientation (35). Moreover, even in mild osteoporosis cases distal fixation can be insufficiently stable, leading to reduction loss (35). Nonetheless, Pelfort et al (47) demonstrate that some degree of hyperextension malunion does not alter neither knee prosthesis stability nor functional result. Conversely, valgus deformity may be poorly tolerated. Gliatis et al (44) report on a case of valgus malunion after retrograde nailing requiring prosthetic revision.

Literature comparing locking plates and retrograde nailing generally report the absence of significantly different outcome in terms of operative time, functional recovery, time to full weight bearing, KSS score and time to union (15, 31, 32, 35, 48, 49. A trend favoring retrograde nailing with respect to locking plates in terms of union rate has been reported in a recent review, despite the difference was not statistically significant (35). Conversely, Ristevski et al (35) reported a statistically significant difference in malunion rate in favor of locking plate fixation.

Prosthetic revision is indicated in fractures causing prosthesis loosening or in case of preexisting implant loosening. Moreover, implant revision might be indicated in case of internal fixation failure. Therefore, when internal fixation is likely to fail due to bone quality or fracture morphology implant revision can be recommended (6, 7). In these cases a stemmed component is chosen to obtain immediate stable fixation in intact bone while bridging the fracture site (6, 7, 50). Several authors reported satisfactory clinical outcomes with good functional recovery and early weight bearing (51–54).

In patients with massive osteolysis, severe osteoporosis, failure of internal fixation and joint instability prosthetic revision may be challenging. In these cases a hinged prosthesis may be indicated, occasionally coupled with structural allografts. The advantage of rotating hinge knee prosthesis in these cases resides in the mediolateral and antero-posterior stability combined with the possibility of rotational movement that reduces the bone-implant interface stress (12, 55). Rahman et al (49) reported at mean 33.9 months follow-up good clinical and radiographic results in 17 patients treated with revision rotating hinge knee prosthesis. Mean ROM was 90.2° in flexion with mean 2° of extension loss, and a mean 67.15 KSS score was obtained. On

the other hand, knee revision in periprosthetic fracture setting is frequently associated with limitation of range of motion (ROM). This complication might be considered as a direct consequence of bone and soft tissue damage severity. Srinivasan et al (51) reported a mean extension loss of 7.7° and a mean flection of 66° at mean 24 months follow-up. The authors underlined the importance of an adequate physical therapy program after surgery to limit ROM loss. Despite mean good clinical results a relevant complication rate is reported in the literature. Mortazavi et al (50) noted a 50% complication rate in 20 patients who underwent knee revision, with 4 requiring new surgery. Likely, Poor et al (53) reported a high complications incidence in their population, identifying the cause in medical comorbidities, inadequate bone stock and previous surgeries.

A treatment algorithm for periprosthetic tibia fractures is difficult to delineate because of the few literature reports. Anyway, Felix classification (29) can be successfully used to assess the correct indication for treatment. In type I fracture implant revision is generally indicated, being the tibial plateau involved and the frequent association with tibial component malalignment and/or loosening (6). In type II fractures, conservative management can be considered in case of undislocated fracture and stable implant (6, 29). In case of loosened tibial plateau implant revision is indicated, requiring a stemmed implant that bypasses the fracture obtaining stable fixation in tibial diaphysis (6), eventually associated with internal fixation. In type II and III dislocated fractures internal fixation is indicated if stability of the implant is not questioned. The same indication is valuable for type IV fractures, in which preserving the functional integrity of extensor apparatus is fundamental (6, 29). When internal fixation results indicated locking plates are the treatment of choice, especially with minimally invasive techniques. Intramedullary nails cannot be applied to these fracture because of tibial component design. Kim et al (56) reported in a recent study the results of locking plate fixation of 16 tibia periprosthetic fractures, of which 6 were type II and 10 type III. Mean KSS score was 88.9 at average 29.7 months follow-up. Healing was noted in 14/16 cases, with non-union and infection complicating the 2 remaining cases.

Patella fractures are treated considering fracture morphology, extensor apparatus continuity and stabil-

ity of patella resurfacing implant. Therefore, Goldberg classification (30) can be usefully applied to patella fracture as a guide for treatment. Literature reports demonstrate conservative management to be preferred in about 68% of cases (10). Nonetheless, type I fractures according to Goldberg, characterized by a stable implant and an uncompromised extensor apparatus with stable fracture pattern, are reported to be the most common. Particularly in these cases conservative treatment can lead to a successful outcome. Ortiguera et al (13) report about the results of conservative treatment in 38 cases of periprosthetic patella fractures. The authors obtained absence of pain and instability in 82% of cases at 3.6 years follow up, with only 1 case in which surgery was required. On the other hand, dislocated fractures with extensor apparatus compromise and/or patellar component loosening are much more difficult to manage. In these cases surgical treatment is commonly indicated, with different possible solutions comprising internal fixation, partial or total patellectomy and implant revision. In type II fractures, internal fixation has been reported to lead to failure in up to 92% of cases (10). Therefore, partial patellectomy with extensor apparatus repair is more commonly indicated, although complications rate can reach 50% of cases (13, 14). In type III fractures, characterized by a loose implant, residual bone stock is the main issue to consider. Revision of patella resurfacing implant can be successful if a minimum bone thickness of 10mm is present (6). Otherwise, partial or total patellectomy is preferred, although clinical results can be questionable (10, 13). Ortiguera et al (10) report in type III fractures residual symptoms in 54% of cases, complications in 29% and need to reintervention in 11% of cases. Therefore, in consideration of high complications incidence and failure rate with all surgical options, several authors attempted conservative treatment also in Goldberg type II and III fractures, especially when scarcely symptomatic (57).

# Conclusions

Periprosthetic knee fractures are a growing clinical problem. Correct clinical management requires adequate diagnosis and evaluation of risk factors. Con-

servative treatment is rarely indicated, except for patella fractures. Locking plate fixation, intramedullary nailing and revision arthroplasty are all valuable treatment methods. Surgical technique should be chosen considering age and functional demand, comorbidities, fracture morphology and location, bone quality and stability of the implant. Given a correct indication all surgical treatment can lead to satisfactory clinical and radiographic results despite a relevant complication rate.

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