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Challenges in the management of floating knee injuries: Results of treatment and outcomes of 224 consecutive cases in 10 years

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ABSTRACT

Introduction: Floating knee is a flail knee joint resulting from fractures of the shafts or adjacent metaphyses of the femur and the ipsilateral tibia. It is usually associated with several complications and mortality. This study was designed to present our experience with the treatment of this injury.
Material and method: This study was performed between January 2004 and December 2014. 224 cases of floating knee injuries gathered from the 34,480 lower extremities trauma files were studied, and the target information recorded. The injuries most frequently occurred in subjects between 16 and 35 years of age (60.71%), and in male subjects (85.71%). The most frequent mechanism of injury was traffic accident (92.85%). External fixation was the common type of treatment (82.14%) in emergency or as a definitive treatment. The treatment was performed within 24 h of the trauma. We performed a 36-month follow up with clinical examination, radiographs, assessing the complications, and using the Modified Cincinnati Rating System Questionnaire (MCRSQ) and the Karlström/Olerud Score (KOS) to evaluate the progression of the outcomes.
Results: Early complications included 8 cases of compartment syndrome, 60 open fractures and 24 partially amputated limbs. A total amputation was performed in 3 patients. The most common late complication was heterotopic calcifications of the knee ($n = 68$, 30.6%). Good scores for MCRSQ and KOS were obtained only after patients were sent to a reference center for knee surgery.
Conclusions: Our experience revealed that the complication rate associated with floatingknee injuries remains high, regardless of the performed treatment. Surgeons should focus on reducing complications while treating these severe injuries.

Introduction

Floating knee is a flail knee joint resulting from fractures of the Challenges in the Management of Floating Knee Injuries: Results of Treatment and Outcomes of 224 Consecutive Cases in 10 Yearsshafts or adjacent metaphyses of the femur and the ipsilateral tibia (Fig. 1). Floating knee injuries may include a combination of diaphyseal, metaphyseal, and intra-articular fractures [1]. This severe injury appears to be increasing in frequency, with a male preponderance observed, particularly in young adults between 20 and 30 years [1]. Road traffic accidents are the most common mechanisms of trauma, followed by gunshot wounds and falls from high heights [1]. In 1975, Blake and McBryde described the severity of this injury, which is generally caused by a high-energy trauma [2]. Local trauma to soft tissues (Fig. 2) is often extensive, and life-threatening injuries to the head, chest, or abdomen may also be present [2]. In 1978, Fraser et al. [3] performed a prognostic classification of the floating knee. An initial evaluation to establish the extent of a patient's injury is of critical importance, and this

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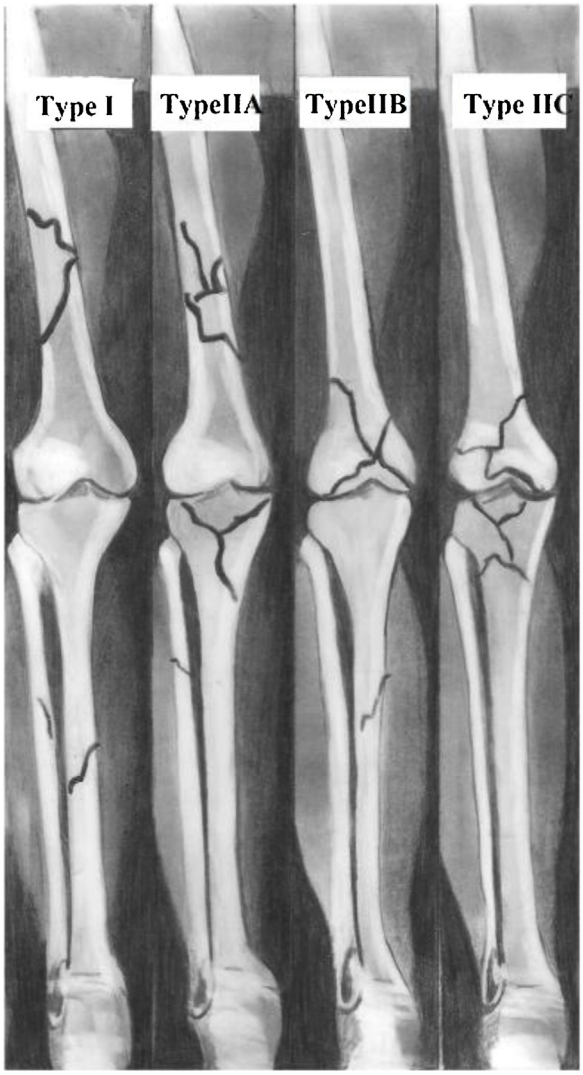

Fig. 1. Explanatory picture of Fraser's classification.

evaluation should be followed by appropriate emergency diagnostic and therapeutic measures [3]. Orthopaedic surgeons usually recommend several treatments for floating knee injuries, especially aggressive and early stabilization of both femoral and tibial fractures, regardless of the type of treatment [3–6]. Rates of infection, nonunion, malunion, and stiffness of the knee, are relatively high [5]. These complications can lead to functional impairment and frequently cause unsatisfactory results [1,4–6]. The purpose of this study was to determine the outcome of patients after our surgical management for the floating knee, to assess the impact of associated injuries, and to evaluate the final outcomes of this pathology.

Materials and methods

This retrospective study encloses patients accepted with a diagnosis of floating knee between January 1st 2004 and December 31th 2014. Patients were treated according to the Helsinki Declaration of Ethical Standards, so they were asked to read and understand the patient information sheet and sign the informed consent form. Given the retrospective nature of this study, ethical committee approval was not necessary. Inclusion criteria were the presence of a floating knee fracture pattern with an indication for surgical or conservative treatment, male patients >70 years, female patients >65 years, polytrauma patients who were alive at presentation and survived to their injuries, and a minimum 12-month follow-up. Exclusion criteria were patients who whose follow-up was discontinued, patients with a history of metabolic bone diseases or other bone diseases, and patients with history of malignancy and pathological fractures. A total of 332 patients met the inclusion criteria, but only 224 patients were selected for the final review. Standard radiographs and, in selected cases, CT scans with 3D reconstructions (like in case of Fraser's type II injury) were performed. Number of surgeries, the subjectiveModified Cincinnati Rating SystemQuestionnaire (MCRSQ), the objective/subjective Karlström/Olerud Score(KOS) and complications [1] were documented, and data recorded on an electronic spreadsheet for further processing. Surgical techniques and implants were selected according to the patient's physiological state at presentation and soft tissues conditions. The first follow-up evaluation was made 12 months after the injury, while the second evaluation was made after 36 months.The follow-up consisted of radiographic control of the injured segments, clinical control using both MCRSQ and KOS scores, and evaluation of complications. Descriptive statistics was performed to summarize the characteristics of the study group and subgroups, including means and standard deviations of all continuous variables. The *t*-test was used to compare continuous outcomes. The Chi-square test or Fisher (in subgroups smaller than 10 patients) exact test were used to compare categorical variables. Statistical significance was set at $76p < 0.05$.

Results

The final study group made of 224 unilateral floating knee injuries presented an average age of 29.6 (range 16–68) and a gender ratio (M:F) of 7:1. Table 1. Patients' occupations, type of trauma accident, distribution of fracture type according to Fraser's classification, and comorbidities upon admission (such as open fractures) are reported in Table 1. Interestingly, most trauma occurred due to traffic accident ($n = 208$, 92.85%). External fixation was the mostly performed first type of emergency surgery ($n = 188$, 84.12%). The average time elapsed until the second operation was 8.7 days (range 7–12) (Table 1). Floating knee associated-injures are reported in Table 2, with the most commonly encountered having been: spine fractures ($n = 96$, 42.85%), rib fractures ($n = 92$, 41.07%), and patellar fractures 88($n = 92$, 41.07%). Upon admission to the emergency room, Injury Severity Score (ISS), Glasgow Coma Score (GCS), and Mangled Extremity Severity Score (M.E.S.S.) with no plantar reflex were performed (Table 2). After initial instrumental (radiographs) and clinical evaluations, an emergency CT scan was performed for Fraser's type II patients. Knee ligaments injury were frequent, with the medial collateral ligament having been the most involved one ($n = 88$, 91.67%) (Table 2).

At the second evaluation at a 36-month follow-up, only 144 patients out of 224 (64.29%) could be evaluated. An MRI examination performed 8 months after the trauma in 128 Fraser's type I patients revealed injuries to the knee's soft tissues, especially medial meniscus injuries ($n = 104$, 81.25%) 97(Table 2). After an average of 4.2 months (range 3–7), a surgical conversion of the 62.5% of patients treated with External Fixation were performed. Fraser's Type I Fractures were converted from External Fixation into femoral intramedullary nails (108 cases, 60 treated with anteretrograde T2 Striker® Nails, and 48 with retrograde T2 Striker® Nails), and into tibial intramedullary nails (96 cases, treated with anteretrograde T2 Striker® Nails). 20 patients still presented an external modular fixation (Table 3). 12 patients from the Fraser's Type I group underwent an under the knee amputation in the first week after surgery (Table 3). Fraser's Type IIA Fractures were converted from External Fixation into femoral intramedullary nails (32 cases, 24 treated with anteretrograde nail, and 8 with

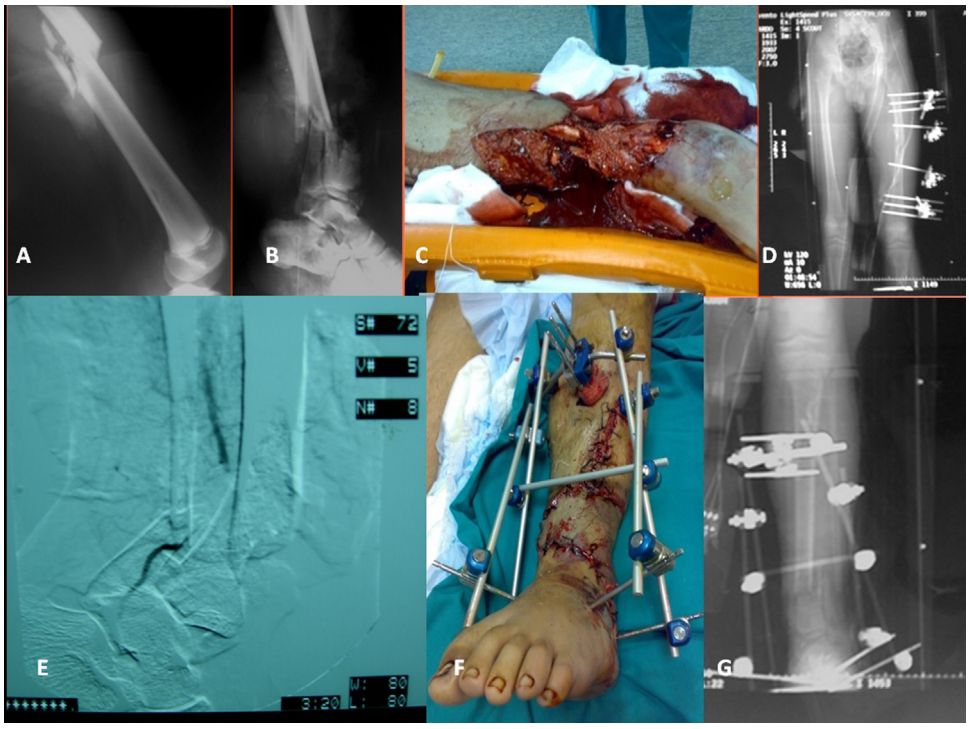

Fig. 2. 32-year-old male patient with Fraser Type I (A–B) with sub-mutation of the leg (C) GA IIIC Exposure, MESS = 11 points. We did a femoral shaft fracture damage control with External Fixation (D). Lower leg's angiography shows serious lesions of the anterior tibial artery (E). Attempt to rescue the leg with external fixator (F–G).

Table 1
Description of Population.

Description Of Population	
Numbers Of Patients	224
Average Age Of Patients	29.6
Range Of Age Of Patient	16-68
Gender Ratio (M:F)	7:1(49:7)
Range of Ages	16-35: 136(60.71%) 36-50: 56 (25%) 51-59: 24(11.72%) >60: 8(3.57%)
Work Of Population:Number (%)	Agricultural Activity: 80(35.71%) Industrial Sector: 96(42.85%) Tertiary Industry: 48(21.44%)
Type Of Accident: Number (%)	Fall From Height: 4(1.79%) Traffic Accident: 208(92.85%) Accident Agriculture: 12(5.36%)
Type Of Fractures According Fraser's Classification: Number (%)	Type I: 128(57.14%) Type IIA: 40(17.86%) Type IIB: 32(14.86%) Type IIC: 24(10.14%)
Open Fractures:Number (%)	128(57.14%) Gustillo Anderson Classification: Type II: 92 patients 72% Type III: 36 patients 28%
Compartimental Syndrome: Number (%)	8(3,7%)
Subamputed Limbs:Number (%)	28(12.5%)
Type of treatment in first surgery Number patients(%)	External Fixation: 188(84.12%) Nailing: 20(8.92%) Plates and Wires:14(6.96%)
Average Days for the second surgery(range)	8.7(7-12)

Table 2
Description of associated injures and Injures Score in the floating Knee.

INJURIES ASSOCIATED WITH THE FLOATING KNEE:NUMBER (%)	Cerebral Concussion: 44 (19.64%) Fat Embolism:8 (3.57%) Hemopneumothorax:60 (26.78%) Liver Injuries:24 (10.71%) Spleen Injuries:20 (8.92%) Bowel Injuries:8 (3.57%) Contralateral Femur Injuries: 28 (12.5%) Contralateral Tibia Injuries:44 (19.64%) Rib Fractures: 92 (41.07%) Clavicle Fractures: 76 (33.92%) Humerus Fractures:24 (10.71%) Forearm Fractures:40 (17.85%) Metatarsal Fractures: 64 (28.57%) Patella Fractures:92 (41.07%) Pelvic Injury:16 (7.14%) Acetabulum Fractures: 36 (16.07%) Spine Fractures: 96 (42.85%)
Knee's Soft Tissues Injuries In 24 Patients Fraser's Type II: NUMBER (%)	Lateral Meniscus Injuries: 40(41.67%) Medial Meniscus Injuries: 80(83.33%) Posterior Cruciate Injuries: 32(33.33%) Anterior Cruciate Injuries: 72(75%) Medial Collateral Ligament: 88(91.67%) Lateral Collateral Ligament: 68 (70.83%)
Average Injury Severity Score (ISS); (range)	29.1(12-54)
Average Glasgow Coma Score (GCS); (range)	12.7(9-15)
Average Mangled Extremity Severity (M.E.S.S.) in limb subamputed with Not plantar reflex presence;(range)	9.7(8-11)
Knee's Soft Tissues Injuries In 32 Patients Fraser's Type I: NUMBER (%)	Lateral Meniscus Injuries: 56(43.75%) Medial Meniscus Injuries: 104(81.25%) Posterior Cruciate Injuries: 36(28.12%) Anterior Cruciate Injuries: 100(78.12%) Medial Collateral Ligament: 88(68.75%) Lateral Collateral Ligament: 72(56.25%)

Table 3
Description of the surgical step in the treatment of Floating knee.

Amputee under the knee in the first week after the surgery	12 of 224 patients 9.37%
The amputee patients are from:	Fraser's Type I: 28(58.33%) Fraser's Type II A: 8(16.67) Fraser's Type IIB: 8(16.67%) Fraser's Type IIC: 4(8.33%)
Average month for the surgical conversion:	4.2 months(range 3-7)
Number of patients went under conversion	140 (62.50%)
Type of Conversion from External fixation :	Fraser's Type I Fractures: 108 femoral intramedullary nail(60 anteretrograde Nails, 48 retrograde Nails) and into 96 tibial anteretrograde Nails. 20 patients still had external modular fixation. Fraser's Type IIA Fractures: 8 femoral intramedullary nail(6 anteretrograde Nails, 2 retrograde Nails) and into 8 tibial plates. 4 patients still had external modular fixation. Fraser's Type IIB Fractures: 16 femoral plates and 12 retrograde and into 28 Tibial anteretrograde Nails. 4 patient still had external modular fixation. Fraser's Type IIC Fractures: 16 femoral plates and 16 tibial plates. 8 patients still had external modular fixation.
Average Time Of Bone Healing	6.7 months (range 3 months to 11 months)
Average surgical treatments per patient during the follow up	4.8 (3-12)
Average time of the first surgical treatment per the knees' soft tissue injuries	Fraser's Type I: Fractures: 80 patients(62.5%) Arthroscopic surgery of the knee; 48 patients(37.5%) have not undergone surgery in our center. Fraser's Type II Fractures: 72(75%) Judet's Quadricepsplasty in 96 arthroscopic surgery of the knee (100%).

retrograde nail) and into tibial plates (32 cases). 8 patients still presented an external modular fixation (Table 3). Fraser's Type IIB Fractures were converted from External Fixation into femoral plates (16 cases), femoral intramedullary nails (12 cases treated with retrograde), and tibial intramedullary nails (28 cases treated with anteretrograde nail). 4 patients still presented an external modular fixation 111(Table 3). Fraser's Type IIC Fractures were converted from External Fixation into femoral plates (16 cases), and tibial plates (16 cases). 8 patients (Fig. 3) still presented an external modular fixation (Table 3). During the first week after surgery, 8 out of 224 patients treated (3.6%) suffered from compartment syndrome (Table 1). Vacuum therapy was applied in one of the compartment syndrome cases during the first surgical step (Fig. 4), and then on 60 open fractures and 24 subamputated limbs after an average of 4.3 days (3–9) after the first surgery. Patients underwent an average of 4.8 surgical treatments (3–12) during the follow up. Treatment of knee soft tissue injuries was performed during an average of 9.6 months (range 6–18) after the initial trauma. 62.5% of Fraser's Type I Fractures with meniscus and other ligaments injuries underwent an arthroscopic surgery of the knee. The other patients did not undergo surgery, even though they were informed of the internal injuries to the knee. (Table 3). They decided to perform elective surgery on the knee only in a reference center. The reference center surgeries of patients with Fraser's Type II Fractures were Judet's Quadricepsplasty for 75% of patients and arthroscopic surgery of the knee for 100% of patients (Table 3).

The MCRSQ scores from before the trauma to 36 months after trauma are reported in Table 4. There was a significant difference of the MCRSQ score between 24 months and 36 months. The KOS scores from before the trauma to 36 months after trauma are reported in Table 5. There was a significant difference in the KOS scores between 24 months and 36 months. The complications reported by patients within the 36-month follow up are reported in Table 6, with the most commonly encountered having been: heterotopic calcifications of the knee ($n = 68$, 30.6%), stump wound dehiscence ($n = 16$, 7.14%), and unlocked knee under anesthesia ($n = 16$, 7.14%).

Discussion

Every year 5.8 million people <45 years old die from high energy trauma [7]. This incidence in young population has a greater influence over the National Health and National Providence than neoplasia and heart disease [8]. Studies showed that the floating knee is associated to injuries such as head injuries, chest injuries, abdominal injuries, injuries to other extremities and others [1–6]. The treatment of patients with multiple fractures has been largely reconsidered in the last decades. The debate between Early Total Care (ETC) and Damage Control Orthopedics (DCO) is still the main issue. The current approach is that trauma surgeons and anesthesiologists should carefully evaluate and classify patients into one of the four treatment categories: stable, borderline, unstable, and in extremis [9,10]. ETC is the preferred treatment for stable patients, while DCO is the preferred approach in unstable or in extremis patients [11]. However, there is a large debate between ETC and DCO for patients in borderline status. In uncertain cases, DCO is preferred considering the potential reduction of surgical time, bleeding and metabolic shock response [12].

The rationale for the use of external fixation in the 84.12% of our patients is supported by Nouerai et al. [5] and Pape et al. [12], since it is asserted that in the early treatment of floating knee the outcome of hemodynamic stability must be optimized, which is a function of the combined treatment of both fractures, which this injury requires. In this group of patients, only lifesaving surgery and limb amputation can be carried out during the initial phase. Long bone fractures can be stabilized quickly with simple temporary external fixation.Failure to stabilize even one of the two fractures generates loss of the knee's movement. In 1984, Veith et al. [13] reported 92% good to excellent results in patients treated with surgical stabilization of both fractures. The management with external fixation of shaft and joint fractures is still debated. According to many studies, and to our own experience, it is essential to perform a DCO or an ETC in shaft fractures and joint fractures of the femur and tibia [14–18].

The external fixation in lower extremities trauma is recommended for the management of the patient in reanimation [19,20], since it also prevents a second hit in patients with brain injuries [21,22]. We had 72% of open fractures of Gustillo Anderson Classification Type II, 28% with Type III, 12.5%had amputated Limbs without plantar reflex with an average MESS score of 9.7 points. Three of the sub-amputations were the result of severe open tibial fractures that could not be rebuilt – even without the presence of ipsilateral femoral fracture. We performed the ETC in stable patients. We performed the second hit at an average of 8.7 (range 7–12) weeks after the first surgery [23]. We performed an average of 4.8 (range 3–12) surgical treatments per patient during the follow up. We had 8 cases (3.7%) of compartment syndrome, which was caused by treatment with a simple splint pinstripe performed

Fig. 3. 45-years-old male patient after a traffic accident suffered by open fracture (GA III B) of femur (A), already worked 6 years ago with plaque and screws for 33.A1, under floating knee Type IIC according Fraser (B–C). Early Total care with femoral-tibial hybrid extrernal fixator (D-E-F).
X-rays at 6 months from the surgery showed the bone healing (G–H).

in other hospitals. Vacuum therapy was used in one case of fasciotomy for compartment syndrome since the vacuum- assisted closure appeared to be a viable adjunct for the treatment of open high-energy injuries. Application can be performed as a bedside procedure, but additional soft tissue reconstruction may be needed for definitive coverage. This device does not replace the need for formal debridement of necrotic tissue, but it may avoid the need for a free tissue transfer in some patients with large traumatic wounds [24]. Knee ligaments injuries are commonly associated with floating knee injuries [25]. In our cases, not all associated ligaments injuries were treated, following the Orthopaedic and Traumatology Association (OTA) algorithm [26], since many injuries were open fractures. Szalay et al. reported that 53% of patients with ipsilateral fractures of the femur and tibia showed ligamentous laxity of the knee, compared with only 27% of patients with isolated fractures. 80% of patients with floating knee reported knee instability at a mean follow-up of 3.7 years [25]. In the floating knee, the percentage of internal knee injuries is high [27]. An Australian paper reported that 83% of patients with pelvis or lower limb trauma do not regain full functionality after 2 years from the accident, 35% do not return to work, and 30% report persistent and significant pain [28]. The peak improvement in our outcomes (evaluated with the MCRSQ and KOS scores) was seen starting from 24 months after the trauma, because the more complex patients were sent to referral centers for knee surgery (Tables 4,5). However, our results seem to be distorted by a bias due

Fig. 4. 38-years-old woman, transferred to our hospital by Level II trauma center. She was affected by Fraser's Type I(A–B). During ambulance transport, compartmental syndrome appeared on the entire lower limb(C–D). We did a wide fasciotomy of the lower limb(E–F), after we fixed the fractures by polyaxial external fixation and Application of vacuum therapy(G–H). Skin healing in 3 months(I). We did before the femoral nailing(JK) and after 2 months the tibial nailing(L–M).

to the psychological condition of the patient in the subjective evaluation of functional recovery of the knee. The encountered complications (Table 6) are common in floating knee [1,5,6,27,29–32]. This study showed some limitations. The first limitation is the retrospective nature of the study, since it presents an inferior level of evidence compared with prospective studies, subject to confounding (other risk factors may be present that were not measured), cannot determine causation, only association, and some key statistics cannot be measured. Another limitation is that measurements and interventions were made without randomization of the researcher to the experimental groups, which have potential for bias. Finally, other potential limitations could be: potential for regression to the mean, presence of temporal confounders, and the mention of subjective score.

Conclusions

The floating knee is a complex injury that involves more than just ipsilateral fractures of the femur and tibia. The associated injuries along with the type of fracture are prognostic indicators for both initial and final outcomes (Table 7). Our experience revealed that the rate of complications associated with the floating knee remains high, regardless of the performed treatment. Surgeons should focus on reducing complications when dealing with the floating knee. We recommend an initial assessment of patients with potential life-threatening injuries, surgical fixation of both fractures (preferably in emergency with external fixation), and appropriate treatment of soft tissue injuries. Internal fixation, knee ligament assessment for associated injuries and rigorous post- operative rehabilitation, along with meticulous adhesion to the management protocols, should be also performed to reach good final outcomes.

Limitations in investigational methodology

The limits of the current study was the number of surgeon and their preferences to treat these injures, non-probability sample of convenience, due to few centric sample, Level 1 Trauma Center. Another limit is the fact that it's a retrospective study with data by recalling patients and telephonic interview. Disadvantages of retrospective studies: inferior level of evidence compared with prospective studies; subject to confounding (other risk factors may be present that were not measured); cannot determine causation, only association; some key statistics cannot be measured. Selection of patients may be biased, making generalization of results difficult. It may be unclear whether the confluence of findings is merely a chance occurrence or is truly characteristic of a new disease or syndrome.

Table 4
The performance ofModified Cincinnati Rating System Questionnairein patients with a minimum follow-up of 36 months (144 patients out of 224). The net improvement has occurred because at 18 months from the trauma patients were sent to a reference center of the knee surgery.

Time	Modified Cincinnati Rating System Questionnaire
Before Trauma	**94(range 88-100)**
Trauma	**20(range 0-42)**
1 Month	**32(range 16-54)**
3 Months	**34(range 16-60)**
6 Months	**44(range 16-72)**
12 Months	**52(range 28-80)**
24 Months	**64(range 28-88)**
36 Months	**84(range 46-94)**

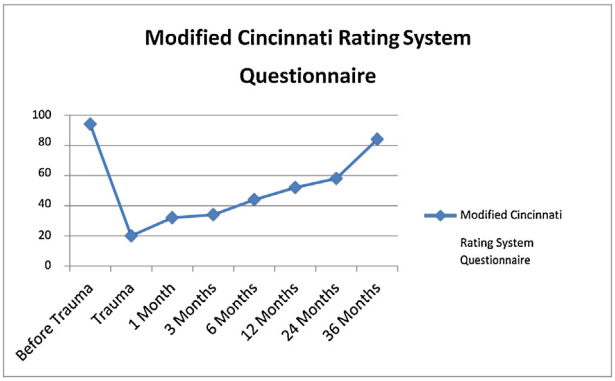

Table 5
The trend of Karlström / Olerud Score in patients with a minimum follow-up of 36 months (144 patients out of 224). The net improvement has occurred after 24 months because patients were sent to a reference center of the knee surgery.

Time	Karlström/Olerud Score
Before Trauma	**33**
Trauma	**8(range 0-25)**
1 Month	**10(range 10-26)**
3 Months	**14(range0-30)**
6 Months	**16(range 7-30)**
12 Months	**22(range 7-33)**
24 Months	**25(range7-33)**
36 Months	**27(range 15-33)**

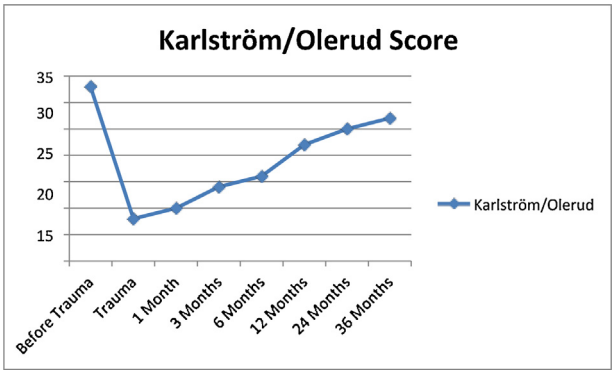

Table 6
Type of Miscellanea complications.The most common late complications were heterotopic calcifications of the knee in 17 cases (30.6%).

Type of Complications	Number of cases(%)
DeepVeintrombosis	**12(5.35%)**
Infection of Fiches/pins tract	**4(1.79%)**
Surgical Wound Dehiscence	**4(1.79%)**
Stump wound dehiscence	**16(7.14%)**
Unlock knee under anesthesia	**16(7.14%)**
Irreversible paralysis of the EPN	**4(1.79%)**
Non Union	**4(1.79%)**
Osteomyelitis	**4(1.79%)**
Heterotopic Calcifications of the Knee	**68(30.6%)**
Malunion	**12(5.35%)**

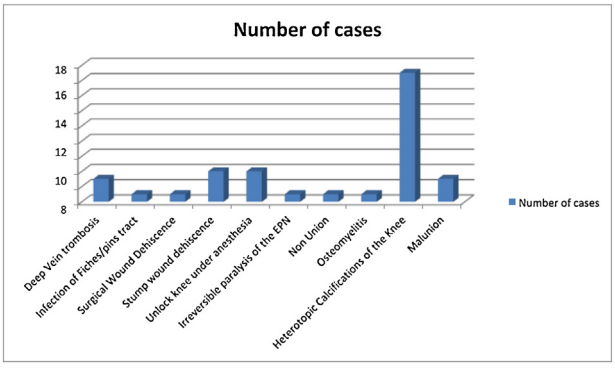

Table 7
Year of publication, study design, type of floating knee and Karlstrom and Olerud [1] criteria used in all studies listed.

Name of authors	Type of Study	Number of patients	Type of Floating Knee According Fraser	Karlström and Olerud score. At 12 months	Karlström and Olerud score. At 24months	Karlström and Olerud score. At ≥36 months
Feron JM et al [30] (2015)	Retrospective cases series	172 adults	I : 123 (71.5%) IIA: 14(8.2%) IIB: (11.6%) IIC: (8.7%)	N = 116 Excellent 23 (20%) Good 38(33%) Fair 35(30%) Bad 20(17%)	N = 89 Excellent 15 (17%) Good 33 (37%) 30 Fair (34%) Bad 11 (12, 5%)	Not Reported
Ran et al [3] (2013)	Retrospective cases series	28 adults	I: 2(7.14%) IIA: 8(28.57%) IIB: 7(25%) IIC:11(39.29%)	N = 28 Excellent 7(25%) Good 13 (46.43%) Fair 5(17.86%) Poor 3(10.71%)	Not reported	Not reported
Dahmani O et al [31] (2014)	Retrospective Case Series	9 adults	I 9(100%)	N = 9 Excellent 2(22.22%) Good 4 (44.44%) Fair 2(22.22%) Poor 1(11.12%)	Not reported	Not reported
Hegazy [6] (2011)	Retrospective Case Series	15 adults	I: 5(33.33%) IIA: 3 (20%%) IIB: 4(26.67%) IIC: 3(20%)	Not reported	N = 15 Excellent 8(53.34%) Good 4 (26.67%) Fair 2(13.33%) Poor 1(6.66%)	Not Reported
Hee [32] (2001)	Retrospective Case Series	89 adults	I: 56(62.92%) IIA: 17 (19.10%%) IIB: 10(11.24%) IIC: 6(6.74%)	Not reported	Not reported	N = 88(fu:60 m) Excellent 6(53.34%) Good 53 (26.67%) Fair 25(13.33%) Poor 4(6.66%)
Elmrini A et al [4] (2006)	Retrospective Case Series	18 adults	I: 56(62.92%) IIA: 17 (19.10%%) IIB: 10(11.24%) IIC: 6(6.74%)	Not reported	N = 18(fu:30 m) Excellent 7(38.9%) Good 6(33.4%) Fair 0(0%) Poor 5(27.7%)	Not reported

Another limitation was that the measurements and intervention were made without randomization of the researcher to the experimental groups, which have potential for bias. Finally other limiting factors of the study acknowledged by the authors can be: the potential for regression to the mean, the presence of temporal confounders and the mention of subjective score.

Conflict of interest statement

The authors disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Human and animal right

For this type of study is not required any statement relating to studies on humans and animals. All patients gave the informed consent prior being included into the study. All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments. This paper did not need the ethical committee's approval.

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None

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