The Influence of Initial Cartilage Damages in Pilon Fractures on the Development of Osteoarthritis and Functional Outcomes: A Prospective Multicentre Case Series

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Abstract

Objectives: Pilon fractures have a long-term negative impact on patients. Both initial cartilage damages (CDs) and osteoarthritis (OA) have been suggested to influence outcomes, but direct clinical evidence has been lacking. This study aims to investigate the association of initial CDs, OA occurrence, and functional outcomes. **Methods:** This is a prospective multicentre observational case series with a 2-year follow-up (FU). Initial CDs were evaluated intraoperatively in 116 enrolled patients; the postoperative OA was evaluated using FU radiographs. Functional outcomes were assessed using the Foot and Ankle Ability Measure (FAAM) for the activity of daily living (ADL) and sports activities (Sports). Change of FAAM scores over time was analyzed using mixed-effects model. **Results:** The 2-year loss-to-FU rate was 44.0%. Initial CDs on weight-bearing talus were statistically significantly associated with OA development (1-year, P < 0.001 and 2-year, P = 0.018) and poor functional outcomes (2-year ADL, P = 0.012 and 2-year Sports, P = 0.001). The existence of OA was statistically significantly associated with lower 1-year ADL scores (P = 0.018), 1-year Sports scores (P = 0.023), and 2-year Sports scores (P = 0.023). Patients with "good" reduction had higher outcome scores compared to patients with "satisfactory" reduction. **Conclusions:** In patients with well-reduced pilon fractures, initial CDs were associated with early/mid-term OA development and worse functional outcomes. OA occurrence was associated with worse functional outcomes. Current results need confirmation with a larger cohort.

Keywords: Cartilage fractures, fracture fixation, intra-articular fractures, osteoarthritis, outcome assessments, tibial fractures

INTRODUCTION

Pilon fractures are fractures involving the weight-bearing articular surface of the distal tibia and varying extent of the metaphysis. The management of pilon fractures is challenging due to the likely existence of articular comminution, multiple displaced fragments, metaphyseal bone loss, and extensive soft-tissue involvement in the case of a high-energy trauma. It occurs usually in younger adults with high demands for future physical activities, making it even more critical to understand the variables that influence optimal functional recovery.^[1,2]

In recent decades, both surgical techniques and treatment algorithm have greatly advanced. Aside from the previous sole focus on fracture reduction, alignment, and anatomical articular reduction, it is now understood that soft-tissue management is just as critical and has become an integral part of pilon fracture management. This practice has resulted in much reduced

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surgical complications and improved outcomes.^[2] Even so, studies have shown that pilon fractures have a negative effect on general health and return-to-work rates in the mid term (2–5 years) and long term (>5 years) after the injuries.^[3-7] Due to the poor outcomes even when the fractures have been well reduced, some have advocated that acute injury to the articular cartilage may be a more important factor in deciding

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the outcome than the quality of reduction.^[8] One mechanism suggested for the involvement of cartilage in outcomes is that cartilage damages (CDs) may lead to a chain of cellular and biochemical events, these, in turn, lead to the development of osteoarthritis (OA).^[9-11] However, the role of posttraumatic OA in influencing pilon fracture outcomes is also unclear. Ankle OA has been shown to cause physical impairment comparable to those associated with conditions such as end-stage kidney disease and congestive heart failure;^[12] yet, clinical studies on the outcomes of pilon fractures showed conflicting evidence for OA's association with functional outcomes.^[7,13-17]

We have previously published the data of an international multicentre case series and demonstrated that quality of reduction was associated to some extent with functional outcomes as assessed by the Foot and Ankle Ability Measure (FAAM).^[6] We now attempt to address the role of CDs in functional outcomes and the occurrence of OA through the analyses of secondary end point data collected from the same study.

MATERIALS AND METHODS

Study design

This is a *post hoc* analysis of data from selected secondary endpoints of an observational, prospective, multicentric case series study with a follow-up (FU) period of 2 years.^[6] A sample calculation was performed for the original primary endpoint but not for this *post hoc* analysis.

Patients

Eligible patients from the USA, Switzerland, Austria, and Brazil were recruited between June 2012 and March 2014 for the study. The inclusion criteria were patients aged 18 years and older, who were diagnosed with unilateral intra-articular pilon fractures of the AO/OTA type 43-B or 43-C, and those who received definitive fracture fixation with screws and plates within 30 days after the injury.^[18] Exclusion criteria included contralateral fractures of the distal half of the tibia/fibula/ talus, pathological fractures, severe polytrauma, preexisting severe vascular diseases, problems with drug or alcohol abuse, American Society of Anesthesiologists classifications of V or VI, inability to walk independently prior to the injury, neurological or psychiatric disorders that would preclude reliable assessment, or prisoners. Women that were pregnant (urine pregnancy test positive) or planning to conceive within the 1st year of the study were also excluded from the study.

Outcome measures

Fracture displacement

Anonymized preoperative DICOM radiographs (anteroposterior mortise view and lateral view) were used for fracture displacement assessment by two senior surgeons independently (discrepancies were resolved through discussions). Fracture displacements were classified in the direction of the angulation of the distal fragment as valgus, varus, flexion, extension, a combination of those, or pure axial impaction. Angulation of more than 5° was considered meaningful.

Cartilage damages

CDs on tibial plafond and talar surface were assessed intraoperatively by the treating surgeon according to the arthroscopic definition of the International Cartilage Repair Society (ICRS) for the knee.^[19] Macroscopically visible osteochondral lesions were assessed as follows: size (measured in square millimeters), severity (assessed according to the ICRS grading), and location (see the next two paragraphs). Due to the low event number of different grades and locations, the CDs were ultimately assessed as yes (ICRS Grade 1–4) or no (ICRS Grade 0).^[20] Evaluations of "not observable" were treated as missing values.

The localization of such damages on the distal tibia was assigned according to the nine-zone grid scheme of Elias *et al.*^[21] In the current analyses, CDs were grouped according to a modified scheme, "medial" included zones 1, 4, and 7 of the original scheme; "central," the original zones 2, 5, and 8; "lateral," the original zones 3, 6, and 9; anterior, the original zones 1–3; and "posterior," the original zones 4–9 [Figure 1a].

The assignment of CDs on the talar surface was based on the eight-zone grid scheme from Leontaritis *et al.*,^[22] but with a modified grouping in which only the weight-bearing area was considered and the original medial and lateral regions were excluded (i.e., both the articular surface to the medial and lateral malleolus were excluded). The modified scheme divides the weight-bearing area into medial, central, lateral, anterior, and posterior regions [Figure 1b]. Patients were treated as having missing values when the evaluations were missing or when "not observable" was entered in all fields.

Osteoarthritis

The occurrence of OA was assessed using both the anteroposterior and lateral view radiographs obtained at the 1-year and 2-year FUs. The occurrence of OA in the anterior, posterior, medial, lateral, or central area was assessed by two senior surgeons independently using the criteria according to Kellgren and Lawrence with modifications by Kijowski *et al.*:^[23,24] joints classified as Grade 0 and 1 were defined as OA negative, and joints classified as Grade \geq 2 were assessed as OA positive.

Quality of reduction

The quality of the overall reduction was visually assessed by two senior surgeons independently based on the variables, with some modification, described by Teeny and Wiss.^[25] Using the postoperative (0 to 3 days after surgery) radiographs, axial alignment, length of the fibula (i.e., if shorter in comparison to the tibia), talar shift, and intra-articular steps and gaps were assessed, and disagreements were resolved through consensus. The reduction was classified as good, satisfactory, or bad. The good reduction was defined as coronal and sagittal axial alignment with a deviation of 5° or less, shortening of the fibula of 2 mm or less, talar shift of 3 mm or less, intra-articular steps of 1 mm or less, and intra-articular gaps of 2 mm or less. The bad reduction was defined as coronal and sagittal axial alignment with a deviation $>10^\circ$, shortening of fibula >4 mm, talar shift >6 mm, and intra-articular steps and/or gaps >3 mm. Satisfactory reductions were reductions that fall in between the good and bad reductions.

Functional outcomes

Functional outcomes were measured using the FAAM. The FAAM questionnaire was developed to assess patient-reported functional outcomes on both activities of daily living (ADL) and sports activities (Sports).^[26] It has been tested on a heterogeneous group of patients with foot and ankle complaints due to fractures and injuries such as bone injuries, tendon ruptures, and sprains and showed good psychometric properties. FAAM data were included in the analysis only when patients completed at least 90% of the items; no special adjustments were made for missing data as the rates of missing answers were within the normal bound. FAAM scores were assessed at the 6-month, 1-year, and 2-year FUs.

Statistical analysis

Descriptive statistics were used to analyze all data. Comparison of outcomes between different patient groups was assessed using Chi-square tests or *t*-tests as appropriate. FAAM scores and their change over time were analyzed using mixed-effects model for repeated measures with unstructured covariance. P < 0.05 was considered statistically significant. Statistical analyses were performed using the software SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Patient demographics and baseline injury information

In total, 116 patients were enrolled in the study with a planned FU period of 2 years.^[6] Eighty-four (72.4%) patients suffered high-energy trauma and 96 (82.8%) were classified as 43-C type fractures according to the AO/OTA Fracture and Dislocation Classification [Table 1].^[18] Fifty-one (44.0%) patients dropped out before the end of the 2-year FU period; the high dropout rate was speculated to be associated with local reimbursement policy.^[6] Valgus extension and varus extension were the most frequent fracture types [Figure 2].



Figure 1: (a) Assignment of cartilage damages on the distal tibial surface (right ankle, view from below). Zone assignment according to Elias *et al*.^[21] m: medial – zones 1, 4, and 7; c: central – zones 2, 5, and 8; l: lateral – zones 3, 6, and 9; a: anterior – zones 1–3; p: posterior – zones 4–9. (b) Assignment of cartilage damages on the weight-bearing area of the talar surface (right talus, view from the top). Line drawing based on Leontaritis *et al*.^[22] m: medial (original posteromedial + anteromedial); c: central (original anterior + posterior); l: lateral (original posterolateral + anterolateral)

In the current study, all surgeries were performed with an open technique, frequently with the help of a distractor; the articular surface, for the most part, could be visualized during surgery, and an assessment of CDs was possible. Intraoperative examinations determined that 47 (46.1%) out of 102 patients sustained CDs on the weight-bearing area of talus and 92 patients (90.2%) sustained CDs on the distal tibia. Among these, five patients suffered CDs on weight-bearing area of talus only, 50 patients suffered CDs on distal tibia only, and 42 patients suffered injuries on both the weight-bearing area of talus and distal tibia. Both on the weight-bearing area of talus and distal tibia, the anterior and lateral regions had the highest incidence of CDs and fracture displacement in extension, either in combination with varus or valgus deformity [Figure 2]. Missing values were reported at a rate between 11.6% and 28.6% on talus and between 12.5% and 21.4% on the distal tibia.

Association between cartilage damage and functional outcomes

The association between CDs and FAAM scores was evaluated at different FU time points. Mixed-effect model analyses showed that at 2 years after surgery, patients with CDs of the talus performed worse in ADL than patients without such damages (mean score for patient group with CDs was 63.9, 95% confidence interval [CI] = 55.9; 71.8; mean score for patient group without CDs was 78.5, 95% CI = 70.5; 86.5, P = 0.012) [Figure 3a]. The same association was observed in the Sports scores at the 2-year FUs: the mean score for patients

Table 1: Patient demographics and injury	details (N=116)
Variables	n (%)
Gender	
Female	34 (29.3)
Male	82 (70.7)
Age (years)	
Mean±SD	44.9±13.4
Current smoker	
No	85 (73.3)
Yes	31 (26.7)
Practicing sports before the injury	
At least once a week	47 (40.5)
Less than once a week	19 (16.4)
No	50 (43.1)
BMI (kg/m ²)	
Mean±SD	28.7±7.4
Injury impact type	
High-energy trauma	84 (72.4)
Low-energy trauma	32 (27.6)
AO Mueller classification	
43-B1/B2/B3	20 (17.2)
43-C1/C2/C3	96 (82.8)
Type of injury	
Closed	90 (77.6)
Open	26 (22.4)

SD: Standard deviation, BMI: Body mass index

with CDs on talus (mean = 29.6, 95% CI = 19.6; 39.7) was lower than those for patients without such damages (mean = 54.5, 95% CI = 44.2; 64.7) (P = 0.001) [Figure 3b]. A statistically significant association was not observed for the ADL or the Sports scores at 6 months and 1 year after surgery. An analysis of the association between FAAM scores and CDs on the distal tibia was hampered by the low number of patients without CDs on distal tibia (n = 10) and the imbalance of the two groups (patients with CDs on the distal tibia, n = 92). As shown in Figure 4a and b, patients without CDs did not consistently score better or worse in the FAAM scores throughout the FU period.

Association between osteoarthritis and cartilage damages

Forty-nine (45.4%) patients at the 1-year FU and 25 (52.1%) patients at the 2-year FU developed OA based on radiographic assessment. At the 1-year FU, patients with OA in the anterior region of the joint were most prevalent (33 patients, 30.8%), followed by the lateral region (30 patients, 27.8%); at the 2-year FU, patients with OA in the anterior region of the joint were still the most prevalent (21 patients, 43.8%), followed by the lateral region (12 out of 48 patients) [Table 2].



Figure 2: Fracture displacement and cartilage damage. *Cartilage damages were assessed intraoperatively. Patients were treated as having missing values when the evaluations were missing or "not observable" in all fields



Figure 3: (a) Outcome score comparison between patients with and without cartilage damages on talus, Foot and Ankle Ability Measure, activities of daily living. (b) Outcome score comparison between patients with and without cartilage damages on talus, Foot and Ankle Ability Measure, Sports. Vertical bars: 95% confidence intervals. n = Number of patients with scores available. Cartilage damages were assessed intraoperatively. Patients were treated as having missing values when the evaluations were missing or "not observable" in all fields

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Figure 4: (a) Outcome scores comparison between patients with and without cartilage damages on distal tibia, Foot and Ankle Ability Measure, activities of daily living. (b) Outcome score comparison between patients with and without cartilage damages on distal tibia, Foot and Ankle Ability Measure, Sports subscale scores. Vertical bars: standard deviations. n = Number of patients with scores available. Cartilage damages were assessed intraoperatively. Patients were treated as having missing values when the evaluations were missing or "not observable" in all fields

Chi-square test was applied to analyze the association between the occurrence of OA and the initial injury to the cartilage. Results showed a statistically significant association between CDs on the weight-bearing area of the talus and the existence of OA: at the 1-year FU, more patients with than without CDs on the weight-bearing area of talus had developed OA (66.7% vs. 30.2%, P < 0.001). Similarly, at the 2-year FU, more patients with than without CDs on the weight-bearing area of talus had developed OA (73.7% vs. 37.5%, P = 0.018) [Table 3].

Patients without CDs in distal tibia had a lower incidence of OA than patients with CDs (three out of eight patients vs. 41 out of 87 patients) at 1 year after surgery [Table 3]. This is consistent with the results at 2 years, where a lower OA incidence was also observed in patients without CDs in distal tibia (three out of seven patients vs. 20 out of 36 patients). Due to the small sample size of patients without CDs and the imbalance of the groups, no statistical test was performed.

Association between osteoarthritis and functional outcomes

Functional outcomes were compared between patients with and without radiographic OA at 1 year and at 2 years after surgery. At 1 year, patients with radiographic OA achieved a mean score of 62.3 (95% CI = 53.6; 71.0) in ADL, which was lower than those achieved by patients without OA (mean = 75.7, 95% CI = 68.5; 82.9); the difference is statistically significant (P = 0.018). The same statistically significant association was observed for the Sports outcomes with a mean score of 30.4 (95% CI = 18.5; 42.2) for patients with OA and 49.5 (95% CI = 37.8; 61.2) for patients without OA(P=0.023). At 2 years, statistically significant association was demonstrated between OA and Sports scores (mean = 39.1, 95% CI = 24.6; 53.5 for patients with OA and mean = 64.1, 95% CI = 47.0; 81.2 for patients without OA, P = 0.023) but not between OA and ADL (mean = 70.3, 95% CI 60.2; 80.5 for patients with OA and mean = 78.5, 95% CI = 67.3; 89.7 for patients without OA, P = 0.266).

Table 2: Development of osteoarthritis (N=116)				
Variables	n (%)			
Existence of OA at 1 year, n=108	49 (45.4)			
Medial, n=108	21 (19.4)			
Central, n=107	17 (15.9)			
Lateral, n=108	30 (27.8)			
Anterior, n=107	33 (30.8)			
Posterior, <i>n</i> =107	12 (11.2)			
Existence of OA at 2 years, n=48	25 (52.1)			
Medial, n=48	9 (18.8)			
Central, n=48	7 (14.6)			
Lateral, n=48	12 (25.0)			
Anterior, n=48	21 (43.8)			
Posterior, n=48	6 (12.5)			

At 1 year, OA existence could not be assessed at several areas in three patients. At 2 years, OA existence could not be assessed in all areas in one patient. OA: Osteoarthritis

Quality of reduction and functional outcomes

The reduction quality in 92 (79.3%) patients was judged as "good" and as "satisfactory" in 24 (20.7%) patients; no patients were judged to have received a bad reduction.

Patients received "good" reduction had higher FAAM scores on average: at 1 year, patients with good reduction had ADL and Sports mean scores of 71.7 ± 25.6 and 42.7 ± 34.9 , respectively, whereas patients with satisfactory reduction had ADL and Sports mean scores of 62.5 ± 21.1 and 33.7 ± 24.9 , respectively. At 2 years, patients with good reduction had ADL and sports mean scores of 74.8 ± 22.9 and 48.1 ± 33.7 , respectively, whereas patients with satisfactory reduction had ADL and Sports means cores of 63.6 ± 25.5 and 31.0 ± 29.8 , respectively. Due to the small sample size and the lack of patients with bad quality of reduction, no statistical testing was performed.

DISCUSSION

The goal of the current analyses was to understand the

Table 3: Association between osteoarthritis development and cartilage damages										
	Talus, weight-bearing area CDs*			Distal tibia CDs*						
	No (<i>n</i> =55)	Yes (<i>n</i> =47)	P [†]	No (<i>n</i> =10)	Yes (<i>n</i> =92)	P ^{††}				
Existence of OA at 1 year, n (%)	<i>n</i> =53	<i>n</i> =42		<i>n</i> =8	<i>n</i> =87					
No	37 (69.8)	14 (33.3)	< 0.001	5 (62.5)	46 (52.9)	-				
Yes	16 (30.2)	28 (66.7)		3 (37.5)	41 (47.1)					
Existence of OA at 2 years, n (%)	<i>n</i> =24	<i>n</i> =19		<i>n</i> =7	<i>n</i> =36					
No	15 (62.5)	5 (26.3)	0.018	4 (57.1)	16 (44.4)	-				
Yes	9 (37.5)	14 (73.7)		3 (42.9)	20 (55.6)					

*CDs were assessed intraoperatively: Patients were treated as having missing values when the evaluations were missing or "not observable" in all fields, [†]Chi-square test, ^{††}*P* values not calculated due to the small sample size in the "no" group. OA: Osteoarthritis, CDs: Cartilage damages

relationship between CDs, fracture displacement, quality of reduction, the occurrence of OA, and functional outcomes in surgically treated pilon fractures. Our analyses showed that the existence of CDs on the weight-bearing area of talus was significantly associated with poorer functional outcomes at 2 years and the development of OA at 1 year and 2 years. The existence of OA was significantly associated with both lower FAAM ADL and Sports scores at 1 year and with lower Sports scores at 2 years postinjury. Descriptive analysis revealed that patients with "good" quality of reduction had higher FAAM scores at 1 and 2 years compared to patients with "satisfactory" reduction.

Outcomes of high-energy pilon fractures are influenced by multiple factors such as the severity of the trauma, quality of reduction, soft-tissue conditions, initial CDs, socioeconomic status, and demographic factors.^[1,4,15,25,27,28] The individual contribution of various factors to the outcomes of high-energy pilon fractures is difficult to assess because some of the factors are closely linked. For example, fracture severity and quality of reduction have been shown to be closely associated, and CDs can be related to fracture severity (and therefore to outcomes) and presumably contribute to the development of OA.^[8,14,16] Meanwhile, an influence of OA (assessed radiographically or via computed tomography scans) on clinical outcomes of pilon fractures has not been clearly demonstrated in the literature, and contradictory results have been reported.^[7,13,14,16] Overall, clear evidence for the association between CDs and OA occurrence in the literature is scarce; to our knowledge, the best clinical evidence in the lower extremity comes from research on ankle fractures.[29]

The tibiotalar articulation has been said to be more sensitive to CDs than other joints.^[8,16] The current results showed that CDs on the weight-bearing area of talus were associated with lower functional scores in both ADL and Sports subscales at the 2-year FU. The Sports scale seemed more sensitive than the ADL scale as demonstrated by a greater difference in mean scores for Sports (24.9) than ADL (14.6) between patient groups with and without CDs. Similarly, the a greater difference was observed in the mean Sports scores (25.0) than the mean ADL scores (8.2) between the patient groups with and without OA at 2 years. This result is consistent with the report from Boraiah *et al.* that osteochondral lesions of the talus (OCLT) suffered through ankle fractures had a significant impact on only the scores of the Sports subscale but not others (pain, symptoms, ADL, and quality of life) using the Foot and Ankle Outcome Scoring system.^[30] The authors reasoned that "...the increased physical demand...may worsen the symptomatology in patients with OCLT." In our case, the disability of patients with initial CDs might have become symptomatic only under the greater performance demand of sports in comparison to ADL activities.

The current analyses demonstrated that the existence of CD on the weight-bearing area of talus was associated with OA development at both 1 and 2 years in pilon fractures. Whether or not CDs on distal tibia were associated with the development of OA cannot be determined based on the current results due to the imbalanced group sizes and that only ten patients did not have distal tibial CDs. The main reason for the imbalance between these two groups (as opposed to the balanced groups for CD on talus) resides presumably in the inclusion criteria that patients must be diagnosed with intra-articular distal tibial pilon fractures. The most frequent locations of damage on both talus and distal tibia were the anterior and lateral aspects – locations that correspond to the most frequently observed locations of OA occurrence. This could either indicate a general causal relationship between CD and OA development or that CDs on the anterior and lateral aspects of the talus (as opposed to other locations) were more prone to develop into OA, as has been suggested by Stufkens et al.[29]

The current mapping of CDs to be most frequently located in the anterior and lateral regions of the weight-bearing area of talus and distal tibia is different from that of previous reports where osteochondral lesions were most frequently located in the medial and posterior regions of the distal tibia (osteochondral lesions on distal tibial plafond [OLTP]) and in the lateral and medial domes of the talus (OCLT) in ankle fractures.^[21,30] The difference might lie in both the patient population/injury pattern and the methods of assessment. In the OLTP example, the previous paper identified 38 patients retrospectively using keywords such as "osteochondral defect," "osteochondral lesion," and "distal tibia;" the injury patterns range from simple ankle fractures to possibly complex pilon fractures. In the OCLT example, the patient population was ankle fracture patients. In both cases, the lesions were assessed using magnetic resonance imaging images, whereas in the current study, CDs were assessed via direct intraoperative observation in 116 prospective pilon fractures patients.

An assessment of the influence of quality or reduction on outcomes is particularly difficult nowadays. Many researchers are likely to have (or have had) the same difficulties our current study showed, namely, the surgeons strove to achieve the best possible reduction, leaving one end of the spectrum (i.e., poor reductions) missing. As demonstrated in the current analysis, all surgeons involved in the study demonstrated a high level of operative competence and resulted in no case where the quality of reduction was evaluated as "bad," which, in turn, resulted in an insufficient statistical power to determine the influence of quality of reduction on outcomes. The important influence of the quality of reduction on outcomes, however, has been suggested in the literature. In addition, available evidence demonstrated that articular steps and gaps led to worse functional outcomes, and increased contact stress had been shown to correspond to the occurrence of OA.^[2,14,31] Despite the discussion on whether anatomic reduction of the articular surface is relevant or not, achieving the best possible reduction quality as long as the condition of the soft tissues would allow should be the first-line goal. Based on the current findings, neither the surgical approaches nor the techniques should change - as these should be based on the individual fracture pattern and soft-tissue condition. Future research on the various ways of mending injured cartilage could further advance the treatment of pilon fractures.

The strength of the current study is its prospective design allowing data collection in a patient population with well-defined baseline, surgical condition, and outcome parameters. Although the lack of cases with poor reduction quality made it difficult to assess the influence of the quality of reduction on outcomes, the relatively uniform quality of reduction underscores the validity of the observed association between CDs, functional outcomes, and OA.

The main limitation of the current study is the high dropout rate. The lack of statistically significant association of CDs and FAAM scores at 6 months and 1 year and between OA and ADL score at 2 years most likely reflected a lack of statistical power. In addition, some statistical analyses were not performed due to the small patient population, leading to insufficient statistical power, for example, the association between CDs on the distal tibia and functional outcomes and the influence of the quality of reduction on FAAM scores. The 2-year FU period might be another limitation: previous reports showed that pilon injuries continued to improve for a long time, with the maximal improvement being between 9 months and 5 years.^[7] With a FU period of up to 2 years, the current results may pertain to only the early to mid-term outcome after pilon fractures.

CONCLUSIONS

The results of this prospective case series study provided evidence that under the condition of good or satisfactory quality of reduction, CDs were associated with early/mid-term OA development and with worse functional outcomes after pilon fractures.

Ethical consideration

The study was conducted in accordance to the ethical principles of the Declaration of Helsinki, the International Council for Harmonisation Good Clinical Practice (ICH GCP) guidelines, the European Standard EN ISO14155/2003-2011, and the laws and regulations of individual countries where the research was conducted. Ethical approval was obtained from all local authorities. All patients had given informed consent. The study was registered at the ClinicalTrials.gov, NCT01316289.

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Conflicts of interest

There are no conflicts of interest.

Authors' contributions

All authors are qualified for authorship. CS, AJ, and KS contributed to the study design, CS and DV contributed to conducting the study, KE conducted the statistical analysis; MSC prepared the manuscript; all contributed to the concept of the manuscript, data analysis, and all authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript. CS is the guarantor of the manuscript.

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