Scoring System for Identifying Impending Complete Fractures in Incomplete Atypical Femoral Fractures

Byung-Woo Min,[1]* Kyung-Hoi Koo,[2]* Youn-Soo Park,[3] Chang-Wug Oh,[4] Seung-Jae Lim,[3] Joon-Woo Kim,[4] Kyung-Jae Lee,[1] and Young-Kyun Lee[2]

[1]Department of Orthopaedic Surgery, Keimyung University, Dongsan Medical Center, Daegu 41931, South Korea; [2]Department of Orthopedic Surgery, Seoul National University Bundang Hospital, Seongnam 13620, South Korea; [3]Department of Orthopaedic Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine Seoul 06351, South Korea; and [4]Department of Orthopaedic Surgery, Kyungpook National University Hospital, Daegu 41944, South Korea

Context: Although impending incomplete atypical femoral fractures (AFFs) require prophylactic fixation, there is still a lack of study on predicting complete fracture among the incomplete AFFs.

Objective: Our purposes are to develop a scoring system to predict progression into complete fracture and to evaluate its reliability and validity.

Design, Setting, and Patients: We reviewed 46 incomplete AFFs in 44 patients who did not undergo prophylactic fixation. A weighted scoring system, including four identified risk factors (the site, severity of pain, status of the contralateral femur, and the extent of radiolucent line), was developed. We evaluated its interobserver reliability by using intraclass correlation coefficiency (ICC) and its accuracy using receiver operator characteristic (ROC) curve. The validity of the scoring system was tested in a different cohort.

Intervention: Observational study.

Main Outcome Measure: Progression to complete fracture within 6 months.

Results: Among 46 incomplete fractures, 13 developed a complete fracture within 6 months. The probability of complete fracture increased abruptly when the score was 8 points or more. The proposed scoring system showed an almost perfect reliability (ICC, 0.997; 95% confidence interval, 0.995 to 0.998) and higher accuracy than any single risk factor in ROC curve. In the different series, the positive predictive value was 100% and the sensitivity was 75%, when cutoff value was 8 points.

Conclusion: The progression to complete fracture could be predicted by using our scoring system. Incomplete AFF with scores <8 points can be treated conservatively, whereas lesions with scores ≥ 8 require prophylactic fixation. (***J Clin Endocrinol Metab*** **102: 545–550, 2017)**

Atypical femoral fractures (AFFs) have recently appeared as serious complications associated with the long-term use of antiresorptive agents such as bisphosphonates, denosumab, and romozosumab (1–5). These atypical femoral fractures involve subtrochanteric area and diaphysis of the femur, whereas ordinary osteoporotic fractures occur at the femoral neck and intertrochanteric region (1,2).

The atypical femoral fracture includes incomplete fracture as well as complete fracture, and it occurs in the femur from just below the lesser trochanter to distal shaft (1). Radiographic features of incomplete atypical femoral fracture include focal or diffuse thickening of the lateral cortex and radiolucent line with periosteal callus formation (1). An incomplete atypical femoral fracture can progress into a complete fracture with low energy trauma or

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*These authors equally contributed to this work and should be considered co-first authors.
Abbreviations: AFF, atypical femoral fracture; AUC, area under curve; BMI, body mass index; ICC, intraclass correlation coefficient; ROC, receiver operator characteristic.

without extrinsic trauma (6). Once a complete fracture occurs, the surgery becomes a challenge with a higher complication rate resulting in poor clinical outcomes (7–9).

Therefore, there is a consensus that prophylactic fixation should be done in the stage of incomplete fractures, when associated with a risk of impending complete fracture (7–10).

Several factors, including prodromal pain, subtrochanteric involvement, and the presence of a radiolucent line on radiographs, have been reported as risk factors for complete fracture (11–13). However, there is no agreement on the specific criteria of impending complete fracture and the need for prophylactic fixation. The purposes of this study were as follows: 1) to establish a weighted scoring system to identify impending complete fractures among incomplete atypical femoral fractures; 2) to evaluate the reliability; 3) to determine the accuracy; and 4) to test the validity of the proposed scoring system.

Materials and Methods

We retrospectively reviewed the medical records and radiographs of 88 incomplete AFFs in 70 consecutive patients who were diagnosed and treated at 3 tertiary referral hospitals from June 2006 to December 2014. The inclusion criteria were as follows: 1) atypical femoral fracture; 2) incomplete fracture at the time of diagnosis of an atypical fracture; 3) no prophylactic fixation within 6 months after the time of diagnosis; and 4) medical records and radiographs available until the time of developing a complete fracture or at least 6 months after the diagnosis of an incomplete atypical femoral fracture without developing a complete fracture.

A diagnosis of incomplete AFFs was made according to the radiographic criteria defined by the Task Force of the American Society for Bone and Mineral Research (1): 1) location from anywhere distal to the lesser trochanter to proximal to the supracondylar flare of the distal femoral metaphysis; 2) focal or diffuse thickening of the lateral cortex; and 3) an occasional discrete transverse lateral cortex translucency with periosteal callus formation.

Among 18 patients who had bilateral involvement, 9 patients underwent bilateral prophylactic fixations and 7 patients unilateral prophylactic fixation within 6 months after the diagnosis of an incomplete atypical femoral fracture. Among 52 patients with unilateral incomplete fractures, 17 patients underwent prophylactic fixation within 6 months after the diagnosis. The remaining 46 incomplete atypical femoral fractures in 44 patients were subjects of this study (Fig. 1). All patients were women with a mean age of 72.7 years (range, 54 to 90 years) and a mean body mass index (BMI) of 23.0 kg/m^2 (range, 17.4 to 32 kg/m^2). The mean duration of bisphosphonate treatment was 4.1 years (range, 1 to 8 years). Alendronate was the most commonly used bisphosphonate. Of the 44 patients, 2 patients (4.5%) used teriparatide for 1 month and 2 months, respectively, after the diagnosis of incomplete AFF.

We defined impending fracture as a fracture that progressed to a complete fracture within 6 months after the diagnosis of incomplete fracture (14). The outcome for this study was defined as complete fracture or noncomplete fracture within the 6 months.

Among the 46 incomplete fractures in 44 patients, 13 (28.3%, 13/46) completely fractured within 6 months after the diagnosis (range, 7 days to 5 months; mean, 1.2 months), and the remaining 33 (71.7%) did not fracture during the follow-up of 6 to 91 months (mean, 42.6 months).

To determine the risk factors of complete fracture in incomplete atypical femoral fractures, clinical information and radiological findings were compared between the complete fracture group and noncomplete fracture group.

Clinical information included age, gender, BMI, type of bisphosphonate, duration of bisphosphonate treatment, and severity of pain. The severity of pain was classified as nonfunctional (mild) and functional pain. The functional pain was defined as a pain, which was aggravated by limb function such as walking or weight bearing.

Radiological findings included location of the fracture (subtrochanteric or diaphyseal), status of the contralateral femur (complete fracture, incomplete fracture, or intact), and the extent of radiolucent line (only cortical thickening, radiolucent line $<1/2$ or $\geq 1/2$ of diameter of the involved femur) (Fig. 2).

A subtrochanteric involvement was defined when the fracture occurred within 2 inches distal to the lesser trochanter (15,16). Radiologic evaluations were performed by independent 2 orthopedic surgeons (K.-J.L. and Y.-K.L.), who were blind to the clinical information. If the two observers disagreed, the final decision of the radiologic findings would be made by a third observer (B.-W.M.).

To develop a scoring system, the clinical and radiological variables with statistical significance (p value <0.05) were reviewed by a consensus committee, which included 4 orthopedic surgeons (B.-W.M., K.-H.K., Y.-K.L., and K.-J.L.), who had 12 to 26 years of experience as orthopedic surgeons. Each committee member independently evaluated statistically significant variables and allotted points to each variable according to the degree of risk. Afterward, a discussion was made to finalize the scoring system.

We compared the score of complete fracture group with that of noncomplete fracture group, and the cumulative probability of complete fracture was also calculated for each score. To test interobserver reliability of the final scoring system, the intraclass correlation coefficient (ICC), which is an inferential statistics to assess consistency or reproducibility of quantitative measurements made by different observers measuring the same quantity, was calculated for the scores from the 3 observers.

To evaluate the accuracy, the sensitivity (true positive rate) and specificity (true negative rate) were compared using a receiver operator characteristic (ROC) curve (17).

To test validity of the proposed scoring system, we applied the scoring system to 35 incomplete atypical femoral fractures in 30 women who were diagnosed as having incomplete atypical femoral fracture and met our inclusion criteria at an independent hospital from June 2006 to December 2014, calculating positive predictive value and sensitivity of the scoring system. Their mean age was 67.5 years (range, 46 to 80 years), and BMI was 24.7 kg/m^2 (range, 18.2 to 31.6 kg/m^2). The mean duration of bisphosphonate use was 5.2 years (range, 1 to 13 years).

Of the 35 incomplete fractures, 4 (11.4%, 4/35) completely fractured within 6 months after the diagnosis (range, 3 to 6 months; mean, 4.5 months), and the remaining 31 (88.6%)

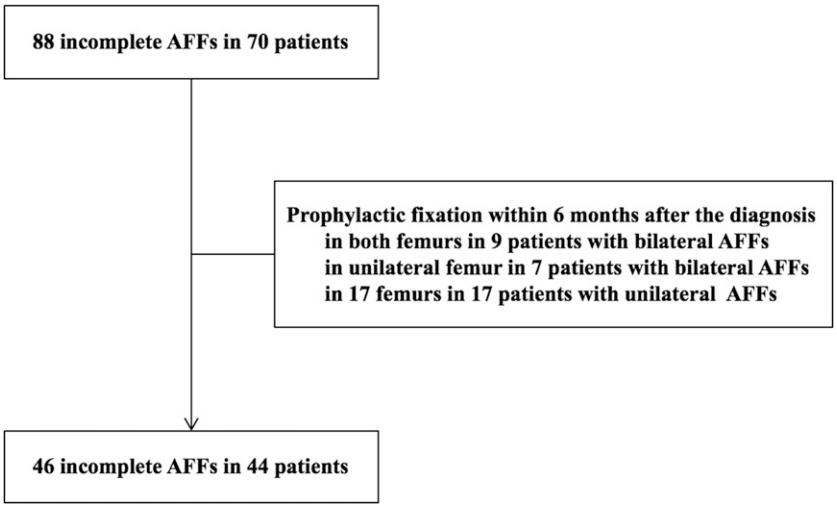

Figure 1. Flow chart to identify subjects who met the inclusion criteria.

did not fracture during the follow-up of 6 to 100 months (mean, 43.4 months).

Statistical analysis

The Mann–Whitney test was used to compare continuous variables and Fisher's exact test for categorical data of complete fracture and noncomplete fracture groups.

ICC was used to test reliability of scoring system. ICCs and their 95% confidence intervals were calculated in the setting of a two-way random effect model, assuming a single measurement and absolute agreement. Criteria for determining the adequacy of reliability were as follows: 0.00 to 0.20, slight; 0.21 to 0.40, fair; 0.41 to 0.60, moderate; 0.61 to 0.80, substantial; 0.81 to 1.00, almost perfect (18,19).

The sensitivity and specificity of the final scoring system were plotted on the ROC curve. Subsequently, we compared the ROC curve of the scoring system with that of each separate risk factor to determine whether the scoring system was more accurate than any other risk factors by comparing the area under curve (AUC) of the ROC curve. An AUC of 0.5 is equivalent to random chance (a diagonal line), AUC >0.7 indicates a moderate prognostic model, and AUC >0.8 (a bulbous curve) indicates a good prognostic model (17).

Statistical analysis was performed with SPSS software (version 16; Chicago, IL). P values <0.05 were considered statistically significant. Institutional review board approval was obtained at each hospital for the design and protocol of this study.

Results

The complete fracture in incomplete atypical femoral fracture was associated with subtrochanteric involvement ($P = 0.006$), severity of pain ($P < 0.001$), status of contralateral femur ($P < 0.001$), and the extent of radiolucent line ($P < 0.001$) (Table 1).

Only 1 (4%, 1/25) of 25 incomplete fractures that had a contralateral complete fracture developed a complete fracture.

Statistically significant variables that were chosen as risk factors were the site, pain, contralateral femur, and the length of radiolucent line (Table 2). We allotted one to three points to each risk factor, providing for a maximum score of 12 points.

The score of the complete fracture group (10.1 ± 1.7) was significantly higher than that of the noncomplete fracture group (6.3 ± 1.2) ($P < 0.001$).

The probability of complete fracture increased abruptly when the score was 8 points or more (Fig. 3; Supplemental Fig. 3).

The ICC was 0.997 (95% confidence interval, 0.995 to 0.998), showing almost perfect reliability of the scoring system (Supplemental Fig. 1).

The ROC curve showed that the score of 8 is the most optimal cutoff value to diagnose an impeding complete fracture. The AUC of scoring system was highest than any single variable (Fig. 4; Supplemental Fig. 2). It means that the scoring system, including all 4 variables, had highest accuracy to identify impending complete fracture in incomplete atypical femoral fractures.

In the validation test, the positive predictive value was 100% and sensitivity was 75%, when a cutoff value of 8 points was adopted to predict impending complete fracture.

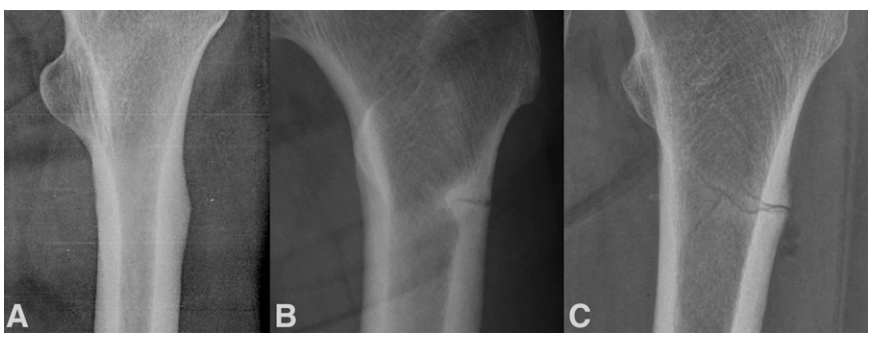

Figure 2. Radiologic change. (A) Focal cortical change, (B) radiolucent line <1/2 of bone diameter, and (C) radiolucent line >1/2 of bone diameter.

Discussion

We established a practical scoring system to identify impending complete fracture among incomplete atypical femoral fractures. The proposed scoring system appeared accurate, reliable, and valid in our study. The system might be useful to determine how to treat incomplete atypical femoral fractures.

In this study, 28.3% of the lesions subsequently fractured within a period

Table 1. Comparison Between Complete Fracture Group and Noncomplete Fracture Group

Variable	Complete Fracture Group (n = 13)	Noncomplete Fracture Group (n = 33)	*P* Value
Age	71.3 ± 9.3	73.2 ± 8.4	0.511
BMI	23.5 ± 2.8	22.7 ± 3.1	0.429
Type of bisphosphonate			0.618
Alendronate	9	27	
Risedronate	3	4	
Ibandronate	1	2	
Duration of bisphosphonate	3.7 ± 1.6	4.3 ± 1.7	0.323
Location diaphyseal	3	24	0.004
Subtrochanteric	10	9	
Pain none	3	20	<0.001
Mild pain	2	13	
Functional pain	8	0	
Contralateral femur			<0.001
Complete fracture	1	24	
Incomplete fracture	4	5	
Intact	8	4	
Radiographic change			<0.001
Focal cortical change	3	26	
Radiolucent line <1/2	2	7	
Radiolucent line >1/2	8	0	
Follow-up duration (months)	1.2 ± 1.3	42.6 ± 24.6	<0.001

of the 6 months. Subtrochanteric location, functional pain, intact contralateral femur, and radiolucent line >50% of diameter of the femur were identified as risk factors for occurrence of complete fracture (12,13,20–23).

Atypical femoral fracture usually occurs in the subtrochanteric region or femoral shaft (24). The stress concentration at the subtrochanteric region might be the reason for the predominance of atypical fracture at this region and frequent requirement of operative fixation (12,24).

Pain is a prodromal diagnostic clue of atypical femoral fracture (20–23,25). Some studies stated that pain should be considered as an indication for the need of prophylactic fixation (1,6,12,26). In the scoring system, pain is classified as nonfunctional (mild) and functional (severe or aggravated by limb function). Functional pain is suggestive of a decrease in the mechanical bone strength, which is a warning symptom of impending fracture. In this study, 3 painless lesions developed a complete fracture, which can be a notable result because all of them had scores >8 points. The proposed scoring system could predict impending complete fracture better than pain alone.

In this study, the presence and severity of atypical fracture in the contralateral femur were also associated with further progression into a complete fracture. The presence of a complete fracture in the contralateral femur was associated with lower occurrence of complete fracture, whereas initial unilateral involvement was associated with higher risk of complete fracture. When a complete fracture developed and was treated with therapeutic fixation, incomplete fracture at the opposite femur was diagnosed at early stage. The early detection of incomplete fracture and limited activity with protected bearing might have contributed to decrease the risk of complete fracture. Majority (28% to 44.2%) of incomplete atypical femoral fractures were detected in contralateral femur, when a complete fracture occurred in 1 femur (12,13,20–23). Twenty-five (54.3%) of our patients were diagnosed as incomplete atypical femoral fractures at the time of surgery for contralateral complete atypical femoral fractures. Prediction for second femur fracture should be necessary in these patients. Our results suggested when they start conservative management and how they use the proposed scoring system to decide the time of prophylactic fixation. All of the 25 incomplete fractures, which were diagnosed when complete fracture occurred in the contralateral femur, had scores ‹8 points, and only 1 femur (4%) developed complete fracture within 6 months.

Saleh *et al.* reported their experience with 14 incomplete atypical femoral fractures. They presented that incomplete fracture without radiolucent line could be treated with conservative methods (13). They made no attempt to measure the size of the radiolucent line. In this study, we measured the length of the radiolucent line and expressed the length as a percentage of the diameter of the

Table 2. Scoring System

	Score		
Variable	**1**	**2**	**3**
Site	Others	Diaphyseal	Subtrochanteric
Pain	None	Mild	Functional
Contralateral	Complete	Incomplete	Intact
Radiolucent line	Focal change	<1/2	>1/2

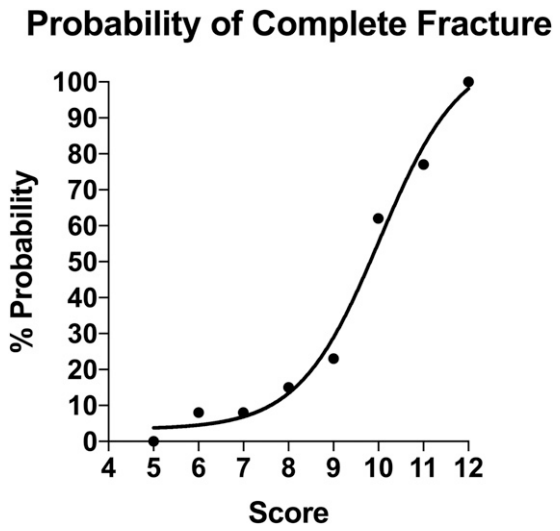

Figure 3. Cumulative probability of complete fracture for each score.

femur. Among 17 femurs, which had a radiolucent line, 7 (41%) did not fracture until the 6 months. All of 8 incomplete fractures with radiolucent line >50% of diameter of femur developed a complete fracture within the 6 months.

In planning the treatment of incomplete atypical femoral fracture, the problem lies in accurately distinguishing between nonpending fractures that can be treated without surgery and impending fractures that require prophylactic fixation. A score of 7 is suggestive (probability of fracture, 8%) of an impending fracture, whereas a score of 8 is diagnostic (probability of fracture, 15%). When a score of 9 or more is obtained, the probability of fracture warrants prophylactic fixation. Conversely, incomplete atypical femoral fracture with a score of 7 or less may be treated conservatively.

Patients who had painless incomplete AFF should be informed that pain might be a prodromal symptom for the progression to a complete fracture, and follow-up evaluations should be done frequently. During the follow-up, physicians should recalculate the proposed scoring system according to the changes of pain intensity and radiographic feature.

Our study had some limitations. First, we established the scoring system from a retrospective multicenter study. Nevertheless, we evaluated the validity of proposed scoring system in another group from a different hospital, and the validity evaluation showed a satisfactory positive predictive value and sensitivity. Second, there might be a selection bias because our study was not a regional cohort study. Third, we could not evaluate the effect of gender because there was no male in the subjects of this study. The explanation for this might be that majority of atypical femoral fractures have occurred in women taking bisphosphonate to treat osteoporosis. Fourth, we included only Asian patients. Asian women who have lateral bowing of the femoral diaphysis may be more likely to sustain atypical femoral fracture (1,27,28). To generalize this scoring system, it should be validated in patients from Western countries. Fifth, incomplete atypical femoral fracture can develop to complete fracture even after the 6 months, which is the time for

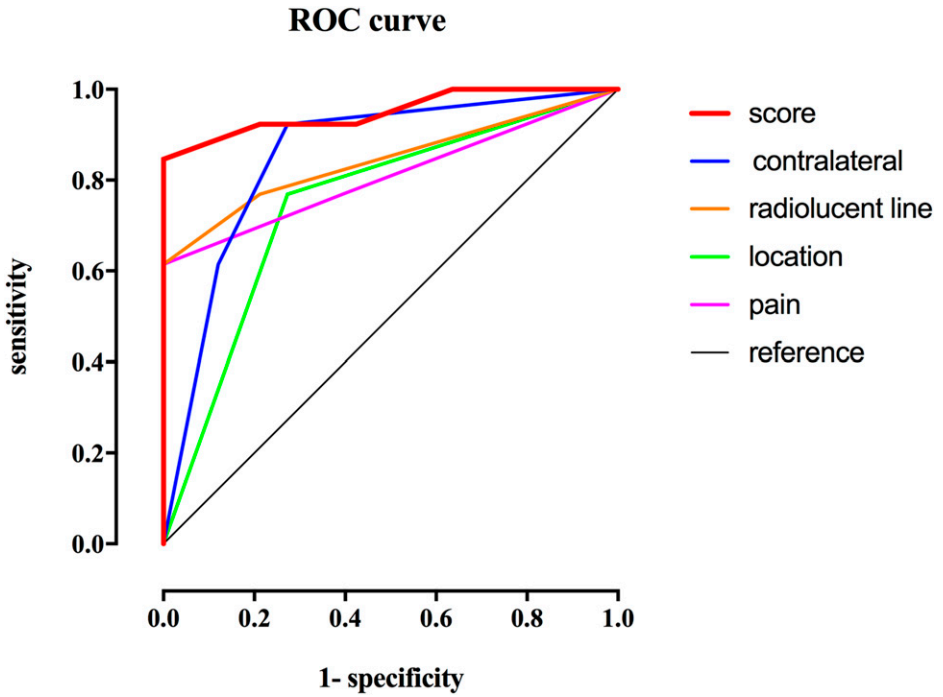

Figure 4. ROC curve comparing accuracy of scoring system to each risk factor.

outcome in this study. Therefore, physicians should be cautious when they cannot evaluate patients frequently.

The proposed scoring system could provide physicians greater accuracy than any single risk factor when determining the risk of impending fracture and whether to perform prophylactic fixation.

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Address all correspondence and requests for reprints to: Young-Kyun Lee, Department of Orthopedic Surgery, Seoul National University Bundang Hospital, 82 Gumi-ro, 173 Beon-gil, Bundang-gu, Seongnam, Gyeonggi-do, 463-707, South Korea. E-mail: ykleemd@gmail.com.

Author contributions: Y.-K.L., B.-W.M., and K.-H.K. conceived the study and designed the experiments. K.-J.L. and Y.-K.L. coordinated sampling and data collection. Y.-S.P., C.-W.O., S.-J.L., J.-W.K., B.-W.M., and K.-H.K. supported data collection. B.-W.M., K.-H.K., and Y.-K.L. wrote the manuscript. B.-W.M. and K.-H.K. provided critical review of the manuscript. All authors approved final manuscript.

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