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Research article

Value of a radiographic score for the assessment of healing of nailed femoral and tibial shaft fractures: A retrospective preliminary study

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ABSTRACT

Objectives: To assess the value of a radiographic score for the detection of delayed union in nailed fractures.
Methods: The modified radiographic union score (mRUS) values were determined by three separate radiologists on 259 radiographic sets of 58 nailed tibial or femoral fractures obtained at different timepoints after fracture (mean of 4.5 radiographic sets per fracture). A surgeon determined fracture outcome (normal or delayed union) at a mean of 192 days after injury. Mean radiographic scores obtained at different timepoints after fracture were compared between fractures with normal or abnormal healing at follow-up.
Results: The mean score values increased significantly over time for fractures with normal healing for all readers ($p < 0.001$). The mean score values determined 11–14 weeks after injury were higher in fractures with normal healing than in fractures with delayed union at follow-up ($p < 0.05$). Scoring of radiographs obtained at about 3 months after injury or later enabled detection of fractures with delayed union with a sensitivity of 0.63–0.77 and a specificity of 1.0 (area under curve: 0.77- 0.88).
Conclusions: The mRUS score can contribute to the detection of delayed union at a delay of about 3 months after injury in nailed shaft fractures.

1. Introduction

Evaluation of the healing process of bone fractures relies on both clinical and radiological criteria [1–3]. Assessment of fracture healing on radiographs remains challenging [4] and several scoring systems have been proposed to provide a more reproducible quantitative evaluation of the radiographs [5–10]. In 2010, Whelan et al. [11] proposed the Radiographic Union Score for Tibial fracture (RUST) for the assessment of tibial fracture which was later applied to other bone fractures [12–19]. More recently, Litrenta et al. proposed a modified Radiographic Union Score (mRUS) that focussed on callus appearance [15]. To the best of our knowledge, we are not aware of any longitudinal study that adressed the predictive value of radiographic scoring systems in nailed long bone fractures. We hypothesized that radiographic scores could differ between fractures with normal and abnormal healing. In the current retrospective study, three radiologists scored serial radiographs obtained within six months after injury in a series of nailed tibial and femoral shaft fractures with normal or abnormal healing at follow-up. Our aim was to assess the value of the mRUS for the detection of delayed union in nailed fractures.

2. Material and methods

2.1. Selection of patients

In July-August 2015, a musculoskeletal radiologist with 3 years of experience (V.P.) and a fifth year resident in radiology (A.C.) retrieved the radiographs of thighs and legs obtained in our emergency department between January 2007 and January 2015 in patients aged between 18 and 80 years. They examined the radiographic files of 482 eligible patients with femoral or tibial fractures to include 58 patients who met the following criteria: (a) diaphyseal femoral or tibial fracture, (b) surgical fixation by using an intramedullary nail and (c) availability of at least 3 sets of antero-posterior and lateral radiographs obtained at baseline after surgery until 6-months after fracture. Four hundred and twenty-four patients were excluded because of conservative treatment

Abbreviations: mRUS, Modified Radiographic Union Score

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(n = 35), plate fixation (n = 20), associated epiphyseal fracture (n = 277), multiple fractures (n = 7), pathological fracture/septic fracture/pre-existing metallic hardware (n = 36) and lack of 3 sets of radiographs (n = 49). The study population included 36 men and 22 women (mean age +/− SD: 50.43 +–16.99 years) including 19 smokers. There were 47 (81%) tibial and 11 (19%) femoral fractures.

In February 2016, an orthopedic surgeon with 15 years of experience (D.P.) responsible of the trauma section in the orthopedic department reviewed the files of the 58 patients to determine for each patient the smoking habit, the fracture type according to the AO classification and the clinical outcome. According to the AO classification, there were 37 type A fractures, 10 type B fractures and 11 type C fractures. The clinical outcome of the fracture was determined by reviewing the medical files completed by the surgeon in charge of the patient at a mean delay of 192 days +/− 26 days (range: 151-243 days) after fracture. Healing evaluation had been performed according to standards of good practice based on clinical and radiological findings [20–22]. Normal healing was defined by the ability of the patient to walk without assistive device with any pain at the fracture site and by the overall estimation by the surgeon of the presence of bridging callus on three or more cortices on the radiographs. Delayed union was defined by the presence of pain when bearing weight or upon palpation on physical examination and by the absence of bridging callus on radiographs. Delayed union was also considered when surgical revision with screw ablation was performed during the first 6 months. Skin debridement was not considered as revision surgery. At clinical follow-up, normal healing was noted in 48 (82.7%) fractures and delayed union was noted in 10 (17.3%) fractures including 8 (13.7%) tibial fractures and 2 (3.4%) femoral fractures.

2.2. Selection and analysis of the radiographs

In our PACS, 259 radiographic sets were obtained at follow-up in these 58 fractured bones (mean of 4.5 radiographic sets per fracture) according to our institution guidelines that recommend serial radiographs at hospital discharge and at approximately 1-, 3- and 6-months after fracture. In September 2015, a data manager encoded the 259 radiographic examinations in an excel spreadsheet and added a categorical variable according to the time delay between the fracture and the moment at which the radiographs had been obtained. The 6-month follow-up time was divided in 7 periods defined as follows: 1–2 weeks after fracture (T0); 3–4 weeks (T1); 5–7 weeks (T2); 8–10 weeks (T3); 11–14 weeks (T4); 15–18 weeks (T5) and 19–24 weeks (T6). The 259 sets of radiographs were anonymized, re-identified after randomization by an independent statistician (C.B.) and stored in our PACS.

In December 2015 and January 2016, the 259 radiographic examinations were read separately by three radiologists including the two radiologists (V.P./A.C.) who had included the patients and a musculoskeletal radiologist with 20 years of experience (B.V.). The readers were blinded to all clinical information including the date of fracture and the date at which the radiographs had been obtained. Readers scored each set of antero-posterior and lateral radiographs on a PACS workstation (Eizo Radiforce Screens RX240 21.3″ (54 cm) 2MP (1200 × 16)). Each reader scored the two fracture sites at which the X-ray beam was tangent on each radiograph using the mRUS score as described in the previous paper (part one). A cortical score from 1 to 4 was given to each cortical segment of the fracture site according to the scoring of Litrenta et al. [15]: score 1: lack of callus; score 2: non bridging callus; score 3: bridging callus; score 4: remodeled bridging callus. For each bone fracture, the mRUS value was calculated by adding the four cortical scores. If the cortical segment was not visible, scoring was considered to be not feasible and the reader had to select at least one of the three following explanations: (a) superimposed metal hardware, (b) superimposed adjacent bone (leg and fore −arm), (c) another reason such as blurring of the radiograph or inadequate exposure. No radiographic set was excluded because of non-feasibility.

The study has been approved by the Ethics Committee of our institution.

2.3. Statistical analysis

All summary tables, data listings and graphs are produced using the statistical software JMP v12. All statistical tests were conducted at the significance level of 5%.

Descriptive statistics were done for each variable: continuous variables are presented using the mean, standard deviation (SD), and 95%-confidence interval. For categorical variables, the population size (N), the number of events, the number of subjects with events (n) and the proportion of subjects with events (p = n/N) are reported.

Differences in patient characteristics between the two clinical endpoints were tested using 2-sided Mann-Whitney test for continuous variables and chi-squared test for categorical variables. Mean RUS score between the two clinical endpoints were tested using 2-sided Mann-Whitney test.

The intra-class correlation coefficient (ICC) adapted to the random factorial design was computed to assess the agreement between the three readers. The interobserver agreement was interpreted according to Landis and Koch, with ICC values < 0.00 defined as poor, 0.00-0.20 defined as slight, 0.21-0.40 defined as fair, 0.41-0.60 defined as moderate, 0.61-0.80 defined as substantial, and values of 0.81 −1.00 defined as almost perfect [23].

Binary logistic regression was used to estimate the probability of healing in order to find a threshold for the total RUS value to predict healing. Threshold was evaluated using a ROC (receiver operating characteristic) curve and the area under the curve (AUC) was reported to evaluate performance of the prediction.

A two-way ANOVA with random effects was performed to assess differences in scores and, to determine if time after injury was associated with the difference. Time (in days) was considered to represent a fixed factor, while readers were considered to represent a random sample drawn from a larger population of observers (random factor).

3. Results

3.1. Changes in mean mRUS values over time

For each reader, the mean mRUS values calculated at each time point showed a progressive increase over time for fractures with normal healing (Figs. 1 and 2) but not for those with delayed union at follow-up (Figs. 3 and 4) (Table 1). For all readers confounded, the mean mRUS increased significantly over time for fractures with normal healing (p < 0.001). Interobserver agreement for the mRUS values was almost perfect (ICC: 0.81).

3.2. Comparison of the mean mRUS values between fractures with normal healing and those with delayed union at follow-up

At timepoints T0, T1, T2 and T3, the mean mRUS values of fractures with normal healing were not statistically significantly different from those with delayed union. The mean mRUS values were statistically significantly higher in fractures with normal healing than in fractures with delayed union at timepoints T4 (from 11 to 14 weeks after fracture) and timepoint T6 for all readers (p < 0.05) and also at timepoint T5 for reader 2 (p = 0.01). The mRUS threshold, sensitivity and specificity values for detecting delayed union in nailed fractures at each timepoint were derived from ROC curves (Table 2). At T4 (from 11 to 14 weeks after injury), an mRUS score lower than 7 (reader 1), 7.5 (reader 2) or 5.5 (reader 3) enabled detection of patients with delayed union with a sensitivity that ranged from 0.63 to 0.77 and a specificity of 1 (AUC: 0.77–0.89). Interobserver agreement for the mRUS values varied from 0.661 to 0.920 according to time points and appeared to decrease with fracture age (Table 2).

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