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Original Research

Radiographic Union Scoring Scale for Determining Consolidation Rates in the Calcaneus

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ABSTRACT

The reliable evaluation of osseous consolidation after hindfoot osteotomy can be difficult. Concomitant hindfoot osteotomies often dictate the advancement of weightbearing, and radiographs are the mainstay imaging tool owing to cost, efficiency, and radiation exposure. Understanding the radiographic parameters that can be used to reliably determine osseous healing is paramount. However, currently, no reliable or validated method is available to determine osseous healing of hindfoot osteotomies in irregular bones of the foot. The purpose of the present study was to develop a radiographic healing scoring system that would enhance the diagnostic healing assessment after elective calcaneal osteotomy. We adapted existing orthopedic scales validated for healing in the leg for application in the irregular bones of the foot. A total of 168 cases were evaluated by 6 blinded assessors to test the interrater reliability of subjective healing assessment compared with the proposed scoring system. The radiographs were classified by postoperative period: ≤4 weeks, 5 to 12 weeks, and >12 weeks. The proposed scale had high interrater reliability but was burdensome. Using a priori item reduction protocols, a limited 6-item scale further improved internal consistency and reduced the burden. The result was excellent interrater reliability ($\alpha = 0.98$, standard deviation 0.02, 95% confidence interval 0.91 to 0.96) among all assessors when using the scoring scale compared with unacceptable reliability ($\alpha = 0.438$) for subjective osteotomy healing. The reliability of our system appeared superior to that of subjective assessment of osseous healing alone, even in the absence of clinical correlates after osteotomy of the calcaneus.

A complex issue facing foot and ankle surgeons is the difficulty in determining the exact postoperative course and when to advance a patient's care after surgical or traumatic osseous injury (1–7). The provider must rely solely on clinical judgment, radiographic appearance, and, on occasion, advanced imaging modalities to guide postoperative care and patient activity after osteotomy or fracture fixation in the bones of the foot, including the calcaneus (8–10). Postoperative care is often dictated by the most proximal and complex procedure such as calcaneal osteotomy in flatfoot surgery. For the tarsal bones of the foot, no reliable validated methods are available to determine the postoperative intervals and when to advance the patient's course. As such, the introduction of range of motion and weightbearing activities relies mostly on clinical judgement and subjective standards within the field. The exact determination of healing is difficult in the absence of correlating clinical factors such as pain and instability. This is particularly poignant in the setting of research outcomes in which the assessor is asked to make a blinded judgment regarding healing. The timeframe varies from patient to patient and the subjective analysis varies

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between practitioners, making it inconsistent. Surgeons must therefore rely on the radiographic assessment to provide a more objective outlook regarding patient healing status and to guide clinical advancement. However, radiographic artifacts, technique, implants, and osseous overlap can interfere with the radiographic evaluation and contribute to inappropriate clinical decisions (4,5,7,11,12). Considering these points, the everchanging field of medicine, and the emphasis on evidence-based medicine, it behooves us as foot and ankle surgeons to develop a better method to analyze radiographs to help guide the creation and use of postoperative protocols.

Focused attempts have been made in recent years to develop validated orthopedic scoring systems to interpret postoperative radiographs of the hip and long bones of the leg (radiographic union scale, radiographic union scale for hip, and radiographic union scale for tibial fractures) (6,13–15). These scoring systems within their respective populations have been validated and stand as important decision-making tools to support recognition of osseous healing. Through the use of a unified method, this has improved the ability of surgeons to reliably make appropriate clinical decisions and advance patient care. Although the benefit of a scoring system dedicated to a zone of the body is obvious, no scales for grading radiographic osseous union after elective osteotomy of the calcaneus have been validated (2,8,16). In a previous study by Summers et al (17), a scoring system was developed for elective osteotomies in the long bones of the foot; however, further studies are needed to determine whether this scoring scale can be applied to short or irregular bones of the foot and ankle such as the calcaneus.

The lack of validated instruments for measuring radiographic healing exposes much of the podiatric data to potential classification, interpretation, and measurement biases. The larger issue is that inconsistent clinical determination of osteotomy healing can lead to misinformed and poor decision-making in postoperative protocols, leading to a greater incidence of adverse outcomes (4,5,7,11,12). As such, little consistency exists in postoperative protocols regarding lower extremity outcomes. The foot and ankle are uniquely difficult to evaluate radiographically because of interference, artifact, overlap, and the varied relevant angles. The calcaneus can be even more difficult to evaluate, because the lateral projection is often the only primary view without interference. An established scoring system, as previously discussed for the long bones of the foot, showed benefit in assessing osseous healing from both a surgical healing and a radiographic standpoint (17). Expanding that model to the calcaneus would provide a more organized and reliable approach to radiographic assessment, which could supplement clinical assessments. A reliable radiographic scoring scale would also be valuable in developing validated research data and establishing a standard of care for patient treatment protocols after osteotomy of the calcaneus. Studies have shown that generic temporal guidelines of 6 to 8 weeks for osseous union of the bones of the foot fail to account for the variable surgical circumstances and are not reliable. Therefore, a standardized radiographic assessment that establishes a reliable composite of bone healing is necessary to enhance the diagnostic assessment (18).

The primary aim of the present study was to develop a reliable radiographic healing scoring system of the calcaneus after elective osteotomy without the use of computed tomography (CT) scanning. We hypothesized that the final instrument would have greater reliability than standard subjective physician radiographic assessments alone in determining osseous healing after elective osteotomy of the calcaneus.

Patients and Methods

A prospective reviewer-blinded study was undertaken to evaluate the reliability of a newly proposed radiographic osseous union scoring instrument after osteotomy of the calcaneus (institutional review board approval no. 024–2015) that had previously only been studied and applied to the long bones of the foot (17). Instrument development proceeded with a modified Delphi approach to determine the items that should be included in the scoring system and represented radiographic signs of healing. The development team first identified existing radiographic bone healing scales or instruments that have been previously validated in orthopedic studies for other bones of the leg and hip (radiographic union scores, radiographic union scale for hip, radiographic union scale for tibial fractures, and long bones of the foot) (6,13,15,17). Members of the development team then adapted portions of these scales to generate an initial scoring scale that would be subjected to a validation process (Fig. 1). The inter- and intrarater reliability of the initial scoring scale components had been previously confirmed in a recent study assessing radiographic osteotomy healing in the long bones of the foot (17).

A validation process for assessing radiographic osteotomy healing in the cancellous hindfoot was subsequently designed. A total of 168 included lateral radiographs were obtained from a picture archive and communication system of all consecutive calcaneal osteotomies from May 2003 to July 2014, identified using an institution billing database and Current Procedural Terminology (American Medical Association, Chicago, IL) code 28300. Cases were excluded if any of the following features were present: osteotomies not involving the calcaneus, poor image quality, <1 year minimum of radiographic follow-up data available, and signs on the radiographs that made it obvious a patient was in the immediate postoperative period, including overlying dressings, casts, or staples that could not be stripped from the images. The radiographs were required to be free of identifiers that could imply temporality, including the presence of casts, splints, dressings, and staples.

All patient identifiers and indicators of date and time were removed from all the images. All images were standardized to size, scale, and background and then placed into a neutral digital format that permitted viewing but not adjustment of magnification, contrast, or any other image manipulation (Fig. 2). Only lateral radiographs were assessable for calcaneal osteotomies because calcaneal axial, long leg, anteroposterior, and oblique foot views are not reliably visualized. The radiographs were collected and organized into 3 distinct postoperative periods: ≤4 weeks, 5 to 12 weeks, and >12 weeks. A lateral radiograph was selected for each patient from these 3 periods and placed into a file for blinded reviewer assessment. To minimize bias, each radiograph from a given period was assigned a number, and then a random number generator was used to assign the order in which the blinded assessors would view the cases.

A power calculation was performed to determine the necessary minimum number of radiographs and assessors needed to complete the present study. Using the formula $[2 \times (\text{no. of assessors})^2]$, we determined that a minimum of 72 patient cases with 6 blinded assessors would provide a high degree of precision for diagnostic validation of the scoring scale (6). To enhance the robustness of the results, the first 168 radiographs meeting the selection criteria were included.

Each of the 6 blinded assessors were instructed to evaluate each radiographic image pair for healing in 2 stages (the first stage was the subjective score and the second stage was the osteotomy assessment tool score). In the first stage (subjective score), the assessors were asked to evaluate the images using their own experience and expertise and to indicate whether they believed the osteotomy had healed by simply indicating "yes" for healed and "no" for not healed.

In the second stage, the assessors were given the same images in a newly randomized order and instructed to reassess each lateral radiographs again using the proposed osteotomy assessment tool that had been developed using the modified Delphi process. The reliability of medial cortex bridging, lateral cortex bridging, medial cortex line disappearance, and lateral cortex line disappearance could not be calculated because only lateral radiographs were assessable (Fig. 1). The assessors were not permitted to go back and change answers after moving onto the next radiograph in the sequence. This prevented the assessors from changing their response if they recognized the same case at a different period later in the evaluation sequence. Each assessor evaluated 168 lateral radiographs in accordance with the instructions.

Validation of the scale proceeded with assessments of interrater reliability and sensitivity analyses of radiographic imaging evaluations. The interrater agreement of the binary subjective score was analyzed first (binary subjective assessment of whether the osteotomy had healed using the assessor's own experience and expertise). Agreement of the binary subjective score was then compared with the agreement of the osteotomy assessment tool. Interrater reliability was determined using Cronbach's α correlation coefficient (19) (Table 1).

Individual components of osteotomy healing from the radiographic osteotomy assessment tool were then analyzed to test the possibility of domain redundancy, because this could lead to item reduction to decrease instrument burden. Sensitivity analyses were conducted by removing various components of the scores to determine whether item reduction resulted in improved instrument stability. A second sensitivity analysis determined how many osteotomies from ≤4 weeks postoperatively were designated as "healed" by the assessors' binary subjective assessment.

Results

Interrater reliability of the initial binary subjective score remained in the unacceptable range. The Cronbach α results for all assessors was 0.438, for residents, it was 0.311, and for board-certified surgeons, it was 0.134. Introduction of the initial proposed osteotomy tool with

Cortex Assessment

Cortex Bridging: Consolidation and evidence of new bone formation between or around the cortex.	No Cortical Bridging = 0	Some Cortical Bridging = 1	Complete Cortical Bridging = 2
Medial Cortex Bridging			
Lateral Cortex Bridging			
Dorsal Cortex Bridging			
Plantar Cortex Bridging			
Total			

Cortical Osteotomy Line: Disappearance of the cortical osteotomy lines	Osteotomy Line Fully Visible = 0	Osteotomy Line Partially Visible = 1	Osteotomy Line Not Visible = 2
Medial Cortex			
Lateral Cortex			
Dorsal Cortex			
Plantar Cortex			
Total			

Trabecular/Cancellous Assessment

Defined by decreasing visibility of the osteotomy line as new trabecular/cancellous bone is formed.	Osteotomy Line Fully Visible = 0	Osteotomy Line Partially Visible = 1	Osteotomy Line Not Visible = 2
Osteotomy Line			
Total			

Trabecular/cancellous consolidation is defined by evidence of new bone formation along the osteotomy lines in the trabecular/cancellous region of the bone.	No Consolidation = 0	Some Consolidation = 1	Complete Consolidation = 2
Amount of Consolidation			
Total			

Callus Formation

Was callus formation present (yes/no)?

Fixation

Was there lucency present around the hardware (yes/no)?

Image Quality

Is the quality of the image acceptable (yes/no)?

Did the quality of the image inhibit your assessment (yes/no)?

Did placement/position of hardware inhibit your assessment (yes/no)?

Fig. 1. The osteotomy assessment tool was adapted using a modified Delphi approach and based off previously validated radiographic osseous union scores for the long bones of the leg and hip (radiographic union score, radiographic union scale for hip, radiographic union scale for tibial fractures, and long bones of the foot) (6,13,15,17).

8 items resulted in overall improved interrater reliability, with certain components showing greater reliability than others (Table 2).

It was determined via Cronbach's α correlation coefficient that the following components were the most reliable: cortex bridging (dorsal and plantar), cortex line disappearance (dorsal and plantar), trabecular osteotomy line disappearance, and trabecular consolidation. It was also determined that plantar cortex assessments had greater reliability than dorsal cortex assessments. Interrater reliability was further improved by removing the least reliable radiographic components (callus formation and screw lucency). The interrater reliability was comparable between the attendings and residents (Table 3). The most reliable final scale is provided in Table 4 as the final osseous healing instrument.

Given that no osteotomies would have healed within the immediate postoperative period, a subanalysis was performed to evaluate the proportion of assessors who graded an osteotomy as having healed during that time. No clinical data were provided to the assessors, and all radiographs were free of dressing and cast outlines, staples, or other features that would cue a physician to identify a recent operation. It was determined that 35.69% $\pm$ 22.76% (95% confidence interval [CI] 11.8% to 59.58%) of the radiographs in the $\leq$4-week period from the index osteotomy had been graded as subjectively "healed" by the assessors. No significant difference was found between the resident (37.1% $\pm$ 14.3%) and attending (34.3% $\pm$ 32.3%) assessments.

The assessors were also asked to evaluate image quality. A mean of 92.66% $\pm$ 3.94% (95% CI 88.52% to 96.79%) radiographic images had acceptable radiographic image quality. Only a mean of 7.44% $\pm$ 4.07% (95% CI 3.17% to 11.71%) radiographs had reduced image quality that inhibited proper assessment per the assessors.

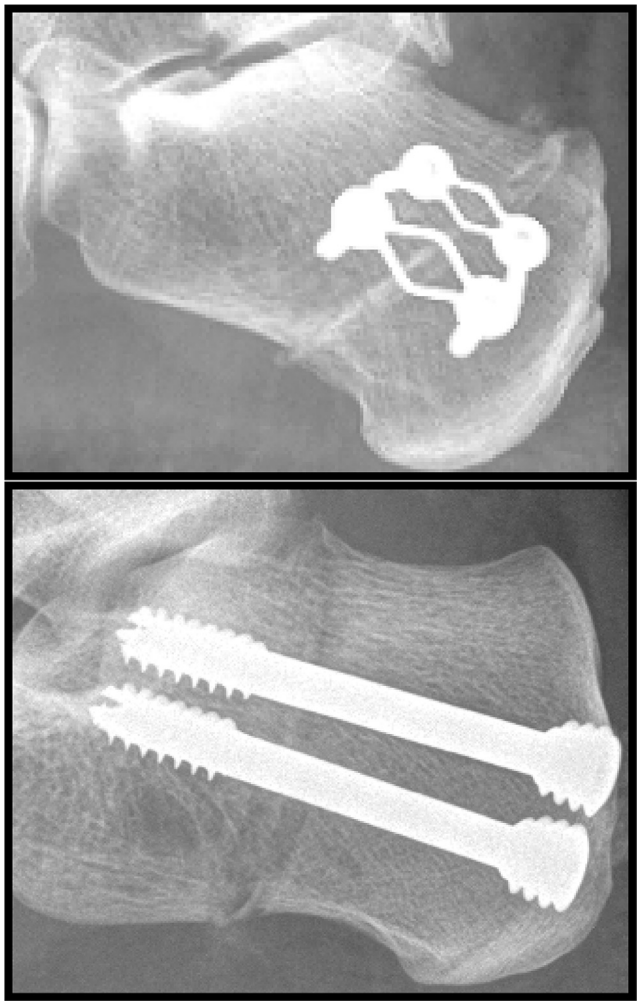

Fig. 2. Example of 2 de-identified patient cases consisting of a clear lateral radiograph.

A greater percentage of assessors reported that hardware obstructed the necessary areas for assessment. A mean of 21% ± 6.27% (95% CI 14.41% to 27.56%) radiographs were reported by assessors to have hardware inhibiting the desired osteotomy assessment. Further analysis revealed that those with metallic cancellous grafts had the greatest percentage of obstructive hardware. Assessors identified a mean of 58.08% ± 10.04% of radiographs with metallic cancellous grafts having hardware inhibiting the osteotomy assessment. Only 11.81% ± 8.28% of other hardware, such as screws and plates without metallic cancellous grafts, were classified as inhibiting the osteotomy assessment.

Discussion

The present study has illustrated the difficulty in analyzing and correlating radiographic osseous union of calcaneal osteotomy. These results showed a clear and unacceptable difference in the subjective ability of the assessors to be in agreement, in the absence of clinical correlates, when determining whether osseous union was present on lateral radiographs after calcaneal osteotomy. This was especially notable in the immediate postoperative group (≤4 weeks). The radiographic union scoring instrument of interest, when properly applied, significantly improved interrater reliability, leading to a more reliable process for the determination of healing of calcaneal osteotomies. This was true for both board-certified attendings and residents alike, suggesting that surgeons can benefit from this tool, regardless of their experience or extent of training.

The osteotomy assessment tool tested in the present study was composed of valid and reliable measures of radiographic bone healing (6,13,15). It was then adapted via the modified Delphi approach, followed by a priori item reduction protocols, to reduce the usage burden. Both historical and contemporary systems assessing bone healing have been related to trauma; however, the scale proposed in the present study assesses bone healing after elective osteotomies. Some radiographic components were more reliable than were others. When the least reliable items were eliminated, the composite interrater reliability achieved an excellent score via Cronbach's α. The final osteotomy assessment tool included a 6-item instrument (instead of a 10-item instrument), because this resulted in the best internal consistency and reliability among all the assessors. Despite the reduction in total items, the reliability was considerably greater ($\alpha = 0.938$) than the subjective score alone ($\alpha = 0.438$; Table 3).

Of interest, the present study found that some of the least reliable components were features that are commonly assessed as part of a standard radiographic evaluation. Both the presence of hardware lucency and callus formation were the least reliable components across the assessors. This is an important finding, given that the presence of hardware lucency and osseous callus formation are used in routine assessments. However, none of the radiographs demonstrated excessive overt lucency or significant exogenous production that would indicate exuberant callus formation. Nonetheless, the present data support that these signs are not very reliable in cases of subtle lucency or callus formation. A future study will attempt to characterize both periimplant lucency and callus formation in terms of the positive and negative predictive values; such an investigation was beyond the scope of the present project.

Table 1
Interpretation of internal consistency for interrater reliability (Cronbach's α) (19)

Cronbach's α	Description
≥0.9	Excellent
≥0.7 but <0.9	Good
≥0.6 but <0.7	Acceptable
≥0.5 but <0.6	Poor
<0.5	Unacceptable

Table 2
Interrater reliability results

Variable	All Assessors (n = 6)	Residents (n =3)	Attendings (n =3)
Subjective assessment of healing*	0.438	0.311	0.134
Scoring scale components			
Dorsal cortex bridging	0.784	0.646	0.655
Plantar cortex bridging	0.865	0.753	0.783
Dorsal cortex line disappearance	0.765	0.610	0.580
Plantar cortex line disappearance	0.845	0.707	0.755
Trabecular osteotomy line disappearance	0.826	0.670	0.727
Trabecular consolidation	0.822	0.702	0.715
Callus formation	0.536	0.398	0.176
Hardware lucency	0.13	0.202	−0.018

* Before scoring scale implementation.

Table 3
Improved interrater reliability after removal of least reliable radiographic components (callus formation and hardware lucency) from osteotomy assessment tool

Assessors	Interrater Reliability
All 6	0.938, SD = 0.02; 95% CI 0.91 to 0.96
Attendings (n = 3)	0.930, SD = 0.02; 95% CI 0.88 to 0.99
Residents (n = 3)	0.930, SD = 0.03; 95% CI 0.87 to 0.99

Abbreviations: CI, confidence interval; SD, standard deviation.

Table 4
Final osseous healing instrument with most reliable components retained

Scoring Scale Components	All Assessors (n = 6)	Residents (n = 3)	Attendings (n = 3)
Dorsal cortex bridging	0.784	0.646	0.655
Plantar cortex bridging	0.865	0.753	0.783
Dorsal cortex line disappearance	0.765	0.610	0.580
Plantar cortex line disappearance	0.845	0.707	0.755
Trabecular osteotomy line disappearance	0.826	0.670	0.727
Trabecular consolidation	0.822	0.702	0.715

The limitations of the present study were that the population was limited to elective calcaneal osteotomies and largely associated with generalizability. In our review of the published data, we were unable to identify any resources that would support a difference in bone healing among the various irregular bones of the foot. The exceptions to this were the navicular and talus with a varied blood supply and more tenuous vascularity. Although the difference in radiographic projection necessary to evaluate other tarsal structures is a valid concern, relatively few tarsal bones undergo osteotomy. Most are associated with arthrodesis, which will be addressed in a subsequent study. Additional validity measures such as true osteotomy healing could not be calculated because CT scans are not warranted for the evaluation of all elective calcaneal osteotomies. Although a CT scan has been classified as the reference standard imaging study for osseous healing, CT scan use in the present study failed to meet equipoise because of the excessive cost and unnecessary radiation exposure. Instead, the comparison was made to the standard of care, subjective healing, which shares the same cost and radiation exposure with the proposed instrument. Further limitations included the uncertain correlation of the proposed radiographic assessment tool with clinical findings. Future studies will include clinical correlates with assessor results to further assess the tool's validity, reliability, and reproducibility.

In conclusion, we found the use of the proposed instrument to be superior to subjective assessments in terms of reliability and accuracy in determining the healing of calcaneal osteotomies via a single lateral radiographic projection. The assessment scale significantly outperformed the subjective assessment across the spectrum of experience from residents to attendings. Although the proposed system has the drawbacks of additional effort and time demand compared with the subjective assessment, the substantial enhancement of consistency and reliability are certainly worth the tradeoff, particularly in the setting of outcomes-based research.

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