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International consensus for a core radiological monitoring protocol of proximal humerus fractures☆

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ABSTRACT

Background: Proximal humerus fractures (PHF) should be subject to standardized monitoring during treatment, whether non-operative or operative, to document and adequately assess bone healing. The purpose of this study was to develop a standardized protocol for an image-based monitoring of PHF for joint-preserving treatment options, including a minimum set of descriptors or definitions of features of radiographic images, to be applied in clinical routine practice and studies.
Methods: A Delphi exercise was implemented with an international panel of experienced shoulder trauma surgeons self-selected after invitation of all AO Trauma members. Using open questions participants recommended the type and timing of desired diagnostic images, and formulated definitions for the imaging parameters they considered most important. Formulated recommendations for the type and timing of radiological fracture monitoring and clarification of the definitions of the proposed radiological parameter set were subjected to further survey. Consensus for each factor was considered to have been reached when there was at least a two-thirds agreement in the survey participants.
Results: Response rates of 231 interested surgeons were 66% and 44% for the first and second survey respectively. Sixty percent of participants to the first survey responded to the second (131/219). 93% of respondents considered radiographic monitoring to be an important part of fracture care. 92% of respondents to the first survey considered that 'malreduction' should be assessed, and 165 of 189 respondents provided a suggestion for a definition for this parameter. 88% of respondents to the second survey agreed on a redefinition of the term 'malreduction' as 'non-anatomical fracture reduction'. There was substantial agreement about the radiographic views and orientation of radiographs to be recorded (80%) and the timing of radiological reviews (67- 78% for time points during follow up). Just over half of respondents recommended cessation of radiological review when fracture healing was considered to have occurred by radiological evaluation.
Conclusion: Our work confirmed the need for clear definitions of radiological features that should be considered in the follow-up of proximal humeral fractures. It has resulted in the development of an international consensus monitoring protocol for PHF treatment with a structured core set of radiological parameters. Clinical application and validation of the monitoring process are needed.

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Introduction

Proximal humeral fractures are common. Radiological assessment of acute PHF remains the basis of diagnosis and the common method by which the healing process and resulting bone morphology following different treatment methods may be compared. Key challenges to understanding the relationship between the radiological evolution of a healing PHF, whether treated non-operatively or operatively, and the eventual functional outcome include: the lack of a common set of descriptors or definitions of radiological features by which different patient cohorts and treatments might be compared; agreement about the timing of radiological assessments in relation to the anticipated stages of fracture healing; and the diagnosis of completion of healing. Acute radiological assessment of PHF relies on a series (the 'trauma series') of orthogonal radiographs as described and recommended by Neer [1]. These radiographs, particularly the true axillary view, can be difficult to achieve in the acute trauma setting and the definition of 'orthogonal' remains one of practicality ('whatever views are possible') rather than a strictly applied set of recommendations. There remains no consensus as to whether radiographic monitoring of PHF, whether treated non-operatively or operatively, is of value in the management of a patient after PHF fracture, which radiographic views contribute optimally to reliable and reproducible management of a PHF, and how to define perturbations of bone health, bone displacement, and bone healing.

The purpose of this study was to develop a standardized protocol for an image-based monitoring of PHF for joint-preserving treatment options to be applied in clinical routine practice and studies. This was conceived to include a defined core set of radiographic parameters as well as minimum protocol requirements governing the radiograph type, views and schedule. A structured assessment tool was achieved through consensus by an international panel of experienced shoulder trauma surgeons utilizing a Delphi protocol as previously described by [2] for monitoring the sequelae of PHF following treatment by shoulder arthroplasty (SA).

Materials and methods

Delphi methodology and selection of panel members

The same methodological process as that used for shoulder arthroplasty (SA) [3] was used to develop a PHF monitoring protocol including a minimum set of imaging parameters. A modified Delphi technique was used with two successive on-line surveys using the REDCap system [4] as presented in detail in a companion paper describing the data [5]. An international panel of shoulder trauma surgeons ('the panel') was selected from AOTrauma members who reported treating more than 20 PHF annually and having more than 5 years of experience in orthopedic trauma. Respondents to at least one survey were acknowledged as members of the PHF Consensus Panel. The authors acted as the steering group for this project.

First online survey

Panel members were first asked if the definition of a core set of radiological parameters as a means to monitor fracture reduction and healing was appropriate [5], followed by a series of questions regarding the alternative imaging modalities for monitoring these parameters. Panel members also provided their opinion on most relevant parameters to consider in the context of various treatment options, along with proposal for definitions.

Second and final online survey

Based on the initial responses, a second survey was prepared to propose a formulated core monitoring protocol along with terms and definitions [5]. We asked which radiographic views should be considered as 'standard', as well as the minimum frequency and timing of radiological assessment. The terms "malreduction" and "malunion" were redefined as a result of the first survey. We proposed a series of binary questions to document "fracture anatomical reduction". Definitions and specifications were proposed for the monitoring parameters "fracture healing", "bone resorption", "bone formation" and "humeral head necrosis". Delayed healing and nonunion were defined in relation to the extent of mineralized callus formation that should be observed on all bone cortices on two orthogonal radiographs taken 3 and 6 months after the fracture respectively. Bone resorption was classified according to its location in the epiphysis, metaphysis or diaphysis. Head necrosis was considered to be an epiphyseal bone resorption and classified according to the Cruess classification [6] adapted by Hattrup and Cofield [7]. Bone formation (ossification) was distinguished between being orthotopic or heterotopic, the latter being classified according to a modified Brooker classification (Table 3).

Data analysis and final adjudication

Intercooled Stata version 14 (StataCorp LLC, College Station, TX) was used for standard descriptive analyses of survey data. Consensus was achieved upon agreement of at least two-thirds of the respondents. All comments and suggestions made were listed and reviewed. Final amendments and adjudication of the monitoring protocol were made by the steering group if they were considered improvements for correctness, clarity and practical application.

Results

Consensus panel

The PHF consensus panel comprised 231 clinicians invited from around the world, affiliated to AOTrauma (Supplementary File 1), and who responded at least partly to one of the two consecutive surveys. Response rates were 66% (219/231) and 44% (143/231) at the first and second survey, respectively. Sixty percent of participants to the first survey responded to the second (131/219).

Initial survey

The idea of developing a core set of radiological parameters to monitor fracture reduction and healing was highly supported with 93% (118 "Yes, definitively" and 77 "Rather yes"/209) agreement among the first survey participants. Ninety-two percent (189/206) of respondents agreed that "malreduction" should be such a parameter and provided 165 suggestions for a definition [5]. Forty-one percent (84/204) of respondents considered that imaging other than standard radiographs should be considered for monitoring fracture reduction and healing. This included CT scans, with or without 3D reconstruction, used to assess specific features of fractures or at specific time points (eg. 6 months). Intra-operative fluoroscopic imaging was also considered relevant. Among radiological parameters the panel recommended for consideration were: implant positioning; screw perforation; fracture "anatomical" reduction parameters (position of the head and tuberosities [offset, height, glenohumeral joint alignment]; head-shaft angle [varus/valgus]; integrity of the humeral calcar; fracture collapse; fracture distraction); fracture healing (tuberosities, callus formation); the presence of a new fracture; avascular necrosis of the humeral head (AVN); bone quality; and degree of post traumatic

Table 1
Minimum consensus radiographic protocol.

Protocol	Description
Image type	True anteroposterior (AP) view in 0° abduction in neutral position Axillary view in 90° abduction Y-view *
Timing	Within 2 weeks of arm immobilization / fracture fixation 6 weeks 3 months 6 months 12 months

* if axillary view cannot be obtained due to limited abduction capacity.

arthritis. It was also suggested that monitoring the rotator cuff by ultrasound examination should be included.

Second and final survey

Radiographic views

Eighty percent (109/136) of respondents agreed that required standard radiographic views should include a true anteroposterior (AP) view in 0° abduction in neutral position, and 65% (89/136) would include an axillary view in 90° abduction. Three-quarters (101/136) of respondents agreed about the value of a scapular Y-view, when an axillary view cannot be obtained due to limited abduction capacity (Table 1). The inclusion of AP views in 0° abduction in both internal and external rotation reached 35% agreement, and 10% suggested other views such as “true AP of the glenohumeral joint”, “lateral”, “axial view in less than 90° abduction (eg. 30°) in the scapular plane”, “Neer I, Neer II” or “Velpeau” views.

Radiographic monitoring time-points

We received 92 valid responses suggesting between one and a maximum 6 time points for radiographical images (median 2) within the first three months. Most respondents (74%; 68/92) agreed on the 6-week time point. Eight participants suggested that the timing may differ depending on the fracture type or treatment (e.g. not necessary for non-displaced fractures; week 1, 2 and/or 3 only after non-operative treatment). Consensus with 77%, 67% and 78% agreement were reached also for the time points at 3, 6 and 12 months, respectively (Table 1). Twenty-three percent (32/135) supported monitoring at 2 years, and 44% (60/135) considered radiological assessment at the time of implant removal, if performed. Fifty-three percent (71/135) agreed that monitoring should be stopped when PHF healing was documented. 41% of respondents considered that other imaging modalities should be considered for monitoring of fracture position (reduction) and healing. Intraoperative fluoroscopy and computerized tomographic scanning (42 of 84 respondents) were the most prevalent adjunctive modalities, the latter to be used particularly if a complication (eg non-anatomical reduction, delayed healing) was suspected.

Radiographic parameters

After refining definitions derived from the first survey, the second survey enquired after the radiological parameters considered relevant by the panel for monitoring PHF. These included issues of bone health and bone shape. The definitions eventually achieving the desired level of consensus or greater after the second survey are tabulated in Table 2.

There was an 88% agreement (117/133) by panel members for the assessment of the accuracy of anatomical reduction after operative intervention as defined by fracture lines using a series of binary questions rather than by the term ‘malreduction’. The same descriptive system could be adapted for definition of anatomicity after non-operative PHF management.

Bone health

Parameters considered for bone health included: ‘bone resorption (including head necrosis)’; ‘bone formation’; ‘fracture healing’; and a new term, ‘peri–implant fracture’ (in cases of surgical fixation only). Levels of agreement among respondents ranged from 89% to 98% regarding these terms, definitions and specifications. Details are given elsewhere [5].

Bone formation and bone resorption

A total of 105 responses concerning the type, character, and extent of either condition demonstrated the difficulty of defining these parameters. Many referred to the time-dependent formation of callus and defined this as related to the endosteal location, periosteal surface, or both. When bone formation in excess of that required for successful fracture healing was noted, the panel agreed (95% consensus, 122/128 responses) that this was either orthotopic (ossification within tissue destined to become bone) or heterotopic (ossification in tissues that would not be destined to become bone under normal conditions). The latter was graded according to the modified Brooker system [8], shown in Table 3.

The definition of bone resorption was agreed by 98% (127/129 respondents). Specific locations at which bone resorption was frequent were suggested, including the greater tuberosity, and around implants. Radiographic evidence of bone resorption was also considered to accommodate the process of ischemia (98% agreement, 124/127 respondents) leading to avascular necrosis and subsequent humeral head collapse: some panel members commented about the duration of review required to confirm the absence of bone resorption due to ischaemia, while others referred to the role of magnetic resonance (MR) imaging to evaluate the ischaemic condition. We did not evaluate the role of further imaging in the monitoring of PHF, although both CT and MRI are frequently used for evaluation of specific fracture-related events or complications, since the purpose of the study was to agree a set of recommended plain radiographic terms.

Fracture healing

There was 89% (115/129 respondents) agreement on the definition of fracture healing. This was closely related to the linked adverse events of delayed union and nonunion. Most respondents referred to a time point 3 months after the index event (by which time mineralized callus was expected to be radiographically visible) for the definition of delayed union if the expected callus response had not been seen on radiographs. The majority considered the absence of callus on more than two cortices on orthogonal radiographic views at 6 months to define nonunion.

Peri-implant fracture

Emphasis was placed on this being the result of a new injury during which a new fracture line was noted to propagate in proximity to an implant (95% agreement, 126/132 respondents). Respondents distinguished between a novel fracture that was not present at initial presentation or during an operative procedure and a fracture that occurred intraoperatively and distinct from the original fracture, which could be attributed to the method of reduction or implant positioning.

Bone shape

It was recommended that the injured bone shape should be compared to the patient’s contralateral or expected normal

Table 2
Definitions of radiological monitoring parameters.

Parameter	Definition and specifications	Agreement
Fracture anatomical reduction (only for fracture fixation)	A series of binary questions are asked depending on the fracture pattern in order to assess if the fracture was reduced and/or healed in a position that can be described as "anatomical". Are greater tuberosity and head reduced anatomically? (Yes / No / n.a.*) Are greater tuberosity and shaft reduced anatomically? (Yes / No / n.a.*) Are greater and lesser tuberosities reduced anatomically? (Yes / No / n.a.*) Are lesser tuberosity and head reduced anatomically? (Yes / No / n.a.*) Are lesser tuberosity and shaft reduced anatomically? (Yes / No / n.a.*)	88% (117/133)
Fracture healing	The presence of mineralised callus circumferentially around the fracture zone visible on at least two orthogonal radiographs† or postoperative CT. Delayed healing: the absence of bridging callus on at least one of four cortices in the fracture zone on two orthogonal radiographs taken at 3 months after fracture Nonunion‡: the absence of bridging callus on at least one of four cortices in the fracture zone on two orthogonal radiographs taken at 6 months after fracture	89% (115/129)
Bone resorption	The progressive disappearance of bone from the proximal humerus (either medullary or cortical) when compared to the immediate postoperative or initial non-operative condition, in excess to that expected during normal fracture healing. Epiphyseal § Metaphyseal: involvement of the calcar region and/or the tuberosities (greater or lesser) Diaphyseal: involvement of endosteal or periosteal regions	98% (127/129)
Head necrosis	Epiphyseal bone resorption compared to immediate postoperative or initial non-operative radiographs. It is defined as maximum involvement in any radiological view and divided into 4 stages according to an adapted Cruess classification ‖: Stage 2: mottled sclerosis Stage 3: subchondral fracturing Stage 4: overt collapse of humeral head Stage 5: presence of glenoid degenerative changes	98% (124/127)
Bone formation	The progressive apposition of bone on or within the humerus when compared to the immediate postoperative or initial non-operative condition, more than that required for fracture healing (that is, more than the expected extent of callus). Orthotopic bone formation (ossification) is bone formation within the confines of the bone including the periosteum: bone is formed within tissue that is destined to be or become bone under normal healing or loading conditions (eg. excessive callus formation) Heterotopic bone formation (ossification) is a subset of excess bone formation within or between tissues that is not destined to be or become bone under normal healing or loading conditions. Heterotopic bone formation is classified according to a modified Brooker classification (Table 3)	95% (122/128)
Varus or valgus head position	Slippage of the head in varus or valgus position leading to a secondary cut out of the screws through the head ¶	95% (126/132) **
Tuberosity migration	Any perceived migration, in comparison to initial radiographs	95% (126/132) **
New peri–implant fracture (only for fracture implant fixation)		95% (126/132) **

* n.a. = not applicable, ie. these two bony entities are not separated by a fracture line.
† a clinician might use three orthogonal views (AP, lateral and axial views - the so-called Neer series), however because this series is not universally achieved in practice, any paired combinations may be considered, ie. AP and lateral, AP and axial, or lateral and axial combinations.
‡ Nonunion (requiring an additional intervention) is considered an adverse event to be documented.
§ Humeral head avascular necrosis is one form of epiphyseal bone resorption.
‖ Cruess classification [6] adapted by Hattrup and Cofield [7]. The initial stage 1 of this classification (pre-radiographic stage) cannot be observed on radiographs.
¶ terms "Cutout / Cut-through", "Head collapse" and "Loss of reduction" relates to the same event process and should be defined as such.
** overall level of agreement related to the proposed set of parameters. There was no perceived need to define or classify peri–implant fractures.

anatomy. Parameters considered relevant included secondary displacement of the head into a varus or valgus position and tuberosity migration, for which agreement was reached in 95% (126/132 respondents) in both circumstances.

Secondary displacement of the humeral head (as opposed to other segments of the proximal humerus) was defined as any adverse migration that occurred after the index event resulting in a deterioration in position of the humeral head, which can occur after all head-preserving treatments, including non-operative management. After osteosynthesis this might lead to cut-out or cut-through of fixation screws (or bolts) in the humeral head. Penetration of the articular surface by incorrect positioning of fixation screws at the time of surgery was considered separately as an adverse event, rather than an event for which monitoring was required.

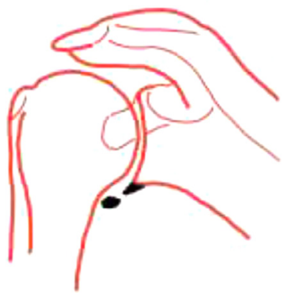
Tuberosity migration was considered to be a specific subset of secondary displacement, and dependent on the position of the tuberosity being anatomic at the index time. If the segment (the greater tuberosity) was in an anatomically acceptable position initially but displaced into an adverse position, we defined this as migration. If the tuberosity had healed and apparent bone loss without evidence of tuberosity displacement had occurred this was defined as resorption.

Discussion

Using a modified Delphi technique, we achieved consensus among an expert panel of specialized shoulder trauma surgeons for a standardized core set of radiographic monitoring parameters after PHF either surgically fixed or treated non-operatively. This set can be applied to routine monitoring in clinical practice as well as for trauma registries. The core set should be considered a minimum, since additional imaging types, parameters and time points may be considered, notably in the context of scientific studies.

The international expert panel comprised 231 clinically active trauma clinicians. Response rates were considered high given that

Table 3
Classification of heterotopic bone formation in the shoulder*.

Grade	Illustration	Definition
1		Islands of bone within the soft tissues around the shoulder
2		Bone spurs from the proximal humerus or scapula, leaving at least one centimeter between opposing bone surfaces
3		Bone spurs from the proximal humerus or scapula, reducing the space between opposing bone surfaces to less than one centimeter
4		Apparent bone ankylosis of the shoulder

* adapted from the Brooker classification [8].

the initial survey was demanding for the participants, and two-thirds of participants from the first survey responded to the second. In addition, the levels of agreement reached for the various parts of the core set was considerably greater than our predetermined threshold of a two-thirds consensus. The final consensus proposal was robust, even though implementing such Delphi exercise again with a similar panel of experienced clinicians may inevitably lead to differences in terminology and formulations. Although somewhat speculative, we believe such differences are unlikely to be major.

The definition of fracture healing was focused on externally formed (subperiosteal) new mineralized callus, forming a continuous bridging between adjacent fracture segments, that can be observed on radiographs, since the presence and extent of endosteal callus is difficult to define. By focusing on radiographic evidence, the requirement for a clinical definition of union, in which the presence of fracture-site or fracture-related pain is often considered, was obviated.

The definitions suggested for the terms “malreduction” and “malunion” in the first survey reflected concerns about inadequate surgical performance and subsequent management. Non-operative management results in a spectrum of “malunion” yet healing of fracture fragments in a displaced position is often well tolerated. The extent (interfragmentary displacement) of “malunion” and “malreduction” that can be tolerated by an individual patient are not well defined and some guidelines would be extremely useful. It was not the objective of this project to develop such guidelines but to define a common system of radiological definitions to support the development of such guidelines in the future. The definitions of threshold values of valgus or varus displacements beyond which functional outcomes were considered likely to be impaired were many and varied. Rather than define linear or angular measurements the panel agreed that a binary description of fracture segment alignments (‘are the related segments anatomically aligned: yes/no’) was less likely to be subject to observer bias and therefore a more reliable method of documenting malposition of fracture segments.

The commonly used terms "cutout / cut-through (of fixation screws and/or bolts)", “head collapse (the displacement of the head segment rather than the process of necrosis)” and "loss of reduction (as a secondary event)" were considered to relate to the same process, the end result of which was a secondary displacement of the head segment caused by a failure of support of bone by bone. In those cases treated by humeral head preserving surgical techniques this also included an unintended penetration of fixation devices through the surface of the head segment caused by the secondary displacement. Head collapse may also occur in cases treated non-operatively but without the additional adverse event of screw or bolt penetration. It was considered that these radiographic events could be combined within one definition.

Regarding bone resorption, it is recognized that focal but variable bone resorption is expected at or within fracture regions as healing progresses, but the bone is restored (usually but not always completely) at the completion of healing. Bone resorption to a greater extent than that seen in normal fracture healing may be progressive, permanent (that is, not restored as a result of healing), and non-focal. The panel agreed on a simple definition of the site of resorption as epiphyseal, metaphyseal or diaphyseal. Humeral head necrosis (a histopathological process) was characterized by resorption of bone (the radiographic equivalent appearance) in the epiphyseal segment, resulting in partial or complete bone collapse. Therefore, humeral head necrosis was considered to be a subset of epiphyseal bone resorption. The panel agreed that the modification of the Cruess criteria [6]for bone necrosis should be adopted for the PHF: stage 1 disease (pre-structural change) is not radiographically evident, therefore only grades 2 – 5 are noted in monitoring.

We used a Delphi consensus process that favoured the participation of a large international expert panel, achieving a response rate of 44% for the second (final) survey, two thirds of whom had responded to the first survey. Although we had a concept about relevant parameters, the first survey was implemented mostly with open questions to ensure that all potentially relevant parameters were considered. Comments and suggestions were evaluated equally without knowing the respondents’ identity to avoid biased value judgments. Steering group members met formally to refine the definitions of all selected parameters and to formulate proposals for definitions with an increased chance of support by the whole panel.

This study has limitations inherent to the Delphi methodology including the choice of the panel and steering committee, the formulation of suggestions and questions, the survey implementation, as well as the analysis of responses and final decision. We cannot exclude that another similar initiative would have resulted in the selection of other parameters or defined them differently. We also only involved experienced shoulder trauma surgeons, however other professionals (eg. researchers, register coordinators, data managers, …) as well as patient representatives may provide valuable input to the proposal. While we believe that the present proposal has face validity, wide application of this monitoring tool in multiple settings will assess its practicality for routine practice and research. Because of its length and remaining apparent complexity, surgeons may use it in practice only within the structure of organized documentation systems such as in the context of trauma registries. Field application and the centralization of standardized data will almost certainly lead to the continuous evaluation and revision of our tool.

Conclusion

This international Delphi consensus process contributes to the derivation of a common language for the description of a core set of radiographic features of healing of PHF.

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Level of evidence

Expert opinion; Consensus development.

Institutional Review Board/Ethics Committee Approval was granted by the following institution

Not applicable

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.injury.2022.07.026.

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