**RESEARCH ARTICLE** 

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# Complications after non-surgical management of proximal humeral fractures: a systematic review of terms and definitions

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# Abstract

**Background:** A majority of proximal humeral fractures can be managed without surgery. Recent randomized clinical trials and meta-analyses even question the benefit of surgical treatment for displaced 3-, and 4-part fractures. However, evidence-based treatment recommendations, balancing benefits and harms, presuppose a common reporting of complications and adverse events, which at the moment is largely missing. Therefore we systematically reviewed the use of terms and definitions of complications after nonsurgical management of proximal humeral fractures.

**Methods:** We searched PubMed, EMBASE, Cochrane Library, Scopus and WorldCat (2010–2017) and included articles and book chapters containing complication terms or definitions. Two reviewers independently extracted and grouped terms and definitions according to a predefined scheme. Terms and definitions concerning non-surgical management were tabulated, grouped and analyzed qualitatively.

**Results:** The initial search identified 1376 references from which 470 articles were selected for full-text retrieval. Data-extraction included first articles published in 2017, was then performed iteratively in batches of 20 articles, and terminated after retrieval of 91 articles when no additional definitions or terms was found. In addition, 12 book chapters were reviewed from an initial list of 100. No general definition of a complication was found. A total of 69 terms for complications after non-surgical management were identified from 19 articles. Sixty-seven terms regarded local events. The most commonly reported event terms regarded osteonecrosis, malunion, secondary displacement and rotator cuff problems. Seven individual terms were accompanied by some kind of definition. Most terms and definitions were based on radiographical assessments.

**Conclusions:** We found no consensus in the use of terms and definitions of complications after nonsurgical management of proximal humeral fractures. Multiple terms, some synonymous, some partly synonymous, some distinct, were used. Few complication terms were explicitly defined. Development and validation of an internationally consensus-based core event set for complications after proximal humeral fractures managed non-surgically is needed.

Keywords: Proximal Humeral fractures, Non-surgical, Complications, Adverse events, Systematic review

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# Background

Proximal humeral fractures (PHF) are common fractures and account for 4-6% of all fractures [1-3]. They are associated with osteoporosis and 78% of the fractures are seen in patients above the age of 65 [4]. Since 1970 it has been widely believed that 85% of all PHF were minimally displaced and could be managed non-surgically while the remaining 15% were displaced and should be managed surgically [5]. However, more recent epidemiological studies have consistently reported much higher prevalences of displaced fractures ranging from 51 to 86% [3, 6–8]. The most commonly performed surgical procedures include internal fixation with locking plates or humeral nails or replacement of the humeral head with a hemiarthroplasty or a total reverse prosthesis. However, recent randomized clinical trials [9-12] and meta-analyses of randomized trials [13 - 18]or non-randomized trials [19, 20] have questioned the benefits of these procedures, even for displaced fractures. A call for more non-surgical treatments of PHF has emerged in the scientific literature [21-24].

Any evidence-based recommendation of a treatment modality, surgical or non-surgical, presupposes knowledge on benefits and harms. Guidelines for reporting of clinical effects with validated clinical outcome instruments are available and widely used. However, when it comes to reporting of complications and adverse events after management of PHF there is a paucity of standardized and validated terms and definitions. The majority of clinical studies on PHF deal with surgical management [25] and some complications like hardware failure and infection are obviously linked to surgery. However, complications following non-surgical management of PHF have not been systematically reviewed. Therefore, we aimed to systematically review the use of terms and definitions of complications after non-surgical management of PHF.

#### Methods

We conducted a systematic review of published peer-reviewed articles and book chapters according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [26].

# Search strategy

A search was conducted (June 2017) in PubMed, EMBASE, Cochrane Library and Scopus covering the years 2010–2017. The search strategy for journal articles is found in Additional file 1. For book chapters we searched WorldCat (2016–2017) using the search terms (humer\* fra?tur\* OR shoulder fra?tu\*). We included references in English, German and French language.

#### Study selection and data-extraction

After exclusion of duplicates, two reviewers (A.S. and N.A.) screened the initial reference list by title and abstract. A third author (L.A.) reviewed any ambiguous abstracts to reach consensus on the article's inclusion. Considering all included references we started full-text review and data extraction with the most recent references published in 2017 followed by consecutive series of 20 randomly selected references within previous years in reverse chronology. This process was terminated when all reviewers agreed that no additional relevant information was obtained. For all included references we documented bibliographical data and noted any general definition of 'complication' or 'adverse event' and any definition of individual complications or adverse events. We documented all individual complication terms reported and grouped them according to the relevant interventions. Terms related to non-surgical interventions extracted for further analysis. were The initial data-extraction was checked by a second reviewer and discrepancies were resolved by consensus. All data were managed and stored in a database using the data capture system REDCap [27] (Version 6.16.5,© 2018 Vanderbilt University).

#### Data synthesis

Extracted event terms were organized according to predefined event groups and specifications adapted from Audigé et al. [28]. Event term definitions were tabulated.

#### Results

The initial search yielded 1376 references (Flow chart, Fig. 1). Based on titles and abstracts we excluded 906 references that did not comply with the inclusion criteria. Thus, 470 references remained for full-text retrieval. Data extraction was terminated in consensus within the review group when 91 articles and 12 book chapters had been retrieved in full text and no new terms or definitions was identified in the last group of references.

A total of 19 references (15 articles [13, 29–42] and 4 book chapters [24, 43–45]) reported terms and definitions of complications after non-operative management of PHF. The remaining references were excluded because they dealt with surgical management exclusively. From all the terms that were documented as being reported in the context of non-operative treatment, we identified the related papers, and then by checking back to these papers found out that only 19 papers were specifically focused on non-operative management.

After excluding spelling errors and clearly synonymous words 69 complication terms remained for further analysis (Table 1). They were grouped into 7 broad groups



and 11 subgroups. Seven complication terms were defined.

# **Complication terms**

All 69 complication terms were initially divided into local and non-local events. Local events were further grouped into 'osteochondral', 'instability', 'shoulder pain', 'neurological', 'soft tissue (superficial)', and 'soft tissue (deep)'.

The largest group (39 terms) was the 'osteochondral' group covering the subgroups 'arthritis', 'tuberosity migration/resorption', 'osteonecrosis', 'delayed union', 'malunion' and 'secondary fracture displacement'. All 39 event terms in this group were radiographically based.

The second largest group, 'soft tissue (deep)' (21 terms) covered 'impingement', 'capsular', 'stiffness' and 'rotator cuff'. These event terms were defined clinically or by magnetic resonance imaging (MRI).

The remaining event terms were related to instability, pain, neurological injury, skin problems and the non-local events pneumonia and deep venous thrombosis.

# Definitions

Among the full text searches we found 7 complication definitions. Six out of 7 definitions regarded radiographically defined events like malunion, nonunion, displacement and avascular necrosis (Table 2). Loss of power in arm was the only non-radiographically defined event term.

# Discussion

We found no consensus in the use of terms and definitions of complications after non-surgical management of PHF. Only very few definitions of complications and adverse events were identified. Relatively few references on non-surgical management were identified compared to surgical interventions. This confirms the findings of Slobogean et al. [25] who conducted a scoping review of the literature on PHF and reported that less than 5% of the body of literature dealt with non-surgical management compared to more than two thirds concerning surgical management. Despite this bias towards surgical literature we find it important to focus on complications after non-surgical management. A systematic reporting of complications and adverse events is needed for evidence-based suggestions and balanced decision-making [46].

# 'Radiographical complications'

Most terms and definitions of adverse events are based on assessments of radiographs. Assessments based on radiographs may favor surgical management as osteosynthesis and arthroplasty aim to restore the anatomy of the proximal humerus or to replace the damaged joint. To designate a certain radiographic pattern as a complication or an adverse event does not necessarily mirror the functional outcome and expectations as reported by the patient. Displaced fractures in adults can be expected to heal with some degree of malunion when treated non-surgically. In that sense, a malunion is not necessarily an adverse event from the patient's perspective. Even severe maluninon may be tolerated by patients with limited functional demands. More knowledge is needed to clarify the association between patient reported outcome radiographically defined and complications after non-surgical management.

Displacement, migration, malunion and nonunion are continuous variables brought into distinct categories often by poorly defined cut-off values. Three references proposed explicit definitions of 'secondary varus displacement' [13] 'tuberosity displacement' [39] and 'varus

# Table 1 Adverse event terms

# Table 1 Adverse event terms (Continued)

Event group	Event subgroup	Event term	Event group	Event subgroup	Event term		
Osteochondral		Heterotopic bone formation			Malreduction <sup>a</sup>		
		Humeral head resorption			Poor fracture reduction <sup>a</sup>		
	Arthritis	Degenerative arthritis	Instability		Recurrent shoulder dislocation		
		Osteoarthritis	Shoulder pain		Pain		
		Post-traumatic arthritis			Persistent pain		
		Post traumatic osteoarthritis			Shoulder pain		
	Tuberosity migration/ resorption	Superior migration of greater tuberosity	Neurological		latrogenic neurovascular		
		Posterior migration of lesser tuberosity			Axillary nerve lesions		
		Medial displacement of the greater tuberosity		Complex regional pain syndrome			
		Displaced greater tuberosity	Soft tissue		Skin irritation		
	Osteonecrosis	Osteonecrosis	(superficial) Soft tissue Impingement (deep)				
		Osteonecrosis of the humeral head		Impingement	Impingement		
		Necrosis of the humeral head			Impingement of the greater tuberosity		
		Avascular necrosis of the			Subacromial impingement		
		humeral head			Internal rotation		
		Avascular necrosis		Coracoidal impingement			
		Head avascular necrosis		Impingement of the greater			
		Humeral head ischemia			tuberosity on the acromion		
		Loss of perfusion of the humeral head		Capsular	Capsular contracture		
	Delayed union	Delayed union			Capsulitis		
		Prolonged delayed union			Adhesive capsulitis		
	Malunion	Malunion			Secondary adhesive capsulitis		
		Valgus malunion			Frozen shoulder		
		Varus malunion		Stiffness	Stiffness		
		Varus malunion in anteversion			Shoulder stiffness		
		Varus malunion in			Stiff shoulder		
		retroversion			Self-limiting stiffness		
		Greater tuberosity malunion		Rotator cuff	Rotator cuff tear		
		Malunion of the tuberosities			Rotator cuff pain		
	Nonunion	Nonunion			Rotator cuff weakness		
		Fracture non-union			Rotator cuff deficiency		
		Pseudoarthrosis			Rotator cuff dysfunction		
	Secondary fracture displacement	Secondary displacement			Rotator cuff injury		
			Non-local		Pneumonia		
		Fracture displacement			Deep Venous Thrombosis		
		Varus collapse	<sup>a</sup> After closed red	<sup>a</sup> After closed reduction			
		Cephalic collapse	malunion'	malunion' [41] based on measurements of degrees and millimeters on radiographs. The scientific and clinical			
		Complete displacement of the humeral shaft	millimeters				
		Malaasitian of lesser	validity of s	such definitions m	av be duestioned and fur-		

Malposition of lesser tuberosity

d l ther studies may contribute to elucidate the clinical relevance of these commonly used complication terms.

 Table 2 Summary of definitions of adverse events

Author	Event term	Event definition	
Handoll (2015) [13]	Avascular necrosis (score 2–0)	Score 2 = no changes/1 = changes to normal trabecula organisation < 50% of humeral head/0 = > 50% of humeral head or partial collapse	
Handoll (2015) [13]	Secondary varus displacement	> 10°	
Kancherla (2017) [39]	Tuberosity displacement	> 5 mm.	
Fang (2017) [29]	Loss of power in arm (grade 0–5)	Medical Research Council Scale (grade 0–5) [47]	
Papakonstantinou (2017) [41]	Delayed union/non-union/prolonged delayed union	Union between 61 and 89 days/when fractures had not united by 90 days/union after 90 days	
Papakonstantinou (2017) [41]	Varus malunion	Neck-shaft angle ≤110°	
Papakonstantinou (2017) [41]	Non-union (indirect definition)	Presence of callus uniting the main fragments of fractures in 3 of the 4 bone cortices	

The complication terms and definitions identified for non-surgical management can roughly be divided generically into three groups:

#### Pathoanatomical entities

'Humeral head necrosis' and 'capsulitis' are pathoanatomical diagnoses applied to radiological, clinical or intra-operative findings. Similarly, non-local terms like 'pneumonia' and 'DVT' are clinical and para-clinical (radiographs, ultrasound, blood tests) diagnoses rarely verified by pathologists.

#### Pathophysiological entities

'Loss of perfusion' leading to 'humeral head ischemia' and eventually 'avascular necrosis of the humeral head' are successive changes in a pathophysiological process. This process is quantified in the 3-stage definition of 'avascular necrosis' [13].

The process leading to 'non-union' or 'pseudoarthrosis' is captured in the 3-stage definition 'delayed union', non-union', or 'prolonged delayed union' [41].

# **Biomechanical entities**

The terms related to rotator cuff problems are based on a biomechanical understanding of successive changes caused by muscular imbalance. The term 'rotator cuff' is usually followed by specifications like 'tear' and 'injury' (based on imaging), 'pain' (based on history), or 'dysfunction' and 'deficiency' (based on a functional understanding).

The terms related to 'impingement' are based on a biomechanical understanding of the process leading to pain and impairment. 'Internal rotation impingement' is clinically defined while 'impingement of the greater tuberosity on the acromion' illustrates a biomechanical understanding.

#### **Future aspects**

To obtain consensus on terms and definitions we plan to apply a Delphi consensus process based on the findings from the systematic review. An international group of shoulder surgeons will independently assess and comment on the proposed terms and definitions through a series of online surveys. A core event set will be developed and further validated. A similar approach has previously been applied to complications associated with arthroscopic rotator cuff tear repair [28].

#### Conclusions

Based on this systematic review we found no consensus on terms and definitions of complications and adverse events after non-surgical management of PHF. Most terms and definitions are based on radiographical assessments and the clinical relevance of terms and definitions from the patients' perspective remains to be demonstrated. We recommend steps towards the development of a core event set of complication terms based on consensus among shoulder and trauma specialists and with involvement of patient representatives in the validation process.

# **Additional file**

Additional file 1: Search protocol for proximal humeral fractures in PubMed, Medline, Embase, Cochrane Library and Scopus. (PDF 649 kb)

#### Abbreviations

DVT: Deep venous thrombosis; MRI: Magnetic resonance imaging; PHF: Proximal humeral fracture

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#### Availability of data and materials

The final dataset will be available from the corresponding author.

#### Authors' contributions

SB: project plan, data extraction, data analysis, preparation of manuscript. NA: initial reference selection, data extraction, data analysis, review of manuscript. CB: project plan, data extraction, review of manuscript. AJ: project plan, review of manuscript. AS: initial reference selection, data extraction, data analysis, review of manuscript. LA: project leader, project coordination, project plan, database development and management, reference selection, data verification, statistical programming, data analysis, preparation of manuscript. All authors have read and approved the manuscript.

#### Ethics approval and consent to participate

N/A

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N/A

#### **Competing interests**

The authors declare that they have no competing interests.

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