Physiotherapeutic interventions and rehabilitation regimen of the surgically stabilized proximal humeral fracture – a literature review

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Abstract

Proximal humeral fractures requiring surgical stabilization remain a therapeutic challenge, and a fully functioning joint is rarely the outcome after traumatic proximal humeral fractures. A systematic review was conducted to present the current state of knowledge concerning the postoperative rehabilitation. Three databases were searched (PubMed, PEDro and the Cochrane library), presenting 25 publications eligible for further review and assessment. The literature was evaluated using PEDro and The Swedish Council on Health Technology, SBU's, evaluation grading system GRADE. The main functional impairments were pain and reduced range of motion in the shoulder joint, and were measured by several different scoring systems for functional outcome. Reported results were contradictory and inconsistent, and current studies typically lack randomization, and independent evaluation, with a resultant inability to produce clinical conclusions. According the post-operative rehabilitation procedure, only careful conclusions can be drawn from the literature reviewed which does not focus on, emphasize or explore the physiotherapeutic interventions at any length. It was therefore not possible to compare or connect the Axelina rehabilitation regimen with the literature. The Axelina rehabilitation program of the shoulder joint, are the most commonly used regimen at the physiotherapeutic ward at Uppsala University hospital. Neither was it possible to determine if the post-operative treatment should be different according to classification of fracture or method of stabilization. The results from this systematic review suggest that the data from the published literature are inadequate for evidence-based decision making as regards the treatment and post-operative rehabilitation for complex proximal humeral fractures.

Key words:
Proximal humeral fracture, operative treatment, physiotherapy, post-operative rehabilitation, treatment modalities.
1. BACKGROUND

Proximal humeral fractures (PHFs) account for approximately 4-5% of all fractures and are secondary only to hip fractures and distal radius fractures in the elderly population. The incidence is approximately 3 / 10 000 persons a year and is rapidly increasing with age (1-3). Women are affected twice as often as men and the majority of patients with this fracture are elderly than 80 years of age, which increases the risk for their bones to be osteoporotic or brittle. The quality of the bone seems to be crucial both for the post traumatic intervention and the functional outcome (2). Furthermore, an elderly patient’s physical and sometimes psychic or mental fragility can create difficulties during the rehabilitation and the return to normal status after a trauma and the following rehabilitation period. The majority of PHFs are caused by what is called low energy trauma, for example, a fall from a standing position with an arm stretched out (2, 4, 5). PHFs remain a significant and growing medical concern due to the strongly associated morbidity and epidemiological trends indicating an aging population (3, 5).

1.1 Classification and treatment of proximal humeral fractures

There are several different classification systems regarding fractures of the human skeleton, and there is little consensus concerning which system to use by orthopaedic surgeons. One of the most commonly referred classification systems concerning the proximal humeral fractures were developed and presented by the orthopaedic surgeon Charles Neer (figure 1) in 1970 (6). The system was based on the absence or presence of displacement of each of the four major segments of the proximal humerus; articular surface of the humeral head, greater tuberosity, lesser tuberosity and shaft (Figure 2). The classification system is, despite its deficiencies, until today the most applied (6, 7). The orthopaedic treatment, i.e. the operative or conservative (not operative) treatment is determined by some crucial factors; degree of dislocation (1, 6, 8, 9) (which is deterrent for the blood supply to caput humeri), status of the rotator cuff (1, 6, 8-10) (the generic term for the muscles and ligaments which control the function and stability in the glenohumeral joint or the shoulder joint), the quality of the bone (6, 8, 9), the amount of time between the initial trauma and surgery (6, 8, 9), the skill of the surgeon (6, 8, 9) and the patient’s general health, age and functional expectations (6, 8-10) which can affect the compliance to post-operative regimen and rehabilitation guidelines (1, 2, 6, 8-10).
Aside from conservative treatment of the minimally displaced fracture, generally involving closed reduction and immobilization of the injured arm, surgical interventions and techniques for treating the complex proximal humeral fracture vary considerably and include; external fixation (12), open reduction and transosseous suture fixation (13), Tension-band osteosynthesis (14), open reduction and conventional plating (15), angular stable plating (PHILOS [proximal humeral internal locking] plates or AO [Association for Osteosynthesis] plates) (16-18) intramedullar nailing (19), hemiarthroplasty (1, 10, 20-35), or reverse shoulder arthroplasty (32). There is little evidence and little consensus concerning the optimal treatment modality (2, 5, 6, 8, 22, 34, 36), but the goals of surgery are to obtain anatomic fracture reduction and stable primary fixation to ensure rapid fracture healing and immediate postoperative functional therapy without prolonged immobilization (19, 36, 37).

1.1.1 Classification of proximal humeral fractures according to Neer

*Group I*, minimum displacement and *Group II*, articular segment displacement. The line of fracture can occur at all levels of the proximal humerus; caput, collum anatomicum, the greater and lesser tuberosity and collum chirurgicum. Collum chirurgicum is a commonly used generic term for this group of fractures. The undisplaced or undislocated fractures of group I & II constitutes over 85% of all PHFs and are most commonly treated conservatively with closed reduction followed by immobilization in a sling and physiotherapeutic supervised exercises (1, 6, 8, 38, 39).
Group III, shaft displacement. The rotator cuff holds the fractured caput fragment in location. This type of fracture might need operative treatment and stabilization with a short intramedullar nail to prevent the caput fragment to dislocate from the shaft.

Group IV, greater tuberosity displacement. These type of fractures often occur with substantial damage to the rotator cuff which can lead to greater dislocation of the shaft and therefore demands operative treatment. Fractures of the greater tuberosity generally occur together with a fracture through the caput where the blood supply to the caput fragment is crucial for the outcome of the operation and the rehabilitation. Those fractures must be operatively treated, most common with some kind of osteosynthesis or conventional plating (generic term for methods of fracture stabilization using so called locking plates along with screws, pin or springs, wire and sutures).

Group V, lesser tuberosity displacement, is commonly co-occurring with a fracture through the caput. Isolated lesser tuberosity fractures can be treated conservatively, but if there is a tear in the rotator cuff or another fracture line operative treatment is requisite.

Group VI, displaced three- or four parts fractures, implies a displacement of the caput, the collum anatomicum, the greater or lesser tuberosity or the collum chirurgicum. Furthermore, there is commonly a substantial tear to the rotator cuff and a displacement of the articular fragment with risk for following avascularity of one or more fragments. If the lesion is raised through high energy trauma, there is a risk for damage on the cartilage or bone in the articular surface which can provide difficulties at the surgery and also have a negative effect on the rehabilitation (2, 5, 6, 8, 39).
1.2 Complications following the operative treatment of proximal humeral fractures

Reduced range of motion and pain are commonly reported complications after the operatively treated proximal humeral fracture (1, 2, 5, 6, 8, 10, 12, 16, 28, 29, 38-40). However, opinions vary considering how the postoperative symptoms best are evaluated (2, 6, 8). Early exercises seems to be crucial for the future range of motion and active function (5, 6, 8, 10, 20, 21, 29, 40), but can as a secondary effect cause instability in the greater and lesser tuberosities, causing them to migrate or displace which causes pain, reduction of function and in worst case scenario, reoperation (1, 5, 6, 8, 10, 20, 21, 29, 40). On the other hand, if movement restrictions are applied in order to let the tuberosities heal, the outcome can be a stiff and weak shoulder (5, 6, 8, 10, 21, 24, 29, 40). Post-operative complications mentioned in the literature was: loosening of the tuberosities (1, 2, 5, 6, 8, 10, 12, 16, 28, 29, 38-40), postoperative infections (1, 10, 12, 28, 39, 40), avascular necrosis (2, 5, 6, 8, 12, 39),
loosening of the prosthetic head (6, 8, 10, 28, 29, 39) malunion (6, 8, 10, 16, 39), instability in the joint due to inadequate status or tear in the rotator cuff (1, 5, 6, 8, 10), neurological damage to the arm plexus (1, 16, 28, 29), non-union (6, 8, 12, 39), dislocation of the prosthetic head (1, 10, 28, 39), ectopic bone formation (1, 39) and glenoide erosion. Along with the development of the operative techniques and methods of stabilization the post-operative rehabilitation can hold a more progressive and active approach and this can have a positive effect on post-operative pain and the future function of the joint (2, 5, 10, 20, 26, 29, 30).

1.2.1 Range of motion in the shoulder joint

Of all the joints, the shoulder has the greatest range of motion (ROM). The complexity of shoulder kinematics due to the contribution of the scapula and the clavicle makes it difficult to analyze shoulder motion (41, 42). The most used tool to measure range of motion in any joint is the goniometer (42). The direction of movement in the shoulder joint can be presented as;

**Forward flexion** when the arm moves forward in neutral rotation and 0° abduction.

**Elevation** when the arm moves forward in slight internal rotation and 30° abduction. This is also called the scapular plane and is considered to be more a lenient movement than forward flexion due to the relaxed status of the rotator cuff and the pliability of the structures of the joint capsule. Therefore, the flexion and the elevation are not to be considered exchangeable and can not be compared as equals concerning the ROM.

**Abduction** when the arm moves out from the body in the shoulder plane.

**External rotation** when the arm rotates outwards from the abdomen in the horizontal plane.

**Posterior internal rotation** when the arm rotates inwards from the side of the thigh and backwards in the horizontal plane. Rotation is a key for maintaining independent life as rotational movements are important for the maintenance of personal hygiene and for normal eating (24).

1.3 Physiotherapeutic intervention and rehabilitation regimen after the surgically stabilized proximal humeral fracture

The post-operative rehabilitation regimen established by the responsible surgeon is considered to be the guideline for the physiotherapeutic intervention. Functional outcome is a collected assessment of abilities following the rehabilitation period. The formulation of disability or functional impairment is used to describe a lost or sub optimal function. The
impairment or disability can regard a structure, joint function or capacity, physical or physiological.

In Neer’s second article from 1970 (8) immediate active exercises for the hand and elbow is advocated. During the initial 3 weeks, passive exercises were recommended and between the sessions the shoulder and the arm was immobilized in a shoulder bandage. The following 3 weeks the arm was still supported in a sling and active assisted exercises began. Active elevation above the shoulder was to be avoided until the tuberosities healing was radiologically sanctioned, after 9 weeks at the earliest. Passive stretching or weighted exercises were not to begin until 12 weeks after surgery. This regimen is the most frequent cited in the literature (8, 10, 16, 23, 25, 27, 28, 30, 40).

At Uppsala university hospital, the postoperative regimen is based on the Axelina rehabilitation program for shoulder prosthesis after proximal humeral fracture. The Axelina rehabilitation program is a rehabilitation regimen for the shoulder joint, developed by experienced physiotherapists and surgeons to support physiotherapists in individualizing the rehabilitation of patients with impairments in the shoulder joint both pre- and post-operative and for impairments that do not demand surgical treatment. The regimen in the Axelina rehabilitation program is built on phases or stages concerning the patient’s abilities and function of muscular control and has recommendations for range of motion and functional goals to be achieved before moving on to the next phase or level of exercises. However, the Axelina regimen also starts with supporting the arm in a sling, but is henceforth somewhat more progressive than the regimen presented by Neer and advocates active assisted exercises, where the impaired arm is supported by the unimpaired one, from the first post-operative day to complement the passive pendulum exercises. Furthermore, careful isometric exercises for the shoulder joint are started as soon as 4-6 weeks after surgery followed by active exercises with the patient lying down on the back or up to shoulder level, to reduce the impact of gravity on the joint. Nevertheless, it is also recommended in the Axelina rehabilitation program that active exercises above shoulder level is not to be introduced until after 8-12 weeks post-operatively, followed by passive stretching and weighted exercises. The purpose of treatment with the Axelina rehabilitation program aims, except for increased range of motion in the shoulder joint, to give the patient implements for the post-operative treatment and rehabilitation regimen, understanding of the anatomy of the shoulder, the healing of the tissue, functional movement, reduced pain, adequate muscular control and to enhance the patients own responsibility for continuing the exercises and training at its own after and under the period of treatment. The Axelina rehabilitation prograe is lacking references to
publications regarding functional outcome after surgery, but the program is used in 17 of the 21 major hospitals and counties in Sweden (43).

As a consequence of patients having great postoperative difficulties regarding decreased range of motion and severe pain, increased knowledge concerning the postoperative physiotherapeutic treatment of patients with surgically stabilized proximal humeral fractures are required. The rehabilitation program used for rehabilitation of surgically treated proximal humeral fractures at the physiotherapeutic department at Uppsala university hospital does not mainly focus on patients who receive shoulder prosthesis due to fracture, but for patients who receive a total shoulder replacement related to arthritis or other rheumatic decease or conditions. Therefore there is a need to conduct diagnose specific rehabilitation programmes of the surgically stabilized proximal humeral fractures hence the anatomical conditions are different comparing to the anatomy in the arthritic shoulder. There is an urgent need to summon an up to date, evidence based basis for the physiotherapeutic rehabilitation for this category of patients.

1.4 Aims and research questions

The primary aim of the thesis was to describe the current state of knowledge concerning the post-operative physiotherapeutic interventions and rehabilitation for the surgically treated proximal humeral fracture by conducting a review of the published literature.

Research questions
1. What functional impairment was described in the literature with patients who have been treated surgically after proximal humeral fracture and how were they measured?
2. What physiotherapeutic interventions or rehabilitation regimen was described in the literature, when after surgery was they initiated and what were their results?
3. Was the postoperative rehabilitation different according to fracture classification or according to method of osteosynthesis?
4. Is the Axelina rehabilitation programme consistent with the regime presented in the literature?
2. METHOD

This paper was written in a descriptive design to illustrate how the postoperative rehabilitation and the physiotherapeutic interventions were described in the literature.

2.1 Search of databases

Three search sessions, conducted through three search engines, were performed and are presented in Table 1. An electronic search of the Medline database was carried out using the PubMed search engine. The search was conducted by Medical Subject Headings (MeSH terms) as follows: “proximal humeral”, “shoulder fractures/surgery”, “functional outcome”, “rehabilitation”, “therapy” and “physiotherapy”. The query was limited to manuscripts published in English, and limited according to year of publication beginning 1990. The results (376 publications) where sorted by title and then by abstract, leaving 142 publications. Articles were considered to be eligible for review if they met the following inclusion criteria, based on the aim and questions of the thesis:

1. Proximal non-pathological humeral fractures surgically treated and stabilized with either osteosynthesis or hemiarthroplasty in skeletally-mature patients.
2. Description of outcome of functional impairment including pain, range of motion, evaluation or rehabilitation in the publications MeSH-terms.
3. Description of rehabilitation treatment or regime.

Articles concerning studies of human cadavers as well as letters and comments on publications were excluded.

Remaining publications were sorted a second time by a more thorough search based on the questions and aims of the thesis. This second search reviewing the remaining abstracts for
1. Number of patients included in the study (minimum 20 patients).
2. Number of treatment centres involved in the study, multicenter studies preferred.
3. Emphasizing of treatment outcome and rehabilitation following a primary surgery.

Publications aiming for second treatment or reoperation were excluded.

Through the second search, the number of interesting publication diminished to 43, and where then sorted by publication type: “Reviews” (8), “Randomized controlled trials” (3) “Clinical trials” (9) and “Evaluation and comparative studies” (13). Articles that did not suit any of the above categories but contained interesting material for the subject were placed in a fourth category namely “Physiotherapeutic interesting articles” (10). “Physiotherapeutic interesting articles” and Reviews were not included in the final review, but did add interesting material to the background and discussion of this thesis.
A second electronic search was performed using the Physiotherapy evidence database (PEDro) search engine. A “simple search” and an “advanced search” were conducted with the terms “proximal humeral fracture” respectively “shoulder fracture”, “surgery” and “rehabilitation”. The search was not possible to limit to publications in English only. The result, 9 and 28 publications respectively, was studied by language, title and abstract and left only four articles with the inclusion criteria, those articles were already included in the study from the search above (2, 5, 10, 14).

A third electronic search was conducted using the Cochrane Library Database. The same search terms were, “proximal humeral fracture” was used and the search only gave one result (2) (Handoll -03). Continuous through the review, lists of reference was searched for supplementary literature and to create a further batch of research articles. This did not, however, result in further addition to the reviewed list of publications, but it did add publications to the forth category “physiotherapeutic interesting articles”. The search engines and databases used for the search were used because of their large data of articles that would enhance the chances of hits on up to date and accessible articles.

Table 1. Search result.

<table>
<thead>
<tr>
<th>Database / Search term</th>
<th>Number of hits</th>
<th>Relevant publications</th>
<th>Included articles</th>
<th>Articles for review</th>
</tr>
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<tbody>
<tr>
<td>PubMed Proximal humeral, AND “shoulder fractures/surgery” (MeSH), AND “functional outcome”, OR “rehabilitation”, OR “therapy” OR “physiotherapy”</td>
<td>376</td>
<td>142</td>
<td>43</td>
<td>25</td>
</tr>
<tr>
<td>PEDro Proximal humeral fracture, shoulder fracture, surgery, rehabilitation</td>
<td>28</td>
<td>4 (duplicates)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cochrane Proximal humeral fracture</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
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2.2 Instruments for assessment of literature

The publications selected for the review were further studied and evaluated using the PEDro assessment scale (appendix 1). The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (44) and aims to rate the methodological quality of clinical studies evaluating physical therapist interventions by a 11-item scale. Every criterion gives one point, but in the final assessment only ten criterions are concluded giving a maximum score of 10. The first criterion relates to the external validity of the trial and is therefore not included in the final score, hence the criterion 2-9 relates to internal validity and criterion 10-11 relates to statistical information to enhance the interpretability of the results. Randomized controlled trials with blinded subjects, therapists and assessors, and adequate statistical information gives high PEDro scores. However, no consideration is given the results or number of subjects, which makes it hazardous to draw rash conclusions of high PEDro score and the effect of treatment. The PEDro scale is considered reliable concerning individual PEDro items as well as total PEDro score (45). Furthermore, preliminary evidence states that the PEDro total score consists convergent validity (the extent to which scores of a particular instruments correlate with other measures of the same construct) and construct validity (the extent to which scores on a particular instrument relate to other measures in a manner that is consistent with theoretically derived hypotheses concerning the concepts that are being measured) (46).

Additionally, the publications labelled as randomized controlled trials were further assessed using the The Swedish Council on Health Technology - SBUs Assessment scale for Randomized Controlled Trials (47). The quality of the study refers to the scientific quality of a certain study and the study’s ability to answer a certain question in a reliable way. The level of evidence is an assessment of how high the total scientific basic data is to answer a certain question in a reliable way. The level of evidence can be affected by weakening or strengthening factors as quality, relevance, concordance, relation, and size of effect, data precision, risk of bias, and more. A method of treatment can be considered having limited or inadequate level of evidence due to lack of relevant or up to date research. This does not necessarily mean that the method of treatment is no good. The SBU uses the GRADE system to assess the level of evidence of publicised studies. The acquired level of evidence can be established when several scientific studies concerning the same subject are assembled. Subsequently, it can be established however a method of treatment has sufficient level of evidence and if it should be recommended for use in clinic.
The assessment systems used in this paper were chosen because PEDro are the only assessment system used by physiotherapists for control and test of clinical significance, and GRADE is an accepted system for assessment of clinical studies and reviews.

Table 2. Level of evidence by SBU, the GRADE system

<table>
<thead>
<tr>
<th>Level of evidence by SBU</th>
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</thead>
<tbody>
<tr>
<td><strong>High level of evidence</strong></td>
</tr>
<tr>
<td>Ads to studies of high quality without weakening factors at a collected assessment.</td>
</tr>
<tr>
<td><strong>Average level of evidence</strong></td>
</tr>
<tr>
<td>Ads to studies of high quality with few weakening factors at a collected assessment.</td>
</tr>
<tr>
<td><strong>Limited level of evidence</strong></td>
</tr>
<tr>
<td>Ads to studies of high or average quality with weakening factors at a collected assessment.</td>
</tr>
<tr>
<td><strong>Inadequate level of evidence</strong></td>
</tr>
<tr>
<td>Ads to studies when scientific basis is lacking, accessible studies have inadequate quality or studies of equal quality with contradictory results. Should not be considered as sufficient for conclusions for evaluation of treatment.</td>
</tr>
</tbody>
</table>

Note: [www.sbu.se](http://www.sbu.se)

3. RESULTS

Functional impairments, physiotherapeutic interventions and authors conclusions in the reviewed literature are presented in Table 3.

3.1 Functional impairment after surgery

Pain and decreased range of motion were the functional impairments described in the literature.

3.1.1 Pain

Pain was evaluated as the most important consideration to the patient. The post-operative result in any patient with significant pain was to be considered as a failure as acute or chronic pain can lead to various degrees of altered behaviour, dysfunction or disability (6, 48). Post-operative pain is discussed in some (1, 10, 13-18 22-33, 35) but not all, of the reviewed studies, but the different methods of evaluating pain and how pain relief are variously defined
throughout the studied literature complicates the drawing of clinical useful conclusions. Furthermore, there is little consensus to support the terms “satisfactory” or “unsatisfactory” or “good” to “excellent” used in the reviewed literature. It is pointed out that patients suffering from fractures most often have had no symptoms before the injury and that it therefore can be argued that the outcome “satisfactory” should include no pain from the patient’s point of view (25). On the other hand, Pandua et al (23), reported that patients with shoulder replacements and hemiarthroplasty after trauma enjoyed a quality of life similar to that of a healthy population despite pain and decreased functional outcome. Pain is also included as a variable in methods of functional scoring, (see 3.1.3). In table 3 the author’s reports of pain are presented in full.

3.1.2 Range of motion

The aspects or grades of ROM reported in the literature differed greatly in presentation and as tool of assessment of functional outcome. Studying the presented ROM in the reviewed literature, no or only tentative conclusions can be derived from how the method of stabilization or complexity of the fracture can have an effect on the postoperative active ROM, from almost full recovery (26) to barely active shoulder level forward flexion (22). However, earlier conducted literature reviews, concluded that a good functional outcome could be regarded as an active abduction and elevation of 90°, external rotation of 25° and posterior internal rotation good enough to touch the L1 vertebra (5, 37). ROM is also included as a variable in methods of functional scoring, (see 3.1.3). In table 3 the author’s reports of range of motion are presented in full.

3.1.3 Methods of functional scoring

Different shoulder outcome instruments reported in the reviewed publications do not reflect health-related quality of life well and correlate poorly with each other (23, 49). As a consequence, results from different outcome instruments can not be compared and are of little practical value. Below, the most commonly used functional outcome assessment methods in the reviewed literature are briefly presented. The literature does inadequately report however the outcome instruments are tested for reliability or validity.

The Constant Shoulder Assessment (CSA) [in the literature commonly abbreviated Constant Score (CS)] (50) is the most widely used shoulder questionnaire in Europe (49). The score is rated as 0 (severe disability) to 100 (no disability) and has two subjective components, pain (25 points) and activities of daily living (ADL) (20 points), and two
objective components, Range of motion (ROM) (40 points) and strength (25 points). Range of motion is measured with a goniometer and strength with a commercial digital spring balance (1, 10, 13, 14, 16-22, 24-26, 28-30, 32-35).

The American Shoulder and Elbow Surgeons (ASES) evaluation form (27, 49) is composed of a visual analogue scale (VAS) for pain, and a function score based on a 12-item questionnaire concerning activities of daily living graded according to difficulty. Ten activities of daily living are assessed on a four point ordinal scale (0-3) grading the ease with which they can perform the activity. Range: 0 (severe disability) and 30 (no disability) (15, 23, 24, 27, 31, 32).

Grading results according to Neer (6) adjusted by Cofield (51) is a grading system for evaluation of results with a maximum score of 100 units divided in four categories; pain, function, range of motion and anatomy. Every category is graded by the assessor and the results is summoned to Excellent >89 units: when the patient with no or mild pain actively elevated the shoulder >130° and actively rotates externally 45°. Satisfactory >80 units, when the patient with persistent moderate pain actively elevates 90-130° and actively rotates externally 20-45°. Unsatisfactory >70 units is anything that will not fit the above categories, and Failure < 70 units (21, 30).

The simple shoulder test (TSS) (49) is a standardized shoulder-specific self-assessment tool, a quick, subjective questionnaire composed of 12 questions with yes or no response options, range: 0 (no disability) and 12 (severe disability) the questions were derived from common presenting complains of patients with shoulder symptoms (23, 27)

The Disability of Arm, Shoulder and Hand (DASH) questionnaire (52) consists of 30 questions about symptoms and function of the upper limbs that are affected by orthopaedic or neurologic disorders. It provides a single main score, the DASH function score, which is a summation of the responses on a scale 1-5 with 0 (no disability) to 100 (severe disability). The questionnaire tests the degree of difficulty in performing a variety of physical activities because of arm, shoulder or hand problems (21 items). They also investigate the severity of pain, active-related pain, tingling, weakness and stiffness (5 items), as well as the effect of the upper limb problem on social activities, work, sleep and self-image (4 items) (15, 23, 32).

The Oxford Shoulder Questionnaire (OSQ) (53) is a purely subjective, site specific tool that contains 12 items/questions. The OCQ provides a single score, which is a sum of the responses on a scale of 1-5, scored 12 (attributes the best outcome with no disability) to 60 (attributes to the worst outcome with severe disability) (10, 23).
The Western Ontario Rotator Cuff Index (54) is a self-report questionnaire that is designed to measure health-related quality of life in patients with conditions of the rotator cuff, it includes 21 questions in 5 domains: pain and physical function, sports and recreation, work, lifestyle and emotions. The respondent answers on a visual analogue scale ranging from “no pain/difficulty” to “extreme pain/difficulty”, a higher score correlating to higher degree of difficulty (31).

3.2 Physiotherapeutic interventions or rehabilitation after surgery

The post-operative physiotherapeutic intervention was sparsely discussed in the reviewed literature. Although almost all studied publications stated that rehabilitation was an important part of functional outcome, post-operative rehabilitation or regimen or programmes was not discussed as a confounding factor as, for an example, age, gender, severity of the fracture or method of stabilization.

A large number of articles and publications regarding the classification and different operative techniques could be found with Neer as precursor (6, 8), but concerning the physiotherapeutic intervention and rehabilitation following the surgically stabilized proximal humeral fracture, publications were scarce (2, 5, 14, 21, 40). This gave few, if any, evidence based recommendations, and the literature on the subject seemed to give little recommendations concerning the post-operative regimen or guidelines for rehabilitation.

The arm was usually immobilized in a sling for a mean time of 2 weeks (0-8) (10, 14, 18 – 22, 27-29, 33, 34) and immediate active movements for the elbow and hand was usually advocated followed by passive pendulum movements for the shoulder (1, 10, 13, 15-20, 23-30, 33, 34). There seemed to be little consensus to what movements to be called “active assisted” and “active”, with no regards or discussion of the effect the different movements had to the shoulder joint and the torque of the rotator cuff, and when the movements were to be initiated (0-12 weeks). However, there seemed to be a common concern that the tuberosities should be radiologically healed before weighted exercises should be initiated, at the earliest 9 weeks after surgery (1, 13, 16, 19, 23, 27, 30). This regimen was to some extent accordant with, the earlier presented, regimen by Neer (6, 8), and this was also the most cited recommendation in the literature (10, 13, 23, 27, 28, 30, 34).

The studies varied between 7-0 according to the PEDro scale; two with score 7, two with score 6, one with score 5, four with score 4, four with score three, eleven with score 2 and one with score zero. According to the level of evidence by SBU, no study was considered high level of evidence (Table 3). None of the reviewed studies gave sufficient evidence that any of
the presented physiotherapeutic or rehabilitation treatment options can be recommended to be used in clinic.

3.3 Post-operative physiotherapeutic interventions or rehabilitation according to fracture classification or method of osteosynthesis

In the literature studied, only some consistency could be found regarding the guiding principle of choosing method of osteosynthesis according to classification of fracture, with Neer (6, 8) as persecutor. Neers study argues for restoration of the humeral head in minimally displaced fractures where avascularity of the humeral head was not risked, and for younger patients with less risk of osteoporotic bone. Hemiarthroplasty were recommended for displaced 3- and 4-part fractures and for elderly patients with greater risk of osteoporotic bone. This is a guiding principle often referred to in the literature. However, as presented above, the post-operative physiotherapeutic interventions or rehabilitation regimen was much sparsely discussed and the question whether the regimen should be different according to method of osteosynthesis or fracture classification remained unanswered related to the inconsistency and lack of conclusions.

3.4 Is he Axelina rehabilitation regimen corresponding to the regimen presented in the literature?

The postoperative regimen was sparse commented upon in the reviewed literature and there seemed to be no consensus or recommended rehabilitation regimen other than presented in Neer as early as 1970 (8), which was presented above. So, studying the Axelina rehabilitation regimen, the postoperative program commonly used in the orthopaedic department and the physiotherapeutic department at Uppsala University hospital. It is clear that the Axelina rehabilitation programme, which provides both surgeon and physiotherapist with tools and follow up methods to enhance the postoperative regimen and outcome of functional results, has no evidence base. Since the rehabilitation programme is presented in a consecutive series divided in subsequent phases, any therapist who has taken the introduction course in the Axelina rehabilitation programme can continue, proceed and evaluate the patient’s results and functional outcome. This minimizes risks and errors of misconceptions during the period of rehabilitation when the patient often translates through the line of care from the surgical award to the primary care centre. Comparing the Axelina rehabilitation regimen to Neers’, it is clear that the Axelina regimen is more progressive, advocating active assisted exercises from the first post-operative day compared to Neers’ passive pendulum exercises. However, the Axelina rehabilitation regimen is not presented or referred to in the
studied literature, and only one author in the review presented a regimen similar to Axelinas’
(15) unfortunately a study with limited level of scientific evidence and a PEDro score of 3,
which makes any further conclusions drawn from the result of this study risky and
unscientific. The Axelina rehabilitation regimen and its post-operative exercise program are
developed as a consensus of experienced physiotherapists and surgeons. Although, through
this review, it was not possible to further compare or connect the Axelina rehabilitation
regimen to the literature concerning functional outcome.

4. DISCUSSION

4.1 Summery of results

Proximal humeral fractures represent an increasing challenge to the health care system,
partly because of the increasing proportion of elderly individuals in the population, a
proportion that some predict will triple by the year 2030 (3, 17). The majority of patients with
this kind of fracture are more than 65 years of age, and the great majority of PHFs is due to
osteoporosis. The ideal treatment of displaced PHFs remains controversial and is a subject of
much debate in the literature. Reported results were contradictory and inconsistent, and
current studies typically lacked randomization, comparable resources, and independent
evaluation, with a resultant inability to produce clinical conclusions. Most reported articles on
treatment included small numbers of patients and a short follow up period. The review
consisted of assessed randomized clinical trials (10, 14, 20), controlled clinical studies (1, 13,
21, 22, 24, 26, 27, 28, 31) and evaluation and comparative studies (15-19, 23, 25, 29, 30, 32-35)
that because of their inadequate nature contained significant bias. The scientific value and
quality of the literature reviewed was varied, and the results were not presented in a manner
which allowed further statistical calculation to strengthen any evidence by the use of meta-
analysis.

4.2 Discussion of results

There were few randomized controlled trials evaluating treatment and rehabilitation
options for surgically stabilized proximal humeral fractures in adults (10, 14, 20), and none of
the assessed RCTs was performed or presented according to a “golden standard”, resulting in
low PEDro scores and unfulfilled inclusion criteria for high level of evidence assessed by
SBU.
The postoperative management of PHFs is challenging, especially with more complex fractures where there is a significant complication rate irrespective of how they are surgically treated. However, there was lack of data to support one treatment option over another and methods of rehabilitation after prosthetic replacement for proximal humeral fractures remains contentious. Measurement of functional outcome is essential for evaluating any surgical or physiotherapeutic intervention. However, since several scoring systems were used to assess functional outcome and functional impairment in the reviewed articles, it was not possible to compare outcome between different operational techniques or rehabilitation regimens and the treatment of displaced and unstable proximal humeral fractures remains controversial. The preferred operation technique seemed to depend on the nature and choice of the surgeon or team of surgeons, more than on the fracture type, patients’ age, bone quality and functional expectation.

The goal of the surgical treatment was to obtain anatomic fracture reduction and stable primary fixation to ensure rapid fracture healing and immediate postoperative functional therapy without prolonged immobilisation. Negative influences on healing after a PHF, with no regard to method of stabilization were presented in the literature; comminute and displaced fractures, over 75 years of age and woman are of greatest importance it seemed. The factor of the genders negative influence on functional outcome and pain is debatable, and in the literature reviewed it was argued that the cause could be many factors (2-5). Women are more commonly fractured at higher age and by low energy trauma, for example a fall from a standing height, whereas men are more commonly fractured at a younger age and by high energy trauma such as traffic accidents (2-5).

Functional outcome improved for up to six months postoperative, but did not improve significantly more between six and twelve months (5, 17, 20, 36). However, if this improvement in active range of motion and decreasing levels of pain was due to the natural course of healing and progression or due to rehabilitation was unclear when the authors was persistent unwilling to discuss the rehabilitation regimen used in the articles (5, 17, 20, 36). Only Amirfeyz and Sarangi (21) make the connection between indolently to the postoperative regimen and less than optimal functional outcome, but, as the authors emphases, considering the significant risk of bias – the reason for failure of success or satisfacional functional outcome was yet to discover.

Summarizing the information derived from the studies and articles, it must be recognized that there is no strong scientific evidence to support the frequency, dosage, duration, sort or method of the physiotherapeutic intervention or the rehabilitation regime following the
surgically stabilized proximal humeral fracture. The most reported and analyzed data presented in the literature, were objective issues as range of motion and radiographic results, which in some way or another were present in all in the reviewed articles. Recently, quality of life measurements have become more increasingly important in clinical research, but the only authors in the reviewed literature discussing post traumatic health related quality of life were Padua et al (23), thus opening the discussion for subjective results and outcomes more relevant for the patient.

The postoperative regimen or physiotherapeutic intervention or rehabilitation regimen were sparsely mentioned in the reviewed literature, and were not discussed as confounding factors related to functional outcome as were age, fracture classification or the stability of the osteosynthesis. The authors discussed functional outcome seemingly without hesitation or further consideration to the rehabilitation period or content and, as clearly stated above, no conclusions can be derived from such inconclusive material.

Furthermore, few authors (6,40) discussed the need to inform the patient preoperatively concerning the rigorous postoperative rehabilitation. Neer (6) did emphasize the significance of the patient being informed of the protracted course of rehabilitation, and the importance of encouragement and support during the rehabilitation period which could prolong over many months. Compito et al (40) did indeed accentuate that the preoperative examination should contain mental and functional assessments where the patients’ abilities and demands for a functioning life was made clear. This assessments should then determine whether the patient was to be surgically or conservatively treated, thus, the result of a well-performed surgical stabilization followed by improper or inadequate physiotherapy or rehabilitation was in risk to be worse than the end result of conservative treatment. The authors further stated that the postoperative rehabilitation plan is to be conducted by the surgeon in close cooperation with the physiotherapist.

Agorastides et al (10) in what is stated as the only randomized controlled trial available on the subject, did only briefly discuss the actual physiotherapeutic interventions but focused on the time the joint was kept immobilized before the actual intervention started. However, the authors did describe one of the most progressive interventions in the studied literature together with Gradl et al (19). Grönhagen et al (1) could not find statistically significant correlation between fracture classification or length of time with supervised physiotherapy and Constant Score, but they did see significant correlation between rotator cuff integrity and functional results. Martinez et al (16) stated that a cooperative patient was required for a
successful postoperative functional outcome, but did not discuss the physiotherapeutic intervention further.

An interesting area of analysis would be to compare the Axelina rehabilitation regimen with Neers’ with focus on union of the tuberosities and functional outcome, committing to the discussion of early/late mobilization and the stability of the tuberosities. Throughout the review, Machani et al (15) and Gradl et al (19) were the only authors presenting a postoperative rehabilitation regimen reminding of Axelinas’.

Among the few randomized or controlled clinical trials studied, Zyto et al (14) randomized the subjects to different operative or conservative treatment groups with consistency of base line similarity according to fracture type. However, the rehabilitation regime was the same for both groups after initial treatment. The only authors reviewed who separated the postoperative regimen was Agorastides et al (10) who studied if the length of time the operated shoulder was immobilized in a sling (2 vs. 6 weeks) had any effect on the healing of the tuberosities or on the postoperative range of motion. Thus, the postoperative rehabilitation regimen was the same for the two groups.

Neither could the Cochrane review (2) authored by Helen Handoll give a concise answer to the question if the fracture classification or the operative treatment should define the rehabilitation regimen, but stated that this must be carefully considered by the responsible surgeon.

There was no consensus to be found in the studied literature concerning the research questions which have guided this paper. However, there was a common conception that hemiarthroplasty as treatment for the severely fractured proximal humeral fracture resulted in a pain free shoulder with almost shoulder level function (22, 23, 26, 27, 29, 33, 41). Zyto et al (22) did advocate that the traumatized shoulder will improve in both movement and pain if they undergo surgical treatment, but they also discussed the problems of classification systems and tools to define which patients to undergo operation, operation modality and who to treat conservatively. Movin et al (25), on the other hand, concluded that treatment of severely displaced proximal humeral fractures with a prosthesis did not give total pain relief and results in a impaired shoulder function. Neither did they see any significant difference between late (after 3 weeks) and early (within 3 weeks) surgery as a contrast to Mighell et al (27).

Robinson et al (28) and Amirfeyz & Sarangi (21, 28) asserted that the patient’s age seemed to be the single most important factor for functional outcome after surgery. The influence of age on the outcome was likely to reflect on many factors that adversely affect
outcome; including degenerative change in the rotator cuff, osteoporosis, and the lack of motivation to achieve a range of motion beyond the limited functional needs of an elderly patient. On the contrary, neither Mighell et al (27) or Fallatah et al (31) found any correlation between age, fracture pattern, presence of nerve injury or type of implant.

However, Mighell et al did find correlation between time from trauma to surgery and quality of anatomical reconstruction. Furthermore, the authors correlated absence or presence of pain, as deliverance for patient satisfaction – not restored functional movement. Fallatah et al (31) on the other hand, found no such correlations and stated that the only factor to influence functional outcome was the status of the rotator cuff. Krause et al (29) among others, Agorastides et al (10), Amirfeyz & Sarangi (21), Boileau et al (30) and Kralinger et al (33) firmly stated that the single most important factor for postoperative success was the stability of the tuberosities. The position of the tuberosities defined both the position of the hemiarthroplastical head in the joint, as well as the function of the rotator cuff, thus influencing both the position of the lever arm in the joint as well as the function and capacity of the muscles performing the activity in the joint, resulting in a week, stiff and painful shoulder.

Amirfeyz & Sarangi (21) and Agorastides et al (10), whom both studied a prolonged postoperative immobilization period, both found statistically significant results that a prolonged immobilization period resulted in a higher percentage of healed tuberosities but no difference in follow-up functional outcome. And then again, on the contrary, other authors, like Bufquin et al (32), found no such statistically significant trends related to the stability of the tuberosities and concludes that time of immobilization was of little significance for functional outcome. Finally, Boileau et al (30) contributed to the discussion by advocating for a slowing rehabilitation coarse for patients over 75 years of age, taking into calculation the degree of osteophenia, in itself a severely disadvantaging prospect concerning the negative influence osteophenia has on the bones ability to heal.

4.3 Discussion of method

The search for literature was conducted though three databases which were a strengthening factor for this paper. In the MedLine database, the search engine PubMed’s suggestions for probable Medical Subject Headings, MESH terms, were used to include all relevant articles and publication on the subject. In the PEDro and Cochrane databases this was not applicable and so key words and search terms was differently combined to get such a wide search as possible. The searches for this review were thoroughly conducted but can not be considered comprehensive because only publications in English were studied, and this might
be expected to weaken the results. Perhaps further publications now excluded on language basis could have shredded a little more light on conclusion. Furthermore, a limit in year of publication was added only to include articles published from 1990. This limit was based on the plausible conclusion that medical research and scientific forthcomings makes results from those publications out of date. It is noted in the reviewed literature that many later publications refer to elder publications, published before 1990 and this could have acted as a weakening factor to this review. Further exclusion criteria were publications concerning biomechanical experiments on human cadaver as well as letters to editors, which was not considered to further enlighten the aim and research questions of this paper.

Furthermore, using the PEDro and the SBU’s GRADE system in the assessment and evaluation process of the literature reviewed was both necessary and frustrating. Neither of the grading and assessment systems were originally developed for studies not designed as RCTs which maked the results and evaluation process sometimes difficult to assess when the great majority of the studies reviewed did not qualify as RTCs.

4.4 Conclusion

Proximal humeral fractures are the third most common fracture in the elderly population and are considered to give poor post-operative functional outcome. The area of research and scientific evaluation of treatment modalities were disappointingly inconclusive and of inadequate level of evidence. The management of displaced proximal humeral fractures is challenging and often reflects the personal experience of the physician or therapist treating the injury. Treatment opinions in the reviewed literature included external fixation, open reduction and internal fixation, and hemiarthroplasty. However, each method of stabilization is associated with a high risk of complications, and a fully functioning joint is rarely the outcome after traumatic proximal humeral fractures. Thus, the post-operative functional outcome seemed to be dependent on the proper evaluation and classification of the fracture, surgical technique and skill, followed by a clearly advocated postoperative regimen and a motivated patient prepared for a long rehabilitation period. According to the post-operative rehabilitation procedure, only preliminary conclusions could be drawn from the reviewed literature which did not focus on, emphasize or explore the physiotherapeutic interventions at any length. Further high quality trials which also emphasize and assess the physiotherapeutic treatment and post-operative rehabilitation of the surgically stabilized proximal humeral fracture are required if we are eventually to improve the patient’s health.
Referenser


<table>
<thead>
<tr>
<th>Article</th>
<th>Study design and subject</th>
<th>Number of participants</th>
<th>Pain</th>
<th>ROM range of motion</th>
<th>PT intervention</th>
<th>Authors conclusion</th>
<th>Measurement method, functional outcome</th>
<th>PEDro Scale /10</th>
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<tbody>
<tr>
<td>Agorastides -07(10)</td>
<td>RCT Early vs. late mobilization after hemiarthroplasty Single blind</td>
<td>59, 17% drop out = 49: 26 early 23 late Mean follow up time 12 months</td>
<td>70 (34-85) 39/10</td>
<td>Pain Reported as sub group in Constant Score</td>
<td>Early mob. group: Elev: 80° ER: 14° IR: L4 Late mob. group: Elev: 78° ER: 18° IR: L4</td>
<td>2 weeks resp. 6 weeks imob. in sling. According to Neer: Pendulum and elbow exc. After 3-6 (7-12) weeks AA exc. After 6 (13) weeks A exc. Free ROM.</td>
<td>Late mobilization is equally safe as early mobilization considering functional outcome and pain. Early mob significantly greater risk of loose tuberosities.</td>
<td>Constant Shoulder Assessment (CS) components; Pain ROM Power ADL mean Constant Score: Early: 47, late:40</td>
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<tr>
<td>Zyto, Ahrengart -97 (14)</td>
<td>RCT Conservative treatment vs. Tension-band osteosynthesis Blindness not reported</td>
<td>40, 5% drop out = 38: 19 conservative 19 tension-band Mean follow up time 12 months</td>
<td>74 (no span) 35/5</td>
<td>Pain reported as sub group in Constant Score</td>
<td>Not reported in ROM, only reported as sub group in Constant Score</td>
<td>Not described: “the injured arm was supported in sling for 7-10days, followed by physiotherapy according to standard regimen”</td>
<td>Similar functional outcome, more complications in surgically stabilized group</td>
<td>Mean CS: Conservative: 65 Surgery: 60</td>
</tr>
<tr>
<td>Fialka -08 (20)</td>
<td>RCT EPOCA vs. HAS prosthesis Blindness not reported</td>
<td>40, 12% drop out = 35: 18 EPOCA 17HAS Mean follow up time 12 months</td>
<td>74 (58-88) 28/7</td>
<td>Not reported</td>
<td>EPOCA: Flex: 105° abd: 108° ER: 30° HAS: Flex: 62° abd: 62° ER: 17°</td>
<td>2 weeks imob. in sling. Passive exc by PT 15min /day. After 2weeks A exc to horizontal level. After 4weeks A ER. Same protocol for both groups</td>
<td>Prosthetic design, with emphasis on stability of tuberosities, significant for functional outcome.</td>
<td>Constant Score Mean CS: EPOCA: 52 HAS:33</td>
</tr>
</tbody>
</table>

Table 3. Functional impairments, physiotherapeutic interventions and authors conclusion in the reviewed literature.
<table>
<thead>
<tr>
<th>Article</th>
<th>Study design and subject</th>
<th>Number of participants</th>
<th>Age (span)</th>
<th>Gender: w/m</th>
<th>Pain</th>
<th>ROM range of motion</th>
<th>PT intervention</th>
<th>Authors conclusion</th>
<th>Measurement method, functional outcome</th>
<th>PEDro Scale</th>
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</thead>
<tbody>
<tr>
<td>Gradl -09 (19)</td>
<td>Evaluative and comparative study Locking nailing vs. Locking plate fixation for PHFs</td>
<td>169 10% drop out = 152; 76 matched pairs</td>
<td>Mean follow up time 12 months</td>
<td>63 (47-81) 104/48</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Immobilization 2weeks. AA exc. free ROM After radiologically stable tuberosities (earliest 6weeks) weighted exc.</td>
<td>No difference in functional outcome considering method of osteosynthesis. Difference in functional outcome considering severity of fracture.</td>
<td>Constant Score Mean CS: Locking nail: 81 Locking Plate: 77</td>
<td>10</td>
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<tr>
<td>Amirfeyz -08 (21)</td>
<td>Clinical Trial Hemiarthroplasty with conservative rehabilitation regimen</td>
<td>40 2.5% drop out = 39 55months (12-95)</td>
<td>Mean follow up time 39 months</td>
<td>68 (39-92) 29/10</td>
<td>Not reported individually</td>
<td>Flex: 132° ER: 40.4°</td>
<td>Immobilization 4 weeks. Limited elbow exc. no pendulum exc. After 5-10 weeks passive and AA exc. After 11 weeks A exc.</td>
<td>Good functional outcome after Hemiarthroplasty. Prolonged immobilization period could reduce rate of tuberosity failure.</td>
<td>Constant Score Mean CS 73</td>
<td>5</td>
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<tr>
<td>Zyto, Wallace -98 (22)</td>
<td>Clinical Trial Hemiarthroplasty for 3- and 4 part fractures</td>
<td>37 28% drop out = 27 55months (12-95)</td>
<td>Mean follow up time 39 months</td>
<td>71 (48-91) 15/12</td>
<td>Reported as sub group in Constant Score: None: 30% Mild: 37% Moderate: 26% Severe: 7%</td>
<td>Flex: 70° Abd: 65° IR: 45° ER: 40°</td>
<td>Not described “the arm was the immobilized for approximately 3weeks”</td>
<td>No significant difference according to fracture classification. Worse functional outcome compared to other studies.</td>
<td>Constant Score Mean CS: 3-part: 51 4-part: 46</td>
<td>4</td>
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<tr>
<td>Padua -08 (23)</td>
<td>Comparative and evaluative study: Health-related quality of life and subjective outcomes after Hemiarthroplasty</td>
<td>21 5% drop-out = 20 Mean follow up time 39-41 months (2-4yrs)</td>
<td>Mean follow up time 39-41 months (2-4yrs)</td>
<td>70 (57-82) 18/3</td>
<td>Reported as sub group in SF-36 DASH OSQ ASES SST</td>
<td>Elev: 113° Abd: 88° ER: 46° IR: L2</td>
<td>According to Neer: Immediate p exc. (pendulum) After 3weeks aa exc. After 9weeks A exc. After 12w weighted exc.</td>
<td>Shoulder replacement after trauma has little impact on quality of life 12 months post-operatively.</td>
<td>Mean SF-36: 57 Mean DASH: 39 Mean OSQ:28 Mean ASES: 74 Mean SST: 7</td>
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<tr>
<td>Article</td>
<td>Study design and subject</td>
<td>Number of participants drop out percentage</td>
<td>Mean follow up time</td>
<td>Age (span) Gender: w/m</td>
<td>Pain</td>
<td>ROM range of motion</td>
<td>PT intervention</td>
<td>Authors conclusion</td>
<td>Measurement method, functional outcome</td>
<td>PEDro Scale /10</td>
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<td>Sosna -08 (35)</td>
<td>Comparative study New technique for fixation of tuberosities after Hemiarthroplasty</td>
<td>76 (no drop out)</td>
<td>Acute:</td>
<td>57 (32-78) 27/16</td>
<td></td>
<td>Reported as sub group in Constant Score</td>
<td>Not described: “all patients, regardless of age, received daily physiotherapy”.</td>
<td>Stable fixation of tuberosities gives significant better functional outcome. Early operation gives significant better functional outcome.</td>
<td>Constant Score Mean CS: Acute: 75.5 Late: 53.5</td>
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<td>Late:</td>
<td>58 (39-75) 20/13</td>
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<td>Reported as sub group in Constant Score</td>
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<td>Mean follow up time</td>
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<tr>
<td>Thalhammer -07 (18)</td>
<td>Evaluative and Comparative study Angular stable fixation plates</td>
<td>48 13% drop out = 42</td>
<td>58 (32-90) 26/16</td>
<td>Reported as sub group in Constant Score</td>
<td>Reported as sub group in Constant Score</td>
<td>Shoulder bandage for 2 weeks. Immediate passive exc. After 2-4 weeks A exc, depending on quality of bone stock.</td>
<td>No significance, but trends towards worse functional outcome for severely displaced fractures. Also trend towards worse outcome according to age.</td>
<td>Constant Score Mean CS: 74</td>
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<tr>
<td>Grönhagen -07 (1)</td>
<td>Clinical Trial Hemiarthroplasty for 2,3 and 4- part fractures</td>
<td>82 44% drop out =46</td>
<td>72 (49-91) 65/17</td>
<td>Reported as sub group in Constant Score: None 24% Mild 61% Moderate 15% Severe 0%</td>
<td>Not reported in ROM, only reported as sub group in Constant Score</td>
<td>Passive exc from first day. After wound healing water therapy. After 6 weeks A exc. After 10 weeks weighted exc.</td>
<td>Hemiarthroplasty gives adequate pain relief but restricted ROM and strength. Poor function related to poor rotator cuff integrity. Proper patient selection important for good results.</td>
<td>Constant Score Mean CS: 42</td>
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<td>Article</td>
<td>Study design and subject</td>
<td>Number of participants drop out percentage</td>
<td>Mean follow up time</td>
<td>Age (span) Gender: w/m</td>
<td>Pain</td>
<td>ROM range of motion</td>
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<td>Bufquin -07 (32)</td>
<td>Evaluative study Reverse shoulder arthroplasty for 3- &amp; 4-part fractures in the elderly</td>
<td>43 5% drop out = 41</td>
<td>78 (65-97) 41/2</td>
<td>Elev: 97° Abd: 86° ER: 8°</td>
<td>Reported as sub group in CS: Mean 12.5 points of 15 = “moderate”</td>
<td>Not reported “active but gentle physiotherapy for 7 months”</td>
<td>Reversed shoulder replacement provides excellent pain relief and easier functional recovery compared to Hemiarthroplasty in patients over 75.</td>
<td>Constant Score Mean CS: 44 ASES scores: 9 DASH score: 44</td>
<td>3</td>
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<tr>
<td>Bastian -09 (34)</td>
<td>Comparative study osteosynthesis (group A) and Hemiarthroplasty (Group B)</td>
<td>100 22% drop out = 76</td>
<td>Group A: 50 (21-88) Group B: 66 (38-87)</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Immediate passive/pendulum exc. Immobilization in sling 6weeks. After 6weeks AA exc. &lt;90° Same for both groups</td>
<td>Both methods of stabilization yield satisfying results for selected patients.</td>
<td>Constant Score Mean CS Group A: 77 Mean CS Group B: 70</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Machani -05 (15)</td>
<td>Evaluative study PlantTan plate for stabilization of displaced PHFs</td>
<td>68 9% drop out = 62</td>
<td>61 (19-76) 42/20</td>
<td>Reported as sub group in ASES scores</td>
<td>Not reported</td>
<td>Instruction of correct resting positioning for comfort. Immediate pendulum, AA + isometric exc. A exc. when well controlled pain. Emphasis on muscle control throughout the ROM.</td>
<td>Equal results in functional outcome compared with other methods of stabilization, significantly more complications and re-operations. The implant was taken out of use.</td>
<td>Mean ASES: 20</td>
<td>3</td>
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<td>Article</td>
<td>Study design and subject</td>
<td>Number of participants drop out percentage Mean follow up time</td>
<td>Age (span) Gender: w/m</td>
<td>Pain range of motion</td>
<td>PT intervention</td>
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<tr>
<td>Reuther -03 (24)</td>
<td>Clinical Trial Multi centre analysis, retrospective Hemiarthroplasty Tuberosity healing</td>
<td>153 Consecutive 33% drop out = 102 Mean follow up time 28 months</td>
<td>71 (61-81) 88/14</td>
<td>Reported as sub group in Constant Score None or only mild pain was reported by 76% of the patients</td>
<td>Not reported in ROM, only reported as sub group in Constant Score</td>
<td>Not described: &quot;Regimen determined by the surgeon, based on estimated stability of the tuberosity fragments&quot;</td>
<td>Significant correlation of stability of tuberosities and functional outcome. Women having a 11-fold risk of complications and non-union.</td>
<td>Constant Score Mean CS: 45 Mean ASES: 16.5</td>
<td>2</td>
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<tr>
<td>Movin -98 (25)</td>
<td>Evaluative study Hemiarthroplasty after acute and late surgery (after 3 weeks)</td>
<td>45 36% drop out = 29 Mean follow up time 3 years</td>
<td>71 (47-87) 24/5</td>
<td>Pain reported both as CS score and assessed with VAS separately. 21mm at rest and 47mm at motion</td>
<td>Flex 55°</td>
<td>Daily passive and AA exc for 6weeks, followed by PC PT. After 6weeks A exc.</td>
<td>No significant difference in functional outcome between late and early surgery.</td>
<td>Constant Score Mean CS: 38</td>
<td>2</td>
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<tr>
<td>Kontakis -09 (26)</td>
<td>Clinical Trial Outcome after Hemiarthroplasty with the Aequalis fracture prosthesis</td>
<td>33 12% drop out = 28 Mean follow up time 39 months</td>
<td>66 (38-80) 23/5</td>
<td>Reported as sub group in Constant Score None: 67% Mild: 25% Moderate: 7% Severe: 0%</td>
<td>Elev: 170° Abd: 144° ER: 26°</td>
<td>Pendulum and daily passive exc. initiated first postoperative day and was continued for 6weeks. After 6weeks A exc.</td>
<td>Lack of control group makes comparison to other methods of stabilization hazardous.</td>
<td>Constant Score Mean CS: 68.2</td>
<td>2</td>
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<tr>
<td>Mighell -03 (27)</td>
<td>Clinical Trial Outcome after Hemiarthroplasty</td>
<td>71 8% drop out = 66 Mean follow up time 36 months</td>
<td>66 (39-89) 54/17</td>
<td>Reported as sub group in ASES score</td>
<td>Flex: 128° ER: 43° IR: L2</td>
<td>A elbow and hand exc. Immediate passive exc. Immobilizer 3weeks. After 3weeks AA exc. After 9weeks A elev. After 12weeks weighted exc.</td>
<td>Fracture pattern, type of implant, presence of neurological injury, and patients’ sex and age do not affect functional outcome to the extent timing of surgery and quality of tuberosity reconstruction do.</td>
<td>Mean ASES: 77 Mean SST 7.5</td>
<td>2</td>
<td></td>
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<tr>
<td>Article</td>
<td>Study design and subject</td>
<td>Number of participants</td>
<td>Age (span) Gender:</td>
<td>Pain</td>
<td>ROM range of motion</td>
<td>PT intervention</td>
<td>Authors conclusion</td>
<td>Measurement method, functional outcome</td>
<td>PEDro Scale /10</td>
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<tr>
<td>Robinson -03 (28)</td>
<td>Clinical Trial Retrospective evaluation of patients with Hemiarthroplasty</td>
<td>163 consecutive</td>
<td>68 (32-90) 96/42</td>
<td>Reported as sub group in Constant Score</td>
<td>Reported as sub group in Constant Score</td>
<td>Immediate passive exc. &lt;90° flex. Immobilizer 3weeks. After 2weeks AA exc. After 6weeks isometric exc. and A exc. PT supervised rehab. for a mean time of 6 months.</td>
<td>Age significantly corresponding to poor functional outcome. A pain free but stiff joint is to be expected after stabilization with Hemiarthroplasty.</td>
<td>Constant Score Mean CS: 64</td>
<td>2</td>
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<tr>
<td>Krause -07 (29)</td>
<td>Comparative study: Reattachment of the tuberosities with two different suture techniques after Hemiarthroplasty</td>
<td>82</td>
<td>64 (26-90) 30/28</td>
<td>Reported as sub group in Constant Score</td>
<td>Reported as sub group in Constant Score</td>
<td>Im mobilizer 3weeks. From first day post op. AA exc., free ROM After 6 weeks A exc. Same routine for both groups</td>
<td>Significant difference in functional outcome between methods of tuberosity stabilization.</td>
<td>Constant Score Mean CS: Group 1: 51 Group 2: 37</td>
<td>2</td>
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<tr>
<td>Martinez -09 (16)</td>
<td>Comparative study: PHILOS plate fixation of 3-and 4-part fractures</td>
<td>58 drop out not noted</td>
<td>61 (36-73) 27/31</td>
<td>Reported as sub group in Constant Score</td>
<td>Reported as sub group in Constant Score</td>
<td>Immediate passive exc. After 6weeks A exc. Weighted exc. when union was ensured (no time)</td>
<td>No significance, but trends towards worse functional outcome and age. Also trend towards better functional outcome and lesser fracture.</td>
<td>Constant Score Mean CS: 80</td>
<td>2</td>
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<tr>
<td>Article</td>
<td>Study design and subject</td>
<td>Number of participants drop out percentage Mean follow up time</td>
<td>Age (span) Gender: w/m</td>
<td>Pain</td>
<td>ROM range of motion</td>
<td>PT intervention</td>
<td>Authors conclusion</td>
<td>Measurement method, functional outcome</td>
<td>PEDro Scale /10</td>
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<tr>
<td>Dimakopoul os -07 (13)</td>
<td>Clinical Trial Transosseous suture fixation of PHFs</td>
<td>188 11% drop out = 165 Mean follow up time 5.4 yrs (3-11 yrs)</td>
<td>54 (18-75) 94/71</td>
<td>Reported as sub group in Constant Score</td>
<td>Elev: 167° ER: 75° IR: T10</td>
<td>Immediate passive pendulum exc. After 3-4 weeks AA exc. After 5-10 weeks A + weighted exc. for 6months</td>
<td>Careful patient selection and adherence to defined indications are important for success of therapeutic regimen. Completion to the full rehabilitation program is integral to obtaining optimum outcome.</td>
<td>Not described individually; Constant Score Mean CS: 91</td>
<td>2</td>
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<tr>
<td>Boileau -02 (30)</td>
<td>Evaluative study Tuberosity malposition and migration: reasons for poor outcomes after Hemiarthroplasty</td>
<td>73 10% drop out = 66 27 months (18-59)</td>
<td>66 (31-85) 45/21</td>
<td>None; 30% Mild: 58% Moderate: 11% Severe: 1%</td>
<td>Elev: 101° ER: 17.5° IR: L3</td>
<td>According to Neer: Immediate p exc. (pendulum) After 3 weeks AA exc. After 9 weeks A exc. after 12 weeks weighted exc.</td>
<td>Resting position of arm important for decrease horizontal plane forces on the greater tuberosity osteosynthesis from the supraspinatus and teres minor muscles.</td>
<td>Constant Score Mean CS: 56</td>
<td>2</td>
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<tr>
<td>Fallatah -07 (31)</td>
<td>Clinical Trial Functional outcome after PHFs treated with Hemiarthroplasty</td>
<td>56 20% drop out = 45 Mean follow up time 48 months (24-123)</td>
<td>63 (52-74) 33/12</td>
<td>None or Mild: 64% Moderate: 21% Severe 15%</td>
<td>Elev: 87° Abd: 63° ER: 22° IR: L1</td>
<td>Not reported</td>
<td>Experienced surgeons provide better post-operative results. Newer modular designs of prosthetics gives better offset compared with elder designs.</td>
<td>Mean ASES scores: Not reported</td>
<td>2</td>
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<tr>
<td>Südkamp -09 (17)</td>
<td>Evaluative Study Multicenter Locking Proximal Humerus Plate (LPHP/ PHILOS)</td>
<td>187 17% drop out = 155 Mean follow up time 12 months</td>
<td>63 (49-78)</td>
<td>Not noted after drop out</td>
<td>Flex: 132° Abd: 122° ER: 45° IR: 77°</td>
<td>Immediate passive exc. After 1-3 weeks A exc. &gt;90°</td>
<td>Patient selection important for optimum results. Worse results considering post-operative complications compared to other studies.</td>
<td>Constant Score Mean CS: 71</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Article</td>
<td>Study design and subject</td>
<td>Number of participants</td>
<td>Age (span)</td>
<td>Gender: w/m</td>
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<tr>
<td>Kralinger -04 (33)</td>
<td>Evaluative study Retrospective multicenter study, functional outcome after Hemiarthroplasty</td>
<td>167 Drop out not noted</td>
<td>70 (22-91) 127/40</td>
<td>None: 40% Mild: 39% Moderate: 13% Severe: 8%</td>
<td>Not reported</td>
<td>98% immobilized for 1-10weeks. Passive exc. was initiated on 1-49:th day post.op. A exc. started on 30:th day.</td>
<td>Trends towards experienced surgeon and better results. Functional outcome related to healing of the tuberosities.</td>
<td>Constant Score Mean CS: 55</td>
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</tbody>
</table>

RCT; randomized controlled trial. CT: Controlled trial/Clinical trial. PT; physical therapist. Mob; mobilization. Flex: flexion Abd; abduction. Elev; elevation. ER; external rotation. IR; internal rotation. ADL; activity in daily living. PC; Primary Care. Rehab; rehabilitation. CSA; Constant shoulder assessment. ASES: American Shoulder and Elbow Surgeons Assessment scale. SF-36: Medical Outcomes Study Short Form 36 Health Survey. DASH: Disability of Arm, Shoulder and Hand questionnaire. OSQ: Oxford Shoulder Questionnaire. SST: Simple Shoulder Test. WORC: Western Ontario Rotator Cuff Index
## PEDro scale

<p>| | | | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>eligibility criteria were specified</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>2.</td>
<td>subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>3.</td>
<td>allocation was concealed</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>4.</td>
<td>the groups were similar at baseline regarding the most important prognostic indicators</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
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<tr>
<td>5.</td>
<td>there was blinding of all subjects</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>6.</td>
<td>there was blinding of all therapists who administered the therapy</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>7.</td>
<td>there was blinding of all assessors who measured at least one key outcome</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>8.</td>
<td>measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>9.</td>
<td>all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by “intention to treat”</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>10.</td>
<td>the results of between-group statistical comparisons are reported for at least one key outcome</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
</tr>
<tr>
<td>11.</td>
<td>the study provides both point measures and measures of variability for at least one key outcome</td>
<td>no</td>
<td>yes</td>
<td>where:</td>
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</tbody>
</table>

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP et al. 1998), *The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus*. *Journal of Clinical Epidemiology*, 51(12):1235-41. The list is based on “expert consensus” note, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to “weight” scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (i.e., RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or “generalisability” or “applicability” of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the “validity” of a study’s conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the “quality” of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999