Outcome following reverse shoulder arthroplasty for acute proximal humerus fractures with different humerus inklination angels versus non-surgical treatment

Background:

The optimal treatment of proximal humerus fracture (PHF) Neer type III and IV AO B2 and C2 is controversial. National clinic guidelines for Denmark are official since 2015 and updated 2019. They recommend conservative treatment to all kinds of PHF for patients aged above 60 years. Exceptions are dislocations, headsplits or surgical conditions, were intervention is mandatory like perforations, nerv- or circulationproblems.

Recently reverse shoulder arthroplasthy (RSA) has gained expanding popularity in treating PHF[[1]](#endnote-1). Compared with osteosynthesis (ORIF) or hemiarthroplathy (HA) outcomes were superior[[2]](#endnote-2),[[3]](#endnote-3). The impotence of tuberosity healing for good functional outcomes has lead to development of different implants and fixation techniques. The original RSA design by Gramont with 155 degree was for cuffarthropathy and distalisese the humeral head with further tension on the tuberosities. In contrast “anatomical” designed humeral implants 135 degree enables anatomical refixation of the tuberosities without tension and might avoid resorbtion or displacement of these fracutureparts. Usually in PHF the rotator cuff (RA) is intakt. To implant a 155 degree RSA the surgeon has to remove parts of the rotator cuff, in 135 degree a cuff sparing technique is possible.

The aim of the study is to compare outcomes of different designed RSA versus conservative treatment of PHF Neer type III or IV / AO B2, C2.

Methods and Material

Patients, who meet the inclusion parameters, will be blok-randomimized to one of the three groups. 30 patients in each group will be treated surgical or non-surgical and follow a standardized rehabilitation in public health-system.

Follow-up will be at 3,12,24 month by Western Ontario Osteoarthritis score (WOOS)[[4]](#endnote-4), Constant Murley (CS)[[5]](#endnote-5) and Subjective shoulder Volume (SSV)[[6]](#endnote-6). X-rays will be valuated independently by to researchers to state union/ non-union/ pseudarthosis in the non-surgical group and TH as healed, displaced over 5 mm or resorbed. Complication and revisions will be noticed.

Sample size and Randomization

30 participant in each group has to be included by block randomization by using STATA 1.6

**CONSORT Flow Diagram**

## Follow-Up

## Analysis

## Allocation

Randomized (n=90)

Excluded (n= )

  Not meeting inclusion criteria (n= )

  Declined to participate (n= )

  Other reasons (n= )

Assessed for eligibility (n= )

## Enrollment

Allocated to 155 (n= )

 operated (n= )

 complications-revisions (n= )

Allocated to non-surgical (n= )

 stay conservative (n= )

 convertet to surgery (give reasons) (n= )

Allocated to 135 (n= )

 operated (n= )

 complications-revisions (n= )

Lost to follow-up (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Lost to follow-up (give reasons) (n= )

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

Analysed (n= )
 Excluded from analysis (give reasons) (n= )

**Analyzes**

The data will be analyzed using multivariate mixed regression to take into account the different measurements at follow-up time points 3,12,24 month after fracture/surgery.

X-rays will be valuated interim independently.

**Patient information**

Patient will be asked verbally and in writing when diagnosed PHF Neer type III / IV AO B2 C2, in the orthopedic outpatient clinic when they get offer treatment either non-surgical or surgical.

**Risks of side effects, disadvantages, injuries**

 The orthopedic department of university southern Denmark, Esbjerg is specialized in shoulderreplacement and cover a population of about 1 million citizens. Three experienced surgeons will perform the procedures at a public hospital. The rehabilitation is standardized and similar in each group.

All participant are covered by the patient-insurance of region southern Denmark.

Sponsors

Non, all treatment-costs are covert by the Danish public health-system without any charge. The authors declare no financially interests of any kind of treatment.

Discussion

PHF is common and non-operative treatment is indicated in all factures Neer type I and II. In type III or IV, in headsplints or fractures with luxations surgical treatment can be necessary. In Denmark national treatment guidelines are published in 2015 and updated in 2019. They recommend conservative treatment for all patients with PHF age over 60, unless headsplint or dislocations accour. Support for non-operative treatment comes by Rasmussen S., Hvass I. 1992[[7]](#endnote-7), they stated, that displaced PHF can be treated satisfactory. A systematic Review of non-operative treatment of PHF by Iyengar J 2011[[8]](#endnote-8) found high rates of radiographic healing, good functional outcomes and modest complicationrates. Rangan A 2015[[9]](#endnote-9) compared surgical vs non-surgical treatment of PHF and found no significant difference. Of 109 operations performed by 66 surgeons in 30 centers, 90 were ORIF, 4 nails, 10 hemiarthroplasthy , 5 others. No fracture classification was used. Recently Soler-Peiro M. 2020[[10]](#endnote-10) reviewed systematically conservative treatment of Neer 3- and 4 part PHF. They found consolidation I most fractures with negligible rate of mal-unions, good functional results with few complications.

The use of a standardized treatment algorithm by [Katthagen JC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Katthagen%20JC%5bAuthor%5d&cauthor=true&cauthor_uid=28421293) 2017[[11]](#endnote-11) looked into failure and revision rates**.** Other studies compareddifferent surgical approaches. Fraser AN, Fjalestad T 2020[[12]](#endnote-12) conducted a multicenter RCT (DelPhi) and found at 2 –years follow-up advantage of RSA over ORIF in displaced OTA/AO type B2 and C2. RSA vs HA for PHF by Ball CM[[13]](#endnote-13) 2017 is based on the shoulderarthroplasty registry of New Zealand and included 218 RSA and 427 HA from 1999 to 2014. The RSA group was older and 90% female, the revision rate was lower for RSA and the functional outcome better at 5 years. Significant difference were not demonstrated. Tokisch JM[[14]](#endnote-14) 2017 retrospectively compared outcomes non-operative N19 vs RSA N20 for 3/4-part PHF with 1 year FU, they found only minimal benefits of RSA over non-operative treatment. Marco F[[15]](#endnote-15) 2019 analyzed in a prospective RCT 30 non-operative vs 29 RSA age 85/ 82 and ound no significant difference between both groups. Retrospective found Argenson JN[[16]](#endnote-16) 2019 in an age-group older than 70 years, RSA vs non-operative for 3 and 4-part PHF significant better results for RSA and Constant-score, the complications rate was higher for RSA. They suggested RSA for higher demand patients. A registry analysis of 5946 patient from Australia by Critchley O 2020[[17]](#endnote-17) RSA vs HA focused on revision rates between 2004 and 2014. 51% RSA vs 49% HA had lower revision rates within 9 years 7,0 vs 11,7%, Younger males (55-64) had more luxations, cemented stems had lower revision rate. The importense of greater tuberosity healing for clinical outcomes is shown by Ohl X., Boileau P 2018[[18]](#endnote-18). They compared outcomes after tuberosity excision, failed fixation or anatomical healing and found that anatomical tuberosity healing in RSA for PHF improves objective and subjective outcomes, excision was associated with worst outcome. Tuberosity healing after reverse shoulderarthroplasty for acute proximal humerus fractures: the ‘‘black and tan’’ technique Levy,J,Rosas S[[19]](#endnote-19), JSES 2015. This technique together with standard suture repair and an implant that support tuberosity healing results in a high healing rates with restoration of external rotation after reverse shoulder arthroplasty for fracture.

Brorson St and Rasmussen J[[20]](#endnote-20) 2013 did one systematic review for RSA in acute PHF. They found the functional outcome not clearly superior to HA, with higher complicationrates for RSA and risk for scapular notching. A Nordic registry-based study of 6756 replacements by Brorson St and Rasmussen 2017[[21]](#endnote-21) looked into revision rates after shoulder replacement for acute PHF. Between 2003 and 2013 90% were HA, 8,4 % RSA. The 5 year survival rate was 0,96 for both, the relative risk for revision 1,4 RSA/HA, higher in the age group less than 75 years. Reasons for revision were mainly infections, instability, periprothetic fractures or loosening.

The influence of humeral head inclination in RSA was reviewed by Romeo A[[22]](#endnote-22) 2015, They found lower rates for scapular notching and dislocation in the 135 degree group. External rotation were significant better in this anatomic group, too. No subgroups for different indications were made. Walch G[[23]](#endnote-23) 2015 found dramatic improvement in adduction, extension and external rotation with varus inclination prostheses. Denard P[[24]](#endnote-24) 2015 found similar results. Uncemented RSA as initial treatment for PHF by Wiater B[[25]](#endnote-25) 2019 showed 97% stable humeral stemfixation and 70% healing of the tuberosities. Good functional results were achieved. Krishnan S[[26]](#endnote-26) 2021 reported on 60 uncemented RSA with excellent ROM and functions-scores, 91% TH, 6,7% revision rate. The study on 135 degree RSA for PHF focused on TH by Gerhardt Ch[[27]](#endnote-27) 2020 with four years FU showed adjusted CS 61, TH 82%, SSV 79 %, revision rate 5%, scapular nothching 3%. Half of the implants were uncemented. They suspected that RSA with humeral inclination of 135 degree allows refixation of the tuberosties in a more anatomic position and therefor might result in decreased stress on the tuberosity repair. A biomechanical study compared stability of the tuberosity fixation in reverse fracture arthroplasty with different humerusinclination angels and found higher stability for 135 degree[[28]](#endnote-28). Cuff DJ 2013[[29]](#endnote-29) compared HA vs RSA for PHF with 135 degree fracture-stem with similar good TH.

Publications of the results

The result will be scientiffically published in a peer-view journal

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