

Outcome following reverse shoulder arthroplasty for acute proximal humerus fractures in patients 60 years of age and older with different humerus inclination implants versus non-surgical treatment- trial protocol: a prospective randomised controlled trial, single blinded.

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Abstract

Introduction:

The optimal treatment of proximal humerus fracture (PHF) Neer type III and IV AO B1.1,1.2 and C1.1,3.1 is controversial. National guidelines for Denmark have been published in 2015 and updated 2019. They recommend conservative treatment to all kinds of PHF for patients aged above 60 years. Exceptions are fracture-dislocations, headsplits or surgical conditions, where intervention is mandatory like open fractures and impaired nerve- and circulation.

Recently reverse shoulder arthroplasty (RSA) has gained expanding popularity in treating PHF¹. Compared with osteosynthesis (ORIF) or hemiarthroplasty (HA) outcomes were superior^{2,3}. The importance of tuberosity healing for good functional outcomes has lead to development of different implants and fixation techniques. The original RSA design by Grammont with 155 degree inclination of the humeral stem was made for cuffarthropathy. This design moves the center of rotation in a medial direction, and increase the tension on the tuberosities.

In contrast “anatomical” designed humeral implants with 135 degree enables more anatomical refixation of the tuberosities with less tension and might reduce the risk of resorption or displacement of the fragments. To implant a 155 degree RSA the surgeon has to remove parts of the rotator cuff, to enable the sliding rotation. On the other hand with a 135 degree inclination humeral component, a cuff sparing technique is possible.

The aim of this study is to compare outcomes of two different designed RSA stems versus conservative treatment of PHF Neer type III or IV / AO B&C.

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Methods:

The study design is a prospective randomized controlled, single blinded for the patients, single unit trial to compare outcomes of displaced proximal humerus fractures treated either non-operative versus reverse shoulder arthroplasty. Subgroups for RSA differs in inclination of the humeral stem (HI) 135 versus 155 degree. The elderly, 60 to 90 years of age includes in this trial. Patients, who meet the inclusion parameters, will be block randomized to one of the two groups. Sixty-four patients will be treated non-surgically (Group A). Thirty-two patients in each group will be treated surgically (Group B & C). All follow a standardized rehabilitation program in the public health-system.

The primary outcome is Western Ontario Osteoarthritis of the Shoulder Index (WOOS)⁴, Minimal Clinical Important Difference (MCID) assumed to be 12.3 points⁵. Secondary outcomes include Constant Murley (CS)⁶ and Subjective shoulder Volume (SSV)⁷. Radiographs will be evaluated independently by two researchers to state union/ non-union/ pseudoarthrosis in the non-surgical group and Tuberosity Healing (TH) as healed, mal-union more than 5 mm or resorbed in the surgical group.

Complication and revisions will be noticed within two years of follow-up.

Serious Adverse Events (SAE)

Luxation

Infections

Fractures

Non-union

Caput-necrosis

are the main reasons for revisions/ secondary interventions.

Adverse Events (AE)

Nerve-injuries

Vascular-injuries

Persistent pain

Participants from non-surgical group, who are treated operatively at a delayed time point (cross-overs) will be noted.

The follow-up timetable:

| Assessment | Time 0 | 2 weeks | 3 mths. | 1 year | 2 years |
|----------------|--------|--------------|---------|--------|---------|
| x-ray | X | X (non-surg) | X | X | X |
| CT | X | | | | |
| Ex-/inclusion | X | | | | |
| Consent | X | | | | |
| WOOS | | | X | X | X |
| Constant | | | X | X | X |
| SSV | | | X | X | X |
| Elevation subj | | | X | X | X |

Ethics and dissemination:

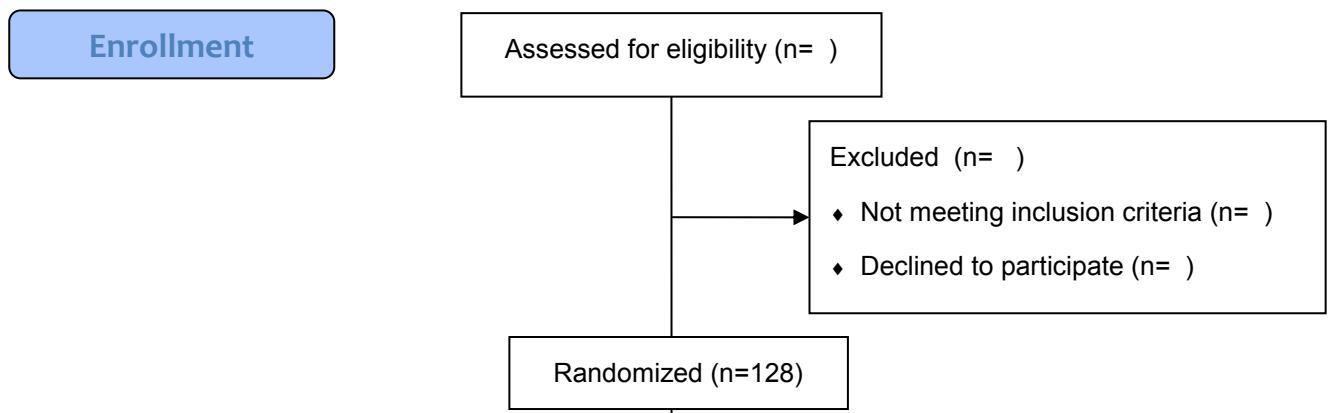
This trial has been approved by the Regional Sientific Committe for Region southern Denmark
01.september 2021 (21/38868). Trial registration number <https://www.isrctn.com/ISRCTN85422168>

The results will be disseminated in an orthopedic publication.

Sample size and Randomization

participants in each group has to be included by block randomization

CONSORT Flow Diagram



| | | |
|---|---|---|
| Allocated to non-surgical (n=64) <ul style="list-style-type: none"> ♦ stay conservative (n=) ♦ converted red to surgery (give) | Allocated to 155 (n= 32) <ul style="list-style-type: none"> ♦ operated (n=) ♦ complications-revisions (n=) | Allocated to 135 (n= 32) <ul style="list-style-type: none"> ♦ 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=) <ul style="list-style-type: none"> ♦ Excluded from analysis (give reasons) (n=) | Analysed (n=) <ul style="list-style-type: none"> ♦ Excluded from analysis (give reasons) (n=) | Analysed (n=) <ul style="list-style-type: none"> ♦ Excluded from analysis (give reasons) (n=) |

Analysis and statistics

The first hypothesis of this trial is that RSA provides better results than non-surgical treatment.

The second hypothesis is that RSA with less degree humeral inclination achieve the better outcome than RSA with high degree. The trial setting has been drafted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statements.

Out of our previous results for fracture cases treated with RSA we determined the standard deviation as 22.9 and calculated with the estimated MCID of 12.3 a sample size of 58 in each group non-operative versus operative. (Confidence Interval (2 sided) 95%, Power 80%).

After randomisation 16 cases per block, eight blocks are needed to include 128 patients. Some drop out or cross-over is expected and thereby taken into account.

Patient information

Patient will be asked verbally and in written form after been diagnosed PHF Neer type III / IV AO B, C, in the orthopedic outpatient clinic. They get offered treatment either non-surgical or surgical.

Patient selection

The eligible study population will comprise all consecutive patients aged 60 years or older with a proximal humerus fracture Neer Type 3&4 operated within 14 days of the trauma or treated non-operative. The lower age limit was chosen according danish national guidelines, recommending conservative treatment to all kinds PHF in this age-group, exceptions made for headsplits and dislocations.

Exclusion criteria:

- Patients younger than 60 or older than 90 years of age
- Neer Type 1&2, Head splits, gleno-humeral dislocations
- pathological fractures
- refuse to participate in the study
- non-compliant, drug/alcohol abuse or institutionalized (Low-cooperative)
- surgical contraindications or surgical condition, where operative treatment is mandatory
- Does not understand written and spoken guidance in local languages.

Randomization

Patients will be randomized using lottery in block allocation fashion in sealed non-transparent envelopes. Four blocks of 16 lots will be used for the three groups (A,A,B,C)

Non-operative treatment

Patients in the non-operative group will be immobilized in a sling for 2 weeks before starting self-exercises and instructed physiotherapy. Postoperative treatment differs with respect to timeline between the surgical treatment group and the non-operative group due to the different degree of stability for a reversed prosthesis and a non-operatively treated displaced fractures. The elements

of physiotherapy will, however, be the same. Subgroups for varus-inclined fractures with more than 20 degrees versus valgus impacted fracture types with more than 30 degrees of angulation will be made.

Surgical treatment

Operative treatment will be performed as a daytime procedure by trained and experienced upper extremity surgeons. The standardised approach will be the delto-pectoral. The Delta Xtent (Depuy Johnson&Johnson) humeral stem, modular HA-coated, 155 degree will be the implant in the second group. Emphasis will be made at the humeral side on cementing and auto-transplanting technique (black-tan)⁸ and refixation of the tuberosities in “Nice-knot” fashion⁹. Parts of the supraspinatus-tendon will be removed. On the glenoid-side glenosphaere-size 42 will be the implant of choice to gain stability.

Univers Revers (Arthrex) will be the implanted for group 3. On the humeral side an uncemented modular stem in 135 degree inclination will be used. In unstable humeral conditions cementing is optional. Fixation of the tuberosities and grafting will be made in similar fashion. The MGS-glenoid will be used with 4 mm lateral offset at the glenoshaere. Tendon-resection will not be necessary, restoring of the gothic arc the goal.

Rehabilitation

In order to achieve as good functional outcomes as possible, the rehabilitation protocols will be standardized in all treatment groups and the patients will be given a written protocol. Patients in all groups will be guided by in-ward physiotherapists and will be given written physiotherapy guidelines for both instructed physiotherapy and self-exercises. After discharge from the hospital, patients will be referred to physiotherapy for further guidance. Patients in the operative group will start exercises from the first postoperative day.

Risks of side effects, disadvantages, injuries

The orthopedic department of university south west Denmark, Esbjerg is specialized in shoulder replacement 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

No sponsors. All treatment-costs are covered by the Danish public health-system without any charge. The authors declare no financial interests of any kind of treatment.

Trial schedule

The recruiting and allocation started in september 2021 and is expected to last three years. Further two years of follow-up are needed; publishing will be earliest late in 2026.

Results

| | Non-operative | Delta Xtent 155 | Univers reverse 135 |
|-------------------------|---------------|-----------------|---------------------|
| N total | 30 | 10 | 12 |
| N female/ median age | 28/72 | 8/70 | 10/73 |
| N male/ median age | 2/75 | 2/83 | 2/70 |
| WOOS 3 month | 55 | 58 | 68 |
| WOOS 12 m | 58 | 77,7 | 80 |
| WOOS 24 m | | | |
| Elevation 3 month | 90 | 86 | 87 |
| Elevation 12 m | 81 | 108 | 120 |
| Elevation 24 m | | | |
| Constant-Murley 3 month | 34 | 36 | 37 |
| CMS 12 m | 38 | 45 | 49 |
| CMS 24 | | | |
| SSV 3 month | 41 | 41 | 56 |
| SSV 12 m | 47 | 64,8 | 82 |
| SSV 24 m | | | |
| satisfied | 11 | 6 | 11 |
| non-satisfied | 10 | 3 | 1 |
| cross-over | 1 | | |
| Tuberculi healed anat. | 5 | 10 | 7 |
| Tuberculi healed displ | 10 | | |
| Tuberculi not healed | 4 | | |
| Complications/ % | | | 1 (infection) |
| Death/ % | | | |

Discussion

PHF is common and non-operative treatment is indicated in most fractures Neer type I and II. In type III or IV, in head splints or fractures with luxations surgical treatment can be necessary. In Denmark national treatment guidelines were published in 2015 and updated in 2019. They stated conservative treatment for all patients with PHF age over 60, unless head splint or dislocations occur. One update review by Handoll H 2022¹⁰ base on one RCT's reported nonoperative versus RSA of the study by Lopiz (19). The review by Lin Ch¹¹ draws a slightly different conclusion: RSA for an acute PHF is indicated in patient who are >65 years of age with 3- and 4-part fracture-dislocation, head-split fractures, and severely displaced fractures, and is an option in patients who are not able to tolerate nonoperative treatment of severely displaced 3- and 4-part fractures.

Support for non-operative treatment comes by Rasmussen S. 1992¹², they stated, that displaced PHF can be treated satisfactorily. A systematic Review of non-operative treatment of PHF by Iyengar J 2011¹³ found high rates of radiographic healing, good functional outcomes and modest complication rates. Robertson T. 2017¹⁴ retrospective reviewed 19 nonoperative, who declined surgery versus 20 RSA and found minimal benefit of RSA. The PROPHER RCT Rangan A 2015¹⁵ 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 hemiarthroplasty, 5 others. No fracture classification was used. Recently Soler-Peiro M. 2020¹⁶ reviewed systematically conservative treatment of Neer 3- and 4 part PHF. They found consolidation in most fractures with negligible rate of mal-unions, good functional results with few complications.

The use of a standardized treatment algorithm by Katthagen JC 2017¹⁷ looked into failure and revision rates. Other studies compared different surgical approaches. Fraser AN, Fjalestad T 2020¹⁸ conducted a multicenter randomised controlled trial (DelPhi) and found at 2 –years follow-up advantage of RSA over ORIF in displaced OTA/AO type B and C. RSA versus HA for PHF by Ball CM¹⁹ 2017 is based on the shoulder arthroplasty 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. Lopiz Y.²⁰ (2019) analyzed in a prospective RCT 30 non-operative vs 29 RSA age 80 and older. They found no significant difference between both groups. Retrospective Chivot M.²¹ (2019) found 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 2020²² 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 importance of greater tuberosity healing for clinical outcomes is shown by Ohl X. 2018 (9). 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 shoulder arthroplasty for acute proximal humerus fractures: the “black and tan” technique Levy J, (2015)²³ showed significant improvement in TH. This technique together with standard suture repair and implants, who support tuberosity healing results in a high healing rates with restoration of external rotation after reverse shoulder arthroplasty for fracture.

Brorson St and Rasmussen J²⁴ 2013 did one systematic review for RSA in acute PHF. They found the functional outcome not clearly superior to HA, with higher complication rates for RSA and risk for scapular notching. A Nordic registry-based study of 6756 replacements by Brorson St and Rasmussen (2017)²⁵ 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, periprosthetic fractures or loosening. Jonsson E (2021)²⁶ randomized 99 patients to RSA versus HA and conclude that RSA provides better function by CMS , patients are more satisfied , aged > 80 years benefit less from RSA.

The influence of humeral head inclination in RSA was reviewed by Romeo A²⁷ (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 G²⁸ 2015 found dramatic improvement in adduction, extension and external rotation with varus inclination prostheses. Denard P²⁹ 2015 found similar results. Uncemented RSA as initial treatment for PHF by Wiater B³⁰ 2019 showed 97% stable humeral stem fixation and 70% healing of the tuberosities. Good functional results were achieved. Krishnan S³¹ (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 Ch³² (2020) with four years FU showed adjusted CS 61, TH 82%, SSV 79 %, revision rate 5%, scapular notching 3%. Half of the implants were uncemented. They suspected that RSA with humeral inclination of 135 degree allows refixation of the tuberosities 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 humerus inclination angles and found higher stability for 135 degree³³. Cuff DJ (2013)³⁴ compared HA vs RSA for PHF with 135 degree fracture-stem with similar good TH with DJO Reverse implant. Uncemented 135 HI stem SMR by Lima have been used be Sebastia-Forcada (2014)³⁵. They found better pain and function and lower revision rate in RSA. Revision from HA to RSA does not appear to improve outcomes. Youn S-M. (2016)³⁶ used the same uncemented implant. They found no early loosening or failure. In one systematic review of tuberosity healing O`Sullivan J. (2020)³⁷ found RSA for fractures abduction highest in 155 degree group, tuberosity healing 83 %. With tuberosity healing 18 degree higher forward flexion and 16 degree greater external rotation. They recommend a 135 degree HI prosthesis when RSA is used for fractures.

Cemented versus uncemented RSA has been reviewed and meta analyzed by Rossi LA (2022)³⁸, they found similar functional outcomes and reoperation rates with significant higher complication rates for uncemented stems. They concluded, that uncemented stem seem to be a valid alternative for the management of patients with PHF.

Fracture pattern and age can't be the only factors considering treatment options of complex proximal humeral fractures, the Charlson Comorbidity Index³⁹ may be used to help decision making, too.

Earlier unpublished results from our department status

07/23

| | Delta Xtent FX | Univers revers FX | Global FX |
|-------------------------|----------------|-------------------|-------------|
| N total | 112 | 14 | 34 |
| N female/ median age | 92/77,3 years | 11/76 years | 25/68 years |
| N male/ median age | 20/72,5 years | 3/ 66,7 years | 9/ 65,6 |
| WOOS 3 month | 53 | 59 | 41 |
| WOOS 12 m | 65 | 71 | 40 |
| WOOS 60 m | 74 | ? (missing data) | 37,5 |
| Elevation 3 month | 80,4 | 71,5 | 64 |
| Elevation 12 m | 70 | 107 | |
| Elevation 60 m | 132 | | 73 |
| Constant-Murley 3 month | 34 | 35 | 26 |
| CMS 12 m | | 48,7 | |
| CMS 60 | 52 | | 42 |
| SSV 3 month | 42 | 45 | 28 |
| SSV 12 m | 50 | 59 | |
| SSV 60 m | 68 | | 36 |
| Complications/ % | 4/ 3,6 | 1/ 7,1 | 3/ 8,8 |
| Death/ % | 13/ 11,6 | 1/ 7,1 | 9/ 26,4 |

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