

## Outcome Following Reverse Shoulder Arthroplasty for Acute Proximal Humeral Head Fractures in Patients Aged 60 Years and Older with Different Humeral Inclination Implants Versus Non-Surgical Treatment - Trial Protocol: A Prospective Randomized Controlled Trial, Single-Blinded

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### Abstract

The optimal treatment for proximal humeral head fractures (PHF) Neer type III and IV AO B1.1,1.2 and C1.1,3.1 is controversial. The national guidelines for Denmark were published in 2015 and were updated in 2019. They recommended conservative treatment for all types of PHF in patients aged >60 years. The exceptions are fracture-dislocations, head splits, and surgical conditions where intervention is mandatory, such as open fractures and impaired nerves and circulation. Reverse shoulder arthroplasty (RSA) has recently gained popularity for the treatment of PHF.<sup>1</sup> Compared with osteosynthesis (ORIF) or hemiarthroplasty (HA), the outcomes were superior.<sup>11</sup> The importance of tuberosity healing for good functional outcomes has led to the development of various implant and fixation techniques. The original RSA design by Grammont, with 155° inclination of the humeral stem, was designed for cuff arthropathy. This design moves the center of rotation in the medial direction and increases tension on the tuberosities. In contrast, "anatomical" designed humeral implants with a 135° inclination enables more anatomical re-fixation of the tuberosities with less tension and might reduce the risk of resorption or displacement of the fragments. To implant a 155° RSA, the surgeon may be forced to remove parts of the rotator cuff. On the other hand, with a 135° inclination of the humeral component, the cuff-sparing technique is easier. The aim of this study was to compare the outcomes of two differently designed RSA stems versus non-operative treatment of PHF Neer type III or IV/AO B&C.

**Keywords:** Arthroplasty, Replacement, Shoulder, Fracture, Treatment.

### Methods

The study design was a prospective, randomized, controlled, single-blinded study for patients and a single-unit trial to compare outcomes of displaced proximal humeral head fractures treated with either non-operative or reverse shoulder arthroplasty. The subgroups for RSA differed in the inclination of the humeral stem (HI) at 135° versus 155°. Elderly individuals aged 60–90 years were included in the trial. Patients who met the inclusion criteria were randomized into one of two groups. Two patients were treated non-surgically (Group A). Sixteen patients in each group were treated surgically (Groups B and C). All the participants followed a standardized rehabilitation program for the public health system.

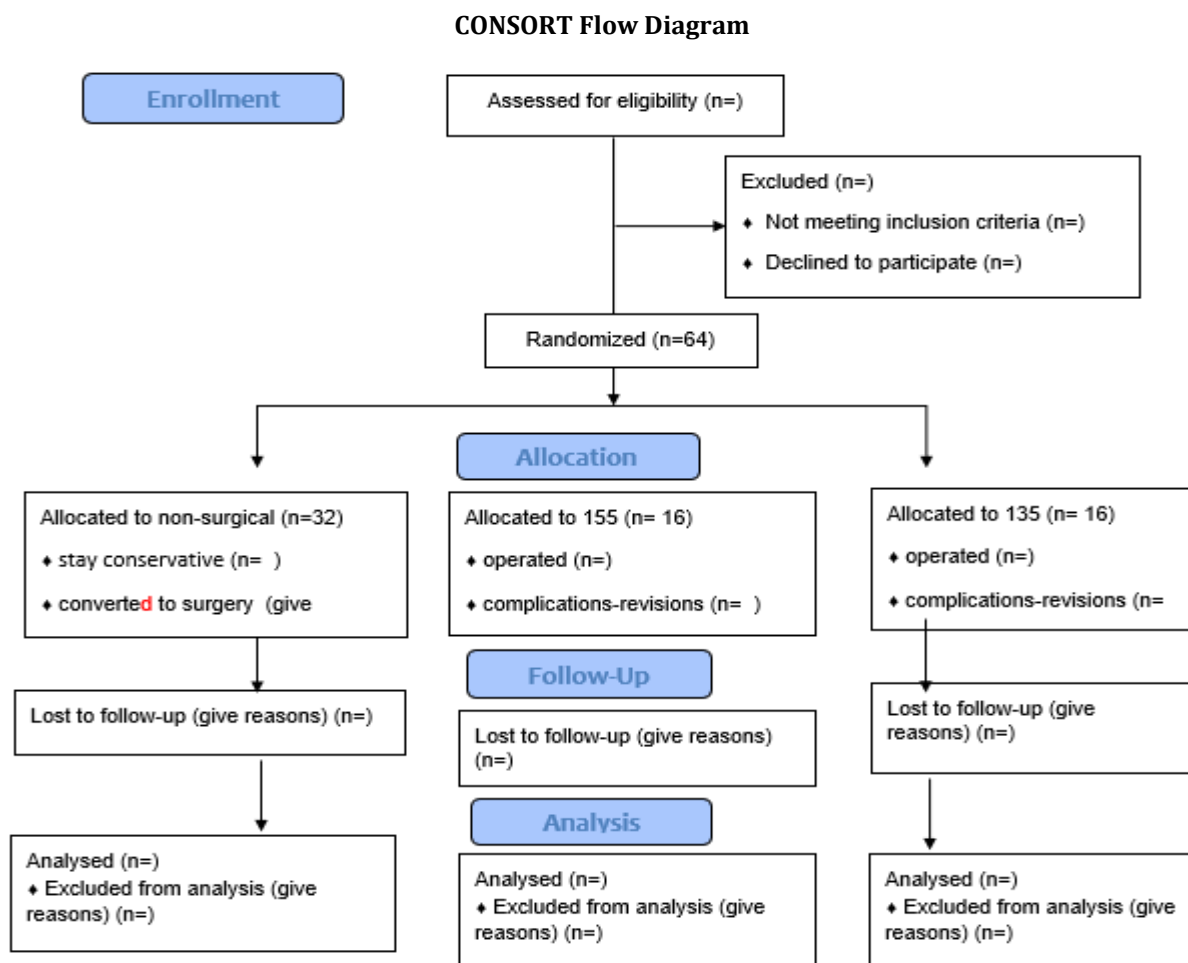
The primary outcomes were Western Ontario Osteoarthritis of the Shoulder Index (WOOS) [1] and minimal clinically important difference (MCID), assumed to be 12.3 points [2]. Secondary outcomes included Constant Murley (CS) [3] and subjective shoulder volume (SSV) [4]. Radiographs will be evaluated independently by researchers to state union/non-union/pseudoarthrosis in the non-surgical group and tuberosity healing (TH) as healed, malunion >5 mm, or resorbed in the surgical group. Complication and revisions will be noticed within two years of follow-up.

Table 1 shows the timetable for the follow-up.

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

**Table 1:** The follow-up timetable

**Figure 1:** presents a flowchart.



- Serious Adverse Events (SAE)
- Luxation
- Infections
- Fractures
- Non-union
- Caput-necrosis
- Main reasons for revisions/ secondary interventions.
- Adverse Events (AE)
- Nerve-injuries
- Vascular-injuries
- Persistent pain
- Participants in the non-surgical group who were treated operatively at a delayed time point (crossover) were noted.

**Ethics**

This trial was approved by the Regional Scientific Committee of southern Denmark 01. September 2021 (21/38868).

**Trial registration**

NCT06444828 ClinicalTrials.gov  
<https://www.isrctn.com/ISRCTN85422168>

**Dissemination**

The results will be disseminated in an orthopedic publication.

**Analysis and statistics**

The first hypothesis of this trial was that RSA provides better results than non-surgical treatment. The second hypothesis is that an RSA with a lower degree of humeral inclination achieves a better outcome than an RSA with a higher degree. The trial was drafted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statements.

Based on our previous results for fracture cases treated with RSA, we would determine the standard deviation as 22.9 and calculate it with an estimated MCID of 12.3, a sample size of 32 in each group (non-operative versus operative). Confidence interval (two sided) 95%, power 80%.

Sixty-four patients who would be included in the study after randomizing 16 cases per block, four blocks are needed to include 64 patients. Some dropouts or crossovers are expected to be considered.

**Patient information**

Patients will be asked verbally and in written form after being diagnosed with PHF Neer types III/IV AO B and C in the orthopedic outpatient clinic. They would be offered treatment, either non-surgically or surgically.

**Patient selection**

The eligible study population will comprise all consecutive patients aged 60 years or older with a proximal humeral head fracture and Neer Types 3 and 4 operated on within 14 days of the trauma or treated non-operatively. The lower age limit was chosen according to Danish national guidelines, which recommend conservative treatment for all types of PHF in this age group, except for head splits and dislocations.

**Exclusion criteria:**

- Patients younger than 60 years or older than 90 years.
- Neer types 1 and 2, head splits, glenohumeral dislocations.
- Pathological fractures.
- Refusal to participate in the study.
- Noncompliant, drug/alcohol abuse, or institutionalized.
- Low cooperation.

- Surgical contraindications or surgical conditions where operative treatment is mandatory.
- Does not understand written or spoken guidance in local languages.

**Randomization**

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

**Non-operative treatment**

Patients in the non-operative group will be immobilized in a sling for two weeks before starting self-exercise and undergoing physiotherapy. Postoperative treatment differed with respect to the timeline between the surgical treatment group and the non-operative group because of the different degrees of stability for reversed prosthesis and non-operative treated displaced fractures. However, the elements of the physiotherapy were the same. Subgroups for varus-inclined fractures with >20° versus valgus impacted fracture types with >30° angulation will be made.

**Surgical treatment**

Operative treatment will be performed as a daytime procedure by trained and experienced upper extremity surgeons. The standardized approach is the delto-pectoral approach. The Delta Xtent (Depuy Johnson & Johnson) humeral stem, modular HA-coated, 155°, will be used as the implant in the second group. Emphasis will be made at the humeral side on cementing and auto-transplanting technique (black-tan) [5] and refixation of the tuberosities in “Nice-knot” fashion [6]. Parts of the supraspinatus tendon were then removed. Glenoid-side glenosphere-size 42 is the implant of choice to achieve stability.

Univers Revers (Arthrex) will be implanted in group 3. An un-cemented modular stem, with an inclination of 135°, was used on the humeral side. Under unstable humeral conditions, cementing is considered optional. The fixation of the tuberosities and grafting were performed in a similar fashion. The MGS-glenoid was used with a 4 mm lateral offset at the glenosphere. Tendon resection is not necessary to restore the gothic arc. Earlier experience and results are shown in table 2.

**Table 2:** Earlier results from our department.

	Delta Xtent FX	Univers revers FX
N total	97	12
N female/ age	83/77,3 years	11/78,1 year
N male/ age	14/73 years	1/ 78,0 years
WOOS 3 months	54,4	64,6
WOOS 12 m	64,4	68,9
WOOS 60 m	67,0	? (missing data)
Elevation (subjective) 3 month	80,4	76,6
Elevation (subjective) 12 m	70	76,6
Constant-Murley 3 month	33,7	40

### Rehabilitation

To achieve the best functional outcomes possible, 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-exercising. After discharge from the hospital, the patients will be referred for physiotherapy for further guidance. Patients in the operative group will begin the exercises on the first postoperative day.

### Risks of side effects, disadvantages, injuries

The orthopedic department of the University of Southern Denmark, Esbjerg, specializes in shoulder replacement and covers a population of approximately one million citizens. Three experienced surgeons will perform the procedures at a public hospital. Rehabilitation was standardized and similar in each group.

All participants would be covered by the patient-insurance of the southern Denmark region.

### Sponsors

No sponsors. All treatment costs would be covered by the Danish Public Health System without charge. The authors declare no financial interest regarding any treatment.

### Trial schedule

Recruitment and allocation began in September 2021 and is expected to last for five years. A further two years of follow-up is needed; publishing will be in late 2028 at the earliest.

### Discussion

PHF is common, and nonoperative treatment is indicated in most cases of Neer types I and II. In type III or IV fractures, head splits or luxation surgical treatment is necessary. In Denmark, the national treatment guidelines were published in 2015 and updated in 2019. They stated conservative treatment for all patients with PHF aged >60 years unless head splits or dislocations occurred. One updated review was by Handoll et al. [7] based on RCT's reported nonoperative versus RSA in a study by Lopiz [19]. Support for non-operative treatment was provided by Rasmussen and Hvass [8] who stated that displaced PHF can be treated satisfactorily. A systematic review of the nonoperative treatment of PHF by Iyengar et al. [9] found high rates of radiographic healing, good functional outcomes, and modest complication rates. Robertson et al. [10] retrospectively reviewed 19 non-operative patients who declined surgery versus 20 RSA patients and found minimal benefits of RSA. The PROPHET trial [11] compared surgical versus non-surgical treatment of PHF and found no significant difference. Of the 109 surgeries performed by 66 surgeons in 30 centers, 90 were ORIF, four were nails, 10 were hemiarthroplasty, and five were others. No fracture classification was used. Recently, Soler-Peiro et al. [12] systematically reviewed the conservative treatment of Neer 3- and 4-part PHF. They found consolidation in most fractures, with a negligible rate of malunion and good functional results, with few complications.

The use of a standardized treatment algorithm by [Katthagen et al.](#) [13] examined the failure and revision rates. Other studies have compared different surgical approaches. Fraser et al. [14] conducted a multicenter randomized controlled trial (DelPhi) with two-years follow-up to judge the advantage of RSA over ORIF in displaced OTA/AO types B and C. RSA versus HA for PHF by Ball et al. [15] was 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. No significant differences were observed between the groups. Lopiz et al. [16] analyzed, in a prospective RCT, 30 nonoperative vs. 29 RSA patients aged 80 years. No significant differences were found between the groups. Chivot et al. [17] found that in an age group >70 years, RSA vs. non-operative for 3- and 4-part PHF showed significantly better results for RSA and Constant scores, and the complication rate was higher for RSA. They suggested an RSA for higher demand patients. A registry analysis of 5946 patients from Australia by Critchley et al. [18] on 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 rates. The importance of greater tuberosity healing for clinical outcomes has been demonstrated by Ohl et al. [19] They compared outcomes after tuberosity excision, failed fixation, and anatomical healing, and found that anatomical tuberosity healing in RSA for PHF improves objective and subjective outcomes; excision is associated with the worst outcomes. Tuberosity healing after reverse shoulder arthroplasty for acute proximal humeral head fractures, the “black and tan” technique, Levy [20] showed significant improvement in tuberosity healing. This technique, together with a standard suture repair and implants, supports tuberosity healing and results in high healing rates with the restoration of external rotation after reverse shoulder arthroplasty for fractures.

Brorson and Rasmussen [21] performed a systematic review of RSA in patients with acute PHF. They found that the functional outcome was not clearly superior to that of HA, with higher complication rates for RSA and a higher risk for scapular notching. A Nordic registry-based study of 6756 replacements by Brorson and Rasmussen [22] examined the revision rates after shoulder replacement for acute PHF. Between 2003 and 2013 90% were HA and 8.4% RSA. The five-year survival rate was 0.96 for both, the relative risk for revision 1.4 RSA/HA was higher in the age group less than 75 years old. The reasons for revision were infection, instability, periprosthetic fractures, or loosening. Jonsson et al. [23] randomized 99 patients to RSA versus HA and concluded that RSA provides better function by CMS; patients aged >80 years benefited less from RSA.

The influence of humeral head inclination on RSA was reviewed by Romeo et al. [24] who found lower rates of scapular notching and dislocation in the 135° group. External rotation was significantly better in the anatomical group. No subgroups were created for different indications. Walch et al. [25] reported dramatic improvements in adduction, extension, and external rotation with varus-

inclined prostheses. Denard et al. [26] also reported similar results. Un-cemented RSA as initial treatment for PHF by Wiater et al. [27] showed 97% stable humeral stem fixation and 70% healing of the tuberosities. Good functional results were obtained. Krishnan et al. [28] reported on 60 un-cemented RSA with excellent ROM and functions-scores, 91% TH, 6.7% revision rate. A study on 135° RSA for the PHF focused on TH by Gerhardt et al. [29] with four years follow up showed adjusted CS 61, TH 82%, SSV 79%, revision rate 5%, scapular notching 3%. Half the implants were un-cemented. They suspected that an RSA with a humeral inclination of 135° allows re-fixation of the tuberosities in a more anatomic position and, therefore, might result in decreased stress on tuberosity repair. A biomechanical study compared the stability of tuberosity fixation in reverse fracture arthroplasty with different humeral inclination angles and found higher stability at 135°. [30] Cuff and Pupello [31] compared HA vs. RSA for PHF with a 135° fracture stem and a good TH similar to that of the DJO reverse implant. The un-cemented 135° HI stem SMR by Lima was used by Sebastia-Forcada et al. [32] They found better pain and function rates and a lower revision rate in the RSA group. Revision from HA to RSA did not appear to improve the patient outcomes. Youn et al. [33] used the same un-cemented implants. No early loosening or failure was observed. In their systematic review of tuberosity healing O'Sullivan [29] found RSA for fractures abduction highest in 155° group and tuberosity healing of 83%. With tuberosity healing, the forward flexion and external rotation were 18° and 16°, respectively. They recommended a 135° HI prosthesis when the RSA was used for fractures. A review of current evidence of RSA for PHF by Minarro [35] found that although there is still some debate regarding which may be the best treatment for PHF in certain age ranges, RSA seems to offer more predictable results than other surgical treatments for elderly patients. Successful TH seems to correlate with better outcomes. Recent trends indicate interest in cementless fixation, fracture-specific stems and 135-degree PE opening angle. The discuss RSA vs. non-operative treatment and listed a matched-cohort study, that compared 26 RSA with 45 fractures treated non-operatively, all patient over 65 years of age [36]. At 6 months, the RSA group had regained better forward flexion and external rotation. At one-year PROM were superior in patients with RSA.

The review has a chapter RSA vs HA, RSA vs ORIF, RSA acute vs delayed, about importance of TH, supraspinatus retention vs release, Fracture-specific vs conventional stems, cemented vs un-cemented stems, the rule of humeral inclination and differences in postoperative protocols. Earlier experience on fracture RSA showed good and stable results (Table 2).

**Conflict of interest:** "This author, their immediate family, and any research foundation with which they are affiliated did not received any financial payments or other benefits from any commercial entity related to the subject of this article".

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