# A Prospective, Randomized Study Comparing The Outcome of Large-Diameter vs Small-Diameter Glenospheres in Primary Reverse Shoulder Arthroplasty Using the ReUnion System

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Protocol title: **A Prospective, Randomized Study Comparing The Outcome of Large-Diameter vs Small-Diameter Glenospheres in Primary Reverse Shoulder Arthroplasty Using the ReUnion System**

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## Summary

A prospective, randomized, blinded clinical trial is proposed to compare the outcome of primary reverse shoulder arthroplasty using the Stryker ReUnion system with implantation of either a 40 mm glenosphere or a 36 mm glenosphere, both with either a +2 mm or a +6 mm offset. The Stryker ReUnion is a shoulder arthroplasty system approved by the FDA.

Each shoulder will be assessed preoperatively, at 3 weeks, 3 months, one year and two years. The primary end-point will be range of motion at one year. Additional end-points will include dislocation, stress fractures of the acromion, metal ion levels in peripheral blood, neurovascular complications, radiographic notching, implant mechanical failure and revision surgery.

## Introduction

Reverse shoulder arthroplasty has emerged as a very successful procedure for selected patients with severe degeneration of the glenohumeral joint and a deficient rotator cuff. All reverse systems incorporate various degrees of modularity to adapt size, length and other biomechanical parameters to each specific individual. One such parameter is the size of the glenosphere. Smaller glenospheres are easier to implant and seem to provide a good outcome with many reverse systems. Theoretically, a larger glenosphere could provide larger arcs of motion, decrease notching and increase soft-tissue tension. However, the effect of glenosphere size on motion and complications is largely unknown; to date, no study has specifically analyzed clinically the effect of sphere size on reverse outcome.
Modularity with use of multiple metal trunions and Morse tapers also creates concerns regarding metal ions in peripheral blood, a problem well identified in the field of total hip arthroplasty.

## Purpose

The purpose of this study is to compare the outcome of primary reverse shoulder arthroplasty using the Stryker ReUnion system with implantation of either a large (40 mm) or a small (36 mm) glenosphere, both with either a +2 mm or a +6 mm of lateral offset.

## Materials and Methods

Study design

This will be a prospective, randomized, blind clinical trial. Physician's assistants will supervise the running of the study and evaluate all patients. Randomization will be provided through a password-protected computer program developed by Mayo Clinic Division of Biostatistics personnel and communicated to the surgical team for listing. Physician assistants will be blinded regarding glenosphere size at the time of follow-up evaluations.

The indications and contraindication as outlined in Stryker's labelling will be strictly followed. Off-label use of the device is prohibited.

Inclusion and exclusion criteria

Inclusions:

- Subjects willing to sign the informed consent
- Male and non-pregnant female subjects ages 50 – 90 at the time of surgery
- Subjects requiring a primary reverse total shoulder arthroplasty
- Subjects with the diagnosis of cuff-tear arthropathy (CTA), massive irreparable rotator cuff tear (MRCT) or osteoarthritis (OA) with marked posterior subluxation or bone loss

Exclusions:

- Inability to comply with follow-up requirements
- Subjects with inflammatory arthritis
- Subjects with proximal humerus fractures
- Subjects with sequels of trauma
- Subjects that are immunologically compromised
- Subjects with an active or suspected latent infection in or about the shoulder
- Need to add a tendon transfer
- Need for structural humeral bone graft
- Pregnant subjects

Randomization

In order to assign patients to specific treatment groups in an unbiased manner, randomization will occur prior to surgery.

After the patient has met the inclusion criteria and given full informed consent, he/she will be assigned to the treatment group. The randomization will be stratified by variables with potential confounding effects on the outcomes of interest. Specifically, patients will be stratified by gender (male/female), age group (50-65/ 66 – 80 / 81+) and underlying diagnosis. Within each stratum, subjects will be assigned to one of the two treatment groups using a computerized dynamic allocation program as mentioned before.

Sample size

The target sample size was estimated using shoulder range of motion as the primary outcome, and a 15° between-group difference as being a clinically meaningful difference. In a recent study of a cohort of patients undergoing primary RSA, Steen et al (Steen, JSES, 2015) reported the following means and standard deviations of postoperative shoulder flexion, abduction, and external rotation: 153.3 ± 32.7, 140.4 ± 37.4, and 47.1 ± 38.9, respectively. If similar variability is observed in the proposed study, a sample of 100 subjects in each of the two groups (200 total) will provide 80% power to detect a difference of at least 13.1° in shoulder flexion, 14.9° in abduction, and 15.5° in external rotation as being statistically significant (alpha = 0.05, two-sided). In order to protect against a potential subject attrition rate of up to 10% due to drop out or loss to follow-up, the target sample size of 100 in each of the two main groups (36mm glenosphere and 40 mm glenosphere) will be increased to 110 per group (220) total. Although the primary comparisons will be between the 36mm and 40mm study groups, subjects will be enrolled and randomized such that within each group, half of the subjects will have a +2mm offset, and half will have a +6mm offset. Thus there will be 55 subjects with a 36 + 2mm glenosphere, 55 subjects with a 36 + 6mm glenosphere, 55 subjects with a 40 + 2mm glenosphere, and 55 subjects with a 40 + 6 mm glenosphere.

Surgical technique

All procedures will be performed by two shoulder arthroplasty surgeons: Drs. Mark Morrey MD and Joaquin Sanchez-Sotelo MD PhD. The surgeons will implant the prosthesis according to the standard surgical technique for this particular implant system. A biceps tenotomy and tenodesis will be performed in all patients. The subscapularis tendon will be repaired at the end of the procedure when possible. Patients will receive one preoperative dose and two postoperative doses of IV antibiotics separated by a 6-8 hour period. All patients will receive an interscalenic brachial plexus block for pain control unless medically contraindicated. A shoulder immobilizer will be placed in the operating room once the procedure is completed and used for three weeks.

Hospitalization

Patients will be admitted to the hospital on the day of their surgery, unless medical problems dictate earlier admission. Hospitalization of 1 day is routine for these patients, although uncontrolled pain or medical complications could lead to a more prolonged admission.

Physical therapy

Both treatment groups will undergo the same program of postoperative care and physical therapy. A shoulder immobilizer will be used for three weeks. Active and active-assisted motion exercises for the elbow, wrist and hand will be initiated on day 1. Shoulder active-assisted motion exercises will be initiated at week 3. Isometrics will be added at week 6. Therabands will be added at week 8.

Data collection

*Operative data collected*

- Surgical time
- Cuff status preimplantation
- Biceps status preimplantation
- Glenoid bone loss (photograph) preimplantation
- Increase in muscle strain as measured with ultrasound elastography in the conjoined and deltoid muscles
- Implants used
- Intraoperative motion
- Subscapularis repair

*Clinical data collected*

- Demographic data
- Pain (visual analogue scale)
- Subjective shoulder value
- Active and passive range of motion in elevation, external rotation and internal rotation
- Strength in abduction, external rotation, and internal rotation
- Pain along the biceps tendon
- Biceps cramping
- Speed test
- Neurovascular exam
- Oxford shoulder score
- Quick-DASH score
- ASES score
- Satisfaction (visual analogue scale)
- Muscle strain measured with ultrasound elastography

*Laboratory studies*

- CBC, sedimentation rate and C-reactive protein
- Metal ion levels for chrome, cobalt and nickel

*Imaging studies*

- Plain radiographs (AP in external rotation, axillary, whole humerus markers)
- In-growth xrays (only postoperatively)
- Preoperative CT-Scan
- *CT-scan at one year postoperatively*

Radiographic analysis

Preoperative radiographs and CT scans will be measured for canal sizing, bone dimensions and bone loss.

Postoperative radiographs will be measured for length, offset and glenoid version. They will be analyzed for component fixation, glenoid notching, stress fractures of the acromion and screw position. Post-op CT at one year will be obtained.

Visits

#1. Preoperative visit
- Clinical evaluation
- Plain radiographs
- CT scan with three dimensional reconstruction
- Laboratory studies
- Muscle strain measured with ultrasound elastography

#2. Intra-Operative
- Muscle strain measured with ultrasound elastography

#3. First postoperative visit at 3 weeks
- Plain radiographs

#4. Visits at 3 mo, 1 yr, 2 yr, ~~5 yrs~~

- Clinical evaluation
- Plain radiographs + ingrowth radiographs
- Laboratory studies
- CT Scan (only at one year)
- Muscle strain measured with ultrasound elastography (only at one year)

Complications

Any serious complication that occurs related to the device will be documented. If patients are lost to follow-up, it will be noted accordingly.

Recruitment

The physician assistant or research coordinator will carry this out. The study will be described to the patient in detail, and a consent form clearly stating the background and reasoning, will be given to the patient. A consent form will be signed by the patient and a study person authorized to obtain consent. One copy will be given to the participant, a second copy will be scanned in the patient's electronic medical record, and the original consent will be kept in the patient's study folder.

Competency

Study participants must be able to give informed consent.

Gender and Racial/Ethnic Distribution

No gender or racial/ethnic group will be intentionally excluded from this study.

Risks

Participation in this study, involving FDA-approved devices, poses no increased risk to patients undergoing reverse total shoulder arthroplasty surgery. Risk and complications of this procedure include infection, nerve injury, bleeding, blood clots, persistent pain, persistent stiffness, loosening, wear, osteolysis and other forms of mechanical failure.

Analysis and Intended Publications

The primary outcome will be shoulder range of motion in elevation, external rotation, and internal rotation at 1 year post surgery. Additional outcomes will include strength, pain, speed test, Oxford Shoulder Score, ASES score, Quick-DASH score, and patient satisfaction. The analysis will focus on comparing the subjects randomized to the small glenosphere to the patients randomized to the large glenosphere, at 1 year. Additional comparisons will be performed to evaluate data collected at the 3-month, 2-year, and 5-year time points. Variables comprised of discrete data will be analyzed using chi-square tests or Fisher's exact tests (if low expected cell counts are observed). Continuous variables will be analyzed using two-sample t-tests or Wilcoxon rank sum tests, if necessary and appropriate. Two-factor models may be used to analyze the effect of study group and time since surgery simultaneously, including the evaluation of potential interactions between these two factors. Modeling tools may include ANOVA, logistic regression, or generalized linear models, as appropriate based on examination of the data distribution and structure. Furthermore, separate analyses may be undertaken on specific patient subsets,

including those with a primary diagnosis of OA, CTA, or MRTC. Other possible analyses may involve metal ion levels following RSA, correlation of sarcomere length (as measured with ultrasound elastography) with radiographic parameters, biceps symptoms, and screw location and length. All statistical tests will be two-sided and p-values less than 0.05 will be considered significant.

Budget

See enclosed documents

1-75

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