Treatment Effects of Reverse Total Shoulder Arthroplasty for Unilateral Cuff Tear Arthropathy – Outcomes at 6, 12, 24 and 60 Months and Confounders

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Jorg Huber  
Stadtspital Triemli  
joerg.huber2@triemli.zuerich.ch  
Corresponding Author  
ORCiD: https://orcid.org/0000-0002-1413-1314

Ulrich Irlenbusch  
HELIOS Klinikum Erfurt

Max J Kääb  
Sportorthopaedicum Straubing

Falk Reuther  
DRK Kliniken Köpenick

Georges Kohut  
Clinique generale Fribourg

Andy Judge  
Botnar Research Centre

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Cuff arthropathy, reverse shoulder arthroplasty, treatment effect, outcome, confounders
Abstract

Background

Although shoulder arthroplasty is less common than knee or hip arthroplasty, the number of procedures being performed is increasing rapidly. The treatment effect is a simple method to measure outcome of joint replacement for each patient individually. The method was applied to measure outcome of total hip/knee arthroplasty but not yet for shoulder arthroplasty.

Methods

The patients with reversed total shoulder arthroplasty (RSA) of five European clinics were included in this prospective study. The treatment effects (TE) were calculated for each patient as complaint reduction/baseline complaints. 1 is the maximal treatment effect and corresponds to a patient without complaints. A positive number means amelioration, 0 = unchanged, a negative number means worse. The primary aim was to calculate the TE’s for RSA at 6, 12, 24, and 60 months postoperatively. The secondary aim was to analyze the influence of confounders (preoperative grade of cuff tear arthropathy, age, gender, dominance, side of the affected shoulder, general co-morbidities measured using ASA grade).

Results

203 patients were included for this analysis of whom 183 patients had a complete 2 year follow up. Over the 24-months, the mean ASES score augmented significant from 20.5 to 78.7 (p<0.001). The 2 year treatment effects ranged from 1 to 0.09. We had no patient with a negative TE. A higher Hamada grade was associated with better TE’s (Hamada grade 4+ vs. 2, p-value 0.042). For age and dominant side there were weak associations where those aged 80+ and dominant side had better TE’s. The patients with higher ASA grade had lower TE’s (ASA grade 4+ vs. 1, p-value 0.013). The mean TE’s were 0.77 at 6-months, 0.81 12-months, 0.76 24-months and 0.73 at 60-months.

Conclusions

The treatment effects for reverse shoulder arthroplasty vary from 1 to 0.09. The treatment effects change little in the first five postoperative years (from 0.73 to 0.81). The confounders for better TE’s were: higher severity of cuff arthropathy (Hamada grade 3, 4 and 5), less co-morbidities (ASA Grade...
1), higher age (80+) and dominant side. Gender did not influence the 2-year TE’s.

Background
Although shoulder arthroplasty is less common than knee or hip arthroplasty (in 2015 there were 83,886 primary hip arthroplasties, 94,023 primary knee arthroplasties, compared to 5,221 primary shoulder arthroplasties in the UK NJR)[1] the outcome seems to be just as successful or even better in reducing pain and ameliorating shoulder function[2–7]. From 1991 to 2010 the number of shoulder arthroplasties increased very rapidly with 98% for shoulder hemiarthroplasty and 393% especially for reverse total shoulder arthroplasty (RSA) in the New York Stat [8]. In California, a similar trend was found with the incidence for shoulder arthroplasties rising from 6.1/100’000 insured persons to 13.4/100’000 persons in a large cohort of an integrated healthcare system[9].

Reverse total shoulder arthroplasty (RSA) is a biomechanical unique concept of replacement surgery in the shoulder successfully used in elderly patients with cuff tear arthropathy[10]. The underlying concept was to reverse the “ball and socket” principle of the shoulder joint to lengthen the lever arm for the deltoid muscle and the rotator cuff[10] and was first described 1994 by Grammont[11]. The type of prosthesis used in this study (Affinis® inverse, Fa Mathys, Bettlach, Switzerland) was developed and introduced to the market in 2007. It has been clinically and radiographically tested[12] and can be followed in the implant registries of the Netherlands, UK, AUS and NZ. The outcomes of RSA is promising and the good mid-term results are documented in different studies [6, 7, 13–16]. The long-term outcomes (> 10 years) showed a deterioration of clinical results compared to mid-term results and a prosthesis survivorship of 93%[17].

The treatment effect (TE) is a simple method to calculate the outcome for every patient individually. “Classical outcome” compares the state of a patient cohort before and after intervention, in contrast to this treatment effect (TE) measures the change of each patient individually. TE is a variable and can be calculated as complaint reduction/baseline complaints. For a cohort there are instead of one comparison with the “classical outcome” multiple measurements (one for each treated patient). This enables closer analysis of outcome and of confounders. The method has been applied to measure outcomes of total hip/knee arthroplasty, but not yet to shoulder arthroplasty [18]. The TE can be
calculated easy (see Fig. 1). A positive TE corresponds to a reduction of complaints, 0 to no change of complaints, and a negative TE to an augmentation. The best TE score is 1 and corresponds to a patient with no more complaints after intervention [18, 19].

The primary aim of this study was to measure the TE’s for RSA 6, 12, 24 and 60 months postoperatively. The secondary aim was to analyze the influence of confounders (Hamada grade of cuff arthropathy, age, gender, dominant side, ASA grade) on the outcome.

Methods
The European shoulder study group consists of five clinics specialized in shoulder surgery in three different countries (three clinics in Germany, two in France and one in Switzerland). Each clinic included their first consecutive patients in this open multicenter study. Included were patients with unilateral cuff arthropathy Hamada grade \( \geq 2 \) who agreed to the informed consent approved by the local ethical committee. Excluded were the patients with trauma/fracture, secondary osteoarthritis, no informed consent, with rheumatoid arthritis, neoplasia, with incomplete data and who had a revision (change of basic parts of the implants) in the first two years.

Each patient had a primary assessment before surgery with PROM’s (patient reported outcome measurements) in paper form and a clinical/functional examination to calculate the ASES score (American shoulder and elbow surgeons score[20]) and Constant score respectively[21]. In addition, the following information were collected: sociodemographic information (gender, age), dominance, side of the affected shoulder, were documented. Every patient had preoperative radiological assessment with standardized x-rays (shoulder ap/scapula tangential) and MRI or CT-Scan to evaluate the Hamada grade of cuff arthropathy[20].

Each patient had reversed total shoulder arthroplasty (Affinis® inverse, Fa Mathys, Bettlach, Switzerland) in a standardized way in beach chair position with cementless fixation of the base plate of the glenoid component and non-cemented or cemented fixation of the stem. The postoperative treatment with immobilization, physical therapy and beginning of loadbearing of the arm was individual and defined by each participating clinic.

Each patient had at least one complete follow up within two years with identical PROM’s to calculate
ASES score and a clinical examination for the Constant Score. If possible the identical PROM’s were also collected five years after surgery. All data were documented separately in a central register. The ASES Score was used for the outcome as described in the original publication (50% pain, 50% ADL), but for correct calculation of the treatment effect the ASES score was normalized to a score from 0 (best) to 100 (worst). The ASES has just two domains of pain and ADL, and hence was preferred to the Constant Score for the analysis, as this has too many dimensions (symptoms, ROM, force, ability to work).

Statistical methods
The outcome is measured as treatment effects (TE = (preoperative score – postoperative score) / preoperative score). This calculation was performed for each patient at each follow up (6, 12, 24 and 60 months). The ASES Score had to be inversed (0 = best, 100 = worse) to allow us to calculate correctly the TE’s. The confounders of interest were: Hamada grade of cuff arthropathy, age, gender, dominance, side of the affected shoulder, general co-morbidities measured using ASA grades. Descriptive statistics (mean, standard deviation for continuous variables and number, percentage for categorical) are used to compare characteristics of patients that did, and did not complete the 24 month follow up. Box-whisker plots describe change in ASES and Constant scores over pre-operative and follow up time points. Kernel density plots describe the distribution of the REPP score over follow up. Linear regression modeling was used to describe the association of the confounders of interest.

Results
The study included 203 patients. 20 had to be excluded (6 for death, 4 for surgical revision of large parts, and 10 who were lost to follow up) (Fig. 2). This gave 183 patients with at least one clinical follow up, of whom 168 had a complete 2-year follow up ASES score (173 for the Constant Score) and 118 a complete 5-year follow up ASES score. The baseline pain, ASES and Constant scores of all included and excluded patients did not differ significantly (Table 1).
Table 1
Baseline characteristics of the patients at baseline and with at least one clinical follow up over two years

|                      | All Patients with pre-op data | Patients with follow up data |
|----------------------|-------------------------------|-----------------------------|
|                      | N = 203                       | N = 183                     |
| Hamada Grade         |                               |                             |
| Stage 2              | 55 (27.1%)                    | 49 (26.8%)                  |
| Stage 3              | 43 (21.2%)                    | 41 (22.4%)                  |
| Stage 4a; Stage 4b; Stage 5 | 105 (51.7%)                 | 93 (50.8%)                  |
| Age                  |                               |                             |
| Mean (SD)            | 74.9 (6.7)                    | 74.7 (6.5)                  |
| Range                | 41.9 to 91.6                  | 41.9 to 87.5                |
| Gender               |                               |                             |
| Female               | 134 (66.0%)                   | 122 (66.7%)                 |
| Male                 | 69 (34.0%)                    | 61 (33.3%)                  |
| Dominance            |                               |                             |
| Dominant             | 185 (91.1%)                   | 166 (90.7%)                 |
| Non dominant         | 18 (8.9%)                     | 17 (9.3%)                   |
| ASA grade            |                               |                             |
| 1                    | 15 (7.4%)                     | 13 (7.1%)                   |
| 2                    | 22 (10.8%)                    | 20 (10.9%)                  |
| 3                    | 69 (34.0%)                    | 66 (36.1%)                  |
| 4 and 5              | 97 (47.8%)                    | 84 (45.9%)                  |
| ASES                 |                               |                             |
| Mean (SD)            | 20.3 (12.9)                   | 20.8 (12.8)                 |
| Range                | 0.0 to 63.3                   | 0.0 to 63.3                 |
| Constant             |                               |                             |
| Mean (SD)            | 24.6 (13.2)                   | 25.3 (13.2)                 |
| Range                | 3.0 to 67.0                   | 3.0 to 67.0                 |

By 24-months, the mean ASES score augmented from 20.5 to 78.7 (a difference of 58.2 95% CI (55.3 to 61.1), \( p < 0.001 \)) (Fig. 3a), and the Constant score from 25.4 to 67.8 (a difference of 42.4 95% CI (39.9 to 44.9), \( p < 0.001 \)) (Fig. 3b).

The TE’s ranged from the maximum 1 to 0.09 for the 24-months follow up. We had no patient with a negative score. The median 24-month TE was 0.76 95%CI (0.73, 0.79) (see Fig. 4). Comparing different follow-up intervals we found only small differences between the distributions of the median TE’s at 6, 12, 24 and 60-months (See Fig. 5), being 0.77, 0.81, 0.76 and 0.73 respectively.

There was some evidence of an association of Hamada grade on 2-year outcomes. Compared to those with Hamada grade stage 2, those in stage 4 or above had a mean TE that was 0.08 points higher (\( p = 0.042 \)) (Table 2).
Table 2

Results of linear regression model describing association of Hamada grade on TE’s

| Main Predictor | Univariable | Multivariable |
|----------------|-------------|---------------|
|                | TE’s over 24-months | TE’s over 24-months |
|                | N = 168 | N = 168 |
|                | Coef (95% CI) | P-value | Coef (95% CI) | P-value |
| **Hamada Grade** | | | | |
| Stage 2 REF | | | |
| Stage 3 | 0.06 (-0.03, 0.14) | 0.194 | 0.05 (-0.03, 0.14) | 0.229 |
| Stage 4a; Stage 4b; Stage 5 | 0.07 (-0.01, 0.14) | 0.07 | 0.08 (0.00, 0.15) | 0.042 |

| **Confounders** | | | | |
| **Age** | | | | |
| <70 REF | | | |
| 70 to 80 | 0.01 (-0.07, 0.08) | 0.894 | 0.02 (-0.05, 0.10) | 0.546 |
| 80+ | 0.07 (-0.03, 0.17) | 0.177 | 0.09 (-0.01, 0.20) | 0.087 |

| **Gender** | | | | |
| Female REF | | | |
| Male | -0.02 (-0.08, 0.05) | 0.604 | -0.02 (-0.09, 0.04) | 0.518 |

| **Dominant side** | | | | |
| Dominant REF | | | |
| Non-dominant | -0.07 (-0.17, 0.04) | 0.213 | -0.10 (-0.21, 0.01) | 0.07 |

| **ASA grade** | | | | |
| 1 REF | | | |
| 2 | -0.03 (-0.17, 0.11) | 0.673 | -0.02 (-0.16, 0.12) | 0.79 |
| 3 | -0.07 (-0.19, 0.06) | 0.28 | -0.09 (-0.21, 0.03) | 0.157 |
| 4 and 5 | -0.11 (-0.24, 0.01) | 0.065 | -0.16 (-0.28, -0.03) | 0.013 |

The TE’s differed weakly according to confounding factors of age, and dominant side but not for gender (Fig. 6). There was some difference by ASA grade whereby those with higher ASA grade had reduced TE’s (median TE in ASA 1 was 0.85 versus 0.67 in ASA grade 4). This was confirmed by the adjusted linear regression analysis (ASA grade 4+ vs. 1 difference in mean TE’s -0.16 95% confidence interval (CI) (-0.03 to -0.28), p-value 0.013).

**Discussion**

In this study the TE’s of reverse shoulder arthroplasty were calculated for the first time using a standard score (ASES). The high treatment effects found correspond to the clinical success of RSA in patients with cuff arthropathy; mostly all patients had pain reduction and better function after surgery. The good results of earlier studies using the t-test were similar in this study (ASES Score from 20.5 to 78.7, p < 0.001).

The distribution of TE’s as kernel density plots demonstrate that the ameliorations can be seen already 6 months after RSA and change little in the further follow-up to 5 years (range 0.73 to 0.81 in median TE’s).

The most important factors influencing the outcome of the examined parameters were: the severity of
cuff arthropathy as measured by Hamada grade, the grade of general comorbidities measured in ASA grades, age, and dominant side[23]. Interestingly there was no influence of gender.

This study is valuable because it’s a multicenter study with a defined pathology and a single treatment; most other studies have mixed indications (e.g. fracture, revision) [10, 17]. There are few multicenter studies about this type of arthroplasty with such a long follow up. The open design of this study with at least one follow up postoperatively led to a slightly reduced number of two year follow ups. Further, the data were collected in a standardized way.

A bias factor would be the interest and expertise of each participant surgeon in shoulder surgery and in careful patient selection to get good results. That might be a reason to explain that there was no patient with a negative TE. Existing studies also have more homogeneous populations, being single center studies, with only a single follow up time point that is not consistent between patients.

Conclusion
The outcome for RSA in patients with cuff arthropathy can be measured with TE’s using the inverted ASES score. The excellent results also in this study may explain the fast success and rapidly increasing numbers of this treatment. The results can be seen already early six months after RSA with only small changes over a longer follow interval up to 5 years.

Declarations

Ethics approval and consent to participate

The study was approved by the regional ethics committee (Comité intercantonal d'éthique (Jura, Fribourg, Neuchâtel), number 01/2008, 24.09.2008. Written informed consent was obtained from all individual patients included in the study at each hospital site.

Consent for publication

All coauthors signed the author's disclosure and the ICMJE for this publication. The files can be obtained from the corresponding author on reasonable request.

Availability of data and materials

Anonymized source data can be obtained from the corresponding author on reasonable request.

Competing interests
The authors declare, that they have no competing interests.

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**Authors' contributions**

JH and AJ designed the study. The surgeries were performed by UI, MK, FR, GK and TJ. The data were collected in each clinic by UI, MK, FR, GK and TJ. JH and AJ analyzed the data and prepared the manuscript with tables and figures. UI, MK, FR, GK revised the manuscript critically. All authors read an approval of the final manuscript.

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Figures
TE = \frac{\text{preoperative complaints} - \text{postoperative complaints}}{\text{preoperative complaints}}

Example 1: pretreatment score 98, post-treatment score 5;
TE = 98-5/98 = 93/98 = 0.95
Example 2: pretreatment score 55, post-treatment score 36;
TE = 55-36/55 = 19/55 = 0.35
Example 3: pretreatment score 80, post-treatment score 90;
TE = 80-90/80 = -10/80 = -0.125

Figure 1
Calculating treatment effects: 3 examples
Figure 2

Flow chart of the patients

N = 203 met inclusion criteria

N = 6 deceased
N = 4 Revisions (components with bone contact)
N = 4 FU outside interval
N = 6 Lost to FU (without any clinical FU)

N = 183 Patients with at least one clinical FU

6 M  12 M  24 M  60 M
N = 113  N = 118  N = 168  N = 118
Boxplot diagrams showing change of median score for ASES score, and Constant score pre-operatively and over two-year follow up

Distribution of the treatment effects (TE's) for the two-year follow up
Figure 5

Kernel density plots of distribution of TE’s for 6, 12, 24 and 60 months follow up
Figure 6

Box-plot of TE’s for main predictor (Hamada grade) and confounders (gender, age, dominance, comorbidities as ASA Score)