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# 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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## Abstract

**Background:** Although shoulder arthroplasty is less common than knee or hip arthroplasty, the number of procedures being performed is increasing rapidly. The aim of this study was to measure the treatment effects of reverse total shoulder arthroplasty for unilateral rotator cuff arthropathy in a multicenter study over 5 years and analyze the influence of different confounders (preoperative severity of degenerative shoulder pathology as Hamada grade, gender, age, dominant side and comorbidities) on the two-year outcome.

**Methods:** The patients of five European clinics specialized in shoulder surgery in three countries were included in this prospective study. 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 outcome was measured as Treatment Effects (TE's), a number to describe the outcome of each patient (positive = amelioration, 0= unchanged, negative = worse). The treatment effect can be calculated as follows: score reduction/score preop. 1 is the maximal effect and corresponds to a patient without symptoms/impairments. 0 means no effect and a negative TE means more symptoms/impairments than preoperatively. A prerequisite for correct calculation is a positive score, meaning 0 equals no symptoms/impairments and a positive number symptoms/impairments. Therefore the used American Shoulder and Elbow Surgeons (ASES) score needed to be inversed. 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 different confounders (preoperative grade of cuff tear arthropathy, age, gender, dominance, side of the affected shoulder, general co-morbidities measured using ASA grade).

**Results:** A 203 patients were included for this analysis of whom 183 patients had a complete follow-up ASES score. Over the 24-month follow-up period, the mean ASES score augmented significant from 20.5 to 78.7 (a difference of 58.2 ($p<0.001$)). The treatment effects two years postoperatively ranged from 1 to 0.09 (the maximum being 1). We had no patient with a negative TE. The median TE 24-month postoperatively was 0.76. In the adjusted linear regression model a higher Hamada grade was associated with better TE's (Hamada grade 4+ *vs.* 2 differences in TE's 0.08 95% confidence interval (CI) (0.00 to 0.15), p-value 0.042). For age and dominant side there were weak associations where those aged 80+ and dominant side had better TE's. For gender there was no association. The patients with higher ASA grade had lower TE's (ASA grade 4+ *vs.* 1 difference in TE's -0.16 95% Confidence Interval (CI) (-0.03 to -0.28), p-value 0.013). The median TE's for the different follow-up intervals were 0.77 at 6-months, 0.81 12-months, 0.76 24-months and 0.73 at 60-months.

**Conclusion:** The treatment effects for reverse shoulder arthroplasty vary from 1 to 0.09. For correct calculation the ASES score had to be inversed. The treatment effects changed little in the first five postoperative years (varying from 0.73 to 0.81). The confounders for better TE's in this cohort 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.

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## Introduction

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 State [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 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]. In this study we focus on the outcome measured as treatment effects for RSA at 6, 12, 24 and 60 months and the influence of different confounders on 2-year outcomes. The Treatment Effect (TE) is an innovative method to calculate the individual symptom/impairment reduction for every patient. "Classical outcome" compares the state of a patient cohort before and after intervention; "treatment effect" measures the change of each patient individually as numeric score. Instead of one comparison for a cohort there are n numeric scores (for each patient). This enables more precise analysis of outcome and of confounders. The method has been applied to calculate patient outcomes of total hip/knee arthroplasty, but not yet to shoulder arthroplasty [18]. The TE can be calculated easily (Figure 1). A positive TE corresponds to a reduction of symptoms/impairments, a negative to an augmentation. The best score is 1 and corresponds to a patient with no more symptoms/impairments 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.

$$TE = \frac{\text{preoperative score - postoperative score}}{\text{preoperative score}}$$

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.

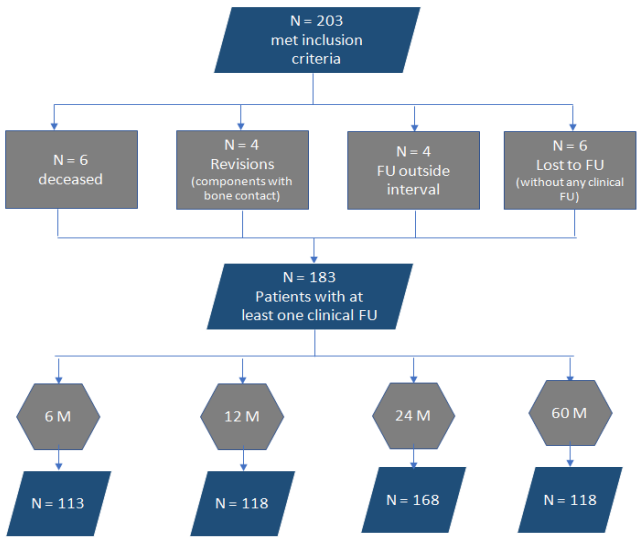


**Figure 2:** Flow chart of the patients.

## Patients and 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 an open multicenter study. Included were patients with unilateral cuff arthropathy Hamada grade >=2 [20] 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: Socio-demographic 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 load bearing 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 inverted ASES score–postoperative inverted ASES score)/ preoperative inverted ASES 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 for RTSA. The confounders of interest were: Hamada grade of cuff arthropathy, age, gender, dominance,

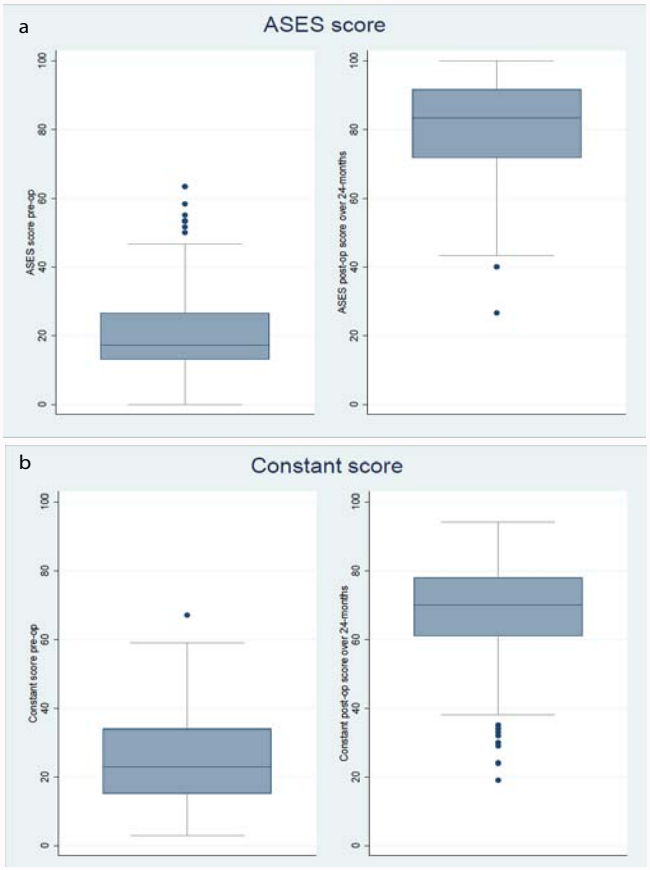


**Figure 3:** Boxplot diagrams showing change of median score for ASES score, and Constant score pre-operatively and over two-year follow-up.

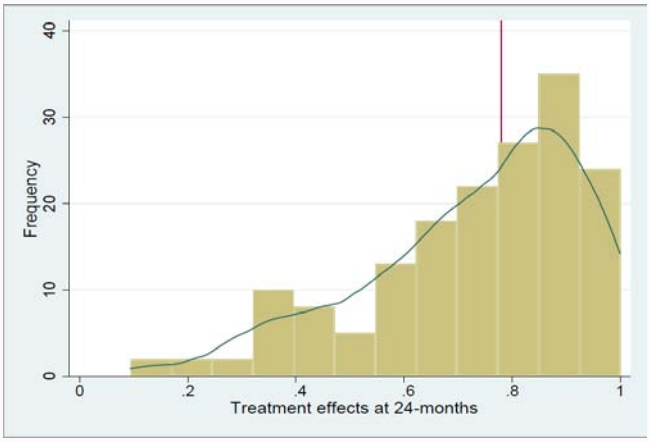


**Figure 4**: Histogram of the treatment effects for over the two-year follow up.

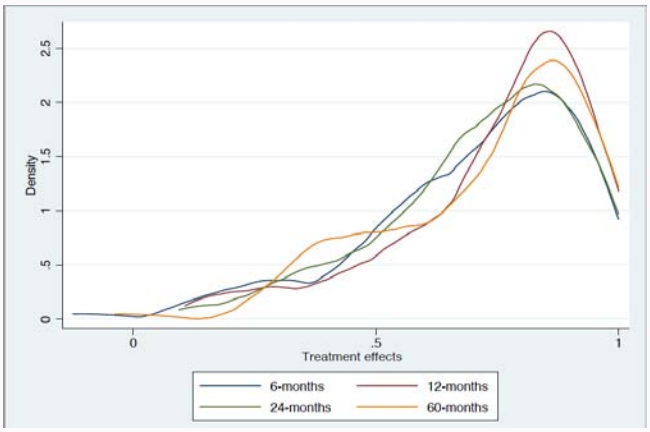


**Figure 5:** Kernel density plots of distribution of TE's for 6 months, 12 months, and 24 months follow up.

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) (Figure 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). 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) (Figure 3a), and the constant score from 25.4 to 67.8 (a difference of 42.495% CI (39.9to 44.9), p<0.001) (Figure 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) (Figure 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 (Figure 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). The TE's differed weakly according to confounding factors of age, and dominant side but not for gender (Figure 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 *vs.* 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 for reverse total 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). Gilmer et al. presented a similar concept based on the maximal improvement possible for the "ream-and-run" arthroplasty using the simple shoulder test (a 12 item questionnaire) [22]. 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. Using the TE's it could be demonstrated clearly

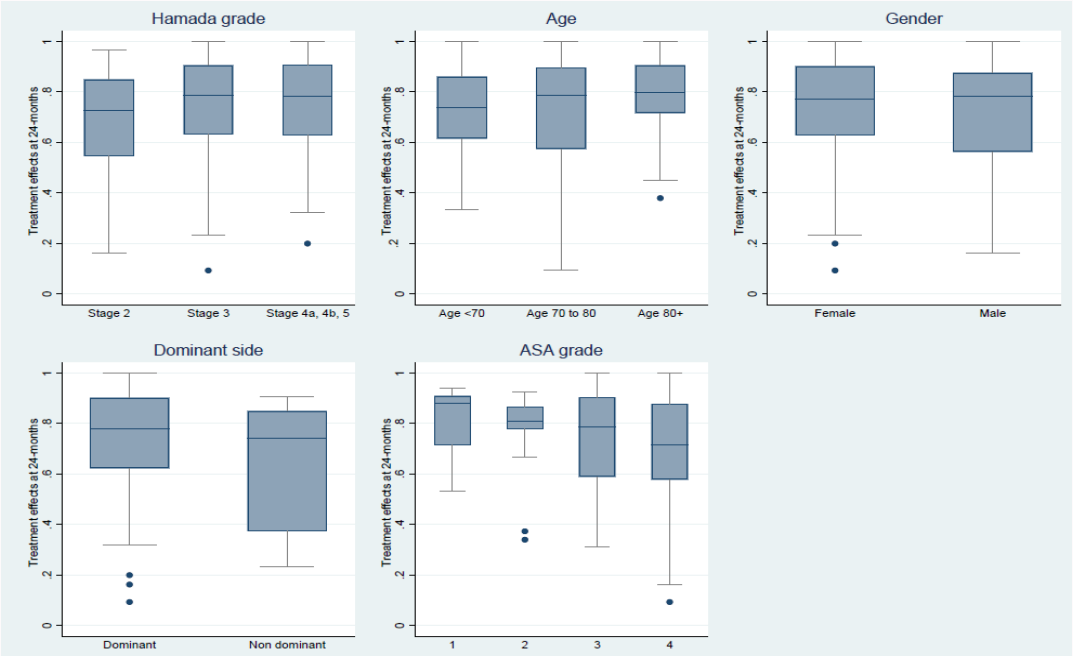


**Figure 6:** Box-plot of TE's for main predictor (Hamada grade) and confounders (gender, age, dominance, comorbidities as ASA Score).

**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 N=203 | Patients with follow up data 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 - 91.6 | 41.9 - 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 - 63.3 |
| **Constant** | | |
| Mean (SD) | 24.6 (13.2) | 25.3 (13.2) |
| Range | 3.0 to 67.0 | 3.0 - 67.0 |

**Table 2:** Results of linear regression model describing association of Hamada grade on TE's.

| | **Univariable TE's over 24-months N=168 Coef (95% CI)** | **P-value** | **Multivariable TE's over 24-months N=168 Coef (95% CI)** | **P-value** |
|---|---|---|---|---|
| **Main Predictor** | | | | |
| Hamada Grade | | | | |
| Stage 2 | REF | | 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 | | 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 | | REF | |
| Male | -0.02 (-0.08, 0.05) | 0.604 | -0.02 (-0.09, 0.04) | 0.518 |
| **Dominant side** | | | | |
| Dominant | REF | | REF | |
| Non-dominant | -0.07 (-0.17, 0.04) | 0.213 | -0.10 (-0.21, 0.01) | 0.07 |
| **ASA grade** | | | | |
| 1 | REF | | 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 |

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). 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). There are few multicenter studies about this type of replacement 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. 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 after RSA for cuff arthropathy can be measured as 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.

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