Onlay versus Inlay humeral steam in Reverse Shoulder Arthroplasty (RSA): clinical and biomechanical study

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Summary. Background and aim of the work: Reverse shoulder arthroplasty (RSA) is becoming treatment of choice in glenohumeral arthropathies with massive lesion of the rotator cuff, due to a gradual extension of indications and new designs that provide better outcome. In this study we compared two different reverse shoulder prosthesis designs, defined as Inlay (or typical Grammont type) and a relatively new model defined as Onlay (that preserves tuberosity bone stock). We analyzed clinical, biomechanical and radiological outcomes, as well as complications of RSA in these two groups. Methods: We performed a prospective study on a population of 42 patients undergoing Reverse Shoulder Replacement by a single expert surgeon. We consider 21 patients (group A) who underwent to reverse shoulder replacement with a curved onlay steam with 145° inclination (Ascend Flex group, Wright medical, Memphis, TN, USA) and 21 patients who underwent to reverse shoulder replacement with a traditional Inlay Grammont steam (Modular Shoulder System SMR, Systema Multiplana Randelli; Lima-LTO, San Daniele del Friuli, Italy) between August 2010 and October 2018. We studied the following items: active range of motion (AROM), radiological parameters (lateralization shoulder angle LSA, Distalization Shoulder Angle DSA), functional scale (Constant-Murley Score), post-operative complications (infection, aseptical implant mobilitazion, residual pain, scapular notching, fractures, tuberosity reabsorbtion, dislocation, bleedings, nerve palsy, pulmonary embolus). Results: A significant improvement in ROM and functional score (Constant Shoulder Score) were observed in both groups. Group A (Onlay design 145°, medial tray) provides improvement in adduction, extension and external rotation compared to group B. No significant differences were found in abduction, external rotation and forward flexion. At 6 months follow-up, pain relief was detected in all patients. Although complications occur in a high percentage of patients in literature, no postoperative complications were observed in our cases series. Conclusions: Our results showed how RSA is a real solution to improve quality of life and to restore pain-free shoulder ROM in patients where cuff tear arthropathy occurs. Onlay design 145° may provides better active external rotation, extension, adduction: it is necessary to continue follow up and include more cases to prove these data. (www.actabiomedica.it)

Key words: reverse shoulder arthroplasty, inlay, onlay, cuff tear arthropathy, outcomes, ROM, Constant Murley Score, SMR, Aequalis Ascend Flex, scapular notching, LSA, DSA

Introduction

Background and aim of the work

Reverse shoulder arthroplasty (RSA) is becoming treatment of choice in glenohumeral arthropathies with massive lesion of the rotator cuff due to a gradual extension of indications and new designs that provide better outcome. In this study we compare two different reverse shoulder prosthesis designs, defined as Inlay (or typical Grammont type) and a relatively new model defined as Onlay (that preserves tuberosity bone stock). We analyzed clinical, biomechanical and radiological outcomes, as well as complications of RSA in these two groups.

Massive cuff tears determinate gradual biomechanical joint alterations: forces and motion vectors are modified resulting in an antero-superior migration of the humeral head, and subsequent alteration of rotation fulcrum of the gleno-humeral joint: in motion, humeral head center showed a medial shift at the late phase of scapular plane full abduction and anterior shift at the internal rotation position during full axial rotation (1, 11, 21). Articular cartilage surface undergo to structural alterations and gradually a new joint is created between upper humeral head and acromial arch. Eccentric osteoarthrosis is the final progression of these alterations, characterized by severe pain (in particular night pain) and gradual restriction of active range of motion that could evolve to a condition defined "pseudoparalytic arm", in which patients can't move the affected arm independently (1, 11). Neer, in 1983, called this disorder "cuff tear arthropathy" (CTA) characterized by the association of gleno-humeral joint arthritis and a massive rotator cuff tear (1) (fig. 1).

The incidence of cuff tear arthropathy is about 2% in patients over 80 years of age (2). Conservative treatment should be tried in early cuff tear arthropathy (5, 6) but lesion dimensions and tendon's quality must be carefully evaluated to give the best chance of success: pre-operative MRI evaluation is mandatory to analyze residual tendons integrity and grade of retraction and fatty infiltration (7, 12). In selected patients with absolute or relative contraindications to MRI, Multidetector Computed Tomography Arthrography (Arthro-MDCT) of the shoulder provides accurate

diagnosis in identifying chondral, fibrocartilaginous, and intraarticular ligamentous lesions in patients who cannot be evaluated by MRI; Arthro-MDCT should be useful also after replacement surgery because it offers less artifacts generated by metal materials compared to post-operative MRI (10).

Computed Tomography (TC) study is indispensable for pre-operative planning (8). Currently we also have software to process TC images and elaborate a complete pre-operative planning: it is possible to choose different size of prosthesis components and perform a movement simulation in intra and extrarotation, abduction/adduction, elevation/forward flexion to find out any possible notching point (es. *Tornier Blue Print 3D Planning – Wright Engineered with IM-ASCAP Tecnology*) (9) (fig. 2).

The original indication for RSA was CTA, but the success of this implant has led to extend the indications. The procedure now is widely executed and RSA is indicated in patients with functioning deltoid muscle and with a unrepairable lesion of the rotator cuff, in the event of: rheumatoid arthritis, pseudoparalitic shoulder, avascular humeral head necrosis, severe proximal humeral fractures (Neer score 4) and fractures sequelae, correction of functional deformities, chronic shoulder instability, post infections arthrosis and revision after failure of previous shoulder arthroplasty or hemirthroplasty (11, 15-19, 24).

The Grammont prosthetic model is characterized by non-anatomical design (Fig. 3), that medializes the rotational center, refining the deltoid muscle lever arm and intrinsic stability of the implant in the absence of a functioning rotator cuff: this design increases deltoid efficiency and reduces mechanical torque at the gle-



Figure 1. "Cuff tear arthropathy" (CTA) characterized by a massive rotator cuff tear that gradually leads to Eccentric Os-teoarthrosis



Figure 2. Pre-operative planning. The red spot on inferior scapular neck shows the Notching point



Figure 3. Reverse Shoulder Arthoplasty (P.Grammont, 1991, Delta III, DePuy)

noid component (decreasing glenoid loosening) (13, 14).

SMR system is a modular implant that consists of inlay humeral stem, reverse humeral body and reverse liner. Due to its modularity, different combinations are allowed: it is possible to adjust reverse liner dimension, diameter of glenosphere (30, 36, 44 mm), angle of retroversion, implant height and glenospheres eccentricity.

Lädermann et al. (25) showed effectively in Fig. 4 the design of traditional Inlay Grammont straight stem (inclination 155°) compared to Onlay curved stem (inclination 145°) and Onlay humeral tray. The red line passes through the center of the stem. Inlay steam causes humeral distalization but Onlay steam causes less humeral distalization and more lateralization (red arrow); moreover, the center of the Liner is medialized with the Inlay curved stem which results in more humeral lateralization (Fig. 4).

Onlay curved steam design also preserve tuberosity bone stock for eventually future prosthetic intervention, both proximally and distally: unlike traditional steams, curved design preserves greater tuberosity bone stock; short steam preserves distal canal bone stock (Fig 5).

Methods

We performed a prospective study on a population of 42 patients undergoing Reverse Shoulder Replacement. We considered 21 patients (group A) who underwent to reverse shoulder replacement with a curved onlay steam with 145° inclination (Ascend Flex group,



Figure 4. a. Inlay steam; b. Onlay curved steam



Figure 5. Onlay Aequalis Ascend Flex curved steam: bone stock preservation zones

Wright medical, Memphis, TN, USA) and 21 patients who underwent to reverse shoulder replacement with a traditional Inlay Grammont steam with 155° inclination (Modular Shoulder System SMR, Systema Multiplana Randelli; Lima-LTO, San Daniele del Friuli, Italy) between August 2010 and October 2018. For the 145° implant a 3,5 mm eccentric humeral tray was positioned in supero-lateral position, to minimize lateralization. All prosthesis were implanted by the same expert surgeon.

Exclusion criteria were: recent glenoid, scapular or humeral fractures, fractures sequelae, chronic or acute shoulder instability, previous shoulder surgery (except for arthroscopic rotator cuff repair), brachioradial plexus deficiency.

Inclusion criteria were: cuff tear arthropathy, eccentric arthrosis, eccentric or concentric arthrosis in patients who underwent to previous arthroscopic rotator cuff repair.

We included all the patients operated with Onlay implant that respected inclusion criteria and the last (temporary criterium) 21 patients operated with Inlay implant that respected inclusion criteria.

Mean age at surgical time in group A was 77 years±3.8, range [68-85] and in group B was 73±8,2, range [55-88]. Median age in group A was 77 years, in group B was 75 years.

Both Group A and group B included 6 male (29%) and 15 female (71%).

Operated arm is dominant arm in 12/21 cases (57%) in group A and in 14/21 cases (67%) in group B.

Both Group A and group B included 3 patient (14%) who previously underwent to an arthroscopic repair of rotator cuff in the same shoulder.

Mean follow up was 12 months.

Deltopectoral approach was performed in all patients, in beach-chair position.

In post-operative time, all shoulders were immobilized by simple brace for 2 weeks. Early passive mobilization was started in 1° post-operative day (except for forcing external rotation to allow subscapularis tendon repair). After 2 weeks patients started active assisted rehabilitation program.

Physical and radiographic assessments were performed pre-operative and during post-operative follow-up at 1, 3, 6 and 12 months after surgery. During physical evaluation, Active Range Of Motion (AROM) was evaluated in abduction-adduction, forward flexion-extension, external rotation (with elbow in anatomic position and 90° of flexion) and internal rotation; according to the International Society of Biomechanics, abduction, flexion were noted positively while adduction, extension, external rotation were noted negatively (20, 21). We found difficulties in standardized internal rotation measurements: most patients were unable to perform active internal rotation in supine position mantaining shoulder at 90° abduction, which is the way suggested to take goniometric parameters: according to the International Society of Biomechanics, internal rotation must be noticed in positive degrees values (20). In this study, to asses Internal rotation, Vertebral levels were converted to points using the method showed by Triplets et Al (22, 23) (fig. 6).

Pain relief was included in functional outcomes and measured using Constant-Murley Shoulder Score (Fig. 7).

We studied the following radiographic parameters: lateralization shoulder angle (LSA), Distalization Shoulder Angle (DSA), acromion-humeral distance (AHD), post-surgery humeral offset, scapular notching, tuberosity reabsorption. LSA and DSA were



Figure 6. Active Internal Rotation: each image has a corresponding vertebral range. Vertebral levels are converted to points for analysis purposes (Triplets et al. (22)

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forza normale p. 25 movimento contro moderata resistenza p. 20 movimento contro gravità p. 15	* movimento a gravità mella p. 10 * contrazione senza movimento p. 5 * paralisi p. 0	

Figure 7. Constant-Murley Score

measured on standard anteroposterior radiographs by a single orthopaedist, blinded to surgical outcome, using the method illustrated by Boutsiadis et al. (28) (fig. 8, 9).



Figure 8. DSA and LSA angle in Inlay RSA (28)



Figure 9. DSA and LSA angle in Onlay RSA (28)

All measurements were calculated using O3 Reporting Workstation (ORWS Insiel FVG Version 3.2.2) with an accuracy up to 0,01 mm. Scapular Notching and Tuberosity Reabsorption were evaluated in subsequent radiographs taken during post-operative follow up at 1, 3, 6 months and 1 year. Scapular Notching was evaluated on AP view in external and internal rotation and classified using Sirveaux Classification (26, 27).

We also reserched any complication during 1 year follow up: infection, aseptical implant mobilization, residual pain, scapular notching, fractures, tuberosity reabsorbtion, dislocation, bleedings, nerve palsy, pulmonary embolus.

Categorical variables were reported as frequencies and percentages. The Student's t test or the Mann-Whitney U test was used to compare continuous variables between the two groups. Statistical significance for all tests was set at a p-value of <0.05. All statistical analysis were performed by Stata/IC 13.0 (StataCorp LP, College Station, USA).

Results

Group A (Onlay steam) and B (Inlay steam) were omogeneus in median age at surgical time, gender composition, surgery related to dominant arm, previous arthroscopic surgery. Median age in group A was 77 years [68-85], in group B was 75 years [55-88]. Both groups included 29% male and 71% female. Operated arm is dominant arm in 57% of group A patients and in 67% of group B patients. Both Group A and group B included 3 patients (14%) who previously underwent to arthroscopic repair of rotator cuff in the same shoulder.

Maximum improvement in ROM was obtained at 6 months and it was maintained at 1 year after replacement in both groups.

At 1 year follow up, in group A (Onlay) mean AROM was: Abduction +142 °[100-170], Adduction -35° [20-45], Forward flexion +153°[120-180], Extension -29° [20-40], extrarotation -42°[30-60]; active internal rotation was 4,6 points (reported as mean score, as show in fig. 6). (Table 1)

Table 1. Postoperative improvement in active ROM: mean abduction/adduction, forward flexion/extension, extra/intrarotation. Degrees are noted as absolute values; internal rotation was reported as mean score



At 1 year follow up, in group B (Inlay) mean AROM was: Abduction +144°[100°-180°], Adduction -24° [15-40], Forward flexion +158°[120-180], Extension -20°[10-30], extrarotation -37°[20-40]; internal rotation was 4,8 (reported as mean score, as show in fig. 6) (Table 1).

Constant Shoulder Score was submitted to patients before surgery, at 1, 3, 6 and 12 months followup (Table 2). Group A (Onlay steam) and B (Inlay steam) were omogeneus in mean pre-operative Constant-Murley Score: Group A 39 points; Group B 41 points. There was no significant difference between two groups in Constant-Murley score at 1, 3, 6 and 12 months post-surgery, with a rapid restoration of painfree AROM of the shoulder (Table 2).

At 3 months pain relief was detected in all patients except of 3 patients in Group A, who declared mild pain that was correlated to delayed phisioterapy: these 3 patients started active exercises 40 days postsurgery and gradually regained AROM in the following 3 months. At 6 months follow-up, pain relief was detected in all patients (parameter included in Constant-Murley Score). One patient declared that he was not satisfied for a distal humerus fracture with a complete lesion of radial nerve occurred 1 year after shoulder replacement but this fracture couldn't be considered as a implant complication (Fig. 10).

Regarding radiological findings, we discovered a linear correlation between LSA values and prosthesis offset (r=0.64, P<0.001): higher LSA values where found in more lateralized RSA (group A); we detected a Linear Correlation between DSA values and acromi-

Table 2. The variation of Constant Shoulder Score showed no significant difference between group A and B



on-humeral distance AHD (r=0.62, P<0.001): higher DSA values where found in more distalizated RSA.

LSA and DSA angles showed negative linear correlation (r=-0,42, P<0.001): more distally the implant is placed, less lateralization is achieved. Mean LSA in group A was $92^{\circ}\pm8.1$, higher than in group B 81 ± 5.4 . Mean DSA in group A was $47^{\circ}\pm6.9$, lower than in group B 49 ± 9 .

We did not find significant positive correlation between LSA and Active External Rotation ($R^2=0,15$) and between DSA and Active Forward flexion ($R^2=0,04$) as demonstraded by Boutsiadis et Al (28).

Six months after RSA, inferior Scapular Notching was detected in 3 patients (24%) in group B. These patients developed a low grade of scapular notching (<5mm) which did not reach the lower screw (26, 27). The radiographic finding of inferior Scapular Notching did not correlates with worst functional outcomes in our series.



Figure 10. Distal humerus fracture with complete lesion of radial nerve occurred 1 year after shoulder replacement



Figure 11. Scapular Notching, grade 1, at six month follow up

During follow up no other patients developed specific complications as: local and systemic infections, aseptical implant components mobilization, residual pain, fractures, tuberosity reabsorbtion, dislocation, bleedings, nerve palsy, pulmonary embolus.

Conclusions

Reverse shoulder arthroplasty (RSA) is an excellent surgical treatment to restore pain-free ROM, function and strength of the shoulder affected by massive irreparable rotator cuff tears and cuff tear arthropaty (3, 4, 32).

Group A (Onlay steam) and B (Inlay steam) were omogeneus in median age at surgical time, gender composition, surgery related to dominant arm, previous arthroscopic surgery. These parameters offered a good starting point for comparison. Outcomes of all RSA showed the capacity to restore pain-free ROM, function and strength, improving the quality of life. Constant-Murley functional score increased significantly after surgery in both groups.

In particular, compared to literature data, in our study, prosthesis reached a more satisfactory mean active range of motion.

It is now how loss of the external rotation is a serious problem, disclosed by several authors; also elevation recovery may not be enough to bring up this deficit; external rotation in these shoulders depends by teres minor muscle conditions: particularly in older patients, this muscle is often retracted, atrophied or fatty infiltrated (11, 33).

Group A (Onlay 145° inclination steam, with tray placed medially) showed at 1 year follow up an improvement in mean adduction (-35° vs -24°), extension (-29° vs -20°) and external rotation (-42° vs -37°) compared to Group B (Inlay traditional 155° inclination steam), while mean abduction (+142° vs +144°) and mean forward flexion (+153° vs +158°) slightly decrease. Internal rotation didn't show significant difference in the two groups. These data partially confirm $L\ddot{a}$ dermann et Al. study (25): they found that there was 9° decrease in abduction and 5° increase in adduction between an Inlay Grammont design and an Onlay 145° design with tray placed medially, which is the tray configuration that minimize total Onlay humerus lateralization; they also described a dramatic improvement in extension and external rotation but in their study forward flexion remains unchanged (25).

Regarding radiological findings, we discovered a linear correlation between LSA values and prosthesis offset (r=0.64, P<0.001): higher LSA values where found in more lateralized RSA (group A); we detected a Linear Correlation between DSA values and acromion-humeral distance AHD (r=0.62, P<0.001): higher DSA values where found in more distalizated RSA.

LSA angle is a reproducible measurement to estimate implant lateralization, DSA is a reproducible measurement to estimate implant distalization. LSA and DSA angles showed negative linear correlation (r=-0,42, P<0.001): more distally the implant is placed, less lateralization is achieved. Mean LSA in group A was 92°±8.1, higher than in group B 81±5.4. Mean DSA in group A was 47°±6.9, lower than in group B 49±9. So, Inlay steam causes humeral distalization but Onlay steam causes less humeral distalization and more lateralization.

These values express how, biomechanically, Onlay prosthesis with its short stem, with curved metafisary grip, is able to lateralize the humerus more than Grammont traditional steam. This evidence is found in our study, on implants where the tray was placed medially (supero-lateral position): therefore it is evident that the design of the model itself gives greater lateralization in comparison with the traditional stem. Lädermann et al. (25) stated that eccentric tray position had a little influence with humeral offset only increasing by 1.8 mm when moving from "supero-lateral position" to "infero-medial position" and concluded that humeral offset is more affected by curved onlay steam design that by inclination (155° -145°) or tray position.

Inlay RSA provided in our study higher DSA values, that correlated with higer distalization (higer acromion-humeral distance): this arm lengthening didn't affect functional outcome.

In comparison to Boutsiadis et Al. study, we did not find significant positive correlation between LSA and Active External Rotation ($R^2=0,15$) and between DSA and Active Forward flexion ($R^2=0,04$) (28). In their study LSA and DSA measurements were correlated with post-operative AROM outcomes: LSA angles between 75° and 95° were correlated to better active external rotation and DSA angles between 40° and 65° resulted in better active forward flexion.

Onlay curved steam design also preserve tuberosity bone stock for eventually future prosthetic intervention, both proximally and distally; unlike traditional steams, curved design preserves greater tuberosity bone stock and short steam preserves distal canal bone stock: these features could be useful to plan RSA in patients younger than 65 years old, who are more likely to undergo to implants revisions (24, 29-31).

Although in literature intraoperative and perioperative complications occur in a high percentage of patients and long term outcomes are difficult to predict, during 1 year follow up none of the patients included in study developed specific complications as: local and systemic infections, aseptical implant components mobilization, residual pain, fractures, tuberosity reabsorbtion, dislocation, bleedings, nerve palsy, pulmonary embolus. A heparin prophylaxis was gave to all patients for 35 post-operative days.

In our study 3 patients in group B (14%) showed a low grade (grade 1 of the Sirveaux classification) of scapular notching six months after surgery but radiographic finding of inferior Scapular Notching did not correlates with worst functional outcomes in our series (26, 27).

Scapular notching has been attributed to a mechanical impingement of the humeral liner against the scapular neck when the arm is fully adducted. It can developed an osteolytic process as a result of wear debris of the polyethylene liner; the radiographic incidence increase with time and concerns between 49% and 70% of patients. It is now unknow if Scapular Notching really affects the function or lead to prosthesis mobilization (3, 11, 26, 27).

We concluded that our experience with SMR and Aequalis Ascend Flex RSA shows two safe and effective surgical options to resolve pain and restore the capacity to perform daily activities.

The major limitation of our analysis was represented by the small population evaluated in the present study (42 RSA). An another important limitation was represented by the short follow-up in the context of arthroplasty surgery. In particular Group A included more recents implants and we need to continuue follow-up to obtain more data, above all about complications, in order to be able to extend safely surgical indications to younger selected patients in the future.

In addition, all patients in this series were operated by the same arthroplasty shoulder surgeon (selection bias). We initially found some difficulty in comparing our data with those provided in literature by similar studies because we had found different and not always specified measurement methods for Active Range of Motion. To facilitate bigger metaanalysis, we suggest to follow the ISB recommendation on definitions of joint coordinate systems (20) and Green and Triplet measure for internal rotation (22, 23).

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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