ORIGINAL ARTICLE

Full-Polyethylene Glenosphere Reverse Shoulder Arthroplasty: Functional outcomes and notching rate at mid-term follow-up

Prothèse totale inversée de l'épaule à glénosphère en polyéthylène: Résultats fonctionnels et taux du conflit scapulohuméral à moyen terme

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Abstract

Introduction-Aim: Full-polyethylene glenosphere reverse shoulder arthroplasty (FP-RSA) known commonly as inverted-bearing concept utilizes a polyethylene glenosphere and metallic humeral liner. The aim was to assess mid-term outcomes of FP-RSA focusing on the incidence of scapular notching.

Methods: A retrospective analysis of 24 consecutive primary FP-RSA performed between 2017 and 2020 was conducted. At a minimum follow-up of 2 years, cases underwent clinical evaluation using Constant score (CS), Subjective Shoulder Value (SSV), American Shoulder and Elbow Score (ASES), pain assessment, range of motion (ROM) and radiological findings evaluating baseplate position, implant stability, and scapular notching.

Results: At a mean follow-up of 3.2 ± 0.6 years, all clinical parameters showed significant improvement except external rotation ($p < 0.05$). Scapular notching rate was 20.83% all grade1 and 2. High glenoid position ($p < 0.001$) was significantly associated with scapular notching, which is correlated with lower CS (69 ± 16 vs. 51 ± 19; $p = 0.049$), SSV (80 ± 15vs. 67 ± 22; $p = 0.026$), ASES (85 ± 16 vs. 71 ± 21; $p = 0.033$), and anterior elevation (147° ± 24°vs. 116° ± 38°; $p = 0.007$). The use of a large glenosphere compared to small glenosphere was associated with better CS (79 ± 10vs. 65 ± 19; $p = 0.006$), external rotation (21 ± 11°vs. 13 ± 9°; $p = 0.036$).

Conclusions: FP-RSA demonstrates favorable safety and efficacy at mid-term follow-up. Scapular notching, associated with high baseplate position, negatively impacts range of motion and clinical outcomes.

Key words: Rotator, Cuff, Reverse Arthroplasty, Outcomes

Résumé

Introduction-Objectif: La prothèse inversée de l'épaule à glénosphère en polyéthylène (FP-RSA) utilise un concept de roulement inversé avec une pièce humérale métallique et une pièce glénoïdienne en polyéthylène. L'objectif de cette étude était d'évaluer les résultats à moyen terme de la FP-RSA en se focalisant sur l'incidence du conflit scapulohuméral.

Méthodes: Une analyse rétrospective de 24 FP-RSA primaires réalisées entre 2017 et 2020 a été effectuée. Au recul moyen de 2 ans, les cas ont été évalués cliniquement en utilisant les scores de Constant (CS), SSV, ASES, l'évaluation de la douleur et l'amplitude articulaire. L'évaluation radiologique rapportait la position de la base, la stabilité de l'implant et le conflit scapulaire.

Résultats: Au recul moyen de 3,2 ± 0,6 ans, tous les paramètres cliniques ont montré une amélioration significative sauf pour la rotation externe ($p < 0,05$). Le taux du conflit scapulaire était de 20,83 %, tous de grade 1 et 2. Un positionnement élevé de la métaglène ($p < 0,001$) était significativement associée au conflit scapulaire qui est corrélé à un résultat fonctionnel diminué par rapport à ceux ayant un positionnement normal : CS (69 ± 16 vs 51 ± 19 ; $p = 0,049$), SSV (80 ± 15 vs 67 ± 22 ; $p = 0,026$), ASES (85 ± 16 vs 71 ± 21 ; $p = 0,033$), et une élévation antérieure (147° ± 24° vs 116° ± 38° ; $p = 0,007$). L'utilisation de glenosphère de grand diamètre était associée à CS plus satisfaisant (79 ± 10 vs 65 ± 19 ; $p = 0,006$) et à une meilleure rotation externe (21 ± 11° vs 13 ± 9° ; $p = 0,036$).

Conclusion: La FP-RSA montre une sécurité et une efficacité favorable à moyen terme. Le conflit scapulaire, associé à une position élevée de la métaglène, impacte négativement la mobilité et les résultats cliniques.

Mots clés: Coiffe, Rotateurs, Prothèse, Inversée, Résultats

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Introduction

Scapular notching is the most described complication following reverse shoulder arthroplasty (RSA), with reported rates ranging widely from 4.6% to 50.8% and up to 96% in several studies (1,2). Notching arises due to the altered biomechanics of shoulder joint created by RSA, which introduces a semi-constrained configuration. Based on causative factors, scapular notching can be classified into two categories (3): mechanical notching which results from contact between the humeral liner and the scapular pillar during specific movements such as adduction, extension, and external rotation (4); and (5) biological notching, characterized by a chronic foreign-body reaction triggered by the formation of polyethylene (PE) debris, leading to progressive osteolysis (5). Sirveaux classification (6) hypothesized that grades 1 and 2 primarily stem from mechanical notching, whereas grades 3 and 4, particularly when extending above the inferior screw, are likely attributable to biological processes (5). The clinical impact of scapular notching remains a topic of debate: some researchers argue that it does not affect functional scores (6-8) while others have linked it to poorer clinical outcomes (9-12).

Theoretically, Full-Polyethylene RSA (FP-RSA) seems reducing PE wear caused by contact between the PE humeral liner and the scapula in traditional designs (13) decreasing biological component of scapular notching.

The aim of this study was to report mid-term functional outcomes of FP-RSA focusing on the incidence of both low grades (1,2) and high grades (3,4) scapular notching.

Methods

We have reviewed retrospectively patients operated with FP-RSA between January 2017 and December 2020. Inclusion criteria were degenerative rotator cuff conditions including massive rotator cuff tears and osteoarthritis, full radiological findings and minimal 2 years of postoperative follow-up. Exclusion criteria were associated neurological conditions (stroke, Parkinson disease) and previous septic arthritis of the operated shoulder.

Surgical management

AGILON® FP-RSA were used in all procedures: metal baseplate included a central peg and possibilities of four screws fixation. The AGILON® stem, designed as an inlay with metaphyseal angle of 135°associated to metallic cap inverse standard and retentive in three sizes and three height increment. Six PE-glenospheres types according to diameter and eccentricity degree (36 mm neutral and eccentrical, 40 and 44 mm in eccentrical design with 2- and 3-mm increment (Figure.1).

Featuring a 40- or 44-mm diameter, aimed to enhance range of motion (ROM) and reduce polyethylene debris through an innovative design that includes an inversion of materials. This design feature includes eccentrical design with inferior sphere extension and superior narrowing to aid implantation and improve ROM. The implant is crafted from highly cross-linked polyethylene (X-UHMWPE) inserted on its metal baseplate already screw-fixed on reamed glenoid and is coupled with TiAl6 V4 acc. to ISO 5832-3 with TiN coatin liners cap inverse (Figure.2).

Figure 1. a) Agilon®RSA inverted bearing modular system, **b)** Metaphyseal cut angle 135°, **c)** FP-glenosphere design with peg, **d)** Eccentrical glenosphere design

Figure 2. a) Insertion of the guide wire central point of the glenoid, **b)** Preparing of the central peg tunnel after reaming glenoid, **c)** Fixation of base plate with 4.2 mm locked partial threaded cancellous screws, **d)** Impaction of FP-glenosphere on baseplate using head impactor, **e)** Final aspect of inverted bearing RSA with metal-PE coupling

The humeral stem was implanted with 0° of retroversion using a forearm ancillary guide with possible increasing length 30, 60, 120,180 and 240 mm in both cemented and cementless option.

Functional assessment

Pre and post operative clinical and radiological assessment were established according functional scores: Constant–Murley score (CS), Subjective Shoulder Value (SSV), American Shoulder and Elbow Surgeon (ASES) score, visual analogue scale (VAS), and range of motion (ROM) especially active anterior elevation (AE), external rotation (ER) in position 1, and internal rotation (IR) (Constant-Murley subcategory). All complications and revisions were meticulously documented.

Radiological assessment

At last follow-up, radiographical assessment was conducted using anteroposterior views of shoulder in neutral position and was performed by two senior orthopedic surgeons specialized in shoulder arthroplasty surgery. Concerning glenoid component, evaluation included position and presence of radiolucent lines (RLL). Loosening of the glenoid component was defined by progressive migration evidenced by shift, tilt, subsidence, or the presence of complete radiolucency ≥ 2 mm in each zone. On the humeral side, evaluation included assessment of humeral radiolucent lines (RLL) and loosening, as well as partial or total resorption of the greater tuberosity (GT), following criteria described by Melis et al (14). Inferior scapular notching was graded according to Sirveaux classification (15). The presence of pillar spurs and ossification within the scapular-humeral space was also recorded. Position

of the metallic baseplate relative to the glenoid's inferior border was reported: The distance from the scapular neck to the inferior glenosphere rim was an additional assessment of inferior positioning and degree of inferior glenosphere overhang. Baseplate inclination (prosthesis-scapular neck angle) was measured as the angle between the baseplate plane (line passing through the inferior and superior margins of the baseplate) and the supraspinatus fossa.

Statical analysis

For statistical analysis, the distribution of collected data was first examined using the d'Agostino-Pearson test. Depending on the distribution results, either a paired t-test or Mann-Whitney test was selected to determine statistical significance. Qualitative data comparisons were conducted using the Chi-square test or Fisher's exact test as appropriate.

All statistical analyses were carried out using Easy Med Stat software (Version 3.20; Amiens, France; www.easymedstat.com, accessed on 24 September 2022).

Results

Respecting inclusion-exclusion criteria, 24 cases were identified and assessed clinically and radiologically, with a mean follow-up of 3.2 ± 0.6 years. Sex ratio was 1.66 with 15 females (62.5%) and 9 males (37.5%). The mean age at arthroplasty surgery was 74 ± 5 years. Rotator cuff arthropathy was the most reported etiology in 14 cases (58.33%) however, primary osteoarthritis, massive cuff tear and fracture sequelae were respectively (6 cases) 25%, (3 cases) 12.5% and (1 case) 4.1%.

One patient developed a postoperative infection that required two-stage revision procedure. Involved bacteriological specimen was Propionibacterium Acnes with satisfied outcomes after revision. Additionally, one patient suffered from axillary neuropraxia, with partial recovery observed. There were no instances of loosening or component disassembly noted at the last follow-up.

Functional outcomes

At the last follow-up, functional scores and range of motion measurements showed improvement compared to preoperative values excepted external rotation: 13◦ ± 11◦ versus 16◦ ± 13◦ (0.054). CS (69 ± 19 vs 22 ± 14; p=<0.001), ASES (79 ± 21 vs 36 ± 24; p= <0.001), SSV (78 ± 17 vs 25 ± 29; p=<0.001), Pain (1.5 ± 2.1 vs 8.1 ± 1.7; p=<0.001), AE (151◦ ± 28◦ vs 62◦ ± 41◦; p= <0.001), IR (5.1 ± 2.4 vs 3.8 ± 2.3, p=<0.001).

For glenosphere size, Patients who received a 44 mm glenosphere (7 cases; 29.16%) demonstrated significantly better ROM compared to those who received a 40 mm glenosphere (11 cases; 70.83%) and 36 mm glenosphere (6 cases; 25%): AE: 151 ± 22◦ versus128 ± 31◦ (p=0.049), ER: 21 ± 11◦ vs 13 ± 9° (p=0.036), IR: 4.9 ± 3.1 vs 4.3 ± 2.4 (p=0.011). concerning CS, ASES, SSV and Pain score, glenosphere size does not interfere with no statical difference between groups (Table 1).

Table 1. Comparison functional outcomes Small FP-glenosphere (36,40 mm) versus Large FP-glenosphere (44 mm).

Outcome	Small FP-Glenosphere	Large FP-Gelenosphere	p Value
CS	65 ± 19	79 ± 10	0.006
ASES	75 ± 17	85 ± 12	0.206
SSV	73 ± 18	83 ± 15	0.141
Pain	1.7 ± 2.3	1.3 ± 1.4	0.062
AE (°)	128 ± 31	151 ± 22	0.049
ER (°)	13 ± 9	21 ± 11	0.036
IR (°)	4.3 ± 2.4	4.9 ± 3.1	0.011

FP-glenosphere (Full-polyethylene glenosphere), CS (Constant score), ASES (American Shoulder and Elbow Surgeon), SSV (Subjective Shoulder Value), AE (Anterior elevation), ER (External rotation), IR (Internal rotation).

Regarding impact of notching on functional outcomes, all functional scores were improved statistically excepted ER (18 ± 11◦ vs 14 ± 12°; p=0.151), IR (5.3 ± 2.8° vs 4.9 ± 3.9°, p=0.511) (Table 2).

Table 2. Comparison functional outcomes presence versus absence of scapular notching

Outcome	Scapular notch	No scapular notch	p Value
CS	51 ± 19	69 ± 16	0.049
ASES	71 ± 21	85 ± 16	0.033
SSV	67 ± 22	80 ± 15	0.026
AE (°)	116 ± 38	147 ± 24	0.007
ER (°)	14 ± 12	18 ± 11	0.151
IR (°)	4.9 ± 3.9	5.3 ± 2.8	0.511

FP-glenosphere (Full-polyethylene glenosphere), CS (Constant score), ASES (American Shoulder and Elbow Surgeon), SSV (Subjective Shoulder Value), AE (Anterior elevation), ER (External rotation), IR (Internal rotation).

In addition, regarding fixation of humeral stem, no difference has been revealed in functional scores and ROM comparing cemented to cementless stem: CS: 76 ± 11 vs 68 ± 15 (p=0.341) and short (less than 120mm) to long stem (more than 120 mm): CS: 77 ± 12 vs 73 ± 09 (p=0.217).

Radiological results

Analyzing glenoid component, radiolucent lines (RLL) less than 2 mm were observed in two cases (8.33%), while one case (4.16%) showed RLL ≥ 2 mm in a single zone, suggestive of progressive changes. Only one case (4.16%) with immediate postoperative subsidence of the baseplate due to incomplete glenoid preparation was diagnosed fortunately stabilized within the first months without progress further by the last follow-up (Figure 3a). Analyzing humeral stem, RLL less than 2 mm were observed in 4 cases (16.66%), primarily confined to position 4 in 3 of these cases. Partial resorption of greater tuberosity (GT) was observed in 3 cases (12.5%) and total resorption in one case (4.16%). Partial resorption of the calcar was noted in 2 cases (8.33%) and total resorption in 1 case (4.16%). Cortical narrowing in zones 2, 3 and 6 was present in 13 cases (54.16%), with 7 patients (29.16%) showing spot welds or condensation lines around the stem tip (Figure 3b).

Scapular notching

Scapular notching was observed in 5 patients (20.83%), with 3 cases (12.5%) classified grade 1 and 2 cases (8.33%) as grade 2. No instances of grades 3 or 4 notching were

documented. All cases exhibited bone spur formation at the scapular neck. Notching was significantly related to a high position of the baseplate, with cases of notching occurring in instances of high baseplate placement compared to only 1 case in low-position placements ($p < 0.001$). There was no significant difference in baseplate inclination observed between patients with and without notching respectively (12° ± 6° vs. 14° ± 7°, $p = 0.432$) (Table 3).

Patients with scapular notching showed a higher incidence of glenoid radiolucent lines (RLL) compared to those without notching (29.7% vs. 7.2%, $p = 0.037$). However, scapular notching was not associated with greater tuberosity (GT) resorption ($p = 0.624$) or calcar resorption ($p = 0.751$).

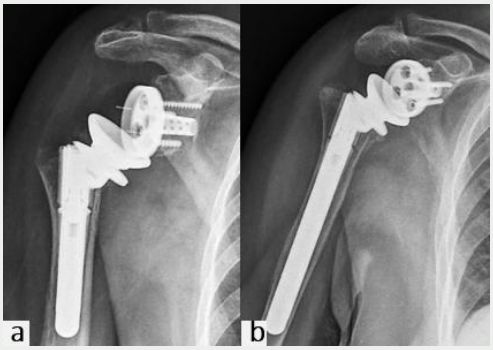

Figure 3. a) Last AP X-ray view with glenoid RLL<2mm, humeral RLL < 2mm in zone 3, complete greater tuberosity and calcar resorption, glenoid spur **b)** Last AP X-ray view with cortical narrowing in zone 2 and 3.

Table 3. Scapular Notching in Relation to Scapular Morphology and Implant Factors

Case	Glenosphere	Notching (mm)	Grade of Notch	Delay (month)	Inferior Glenosphere Overhang (mm)	Baseplate Position (mm)	Preop. Scapular Neck Angle (°)	Postop. Prosthesis-Scapular Neck Angle (°)
Case 1	Concentric	1.4	II	10	3.2	Flush	84	94
Case 2	Concentric	1.1	I	13	3.4	+2.2	113	119
Case 3	Concentric	1.3	I	11	2.2	+3.1	137	118
Case 4	Concentric	2.3	II	9	3.1	+2.4	92	84
Case 5	Eccentric	1.5	I	16	2.1	+2.5	103	104

Discussion

This study demonstrates that FP-Reverse Shoulder Arthroplasty (FP-RSA) is a safe and effective procedure without specific implant-associated complications at mid-term follow-up. Functional outcomes of FP-RSA seem to be equivalent to outcomes of standard RSA (15-17).

Scapular notching remains the most common complication at short and mid-term follow up (18). In our series, notching occurred in 20.83% of cases while this rate varying between 40–68% in traditional RSA systems using classic Grammont humeral stems with or without lateralized glenoid (19-21). Recently, Spiry et al. have shown a significant association between severe notching and late glenoid loosening (11). In response to these challenges, various solutions have been developed since the introduction of the classic Grammont design to mitigate this complication and enhance clinical results. Optimizing glenoid positioning is critical to minimizing notching (22-24). Additionally, lateralizing implants on both the glenoid and humeral sides have demonstrated a reduction in notching rates (24-26). While these approaches primarily address mechanical notching, an alternative solution is FP-RSA. This design features a polyethylene (PE) glenosphere and a metallic humeral liner (13, 22).

Notably, the notching observed in our study has distinct characteristics. In fact, no cases with notching higher than grade 2 were observed at this follow-up. According to literature, higher grade notching extending over the inferior screw likely results from a biological response to polyethylene particles and subsequent osteolysis (5,7). Besides, all cases with notching exhibited a bone spur on the scapular neck. Moreover, notching predominantly occurred in cases where the baseplate was positioned high, which is known to lead to mechanical contact between the prosthesis and the scapula (6,9,22,25). These features suggest that the notching observed in FP-RSA with a hard humeral liner is primarily mechanical in nature, indicating a distinct type of scapular notching that avoids polyethylene wear-induced osteolysis at mid-term follow-up. Similar findings have been reported by other authors using a different FP-RSA system (13).

Based on our findings, achieving optimal (as low as possible) and secure (optimal preparation of the subchondral bone) positioning of the glenoid is crucial to minimize scapular notching.

Further studies are warranted to analyze the long-term evolution of notching with FP-RSA and to determine if notching remains primarily mechanical or evolves to involve the central peg, potentially leading to loosening (13). Histological studies on retrieved implants would provide valuable insights into this phenomenon in vivo.

In contrast to findings by other authors (8,12,11), our series did not find a statistical difference in baseplate inclination between patients with and without notching. This discrepancy may be due to several factors, including the smaller number of patients in our study compared to others, the design of the glenosphere which includes eccentric type may compensate for slight variations in baseplate inclination and the belief that scapular notching is more influenced by the baseplate's inclination relative to the scapular neck (10) or intrinsic neck morphology (25) rather than its inclination relative to the supraspinatus fossa.

In this series, an interesting observation was that greater tuberosity (GT) and calcar resorption were not correlated with scapular notching, which contrasts with findings reported by Mazaleyrat et al. using standard bearing RSA (27). This discrepancy may be attributed to the reduced polyethylene wear-induced osteolysis associated with FP-RSA, potentially affecting proximal humerus resorption. The high incidence of humeral stress shielding observed

here is likely due to metaphyseal fixation of the stem, which is known to cause these radiographical changes (24-27).

Regarding the higher rate of glenoid radiolucent lines (RLL) among patients with notching, we speculate that this finding is influenced by 3 patients in this group who experienced early subsidence leading to non-progressive RLL and notching. However, further studies with longer follow-ups are needed to clarify the evolution of this observation.

The impact of scapular notching on clinical function remains controversial. Some authors have reported no significant influence on clinical function (3,4,6,10,18,22), while others have linked scapular notching to lower functional scores and reduced range of motion, especially in cases of severe notching (9,10,28). In our series, the development of notching significantly adversely affected functional scores and anterior elevation at mid-term follow-up. This negative impact is likely due to the mechanical nature of notching observed with this prosthesis, which is closely associated with improper high positioning of the glenoid. This leads to premature contact between the humeral component and the scapula and acromion, thereby restricting motion (25-26).

Overall, clinical scores and range of motion improved at mid-term follow-up and were comparable with other studies involving FP-RSA (13,29) or standard RSA (15-17). Particularly noteworthy was the finding that patients with a 44 mm diameter glenosphere exhibited significantly better external and internal rotation, higher Constant–Murley scores, and a positive trend towards better anterior elevation. Biomechanical studies have suggested that increasing glenosphere diameter can enhance range of motion (24,26,28). Clinically, some studies have reported similar improvements when using larger diameter glenosphere such as 42 mm or 44 mm (28,30). However, the use of larger glenosphere should be carefully considered, as technical constraints may limit their universal applicability.

Regarding complications, our study reported that only one patient required revision due to infection.

Strengths of this study include the prospective enrollment of all consecutive patients during the study period, uniform use of the same prosthesis and surgical technique across all cases, and evaluation by two well experienced shoulder-surgeons for clinical and radiographic assessments.

However, several limitations should be noted. Firstly, the study's retrospective nature introduces inherent biases. Secondly, the absence of a control group limits definitive conclusions about the observed outcomes. Future comparative studies comparing FP-RSA with standard RSA are necessary to confirm our findings. Thirdly, due to the relatively small sample size, definitive conclusions regarding complication and revision rates cannot be drawn. Lastly, important anatomical measures such as scapular neck angle, neck-shaft angle, and glenoid inclination were not measured in this study, which could potentially influence outcomes such as scapular notching.

Addressing these limitations in future research will provide further insights into the outcomes and complications associated with FP-RSA compared to standard RSA.

Conclusions

FP-Reverse Shoulder Arthroplasty proves to be a safe and effective procedure without specific implant-associated complications at mid-term follow-up. The use of a large glenosphere diameter, compared to small, or medium diameter, results in improved range of motion. The inversion of biomaterials in FP-RSA contributes to a distinct type of scapular notching characterized primarily by mechanical features, with no observed cases of grade 3 or 4 notching. Scapular notching is closely associated with a high position of the baseplate and negatively impacts range of motion and clinical outcomes. These findings underscore the importance of precise surgical technique, particularly in achieving optimal glenoid positioning, to minimize complications such as scapular notching and maximize functional outcomes in patients undergoing FP-RSA.

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