Abstract

Background: Primary shoulder arthroplasty can significantly improve quality of life; however, the glenoid baseplate remains the most common component to loosen, which may result in implant failure and subsequent revision surgery. Radiostereometric analysis (RSA) is considered the gold standard for accurate measurement of micro-motion between implant and bone. The aims of this study were to compare migration of the Lima SMR porous titanium hydroxyapatite (HA) coated and non-hydroxyapatite (non-HA) coated glenoid components through a prospective, randomised two-arm trial using RSA, whilst also comparing clinical and functional outcomes.

Methods: Twenty patients were randomised into two equal (HA and non-HA coated) groups with all patients undergoing primary anatomic shoulder arthroplasty, at which time tantalum beads were also inserted. RSA imaging was performed immediately post-operatively, then at 3, 6, 12- and 24-months post-procedure. These images were digitised and analysed using model-based RSA software. All patients completed Oxford Shoulder Score (OSS), American Shoulder and Elbow Surgeons (ASES) score, Constant Score (CS) and Visual Analogue Scale (VAS) pain scores pre-and post-operatively at the aforementioned time points. Unpaired t-tests were used for clinical outcome data; Mann-Whitney U tests were used for RSA data. Significance levels were set at $p < 0.05$.

Results: Mean age for the HA group was 72.3 years; 69.5 years for the non-HA group. Mean follow-up for both groups was above 36 months. No significant differences in glenoid migration were observed at each of the post-operative time points; the only exception being at 12 months (non-HA group displaying significantly greater rotation in the z-axis). The HA group displayed fractionally more translation in the x- and z-axes at all time points (not significant). Rotation in the z-axis was marginally greater at all post-operative time points in the non-HA group. Median total migration values revealed greater motion for the non-HA group at 3, 6 and 12 months (not significant). All clinical outcome measures improved significantly within each group; no statistical differences were observed between the groups for any outcome measure. One patient in each group underwent revision surgery to reverse shoulder arthroplasty due to unexplained pain (HA group) and cuff failure (non-HA group) only. Radiolucent lines were noted in two patients who are still under follow up.

Conclusion: This study has revealed promising early results of both HA coated and non-HA coated implants, however, hydroxyapatite coating of glenoid components does not significantly improve outcome scores nor provide extra stability compared to non-hydroxyapatite coated implants at 2 years post-procedure.

Level of Evidence: Level II; Randomised Controlled Trial

Keywords: Radiostereometric analysis, metal-backed glenoid, hydroxyapatite, total shoulder arthroplasty, glenoid migration.

Introduction

Primary shoulder arthroplasties have been successfully undertaken for over 40 years in the UK and have become increasingly more common with almost seven thousand performed in 2018.[1] It has been shown to be a successful operation that can significantly improve quality of life.[2,6,10,11] The glenoid baseplate remains the most common component to loosen in anatomic shoulder replacements,[5,8,10] and aseptic loosening of the glenoid component remains a common cause of implant failure and subsequent need for revision surgery.[22]

Whilst metal glenoid components have been used in reverse shoulder arthroplasty since its inception,[9] there have been mixed outcomes demonstrated in the literature in anatomic replacement, with questions raised over the long-term survivorship despite their potential to enhance bony integration.[4] However, more recently the design of metal-backed glenoid components for anatomic shoulder replacements has been improved with the aim of encouraging long term fixation and reducing the incidence of glenoid component loosening.[5] Currently there are a number of designs and coatings. The prostheses in this study are from the Lima SMR modular shoulder system. There are two variants of the metal-backed baseplate on the market; both have a porous titanium surface, with one variant also having an additional hydroxyapatite (HA) coating. Both have the same thickness and mechanical properties, however the non-coated version (FDA approved) has higher porosity due to larger grain size than the model with HA coating (currently only approved for use in Europe) (Fig. 1).

Radiostereometric analysis (RSA) was developed by Goran Selvik in 1974.[15] Our institution has an established background of undertaking clinical and scientific RSA studies and has published many papers in this field. The RSA technique is considered the gold standard for accurate measurement of micro-motion between implant and bone[18] and is well established for assessing implant migration in shoulder arthroplasty.[12,13] Previous studies have shown that all replacements move following insertion.[17,20] It is believed that any continuing migration is highly predictive of loosening and subsequent failure.

The primary aim of this study was to compare migration of the Lima SMR porous titanium hydroxyapatite coated (HA) and non-hydroxyapatite (non-HA) coated glenoid components through the use of a prospective, randomised two-arm trial assessing glenoid component migration using RSA over a 2-year period. Secondary aims were to compare clinical and functional outcomes and survival between the two groups. Identification of any complications and adverse events were also noted. We hypothesised that the HA coated group would migrate less and have superior clinical outcomes than the non-HA coated group.

Materials and methods

The study was undertaken in a single unit in the North West of England which specialises in shoulder arthroplasty. Ethical approval was provided by the local ethics committee (ref no: 13/NW/0357) and was sponsored and funded by Lima (Lima Corporate, Italy).

From 2013 to 2017, all patients awaiting primary anatomic shoulder arthroplasty were approached and asked to participate in the study. Written informed consent was obtained from all study participants. Consenting participants were randomised using a 1:1 ratio. The allocation sequence was prepared with an online random number generator and concealed in sealed opaque envelopes with group allocation revealed to the surgeon at the time of surgery. Prior to surgery all patients had undergone a CT scan and an evaluation of the glenoid morphology and wear pattern using the Walch classification.[21] None of the patients in the study required any form of glenoid augmentation, specifically bone graft.

Surgical technique

All surgery was undertaken by the senior authors in an identical fashion. Patients were placed in the beach chair position and a deltopectoral approach was undertaken. None of the patients had a deltoid release although most had a partial release of the pectoralis major at its insertion. All patients had both an anterior and posterior capsular release dependent on the degree of contracture.

Glenoid and humeral preparation was undertaken as per the manufacturer's recommendations. The Lima SMR Arthroplasty system (Lima, Italy) was used in all cases. The correct glenoid size was chosen to centre the glenoid component, yet allow for full 360° support. The glenoid was then reamed with the appropriately sized reamer down to, but not through, the subchondral bone. The glenoid was then prepared to accept the central peg. All instruments used were cannulated. In no instances was the glenoid vault perforated. The true glenoid component was then inserted and fixed with two 6.5mm screws at 12 and 6 o'clock.

The humeral shaft was then prepared to accept the appropriately sized implant, again as per the manufacturer's recommendations. All humeral components were inserted uncemented in 30° of retroversion using a cutting guide. A humeral head size was trialled for best fit allowing full range of motion and mirroring the resected head. Following insertion of the implant the subscapularis was repaired in all cases; a biceps tenotomy was also performed. In all cases the rotator cuff was intact.

Post-operatively, patients began mobilisation between 24 and 48 hours after surgery; the only restriction being external rotation up to 30° for the first 3 weeks.

Radiostereometric imaging

During the index procedure, 5-6 tantalum beads (measuring 1mm in diameter) were inserted in a standard pattern in the glenoid, coracoid process and acromion using the UmRSA bead injector (RSA Biomedical). Figure 2 demonstrates the different bead positions.

Patients were followed up at regular post-operative intervals with RSA imaging performed immediately post-operatively, then subsequently at 3, 6, 12- and 24-months post-procedure. Stereo pairs of radiographs were obtained by use of the uni-planar UmRSA table (Cage 43, RSA Biomedical EUMEA, UMEA, Sweden). The radiographs were then digitised, anonymised and analysed by use of model-based RSA software (MBRSA; RSAcore, Leiden, Netherlands) using standard computer-aided design (CAD) models provided by Lima and converted by RSAcore. Double examinations were not undertaken for this study as we did not have ethical approval due to the increased radiation dose to the patient. The UmRSA system pre-defines linear movement as translation along the transverse (x-axis, medial/lateral translation), longitudinal (y-axis, proximal/distal translation), and sagittal (z-axis, anterior/posterior translation) axes. Similarly, rotation is defined about the transverse (x-axis, anterior/posterior), longitudinal (y-axis, anteversion/retroversion) and sagittal (z-axis, varus/valgus) axes (Fig. 3). Also measured was maximum total point movement (MTPM), which represents maximum movement of the glenoid component in relation to a fixed bone segment at any given time.

Clinical assessment

All patients completed Oxford Shoulder Score (OSS), American Shoulder and Elbow Surgeons (ASES) score, Constant Score (CS) in addition to Visual Analogue Scale (VAS) pain scores pre-operatively and at 3, 6, 12- and 24-months post-operatively. Patient records were also reviewed for any complications or revision surgery.

Statistical analysis

Clinical outcomes were examined by the use of an unpaired t-test on pre-operative and post-operative measures. Non-parametric statistics were used for all RSA data; the Mann-Whitney U test was used to compare pre- and post-operative RSA migration data between the 2 groups at each follow-up interval. For all comparisons, we considered results to be significant at $p < 0.05$.

Results

Thirty-two patients were randomised into 2 groups (HA and non-HA coated). Twelve patients, however, were excluded from the final analysis for various reasons (incomplete data, withdrawal from study, and technical issues with RSA assessment), but were still followed up clinically. As a consequence, ten patients were left in each group. Demographic data for the 2 groups is summarised in table 1.

Radiostereometric analysis

The relative movement of the glenoid component with the rigid body model formed by the scapular bead markers was measured. The upper limit of the mean error of rigid body fitting was set at 0.35mm and series where the condition number (spread of beads forming the rigid body) exceeded 160 were excluded. Computer-assisted design models matching the specific size of glenoid component implanted into the patient were applied in the software to enable migrations to be calculated. Due to the small group numbers, normality tests were obtained on the group values and it was found that the data did not follow a normal distribution and therefore non-parametric analysis using medians and Mann-Whitney U test was used to analyse the data.

Overall, no significant differences were observed between HA coated and non-HA coated groups at each of the post-operative time points; the only exception being at 12 months post-operatively where a statistically significant difference was observed in median rotation values in the z-axis, with the non-HA group being higher than those for the HA coated group (p=0.020) (Fig. 4-9).

From the graphs, it can be seen that the HA-coated group displayed fractionally more translation in the x- and z-axes at all time points compared to the non-HA coated group (not statistically significant with $p>0.05$ at all time points). Rotation in the z-axis however, was slightly greater at all post-operative time points in the non-HA coated group with the aforementioned statistically significant difference observed at 12 months (Fig. 9).

Median MTPM values revealed greater motion for the non-HA coated implants at each of the 3, 6 and 12-month post-operative time points (Fig. 10). At final 24-month follow up however, there were no statistical differences observed at any post-operative time points.

Clinical analysis

Evaluation of pre-operative CT scans (table 1) highlighted no substantial baseline difference in glenoid morphology[21] between the two groups with four participants having B2 glenoids in the HA coated group and three in the non-HA coated group. All of these were addressed via eccentric reaming; none were greater than 15 degrees retroverted. No augments were used in any patients.

There were no statistically significant differences between the two patient groups either pre-operatively or post-operatively in any of the outcome measures studied (table 2). Statistically significant improvements were noted from pre-operative scores to final follow-up scores in all outcome measures for each group.

Eight of the 10 patients in the HA coated group were both pain-free and displayed full range of motion at 2-year follow-up (range of motion was not measured formally in this study, however, clinical assessment of these patients revealed full and equal range of motion comparable to the contralateral upper limb). Two patients were pain-free, however full range of motion had not been achieved.

Of the ten patients in the non-HA coated group, 9 were pain-free and demonstrated full range of motion at 2-year follow up; the final patient in this group was pain free at 2 years, however, had a fall during the rehabilitation period resulting in an avulsed lesser tuberosity. This went on to uneventful union although the patient was left with some restriction in movement.

One patient in each group eventually underwent revision surgery. In the non-HA coated group, one patient sustained the aforementioned lesser tuberosity avulsion during the rehabilitation process; this was revised to a reverse geometry shoulder replacement after four years due to superior cuff failure (no glenoid loosening evident on radiographs). In the HA coated group, one patient required revision to a reverse prosthesis due to unexplained pain only, with no radiographic evidence of glenoid loosening.

Of those twelve patients excluded from the study initially, all are doing well clinically and there have been no complications or revisions to date.

Radiolucent lines were noted in two patients. One patient with a B2 glenoid in the HA coated group had a radiolucent line around the central glenoid peg on 12-month post-operative radiographs. This was found to be non-progressive on serial CT scans and has not been revised to date. A further patient in the non-HA coated group developed a radiolucent line around the central peg at 24-month post-operative radiographs and is still under follow-up at the time of writing.

Oxford Shoulder Scores, CS, ASES scores, as well as VAS pain scores all improved significantly within each group at the end of 2-year follow up; no statistical differences were observed between the groups for any outcome measure at 2-year follow up (table 2).

Discussion

This study aimed to assess the migration of the Lima SMR HA and non-HA coated metal-backed glenoid components in a sample of patients undergoing total shoulder arthroplasty. To the best of the authors' knowledge, this study is the first to look at such glenoid components using RSA analysis.

No statistically significant differences were identified between HA coated glenoid components and non-HA coated implants in relation to any of the outcome measures studied when compared at two-year follow-up (table 2). Significant improvements were, however, noted within each group when pre- and post-operative outcomes scores were compared. Radiostereometric analysis demonstrated no measured statistical differences in translation and rotation across both groups, apart from at 12 months post-operatively where a statistically significant difference was observed with non-HA coated glenoid implants showing a median increase in rotation as compared with HA coated implants in the z-axis only (p=0.020). Therefore, our study hypothesis was not confirmed.

There were no statistically significant differences in MTPM glenoid motion between the two groups at any time point. Accuracy and precision testing of the system was not performed as part of this study. However, on previous tests at our institution, and from data presented in other studies, generally these values range from 0.22mm to 0.47mm translation accuracy and 0.92 to 1.56 degrees rotation accuracy, and 0.18mm translation and 0.96 degrees rotation precision for the glenoid component.[17] The symmetry of glenoid implants is known to create a source of error, particularly in rotational migrations in RSA measurements along with the small dimensional differences between the original implant and the CAD model.[19]

The early rotational movements observed in this study demonstrate similarities to those found by Nuttall et al.[12] In twenty patients undergoing shoulder arthroplasty using cemented polyethylene glenoid implants, the highest maximum total point movement at 24 months was 2.57mm for keeled components and 1.64mm for pegged components, whereas the largest rotation was anteversion (y-axis), with mean values of 5.5° for keeled components and 4.8° for pegged components. The present study saw the greatest translational movement occur in the z-axis (figure 6) and largest rotational movements occur in the x- and z-axes (figures 7 and 9, respectively); an explanation for this is the symmetrical nature of the glenoid implants.

Streit et al[16] assessed polyethylene glenoid component motion in eleven patients using RSA analysis over a 3-year period. At a mean of just over fifty months, there were statistically significant improvements in outcome scores (ASES and VAS pain scores) and range of motion at final follow-up. Radiolucent lines were detected around 5 components which reflected the high levels of rotational motion demonstrated in the associated RSA data. The greatest rotation was observed in the z-axis with a mean of 3.31º. Although the current series looked at metal-backed glenoid components and has a shorter mean follow-up time of less than forty months, significant improvements were similarly noted amongst the 4 outcome measures studied, with only 2 of the components noted to have radiolucent lines at final 2-year follow up.

In a further study by Gascoyne,[7] where pegged and keeled all-polyethylene glenoid components were assessed in 16 patients using RSA analysis, statistically greater coronal plane migration was discovered in keeled glenoid implants at 12 and 24 months. Functional outcome scores did not differ significantly between the groups at any follow-up. One patient with a keeled glenoid showed high component migration after 24 months and subsequently required revision surgery 7 years post-operatively. No implants in our series to date have required revision surgery due to glenoid component loosening.

Radiolucent lines around glenoid implants are always concerning for implant loosening and subsequent failure, necessitating revision. A systematic review by Papadonikolasis and Matsen[14] discovered that the rates of radiolucent lines and radiographic loosening were lower amongst metal-backed glenoid implants (34.9% and 16.8%, respectively) compared to all-polyethylene glenoid components (42.5% and 21.1%, respectively). However, the rate of revision was more than three times greater with metal-backed components, at a mean of six years post-surgery (14.0% vs 3.8%). The main indication for revision of all-polyethylene glenoid components was component loosening, however those for metal-backed components was more variable including component fracture and dissociation, screw breakage, polyethylene and metal wear, and rotator cuff tear. The current study revealed 2 instances where radiolucent lines could be observed on follow-up radiographs. Neither has required early revision surgery thus far, however further follow-up will be essential to observe their progression.

Boileau[3] reported an increased presence of peri-prosthetic radiolucent lines around polyethylene components when compared to metal-backed glenoids. However, peri-prosthetic radiolucent lines around metal-backed glenoids were progressive and resulted in a higher incidence of loosening, ultimately requiring revision surgery in 3 cases. As stated above, none of the patients in our series have been revised for glenoid loosening. This could be explained by differences in glenoid component design and fixation. Longer term complications, such as polyethylene wear and rotator cuff failure, however, were not the focus of this piece of research.

With regard to patient demographics, the mean age across both groups in this study was representative of the population undergoing primary anatomic shoulder arthroplasty in the UK, where 38% of those undergoing the procedure are aged between 65 and 74 years. The study did however, have a much greater proportion of left sided procedures (16 of all 20 patients) compared to the national data, where left sided arthroplasties accounted for 48% of all procedures.[1] We do not, however, believe this had any adverse effect on our results.

Cost implications of coating the backside of a metal-backed component with hydroxyapatite is also of relevance. Given that the results in this study have shown no benefit with regard to migration/early loosening, the authors conclude that this application is unnecessary. Consequently, this should result in some cost saving.

Although this study highlights some important findings, there are some limitations. The first is patient participation and withdrawal, with twelve patients not completing the study following randomisation. It should be noted however, that this is not uncommon in studies of this nature (due to various potential technical issues), and the authors believe 10 patients in each group is sufficient to draw valid conclusions. We are also aware that our follow-up is short. We do, however, believe that our data, as at other institutions, can be extrapolated and indicate that there is no difference between HA coated and non-HA coated implants. Finally, other potential complications such as polyethylene wear and rotator cuff failure have not been addressed.

Conclusion

This study has revealed promising early results of both the Lima SMR HA coated and non-HA coated glenoid implants with no significant differences noted between the two groups when clinical outcome measures were compared. No significant differences were identified in glenoid migration between the groups, apart from an isolated occurrence in rotation at 12 months in the z-axis. We do not believe this to be noteworthy. As a consequence, hydroxyapatite coating of glenoid components does not significantly improve outcome scores nor provide extra stability compared to non-hydroxyapatite coated implants at 2 years post-procedure.

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Figure and Table Legends

Figure 1 - Lima HA coated (left image) and non-HA coated glenoid implants (reproduced with permission)

Figure 2 - Tantalum bead positions used for RSA

Figure 3 - Axes of translation and rotation

Figure 4 - Median translation in the x-axis in both groups, along with *p* value at each time point

Figure 5 - Median translation in the y-axis in both groups, along with *p* value at each time point

Figure 6 - Median translation in the z-axis in both groups, along with *p* value at each time point

Figure 7 - Median rotation in the x-axis in both groups, along with *p* value at each time point

Figure 8 - Median rotation in the y-axis in both groups, along with *p* value at each time point

Figure 9 - Median rotation in the z-axis in both groups, along with *p* value at each time point

Figure 10 - Mean Total Point Motion (MTPM) translations (median values) across both groups, along with *p* value at each time point

Table 1 - Demographic data for the 2 groups

Table 2 - Mean ± standard deviation pre- and post-operative outcome scores, along with *p* values between and within groups