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Medium-term outcomes following Mathys Affinis Short stemless anatomic total shoulder replacement: clinical and radiologic findings (minimum 5-year follow-up)

James Edward Dixon, MBChB, MRCS*, Iain Alexander Rankin, MBChB, PhD, FRCS(Tr&Orth), Nadia Claire Sciberras, MD, FRCS(Tr&Orth), Lukman Ahmed Kashif Khan, BSc, MSc, MBChB, FRCS(Tr&Orth), Scott Lawson Barker, MBChB, FRCS(Tr&Orth), David Andrew Cairns, BSc, MBChB, FRCS(Tr&Orth), Kapil Kumar, MBBS, FRCS(Tr&Orth)

Orthopaedic Department, Woodend General Hospital, Aberdeen, Scotland

Background: Stemless anatomic total shoulder arthroplasty (aTSA) use has increased in recent years. Despite evidence to suggest good midterm results at 2-year follow-up, there is a scarcity of evidence for longer-term follow-up. This study aimed to investigate outcomes at a minimum of 5 years postoperatively following primary stemless aTSA.

Methods: An observational cohort study using prospectively collected data was performed for all patients who underwent a Mathys Affinis stemless aTSA procedure at our institution. The study period ranged from July 2010 to August 2018 (minimum 5-year follow-up). Clinical outcome measures included revision rate, range of motion, and patient-reported outcomes (Oxford Shoulder Score and Numerical Satisfaction Score). Radiologic outcome was an assessment of radiolucency using Lazarus grading.

Results: A total of 105 stemless TSAs were implanted during the trial period. Following exclusions, 75 aTSAs were included in the final cohort for analysis of 5-year outcomes. Five patients underwent revision (4.8%), and the median follow-up time was 6.1 years. The median age was 69 years, and 81% were female. The Oxford Shoulder Score showed a range of 18-48, with a median score of 47. Satisfied or very satisfied was selected in 94.4%. Median range of motion assessments showed forward elevation 160°, abduction 150°, and external rotation 40°, and mode internal rotation was to the lumbar spine. No glenoid lucency was present in 79.7%. There were 9.5% with Lazarus grade 1 lucency, 5.4% with Lazarus grade 2, and 5.4% Lazarus grade 3. No humeral lucency was observed.

Conclusions: This cohort study represents the largest minimum 5-year follow-up data for the Mathys Affinis stemless anatomic total shoulder arthroplasty, demonstrating excellent clinical and radiologic outcomes.

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*Reprint requests: James Edward Dixon, MBChB, MRCS, Orthopaedic Department, Woodend General Hospital, Eday Rd, Aberdeen AB15 6XS, Scotland.

E-mail address: james.dixon@nhs.scot (J.E. Dixon).

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The articular replacement of the humeral head was first pioneered in 1955 by Charles Neer. This hemiarthroplasty was achieved with a stemmed humeral component, initially used in the treatment of fractures of the proximal humerus.[25] In 1974, Neer pioneered glenoid resurfacing to achieve the first total shoulder arthroplasty (TSA).[24] During the last 50 years, the design of the anatomic TSA (aTSA) has evolved progressively with changes to modularity, humeral stem design, and glenoid design.[11]

Key threats to the longevity of aTSA are rotator cuff failure and aseptic glenoid loosening.[8] However, complications related to the humeral component are not uncommon.[16] Humeral complications include fracture, bone loss, stem loosening, stress shielding, and limitations in restoring native anatomy of humeral head orientation.[5,10]

In an attempt to reduce these humeral component–related complications, design innovation within the past 20 years has gradually shortened the humeral stem. TESS (Biomet Inc., Warsaw, IN, USA), the first stemless aTSA, was designed in 2004 and showed promising radiographic and clinical results.[16] Proposed advantages of the stemless design are decreased operative time,[14] decreased blood loss,[8] reduced stress shielding,[28] bone preservation,[16] and improved implant positioning.[26] Concerns regarding the stemless TSA persist in regard to instability and implant loosening, because of the metaphyseal fit of the anchor within the cancellous bone, compared with the cortical fit of a traditional stemmed implant.[15]

Given the early success of the stemless aTSA, there are now multiple manufacturers offering stemless designs, although there are inherent differences between the implants available.[7] The Affinis Short (Mathys Ltd, Bettlach, Switzerland) arthroplasty system is classified as a stemless implant by the National Joint Registry because the fixation is metaphyseal with no diaphyseal extension.[23]

The Affinis Short humeral implant is made up of 2 components, metaphyseal and articular (Fig. 1). The metaphyseal component has a 4-winged anchor composed of calcium phosphate–coated porous titanium. This calcium phosphate coating promotes osseointegration. The metaphyseal implant is cementless with an impaction implantation.[17] The articular component of the humeral implant is made up of an anatomically shaped ceramic head.[18]

There is published evidence of good midterm results for the Mathys Affinis Short. McMillan published minimum 2-year clinical and radiologic follow-up in 72 TSAs, demonstrating excellent clinical results: a mean Oxford Shoulder Score (OSS) of 45 of 48 and a mean patient satisfaction score of 4.93 of 5. No humeral lucencies were observed.[23]

Jordan et al[17] followed up 207 patients following implantation of the Affinis Short TSA. They demonstrated clinical improvement at 48 months postoperatively, and radiologic evaluation revealed radiolucencies in 2.7% of humeral zones and 14% of glenoid zones at 48-month follow-up. A further study retrospectively investigated 136 Mathys Affinis total shoulder arthroplasties with a mean follow-up of 3.7 years and found good clinical results, with a mean OSS of 43. Radiologically, humeral lucency was seen in 1%, glenoid lucency in 15.2%, and radiologic rotator cuff failure in 22 cases (22.2%).[18] Longer-term outcomes were analyzed in 82 patients following stemless TSA showing 10-year survival of 91.5%.[22] However, this was using the Total Evolutive Shoulder System (TESS; Biomet, USA).

There is a scarcity of evidence demonstrating outcomes at 5 years and beyond. Our study aimed to look at minimum 5-year follow-up for patients who underwent stemless aTSA with the Mathys Affinis, to investigate radiologic and clinical outcomes at midterm follow-up. In addition, we assessed the revision rate and 5-year survivorship.

Methods

This study is an observational cohort study using prospectively collected data of all patients who underwent a stemless Affinis TSA from July 2010 to August 2018 that were performed at a single tertiary referral center, with patients traveling from a large geographical area in order to receive treatment.

Patients with symptomatic end-stage arthritis of the glenohumeral joint were considered for stemless aTSA. The severity of arthritis was graded using the Kellgren and Lawrence classification system.[19] Nonoperative management was initially pursued in the form of analgesia and physiotherapy, with or without intra-articular steroid injection. Surgery was considered when conservative measures failed. In patients with intact rotator cuff function, aTSA was offered. If there was a clinical concern of rotator cuff incompetence, then further imaging was carried out, either ultrasonography or magnetic resonance imaging. All patients underwent plain radiography. Further imaging in the form of computed tomography was carried out when there were concerns about glenoid bone stock or glenoid retroversion. Preoperative planning software was not implemented in our unit during the study period.

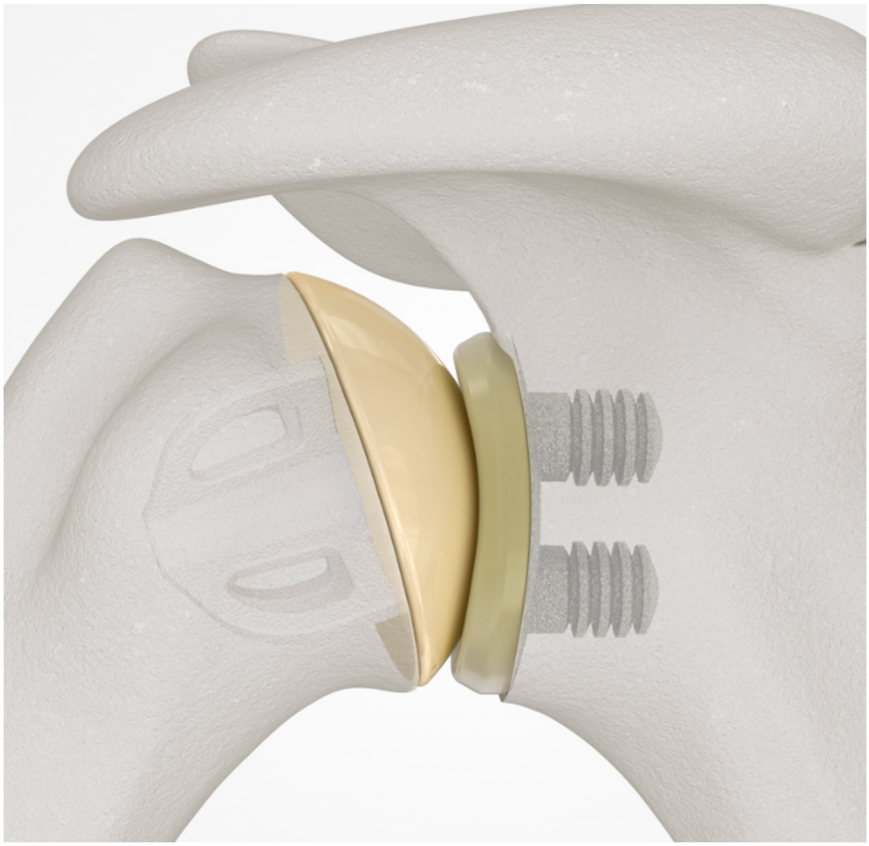

Figure 1 Mathys Affinis Stemless anatomic total shoulder.[1]

Routine follow-up in our unit consists of clinic review at 6 months, 1 year, and annually thereafter. Exclusion criteria included any patients lost to follow-up resulting in a lack of minimum 5-year data.

Surgical technique

Patients were operated by one of 4 fellowship-trained shoulder surgeons, using a deltopectoral approach with the patient in beach chair position. Access to the joint was gained via either a subscapularis tenotomy or a lesser tuberosity osteotomy. An intraoperative assessment of rotator cuff integrity was performed; no patients were converted to a reverse total shoulder arthroplasty (rTSA) . The humerus was sized and prepared in the standard fashion. Following standard glenoid exposure, sizing, and preparation, the definitive glenoid component was inserted using pressurized Optipac Refobacin Bone Cement (Biomet Merck, Darmstadt, Germany). The definitive humeral component was implanted using a press-fit technique. The shoulder was then reduced and an assessment of stability was performed. Subscapularis repair was performed using transosseous FiberWire (Arthrex, GmbH, Munich, Germany).

Postoperatively, all patients were immobilized in a sling for 3-4 weeks. Physiotherapy was commenced postoperatively either on the day of surgery or postoperative day 1.

Clinical outcomes

At follow-up, patients had functional evaluation via range of motion, which was assessed visually using the ability to lift the arm directly above the head as 180°. Patient-reported outcomes (PROMs) questionnaires were sent out to patients routinely. PROMs were assessed using the Oxford Shoulder Score (OSS), a validated widely used outcome score in the United Kingdom.[32] Additionally, a patient satisfaction score (numeric rating scale 0-5, with 0 = dissatisfied and 5 = very satisfied) was used in all patients as part of PROMs monitoring.

Radiographic outcomes

Radiographic assessment was carried out based on true anterior-posterior glenoid view and axillary lateral view. Humeral radiolucency was assessed using the Bell modification of the Lazarus score; this is a technique derived to assess this implant specifically.[3] Glenoid radiolucency was assessed using the Lazarus score.[21] The zones for radiolucency in these techniques are demonstrated in Figure 2. The Lazarus grading criteria is shown in Table I. Radiolucency was assessed by 2 independent reviewers (I.R., N.S.). A κ coefficient was calculated to assess interobserver reliability. Linear regression analysis was used to identify any association between radiolucency and PROMs, ROM, and Satisfaction.

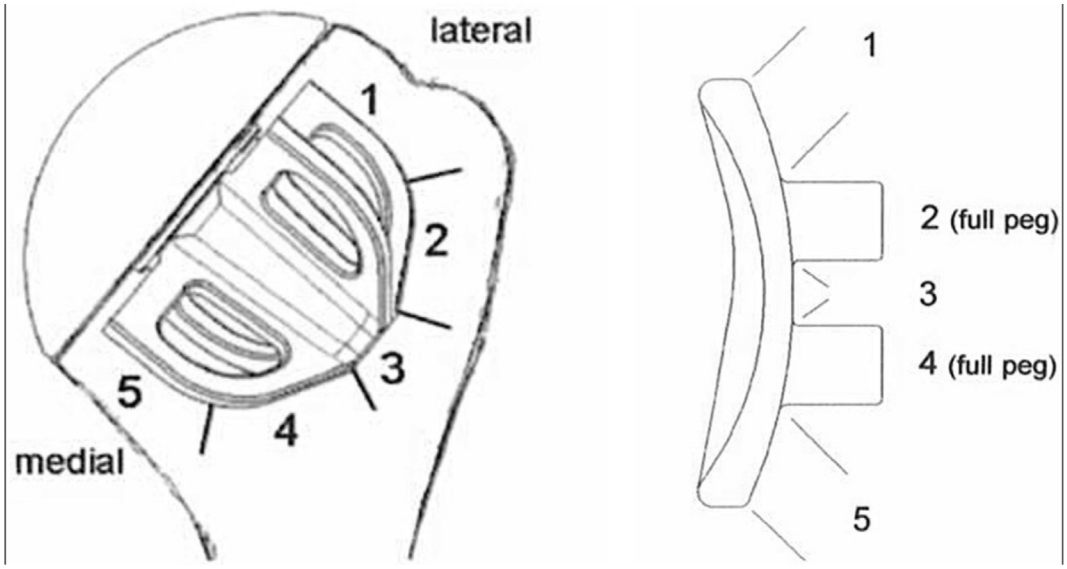

Figure 2 Humeral and glenoid zones for radiolucency assessment.[23]

Table I Criteria for radiolucency grading around pegged glenoid components[21]

Grade	Finding
0	No radiolucency
1	Incomplete radiolucency around 1 or 2 pegs
2	Complete radiolucency (≤2 mm wide) around 1 peg only, with or without incomplete radiolucency around 1 other peg
3	Complete radiolucency (≤2 mm wide) around ≥2 pegs
4	Complete radiolucency (>2 mm wide) around ≥2 pegs
5	Gross loosening

Revision analysis

Patients who underwent revision procedures during the trial period were identified. For patients who moved out of area, Scottish picture archiving and communication system (PACS) was used to identify revisions performed elsewhere in the country. However, patients who moved abroad were excluded from analysis. Kaplan-Meier survivorship curves were calculated as well as the cumulative revision rate over time.

Statistical analysis was performed using SPSS, version 29 (IBM Corp., Armonk, NY, USA).

Results

A total of 105 stemless aTSAs were implanted into 91 patients in the study period. The left shoulder was replaced in 42 cases, and the right shoulder was replaced in 63. Fourteen underwent bilateral TSA. Some patients were lost to follow-up because they moved out of area (4 patients), had died (7 patients), had dementia (5 patients), did not attend (8 patients), or were physically too unwell to attend (2 patients) were excluded. Furthermore, 4 patients were revised before 5 years (included in revision analysis but not 5-year follow-up outcome measure scores), which resulted in a total of 30 cases being excluded from the initial sample of 105.

Seventy-five stemless aTSAs (in 64 patients) were included in the final analysis of 5-year outcomes including ROM, OSS, and radiographic assessment. Sixty-one patients were female, the median age was 69 years (range 53-83 years), and the average body mass index was 30 (range: 18-42). The average American Society of Anesthesiologists (ASA) score was 2 (Table II).

The most common indication for surgery was osteoarthritis (67 patients, 89%), followed by rheumatoid arthritis (5 patients, 7%) and avascular necrosis (2 patients, 3%). One patient had a previous fracture managed with proximal humerus open reduction and internal fixation later complicated by post-traumatic arthritis. Thirty-five patients underwent a magnetic resonance imaging or ultrasonography preoperatively, of which 28 patients had some evidence of tendinopathy.

Length of stay ranged from 1 to 6 days, with a median of 3 days. Follow-up ranged from 5 to 11.97 years. The median follow-up time was 6.1 years.

Revision

Revision information was available for 103 patients as 2 patients left the country; the remaining 2 patients who moved out of area still live in Scotland, so revision data

Table II Demographics of 5-year outcomes cohort

Characteristic	Value
Age, yr, median	69
Gender: female, %	81
BMI, mean	30
ASA grade, mean	2
Laterality: left/right, n	31/44
Indication: osteoarthritis, %	89

BMI, body mass index; *ASA*, American Society of Anesthesiologists.

were available through PACS. Only 5 patients from this cohort underwent revision. Seven patients died, leaving 96 patients with 5 revisions (5.2%). Two were revised because of infection, 2 because of late cuff failure, and 1 because of instability. One patient with cuff failure was revised 8 years later, and full data for 5-year follow-up was available. The other 4 patients were revised within 5 years. No patients underwent revision at any point for aseptic loosening. Kaplan-Meier survivorship analysis showed a 5-year survival rate of 96.12% (Fig. 3). The median time to revision was 3.25 years.

One of the aTSAs complicated by infection was managed with a 2-stage revision to rTSA. The second infected case underwent first-stage revision to cement spacer for low-grade infection with *Staphylococcus capitus* and *Staphylococcus epidermidis*. Because of comorbidities, the patient declined further procedures. The 2 patients who had cuff failure underwent revision to rTSA. The patient with instability was revised to rTSA.

Radiographic results

One patient was excluded from radiographic analysis because of inadequate radiographs; 74 shoulders were assessed for lucency on radiographs at a minimum of 5 years postoperatively. No humeral lucencies were observed. Fifty-nine patients had no glenoid lucency (79.7%). Seven patients were Lazarus grade 1 lucency (9.5%), 4 patients were Lazarus grade 2 (5.4%), and 4 other patients were Lazarus grade 3 (5.4%). In those patients with Lazarus grade 1 (incomplete lucency around 1 peg), the superior peg was affected in 4 cases (57%) and the inferior peg in 3 cases (43%). There was no association between radiolucency and outcomes such as OSS, satisfaction, or ROM.

Cohen κ for humeral assessment was +1 showing perfect agreement and for glenoid it was 0.672, indicating substantial agreement.[20]

PROMs

Oxford Shoulder Score (OSS) completed a minimum of 5 years postoperatively was available for 68 shoulders. The range was 18-48, with a median score of 47 (mode = 48). Five-year satisfaction scores were available for 71 shoulders. The scale ranges from 1 (very dissatisfied) to 5 (very satisfied). In our cohort, the range was 3 (neither satisfied nor dissatisfied) to 5 (very satisfied); 4 patients (5.6%) scored 3, 6 (8.5%) scored a 4, and 61 (85.9%) a 5.

Range of motion

Range of motion measurements were assessed a minimum of 5 years postoperatively. Forward elevation ranged from 90° to 180° (median: 160°). Abduction ranged from 80° to 180° (median: 150°) and external rotation from 30° to 90° (median: 40°). Internal rotation ranged from buttocks to thoracic spine, with the mode being lumbar spine.

Discussion

This study presents the largest single cohort of stemless anatomic shoulder replacements at a minimum 5-year follow-up. Our results show excellent outcome measures for this implant 5 years postoperatively, with a median OSS of 47, high patient satisfaction rates (94% satisfied or very satisfied), low rates of both humeral (0%) and glenoid (20%, of which all grade 3 or less) lucency, and a low revision rate with a 96% 5-year survival rate.

Simon et al[30] published 5-year results for the Affinis in 74 patients, demonstrating similarly excellent results. Radiologic assessment revealed no humeral lucency, and 83.8% of cases had no glenoid lucency. Satisfaction rates of 96% were reported, and there were significant improvements in PROM scores. Karssiens et al carried out a large study of 141 Affinis anatomic TSAs; however, 5-year data were only available for 73 patients. In this smaller cohort, the 5-year implant survival was 95.4%.[18]

Of the patients with available data, the cumulative revision rate was 4.85%. Revision rates for stemless designs have been reported from 3.5% to 8.5%.[18,22] Australian registry data demonstrated a 7.4% cumulative revision rate at 5 years for stemmed aTSA compared with 4.5% for "Mid-Head TSA" (Mathys Affinis would come under this category). In the same report, rTSA showed the lowest revision rate with 4.3%.[2] A previous study showed similar clinical outcomes between stemmed and stemless aTSA in terms of ROM and PROMs; however stemless resulted in decreased blood loss and operative time.[4] These benefits of stemless aTSA combined with the lower revision rate seen in the registry data favor a stemless design over a stemmed aTSA.

In our study, 1.9% of patients had cuff failure, requiring revision to rTSA. The fundamental principle of rTSA forgoes the requirement for rotator cuff function. Advocates of rTSA argue that a primary rTSA procedure in those with an intact cuff prevents requirement for later revision to rTSA following subsequent rotator cuff failure. The

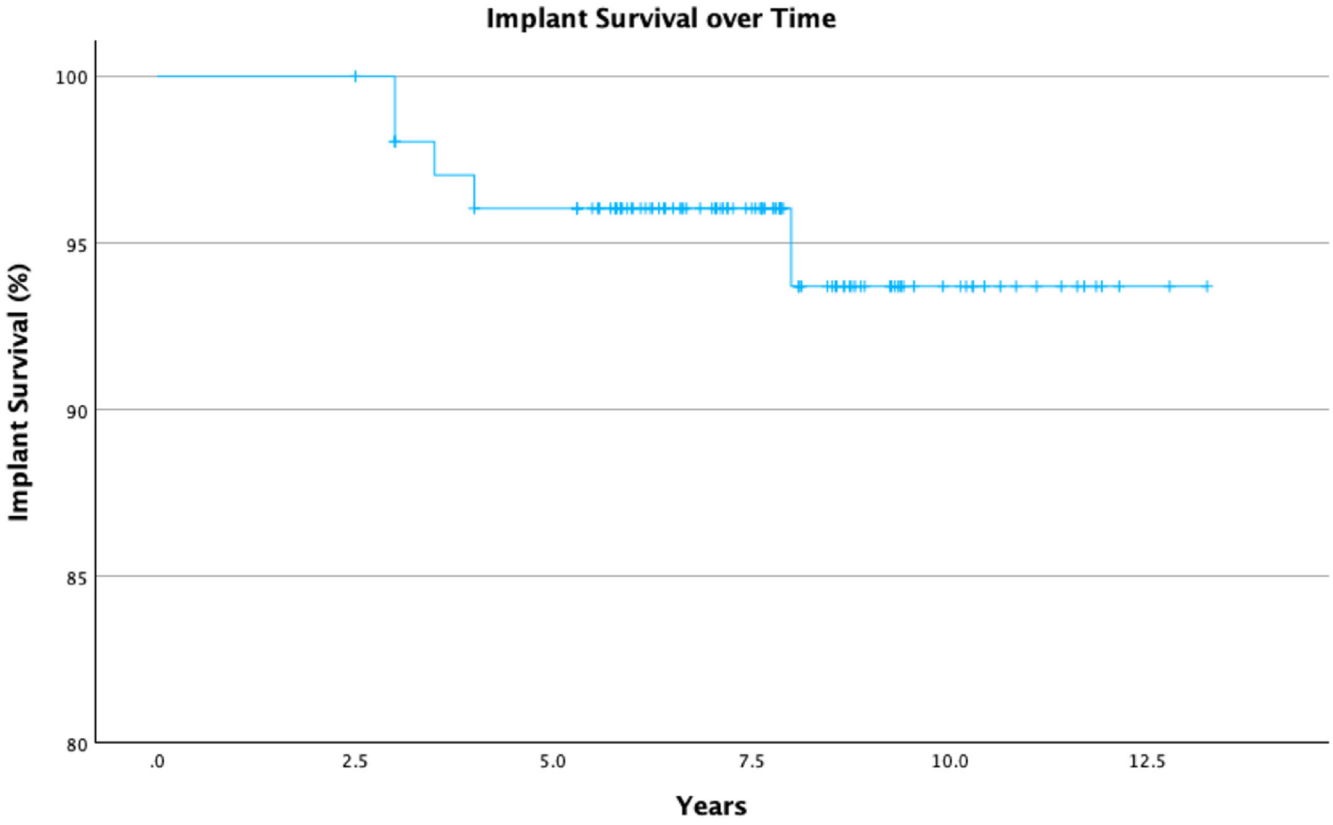

Figure 3 Kaplan-Meir survival analysis curve.

revision rate identified in our study shows a similar 5-year revision rate (4.3% vs. 4.5%) to rTSA, and should an rTSA require revision, it is technically more challenging to perform.[3,6,9] The difficulty in revising an rTSA may even contribute to the low rate, through surgeon decision to not proceed to revision.[9] A further concern with rTSA as the mainstay for primary osteoarthritis would be poorer ROM achieved; 5 years postoperatively following rTSA, the median forward elevation was 137° (compared with 160° observed in our study), the median abduction was 124° (150° observed in our study), the median external rotation was 37° (40° observed in our study), and internal rotation was to lumbar spine (comparable to our study).[31] Given the similar revision rates yet superior ROM using a stemless aTSA, we feel this supports their use as the optimal implant for primary osteoarthritis with intact cuff function.

Our study reported a high median OSS of 47 points. Few studies have used OSS to assess the outcomes of stemless TSA, but OSS is preferred at our institution because of its simplicity for patients and its ability to offer valuable insights into postsurgery improvements in quality of life. The Constant-Murley Score (CMS) has been used to gauge clinical outcomes for the Affinis Short, demonstrating significant score increases from before to after the operation.[3,17] Despite variation in the PROM scores used, the Affinis implant results in improvement in clinical outcome scores across all studies. As described previously, similar PROM scores were demonstrated between stemless aTSA and both stemmed aTSA and rTSA.[4,9] This includes when using alternative stemless implants, such as the Eclipse (Arthrex, Naples, FL, USA) which was compared against the stemmed, Univers II (Arthrex, USA), demonstrating noninferior results of the Constant score at 2 years in 137 Eclipse and 67 Univers II cases.[29]

In our cohort, no patients demonstrated lucency around the stemless humeral component. The stemless humeral component performed similarly in studies by Jordan et al,[17] Karssiens et al,[18] and Bell and Coghlan[3] who also found minimal humeral lucency, with 2.7%, 1%, and 0%, respectively. No revisions were caused by implant loosening. Radiolucency was observed around the cemented pegged glenoid in 20.3% of our cases, which is slightly higher than the levels reported by Jordan et al,[17] Karssiens et al,[18] and Bell and Coghlan,[3] who reported 14%, 15.2%, and 16%, respectively. One possible explanation for this is that our radiologic assessment was performed on most recent radiographs performed at a minimum of 5 years whereas the other studies had a shorter follow-up period with regard to radiographs; for example, Jordan et al used radiographs taken 48 months postoperatively, Karssiens et al's radiographs had a mean time of 33.8 months postoperatively, and Bell and Coghlan used radiographs

taken at 12 months and 24 months. Therefore, it is possible had the other studies followed up patients radiographically for longer, then greater levels of radiolucency could have been seen. Again, importantly no patients in our cohort were revised because of glenoid component loosening. This important finding was mirrored in a recent publication by Raval et al,[27] who reported 5-year outcomes on 51 patients with the same implant as in our study and found no cases of stem loosening requiring revision. There was no association between radiolucency and outcomes such as OSS, satisfaction, or ROM. This is in keeping with a previous study using the same glenoid component that demonstrated glenoid radiolucency was not associated with outcomes.[12]

A limitation of this study includes the lack of preoperative OSS. However, with a median postoperative score of 47 of 48, our results demonstrated excellent postoperative patient-reported outcomes. This mirrors the results of other studies on the Mathys Affinis implant who demonstrated significant improvement in OSS as well as a high overall score.[3,18,30] A further limitation is the lack of goniometric measurements for ROM; however, similar inter-rater reliability has been reported for visual estimation and goniometry. When measuring flexion, intraclass correlation coefficients (ρ) of 0.7 for visual estimation and 0.69 for goniometry were reported. Similarly for abduction, the ρ was 0.66 for visual estimation and 0.69 for goniometry. Measurement of external rotation was superior with goniometry, with a ρ of 0.64 compared with 0.57 for visual estimation. Given these findings, we do not find the lack of goniometric measurements in our study to undermine the excellent results achieved for ROM in our cohort.[13]

Conclusion

This cohort study demonstrates promising clinical and radiologic outcomes for the Mathys Affinis Stemless aTSA at minimum 5 years postoperatively. Clinically patients achieved excellent ROM, and 94.4% were satisfied, with a median OSS at 47 of 48. No radiolucency was observed around the humeral component but there was a 20.3% (grade 3 or less) radiolucency within the glenoid component, and no revisions occurred because of implant loosening. The overall revision rate was 4.85% in keeping with registry data for this implant class.

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