Clinical results and survivorship of the Mathys Affinis Short, Short Stem Total Shoulder Prosthesis

Aims
The Mathys Affinis Short is the most frequently used stemless total shoulder prosthesis in the UK. The purpose of this prospective cohort study is to report the survivorship, clinical, and radiological outcomes of the first independent series of the Affinis Short prosthesis.

Methods
From January 2011 to January 2019, a total of 141 Affinis Short prostheses were implanted in 127 patients by a single surgeon. Mean age at time of surgery was 68 (44 to 89). Minimum one year and maximum eight year follow-up (mean 3.7 years) was analyzed using the Oxford Shoulder Score (OSS) at latest follow-up. Kaplan-Meier survivorship analysis was performed with implant revision as the endpoint. Most recently performed radiographs were reviewed for component radiolucent lines (RLLs) and proximal humeral migration.

Results
Five shoulders underwent revision surgery (3.5%); three for rotator cuff failure, one for infection, and one for component malposition. Survivorship of the implant was 95.4% (95% confidence interval 90.1% to 97.9%) at five and nine years. Mean OSS improved significantly compared to preoperative values from 19.0 (1 to 35) to 43.3 (7 to 48) (p < 0.001). Radiological analysis was undertaken for 99 shoulders. This revealed humeral RLLs in one case (1%), glenoid RLLs in 15 cases (15.2%), and radiological rotator cuff failure in 22 cases (22.2%).

Conclusion
This prospective cohort study shows encouraging short- to mid-term survivorship and clinical and radiological results for the Mathys Affinis Short, Short Stem Total Shoulder Prosthesis.

Level of Evidence: IV

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Introduction
Anatomical total shoulder arthroplasty (TSA) is an established treatment of glenohumeral osteoarthritis (OA) in the presence of an intact rotator cuff.¹ ² The first stemless design was introduced to the European market in 2004 and the use of stemless implants in anatomical TSA is expected to overtake the use of stemmed designs in Europe by 2025.³ ⁴ Compared to stemmed designs, advantages of stemless implants include preservation of humeral bone stock, reduction in stress shielding, reduced chance of periprosthetic fracture both intra- and postoperatively, and less complex revision due to preservation of bone stock and ease of component removal.⁵ ⁶ They also permit more accurate recreation of proximal humeral anatomy and humeral centre of rotation, as there may be little relation between the humeral metaphysis and diaphysis.⁵ Stemless implants have also been shown to result in less intraoperative bleeding and shorter operating times.⁷ ⁹ Compared to resurfacing implants, stemless designs offer better access to the glenoid and allow more predictable restoration of native offset, as the humeral head is excised as opposed to reamed; reducing the chance of ‘overstuffing’ the joint.¹⁰
Table I. Patient characteristics of total shoulder arthroplasty (n = 141).

| Characteristic          | Total |
|-------------------------|-------|
| Mean age, yrs (range)   | 68 (44 to 89) |
| Sex, n (%)              |       |
| Female                  | 84 (59.6) |
| Male                    | 57 (40.4) |
| Unilateral, n (%)       | 113 (89.0) |
| Bilateral, n (%)        | 14 (11.0) |
| Left, n                 | 73     |
| Right, n                | 68     |

Table II. Indications for total shoulder arthroplasty.

| Indication                        | n (%) |
|-----------------------------------|-------|
| Osteoarthritis                    | 134 (95.0) |
| Post-traumatic osteoarthritis     | 3 (2.1) |
| Rheumatoid arthritis              | 2 (1.4) |
| Avascular necrosis                | 1 (0.7) |
| Seronegative inflammatory arthropathy | 1 (0.7) |

The Affinis Short, Short Stem Total Shoulder Prosthesis was introduced by Mathys (Bettlach, Switzerland) in 2009. It is the most frequently used stemless implant in the UK. To date, there have been no independent studies reporting the outcomes of this implant. The aim of this study is to report the survivorship, clinical and radiological outcomes, and complications of the largest independent series of the Affinis Short.

Methods

All patients undergoing TSA with the Affinis Short between January 2011 and January 2019 at our institution under the care of the senior author (SUS) were included in this study. Patients in which the Affinis Short was employed as a hemiarthroplasty were excluded. Institutional review board approval was granted for this prospective cohort study.

Indications. Indication for anatomical shoulder arthroplasty was a painful joint refractory to conservative management for more than six months with arthritic changes on plain radiographs. Conservative management included physiotherapy and oral analgesia. Patients being considered for TSA were not given intra-articular steroid injections. All patients had a clinically intact rotator cuff at the time of operation.

Patient demographics. From January 2011 to January 2019, 141 Mathys Affinis Short prostheses were implanted into 127 patients; 73 were left- and 68 were right-sided. A total of 14 patients received bilateral implants which in all cases were staged, with a mean time interval of 17 months (4 to 40) between operations. Demographic data of patients undergoing TSA are displayed in Table I and indications in Table II. There were 16 deaths (11.3%) at time of writing, at a mean duration of 56 months postoperatively (18 to 98).

Implant. The Affinis Short consists of a cemented all-polyethylene double-pegged glenoid component (either the ultra-high-molecular-weight polyethylene Affinis Glenoid (Mathys) or the Vitamin E stabilised highly-crosslinked polyethylene Vitamys Glenoid (Mathys) and an uncemented modular humeral component. The humeral component consists of an osteoconductive calcium phosphate-coated porous titanium four-finned metaphyseal implant and an anatomically shaped ceramic head (Figures 1 and 2).

Surgical technique. All operations were performed or directly supervised by the senior author (SUS). The anterolateral deltoid-splitting (MacKenzie) approach was used to access the glenohumeral joint. All long head of biceps tendons were tenotomized where not already ruptured. Subscapularis was mobilized by tenotomy. A jig was used to guide resection of the humeral head at...
**Table III.** Postoperative rehabilitation protocol.

| Phase                              | Goals                                                                 | Restrictions                                                                 |
|-----------------------------------|----------------------------------------------------------------------|-------------------------------------------------------------------------------|
| **Phase I (0 to 3 wks)**          | To achieve functional range of motion                                | Avoid combined abduction-external rotation                                   |
|                                   | Removal of collar and cuff                                          | Avoid combined flexion-external rotation                                      |
|                                   | All exercises started as active assisted, progressing to active as    | Avoid early overhead exercises                                                 |
|                                   | comfortable (in supine position):                                   | Avoid hand behind back for six weeks in order to protect subscapularis       |
|                                   | ulleys (shoulder flexion)                                           |                                                                                |
|                                   | Active assisted flexion in the scapular plane in sitting             |                                                                                |
|                                   | Active assisted external rotation to neutral                         |                                                                                |
|                                   | Pendulum exercises                                                  |                                                                                |
|                                   | Active assisted flexion in supine                                   |                                                                                |
|                                   | All supine exercises to be performed with the elbow resting on      |                                                                                |
|                                   | a pillow to avoid extension of the shoulder.                         |                                                                                |
| **Phase II (3 to 6 wks)**         | Isometric exercises of the external rotators, extensors, flexors     |                                                                                |
|                                   | and abductors commenced.                                            |                                                                                |
| **Phase III (6 to 10 wks)**       | More active exercises are encouraged.                               |                                                                                |
|                                   | Active internal rotation started.                                    |                                                                                |
|                                   | Resistance may be added in all other planes of movement.             |                                                                                |
|                                   | At 8 weeks, unrestricted active use of the arm is permitted          |                                                                                |
| **Phase IV (> 10 wks)**           | Stretching and continued strengthening exercises take place.         |                                                                                |

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**Table IV.** Characteristics of revision arthroplasty.

| Age | Sex | Time, mths | Reason               |
|-----|-----|------------|----------------------|
| 63  | F   | 3          | Component malposition|
| 64  | F   | 17         | Rotator cuff failure |
| 65  | F   | 24         | Rotator cuff failure |
| 75  | M   | 24         | Rotator cuff failure |
| 66  | F   | 32         | Periprosthetic infection|

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the anatomical neck. Mathys instruments specific to the lateral approach were used to ensure good visualization of the surgical field and ease of instrumentation. After preparation of the glenoid, the glenoid component was cemented into position using Palacos bone cement (Heraeus Medical, Wehrheim, Germany) with digital pressurization. Humeral head size was based on the size of the resected native humeral head and a trial head was used to assess implant size and soft tissue tension. The definitive stem and head were impacted into the proximal humeral metaphysis until the base of the ceramic head was seated flush to the resected humeral surface. After confirming joint stability, the subscapularis tenotomy was repaired using non-absorbable sutures. Following wound closure, the arm was placed in a collar and cuff sling. Postoperative rehabilitation was undertaken as per the protocol in Table III.

Intraoperative assessment of proximal humerus bone quality was made following the humeral cut. Where bone quality was poor or a large metaphyseal cyst was present, use of the Affinis Short was abandoned and a stemmed Affinis Total Shoulder Prosthesis was used instead. This was necessitated in seven patients; one male and six females. These cases are not included in this study.

**Outcome measures.** The Oxford Shoulder Score (OSS) was used to assess clinical outcomes. The OSS is a tool for assessment of outcomes of shoulder surgery and has been validated for use in primary and secondary OA. Scores were recorded preoperatively, at six weeks postoperatively, then yearly. Scores from the latest available follow-up were compared with preoperative scores. Details of revision or any other procedure performed on included shoulders were collected prospectively and the information was cross-checked with the National Joint Registry (NJR). Shoulders which underwent revision surgery were excluded from OSS analysis.

**Radiological evaluation.** Radiographs were taken at day one postoperatively and annually thereafter. The most recently available radiograph for each patient was assessed by two independent orthopaedic surgeons (TJK, JRG). For shoulders revised to reverse polarity TSA, the latest radiograph prior to revision was reviewed. Radiolucency around the humeral component was classified using the technique described by Bell et al., comprising five zones around the finned stem (Figure 3). Radiolucent lines (RLLs) related to the
glenoid component were classified according to the Lazarus score. Radiological rotator cuff failure was defined as superior migration of the humeral head with acetabularization of the acromion (Hamada Grade 3). Statistical analysis. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) v. 26 (IBM, Armonk, New York, USA). Continuous non-parametric dependant and independent variables were compared with the Wilcoxon signed-rank and Mann-Whitney U tests respectively. A p-value of < 0.05 was considered statistically significant. Kaplan-Meier survivorship analysis was performed with joint revision as the endpoint, defined as an operation in which at least one of the components was changed.

Results

Revision and survivorship. Five shoulders underwent revision surgery, after a mean period of 20 months (3 to 32) (Table IV). Three patients were revised to reverse polarity TSA due to pain with clinical and radiological evidence of rotator cuff failure, one at 17 months and two at 24 months; one of these patients was noted to have a small rotator cuff tear at the time of the index procedure which was repaired intraoperatively. One patient developed periprosthetic infection and underwent the first stage of two stage revision at 32 months. Staphylococcus epidermidis was grown from multiple intraoperative samples. Oral antibiotic therapy with linezolid was initiated. The patient underwent second stage revision to reverse polarity TSA five months later. Of note, this patient was later diagnosed with rheumatoid arthritis. One patient was revised at three months for pain and poor range of motion with anterior subluxation of the humeral head on plain radiograph imaging. Ultrasound imaging revealed an intact subscapularis, which was confirmed at the time of revision. In this case, it was felt that the humeral component was too anteverted; therefore, the humeral surface was re-cut and a new Affinis Short humeral component implanted. Following revision, the patient’s pain settled, and an OSS of 39/48 was achieved at one year.

A total of five revisions were included in the survival analysis. Kaplan-Meier survivorship analysis revealed five-year and nine-year implant survivorship of 95.4% (95% confidence interval (CI) 90.1% to 97.9%) (Figure 4).

Oxford Shoulder Scores. Postoperative OSSs were available for 127/136 shoulders (93%) after the five revised shoulders were excluded; 25 had latest available OSSs at one year, 17 at two, three, and four years, 27 at five years, 11 at six years, nine at seven years, and four at eight years postoperatively. The mean OSS within each of these groups is shown in Table V. Overall mean duration from operation to latest available OSS was 3.7 years (1 to 8). The mean latest available OSS improved significantly compared to preoperative values from 19.0 (1 to 35) to 43.3 (7 to 48) (p < 0.001, Wilcoxon signed-rank test). Mean and median values of pre- and latest available postoperative OSSs are shown in Figure 5.

Complications. One case (0.7%) underwent reoperation at a tertiary unit 14 months postoperatively for pain with attenuation of subscapularis and incompetence of
the rotator interval on CT arthrogram. The rotator cuff was reconstructed, and the patient’s symptoms settled.

There were two cases of intraoperative fracture of the lateral humeral cortex (1.4%), identified on postoperative imaging. In both cases the fracture was minimally displaced. The fractures were likely caused by the impact of one of the fins of the prosthesis on the lateral cortex of the humerus during implantation. Both cases united without the need for operative intervention and achieved an OSS of 48/48 at latest follow-up.

One patient was noted to have a radial nerve palsy postoperatively. An anaesthetic block had not been used. With no clinical improvement after six weeks, nerve conduction studies were arranged. These revealed axonal injury to the radial nerve proximal to the triceps innervation but distal to the posterior cord of the brachial plexus; axillary nerve function was spared. Radial nerve function has since improved and at three years postoperatively OSS was 48/48.

Radiological analysis. Radiographs of a total of 99/141 shoulders (70.2%) were available for analysis. The mean time from index procedure to latest available radiograph was 33.8 months (10 to 94).

Humeral component radiolucency was noted in one patient only (1%), in Zone 5 (Figure 3). This was present on radiographs performed at one-year postoperatively and was not associated with pain or limitation of function. The most recent OSS at two years postoperatively was 42/48.

Glenoid RLLs were present in 15 shoulders (15.2%). Grade 1 RLLs were present in three shoulders (3%), grade 2 in five shoulders (5.1%), and grade 3 in seven shoulders (7.1%) (Figure 6). No shoulders underwent revision surgery as a result of radiological evidence of loosening of the glenoid. The mean latest OSS of patients with all grades of glenoid lucency was 40/48 (21 to 48).

Hamada Grade 3 proximal humeral migration was noted in 22 shoulders (22.2%), representing radiological rotator cuff failure. Three of these shoulders were painful with clinical features of rotator cuff failure, and were subsequently revised to reverse polarity TSA. Mean OSS for patients with proximal migration was significantly improved at latest follow-up compared to preoperatively; 36.2 (7 to 48) versus 18.3 (6 to 35) (p < 0.001, Wilcoxon signed-rank test). However, patients with evidence of gross proximal humeral migration had a significantly lower mean OSS at latest follow-up compared to those without; 36.2 (7 to 48) versus 44.2 (20 to 48) (p = 0.029, Mann-Whitney U test) (Table VI). Patients with gross proximal humeral migration had a higher mean age at the

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**Table V. Breakdown of latest available Oxford Shoulder Scores.**

| Postoperative years | n (%)  | Mean OSS (range) |
|---------------------|--------|------------------|
| 1                   | 25 (19.7) | 42.48 (20 to 48) |
| 2                   | 17 (13.4) | 41.88 (7 to 48)  |
| 3                   | 17 (13.4) | 43.88 (19 to 48) |
| 4                   | 17 (13.4) | 44.35 (29 to 48) |
| 5                   | 27 (21.3) | 42.67 (14 to 48) |
| 6                   | 11 (8.7)  | 43.82 (34 to 48) |
| 7                   | 9 (7.1)   | 43.22 (29 to 48) |
| 8                   | 4 (3.1)   | 46.25 (43 to 48) |

OSS, Oxford Shoulder Score
time of the index operation compared to those without proximal migration; 73.5 years (64 to 88) versus 67.5 (45 to 86).

Discussion
Our study shows that the Affinis Short has excellent survivorship, clinical outcomes, and radiological results. The survivorship of the implant at five years and nine years was 95.4%. Revision rate was 3.5% (5/141 cases), with a mean time to revision of 20 months (3 to 32). No revision was undertaken directly due to failure of the implant. This is comparable or better than the reported survivorship and revision rates in other studies of stemless implants.

A report of 151 Affinis Short TSAs with minimum four year follow-up by Jordan et al\textsuperscript{13} illustrated about 95% survivorship of the implant at nine years, with an overall revision rate of 5.3% (8/151 cases). This was a prospective, multicentre study, the authors of which were consultants for Mathys and had been involved in the design of the prosthesis. Of the eight revision cases, five were due to rotator cuff failure (3.3%), two due to infection (1.3%) and one due to loosening of the glenoid component (0.6%). The revision rate presented is slightly higher than this study, but in both the most frequent indication for revision was rotator cuff failure. Survivorship at nine years was almost identical, supporting the data presented in our study. Bell et al\textsuperscript{10} reported a revision rate of 2% (1/50 cases) at two-year follow-up in another study of the Affinis Short; the revision in this study was also due to failure of the rotator cuff. A systematic review of results of 900 stemless TSAs reported revision rates of between 0% and 8.2% for five different implants,\textsuperscript{3} although it must be noted that the implant with 0% revision rate had only been used in a total of nine cases.\textsuperscript{17} Our overall revision rate of 3.5% compares favourably to this. It is superior to the 5.4% revision rate reported on systematic review and rate of 3.5% compares favourably to this. It is superior to the OSSs reported in the NJR, where median OSS scores for all brands of stemless TSA improved by 22 points preoperatively to six months postoperatively.\textsuperscript{12}

Several complications occurred that did not require revision of the prostheses. Two patients had intraoperative fractures of the lateral humeral cortex (1.4%). Both were minimally displaced and required no operative intervention. There were no intraoperative fractures reported in the studies by Bell et al\textsuperscript{10} or Jordan et al\textsuperscript{13} using the same implant; however, intraoperative fractures of the lateral humeral wall occurred in five of 63 (7.9%) cases in a study of the Biomet TESS (Zimmer Biomet, Warsaw, Indiana, USA) prosthesis by Huguet et al.\textsuperscript{21} It may be that the fractures caused in our study were a consequence of using oversized stems, and smaller stem size selection may have prevented this complication. The fractures reported in our study ultimately had no impact on the OSS; both patients scored 48/48 at latest follow-up.

One patient was postoperatively noted to have a radial nerve palsy (0.7%). The cause of this was unclear, although may have been a traction injury due to intraoperative manipulation of the limb. Bell et al\textsuperscript{10} reported two transient musculocutaneous nerve palsies (2%), likely due to use of the deltopectoral approach as opposed to the deltoid splitting approach used in our study. None of the patients in our study sustained axillary nerve injury;

| Proximal migration | n (%) | Mean age, yrs | Mean latest OSS (range) |
|--------------------|-------|---------------|-------------------------|
| Non-migrated       | 77 (77.8%) | 67.5 (45 to 86) | 44.2 (20 to 48)         |
| Grossly migrated   | 22 (22.2%)  | 73.5 (64 to 88) | 36.2 (7 to 48)          |
| p-value            |       |               | < 0.029*                |

*Mann-Whitney U test.
a commonly-cited risk in the use of a deltoid splitting approach.\textsuperscript{22} One patient underwent reoperation at a tertiary unit for postoperative pain with attenuation of subscapularis and incompetence of the rotator interval on CT arthrogram (0.7%). Neither component was revised, and the patient recovered well following this. The overall complication rate including revision surgery in our study is therefore 6% (9/141 cases).

Radiological follow-up was available for 99/141 (70.2%) shoulders and was undertaken at a mean of 33.8 months postoperatively (10 to 94). One case of humeral radiological lucency (1%) in Zone 5 was noted. Although Bell et al\textsuperscript{10} reported no cases of humeral RLLs at two years follow-up, Jordan et al\textsuperscript{13} noted humeral RLLs in 2.7% of cases with four year follow-up, most frequently around the calcar (Zone 5). The incidence of humeral RLLs in our study is therefore similar to that reported in other studies utilizing the same implant. Systematic review of other stemless prostheses reported presence of humeral RLLs in 18.4% of cases.\textsuperscript{3} Variations in humeral component stem design may account for this considerable difference and it is possible that, in our study, radiological follow-up did not occur after a sufficient period of time for humeral RLLs to develop. A study of the Zimmer Biomet Comprehensive Micro System, which employs an uncemented ‘mini’ humeral stem, revealed medial calcar resorption in 23% of cases and greater tuberosity stress shielding in 14% of cases.\textsuperscript{4} This suggests that stemless implants may result in less stress shielding and bone resorption when compared to even very short stemmed implants.

Overall, 15 of 99 glenoid components showed evidence of RLLs (15.2%). There was no gross loosening or migration of the implant in any of the cases, and none of the cases with glenoid RLLs underwent revision surgery as a result of glenoid loosening. The mean latest OSS for patients with all grades of lucency was 40/48 (21 to 48); the clinical significance of this finding was unclear. Bell et al\textsuperscript{10} and Jordan et al\textsuperscript{13} reported glenoid RLLs in 16% and 14% of cases respectively, using the same glenoid component. Causes of glenoid RLLs are multifactorial, and can include component malposition, increased mechanical stresses on the glenoid, osteolysis, and friction between the components.\textsuperscript{23} RLLs have previously been shown not to correlate with clinical outcome measures for the Mathys glenoid implant, a finding reflected in our study.\textsuperscript{24} Due to variation in anteroposterior radiograph projections, it was not possible to accurately measure acromiohumeral distance and was therefore difficult to infer likely rotator cuff failure solely on the basis of superior migration of the humeral head. Radiological failure of the rotator cuff was therefore defined as Hamada Grade 3 proximal humeral migration. This occurred in 22/99 shoulders (22.2%). Three of these shoulders later underwent revision surgery, but these patients also presented clinical evidence of rotator cuff failure with pain and weakness of the shoulder. Patients with radiological proximal migration were a mean six years older than those without. Patients with radiological proximal migration had significantly higher postoperative OSSs compared to their preoperative scores; however, their postoperative scores were significantly lower than patients who did not have radiological evidence of rotator cuff failure. Therefore, while there is still an improvement compared to preoperative scores, our study shows that radiological rotator cuff failure in the presence of an anatomical TSA does adversely impact clinical outcome measures.

The rate of radiological rotator cuff failure reported in this study is similar to that of other studies of anatomical TSAs. In a study of 703 TSAs or hemiarthroplasties using the Aequalis prosthesis (Tornier, Montbonnot, France) with minimum five years follow-up, Young et al\textsuperscript{25} reported superior migration of the humeral head in a total of 154 shoulders (29.7%), with moderate to severe superior migration noted in 87 cases (16.8%). A 2016 systematic review by Levy et al\textsuperscript{26} analyzed the outcomes of ten studies reporting proximal humeral migration after TSA or hemiarthroplasty; this revealed proximal humeral migration in 29.9% of shoulders at mean 6.6 years follow-up, with moderate to severe proximal migration reported in 18% cases. The studies included in this systematic review utilized a broad range of prostheses. Although it is feasible that anatomical TSA can contribute to development of rotator cuff tears, the prevalence of rotator cuff tears is also known to increase with age in native shoulders.\textsuperscript{27} It is logical to infer that this process still occurs following anatomical shoulder arthroplasty, and the authors do not consider this to represent a failure of the implant itself.

There are a number of limitations associated with this study. It is a single surgeon series with high volume experience of shoulder arthroplasty. Only one outcome score, the OSS, was used to evaluate clinical outcomes, and shoulder range of motion was not assessed. Radiological analysis was possible but limited by availability of radiographs and variability in obtained views. There was no control group with which outcomes could be compared. Further studies are required to investigate the long-term survivorship of stemless implants.

This prospective cohort study of 141 Affinis Short, Short Stem Total Shoulder Prostheses shows encouraging short to medium-term results. Five- and nine-year survivorship of the implant is 95.4% with a revision rate of 3.5%. There was a statistically significant increase in OSS, from a mean of 19 (1 to 35) preoperatively to 43 (7 to 48) at latest follow-up.

**Take home message**
- This is the first independent study of the most frequently used stemless total shoulder prosthesis in the UK.
- There is excellent short- to mid-term survivorship and clinical and radiological results for the prosthesis.
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