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Original article

Adjustable stemmed shoulder hemiarthroplasty: Ten-year results of a prospective multicentre study

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ABSTRACT

Background: Adjustable shoulder hemiarthroplasty (HA) allows the complex anatomy of the proximal humerus, including its centre of rotation, to be restored. However, whether better anatomical adaptation improves clinical outcomes and long-term survival remains unclear. Therefore long-term clinical and radiographic results of an eccentric adjustable hemiprosthesis were examined, focusing on the longevity and fixation of the humeral stem.
Hypothesis: Adjustable shoulder HA enhances long-term functional outcomes and reduces complications.
Materials and methods: In this prospective multicentre study, 120 HAs were performed using a stemmed hemiprosthesis on 115 patients. The clinical and radiologic outcomes were measured at 3, 6, 12, and 24 months, and thereafter at 4, 7, and 10 years with a median follow-up period of 7.7 years (92.3 months, range 2.6–148.5 months). Revision-free survival rates were calculated up to 10 years postoperatively.
Results: The mean Constant-Murley score increased over the first 24 months from 26.2 ± 9.0 to 61.0 ± 17.3 points, then levelled off until the final follow-up. Patients with humeral head necrosis had the best clinical outcomes, while patients with fracture sequelae and rheumatoid arthritis had the worst. Although radiolucent lines were more frequent after cemented fixation, lines of >2 mm only occurred after uncemented fixation. Finally, five cases required secondary glenoid implantation, and survival free from stem revision was 99.0% (95% confidence interval [CI], 92.8%–99.9%) at 4 years, 97.6 (95% CI, 90.6%–99.4%) at 7 years, and 92.2% (95% CI, 81.9%–96.8%) at 10 years.
Discussion: The study showed that adjustable shoulder HA is a safe and effective treatment option for various degenerative disorders of the shoulder joint. Functional scores first increased, then levelled off after 24 months. Moreover, revision-free survival compared well with previously reported values. Observed stable long-term results confirm that adjustable shoulder HA has beneficial clinical outcomes and a low complication rate.

1. Introduction

Modern shoulder arthroplasty has become an established treatment for degenerative disorders of the shoulder joint. In particular, hemiarthroplasty (HA), initially used for treating proximal humeral fractures, is now used for a wide range of shoulder diseases, including osteoarthritis (OA), rheumatoid arthritis (RA), avascular necrosis, and in seldom cases of cuff-tear arthropathy where use of a reversed prosthesis is not suitable [1]. The outcomes for these indications, however, are variable with best outcomes reported with avascular necrosis and worst with rotator cuff-tear arthropathy and posttraumatic fracture sequelae [1]. Furthermore, HA can result in glenoid erosion, which remains the main cause of failure after HA and short- and mid-term revisions [1]. Total shoulder arthroplasty, on the other hand, can result in glenoid component loosening [1]. The decision to perform HA therefore depends on several factors that influence prosthesis survival and functional outcomes [1].

An important factor influencing functional results after shoulder arthroplasty is the reconstruction of the physiological articulation and kinematics of the glenohumeral joint [2–5]. Multiple generations of implants have attempted to address these needs.

Since the early 70's, several prosthesis designs have been developed [6–8]. Earlier prostheses showed that failure to restore the

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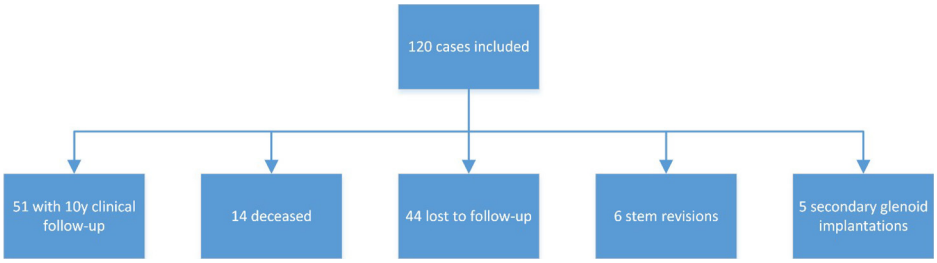

Fig. 1. Flow-diagram of patient selection.

anatomy of the proximal humerus could lead to subacromial impingement, glenoid impingement, coracoid impingement, or shoulder instability [9–11]. Therefore, exact anatomical reconstruction is crucial for shoulder kinetics, rotator cuff function, and reduced eccentric loading of the glenoid [4,9].

Today's adjustable shoulder prostheses allow to combine humeral heads of varying sizes to suit each patient's anatomy [6]. Specifically, adjustable prostheses allow the complex anatomy of the proximal humerus, including its centre of rotation, to be reconstructed, thereby restoring normal shoulder kinematics. In fact, the implant used in this study was shown to reconstruct the anatomical conditions in both frontal and sagittal planes [3,4].

Several studies have confirmed the need for adjustable implants in various clinical [3,12–14] and cadaver settings [5,9,10]. Moreover, mid- and long-term clinical results with adjustable prostheses in different shoulder conditions including primary OA, RA, osteonecrosis, fracture sequalae, humeral head necrosis, cuff arthropathy, and others are encouraging [1,4,13–17]. However, despite improvement in radiographic reconstruction with adjustable implants, it remains unclear whether better anatomical adaptation also improves prosthesis stability and, ultimately, implant survival [4]. In addition, most long-term clinical data either stem from smaller case series or refer to primary OA only [17–20].

This prospective multicentre study therefore examined the long-term clinical and radiographic outcomes for different indications treated with an adjustable stemmed shoulder hemiprosthesis. This prosthesis allows for adjustments to the humerus and its centre of rotation in two planes, thus providing anatomical reconstruction of the humeral head. In this study, we focused on the clinical and radiological results of the stemmed hemiprosthesis including longevity and fixation of the humeral stem.

2. Materials and methods

2.1. Study population

In this prospective multicentre study, 115 consecutive patients (85 women) were enrolled from 4 centres from April 2003 to April 2007. The mean patient age was 65.2 ± 11.5 years (range, 37.6–87.2 years) at the time of the operation. Procedures included 120 anatomical shoulder arthroplasties: 110 monolateral and 10 bilateral arthroplasties. Clinical and radiological follow-up was scheduled immediately after surgery and at 3, 6, 12, and 24 months, and thereafter at 4, 7, and 10 years, with a median follow-up period of 7.7 years (92.3 months, range 2.6–148.5 months).

All patients included provided their written consent to participate in the study and agreed to the follow-up examinations. In addition, the patients were not allowed to simultaneously participate in another clinical study. Patients with a previous ipsilateral shoulder replacement, tumour, metal allergy, or a history of shoulder joint infection were excluded.

A total of 51 cases were clinically followed for up to 10 years after surgery and 44 were lost to follow-up. Additionally, 14 cases belonged to patients that became deceased, 6 required a stem revision, and 5 needed a secondary glenoid implantation; these cases were no longer followed (Fig. 1).

Table 1
Number of cases, mean age at surgery, and mean follow-up times by indication.

Indication	Number of cases (%)	Mean age (years)	Mean FU time (months)
Fracture sequelae	16 (13.3)	61.8	69.8
Shoulder instability arthropathy	19 (15.8)	61.7	81.6
Primary osteoarthritis	60 (50.0)	70.4	76.1
Rheumatoid arthritis	17 (14.2)	54.3	93.4
Various (necrosis etc.)	8 (6.7)	64.3	83.2
Total	120	65.2	79.0

FU: follow-up.

Primary OA was the most frequent indication, followed by shoulder instability arthropathy, RA, fracture sequelae, and other indications, including humeral head necrosis (Table 1). In one third of the cases (42 cases), a former injury, such as a fracture, dislocation, or rupture of the rotator cuff, had occurred.

2.2. Implant design and properties

All patients were treated with the Affinis shoulder prosthesis (Mathys Ltd Bettlach, Switzerland), an adjustable stemmed prosthesis of the shoulder. This implant features a monolithic triple taper design without a collar. The metallic (CoCr) prosthetic heads of the implant are available in eight sizes, ranging from 39 to 53 mm (2 mm increments) in diameter and 13 to 20 mm (1 mm increments) in height. Combining a moveable cone with an eccentric metallic head permits double eccentric placement of the head. This allows the prosthesis head to be freely positioned within a range of ± 6 mm mediolaterally and ± 3 mm anteroposteriorly, enabling anatomical reconstruction of the centre of rotation of the humeral head (Fig. 2) [13]. This range covers almost the entire anatomical range of variability of medial-lateral and anterior-posterior offset of a healthy shoulder [3]. The positions of the head centre were calculated based on the positions of the sliding cone and the head component (3 mm eccentricity).

2.3. Operative technique

All patients were placed in a beach chair position and received general anaesthesia and a scalene block. A single surgeon per clinic operated in all cases using a deltopectoral approach.

The humeral head was osteotomised in anatomical retrotorsion corresponding with the individual relations at an inclination of 130 using a resection guide. After opening the humeral shaft and preparing the bearing, the rasp was used as a trial stem, and combined with a medial-lateral shifting cone with an offset of 3 mm in both directions (Fig. 2). Both, the head of the prosthesis and the trial head possess a bore-hole with a 3 mm offset to the centre of the humeral head. In combination with the sliding cone, this results in

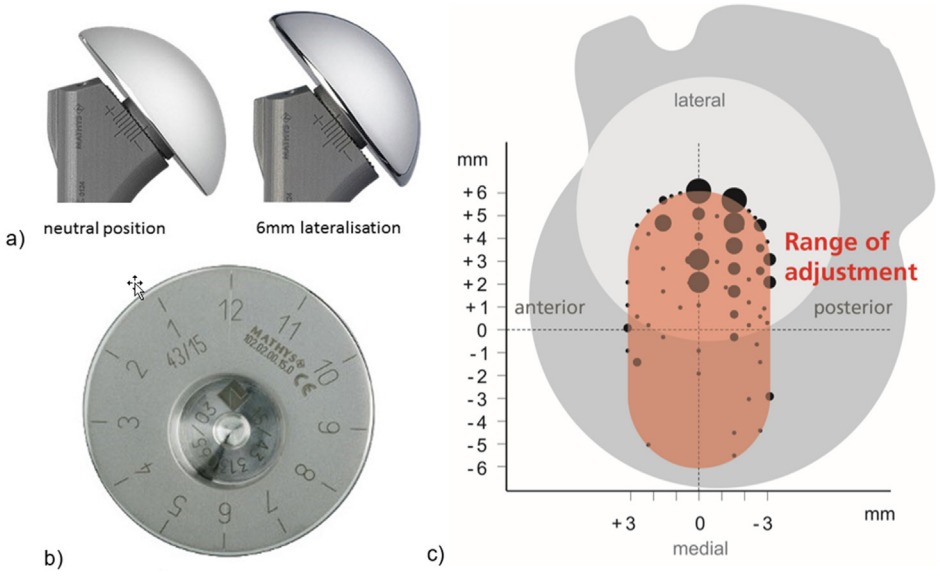

Fig. 2. Adjustable shoulder prosthesis in different configurations. a: neutral and maximum lateral position of the humeral head; b: inner surface of the humeral head with eccentric opening for the sliding cone; c: range of adjustment of the humeral head (orange). Double eccentricity allows the centre of the humeral head to be freely placed within a range of ± 6 mm mediolaterally and ± 3 mm anteroposteriorly. For all humeral heads, the centre of rotation was located mediolaterally and anteroposteriorly.

a functional double-eccenter providing a combined offset of 12 mm in the medial-lateral direction and 6 mm in the posterior-anterior direction (Fig. 2). The position of the cone and the head achieved in the trial implantation were applied to the final implant prior implantation.

Humeral stems were fixed using cemented or uncemented fixation. The cemented stems have a fine lapped surface as well as cement grooves for an additional stabilisation of rotation with form-fit. The uncemented stems have a rough blasted surface and were fixed using press-fit fixation. Cemented fixation was done in 69 cases (57.5%) and uncemented fixation in 51 cases (42.5%).

2.4. Clinical and radiographic assessment

Clinical and radiographic outcomes were evaluated at every follow-up visit. Shoulder function was assessed using the Constant-Murley score (CS) [21] and the American Shoulder and Elbow Surgeons (ASES) shoulder score [22]. The age- and gender-adjusted CS was calculated from the CS as previously shown [23,24]. The scores were then stratified by indication and fixation type (cemented versus uncemented).

The patients' anteroposterior and axillary radiographs were analysed for radiolucencies around the humeral component. The radiolucent lines (RLLs) were assessed with a shoulder-adapted version of the Gruen classification system used for hip assessment [25,26]. The humeral side included seven zones of interest, as described previously (Fig. 3) [27]. Depending on their thickness, RLLs were classified into three categories: ≤ 1 mm, 1–2 mm, and > 2 mm.

All complications were recorded and revision-free survival rates for up to 10 years after surgery were calculated.

2.5. Survivorship

Survival rates free from stem revision and secondary glenoid implantation were determined at 4, 7, and 10 years after surgery. Survival was also stratified according to fixation type (cemented and uncemented fixation).

2.6. Statistical analysis

Descriptive statistics included means, standard deviations, 95% confidence intervals (CIs), and ranges. Follow-up times were reported as medians due to the left-skewed distribution. Functional outcome scores by diagnosis were compared using non-parametric tests: the Wilcoxon two-sample test and the Kruskal-Wallis test (the latter in the case of more than two groups). Association tests between discrete variables were carried out using chi-square tests. The level of significance was set at $p = 0.05$ (two-sided). All statistical analyses were performed with the Statistical Analysis System (SAS), version 9.3 (SAS Institute Inc., Cary, NC, USA).

Prosthesis survival was analysed using the Kaplan-Meier method, censoring patients at death or at lost to follow-up. Loss to follow-up was defined as the date of the last available evaluation. Outcomes included shaft revision, secondary glenoid implantation, and revision due to any reason (shaft revision and/or secondary glenoid implantation, whichever occurred first). CIs were calculated using the arcsine-square root transformation. Equality over groups was evaluated using the log-rank test.

3. Results

3.1. Functional outcomes

Clinical outcomes measured by the CS and ASES shoulder score improved significantly from the preoperative state to the final follow-up ($p < 0.0001$). Over the first 24 months, the mean CS increased from 26.2 ± 9.0 to 61.0 ± 17.3 points, the mean CS for pain from 1.8 ± 2.7 to 12.0 ± 4.3 points, the mean age- and gender-adjusted CS from 35.1% ± 12.4% to 81.1% ± 23.9%, and the mean ASES shoulder score from 24.2 ± 12.4 to 77.8 ± 18.7 points. After this initial improvement, the functional scores levelled off until the final follow-up (Figs. 4 and 5).

Within the indication groups, the best clinical outcomes regarding mean CS at 10 years were achieved in patients with shoulder instability arthropathy, while the least encouraging clinical outcomes occurred in patients with fracture sequelae and primary

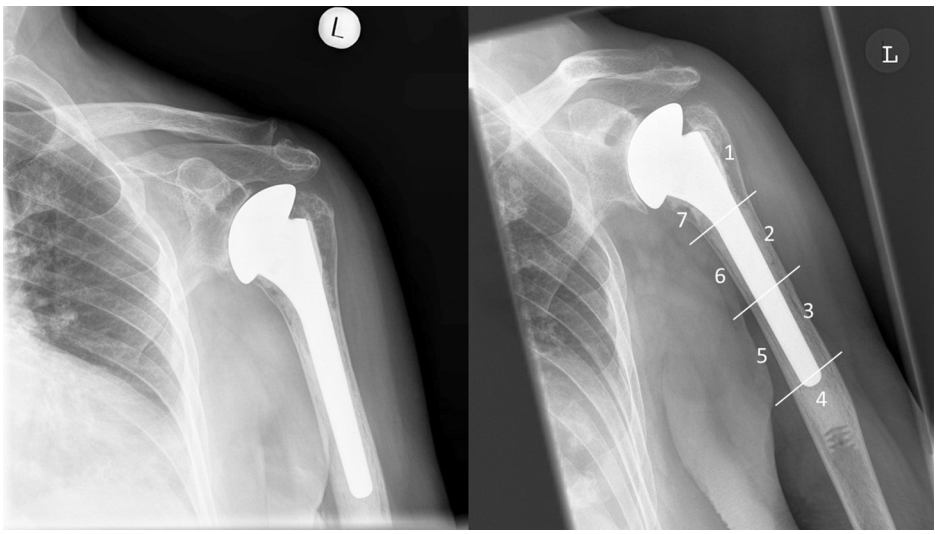

Fig. 3. Anteroposterior x-ray of a left shoulder after cemented anatomical reconstruction of the proximal humerus in an 87-year-old female with primary osteoarthritis of the shoulder. The humerus was divided into seven zones as reported previously: zones 1 and 7 referred to the lateral and medial sides of the proximal third of the stem, zones 2 and 6 referred to the lateral and medial sides of the middle third, zones 3 and 5 referred to the lateral and medial sides of the distal third, and zone 4 was at the tip of the stem [26]. Left: 1 year postoperatively, right: 10 years postoperatively.

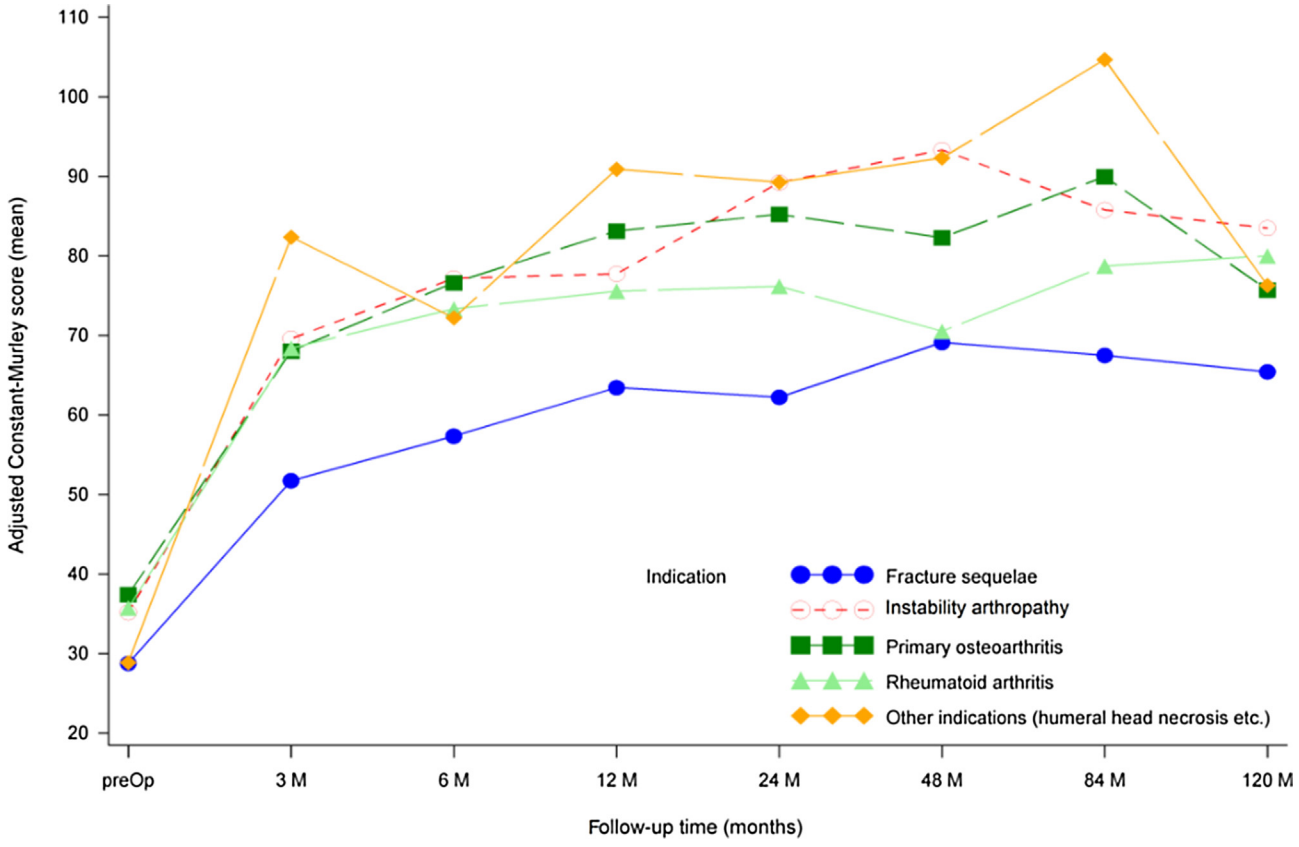

Fig. 4. Graph showing time course of mean age-and gender-adjusted Constant-Murley score by indication.

OA (Fig. 4, Table 2). With regard to the mean ASES shoulder score, patients with other indications including humeral head necrosis and shoulder instability arthropathy showed the best clinical outcomes, while the least encouraging clinical outcomes occurred in patients with fracture sequelae and RA (Fig. 5, Table 2). However, differences within the indication groups were not significant ($p = 0.715$ for mean CS; $p = 0.319$ for mean ASES).

3.2. Radiographic outcomes

RLLs were more frequent after cemented fixation (Tables 3 and 4). However, none of these radiolucencies were >2 mm On the other hand, after uncemented fixation, RLLs of > 2 mm did occur; they were present in at least one zone after 4, 7, and 10 years. However, these were limited to zones 1 and 7.

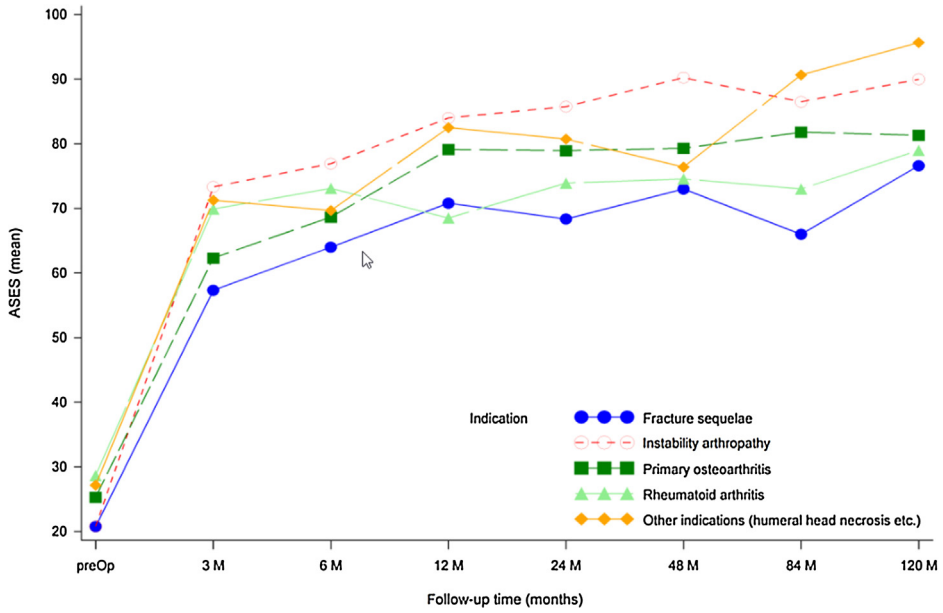

Fig. 5. Graph showing time course of mean American Shoulder and Elbow Surgeons (ASES) shoulder score by indication.

Table 2
Mean functional scores at 10 years by indication.

Indication	Mean adjusted CS (SD)	Mean ASES (SD)
Fracture sequelae	65.4 (15.3)	76.6 (12.7)
Shoulder instability arthropathy	83.5 (23.1)	90.0 (10.1)
Primary osteoarthritis	75.7 (32.4)	81.3 (26.2)
Rheumatoid arthritis	80.0 (20.5)	79.0 (20.3)
Various (necrosis etc)	76.3 (37.4)	95.7 (2.3)
Total	76.5 (27.5)	82.7 (20.4)

SD: standard deviation.

3.3. Revisions

Of all 120 cases, six (5.0%) required a stem revision and five (4.2%) a secondary glenoid implantation after glenoid erosion. Stem revision was performed in 9.8% of cases (5 in 51 cases) after uncemented fixation and in 1.4% of cases (1 in 69 cases) after cemented fixation. The survival rate was higher after cemented fixation, reaching borderline statistical significance (log-rank test, $p = 0.0582$). The reasons for stem revision included two deep infections, two periprosthetic fractures, one impingement with functional impairment, and one extensive osteolysis of the

Table 3
Number of cases showing radiolucent lines in different zones on the humeral side after cemented hemiarthroplasty.

	4 years FU ($n = 42$)			7 years FU ($n = 28$)			10 years FU ($n = 27$)		
	≤ 1 mm	1–2 mm	> 2 mm	≤ 1 mm	1–2 mm	> 2 mm	≤ 1 mm	1–2 mm	> 2 mm
Zone 1	5	2	–	4	2	–	4	2	–
Zone 2	3	–	–	4	–	–	4	–	–
Zone 3	1	1	–	1	1	–	–	1	–
Zone 4	–	–	–	–	–	–	–	–	–
Zone 5	1	–	–	1	–	–	1	–	–
Zone 6	3	–	–	5	–	–	5	–	–
Zone 7	4	1	–	5	1	–	7	1	–
Total	17	4	–	20	4	–	21	4	–

FU: follow-up.

Table 4
Number of cases showing radiolucent lines in different zones on the humeral side after uncemented hemiarthroplasty.

	4 years FU ($n = 39$)			7 years FU ($n = 24$)			10 years FU ($n = 22$)		
	≤ 1 mm	1–2 mm	> 2 mm	≤ 1 mm	1–2 mm	> 2 mm	≤ 1 mm	1–2 mm	> 2 mm
Zone 1	2	1	–	1	2	1	1	–	1
Zone 2	2	–	–	–	–	–	2	1	–
Zone 3	–	–	–	–	–	–	1	1	–
Zone 4	3	1	–	2	1	–	3	–	–
Zone 5	1	–	–	1	–	–	2	1	–
Zone 6	1	–	–	–	–	–	2	1	–
Zone 7	2	1	1	1	1	2	–[a]	–[a]	–[a]
Total	11	3	1	5	4	3	11	4	1

[a]The four patients with radiolucent lines in zone 7 could only be registered through the seven-year follow-up. At the ten-year follow-up, one patient was not available, two patients only received telephonic follow-up, and one patient was revised for a periprosthetic fracture after nine years. FU: follow-up.

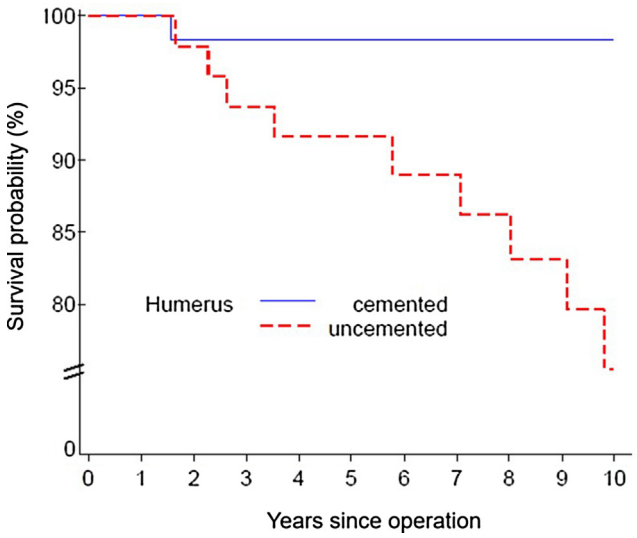

Fig. 6. Kaplan-Meier plot for survival free from stem revision of cemented versus uncemented fixation.

proximal humerus with bone loss of the glenoid in a patient with chronic polyarthritis.

3.4. Survivorship

Survival free from stem revision was 99.0% (95% CI, 92.9%–99.9%) at 4 years, 97.6 (95% CI, 90.6%–99.4%) at 7 years, and 92.2% (95% CI, 81.9%–96.8%) at 10 years. Survival after cemented fixation was significantly higher than after uncemented fixation ($p = 0.0143$). At 10 years, the survival rate was 98.3% (95% CI, 88.8%–99.8%) for cemented fixation and 75.5% (95% CI, 57.0%–86.9%) for uncemented fixation (Fig. 6). Finally, survival free from revision due to any reason was 87.5% (95% CI, 77.4%–93.2%) at 10 years.

3.5. Local complications

Complication data were available for all 120 cases. A total of 16 cases (13.3%) had local complications, which included 3 (2.5%) arthrofibroses, 1 (0.8%) rotator cuff rupture, 1 (0.8%) dislocation, 1 (0.8%) infection, 1 (0.8%) shoulder stiffness, 1 (0.8%) impingement syndrome, 1 (0.8%) temporary partial paresis of the axillary nerve, and 7 (5.8%) other complications mainly related to shoulder pain. None of these cases resulted in surgical revision. However, five cases required secondary glenoid implantation.

4. Discussion

In this study, we evaluated the long-term clinical and radiologic outcomes of an adjustable stemmed hemiprosthesis focusing on the longevity and fixation of the humeral stem. We hypothesised that an adjustable stemmed hemiprosthesis would enhance functional outcomes and reduce complications, such as stem loosening and the need for secondary glenoid implantation. Indeed, our results showed improved functional scores, reduced RLLs, and excellent survival up to 10 years after surgery. We believe these positive outcomes may be attributed to the unique features of the adjustable prosthesis used, which allow anatomical reconstruction of the centre of rotation of the humeral head in both frontal and sagittal planes [3,4].

The functional scores in our study were favourable; the CS reached 61.0 ± 17.3 points and the ASES shoulder score attained 77.8 ± 18.7 points after 24 months. As found in other studies, we initially expected to see the functional results decrease after two years [13,28]. Contrary to this expectation, however, both the CSs and the ASES shoulder scores increased over the first 24 months, then levelled off until final follow-up (Figs. 4 and 5). Therefore, good mid- and long-term clinical outcomes can be expected when using an adjustable hemiprosthesis.

When comparing different indications, patients with shoulder instability arthropathy and with other indications (including humeral head necrosis) achieved the best clinical outcomes, followed by fracture sequelae and primary OA patients, while RA patients showed the least favourable outcomes. Similarly, Gadea et al also had less favourable functional scores in RA patients (mean CS of 55.3 points after at least eight years of follow-up); however, they concluded that HA would still be suitable for RA in patients younger than 50 years of age [1].

Additional clinical studies on adjustable implants used in different indications confirm the positive results of this study in shoulder instability arthropathy [13] and primary OA patients [1,14,16,29]. However, the groups in these studies with the least favourable outcomes were different, ranging from cuff-tear arthropathy [1,14] to RA [1,16] and posttraumatic arthritis [14]. A possible reason for these differences might be ascribed to the small size of subgroups in indications other than primary OA. In addition, two of these studies included total shoulder arthroplasty [14,16].

Our functional results confirmed the need for an adjustable prosthesis. All humeral heads were implanted eccentrically to achieve optimal adjustment to the combined lateral-medial and anterior-posterior offset, using the entire range of humeral head positions (Fig. 2). In most cases, however, the centres of rotation were clustered laterally and slight posteriorly. This could be due to the anatomy of the proximal humerus or due to the fact that the surgeons focused on an optimal transition from the humeral head to the insertion of the supraspinatus tendon, as described previously [3,13]. Moreover, our results coincide with the published theoretical values regarding the shape and dimensions of the proximal humerus [3,9]. Thus, the prosthesis allows for free placement of the head component resulting in optimal reconstruction of the humeral geometry in various deformities of the shoulder, some of which were included in this study.

Radiographic changes, such as the presence of RLLs, may result in humeral component loosening over time, which typically presents as a change in implant position [26]. RLLs present early on and are known to negatively influence clinical outcome [19,27]. The frequency of radiographic changes, however, differs with the fixation technique and implant design [27]. Whereas loosening of the humeral component is not a major concern for cemented stems, it may be for uncemented stems [30]. Despite the loss of cases in the uncemented fixation group between the 7- and 10-year follow-ups, a higher incidence of RLLs of > 2 mm was still observed in uncemented than in cemented fixation. Our results, therefore, confirm the previously published evidence of increased radiographic changes seen with uncemented fixation [31].

Long-term evidence of clinical outcomes and radiographic changes in stemless implants is largely lacking [2,32]. Stemmed implants, on the other hand, are associated with complications arising from the stem; these include periprosthetic fractures and malpositioning or loosening of the humeral component [2]. With our stemmed hemiprosthesis, however, the few radiographic changes observed affected neither implant stability nor survival, especially after cemented fixation. Therefore, when used for the appropriate indication, choosing a stemmed hemiprosthesis with cemented fixation is a good solution. Moreover, secondary rotator cuff rupture was detected only once in our series; this case was not revised. However, we would have expected a higher rate of rotator cuff rupture in our series of stemmed HA as published previously [33].

Long-term survival of the implant is crucial in shoulder arthroplasty, and adjustable prostheses have now reached a stage where long-term clinical evidence is available. In mixed indications treated with HA, adjustable implants revealed revision-free survival rates of 88.1% after 10 years [1]. In this series, mean survival free from any revision was 87.5% at 10 years, and survival free from stem revision was 92.2%, which compares well with the previously reported values. In cemented fixation, we even achieved excellent survival rate of 98.2% at 10 years.

The present study had several limitations. First, not all patients were available for the different reporting periods. The series included several losses to follow-up, and only 51 patients participated physically in the 10-year follow-up visit, which could be attributed to the advanced age of the patients at surgery. Second, secondary glenoid erosion and rotator cuff degeneration were not considered as endpoints, since the study mainly focused on the longevity and fixation of the humeral stem. Third, when stratified by indication, the resulting patient groups were rather small for strong quantitative statements. Nevertheless, the heterogeneity of the patient cohort, together with the multicentre design, provided valuable insights for today's clinical practice. Fourth, a selection bias with regard to humeral fixation cannot be excluded. Finally, the study lacked a control group of patients with non-adjustable hemiprostheses. Although we have mainly discussed our results in line with those published using adjustable hemiprostheses only, any statements regarding the comparison of the results to non-adjustable prostheses should be considered carefully.

5. Conclusions

In summary, this prospective multicentre study confirms that adjustable shoulder HA is a safe and effective treatment option for various degenerative disorders of the shoulder joint. Functional results increased over the first 24 months, then levelled off until the final follow-up. Clinical outcomes varied considerably across the different indication groups, and patients with shoulder instability arthropathy showed the best outcomes. In terms of radiographic results, RLLs of > 2 mm were rare and only occurred after uncemented fixation in the most proximal part of the humerus. Finally, complications were rare except for five cases requiring secondary glenoid implantation, and survival free from stem revision was 92.2% at 10 years, which compared well with the previously reported values. For cemented fixation, the survival rate was excellent with 98.3% at 10 years.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments. Ethics committee approval was received from the cantonal ethics commission of St. Gallen (EKSG 03/015). All patients included provided their written consent to participate in the study and agreed to the follow-up examinations.

Disclosure of interest

U.I. received consultancy payment from Mathys Ltd Bettlach.
P.Z., G.B., and A.B. declare that they have no competing interest.

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The study received partial funding from Mathys Ltd Bettlach. Funds sponsored statistical analysis through an independent consultant, medical writing and editorial support through Medical Minds GmbH, and follow-up examinations and x-ray analysis.

Authors' contribution

All authors were responsible for operations and investigations regarding this study in their clinic.

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