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Short-term results of a second generation anatomic short-stem shoulder prosthesis in primary osteoarthritis

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Abstract

Introduction The aim of the study was to evaluate the short-term clinical results of anatomic total shoulder arthroplasty with a short-stem prosthesis in primary osteoarthritis.

Materials and methods 65 shoulders with a mean age of 70 years (range 47–85 years) were available for minimum follow-up of 24 months. Clinical outcome was determined by range of motion, Constant score (CS) age and sex-adjusted Constant score (CS%), and subjective shoulder value (SSV). The influence of six different factors (high bone adaptations, age > 65 years, female gender, dominant side, atrophy of the supraspinatus tendon ≥ grade 2, glenoid type B2/B3) on the clinical outcome was assessed.

Results At mean follow-up of 37 months (range 24–58 months), the CS improved from 36 ± 8 to 75 ± 12 ($p < 0.001$). The shoulder flexion (100° ± 21° to 159° ± 19°) as well as the external rotation (3° ± 11° to 43° ± 18°) improved significantly ($p < 0.001$). Three complications were noted (transient neuropraxia of the radial nerve, subjective instability, hematoma with superficial wound infection) leading to one revision surgery (wound debridement). No stem loosening was observed. High bone adaptation was present in 19 out of 65 shoulders (29%). The clinical outcome was not influenced by high bone adaptations ($p \geq 0.095$). Age > 65 years ($n = 44$) and female gender ($n = 38$) were associated with worse clinical outcome ($p \leq 0.043$).

Conclusions In the short term, the clinical results of this anatomical short-stem shoulder prosthesis are encouraging. A low prevalence of high bone adaptations was found without any influence on the clinical outcome and stem loosening was not observed.

Keywords Total shoulder arthroplasty · Short stem · Primary osteoarthritis · Anatomical · Shoulder replacement · Stem loosening

Introduction

Anatomical total shoulder arthroplasty has been established as a safe and effective procedure in the treatment of primary glenohumeral osteoarthritis with favorable clinical long-term results [7, 10, 15, 23]. Total shoulder replacement with long humeral stems still represents the gold standard, with a low prevalence of loosening and complications at long-term follow-up [7, 23, 26]. However, revision of long humeral stems is challenging and often associated with massive bone loss [1, 2]. Therefore, investigations on the stem design in total shoulder arthroplasty led to metaphyseal fixation of implants, either stemless or with a short humeral stem, to facilitate stem removal in the case of revision surgery [5, 9, 12].

The first generation of a short-stem shoulder system (Ascend Monolithic, Wright Medical, Memphis, TN, USA) has yielded good to excellent clinical short-term results comparable to those of the third and fourth generations of standard stem arthroplasty [19]. However, detailed radiographic analysis revealed high rates of radiographic changes around the humeral stem in more than half of the patients [18]. Recently, Casagrande et al. reported on 73 patients treated with the same kind of short-stem shoulder prosthesis,

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and 6 out of 73 patients had to be revised for stem loosening in the short term [4].

Meanwhile, design modifications led to a second generation of short-stem shoulder prosthesis (Ascend Flex, Wright Medical, Memphis, TN, USA). Beside the possibility of convertibility from anatomic to reverse configuration, a metaphyseal porous coating was added to promote the metaphyseal bone ingrowth. The aim of the current study was to evaluate the short-term clinical results of this second generation short stem in patients with primary osteoarthritis treated with anatomic total shoulder arthroplasty.

Table 2 Preoperative status of the rotator cuff

N (%)	SSP	ISP	SCP	TM
Grade				
0	23 (35)	52 (80)	58 (89)	61 (94)
1	24 (37)	7 (11)	5 (8)	2 (3)
2	12 (19)	5 (8)	2 (3)	2 (3)
3	6 (9)	0	0	0
4	0	1 (2)	0	0

SSP supraspinatus, *ISP* infraspinatus, *SCP* subscapularis, *TM* teres minor

Materials and methods

A series of 66 consecutive shoulder arthroplasties in 64 patients were performed by one single surgeon (GW) between August 2012 and June 2014. The second generation of an uncemented humeral short stem (Ascend Flex, Wright Medical, Memphis, TN, USA) and cemented keeled glenoid (PERFORM Glenoid, Wright Medical, Memphis, TN, USA) was used in all patients. The inclusion criteria for the study were (1) the diagnosis of primary osteoarthritis; (2) total shoulder replacement with the same kind of short-stem shoulder prosthesis; (3) minimum follow-up of 24 months with clinical and radiological examination; and (4) written informed consent. One patient was lost to follow-up. Finally, 65 of 66 shoulders (98%) were available for clinical and radiological follow-up. The study group consisted of 37 women (58%) and 27 men (42%). The mean age at the time of arthroplasty was 70 years (range 47–85 years). The right side as well as the dominant side was treated in 35 shoulders (53%). The morphology of the glenoid was classified according to Walch [24], and more than half of the patients had a type A2 glenoid (Table 1). The preoperative status of the rotator cuff muscles was assessed by computed tomography scans according the Goutallier classification system (Table 2) [8].

Operative technique and implants

The implant design has been slightly modified in the second generation of this kind of short-stem prosthesis. In the metaphyseal part of the stem, a porous coating was added to promote bone ingrowth. In addition, the possibility of convertibility was added to ease the revision from anatomic to reverse configuration without stem removal. In the current study, the delto-pectoral approach was performed in all patients. After exposure, resection of the humeral head is accomplished either with a special resection gauge or free-hand at the anatomical neck. The compactor for preparation of the marrow cavity has a smooth, slightly indented surface so that the cancellous bone is compacted and condensed but not removed from the metaphysis. The appropriate size for the shaft is found when the trial stem (compactor) cannot be rotated. Although this cohort includes the learning curve with this type of metaphyseal porous-coated short stem, a press-fit fixation of the short stem with high diaphyseal filling ratio should be avoided to minimize the occurrence of humeral bone remodeling [18].

Table 1 Distribution of the glenoid morphology (Walch)

	N (%)
A1	9 (14)
A2	37 (57)
B1	5 (8)
B2	13 (20)
B3	1 (2)

Clinical examination

The clinical outcome was assessed by means of the Constant score (CS), the age- and gender-adapted Constant score (CS%), including a pain score (worst: 0; best: 15), and the subjective shoulder value (SSV). In addition, the active range of motion with flexion (Flex), and external rotation (ER) was measured in degrees (°) using a goniometer. The internal rotation was assessed according to the highest vertebral level the patient could reach with the ipsilateral thumb, and each vertebral level was given the corresponding value (Th8: 4; Th12: 3; L3: 2; sacro-iliac joint: 1; buttock: 0).

Radiographic analysis

The patients underwent a standardized radiographic examination including a true anteroposterior (AP) radiograph and an axillary view of the affected shoulder. The immediate postoperative and final radiographs were evaluated regarding the presence of stem loosening and bone adaptations around the humeral stem. The presence of stem loosening was defined according to the criteria described by Sanchez-Sotelo [17]. The bone adaptations were analyzed according

to the previously published criteria by Schnetzke et al., and bone adaptation was defined as low in the presence of no or mild features of bone remodeling (Fig. 1) and high in the case of moderate or severe features of bone remodeling (Fig. 2) [18]. The clinical outcome of patients with low and high bone adaptations was compared. The humeral bone remodeling was evaluated separately by two blinded observers (MS and PR), who were not involved with the design of the prosthesis. In the event of disagreement, the radiograph was discussed and a consensus was reached. The interobserver agreement was calculated.

Statistics

Means, standard deviations (SD), minimum and maximum values were calculated for continuous variables. Differences between preoperative and postoperative continuous data were analyzed using paired samples *t* tests. The Mann–Whitney *U* test was used to compare two groups of patients. The level of significance was set at $p < 0.05$. Interobserver agreement was calculated with Cohen's κ, and the agreement strength was inferred in accordance with the recommendations of Landis and Koch [11].

Results

At a mean follow-up of 37 months (range 24–58 months), the range of motion as well as the clinical scores improved significantly (Table 3) ($p < 0.001$). The Constant score improved from 36 ± 8 (range 24–59) to 75 ± 12 (range 24–89) and the CS% from 50 ± 11 (range 31–83) to 102 ± 16 (range 38–136). 47 patients (72%) rated their outcome as excellent, 15 patients (23%) as good, 3 patients (5%) as satisfactory and no patient rated the outcome as unsatisfactory.

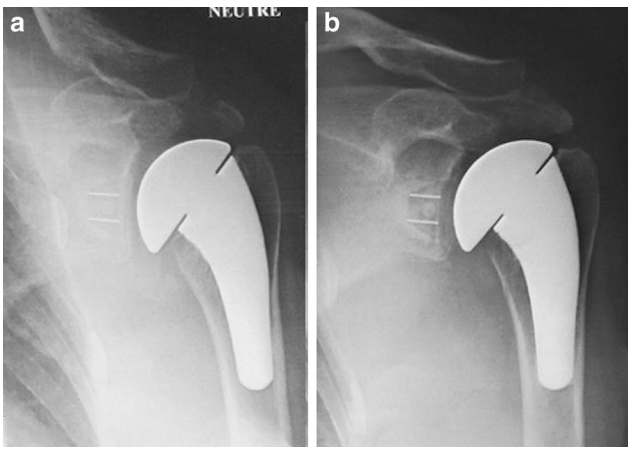

Fig. 1 70-year-old patient with low bone adaptations at the immediate postoperative radiograph (**a**) and at 48-month follow-up (**b**)

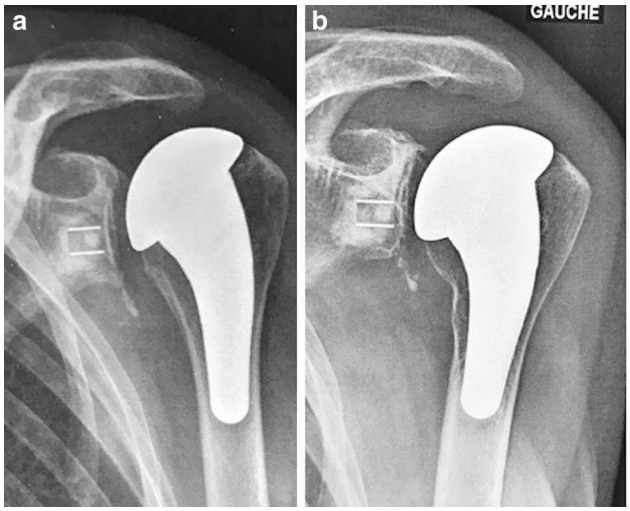

Fig. 2 60-year-old patient with low bone adaptations at the immediate postoperative radiograph (**a**) and high bone adaptions with bone remodeling at the calcar region at 39-month follow-up (**b**)

The SSV averaged $85 \pm 15\%$ (range 40–100%) at final examination.

Three complications (4.5%) were noted (transient neuropraxia of the radial nerve, subjective instability, hematoma with superficial wound infection) leading to one revision surgery (1.5%) with wound debridement.

None of the stems was considered loose or at risk for future loosening. The radiographic changes around the humeral stem were graded as low in 46 shoulders (71%) and as high in 19 shoulders (29%). The interobserver agreement regarding the classification of the radiographic changes was almost perfect between both observers ($\kappa = 0.953$). The presence of high radiographic changes did not affect the clinical outcome (Table 4) ($p \geq 0.095$).

A female gender ($p = 0.006$) and age > 65 years ($p = 0.043$) were associated with significantly lower CS (Table 5). It should be noted that the female study population

Table 3 Clinical results of the study population

	Preoperative	Follow-up	*p* value*
Flexion (°)	100 ± 21	159 ± 19	< 0.001
External rotation (°)	3 ± 11	43 ± 18	< 0.001
Internal rotation (°)	0.7 ± 1.0	2.7 ± 0.9	< 0.001
Constant score	36 ± 8	75 ± 12	< 0.001
Pain	5 ± 1	13 ± 2	< 0.001
Activity	9 ± 2	18 ± 3	< 0.001
Mobility	17 ± 6	34 ± 6	< 0.001
Strength	5 ± 2	9 ± 4	< 0.001
Constant score %	50 ± 11	102 ± 16	< 0.001

*Student *t* test

Table 4 Clinical results in patients with low and high radiographic changes

	Low changes ($n=46$)	High changes ($n=19$)	p value*
Flexion (°)	160 ± 15	156 ± 27	0.949
External rotation (°)	44 ± 16	89 ± 20	0.335
Internal rotation (°)	2.7 ± 0.9	2.7 ± 1.0	0.763
Constant score	76 ± 9	72 ± 15	0.568
Pain	13 ± 2	13 ± 3	0.951
Activity	18 ± 3	18 ± 3	0.853
Mobility	34 ± 5	33 ± 8	0.809
Strength	10 ± 4	8 ± 4	0.095
Constant score %	102 ± 15	102 ± 21	0.279
SSV (%)	86 ± 13	84 ± 18	0.942

*Mann–Whitney U test

Table 5 Analysis of predictive factors for clinical outcome

	Constant score with factor	Constant score without factor	p value*
Age > 65 ($n=44$)	72 ± 13	79 ± 7	0.043
Female ($n=38$)	72 ± 12	78 ± 9	0.006
Dominant side ($n=35$)	76 ± 10	72 ± 13	0.149
SSP status > 1 ($n=18$)	72 ± 17	75 ± 9	0.936
Glenoid B2/B3 ($n=14$)	73 ± 10	75 ± 12	0.443

*Mann–Whitney U test

was older than the male study population (72 ± 9 vs. 66 ± 8 years; $p=0.002$). Other factors such as treatment of the dominant side, atrophy of the supraspinatus tendon ≥ grade 2 or glenoid type B2/B3 according to Walch did not affect the clinical outcome ($p \geq 0.149$).

Discussion

Anatomic shoulder replacement with standard long humeral stems still represents the gold standard with good to excellent long-term results. As people are getting older with higher demands on their physical activity, revision cases will become more frequent. In long humeral stems, revisions are challenging, with the risk of massive bone loss, poor fixation of the new implant, and finally deteriorated clinical outcome. Consequently, investigations on humeral stem design have focused on three main issues: shortening of the stem, metaphyseal stability to avoid diaphyseal fixation that is responsible for a high rate of stress shielding, and development of a convertible modular humeral platform system [14, 25].

The first generation of the Ascend Monolythic short-stem was designed without porous coating at the metaphyseal part. In 2015, our study group reported on the first clinical results of this kind of prosthesis, and we found a favorable outcome with a mean CS of 71 ± 14 and a mean SSV of 86 ± 13 [19]. In a follow-up study, the radiographic changes around the humeral part of the prosthesis were carefully analyzed, and we found that high bone adaptations were present in more than half of the patients (52%) and remained stable until mid-term follow-up of 4–7 years [18, 21]. Moreover, bone reabsorption at the calcar region was observed in 83% of the patients. In the mid-term follow-up, none of the patients had signs of stem loosening or had to be revised due to stem loosening.

Meanwhile, design modifications led to the second generation of short-stem shoulder prosthesis (Ascend Flex) with a porous coating in the metaphyseal part to promote bone ingrowth of the humeral stem. In the current study, the functional scores and the range of motion improved significantly. At a mean follow-up of 37 months, the Constant score improved from 36 ± 8 to 75 ± 12, which is comparable to those clinical results described for the first generation of this short-stem prosthesis and other short-stem or stemless shoulder systems. None of the stems were considered to be loose or at risk for future loosening. High radiographic bone adaptations were found in 19 out of 65 shoulders (29%). Detailed analysis revealed that these radiographic changes did not influence the short-term clinical outcome.

Recently, our study group published the first results of a series of 19 patients treated with the same kind of modified short-stem shoulder prosthesis [20]. Just like the results of the current study, none of the stems were considered to be at risk for loosening and a lower number of stems were classified as showing high bone adaptation (26%) compared to the first generation (52%).

These results are in agreement with the report of Morwood et al., who compared both Ascend short stem types with 34 patients in both groups [13]. In the coated group, no stems loosened. In the uncoated group, one stem was revised for stem loosening and another seven stems were considered to be at risk for future loosening. The authors concluded that uncoated stems appear to be at greater risk of loosening and developing radiolucencies than the coated stems. Edwards et al. published the results of 118 patients treated with the same kind of short-stem prostheses [22]. 85 patients were treated with the Ascend Monolithic prosthesis without proximal porous coating and 3 female patients had gross loosening of their humeral components before 1 year, 2 requiring revision. 33 patients were treated with the Ascend Flex prosthesis with proximal porous coating, and none of the patients had instances of radiolucent lines within an average follow-up of 36 months. The authors concluded

that lack of proximal coating may contribute to early loosening in patients with poor bone quality.

To summarize the results of the current study and the existing literature about the Ascend short-stem prosthesis, the clinical and radiological short- to midterm results are promising. There is, however, one study by Casagrande et al., which is in contrast to the other studies. In 2016, Casagrande et al. reported on their series of 69 patients treated with the Ascend Monolithic prosthesis without proximal porous coating [3]. In total, 5 out of 69 patients underwent humeral stem revision and another 2 patients had humeral stem loosening without revision. Furthermore, the humeral stem was considered to be at risk of loosening in another 6 shoulders. In total, 13 out of 69 patients (19%) had stem loosening or were considered to be at risk for future loosening within a mean follow-up of 33 months. Detailed analysis of the data revealed three possible reasons for these worrying results: First, four patients underwent humeral stem revision for infection. This might be related to the fact that some patients were treated for other indications than primary osteoarthritis. Unfortunately, the indications of the patients are not mentioned in this study. Second, it should be noted that the stem was impacted into the canal using the press-fit technique, which is associated with high diaphyseal filling ratio and bone adaptation. Third, lack of ingrowth surface treatment in the metaphyseal part of the stem seems to be a major risk factor for high bone adaptation and/or humeral stem loosening.

Beside the Ascend short-stem shoulder system, there are other systems available on the market. Romeo et al. published the first results of treatment with the Apex prosthesis (Arthrex, Inc., Naples, FL, USA), with comparable clinical findings at a minimum follow-up of 2 years [16]. The authors found partial osteolysis at the calcar region in 25% of the patients, and 9% of the stems were considered to be at risk of future loosening. In a follow-up study, the authors compared the short-term radiographic findings of the Apex stem and the Ascend stem [6]. The authors found high bone adaptions in 62% of the Ascend group and in 23% of the Apex group (62% vs. 23%). It should be mentioned that they did not differentiate between the two different Ascend stem types, which makes interpretation of these results difficult. In the current study, the rates of high bone adaptation were comparable with the Apex stem (29% vs. 23%). The bone remodeling we observed with the short-stem, porous coated implant could be a sign of "normal" bone adaptation.

The current study is the first one that has analyzed the results the second generation Ascend short stem prosthesis (Ascend Flex) in a considerable large number of patients. The results of the current study are promising and in contrast to the findings of Casagrande et al., who reported alarming results on the first generation of this kind of prosthesis. Hopefully, components with better surface treatment and careful patient selection with strict indication should result in fewer adverse radiological changes over time. Further studies with longer follow-up period are required to confirm the favorable clinical results and to thoroughly understand the significance of the radiographic bone adaptations.

The strengths of this study are consistency of the surgical procedure and rehabilitation protocol in the two participating centers and a follow-up rate of almost 100%. The radiographs were assessed in a standardized fashion under fluoroscopic control according to a well-established method by two independent observers who were not involved with the design of the prosthesis.

However, this study also has limitations. Even though the patients were included in a prospective database, the analysis was done retrospectively. There was no randomization and no control group treated with a conventional prosthesis. With a mean follow-up of 37 months, the long-term outcome remains unknown. In addition, the influence of bone quality was not investigated.

Conclusion

Total shoulder replacement with this short-stem prosthesis provides favorable clinical outcomes in the short term. The occurrence of high radiographic changes did not affect the clinical outcome and none of the stems were found to be loose.

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Compliance with ethical standards

Conflict of interest Gilles Walch received royalties from Tornier/Wright, and Patric Raiss is consultant from Tornier/Wright, which is related to the subject of this work. No company had any input into the study design, protocol, testing, data analysis, or manuscript preparation. The other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

Ethical approval Ethical committee approval was obtained: Lyon/France: No. 2016-20.

Informed consent Informed consent was obtained from all individual participants included in the study.

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