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Pyrolytic carbon humeral head in hemi-shoulder arthroplasty: preliminary results at 2-year follow-up

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Background: In patients with osteoarthritis (OA) and an intact rotator cuff, hemi-shoulder arthroplasty (HSA) can be a viable option as it offers the advantage of keeping the native glenoid intact. However, glenoid erosion has frequently been reported. The aim of this study was to report preliminary clinical results of HSA with a new pyrolytic carbon (pyrocarbon) humeral head.
Methods: This prospective multicenter study included a continuous series of 65 patients who underwent pyrocarbon HSA in 5 centers.
Results: At the time of analysis, 1 patient was lost to follow-up, 3 patients underwent revision, and 61 patients were evaluated at a mean follow-up of 25.9 ± 3.3 months. The mean age at index surgery was 57.9 ± 13.3 years. The indications were primary glenohumeral OA in 37 patients, osteonecrosis in 11, secondary OA in 11, and rheumatoid arthritis in 2. The mean Constant score increased from 31.0 ± 15.8 points at baseline to 74.6 ± 17 points at last follow-up. Radiographic analyses showed that 86% of glenoids remained unchanged whereas 14% evolved slightly.
Conclusions: Pyrocarbon HSA grants improvement in pain and function in patients with primary OA or secondary OA after instability but at a lower level in patients with post-traumatic sequelae (secondary OA or osteonecrosis). These preliminary clinical and radiologic results are encouraging, although they need to be confirmed by longer-term follow-up observations.

Anatomic shoulder replacement can be performed as a total shoulder arthroplasty (TSA) or hemi-shoulder arthroplasty (HSA), depending on the native glenoid status. When the glenoid cartilage is intact, such as in cases of osteonecrosis or humeral fracture, HSA may be a good option. When the glenoid cartilage is damaged, TSA is often preferred but it introduces the risk of glenoid component complications.[5,6,24] For this reason, HSA can still be considered a viable solution for young patients despite the risk of postoperative pain and glenoid erosion—presumably caused by the friction of the metallic humeral head against the glenoid bone.[14,20]

Thanks to its unique tribological and elastic characteristics, as well as its surface properties, pyrolytic carbon (pyrocarbon) is expected to overcome the limitations of conventional HSA with a metallic head. The first clinical use of pyrocarbon was in heart valves in the 1970s. Since the 1980s, pyrocarbon has shown excellent biocompatibility and safety in orthopedic applications. Numerous articles have reported satisfactory results when pyrocarbon was used for hand and wrist arthroplasty, and it has proved to be a durable material, producing little or no wear and therefore granting implant longevity.[4,10,18] Consequently, the material properties might help prevent erosion of the glenoid surface and reduce associated pain.[3,11,19]

The goal of this study was to report clinical and radiologic outcomes, at a 2-year minimum follow-up, of HSA using a new pyrocarbon humeral head in various etiologies affecting young patients.

This study was submitted and approved in advance by the French national ethics committee (EC) (Comité Consultatif sur le Traitement de l'Information en Matière de Recherche dans le Domaine de la Santé [CCTIRS], EC ref. 14209), the German regional ethics committee (Ethik-Kommission der Bayerischen Landesärztekammer, EC ref. 14090), and the Italian regional ethics committee (Servizio Sanitario Regionale Emilia-Romagna, EC ref. 0043753).

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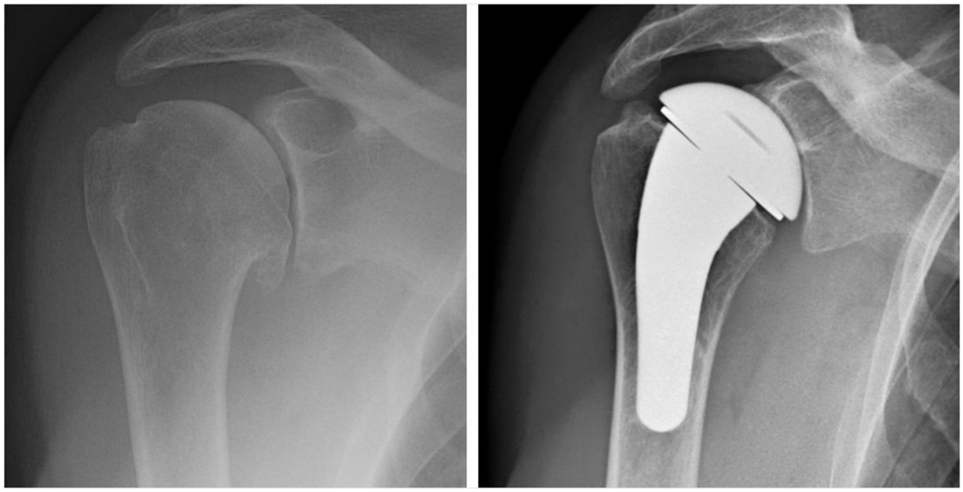

Figure 1 A shoulder with implantation of a humeral stem assembled with a pyrolytic carbon (pyrocarbon) humeral head (*left*, baseline; *right*, 2-year follow-up).

Materials and methods

Study design

We prospectively included 65 consecutive patients who underwent HSA with a pyrocarbon humeral head (Tornier SAS, Montbonnot, France), performed by 5 surgeons in 5 different centers from 3 countries between July 2013 and April 2015. All patients older than 18 years who had a functional rotator cuff and presented with an indication for HSA were included; no exclusion criteria or additional age limits were applied.

The implant consisted of a graphite core coated with a pyrocarbon bearing surface and fixed on a double male cobalt-chromium taper, designed to be assembled onto an Aequalis Ascend Flex convertible humeral stem (Tornier SAS) (Fig. 1). The humeral heads were available in 6 sizes ranging from 39 × 14 mm to 50 × 16 mm, each of which was offered with 2 different eccentricities (low, 1.5 mm; high, 3.5 or 4 mm) to restore the posterior and medial offset.[1] Before any inclusion, approvals of the ethical committees were obtained as required by local regulations, and informed consent was obtained from each participant included in the study.

Clinical and radiologic assessments

Preoperative and postoperative clinical assessments were performed using the Constant score. Patient satisfaction was measured with the Single Assessment Numeric Evaluation (SANE) score. Radiologic assessments were performed in the series of 58 patients having images available both at baseline and at follow-up. Evaluations were systematically performed on axillary and anteroposterior radiographic views (external, neutral, and internal rotation). Preoperative magnetic resonance imaging or computed tomography scans were used to evaluate the glenoid morphology according to the Walch classification.[26] All images were reviewed by 1 central observer (investigator-surgeon, J.G.). Glenoid erosion was evaluated subjectively on a 4-level scale as none, mild, moderate, or severe, as described by Sperling et al[25] and illustrated in Figure 2.

Surgical technique

The deltopectoral approach was used in all shoulders, with tenotomy of the subscapularis from the lesser tuberosity, followed by its reinsertion using transosseous and/or tendon-to-tendon sutures. Tenotomy or tenodesis of the long head of the biceps was performed in at least 55 patients; in the remaining cases, this procedure may have been performed but not reported or may have been performed during previous surgery. The labrum and capsule were preserved to maintain stability and proprioception. Resection of the coracohumeral ligament and/or juxta-glenoid capsulotomy was performed in 9 shoulders with stiffness on external rotation.

Postoperative rehabilitation

All patients followed the same standard rehabilitation protocol as for conventional anatomic prostheses, with shoulder immobilization for up to 6 weeks. Rehabilitation and physiotherapy were prescribed, consisting of passive auto-mobilization in anterior elevation without external rotation to preserve the subscapularis repair. For patients with osteoarthritis (OA) presenting with type B glenoids with posterior subluxation, the shoulders were immobilized in neutral rotation, with no immediate mobilization in internal rotation.

Results

Of the 65 patients enrolled, 1 was lost to follow-up and 3 underwent revision surgery before their 2-year follow-up. Thus, 61 patients, 20 women (33%) and 41 men (67%), with a mean age of 57.9 ± 13.3 years (median, 58 years; range, 19-84 years) at index surgery, were evaluated clinically and radiographically at a mean follow-up of 25.9 ± 3.3 months. The indications (along with glenoid types according to the Walch classification[26]) included 37 shoulders with primary OA (21 type A and 16 type B glenoids), 11 with osteonecrosis (7 atraumatic and 4 post-traumatic), 11 with secondary OA (7 after instability and 4 post-traumatic), and 2 with rheumatoid arthritis (RA) (Table I). Surgery was performed on 27 dominant-side shoulders (44%). Previous surgical procedures had been performed on 22 shoulders: osteosynthesis for fracture in 9, instability surgery in 6, glenoid bone graft to compensate for a bone defect in 1, cuff repair in 1, acromioplasty in 1, coracoplasty in 1, synovectomy in 1, axillary dissection in 1, and cartilage and labrum smoothing in 1. One intraoperative humeral shaft fracture occurred and was repaired with an osteosynthesis plate without sequelae.

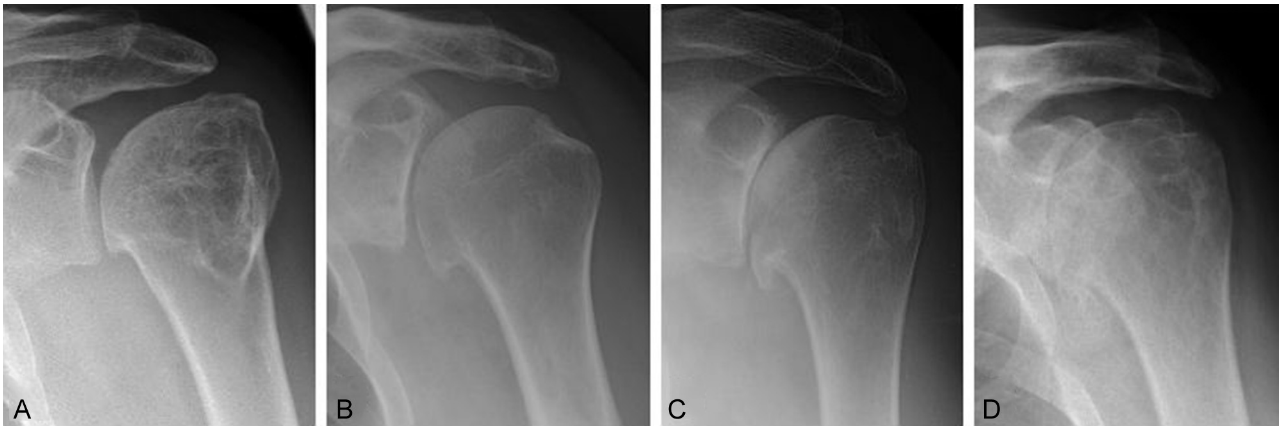

Figure 2 Four-level scale for glenoid erosion assessment: none (**A**), mild (**B**), moderate (**C**), and severe (**D**).

Revisions and implant survival

From the initial cohort, 3 patients, all with primary OA (2 type A glenoids and 1 type B2 glenoid), underwent revision surgery. In 1 patient, the cuff was suspected to be weak because, 1 year after surgery, superior migration of the humeral head was observed with a progressive functional degradation associated with pain and active-mobility impairment. Successful revision was performed in this patient at 16 months after surgery. The pyrocarbon head was explanted, and the stem was preserved and easily converted from an anatomic to reverse configuration. At 16 months after surgery, the other 2 patients underwent revision for persistent postoperative glenoid bone pain. In 1 patient, with primary OA and a type B2 glenoid, revision to reverse shoulder arthroplasty (RSA) was performed easily and successfully, thanks to the convertibility of the stem. In the other patient, revision was performed by a surgeon not participating in the study. We learned that the pyrocarbon humeral head was exchanged for a metallic one. The patient's condition has not improved, and the outcome is still poor. No other postoperative complications were reported. Considering all humeral head removals (n = 3), whatever the reason, the survival rate was 95.3% at 2-year follow-up.

Clinical outcome

The mean total Constant score for the series of 61 patients improved from 31.0 ± 15.8 points preoperatively to 74.8 ± 17.0 points postoperatively (Table I), with a mean increase of 44.4 ± 17.5 points. The pain and activity subscores of the Constant score improved by 9.8 ± 3.1 points and 10.3 ± 4.1 points, respectively (Table II).

Table I
Breakdown of total Constant score by indication and glenoid type

Indication	n	Constant score, points					
		Baseline visit		2-yr FU visit		Improvement (individual changes)	
		Mean	SD	Mean	SD	Mean	SD
Primary OA							
Type A1	14	32.2	13.7	79.7	12.6	47.5	14.9
Type A2	7	34.7	15.3	80.0	9.1	45.3	10.5
Type B1	10	31.9	19.9	78.8	14.4	46.9	21.2
Type B2	6	33.8	16.9	77.7	10.0	44.0	16.0
Secondary OA							
After fracture	4	16.9	10.8	37.5	21.6	20.6	18.5
After instability	7	30.2	17.9	80.9	8.5	50.7	19.3
Osteonecrosis							
After fracture	4	25.8	16.0	55.5	24.1	29.7	16.0
Atraumatic	7	36.6	16.9	79.5	9.8	48.1	16.5
RA	2	20.9	4.4	69.8	7.1	48.9	2.7
Total	61	31.0	15.8	74.8	17.0	44.4	17.5

FU, follow-up; *SD*, standard deviation; *OA*, osteoarthritis; *RA*, rheumatoid arthritis.

In this series, good results were reported for all etiologic subgroups, except traumatic sequelae, with a minimum mean improvement in the Constant score of 44.0 ± 16.0 points (primary OA with type B2 glenoids) and a maximum of 50.7 ± 19.3 points (secondary OA after instability). Conversely, the results for patients presenting with traumatic sequelae—those with secondary OA and those with osteonecrosis—were rather poor, with a mean improvement of 20.6 ± 18.5 points and 29.7 ± 16.0 points, respectively.

Patient satisfaction

The mean SANE score for the whole series improved from 32% preoperatively to 78% postoperatively (Table III). Patients with primary OA and type B2 glenoids were among the most satisfied patients. Patients with primary OA and type A glenoids, secondary OA after instability, or atraumatic osteonecrosis reported a 48% or greater increase in the SANE score after surgery. Patients with RA, secondary post-traumatic OA, or post-traumatic osteonecrosis reported low improvement in the SANE score (<35%).

Radiographic outcomes

Before surgery, among the 58 evaluated patients, 16 glenoids were described as having no erosion, 17 had mild erosion, 13 had moderate erosion, and 12 had severe erosion. At the 2-year follow-up, 50 glenoids (86%) showed no progression of erosion compared with their preoperative status whereas erosion evolved slightly (ie, evolution of no more than 1 level on the 4-level scale of erosion described in the "Materials and methods" section) in 8 glenoids (14%). In some patients presenting with type B glenoids preoperatively, centering of the humeral head in front of a seemingly remodeled glenoid socket could be observed on postoperative computed tomography scans (Fig. 3).

Discussion

The findings of this study provide encouraging results for pyrocarbon HSA. The mean postoperative total Constant score for our whole series was 74.8 ± 17.0 points at a mean follow-up of 25.9 ± 3.3 months, and no major postoperative glenoid erosion was observed. These results will be discussed according to each etiology as outcomes vary greatly from one etiology to another and as it will

Table II
Breakdown of Constant pain and activity subscores by indication and glenoid type

Indication	n	Pain subscore, points						Activity subscore, points					
		Baseline visit		2-yr FU visit		Improvement (individual changes)		Baseline visit		2-yr FU visit		Improvement (individual changes)	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Primary OA													
Type A1	14	3.6	2.1	13.9	2.2	10.3	2.8	6.2	3.0	18.1	3.6	11.9	3.4
Type A2	7	4.3	2.7	14.6	1.1	10.3	3.0	8.0	3.4	18.7	1.8	10.7	3.6
Type B1	10	3.6	2.2	13.2	3.0	9.6	3.2	6.9	2.9	15.0	4.2	8.1	3.9
Type B2	6	2.7	1.8	12.5	2.4	9.8	2.7	7.0	1.8	17.0	1.8	10.0	2.3
Secondary OA													
After fracture	4	2.0	0.8	9.8	5.6	7.8	5.3	3.5	2.6	12.5	4.4	9.0	5.4
After instability	7	2.7	2.3	13.7	1.6	11.0	3.4	4.9	1.9	18.0	2.5	13.1	2.8
Osteonecrosis													
After fracture	4	4.0	3.8	12.0	1.2	8.0	3.7	6.8	3.0	11.3	6.8	4.5	6.5
Atraumatic	7	3.5	2.1	13.4	2.1	10.4	2.5	6.8	1.8	18.1	1.2	11.7	1.9
RA	2	3.5	3.5	9.5	3.5	6.0	0.0	8.0	2.8	16.5	2.1	8.5	0.7
Total	61	3.4	2.2	13.1	2.7	9.8	3.1	6.4	2.8	16.7	3.9	10.3	4.1

FU, follow-up; *SD*, standard deviation; *OA*, osteoarthritis; *RA*, rheumatoid arthritis.

help to identify indications for which pyrocarbon HSA shows the most promising results.

Atraumatic osteonecrosis has already been reported to be a good indication for HSA,[7,21] particularly in young patients with preserved glenoid cartilage.[6] As expected, in our series, the results obtained for this indication were satisfactory, with a mean postoperative Constant score of 79.5 ± 9.8 points and an improvement of 48 points compared with baseline. Conversely, outcomes for post-traumatic osteonecrosis, even without malunion of the tuberosities or cuff tear, were rather poor, confirming results reported in other series.[22] In our cases, the collapses were severe and the shoulders had become stiff. When the head is fully collapsed, implantation of a prosthesis can result in an increase in the joint pressure, causing pain and stiffness. In these cases, RSA[2,23,26] or pyrocarbon interposition shoulder arthroplasty could be a better option.[9,13] Indeed, pyrocarbon interposition shoulder arthroplasty showed good results for patients presenting with post-fracture osteonecrosis without malunion, with a mean postoperative Constant score improvement of 45 ± 35 points at 24 months' follow-up[9] or 65 ± 13 points at 42 months' follow-up.[13]

Post-instability OA has also been reported to be a good indication for HSA.[16] This pathology particularly affects young patients. The clinical results obtained in this group were very satisfactory, with a mean Constant score of 80.9 ± 8.5 points at 2-year follow-up and a mean improvement of 50 points compared with baseline. Conversely, the outcomes for the secondary OA post-traumatic group were poor, as reported in previously published series.[24]

Table III
Breakdown of SANE score by indication and glenoid type

Indication	Baseline visit			2-yr FU visit		
	N	Mean, %	SD, %	n	Mean, %	SD, %
Primary OA						
Type A1	12	36	12	13	88	16
Type A2	6	38	26	7	86	13
Type B1	9	36	9	10	77	16
Type B2	4	23	19	6	82	10
Secondary OA						
Post-traumatic	3	27	25	4	54	36
After instability	7	28	13	7	86	9
Osteonecrosis						
Post-traumatic	2	18	4	4	46	30
Atraumatic	4	29	30	7	78	24
RA	2	38	4	2	68	11
Total	49	32	17	60	78	21

SANE, Single Assessment Numeric Evaluation; *FU*, follow-up; *SD*, standard deviation; *OA*, osteoarthritis; *RA*, rheumatoid arthritis.

Only 2 patients presented with RA, and they did not show the best outcomes of the series; however, they were satisfied with the procedure, mostly because of pain relief, which is an important consideration for these patients. When the cuff is functional, pyrocarbon HSA might be considered a viable option for patients affected by this specific pathology, but a larger cohort is necessary for confirmation.

In patients with primary OA without glenoid bone loss and with a centered humeral head (type A glenoids), good outcomes were expected. With a mean postoperative Constant score of 80 points (improvement of 45 points compared with baseline), the results were satisfactory compared with those reported for TSA and HSA in the literature.[5,6,17]

With this new pyrocarbon implant—using a classic operative technique—outcomes in the group with primary OA with type B1 or B2 posterior subluxations were unexpectedly good. The mean postoperative Constant score was 78.8 ± 14.4 points (type B1) and 77.7 ± 10.0 points (type B2), with a mean gain of around 45 points compared with baseline. Indeed, OA is characterized by cartilage degradation of the joint. When it affects the posterior part of the glenoid (type B glenoid), the pressure of the head is no longer applied centrally but is applied eccentrically, resulting in erosion, first of the posterior glenoid cartilage and then of the bone. Once the glenoid is biconcave, it limits the capability of the head to regain a centered position in any arthroplasty procedures.[12,16,25,27] Surprisingly, in patients presenting with those type B glenoids, a re-centering of the humeral head in front of the glenoid was seemingly observed in some patients. Two main factors could explain this phenomenon: The first factor is a restoration of the anteroposterior translational movement of the humeral head. Indeed, one of the properties of pyrocarbon is to adsorb proteins and phospholipids on its surface, enhancing the formation of a lubricating membrane that reduces friction,[8] thereby facilitating this anteroposterior translation. The second factor is preferential paleoglenoid versus neoglenoid bone remodeling as the bone density of the anterior facet (paleoglenoid) has been shown to be lower than that of the posterior facet (neoglenoid).[15] Thus, the paleoglenoid could more readily undergo a remodeling process to adapt to the humeral head re-centering. Likewise, a slight reduction

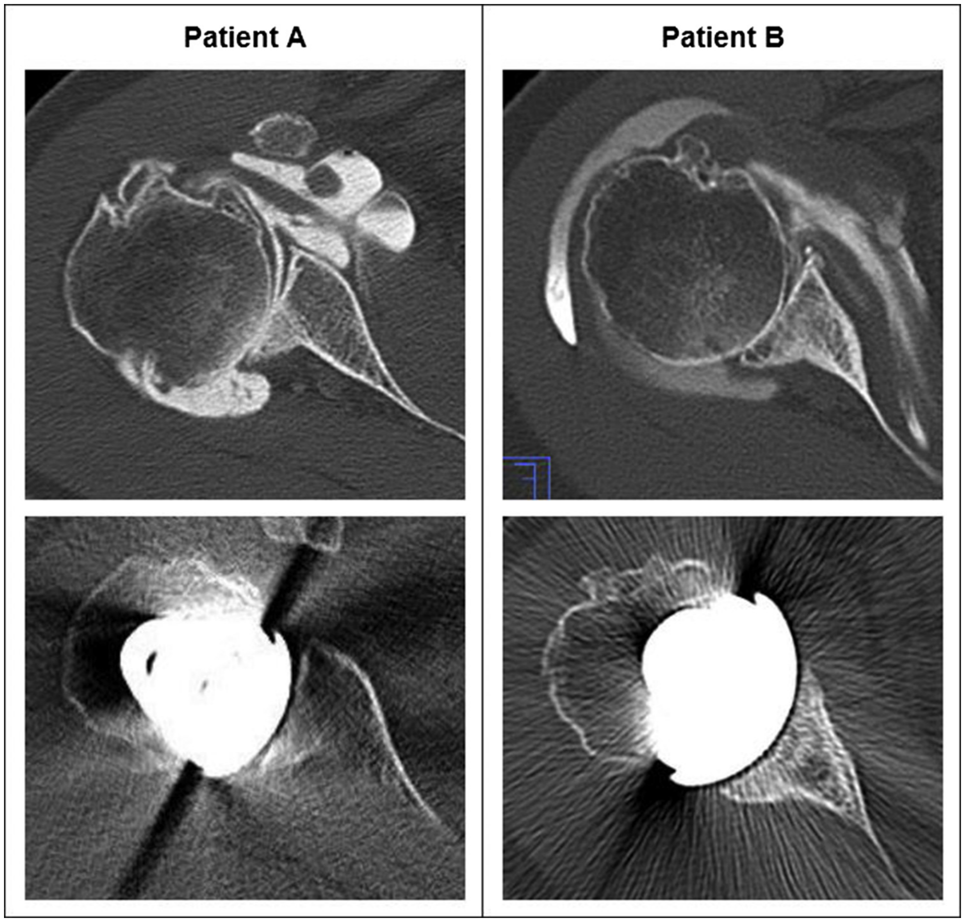

Figure 3 Computed tomography scan images from 2 patients with type B1 glenoids at baseline (*top*) and at 4-year follow-up (*bottom*). A re-centering effect of the humeral head can be observed on the postoperative images.

of the native humeral retroversion, the absence of internal rotation during rehabilitation, or the intraoperative subscapularis release could contribute to the humeral re-centering effect. At this stage, considering the short-term follow-up and the small cohort size, we do not recommend the use of pyrocarbon HSA for patients with type B2 glenoids. Longer-term follow-up, a larger cohort, and a thorough radiologic analysis will be needed to understand and confirm these observations. However, for young patients with type B1 glenoids, we consider pyrocarbon HSA an acceptable option to avoid the risk of long-term complications from TSA or RSA.

Regarding the reported complications, we were not able to identify preoperative risk factors for the 3 reported revisions (all patients presenting with OA). However, in young patients, preserving the glenoid and using a convertible stem are 2 major advantages when considering potential future revisions.

Although this study was a prospective, multicenter, and continuous series on a sizeable whole cohort, covering a wide range of etiologies, it showed some limitations: the absence of a control group, the small size of the cohort of patients with each etiology, and the short clinical follow-up. The decision to perform a noncontrolled study was motivated by an ethical rationale because we considered it inappropriate to perform metal HSA as a control procedure, given its poor published outcomes.

Conclusion

This study is the first to report the outcomes of HSA with a pyrocarbon head assembled onto a convertible humeral stem, with a minimum of 2 years' follow-up. Pyrocarbon HSA showed good clinical and radiologic outcomes in patients presenting with primary OA or post-traumatic secondary OA or osteonecrosis. The outcomes in patients presenting with fracture sequelae (secondary OA or osteonecrosis) were rather poor. These findings are encouraging, although they need to be confirmed by longer-term follow-up observations.

Disclaimer

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