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Midterm results of pyrocarbon interposition shoulder arthroplasty: good outcomes after posttraumatic osteonecrosis without malunion of the tuberosities

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A R T I C L E I N F O

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Posttraumatic osteonecrosis

Level of evidence: Level IV; Case Series; Treatment Study

Background: In vitro data demonstrate the potential benefits of the pyrocarbon as a bearing material against cartilage or bone. And pyrocarbon-free interposition arthroplasty has been used with positive outcomes for over 10 years for hand and wrist joint replacements. This study reports the midterm results of a Pyrocarbon Interposition Shoulder Arthroplasty (PISA) in primary and secondary glenohumeral osteoarthritis and in avascular osteonecrosis.
Methods: This prospective noncontrolled, multicenter study included 67 consecutive patients who underwent PISA in France and Sweden.
Results: A cohort of 48 patients, aged 50 ± 12 years, was available for clinical assessment at a mean follow-up of 67.6 ± 9.3 months. A favorable change was reported with a mean absolute Constant score improvement of 32 ± 20 points. The highest Constant score improvement was observed in patients with avascular osteonecrosis (42 ± 18 points; $P \leq .0001$). Between the earliest and the latest follow-up, radiographic analyses revealed only 2 major glenoid erosions and 4 tuberosity thinnings and thus that 86.4% of 44 shoulders remained stable with no or minor radiologic evolutions. The survival rate was 84 % at 65 months of follow-up considering all causes of revision.
Conclusion: The radiographic findings seem to confirm the interest of pyrocarbon in preserving bony surfaces. But the risk of tuberosity thinning suggests considering the use of PISA with caution in most degenerative glenohumeral joint pathologies, although the midterm outcomes highlight PISA as a suitable solution for patients presenting with posttraumatic osteonecrosis without malunion of the tuberosities and with an intact rotator cuff.

Young and active patients presenting with a degenerative glenohumeral joint remain a dilemma for the surgeon because of high functional demands that necessitate greater durability of the arthroplasty. Total shoulder arthroplasty (TSA) provides predictable pain relief and improvement of function but is limited by the longevity of the implant.[13,15,38] Hemishoulder arthroplasty (HSA) is an option to avoid the glenoid loosening observed after TSA but at the price of a high risk of symptomatic glenoid erosion, which can lead to complex revision. And comparative studies demonstrate the superiority of the clinical outcomes obtained after TSA compared with HSA.[4,24,28,33,45] Reverse shoulder arthroplasty (RSA) is a controversial option in younger patients because there are

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concerns regarding the complications rate and implant survivorship.[14,19,50] A similar dilemma is faced by shoulder surgeons to treat proximal humeral fracture sequelae.[49]

Pyrolytic carbon (pyrocarbon) is a durable material with favorable wear characteristics and bone preservation compared with metals.[12,22,29] The first medical application of pyrolytic carbon (pyrocarbon) in heart valves in the 1970s showed excellent biocompatibility and safety properties for this material.[8,23] Thanks to its superior tribological properties compared with metals, pyrocarbon can slide against bone and cartilage causing limited pain or damage.[8,12,29] The benefits of pyrocarbon as a bearing material for joint replacement have been confirmed with published long-term follow-up (FU) in hands, wrist, and elbow applications.[1,6,9,20,47]

The Pyrocarbon Interposition Shoulder Arthroplasty (PISA) implant is the first and only free interposition device for shoulder arthroplasty. It consists of a spherical graphite core coated with a pyrocarbon bearing surface, freely positioned in a reamed cavity in the proximal humerus, and directly articulating with double mobility against the glenoid and the humerus. The first prosthesis was implanted in a patient in 2010 with the hypothesis to reduce the glenoid erosion and the associated deterioration of the functional results. That new arthroplasty was proposed to the young or active patients with a degenerative glenohumeral joint and patients with posttraumatic sequelae.

The goal of this prospective multicenter study was to report clinical, radiographic, and survival outcomes of the PISA implant used in various etiologies at an average of 5-year FU. Preliminary results from the same cohort at 2-year FU revealed clinical outcomes and implant survival comparable to HSA but inferior to total shoulder arthroplasty (TSA).[17] Our main hypothesis for this study was that based on the 5-year FU radiological results, pyrocarbon would be a better alternative to metals for articulation against cartilage or bone. And our secondary hypothesis was that PISA would be a reliable solution in traumatic avascular osteonecrosis.

Materials and methods

Study design

In this multicenter observational study, 67 consecutive patients who underwent a shoulder arthroplasty with Inspyre implant (Tornier SAS, Montbonnot, France) were prospectively included. Before any inclusion in the study, Ethics Committees approvals were obtained as required per local regulations. Surgeries were performed at 9 investigational sites by 9 surgeons from 2 countries (France and Sweden) between March 2010 and October 2012. All patients aged >18 years, having a functional rotator cuff, and for who the surgeons perceived that PISA would be a viable alternative to either HSA or TSA were proposed to participate in the study with a clear informed of the innovative nature of the implant. All patients provided their consent, per local regulations, to participate in the study. Demographic data are summarized in Table I.

Table I
Demographic characteristics (N = 67).

Parameter	N = 67 (%)
Age at surgery (yr)	50.7 ± 11.4 (19-78)
Gender, female/male	33 (49)/34 (51)
Dominant side	45 (67)
Bilateral shoulder	0 (0)
Diagnosis	
Primary glenohumeral osteoarthritis	42 (63)
Atraumatic avascular osteonecrosis	9 (13)
Posttraumatic arthropathy with malunion	6 (9)
Postinstability osteoarthritis	6 (9)
Posttraumatic avascular osteonecrosis	4 (6)
Previous surgical treatment*	27 (40)
Stabilization procedure postinstability	8 (20)
Open reduction with internal fixation (ORIF) for proximal humeral fracture	7 (10)
Subacromial decompression	6 (9)
Long head of biceps tenotomy	3 (4)
Rotator cuff repair	2 (3)
Others procedures	12 (18)

*Some shoulders had more than one previous procedure.

Clinical and radiographic assessments

Preoperative and postoperative clinical outcomes at a 5-year FU were assessed by the surgeons who performed the procedure using the Constant Score (CS) and the Range of Motion (ROM) evaluation, namely, anterior elevation, external rotation at 0°, and 90° of abduction and internal rotation. A central radiologic assessment, which was an exploratory endpoint, was performed in the series of patients having images available at both baseline and 5-year FU. One single observer (J.G.) assessed on axial cuts of the preoperative computed tomography scan, the initial type of glenoid deformity according to Walch's classification.[51] And, using a standardized protocol, the central observer compared the earliest available postoperative anteroposterior x-ray images (external, neutral, and internal rotations) with the 5-year one to assess the evolution of 2 radiographic criteria over time: glenoid erosion and thinning of the tuberosities. For both criteria, measurements were calculated relative to the implant diameter, to avoid scale errors, using measurements abacus inspired by a radiological study by Nyffeler et al[34] (Fig. 1). Assuming an estimated error rate of 15% in the abacus positioning, the difference between the compared images was qualified as "no difference" (difference ≤15%), "minor" (difference >15% and ≤30%), or "major" (difference >30%).

Surgical technique

The surgical technique is detailed in the publication of the short-term outcomes on this cohort.[17]

Postoperative rehabilitation

All patients followed the same standardized rehabilitation protocol with shoulder immobilization for 4-6 weeks. Passive auto-assisted mobilization was allowed on day 1 after the surgery. After the immobilization, an active ROM was authorized without any load for 3 months.

Statistical analysis

As the study was exploratory, a priori sample size calculation for power analysis was not performed because there was no primary hypothesis.

Quantitative and descriptive statistical analyses were performed depending on whether variables were continuous or discrete. The statistical analysis was performed with Minitab 18 (Minitab INC, State College, PA, USA). Missing data were not replaced. According to the type of criterion, overall descriptive statistics were quantitative (sample size, mean, standard deviation, 95% confidence interval of mean, minimum, median, and maximum) or categorical (absolute and relative frequency for each modality of the considered criterion).

Clinical quantitative parameters (CS and ROM) changes between preoperative and 5-year FU were analyzed by a paired Student's t-test if the normal hypothesis was demonstrated or by a paired

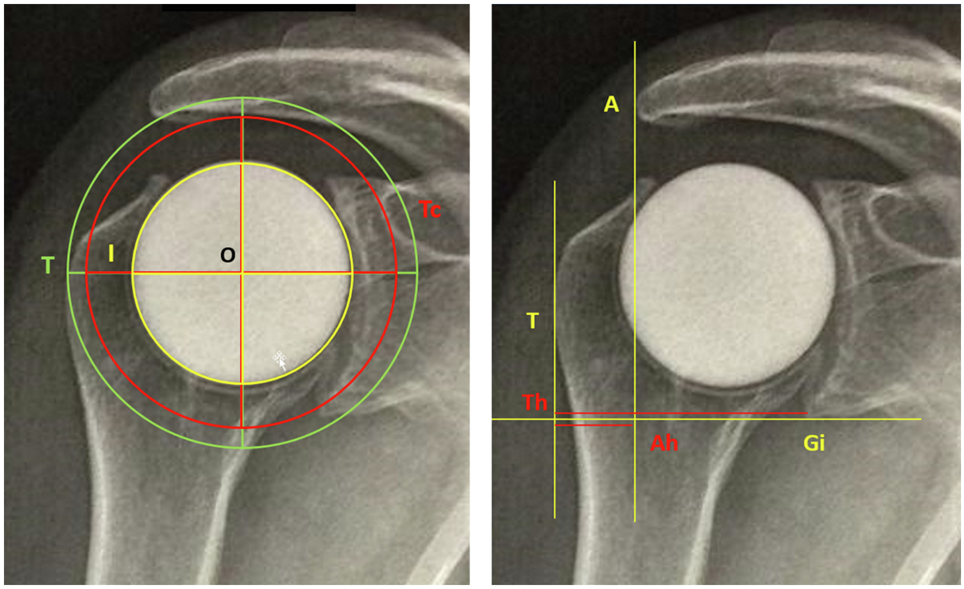

Figure 1 Evaluation of radiological criteria: glenoid erosion (OTc/OI) and tuberosity's thinning (OT/OI).

Wilcoxon test if not. Tests were 2-tailed. P values <0.05 were considered statistically significant, but they must be interpreted with caution, as this is an interim analysis. Survival analysis (failure) was performed using the Kaplan-Meier method. The endpoint was the occurrence of a revision related to the surgery (surgery failure) or the implant (implant failure).

Results

Of the 67 initially enrolled patients, 3 deceased, 6 were unable to return to complete their 5-year outcome assessments, and 1 was lost to FU. In addition, 7 patients underwent revision surgery with implant removal within the first 30 months of FU, and 2 were revised at 60 and 69 months, respectively. As a result, 48 patients, 26 (54.2%) women, and 22 (45.8%) men, with a mean age at surgery of 50 ± 12 years (range, 19-78 years), were assessed at an average of 67.6 ± 9.3 months (range, 53-96 months) FU and included in the clinical analysis. Patients with avascular osteonecrosis had the highest CS improvement with a mean increase of 42 ± 18 points (P < .001) and remain very stable with no noticeable radiologic evolution, since the index procedure, for each of the 2 radiological criteria evaluated.

Clinical outcomes

Clinical outcomes are presented for the previously described series of 48 patients (26 women and 22 men). The mean absolute CS for this series improved from 36 ± 15 points preoperatively to 69 ± 17 points postoperatively, with a mean increase of 32 ± 20 points (P < .001). The main improvements of the CS were observed on the pain and activity subscore, which improved respectively by 8 ± 4 points on a scale of 15 and by 10 ± 5 points on a scale of 20 (Table II). Significant favorable changes were reported in all ROM between preoperative and 5-year postoperative visits (Table III). The results by etiology and glenoid type subgroups are presented in Table IV. A statistically significant increase in CS was not observed in all etiologies. At 5-year FU, lowest CS were observed in primary OA with type B1 and C glenoid and in posttraumatic secondary OA with malunion, whereas highest CS were observed in primary OA with B2 glenoid, and in avascular osteonecrosis. Between preoperative and 5-year FU, the highest CS improvements were observed in avascular osteonecrosis and primary OA with type A glenoid with respectively a mean increase of 42 ± 18 points (P < .001) and 37 ± 14 points (P < .001).

Radiographic outcomes

Glenoid erosion and tuberosities thinning were assessed by a central observer on the earliest (3-6 months) and the latest (mean: 67.6 ± 9.3 months) postoperative x-ray images available at the time of analysis. Two patients had their earliest available x-ray images at 12 and 18 months, respectively, but they were included in the analysis.

The earliest and the latest FU x-ray images were available for 44 patients from the cohort. Glenoid erosion was observed and qualified as minor in 20 (45.5%) shoulders and as major in 2 (4.5%) shoulders. Tuberosity thinning was assessed as minor in 5 (11%) shoulders and as major in 4 (9%) shoulders. In some cases, tuberosities were already quite thin at an early postoperative stage, but no report or sign of fracture was observed except one reported as an intraoperative complication during the initial surgery. Figure 2, *A* and *B* presents, respectively, the mean CS at 5 years according to the glenoid erosion and according to the tuberosity thinning. A statistical difference was observed between the patients without or with glenoid erosion whatever the erosion stage (P = .034) and between the patients without or with the tuberosity thinning whatever the stage (P = .0038). The results from radiographic evaluations by gender, age, and etiologies are presented in Table V. For both criteria, glenoid erosion and tuberosity thinning, no significant effect of gender was reported. No conclusion could be drawn on the effect of age because of the short size of the older group of patients (aged >65 years). Regarding the etiology, all patients operated on for avascular osteonecrosis remain very stable for both criteria, glenoid erosion and tuberosity thinning, with no noticeable radiologic evolution. No statistical difference between the 3 groups of etiology was observed related to tuberosity thinning. While for the glenoid erosion, the difference was significant when comparing avascular osteonecrosis to the primary glenohumeral osteoarthritis (P < .001) and to the secondary glenohumeral osteoarthritis (P = .011).

In the 39 patients for whom the 2-year and the latest FU x-ray images are available, glenoid erosion remains stable in most

Table II
Absolute Constant score at preoperative and 5-year follow-up.

Variable	Statistics	Preoperative	5-year FU	Change 5-y FU vs Preop	*P* value (paired t-test)
Pain (points)	N	48	48	48	
	Mean ± SD	4 ± 3	12 ± 3	8 ± 4	<.001
	Min/Median/Max	0/4.5/14.5	5/14/15	−2.5/8/15	
Activities (points)	N	48	48	48	
	Mean ± SD	7 ± 3.5	17 ± 4	10 ± 5	<.001
	Min/Median/Max	2/6/15	3/18/20	−4/10.5/18	
Mobility (points)	N	48	48	48	
	Mean ± SD	19 ± 9	29 ± 8	10 ± 11	<.001
	Min/Median/Max	4/16/40	12/32/40	−14/13/34	
Strength (points)	N	46	48	46	
	Mean ± SD	5 ± 5	10 ± 6	5 ± 6	<.001
	Min/Median/Max	0/4.5/20	0/10/25	−6/3.5/25	
Absolute Constant (points)	N	46	48	46	
	Mean ± SD	36 ± 15	69 ± 17	32 ± 20	<.001
	Min/Median/Max	8.5/36/68.5	24.5/71/97	−16.5/31.5/79	

FU, follow-up; *SD*, standard deviation; *Preop*, preoperative.

Table III
Range of motion at preoperative and 5-year follow-up.

Motion	Statistics	Preoperative	5-year FU	Change 5-y FU vs Preop	*P* value (paired t-test)
Anterior elevation (degrees)	N	48	47	47	
	Mean ± SD	103 ± 34	141 ± 31	38 ± 43	<.001
	Min/Median/Max	30/100/180	60/150/180	−60/40/120	
External rotation (0°; degrees)	N	48	47	47	
	Mean ± SD	19 ± 20	36 ± 16	17 ± 26	<.001
	Min/Median/Max	0/10/80	10/30/70	−45/20/60	
External rotation (90°; degrees)	N	44	43	40	
	Mean ± SD	33 ± 30	62 ± 25	29 ± 33	<.001
	Min/Median/Max	0/20/90	0/70/90	−60/30/90	
Internal rotation (90°; degrees)	N	37	29	23	
	Mean ± SD	22 ± 22	45 ± 26	22 ± 36	.007
	Min/Median/Max	0/10/80	0/50/90	−60/30/65	

FU, follow-up; *SD*, standard deviation; *Preop*, preoperative.

patients because it was assessed as “without change” in 27 (69%) patients and as “minor” in 10 (26%) patients. On the same group of 39 patients, only 3 shoulders were identified to have had a minor thinning of the tuberosities between the 2-year and the latest FU.

The subjective radiographic observations performed by the investigators finally highlighted a sclerotic bone densification line around the implant in 36 (94%) of the 38 assessed patients' x-ray images for that criterion.

Complications and revisions

One intraoperative complication was reported: fracture of the greater tuberosity without displacement, which consolidated spontaneously during immediate postoperative shoulder immobilization before rehabilitation started.

One immediate postoperative complication was reported: hematoma without impact on the immediate start of the rehabilitation.

Reoperations were reported in 11 patients of the 67 patients included in the study: 2 without implant removal, therefore maintained in the study, and 9 revisions. The 9 revisions were analyzed and classified into “*4 main groups of causes for revision or re-operation*”, namely[17]:

1). Worsening of pre-existing posterior subluxation in 2 patients;
2). Inferior glenohumeral impingement in 2 patients;
3). Rotator cuff tears in 2 patients;
4). Persistent or reoccurring pain in 3 patients.

Implant survival

Of the 9 revisions, 4 were classified by the investigators as unrelated or unlikely related to the device and the procedure:

- Two subsequently to fall, one occurring at 3 months from the index procedure and revised, at 10 months of FU, with an RSA, and the other one occurring at 8 months and revised, at 18-month FU, with a TSA;
- One subsequently to a recurrence of pre-existent posterior subluxation and replaced, 16 months after the index surgery, by another PISA of higher diameter with a simultaneous reaming of the glenoid;
- And, one explanted 61 months after the index surgery subsequently to pain in any activity resulting from an inferior glenohumeral impingement due to a prominent humeral calcar, which was not resected during the initial procedure.

Considering any implant removal whatever the causal relationship, the survival rate was 87% (95% confidence interval, 79%-96%) at 60 months and 84% (95% confidence interval, 74%-94%) at 65 months postsurgery (Fig. 3).

Discussion

This study is a prospective, multicenter, first midterm report on the PISA. At the latest FU, the radiologic analysis revealed that the glenoid erosion was assessed as “major erosion” in only 2 patients (4.5%), which could be treated with a reversed bony or metallic

Table IV
Breakdown of absolute Constant Score by etiologies and glenoid types.

Pathology	N (%)	Constant score preoperative			Constant score 5-year FU			Change in Constant score 5-y FU vs Preop			P value (paired t-test)
	N = 46	Mean ± SD	Min	Max	Mean ± SD	Min	Max	Mean ± SD	Min	Max	
Primary glenohumeral OA											
A1	15 (32.6)	39 ± 13	19	63.5	73 ± 9	56.5	85	34 ± 13	9	57	<.001
A2	5 (10.9)	22 ± 12	11	40.5	69 ± 7	63	82	45 ± 15	24.5	60	.003
Total glenoid A	20 (43.5)	35 ± 15	11	63.5	72 ± 8	56.5	85	37 ± 14	9	60	<.001
B1	5 (10.9)	34 ± 11	22.5	48	44 ± 24	24.5	79	10 ± 28*	−16.5	54	.460
B2	4 (8.7)	42 ± 16	28.5	61.5	80.5 ± 16	63	97	38 ± 23	13	68.5	.047
C	1 (2.2)	41.5	41.5	41.5	36.5	36.5	36.5	−5†	−5	−5	-
Total glenoid B and C	10 (21.7)	38.1 ± 12.6	22.5	61.5	58.0 ± 26.9	24.5	97	19.9 ± 28.3	−16.5	68.5	.054
Total primary glenohumeral OA	30 (65.2)	36 ± 14	11	63.5	67.5 ± 17.5	24.5	97	31 ± 21	−16.5	68.5	<.001
Avascular osteonecrosis											
Atraumatic	5 (10.9)	51 ± 12	37	68.5	82 ± 9	67	91	34 ± 9	22.5	43.5	.001
Posttraumatic	3 (6.5)	22 ± 22	8.5	48	78 ± 11.5	66	89	56 ± 24†	31	79	.057
Total avascular osteonecrosis	8 (17.4)	40 ± 21	8.5	68.5	81 ± 9	66	91	42 ± 18	22.5	79	<.001
Secondary glenohumeral OA											
Postinstability	4 (8.7)	29.5 ± 13	18	47.5	65 ± 10	52	76	35 ± 20.5	4.5	48	.041
Posttraumatic with malunion	4 (8.7)	36 ± 15	19.5	55.5	54 ± 15.5	38	75	18 ± 10‡	7.5	31.5	.100
Total secondary glenohumeral OA	8 (17.4)	33 ± 14	18	55.5	59 ± 13.5	38	76	26.5 ± 18	4.5	48	.004

FU, follow-up; *OA*, osteoarthritis; *SD*, standard deviation; *Preop*, preoperative.
*Not significant: 3 patients showed a total Constant score improvement of 54, 17, and 4.5 points, respectively, and 2 patients showed a total Constant score decrease of 9 and 16.5 points, respectively.
†Not significant: too small number of patients.
‡Not significant: total Constant score improvement was 31.5, 19.5, 13, and 7.5 points, respectively.

augmented glenoid implant in case of revision. In 20 other patients (45.5%), glenoid erosion was assessed as "minor." The fact that in the majority (95%) of the patients, with radiological FU at 2 years and 5 years, the radiologic appearance of the glenoid seems to stabilize suggests that it might be qualified, as described in pyrocarbon hand surgery,[6,41,47] of a bone remodeling which stabilizes over time rather than a continuous erosion as traditionally observed with metal implants. Those midterm radiologic findings and the innovative design of the implant with its specific biomechanics do not allow us to conclude on the superiority of pyrocarbon compared with metals for articulation against cartilage or bone. Further consideration of the radiographic analysis to correlate the findings to the anatomic reconstruction accuracy or the bone density might be useful for drawing such a conclusion. At the same time, McBride et al[32] recently reported that no revision for glenoid erosion occurred in a cohort of 163 pyrocarbon resurfacing hemiarthroplasty followed in the Australian Orthopaedic Association National Joint Replacement Registry. And previously, few short-term studies on HSA with pyrocarbon humeral head have been published. The first multicentric study published[18] reported, at a mean FU of 26 months, that glenoid erosion evolved slightly in 8 shoulders (14%), whereas 50 shoulders (86%) showed no progression of glenoid erosion compared with their preoperative status. In a monocentric cohort of 16 patients reviewed at a mean FU of 2 years, Tsitlakidis et al[48] reported that only one glenoid erosion (6% of the cohort) occurred. And, in another monocentric cohort of 64 shoulders reviewed at a mean FU of 33 months, Cointat et al[11] reported that glenoid erosion had evolved in 23 glenoids (39%) either to correct posterior humeral subluxation (18 cases) or to improve congruency (5 cases). Those results of resurfacing and stemmed HSA with pyrocarbon articulating surface will also help to conclude on the *in vivo* benefits of pyrocarbon and support its consideration as an alternative to metals for arthroplasty bearing surfaces in larger joints than hand, wrist, or elbow.

The evidence of sclerotic bone densification at the interface between the implant and the humeral bone in almost all cases (94%) at the 5-year FU review confirms the observation made on 50 humeri at 2-years FU.[17] It could be the *in vivo* translation of encouraging *in vitro* findings related to the biotribological characteristics of pyrocarbon. Under comparable simulated physiological conditions, pyrocarbon articulating surfaces showed superiority to conventional cobalt-chromium prostheses when tested against fresh bovine cortical bone.[29] In a cartilage-like environment, pyrocarbon could promote type II collagen synthesis, and in a bone-like environment, pyrocarbon could promote a well-organized, well-mineralized, and stiff tissue-like cell membrane.[22] The confirmed and maintained presence of those sclerotic lines also demonstrates a good transmission of load to the humeral concavity based on the understanding of bone remodeling[10,40] and might confirm the formation of a lubricating membrane around the PISA thanks to the ability of the pyrocarbon to absorb proteins on its surface.[16]

Thinning of the tuberosities was observed in 9 patients (20%) and was major in 4 of them; however, no sign of fracture has been observed so far in this cohort and our findings suggest that the thinning stabilizes over time. However, recently, 4 cases of greater tuberosity fractures leading to revision surgery have been reported in a monocenter study on PISA midterm FU[3]: 2 were related to minor traumatic events and 2 occurred spontaneously as stress fractures. That report confirms that tuberosity thinning leads to tuberosity weakness, potentially leading to a secondary rotator cuff tear or greater tuberosity fracture. This finding is to be considered by surgeons preoperatively while selecting patients. And aware of such serious potential complications, surgeons should be cautious while reaming the metaphyseal humeral bone to create the cavity receiving the implant to avoid excessive intraoperative humeral reaming and correlated excessive perioperative thinning of the tuberosities.

Regarding clinical outcomes, the mean postoperative absolute CS for the cohort was 69 ± 17 points at a mean FU of 67.6 ± 9.3 months. The fixed center of rotation conjugated with the "double mobility" between the glenoid and the humerus, specific to free interposition arthroplasty, seems to provide a satisfactory recovery of mobilities.

Midterm results in primary OA with posterior wear (type B or C glenoid, n = 10) showed the lowest results in this cohort, which confirms our short-term results.[17] Worsening of the posterior translation was observed in some patients, with possible inferior

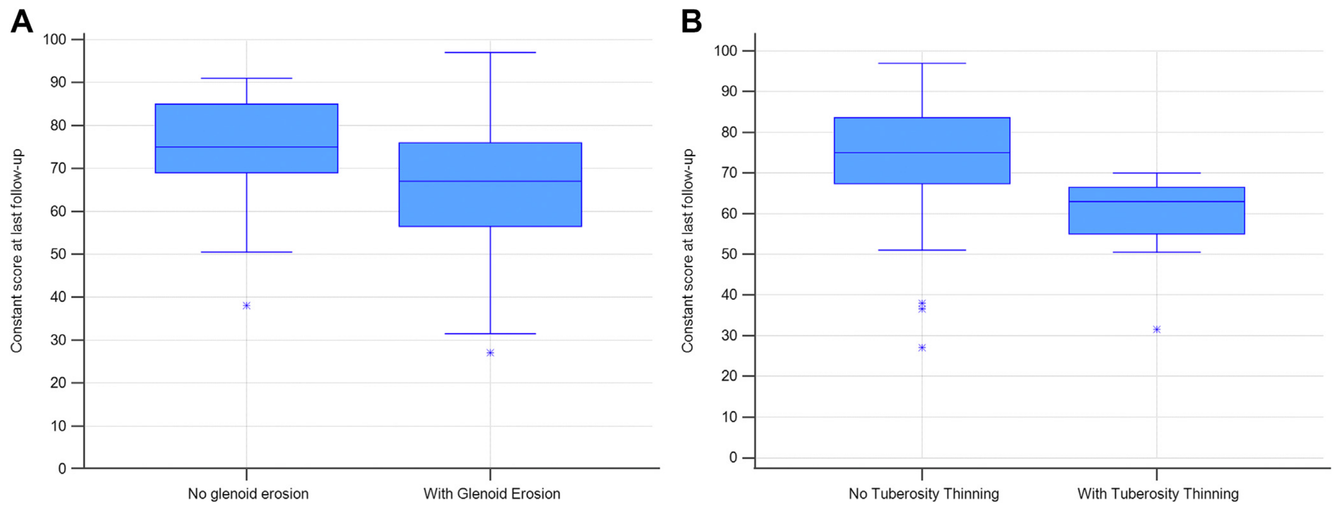

Figure 2 (**A**) Absolute Constant Score at 5-year FU according to the glenoid erosion—Difference is significative ($P = .034$). (**B**) Absolute CS at 5-year FU according to the tuberosity thinning—Difference is significative ($P = .0038$). *FU*, follow-up; *CS*, Constant Score.

Table V
Radiographic evaluation of glenoid erosion and thinning of the tuberosity between earliest and latest follow-up according to gender, age group, and etiology.

Variable	Glenoid erosion, n (%)			Thinning of tuberosities, n (%)		
	No	Yes minor	Yes major	No	Yes minor	Yes major
Gender						
Female	14 (58)	10 (42)	-	19 (79)	3 (12.5)	2 (8.5)
Male	8 (40)	10 (50)	2 (10)	16 (80)	2 (10)	2 (10)
Age						
≤65 years	22 (54)	17 (41)	2 (5)	34 (83)	3 (7)	4 (10)
>65 years	0	3 (100)	0	1 (33)	2 (67)	-
Etiology						
Primary glenohumeral osteoarthritis	10 (36)	16 (57)	2 (7)	20 (71)	5 (18)	3 (11)
Secondary glenohumeral osteoarthritis	3 (43)	4 (57)	-	6 (86)	-	1 (14)
Avascular osteonecrosis	9 (100)	-	-	9 (100)	-	-

glenohumeral impingement. This is consistent with the findings of Hirakawa et al[25] who published 10 cases of PISA with poor results at mean 5-year FU in younger PISA patients with Walch B glenohumeral osteoarthritis. And this is also consistent with the findings of Barret et al[3] who found that persistent or uncorrected posterior subluxation of the humeral implant after PISA is a cause of persistent shoulder pain and revision. In this challenging patient population, we would caution against the use of PISA. Instead, in this indication, recent short-term studies have reported promising results using HSA with pyrocarbon humeral head[11,18,30] or using TSA with augmented glenoid component.[21,26,46]

Similarly, in posttraumatic arthropathy with malunion (n = 4), the results were poor, as already reported at 2 years.[17] The observed findings suggest that PISA should not be indicated in young patients presenting with posttraumatic arthropathy with malunion. In those patients, if no greater tuberosity osteotomy is performed, the results of unconstrained shoulder arthroplasty are predictably good, but if greater tuberosity osteotomy must be performed, RSA is a viable treatment option.[7,36]

The results in primary OA with concentric glenoid deformity (type A glenoid, n = 20) remain stable and satisfactory over time. Glenoid pain was reported by some patients but was not necessarily associated with bone wear, as observed through 3 revisions in concentric glenoid for persistent pain, which could not be explained by radiographic findings. In this indication, pyrocarbon did not prevent persistent pain, and no predictive factors have been identified preoperatively. Although there is a concern with periprosthetic radiolucency and glenoid loosening in the young patient (aged <65 years) undergoing TSA, overall low revision rates and high implant survivorship are reported in the current literature. Therefore, TSA is a viable option with predictable pain relief and improved function at midterm to long-term FU.[33,39]

In the other subset of secondary OA (n = 4), the postinstability OA group, clinical outcomes at midterm were good and stable compared with those reported at 2-year FU.[17] When analyzing the radiographs available for 3 patients of this group, a minor glenoid erosion was observed. At the same time, recently published studies on HSA with pyrocarbon humeral head[11,18] reported excellent results at 2-year FU in this indication. It suggests that, instead of PISA, HSA with a pyrocarbon humeral head should be actively considered as an option in young patients with postinstability OA. In addition, thanks to a larger radius of curvature of the pyrocarbon humeral heads as compared with PISA, larger stress distribution on the glenoid may minimize potential erosion.

Patients with avascular osteonecrosis (n = 8) whatever the cause of the pathology presented good outcomes. The midterm results were comparable between posttraumatic osteonecrosis and atraumatic osteonecrosis. The encouraging results observed with PISA at 2-year FU in this indication are confirmed by a stable radiologic evolution showing no sign of glenoid erosion or tuberosities thinning in those patients at a mean FU of 73 months. In atraumatic osteonecrosis, the results reported in our cohort are comparable with the ones reported in the literature for resurfacing,[37] HSA, or TSA.[24,31,43] The favorable literature for HSA is

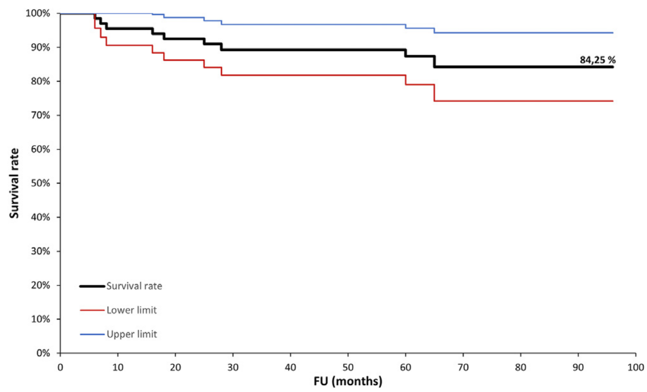

Figure 3 Kaplan-Meier survival with the endpoint being implant revision for any reason. *FU*, follow-up.

reinforced by the short-term results recently reported for HSA with pyrocarbon humeral head, which reported excellent outcomes with marked improvements surpassing the one observed at short-term and midterm with PISA. Added to the fact that radiological outcomes seem less favorable with PISA, pyrocarbon humeral head HSA should be actively considered in atraumatic osteonecrosis. The largest improvement of the CS at a midterm FU was observed in the subset of patients presenting with posttraumatic osteonecrosis with a serious collapse of the humeral head, confirming the short-term results already observed at 2-year FU[17] and also reported by Hudek et al[27] in that indication. Such finding sounds particularly interesting in posttraumatic osteonecrosis without malunion of the tuberosities and with intact rotator cuff, where associated joint stiffness could be responsible for unsatisfactory results with HSA.[44] The result of this study confirm our second hypothesis: PISA could be considered as a viable solution in traumatic avascular osteonecrosis.

The revisions observed in the present cohort underline specific risks of the PISA, such as the inferior glenohumeral impingement or the thinning of the tuberosities, whereas other known risks in shoulder arthroplasty remain, such as secondary rotator cuff tear. Interestingly, similarly to the previous reports,[3,17,27] no infection was reported in these midterm results supporting the possible consideration of using PISA as a temporary spacer or as a salvage procedure in cases of chronic infections, as there is no fully satisfactory solution for patients in the available therapeutic arsenal. As not covered in the present study, this indication should be further investigated. Such absence of infection is also reported in hand and wrist arthroplasty.[1,2,5,6,20,35,42] The shape factor of the implant, the low roughness of pyrocarbon, and its ability to adsorb proteins and phospholipids on its surface[16] are some potential assumptions to explain the absence of bacterial adhesion.

This study has several limitations, mainly the small subset of patients per indication, the number of patients lost to FU or with incomplete data set, and the consideration of the learning curve required by this innovative implant in shoulder surgery. The latter is one probable reason leading to some of the early reoperations or revisions. Also, the lack of a control group does not permit a direct comparison of clinical outcomes. The decision to perform a 1-arm study was motivated by the perception that PISA was complementary to the available therapeutic arsenal and the lack of consensus on treatment options in those indications, particularly in young patients. Another weakness of our study is that all CS and ROM measurements were performed by the surgeons performing the procedures. This could potentially introduce significant bias in the results. Furthermore, the reliability of the radiologic measurements was not evaluated because of the use of a central reading by one observer. This study has several strengths, however, because it is the first prospective multicenter continuous series on a sizable cohort of PISA. All radiologic images were analyzed by one central observer, which avoid interobserver difference in judgment. And this is the first midterm report on the performance of the pyrocarbon bearing surface against bone and cartilage in the shoulder joint.

Conclusion

At midterm, no major progressive glenoid erosions were observed, which seems to confirm the interest of pyrocarbon to preserve bone surface compared with conventional metal HSA. In primary and secondary glenohumeral osteoarthritis, tuberosity thinning cases were observed, increasing the potential risk of tuberosity fracture and secondary rotator cuff tear due to bone insufficiency. This risk suggests considering the use of PISA with caution in this patient population. In this cohort, patients presenting with posttraumatic osteonecrosis with serious humeral head collapse have good midterm clinical outcomes with no tuberosity thinning reported. Posttraumatic osteonecrosis without malunion of the tuberosities and with intact rotator cuff seems to be an optimal indication for PISA; however, further long-term studies are needed to confirm the longevity of the implant in this population.

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