5-year Clinical and Radiographic Outcomes of Pyrocarbon Hemiarthroplasty for Glenohumeral Arthritis and Avascular Necrosis

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Introduction:
Hemiarthroplasty (HA) with cobalt chromium in the treatment of glenohumeral arthritis has been shown to have unpredictable results and concerns for glenoid erosion. Pyrocarbon (PyC) has been theorized to be a suitable substitute due to its low friction-bearing surface, biocompatibility, and elastic modulus that is similar to corticocancellous bone. These characteristics theoretically mitigate the potential for inadequate pain relief and subsequent glenoid erosion. The purpose of this study was to predominately evaluate progression of humeral head medialization from short-term to midterm in patients who underwent a PyC-HA. The authors' hypothesis was that the change in glenoid morphology would be stable from short-term to final imaging and that the clinical results would be favorable at ≥5-year follow-up.

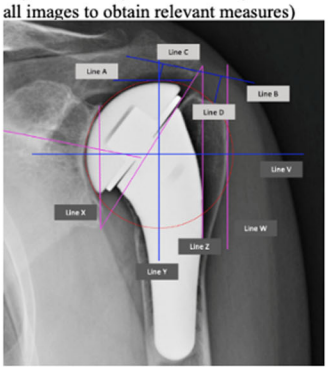
Methods:
This prospective, single-arm study included patients of two surgeons who underwent PyC-HA as part of an U.S. based investigational device exemption protocol. Patients with at least 5-year follow-up were eligible for inclusion. The HA device consisted of PyC humeral head and Ascend Flex Stem® (Stryker, Kalamazoo, MI). Preoperative demographics, glenoid Walch classification, changes clinical outcomes, and revision-free and failure-free survival (defined as dissatisfied/very dissatisfied and/or ASES score <50 at the last follow-up) were recorded. Posterior subluxation of the humeral head in B-type glenoids was evaluated[1]. Changes in glenoid morphology at short term and final follow-up were assessed by one individual blinded to clinical outcomes. The differences in measurement between time periods were quantified. Measures included medialization[2], joint space change, acromiohumeral interval (AHI), critical shoulder angle (CSA), and β-angle[3] (Figure 1a). Statistically significant changes ($p=0.05$) were evaluated for all measures. A post hoc power analysis demonstrated the study had 80% power to detect a 2.5mm change in medialization.

Results:
Fifty-four patients were eligible for inclusion. Of these, 8 were lost to follow-up and 2 were excluded due to conversion to arthroplasty related to low grade infection. Forty-four patients were available for analysis, but one required exclusion due to poor 2-year image quality. The average age at the time of surgery was 52 years and the average follow-up time was 72 months (Figure 2). There were statistically significant improvements in all PROMs and aROM measurements ($p<0.001$) (Figure 3), and the average change across all outcome measures was greater than the minimal clinically important difference. Seven-year revision-free and failure-free survival was 95.7% and 93.3% respectively. Posterior subluxation in Walch B type glenoids decreased from 27.1% preoperative to 19.8% postoperative ($p=0.008$). Average medialization of the humeral head at 2-year follow-up was 3.6 mm ± 3.4, with two patients (5%) showing severe (>10mm) medialization, while the majority were evaluated to have mild (<5mm) to no medialization (72%). At final follow up average medialization increased to 4.5 mm ± 4.1 but the change from 2 years was not statistically significant ($p=0.2$). Four patients (9.3%) demonstrated severe (>10mm) medialization but the majority had mild to no medialization (60.7%). From short term to final follow-up, 30 (70%) patients demonstrated no progression in medialization, 10 (23%) patients progressed one grade and 3 (7%) patients progressed two grades. The difference in medialization between the Walch A and B glenoids was not statistically significant ($p=0.50$). From early postoperative to final imaging there was a >2 mm decrease in the AHI in 86% of patients, with the other 6 patients (14%) exhibiting no to minimal change ($p<0.001$). Changes in all other radiographic measures were not statistically significant (Figure 1b-d).

Discussion:
This study demonstrates that at mid-term follow-up PyC-HA is a reliable procedure to treat glenohumeral joint disease, with stabilization of medialization and joint space narrowing between 2-year and midterm follow-up. Excellent clinical results were observed with minimal change in glenoid morphology in the majority of patients. A limitation of this study was the small sample size and the need to exclude one subject's images in the progression analysis due to rotation of the scapula and humerus at 2-years.

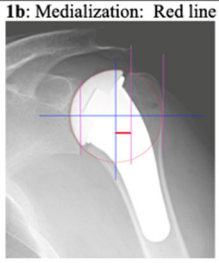
1. Iannotti JP, Norris TR. Influence of preoperative factors on outcome of shoulder arthroplasty for glenohumeral osteoarthritis J Bone Joint Surg Am. 2003;85A(2);251-258.
2. Somerson JS, Neradilek MB, Service BC, Hsu JE, Russ SM, Matsen FA 3rd. Clinical and Radiographic Outcomes of the Ream-and-Run Procedure for Primary Glenohumeral Arthritis. J Bone Joint Surg Am. 2017 Aug 2;99(15):1291-1304. doi: 10.2106/JBJS.16.01201. PMID: 28763415.
3. Moor BK, Bouaicha S, Rothenfluh DA, Sukthankar A, Gerber C (2013) Is there an association between the individual anatomy of the scapula and the development of rotator cuff tears or osteoarthritis of the glenohumeral joint? A radiological study of the critical shoulder angle. Bone Joint J 95(7): 935-941.

Figure 1a: Image demonstrating landmark lines applied to all images to obtain relevant measures)



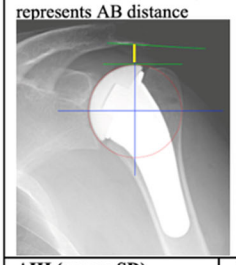
- **Medialization:** change in YZ distance (Somerson; JBJS 2017)
- **AHI:** change in AB distance
- **Beta angle:** angle formed by line X and line along the floor of the supraspinatus fossa (Maurer, JSES 2012)
- **CSA:** angle formed by line X and the line drawn from the lateral border of the acromion to the inferior margin of the glenoid (Moor; Bone Jt Journal 2013)

1b: Medialization: Red line represents YZ measurement



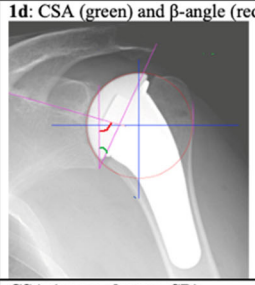
Medialization (mean; SD)	4.3 (4.0)	p<0.001
median (range)	4.0 (-5.5 to 15.1)	
Clinical relevance		
• Severe (>10mm)	4 (9.1%)	
• Moderate (≥5 to 10mm)	12 (27.3%)	
• Mild (≥2 to 5 mm)	16 (36.4%)	
• Minimal (-2 to <2mm)	10 (22.7%)	
• Distance increased	2 (4.5%)	
Joint Space (mean; SD)	-0.5 ±1.3	p=0.020
median (range)	-0.01 (-3.7 to 2.7)	
Clinical relevance		
• >2mm increase	1 (2.3%)	
• No to minimal change	38 (86.3%)	
• >2mm decrease	5 (11.4%)	

1c: SHM as measured by AB distance: Yellow line represents AB distance



AHI (mean; SD)	-4.6 mm ± 3.2	p<0.001
median (range)	-3.9 (-13.3 to 1.9)	
Clinical relevance		
• >2mm increase	0	
• Minimal change	6 (13.6%)	
• >2mm decrease	38 (86.4%)	

1d: CSA (green) and β-angle (red)



CSA (mean change, SD)	1.8 deg ± 4.6	p=0.110
median (range)	2.3 (-14.2 to 9.9)	
Clinical relevance		
• ≥5 deg increase	10 (22.7%)	
• Minimal change	31 (70.5%)	
• ≥5 degree decrease	3 (6.8%)	
β-Angle (mean change; SD)	-1.5 deg ± 5.5	p=0.276
median (range)	-2.0 (-14.6 to 12.1)	
Clinical relevance		
• ≥5 deg increase	6 (13.6%)	
• Minimal change	26 (59.1%)	
• ≥5 degree decrease	12 (27.3%)	

Table 2 Cohort Demographics

	N = 43
Follow-up (months)	
Mean (SD)	72 (7)
Median (Range)	(70, 61-92)
Gender, n (%)	
Female	10 (23%)
Male	33 (77%)
Age at surgery	
Mean (SD)	52 (10)
Median (Range)	(54, 19-69)
Smoking history, n (%)	
Current	3 (7%)
Former	9 (21%)
Never	31 (72%)
Shoulder, n (%)	
Left	15 (35%)
Right	28 (65%)
Primary diagnosis, n (%)	
Primary Glenohumeral Osteoarthritis	38 (88%)
Post traumatic AVN	2 (5%)
Atraumatic AVN	2 (5%)
Capsulorrhaphy arthropathy	1 (2%)
Prior surgery, n (%)	17 (40%)
Walch classification, n (%)	
A1	17 (40%)
A2	5 (12%)
B1	6 (14%)
B2	11 (26%)
C	2 (5%)
None	2 (5%)

Table 3. Patient Report Outcomes Measures and Range of Motion

Cohort outcomes,	Baseline	Final	N=43
Flexion			<0.001
Mean (SD)	122 (25)	156 (9)	
Median (Range)	(125, 50-168)	(155, 132-180)	
Abduction			<0.001
Mean (SD)	115 (32)	158 (12)	
Median (Range)	(115, 25-171)	(162, 125-180)	
External Rotation			<0.001
Mean (SD)	34 (18)	65 (12)	
Median (Range)	(35, 5-75)	(65, 42-88)	
Internal Rotation, n (%)			<0.001
T7	2 (4.5%)	11 (26%)	
T12	12 (28%)	22 (51%)	
L5	9 (21%)	10 (23%)	
SI Joint	8 (19%)	0 (0%)	
Buttock	10 (23%)	0 (0%)	
Thigh	2 (4.5%)	0 (0%)	
Satisfaction, n (%)			<0.001
Very Satisfied	0 (0%)	40 (93%)	
Satisfied	0 (0%)	2 (4.7%)	
Dissatisfied	17 (40%)	1 (2.3%)	
Very Dissatisfied	26 (60%)	0 (0%)	
SANE score			<0.001
Mean (SD)	40 (20)	94 (9)	
Median (Range)	(40, 0-75)	(98, 50-100)	
Pain 0-10			<0.001
Mean (SD)	4.94 (2.53)	0.17 (0.58)	
Median (Range)	(5.00, 1.00-10.00)	(0.00, 0.00-3.00)	
Health status (0-100%)			<0.001
Mean (SD)	73 (16)	86 (10)	
Median (Range)	(75, 20-95)	(90, 50-100)	
ASES score			<0.001
Mean (SD)	49 (16)	96 (8)	
Median (Range)	(52, 25-82)	(98, 53-100)	

[1]Fisher's exact test; Wilcoxon rank sum test