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Retrospective review of pyrocarbon radial head replacement

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Background: Radial head arthroplasty is the preferred surgical management for complex, unreconstructable radial head fractures. There has been increasing use of pyrocarbon prostheses, with potential tribology and modulus advantages over metallic counterparts. This study aims to assess clinical and radiological outcomes for radial head replacement after trauma using a modular, uncemented pyrocarbon prosthesis.

Materials and Methods: Between September 2009 and March 2020, a consecutive series of 22 trauma cases were available for review. Patients underwent radial head arthroplasty using a pyrocarbon prosthesis (Ascension Modular Radial Head System, Austin, TX). Recorded outcomes included clinical assessment, radiological evaluation, and patient-reported outcome measures specific to elbow function.

Results: Twenty-two patients (7 male, 15 female) with an average age of 51 years (range 21-64) were analyzed with a minimum 12 months of follow-up. All patients had complex radial head fractures, categorized as a Mason 3 or 4 injury. At follow-up, mean elbow range of motion included flexion 130° (range 100°-150°), extension 19° (0-50°), pronation 73° (30°-90°), and supination 70° (10°-90°). The mean Mayo Elbow Performance Index score was 83 (55-100), and Disabilities of the Arm, Shoulder and Hand score was 22 (2.5-60). Radiological evaluation showed 14 patients with asymptomatic proximal neck resorption and two patients with radiological stem loosening. In total, 3 of 22 implants were revised—2 were excised, and 1 revised to a long stem for traumatic implant fracture.

Conclusion: Pyrocarbon radial head arthroplasty provided reliable functional results for patients after unreconstructable radial head fracture. The unique potential for fracture of the prosthesis should be considered in long-term follow-up, with appropriate activity advice to patients.

Radial head fractures account for 33% of elbow fractures.[26] They occur with axial and valgus force and can form part of a spectrum of injuries ranging from an isolated fracture to fracture combined with subluxation to frank fracture dislocation. For significantly displaced and/or comminuted factures, primary fixation is preferable to excision,[12] but fractures with loss of cortical contact or more than three pieces reportedly have unsatisfactory rates of 54% with open reduction internal fixation.[23]

If satisfactory primary fixation cannot be achieved, excision or replacement may be considered. The radial head contributes to axial, posterior, and lateral stability of the elbow. Therefore, excision may lead to increased instability and long-term arthritis if there is concomitant capsuloligamentous injury.[3] Excision should not be performed primarily in these cases.[21]

Replacement of unreconstructable fractures of the radial head becomes critical to restoring elbow stability and function.

The ideal radial head arthroplasty would recreate the anatomy and biomechanics of the elbow and provide long-term durability. To date, no such “ideal” implant exists. The radial head is elliptical, not circular, and the cartilage depth is variable.[14] Radial head designs are variable with monopolar, bipolar, modular, or monoblock options available. Variable stem options included cemented or noncemented stems (fixed or loose). Bearing surfaces are traditionally metallic, but pyrocarbon (or pyrolytic carbon) has an elastic modulus similar to bone-improving shared force distribution and has favorable tribology with a low coefficient of friction and boundary layer lubrication.[20] It may have less wear on the capitellum over an equivalent time period than its metallic counterparts.[15] This may be important in minimizing capitellar wear. It is durable and has been used in other arthroplasty procedures, such as those in shoulders and fingers.[17]

Ethics approval was received from the Human Research Ethics Committee (HREC)—Barwon Health (Reference no. HREC/67292/VICBH-2020-237466(v1).

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Table 1
Patient preoperative and postoperative characteristics, including demographics, outcomes, and complications.

Pt	Preoperative						Postoperative				
	Age	Gender	Mason	Transolecranon fracture	Capitellar lesion	Nonunion as an indication	DASH	MEPI	Complication revision	Complication removal	Complication implant fracture
1	54	Female	3				2.5	100			
2	52	Female	3				60	65			
3	51	Female	4				27.5	85			
4	64	Female	3				2.5	100			
5	56	Female	4	Y			20.8	85		Y	
6	52	Male	4	Y			2.5	85			
7	64	Female	4				37.5	75			
8	21	Male	3				38.3	85			
9	54	Male	4				22.5	90			
10	52	Female	4	Y			54.2	55			
11	24	Male	4			Y	23.3	85			
12	39	Female	4		Y	Y	3.3	90		Y	
13	59	Female	3				39.2	80			
14	60	Female	4				20.8	85			
15	52	Male	3				46.7	70			
16	46	Female	3		Y		15	85			
17	51	Male	3				24.2	70			
18	63	Female	3				4.5	85			
19	50	Female	3		Y		2.5	100	Y		
20	57	Female	3				15.8	80			
21	38	Male	4		Y		17.5	70	Y		Y
22	58	Female	3				9.4	100			
	Mean 51 (21-46)	Females 15 Males 7	3 = 12 4 = 10	3	4	2	Mean DASH 23 (2.5-60)	Mean MEPI 83 (55-100)	2	2	1

DASH, Disability of Arm, Shoulder and Hand; *MEPI*, Mayo Elbow Performance Index.
"Y" indicates presence of preoperative feature or postoperative complication.

The aim of this study is to report the functional and radiological results for radial head arthroplasty in trauma using a modular uncemented pyrocarbon prosthesis (Ascension radial head; Ascension Orthopaedics, Austin, TX). It is modular with 2 parts; a press fit stem in 3 diameters and 2 lengths for cementless fixation, and a pyrocarbon bearing surface head which comes in 3 diameters.

Materials and Methods

Ethics approval was obtained. We retrospectively assessed 22 consecutive patients who had the Ascension radial head replacement between September 2009 and March 2020. Surgery was performed by two fellowship-trained elbow surgeons.

Inclusion criteria were a skeletally mature adult who underwent an Ascension radial head replacement with a minimum of 12 months of follow-up. Our indications for replacement were traumatic unreconstructable radial head fractures, replaced at primary surgery or as a salvage of symptomatic nonunited or malunited radial head fractures.

A radiological review was performed by two fellowship-trained elbow surgeons assessing classification according to the modified Mason criteria,[4] neck resorption according to Chanlalit et al,[6] lucency in 7 zones similar to a hip prosthesis according to Abdullah et al,[1] heterotopic ossification according to Brooker et al,[5] and radiocapitellar arthritis according to Broberg and Morrey.[4]

Postoperative outcome was measured with the Disability of Arm, Shoulder and Hand (DASH) and Mayo Elbow Performance Index (MEPI) scores. Range of motion was assessed by the patient's surgeon using a goniometer.

Surgical technique

The operative method used either a lateral approach or a universal approach via a posterior incision. The Kocher or Kaplan intervals were used depending on surgeon preference and associated soft-tissue injury plane. The head was resected perpendicular to the axis of rotation of the forearm at the head-neck junction. The head or head fragments were placed in a sizing ring to identify the diameter. The head trial was placed to ensure the head did not extend beyond the proximal sigmoid notch to prevent overstuffing as described by Athwal et al.[2] The diaphysis was prepared using a rasp to size the diameter of the stem for a press fit. The prosthesis was assembled on the operating table, and the stem and pyrocarbon head were impacted together with a mallet and inserted. X-rays were taken to assess the prosthesis position and to confirm the stability of the elbow joint. Postoperatively, patients were placed in a backslab at 90 degrees and sling. Wounds were checked at 2 weeks, and then active range of motion commenced with no lifting or resistance until 6 weeks postoperatively. A hinged elbow brace was used from 2 to 6 weeks if a collateral ligament repair was performed.

Results

Patient characteristics and surgical indications are shown in Table I. There were 22 patients included in the study, 15 females and 7 males. The mean age was 51 years (range 21-64). Two patients were unemployed. Three patients had office-based occupations. The remainder had manual occupations. Mean follow-up duration was 58 months (12-197 months). There were 12 Mason III fractures and 10 Mason IV fractures, 9 patients had a terrible triad injury,[18] and 3 had transolecranon fracture dislocations. Four patients had chondral lesions noted on their capitellum at the time of surgery.

Surgical indications

Two patients had revisions of nonunions after previous internal fixation. The remainder were for primary fixation for fractures. This included 7 unreconstructable fractures in isolation, 10 acute or chronic radial head fracture associated with elbow instability, and 3

Table 2
Summary of radiological results using described classification systems.

Radiological measurement	Number of patients (n = 22)
Neck resorption	
Chanlalit	
1	2 (9%)
2a	7 (32%)
2b	7 (32%)
3	6 (27%)
Gruen zones	
None	10 (45%)
Mild (≤2)	5 (23%)
Moderate 3-6	3 (14%)
Severe 7	4 (18%)
Brooker	
0	20 (91%)
1	2 (9%)
2	0
3	0
4	0
OA Broberg	
0	19 (86%)
1	2 (9%)
2	1 (5%)
Congruent	20 (91%)
Incongruent	2 (9%)
Capitellar erosion	4 (18%)

acute radial head fractures associated with ulna fracture (Monteggia variant).

Functional results

The mean total arc of elbow flexion/extension was 110° (range 50-145°). The mean flexion was 130° (100-150°), and mean extension was 19° (0-50°). The mean pronation was 73° (30-90°), and mean supination was 70° (10-90°). The mean DASH score was 22 points (2.5-60). The mean MEPI score was 83 points (55-100).

Radiological results

Radiological results were available for all 22 patients (Table II). Fourteen patients had measurable proximal neck resorption. Twelve of the stems had measurable lucency, but only 4 involved all 7 zones; 2 of those who had all 7 zones involved were revised with excision arthroplasty (Table I; patient number 5 and 12).

Complications

Four neuropraxias were recorded: 2 ulna nerve, 1 superficial radial nerve, and 1 posterior interosseous nerve. All neuropraxia resolved.

In total, 3 of 22 (13.6%) implants were revised, 2 were excised and 1 revised to a long stem. Two radial head implants were removed because of symptomatic loosening in the radial shaft; they were not replaced and acted as radial head excisions. One implant was removed at 13 months, and the other at 10 months. Both patients had significant lucency on x-ray (Gruen 7) and forearm pain (Fig. 1).

One patient fractured the pyrocarbon articulating surface requiring a revision 5 years after surgery. The patient was a 38-year-old male who sustained a terrible triad injury in 2014 that was treated with a pyrocarbon radial head, capitellum chondral repair with bioabsorbable pins, and an lateral collateral ligament repair. The patient returned to full contact football in 2019 and experienced increasing pain after a fall at training. The x-ray and CT scan did not reveal the implant problem. His pain was ongoing, and at diagnostic arthroscopy, it was noted the implant had fractured but was nondisplaced (Fig. 2). The implant was removed and treated as a radial head excision. The patient had ongoing elbow pain and was revised 6 months later with a long-stem Ascension pyrocarbon prosthesis with a subsequent reduction in symptoms.

Discussion

Our experience with the pyrocarbon head shows that a good range of motion and functional scores can be achieved. Capitellar wear or arthritic change is low and tends to be minor. Lucency around the stem was common on radiographs, but only 2 were revised. Fracture of pyrocarbon remains a unique material-related complication.

Pyrocarbon has a modulus of elasticity similar to cortical bone and helps facilitate load transfer and preserve cartilage in comparison to metal. This may be particularly important in patients with concomitant capitellar injury as seen in 4 of our patients (Table I). Cook et al carried out prosthetic replacement of canine femoral heads with three types of prostheses: pyrocarbon, chrome-cobalt, and titanium. In terms of survival of joint cartilage at 18 months, pyrocarbon showed 92% survival against 20% for metallic implants.[7] Our results showed very low levels of osteoarthritis on x-ray.

Radial head design—head anatomy

Radial head arthroplasty does not recreate the original radial head anatomy. King et al noted that the radial head is an ellipse, not a circle shape which is so commonly used in arthroplasty.[14] Also, the depth of cartilage is variable, being thicker in the anterior rim than in the lateral rim. Sex differences also exist, with males having thicker cartilage.[29] A radial head arthroplasty that perfectly recreates what is lost does not yet exist. However, Shannon et al noted that neither generic or custom designs improved contact pressure characteristics in biomechanical cadaveric testing, failing to match native radial head congruency.[25] Changes in kinematics are inevitable, but again custom implants, although better, did not show a statistically significant biomechanical improvement when compared to off shelf designs.[24]

Radial head design—stems

Various stem designs are available. These all aim to obtain fixation that is rigid and minimizes loosening. However, the lack of perfect recreation of the biomechanics and anatomy means that forces may be translated to the stem. The Ascension stem used in the present study is a titanium cementless stem. Loosening requiring revision or removal was found in 2 cases. Forearm pain was present in both cases, and this has been found to be a strong indicator of loosening. [19] New onset pain in particular may indicate loosening, which is what we found. Lucency around the stem was noted in 12 of our cases. It should be noted that the presence of lucency around the stem does not always directly correlate with pain and by itself is not an indication of failure.[9]

Removal due to loosening

Removal rates may be higher in cementless press fit stems, but stem length does not seem to be a factor.[13] Most removals occur within 2 years of implantation,[13] similar to our 2 cases (at 10 and 13 months). van Riet et al found that most stems were removed for painful loosening, and capitellar erosion was more common in his removal group.[27] Duckworth[8] reported removal of 28% metallic

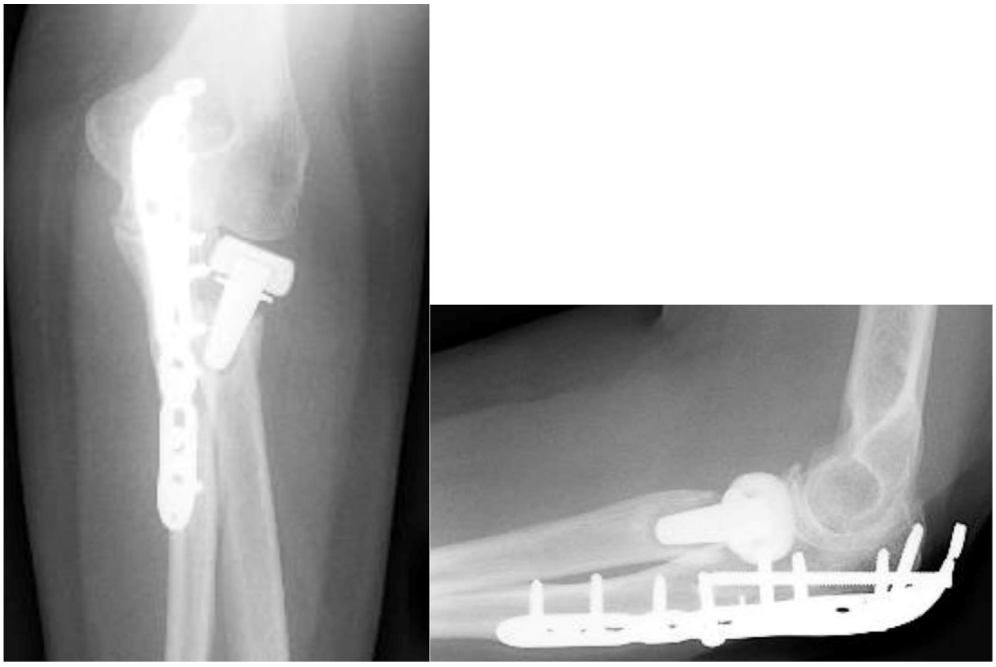

Figure 1 Patient number 5's x-rays before removal of radial head implant. Demonstrates loosening in all 7 Guren zones.

Figure 2 Intraoperative pictures showing the fractured pyrocarbon head, concomitant capitellar chondral shear injury, and carbonised synovium with pyrocarbon particles.

radial head implants with younger age being a risk factor. Flinkkila et al reported that 9 of 42 radial head replacements were revised at an average of 11 months.[10] They concluded that loosening occurred early, which is consistent with our findings.[10]

Results of the same pyrocarbon radial head replacement

Only 1 other article concerning this prosthesis has been recently published, by Viswanath and Watts.[28] They described similar results with 36 patients. A mean flexion arc of 105° and prono-supination of 148° was achieved; 10 stems had lucency, and 4 were revised. They noted lucency to be more common in their revision group, but as we only had 2 revision cases, comparisons are difficult.

Results of other pyrocarbon radial head prosthesis from different manufacturers

The other pyrocarbon radial head available for clinical use is the MOPYC (Tornier, Montbonnot-Saint-Martin, France). It has a longer stem, which is expansile and press fit. Abdullah reported on 21 cases. The mean postoperative DASH score was 10.8, the mean MEPI score was 86.4, and the mean flexion was 133° and extension was 17.5° at 12 months postoperatively. They reported lower rates of periprosthetic loosening than the present study.[1] Lamas et al reported on 27 cases.[16] The mean visual analogue scale was 1, and the mean range of flexion was 6-140°, with 81° of pronation and 76° of supination. Only three of 27 patients had lucencies >2 mm compared to 7 of our 21 patients. There were 2 dissociations of the head from the stem. We had no dissociations in our series.

Alleiu reported on 30 MOPYC replacements. Their MEPI score was 95, mean extension was 15°, and flexion was 122°. Pronation was 74°, and supination was 72°. There were 3 cases of stress shielding. In a larger cohort of 52 patients from the same unit, 48 cases had stress shielding after a mean of 46 months, and there were 9 cases of capitellar wear.[11] We had comparable results with at least mild stress shielding visible in 20 of our 21 cases. Presumably, a well-fixed distal stem leads to stress shielding around the proximal radial neck with time, a pattern seen in some of our patients.

Only one article compares a metallic and pyrocarbon group in 2 historic cohorts.[22] Seventy-five patients had a metallic radial head (Evolve Wright Medical, Memphis, TN) prosthesis followed up for a mean of 41.5 months, and 11 patients had an MOPYC with a mean

follow-up of 46 months. There was no functional difference between the 2 groups in terms of range of motion or patient-reported outcomes. Four complications were noted in the Evolve group, and 3 in the MOPYC group.

Fractured pyrocarbon bearing surfaces

A unique complication of pyrocarbon implants is the potential for fracture. We reported one case in our series that fractured after a fall in a contact ball sport and axial load. The fracture was difficult to detect radiologically but was noted on diagnostic arthroscopy. Fracture has been reported by Boileau in a pyrocarbon shoulder resurfacing implant.[20] The patient presented with acute pain 6 years after index surgery with no trauma. They postulated that overstuffing, failed subscapularis, and the brittle nature of the pyrocarbon may have contributed.[20] We are the first to report a similar complication in a radial head prosthesis. Acute pain not previously experienced by the patient should be further investigated in pyrocarbon implants.

The Ascension pyrocarbon prosthesis requires assembly on the table before insertion. The head is placed in a holder upside down, and the stem is impacted into the head. Given the possibility of fracture, we postulate that careful alignment of the components before impaction may help distribute forces more evenly. Ideally this step would be more controlled using an impaction device or tool that has a more consistent reproducible force, rather than the surgical team using a mallet.

Limitations

This is a retrospective study with selection bias. Indications for surgery were mixed, and there was no comparator group. Preoperative assessments were not available because of the traumatic indications for surgery.

Conclusion

After radial head arthroplasty with a modular uncemented pyrocarbon prosthesis for trauma, our patients showed high function scores with low pain levels and good range of motion. There was very little capitellar wear, which is consistent with animal models using pyrocarbon. Loosening requiring prothesis removal was only required in 2 of 20 patients despite a short cementless stem, and these occurred at around 12 months postoperatively. Fracture of the bearing surface is a unique complication of pyrocarbon, and new pain after trauma should be investigated.

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