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Research paper

Bipolar radial head arthroplasty for management of radial head fractures

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1. Introduction

Radial head fractures constitute approximately 4% of all fractures in adults and represent over 30% of fractures around elbow joint.[1–3] Radial head fractures are known to occur in young and active individuals aged between 20 and 60 years.[4] These fractures present as an isolated lesion or may present in association with other injuries such as fracture of the coronoid process, medial collateral ligament tear, injury to the interosseous membrane and the triangular fibrocartilage complex. These injuries may render the elbow joint unstable to valgus stress, leading to axial instability of the forearm with subluxation of the distal radio-ulnar joint.[4–6]

The principal goal of treatment of radial head fractures is its anatomical preservation, to stabilize the forearm in axial as well as valgus loading of upper limb and regain good pain free elbow function, with ability to achieve adequate motion and joint stability.[7–10] The critical role played by the radial head in overall stability of the elbow and forearm emphasizes the need for all attempts at its reconstruction by internal fixation or to replace it with a prosthesis rather than excision.

Most radial head fractures with extensive comminution are non-reconstructable. Their surgical treatment requires radial head excision or replacement using a prosthesis.[11] Radial head excision alone leads to altered kinematics and instability of the elbow. With radial head replacement, the kinematics and stability of the elbow are restored to near normalcy.[12]

The comminuted fractures of the radial head are mostly treated by excision in most Indian hospitals. However, complications such as cubitus valgus, elbow stiffness, proximal migration of radius, chronic wrist pain and degenerative changes may develop following initial successful treatment.

The lack of radiocapitellar joint may also lead to chronic elbow pain due to degenerative changes in the ulno-humeral joint.[13,14]

Also, when these radial head fractures are associated with ligamentous injury, simple excision generally result in elbow instability in the young. These may be overcome by a prosthetic replacement of the radial head following excision of the radial head.

The ideal radial head prosthesis is still in evolution. Various prosthesis with cemented or a cementless stem and mono/bipolar or modular heads are available in developed nations. However these are not available in India till date. Few indigenous designs are available; however these require further evaluation as regards their metallurgy, bearing surfaces, biomechanical suitability and ease of carrying out the replacement during surgery. We used an indigenously designed and manufactured titanium bipolar radial head prosthesis with a surface-textured stem (Phoenix Surgicals, India) in our study. (Fig. 1).

2. Materials and methods

An observational descriptive study was carried out on thirty patients between years 2013–14 requiring radial head replacement at a tertiary care Orthopaedic centre. The aim was to study the clinical outcomes in patients of non-reconstructable comminuted fractures of radial head managed with radial head replacement prosthesis. The objectives were

(a) To describe early clinical outcome following prosthetic replacement of radial head with regards to symptomatic relief in pain, recovery of motion, grip strength and stability.
(b) To assess the loosening of prosthesis and proximal migration of radius on post-operative follow up radiographs.

Informed written consent from patients and institutional ethical clearance was obtained to carry out the study.

The inclusion and exclusion criteria for the study were as follows:

Inclusion criteria - Radial head fractures in adults with skeletal

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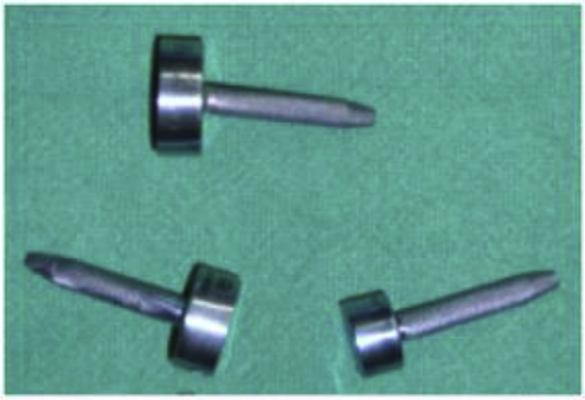

Fig. 1. Titanium Bipolar Radial head prosthesis.

maturity where radial head was comminuted and non-reconstructable.

Exclusion criteria – Pathological fracture, paediatric radial head fracture, psychological and/social conditions with poor compliance, compound fracture/dislocation radial head, patients with known allergy/metallosis, radial head fractures with comminution extending more than a centimetre below the radial articular surface.

The signs of associated ligamentous injuries to the medial side of elbow (swelling, ecchymosis) was documented, however no change in treatment protocol was done, as all comminuted radial head fractures which were not reconstructable were replaced by prosthesis, irrespective of associated medial side injuries.

Patients were operated in a supine position with elbow resting over radiolucent side arm trolley. Kocher's lateral approach was used in all the patients. Radial neck was osteotomised a centimetre below the articular surface so as to have adequate mobility of the bipolar prosthetic head following its insertion. The diameter and length of excised radial head was measured and prosthetic replacement done using implant with 2 mm smaller diameter and the length of radius maintained. (Figs. 3–5). During prosthesis insertion, care was taken to keep the head portion of the prosthesis within the radioulnar joint surface. Any overstuffing of the radio-capitellar joint was avoided by adjusting the depth of insertion and assessed under direct vision. The autologous bone graft from excised head was used for grafting to achieve press fit of the prosthesis. No drains were placed during wound closure. Elbow and forearm movements were allowed in the immediate post-operative period in all patients.

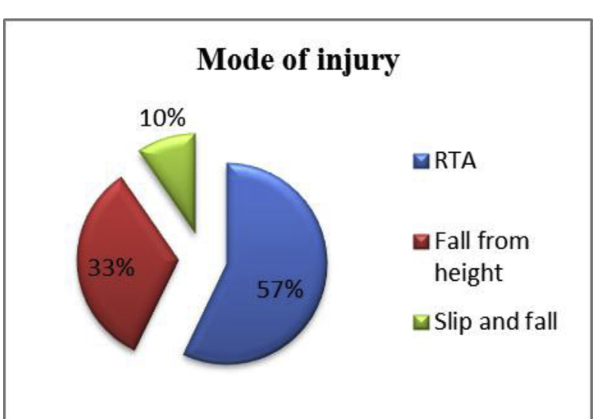

Fig. 2. Pie chart depicting mode of injury.

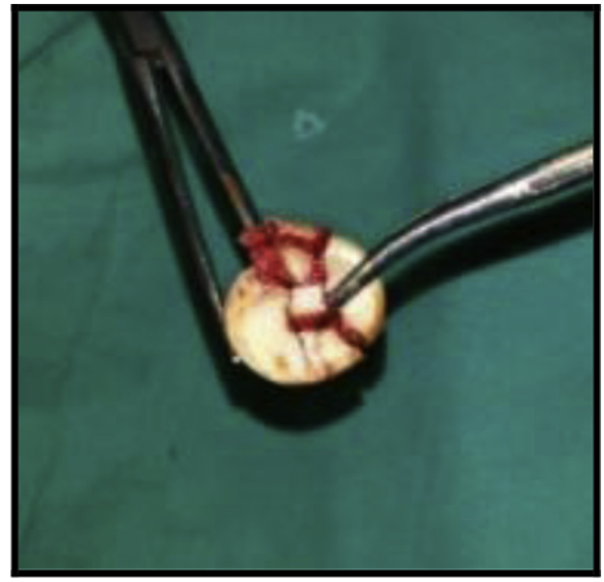

Fig. 3. Reconstruction of excised radial head for sizing.

The following outcome measures evaluated in the study:

a. Subjective - clinical relief of symptoms such as pain. ‘Pain’ was graded using visual analogue scale (VAS).
b. Objective - range of motion, grip strength. ‘ROM’ of elbow flexion-extension and forearm pronation-supination was evaluated using ‘hand-held goniometer’. ‘Grip strength’ was measured using hand held dynamometer and compared with normal limb.

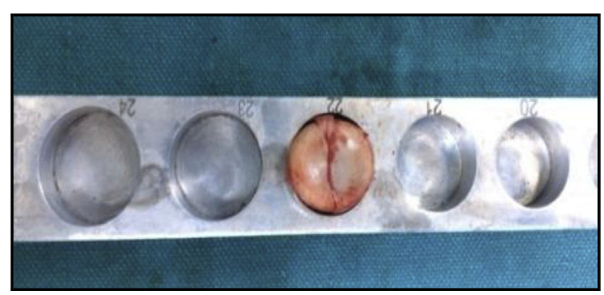

Fig. 4. Measurement of excised radial head using measuring guage

Fig. 5. Radial head prosthesis in situ prior to wound closure.

c. Radiological evidence of loosening of prosthesis and proximal migration of radius.

Follow-up examination was done at 06 weeks, 03 months, 06 months, 1yr and 2yrs using patient's subjective evaluation, functional outcome and radiographic assessment for complications, if any. AP and lateral radiographs of forearm including elbow and wrist was done to assess for loosening of prosthesis and proximal migration of radius. (Fig. 6).

An adverse event or complication was defined as any event that necessitated another operative procedure or additional medical treatment. Post-operative complications like surgical site infection, wound dehiscence, hardware prominence and scar related problems were also noted if any.

3. Observations & Results

30 patients of fracture radial head were managed by replacement. The follow-up rate was 100% at each examination till completion of study. The data analysis was done using SPSS software version 17. Paired *t*-test was used to find the association/significance between various variables. Fischer exact test was used for analysis of demographic variables with outcome variables. The observed results were determined to be significant if the P value was <0.05 and not significant if it was >0.05.

Mean age of patients was 36 years. The commonest mode of injury was road traffic accident.(66.66%).(Fig. 2). Comminuted fracture of radial head was seen more frequently in males (70%) (M: F = 21: 9). 04 patients had associated elbow dislocation which was reduced at the primary health care centre. 02 patients had terrible triad injury and 01 patient had associated olecranon fracture. No patient presented with Essex-Lopresti injury or distal radio-ulnar joint disruption. 60% had an injury to the dominant side.

Mean duration between injury and presentation to hospital was 8.3 days.14 patients (73.33%) were operated within 01 week of injury and remaining were operated within 1–4 weeks due to late presentation. Additional procedures involved tension band wiring for olecranon fracture and interfragmentary screw fixation for coronoid fracture in one patient each. There was no surgical site infection or wound dehiscence.

Mean tourniquet time was 55 min. Mean duration of hospital stay was 8 days. Initial 02 patients who were operated, underwent implant removal at 03 months for restricted ROM of elbow joint. One patient had associated olecranon fracture and other had associated posterior dislocation of elbow joint as initial injury. In both these patients undersizing of the implant was not done and prosthesis of same size as native radial head was used which could have led to radio-capitellum overstuffing resulting in restricted ROM. Following implant removal these patients had significant improvement in ROM. Intra operatively one patient had features suggestive of 'metallosis' while other had heterotopic ossification (HO) (not significant to affect the ROM and did not progress on further follow up). Both patients developed wrist pain and valgus instability at 06 month follow up.

Fig. 6. Lateral & AP elbow radiographs with radial head prosthesis.

3.1. Functional outcome at 06 weeks post op

'Subjective outcome analysis' included elbow pain evaluation using visual analogue score (VAS). The VAS scores were grouped into 03 i.e. mild (<2), moderate (3–7) and severe (>7). The group median VAS was 5; 02 patients (6.66%) had VAS between 3 and 7 while 28 patients (90.5%) had VAS <2. None of the patients had wrist pain and elbow valgus instability.

'Clinical outcome analysis' included elbow flexion, forearm ROM i.e. pronation and supination, grip strength and deformity i.e. fixed flexion deformity at elbow. ROM was grouped into 03 groups i.e. <90°, 90–120° and >120°. Mean elbow flexion was found to be 83° (SD = 8.58). 17 patients (81%) had <90° elbow flexion and 04 patients (19%) were having flexion between 90 and 120°. None of the patients had ROM >120°.

Forearm pronation and supination was evaluated and grouped into 2 groups i.e. <45° and >45°. Mean forearm pronation was found to be 37.6°. 17 patients (81%) had <45° pronation. Mean forearm supination was found to be 40.7°. 12 patients (57%) had >45° supination. Grip strength was evaluated using hand held dynamometer and compared with contralateral normal limb. Mean grip strength was found to be 24%; 18 patients (85.7%) had grip strength <25%. Stiffness and deformity were evaluated and measured using hand held goniometer. Patients were grouped into 2 groups i.e. <30° and >30° fixed flexion deformity. Mean fixed flexion deformity was found to be 37.3°. 19 patients (90.5%) had fixed flexion deformity >30°.

None of the patients had implant loosening in follow up radiographs. 01 patient (4.8%) had radiological evidence of HO in the flexor aspect; however, it did not restrict elbow ROM, hence was offered no active treatment.

3.2. Functional outcome at 03 months post op

Elbow pain evaluation using VAS score showed median score of 2; 17 patients (81%) had VAS <2. None of the patients had wrist pain or elbow valgus instability. Mean elbow flexion was 109° with 19 patients (90.5%) having flexion between 90 and 120°. Mean forearm pronation was 52.3° with 18 patients (85.7%) having >45° pronation. Mean forearm supination was 56.6° with 18 patients (85.7%) having >45° supination. Mean grip strength at 03 months follow up was 55.4% with 11 patients (52.4%) having grip strength in the range of 25–50%. Mean fixed flexion deformity was 25.4° with 15 patients (71.4%) having fixed flexion deformity <30°.

None of the patients had proximal migration of radius or implant loosening. No new case of heterotopic occification was found. 02 patients underwent implant removal at 03 months follow up.

3.3. Functional outcome at 06 months post op

Elbow pain evaluation using VAS showed median score of 1; all patients had VAS <2. Mean elbow flexion was 126° with 16 patients (76.2%) having elbow flexion >120°. Mean forearm pronation was found to be 71° with 19 patients (90.5%) having >45°pronation. Mean forearm supination was 73° with all patients having supination >45°.Mean grip strength was 79.5% with 12 patients (57%) having grip strength >75% compared to other side. Mean fixed flexion deformity was 14°; all patients had fixed flexion deformity <30°.

Radiographs revealed no proximal migration of radius or implant loosening. No new case of heterotopic occification was detected. However, 02 patients (9.5%) who underwent implant removal at 03 months follow up developed valgus instability and wrist pain.

Significant difference between mean elbow flexion, forearm pronation/supination and grip strength was noted at 6 weeks compared with similar movements at 3 months, and between ROM at 6 weeks and 6 months by using unpaired *t*-test.($p < 0.05$). By using paired *t*-test ($p < 0.05$); there was significant difference between mean elbow FFD at 6 week and at 3 month and between 6 week and 6 month.

'Dominant side' had better grip strength at 06 weeks follow up as compared to non-dominant side ($p < 0.05$); however. there was no difference in grip strength on further follow up at 03 and 06 months. Other outcome variables showed no association with dominance of hand. Patients with 'associated elbow injuries' had significantly reduced pronation at 03 months follow up ($p < 0.05$). There was no difference at follow up at 06 months. Other outcome variables showed no association with associated elbow injuries. 'Duration from injury to surgery' had significant association on grip strength at 06 weeks follow up ($p < 0.05$). Patients operated within a week of injury had reduced grip strength; however. there was no difference in grip strength on further follow up. Other outcome variables showed no association with 'duration from injury to surgery. Age and sex of the patient had no significant association with any of the outcome variables i.e. elbow and forearm ROM, grip strength and pain.

3.4. Outcome at 01 and 02 years post op

There was no significant difference recordable in the clinical, radiological and functional outcome parameters of all the patients at 01 and 02 years follow up. None of the patient reported any remarkable changes from previous follow-up. No patient had radiological evidence of loosening or implant breakage at two years follow up.

4. Discussion

The treatment of comminuted fractures of radial head remains controversial and challenging till date and no data is available from Indian subcontinent. Treatment outcomes are further worsened by associated injuries of the elbow. In spite of adequate fixation there is increased incidence of residual pain, stiffness, non-union, osteonecrosis of radial head and secondary osteoarthritis of radio-capitellum joint.[15]

Simple excision of the radial head in isolated uncomplicated fractures of radial head provides good symptomatic relief and full ROM in individuals leading sedentary lifestyle. However, in patients with non-reconstructable comminuted fractures of radial head, excision and radial head replacement is considered appropriate treatment. Poor results have been reported by Mikic, Josefsson, Hall and Leppilahti et al. in their respective studies after radial head excision.[20–24]

Radial head prosthesis restores elbow stability to a level similar to that of the normal elbow when a fracture of the radial head occurs alone or in combination with dislocation of the elbow, rupture of the medial collateral ligament, fracture of the proximal ulna, or fracture of the coronoid process. The bipolar radial head implant acts as a spacer, allowing early soft tissue healing and restoration of mobility similar to native radial head.[16] Results of our study corroborates well with available evidence in existing literature.

Age and sex of the patient was found to have no significant statistical association with any of the 'outcome variables in our study'. Even though 'Sex of the patient' and pain score (VAS) had no statistically significant association, there was clinically increased duration of analgesics intake in 'male population' ($P = 0.061$) in our study. This could be explained by the incidental presence of more 'associated elbow injuries' in male population (which was not a statistically significant association).

Doornberg JN, Shore and Grewal et al. noted multiple associated elbow injuries in their respective studies on radial head fractures. In patients with associated elbow injuries, significantly reduced pronation at 03 months follow up was noted ($p < 0.05$). However. there was no difference in pronation at 06 months follow up. Other outcome variables showed no association with associated elbow injuries.[17,18] On evaluating the effects of 'hand dominance' on 'outcome variables' it was found that 'Dominant side' had better grip strength at 06 weeks follow up as compared to non-dominant side ($p < 0.05$); however there was no difference in grip strength on further follow up at 03 and 06 months. Other outcome variables showed no association with dominance of hand.

On evaluating the effect of duration from injury to surgery on outcome variables, we noticed significant association on grip strength at 06 weeks follow up ($p < 0.05$). Patients operated within a week of injury had reduced grip strength; however. there was no difference in grip strength on further follow up. Other outcome variables showed no association with 'duration from injury to surgery'.

Claudia lamas et al. in their follow up of 04 yrs on 47 patients found that VAS at rest was 1 and mean VAS during activity was 1.7.[27] In our study, at 06 weeks 19 patients (90.5%) had VAS of 3–7. At 03 months, 17 patients (81%) had VAS <2. At 06 months all patients had VAS <2.

There was significant difference ($P < 0.05$) between mean elbow and forearm ROM and fixed flexion deformity at 6 week compared with ROM at 3 month, and between ROM at 6 weeks and 6 months. Our results corroborated well with observations of Grewal R et al., Hung-Yang Chien et al. and Claudia lamas et al.[25–27]

All patients were free of wrist pain and valgus instability at 06 weeks and 03 months follow up. However, in 02 patients (9.5%) implant had to be removed for restricted range of movements. On follow up at 06 months both patients had wrist pain and valgus instability. However, radiographs did not show any proximal migration of radius and differences in ulnar variance on comparing with contralateral side.

None of our patients developed proximal migration of radius or features of osteolysis/loosening till 06 months follow up in contrary to study by John C. Berschback et al. where all 27 patients had some form of lucency around stem on average follow up of 2 year.[19] In the study by John C. Berschback et al. almost 50% patients developed heterotopic bone mass and 4 out of total 27 had to undergo surgery for HO mass removal for restoration of movements.[19] In our study one patient had heterotopic ossification at 06 weeks follow up over the anterior aspect of radial tuberosity which did not increase in size and was found to be not interfering with ROM thus didn't require excision. All the patients were given Tab Indomethacin 25 mg three times a day for 03 weeks post op as prophylaxis for heterotopic ossification.

Grewal R et al. found considerable alteration in radiocapitellar joint pressures with over lengthening of 2.5 mm.[25] Hung-Yang Chien et al. had prosthesis removal in 01 patient out of total 13 patients at 02 months follow up due to restricted ROM caused by overstuffing of implant.[26] In our study, 02 patients underwent implant removal at 03 month follow up for not gaining satisfactory range of movement of elbow joint. One had associated olecranon fracture and other had associated posterior dislocation elbow as initial injury, however these factors had no statistical association with restricted movements in remaining patients. During index surgery both these patients were given implant size which were same as native radial head size. While in all other cases implant size was reduced by 2 mm while measuring assembled fragments of fractured radial head in 'sizer' on table. This ensured inserting prosthesis with size 2 mm less than the native radial head. This reduced radiocapitellar overstuffing and helped achieve satisfactory ROM. None of the patients with 'downsizing' of the implant had valgus instability at any follow up. In the 02 patients who underwent implant removal, intra operative findings included 'metallosis' in one patient while other had features suggestive of 'myositis' (not significant enough to affect the ROM and this HO did not progress on further follow up). Both patients developed wrist pain and valgus instability at 06 month follow up.

4.1. Limitations

This study has few limitations. Apart from small sample size, the main limitation was that a single cohort with non-reconstructable radial head fractures was evaluated with no control or comparison group. The study does not assesses the complexity of pre-operative ligament injuries as well. The study was solely conducted to assess the outcome of an indigenously available prosthesis to manage non-reconstructable radial head fractures in terms of its capability to achieve post-operative pain relief and the incidence of prosthesis loosening and failure. The study does not compare any difference in the outcome in patients with either isolated radial head injuries or those with associated medial side ligamentous disruption.

5. Conclusion

From our study, we have noticed that with our indigenously available radial head replacement prosthesis we were able to restore elbow stability with satisfactory results in terms of pain and elbow movements, and rapidity in regaining grip strength and power of elbow musculature in patients with non-reconstructable radial head fractures. Our results were in line with many other studies in existing literature. Patients were able to perform activities of daily living without any significant morbidity and there was no requirement of further intervention.

It appears that radial head replacement surgery for comminuted fractures of radial head produce satisfactory clinical outcome. However comparative study is needed to assess benefits of radial head replacement over radial head excision. Also studies need to be conducted to assess differences in outcome of replacement of radial head in isolated injuries and in those associated with medial side ligamentous disruption. Further randomized studies with larger sample size and follow up duration are required to determine the advantages of radial head replacement over excision of radial head, type of prosthesis used, bearing surfaces, stem design and other outcome variables.

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