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Radial head replacement with a bipolar system: a minimum 2-year follow-up

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Background: We report the short-term results of a cohort of patients undergoing radial head replacement using a novel radial head prosthesis with a smooth, unfixed, telescoping stem and a bipolar design after a mean follow-up of 34 months (range, 24-48 months).
Materials and methods: Patients were assessed using clinical and radiographic examination as well as with standardized outcome measures. Thirty implants (29 patients) were available for review.
Results: At final follow-up, the average Mayo Elbow Performance Index Score was 92.1 and the Disabilities of the Arm, Shoulder, and Hand Score was 13.8. Clinical examination revealed significant differences between operative and nonoperative sides for flexion/extension and pronation/supination. Radiographic measurement of medial and lateral ulnohumeral spaces revealed re-establishment of a congruent elbow joint. No significant arthritic changes were identified at the radiocapitellar joint. Minimal angular migration of the implant in the proximal radial shaft was observed over time. Complications included 1 patient requiring temporary placement of a hinged external fixator for instability and 1 patient requiring revision surgery at 4 weeks.
Conclusion: This review demonstrates that a bipolar radial head prosthesis with a smooth stem and telescoping neck effectively restores stability to elbows with a comminuted radial head fracture and valgus instability. To date, this is the largest reported outcome analysis of bipolar radial head replacement in the literature.
Level of evidence: Level IV, Case Series, Treatment Study.

Keywords: Radial head; bipolar; radial head fracture; outcomes; Katalyst; elbow reconstruction

Radial head and neck fractures are common orthopedic injuries. They are estimated to account for 1.7% to 5.4% of all fractures[20] and represent one-third of all elbow fractures.[10,17] In addition, 85% of all radial head and neck fractures occur in patients aged between 20 and 60 years.[17]

The treatment goals for radial head fractures are to restore elbow stability, preserve elbow motion, restore forearm rotation, and maintain the length of the radius.[4] Depending on the fracture pattern, these goals may be achieved with open reduction and fracture fixation or radial head replacement. Radial head excision without replacement should be performed with caution in the setting of an acute elbow injury. Associated injury to the collateral

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ligaments or interosseous membrane may lead to valgus elbow instability, longitudinal forearm instability, and loss of strength.[20]

A variety of radial head replacements are currently available. Fragmentation of silicone implants[26] led to the development of metallic devices. Most of these are 1-piece ''monoblock'' or ''unipolar'' implants. Owing to the complex nature of the proximal radioulnar and radiocapitellar joints, bipolar radial head implants were developed to enhance joint congruency throughout elbow and forearm motion. There is basic science evidence that these bipolar designs better reproduce the kinematics of the elbow after radial head replacement.[27]

The Katalyst Radial Head (Integra, Plainsboro, NJ, USA) is a bipolar implant with a smooth telescoping stem. The stem design allows for the precise restoration of radial column ''length'' in situ, without the need to release the lateral collateral ligament and common extensor origin when they are intact. This study reports the early clinical outcome of patients who underwent radial head replacement with this implant.

Materials and methods

Between March 2004 and October 2006, 36 prostheses were placed in 34 patients (21 women, 13 men) at Allegheny General Hospital (AGH) or Rush University Medical Center (RUMC). The radial head was resected in all individuals, followed by replacement arthroplasty with the Katalyst bipolar implant. Replacement arthroplasty was required in 27 patients after acute fracture or fracture-dislocation where the radial head was deemed irreparable at the time of surgery and in 7 patients for post-traumatic arthritis or in the setting of elbow reconstruction indicated by failed previous surgery or fixation at other institutions. Each patient agreed to participate in the study, with an understanding of the research protocol.

Radial head arthroplasty was performed in those cases after acute trauma where the radial head could not be repaired and there was associated valgus laxity of the elbow. There were 4 patients in this series with acute longitudinal instability of the forearm. Radial head arthroplasty was also performed after late radial head resection done for post-traumatic arthritis where there was residual valgus laxity of the elbow (Table I and Table II).

Table I Injuries seen in association with comminuted radial head fractures requiring radial head arthroplasty

Associated injury	Frequency
Lateral collateral ligament complex injury	18
Ulnohumeral dislocation	13
Coronoid fracture/anterior capsular injury	12
Medial collateral ligament injury	9
Olecranon/proximal ulnar fracture	6
Capitellar osteochondritis dissecans/fracture	5
Essex Lopresti/longitudinal injury	4
Proximal radialus dislocation	3
Distal radial fracture	2
TFCC tear/ulnar styloid fracture	2
Triquetrum fracture	1
Previous ulnar nonunion	1
Previous distal humeral nonunion	1
Posterior interosseous nerve palsy	1
Annular ligament rupture	1
Open fracture	1
Sigmoid notch fracture	1
Proximal radial metaphyseal comminution	1
Operations done for chronic conditions*	7

TFCC, triangular fibrocartilage complex.
* Including arthritis, nonunion, failure of previous fixation.

The surgical technique consisted of a lateral, ligament-sparing approach in which the extensor tendon origin and lateral ligament were incised at the midline of the radiocapitellar axis. The radial head was sectioned with a saw, and the appropriate diameter implant was chosen. Implant length was carefully measured using the cutting guide system with the ulnohumeral joint reduced. Intraoperative clinical and radiographic parameters were assessed. The head size varied from 18 to 24 mm in diameter, and the head offset from the stem was between 1 and 3 mm, depending on the radiocapitellar gap to be restored. Formal lateral collateral ligament repair was required in 15 patients due to acute instability, 5 patients underwent concomitant open reduction and internal fixation of an olecranon fracture, and 3 required open reduction of the coronoid.

Prophylaxis with indomethacin (75 mg/day) for heterotopic ossification was administered to each patient undergoing surgery at RUMC, but not to patients undergoing surgery at AGH. All patients were immobilized initially in a long arm splint. Motion was initiated within 7 to 10 days in all cases. For those with instability noted at surgery requiring ligament repair, elbow flexion and extension was performed with the shoulder adducted and the elbow at the patient's side to protect the joint from varus stress. These restrictions were lifted at 6 weeks postoperatively. Patients were monitored with serial examinations and radiographs.

At a minimum of 2 years after surgery, all patients were evaluated for the purposes of this study. Patients completed a Mayo Elbow Performance Index (MEPI), a 10-point visual analog scale (VAS) pain score (0 = no pain; 10 = severe pain), and a Disabilities of the Arm, Shoulder, and Hand (DASH) survey. The clinical evaluations were completed by an independent examiner.

Standardized neutral rotation frontal and lateral radiographs of the affected elbow and wrist, as well as the contralateral elbow and wrist, were obtained. Radiographs for ulnar variance of the wrist were taken with the shoulder abducted, the elbow flexed to 90°, and the forearm in neutral rotation. Radiographs were analyzed and recordings made of the lateral and medial ulnohumeral space, degree of proximal radial migration, change in position of the implant stem within the canal, lucency about the prosthetic stem, bone spur formation, heterotopic bone formation, and sclerosis/radiolucency at the radiocapitellar and ulnohumeral joints.

Statistical analysis

Six distinct quantities allowed direct comparison between affected and unaffected elbows. The kinematic measures of flexion/extension arc, supination, and pronation range of motion and the radiographic measures of medial ulnohumeral space, lateral

Table II Patient-specific injury patterns

Patient	Associated injuries, fracture patterns
C.A.	Radial head fracture, ulnohumeral dislocation
R.A.	Radial head fracture, ulnohumeral dislocation, slight fx coronoid, anterior capsule tear, MCL/LCL rupture
B.A.	Radial head fracture, LCL rupture
P.C.	Radiocapitellar arthritis, proximal radioulnar joint arthritis, ulnar nonunion, elbow contracture
P.C.	Radial head fracture, coronoid fracture, ulnohumeral dislocation, LCL rupture
C.G.	Radial head fracture, LCL rupture, ulnohumeral dislocation
T.K.	Radial head/neck fracture, LCL rupture, capitellar OCD
A.L.	Radial head fracture, coronoid fracture, LCL rupture
J.L.	Radial head/neck fracture, olecranon fracture, LCL rupture
D.M.	Radial head fracture, posterior interosseous nerve palsy
R.N.	Radial head fracture, ulnohumeral dislocation, LCL rupture, coronoid shear fracture
T.P.	Radial head fracture, LCL rupture, ulnohumeral dislocation, distal radius fracture
R.P.	Radial head fracture, LCL rupture
J.S.	Radial head fracture, proximal ulnar fracture, previous (old) nonunion of distal humeral fracture
D.S.	Radial head fracture
J.T.	Radial head fracture, ulnohumeral dislocation, coronoid fracture
T.W.	Radial head fracture, LCL rupture, coronoid chip fracture, capitellar OCD
J.B.	Radial head fracture, comminuted olecranon fracture, elbow dislocation
D.B.	Radial head fracture, MCL rupture, LCL avulsion, capitellar OCD
J.C.	Radial head fracture, LCL avulsion, MCL rupture
R.C.	Radial head fracture, posterolateral dislocation, anterior capsule tear, LCL avulsion, MCL rupture, coronoid avulsion, OCD capitellum, Essex Lopresti
E.H.	Radial head fracture, elbow dislocation, MCL rupture, LCL rupture, capitellar shear fracture, coronoid fracture
E.H.	Radial head fracture, elbow dislocation, type 1 coronoid fracture with anterior capsular avulsion, LCL avulsion
E.P.	Radial head fracture, olecranon fracture, coronoid fracture
M.P.	Radial head fracture, proximal ulnar fracture, LCL rupture, elbow dislocation, Essex Lopresti, MCL avulsion, ulnar styloid fracture
J.P.	Radial head fracture, olecranon fracture, coronoid fracture, type IV (posterior) dislocation, annular ligament rupture
D.R.	Radial head fracture (OPEN), MCL rupture, distal radial fracture
J.R.	Radial head fracture, MCL rupture, elbow dislocation
V.S.	Radial head fracture, longitudinal instability
A.S.	Radial head fracture, elbow dislocation, MCL sprain
E.V.	Radial head fracture, coronoid fracture, posterior (type IV) dislocation, sigmoid notch fracture, Essex Lopresti, LCL rupture, TFCC tear, avulsion fracture triquetrum

LCL, lateral collateral ligament; *MCL,* medial collateral ligament; *OCD,* osteochondritis dissecans; *TFCC,* triangular fibrocartilage complex.

ulnohumeral space, and proximal migration of the radial shaft, as measured at the distal radioulnar joint, provided direct means to evaluate outcome. Paired *t* tests were used to compare the sides in each patient, and unpaired *t* tests were used for comparison of functional scores between patients with acute radial head arthroplasty for trauma and those with previous surgery or chronic conditions such as arthritis. A significance level of 0.05 was used.

Results

Of the 36 implants, 30 were available for review and constitute the cohort evaluated in this study. Follow-up averaged 34 months (range, 24-48 months). Average scores for the entire cohort were MEPI, 92.1 (range, 65-100); VAS for pain, 1.4 (range, 0-5); and DASH, 13.8 (range 0-52.5). When broken down into the 23 procedures performed for acute injury vs the 7 performed for chronic conditions (ie, previous surgeries, elbow reconstruction, arthritis), the mean MEPI score showed the chronic group had poorer than the acute group (94.6 vs 85.0; $P = .034$). No statistical significance was noted in the difference in mean VAS (1.2 vs. 2.2) and DASH (12.01 vs. 21.8) outcomes between the acute ($P = .166$) and chronic groups ($P = 0.127$).

Clinical evaluation revealed an average flexion/extension arc of 126° (range, 95°-150°) in the affected elbow. Forearm pronation averaged 69° (range, 45°-90°), and supination averaged 74° degrees (range, 60°-85°). In comparison, the unaffected elbow measured an average flexion/extension arc of 138° (range 120°-150°), an average pronation of 72° (range, 45°-90°), and an average supination of 80° (range, 60°-85°). The difference in range of motion between the affected and unaffected arms for flexion/extension arc, pronation, and supination was statistically significant ($P = .013$; Fig. 1).

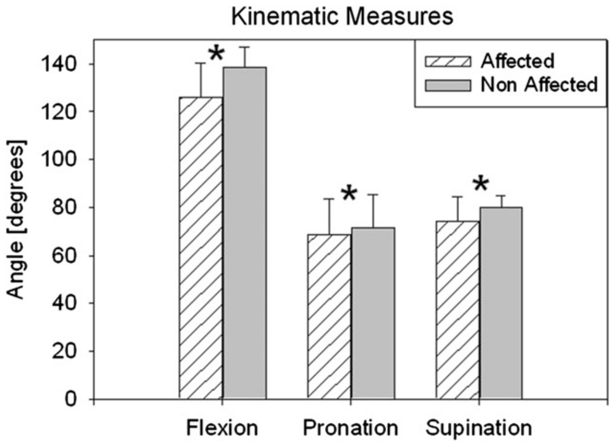

Figure 1 At final follow-up, the difference in range of motion between affected and unaffected extremities in flexion/extension arc, pronation, and supination was significant. *$P = .013$. The *error bars* show the standard deviation.

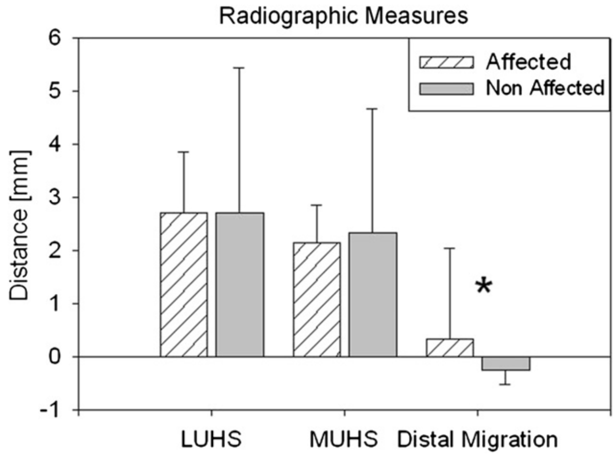

Figure 2 The difference between affected and unaffected extremities in lateral ulnohumeral space (*LUHS*) and medial ulnohumeral space (*MUHS*) measured on an anteroposterior radiograph of the elbow at final follow-up was not significant. The difference between affected and unaffected extremities in distal migration of the radius measured on anteroposterior radiographs of the wrist at final follow-up was significant. *$P = .012$. The *error bars* show the standard deviation.

Analysis of orthogonal radiographs of affected and unaffected elbows revealed an average lateral ulnohumeral space of 2.71 mm (range, 0.5-5.1 mm) on the operative side compared with 2.72 mm (range, 1.0-6.3 mm) on the unaffected side, but the difference was not significant ($P = .317$). The medial ulnohumeral space averaged 2.14 mm (range, 1.0-4.1 mm) on the affected side and 2.34 mm (range 1.0-5.6 mm) on the unaffected side, and this difference was also not significant ($P = .120$).

Wrist radiographs revealed an average proximal migration of the radius of 0.34 mm (range, −3.2 to 4.4 mm) on the affected side compared with an average ulnar-positive variance of 0.26 mm (range, −4.0 to 1.8 mm) on the unaffected side, which was statistically significant ($P = .012$; Fig. 2) No patient reported wrist pain or exhibited evidence of distal radioulnar joint instability on clinical stress testing.

Note was made of a patient (D.M.) who had a positive ulnar variance of 4.4 mm on the affected wrist. At the most recent follow-up, he was satisfied, reported no wrist pain, had excellent function and range of motion of the elbow, and reported a VAS score of 2. His wrist variance was symmetrical with his asymptomatic contralateral wrist.

Further analysis of the radiographs revealed minimal ulnohumeral bone spurs in the elbows of 22 patients, small degrees of non−motion-limiting calcification in 13, and stem lucency in 24 (Fig. 3, *A* and *B*). The stem is smooth and fits loosely in the medullary canal. As a result, a radiolucent border envelopes every stem. Despite this radiolucencyvery little (if any) change in the position of the stem was noted within the canal over time when final radiographs were compared with those taken immediately postoperatively. There were no cystic lesions suggestive of polyethylene wear.

Complications in 2 patients were significant enough to require repeat surgery. In the first patient, who was treated early in the series, the radiocapitellar joint was overstuffed. The intraoperative cutting guide was used improperly, and an extra 2 mm was added to the neck length. The resultant overstuffing was recognized with a combination of postoperative radiographs and a clinical examination that demonstrated a loss of elbow flexion. The problem was easily corrected. The set screw on the adjustable neck was removed, the neck was shortened 2 mm, and the set screw was reinserted. The implant tray now contains wands upon which are the 6 combinations of head diameter and neck length. These wands can be used to trial the head diameter and neck length to avoid this complication.

The second patient had a grossly unstable elbow. During repair of the lateral complex, the elbow translated medially due to an incompetent anterior and posterior capsule and medial collateral ligament. This translation was not recognized on intraoperative radiographs but was clearly apparent on postoperative radiographs. Although this was not a failure of the implant, it did constitute a failure to recognize the translation, a situation that would have been avoidable with better intraoperative imaging. This patient was treated with reduction and stabilization of the joint with a hinged external fixator that was used for 5.5 weeks. This patient went on to an excellent outcome , with 110° of elbow range of motion, 185° of forearm rotation, VAS of 2, MEPI of 85, and DASH of 46. Neither complication was deemed specifically related to the implant.

Discussion

A variety of implants have been used to replace the radial head. These include those made of ferrule caps,[23] metal,[5]

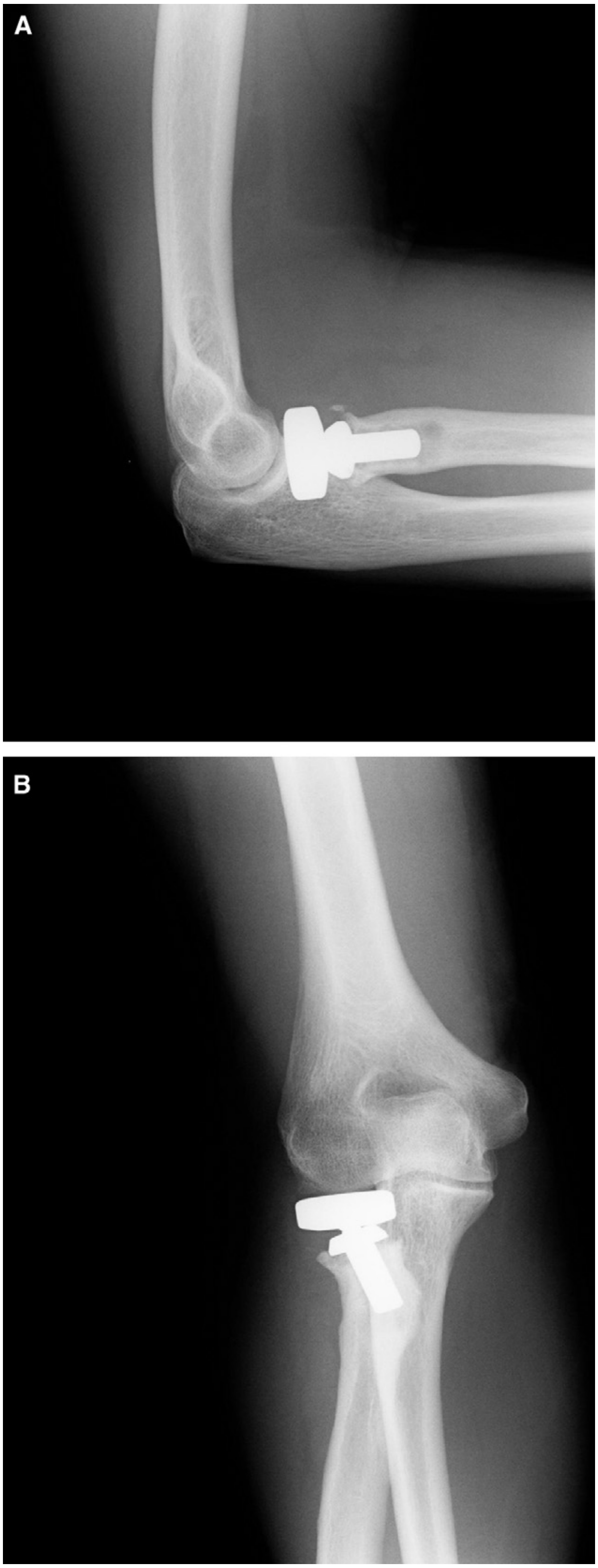

Figure 3 At the final follow-up, **(A)** lateral and **(B)** anteroposterior radiographs of a right elbow reveal a well-aligned ulnohumeral and radiocapitellar joint. A small fleck of ectopic calcification anterior to the neck had no effect on forearm rotation. There is a sclerotic rim of bone at the proximal margin of the radius where the stem rests. We point out that when comparing immediate postoperative radiographs with radiographs obtained at final follow-up, there was very little (if any) change in the position of the stem within the canal over time.

acrylic,[7] and silicone.[24] Silicone was initially popular, but fragmentation[26] and the limited load-bearing capacity of silicone[13] led to the development of metallic implants. A variety of implant designs are currently available; however, little data exist on the superiority of one design over another. Most current implants function as ‘‘monoblock’’ or ‘‘unipolar’’ devices. Malalignment of these implants can lead to decreased radiocapitellar contact area and increased cartilage wear from stress concentration.[27] Bipolar radial head implants were developed to maximize radiocapitellar congruency and contact forces.

The bipolar Katalyst implant has a smooth, stainless steel stem. Within the stem is a telescoping shaft with fluted walls that provide a surface to engage a set screw to fix the shaft in a distracted position. The proximal end of the telescoping shaft contains a ball that couples with the polyethylene liner of the head to allow assembly of the head to shaft in situ. This coupling is a ‘‘snap fit,’’ which makes in situ assembly easy.

The stem was designed to be a smooth, ‘‘loose’’ fit within the canal. This was chosen due to what seemed to be excellent results with a similar stem in a monoblock head (Wright Medical, Arlington, TX, USA). Since this implant’s conception more than 10 years ago, the ‘‘loose,’’ smooth stem design has held up well in long-term follow-up.[9] In this series, we had similarly good experience with this stem design. The stem has a surrounding lucency by design, but did not migrate or tip within the canal during an average follow-up of nearly 3 years.

The polyethylene–stem-coupling mechanism allows in situ assembly. Polyethylene wear is a concern in any implant. To date, we have not had the chance to retrieve an implant that has been in place for more than 7 weeks. Although polyethylene wear could become an issue, it has not been apparent clinically or on radiographs. With rotational loads shared between the stem and the proximal radius, the stem and polyethylene liner, and the head and the capitellum, we expect that the stresses seen at the stem/polyethylene interface are relatively low.

The polyethylene–stem connection is also the heart of the bipolar nature of the implant. Conflicting data have been reported on the function of bipolar prostheses compared with unipolar designs. Using a cadaveric model, Moon et al[18] concluded that a bipolar implant would impart less posterolateral stability to the elbow joint in the face of an incompetent lateral ligament complex. In another laboratory study using cadaveric elbows, Yian et al[27] determined that only a bipolar implant would restore physiologic radiocapitellar alignment and tracking. Clinical short-term to medium-term outcome studies have shown favorable results with both implant designs.*

How long the Katalyst implant retains its bipolar nature is unknown and is currently a subject of investigation in our institutions. Regardless, we believe that the most important factor in treating elbow fracture-dislocations is management of the ligaments, a factor that far exceeds the importance of the hardware.

Implant dissociation at the polyethylene—stem interface is another potential concern; however, this connection has held up well in the 7 years since the first implant was placed. There was no instance in this series where the head dissociated from the stem. In our experience, the coupling is very secure if a loud "snap" is heard when the head is coupled to the stem, the elbow is not overstuffed, and when the lateral complex is intact or repaired.

Conclusion

This report reviews the clinical experience with a bipolar implant for a variety of pathologic conditions, including high-energy trauma. The implant has a telescoping smooth stem design with a bipolar neck. Several head diameters are available, and implant length can be adjusted in 2-mm increments in situ. At a minimum 2-year follow-up, no major complications were identified specifically related to the implant.

Radiographic and clinical evaluations revealed reestablishment of a congruous elbow joint in post-traumatic and reconstructive applications, although function as assessed by MEPI was better in the acutely post-traumatic setting than in reconstructive cases. There was no evidence of capitellar osteopenia, significant proximal radial translation, or migration of the implant. Patients recovered a similar range of motion between affected and unaffected elbows.

Outcomes in this series were optimized by recognition and treatment of the complete injury complex, including associated fractures and collateral ligament insufficiency. Further study will be required to see if these short-term results are maintained over time.

Disclaimer

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* 1-4, 6, 8, 9, 11, 12, 14-16, 19, 21, 22, 25.

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