

Radial head prosthesis disassembly: case report and medico-legal implications

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Abstract. – BACKGROUND: The aim of the treatment of radial head comminuted fractures is the restoration of anatomical normalcy to avoid the risk of several complications such as joint instability.

Among the options for the treatment of such fractures, it is worth mentioning osteosynthesis, resection of the radial head or prosthetic replacement.

In the presence of comminution or severe dislocation of the fracture's fragments, as in our patient's type III Mason fracture, prosthesis implantation is the treatment of choice.

CASE REPORT: This clinical case reports a 22-year-old volleyball player, who during training suffered a comminuted fracture of the radial head, type III according to Mason's classification. A prosthesis was implanted. The post-operative course took place regularly. However, approximately three months after surgery, the patient experienced sudden pain and functional limitation following a normal elbow extension movement, so much so that he required medical attention in our emergency room. Following all the appropriate clinical-instrumental tests, a complete dissociation of the bipolar prosthesis of the radial head was found.

CONCLUSIONS: Our clinical case shows the disassembly of a bipolar radial head prosthesis, a rather rare complication. From a medicolegal perspective, the patients should be aware of the increased risk of requiring further surgery after radial head replacement. When patients are thoroughly informed, they can cooperate and comply with indications more effectively, thus taking an active role in recovery management.

Key Words:

Radial head fractures, Radial head prosthesis, Radial head replacement, Elbow stiffness, Malpractice, Medicolegal implications.

Introduction

Comminuted fractures of the radial head pose a considerable challenge for the orthopedic surgeon, particularly if they occur in young patients. In the past, excision and removal of the radial head was recommended, but patients presented frequent complications such as valgus instability of the elbow¹. To date, however, osteosynthesis treatments with free screws or dedicated plates have been proposed, and if reduction and synthesis of the fracture is not possible, the recommended treatment is the prosthetic replacement of the radial head with a dedicated prosthesis. Different models of prostheses are currently available in terms of materials, silicone or metal, and different modularity, monopolar or bipolar. However, the implantation of a capital prosthesis has been associated with several complications such as joint stiffness, persistent pain, infections, the appearance of heterotopic calcifications, loosening of the prosthetic components with consequent functional reduction of the affected elbow and limitation in normal daily activities². From the standpoint of medicolegal examination, it is important to be able to distinguish complications from errors. Cases have been reported in which the disassembly of a bipolar prosthesis of the radial head has occurred even without any traumatic events. We report here the clinical case of a young patient who suffered the complete disassembly of the bipolar radial head prosthesis. Possible medicolegal implications have also been accounted for.

Case Report

In January 2022, a 22-year-old male patient reported a fall impacting the left hand with the forearm extended during a volleyball game. The patient was admitted to the emergency room of the I.R.C.C.S. Galeazzi Hospital - S. Ambrogio (Milan, Italy), where he immediately underwent clinical and instrumental tests. The radiography of the elbow, performed in two projections (antero-posterior and lateral-lateral), and CT exam documented the presence of a comminuted fracture of the radial head, i.e., type III according to Mason's classification (Figure 1A, Figure 1B).

The patient was then hospitalized. Two days after the traumatic event, the patient underwent prosthetic replacement of the radial head. The operation was performed under local regional anesthesia, using a nerve block of the brachial plexus, with the patient in a supine position, arm abducted on a special support and tourniquet at the root of the affected limb. The humeroradial joint was accessed through the surgical Kocher approach. With a special oscillating saw, an osteotomy was performed to regularize the neck of the radius, after removing and preserving the bone fragments of the head. Subsequently, we continued with the preparation of the medullary canal using dedicated rasps of increasing

diameter until a good fit with the rasp was obtained. We proceeded with the implantation of the definitive radial stem with hydroxyapatite coating and therefore not cemented.

To measure the diameter of the fractured radial head, all the removed fragments were reunited and recomposed with a special measuring device. Through the use of test components, attached to the definitive prosthetic stem, the stability and rigidity of the new joint was evaluated intra-operatively until an optimal result was obtained without impingement. We then proceeded with the implantation of the definitive components of the prosthesis to reconstruct the radial humerus joint. An ANTEA A-EXTREMITY® Adler Ortho SpA (Milan, Italy) prosthesis was implanted, in particular a Ti6Al4V PE radial head with a diameter of 23.5 mm, a TiNbN-coated connector collar with an offset of 2.5 mm, a size 3 radial stem. At the end of the implantation of the definitive components, the new elbow joint appeared stable to flexion-extension, pronation-supination movements and varus-valgus stress, with a complete range of motion (ROM), without sensation of joint jerks or impingement.

In the post-operative control radiographs, correct positioning of the prosthetic components and the absence of free joint fragments were observed (Figure 2).

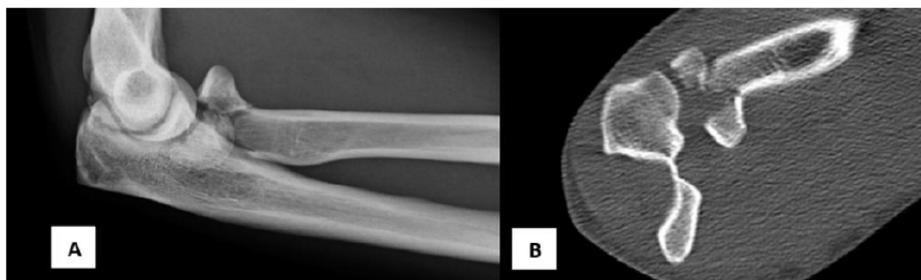


Figure 1. A, Latero-lateral projection x-ray of the left elbow showing the type III radial head fracture according to Mason's classification. B, CT coronal section showing a comminuted fracture of the radial head.

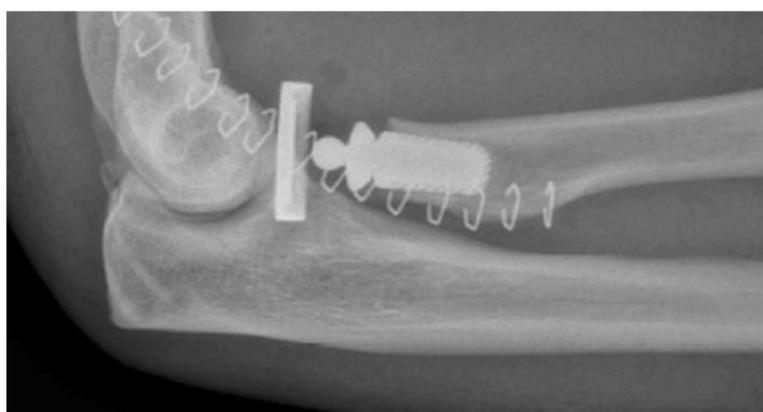


Figure 2. Lateral x-ray of the left elbow showing correct positioning of the prosthesis.

The patient was then protected for 2 weeks with a hemi-elbow cast at 90° of flexion, in neutral pronosupination. At the clinical check-up at 15 days of follow-up (FU), the hemi-elbow brace was removed, with the indication to perform passive mobilization of the elbow for the following 7 days and subsequently to start with active assisted mobilization for the gradual recovery of the elbow. Elbow ROM, until subsequent FU at 30 days post-op.

At the FU 1 month after surgery, the patient presented good range of motion with an active extension deficit of 5°, which could be reducible passively and complete pronation-supination. The radiographic examination, performed at the same time, demonstrated adequate positioning of the prosthetic components.

About three months after the operation, however, the patient experienced sudden pain and functional limitation in the left elbow following a normal elbow extension movement. The radiological study performed in emergency showed a complete dissociation of the bipolar prosthesis of the radial head (Figure 3A and 3B).

The patient was admitted to the trauma division and the prosthesis was removed, with the radial

stem left in place as it was already osteointegrated, and therefore impossible to mobilize without invasive maneuvers on the radius (Figure 4).

The removed prosthetic components, head and collar, did not show any wear or macroscopic damage to the polyethylene. The capitulum humeri showed no signs of damage on the articular surface. The patient was then protected with a soft bandage for seven days and was allowed to move the elbow freely after stitches removal 15 days after surgery. To continuously follow the healing process, the patient was monitored through our Institute's telemedicine service³. At the clinical follow-up 3 months after the second operation, the patient presented an extension deficit of 20°, a flexion deficit of 30° and approximately 10° deficit in elbow pronation. However, he reported a resumption of normal daily activities with no functional limitations at all.

Discussion

Radial head fractures (RHF) account for nearly 33% of elbow fractures and 4% of all fractures⁴.



Figure 3. Lateral x-ray (A) and antero-posterior x-ray (B) of the left elbow showing the dislocation of the prosthetic components.



Figure 4. Lateral x-ray of the left elbow: post-operative check-up showing the removal of the head of the prosthesis, while the radial stem was left in place, as it was osseointegrated.

Radial head resection as a treatment for radial head fractures has reported poor functional outcomes. Therefore, fracture fixation when possible or radial head replacement in case of non-synthesizable fractures have been recommended as first-line treatment options^{5,6}. Different types of prostheses have been proposed since the early 1940s. In 1968, Swanson presented a silicone rubber implant that initially gave good results⁷. However, long-term follow-up and biomechanical studies have shown this type of implant to be unsuitable for radial head replacement⁸. Metal prostheses provide better stability to the elbow joint and are well tolerated even in the long term. Various complications can occur in relation to the implantation of radial head prostheses, including joint stiffness and overstuffing, disassembly of the prosthetic components, erosion of the capitulum humeri, elbow instability, infections, neuro-vascular lesions⁹. In this regard, complications may occur related to inadequate surgical technique and inappropriate choice of implant¹⁰. From a medicolegal point of view, it is essential to know how to distinguish complications from errors¹¹. The complication is the inadvertent, unforeseeable and unpreventable, and sometimes not entirely controllable, “consequence” of a medical-surgical technical activity. The error is the “consequence” of a medical-surgical technical activity that is inadequate or incompatible with the mandatory assumptions characterizing professional conduct. Management of acute nonreconstructible radial head fractures in unstable elbow injuries with radial head replacement has a high risk of reoperation. Patients should be informed about this risk of secondary intervention, which appears to peak within 1 year of implantation¹². For this reason, it is advisable to pay particular attention to the planning of the therapeutic protocol, after an adequate information process and direct involvement of the patient, who must be aware of the possible risks and complications related to the procedure^{13,14}.

However, the radial head prosthesis remains a suitable option for fractures of the radial head that cannot be reduced or synthesized or in cases of malunion with secondary arthritis in the outcomes of conservative or surgical treatment of fractures¹⁵. Adequate neck resection and accurate sizing of the radial head implant constitute two of the main success-conducive factors. Patients, particularly younger ones, should be informed about the increased risk of requiring further surgery after radial head replacement¹⁶. When patients are adequately

informed, they are then able to cooperate more effectively and take an active role in the healing process¹⁷. The timing of communication between doctor and patient constitutes treatment time¹⁸ and enables each patient to make a pondered decision on whether or not to adhere to a specific treatment. It is therefore essential in the informed consent process in order to guarantee full decision-making autonomy. Such an awareness-based process entails the consolidation of a correct preliminary information phase as an essential requirement¹⁹.

The clinical case analyzed herein shows the disassembly of an ANTEA A-EXTREMITY® bipolar radial head prosthesis from Adler Ortho SpA (Milan, Italy). This complication is a rare event in radial head prostheses, but well described in other districts, such as in bipolar hip prostheses²⁰. Although the advantages of bipolar radial head implantation are evident, it does expose the implant to the risks of dislocation and disengagement²¹. In fact, disassembly of the radial head was found only in patients who had received bipolar prostheses, which points to a clear correlation between the inclination angle of the radial head and radiocapitellar subluxation²². Unlike the monopolar metal head, which behaves in a similar way to the native radial head, the resistance to radiocapitellar subluxation is somewhat more vulnerable for the bipolar head, due to its higher degree of inclination favoring subluxation²³.

Disassembly of the bipolar radial head prosthesis is a complication often related to persistent posterolateral instability. Herald et al²⁴, for example, argue that the cause of disassembly may lie in elbow instability. The bipolar head can become engaged under the capitulum humeri, leading to an impingement that favors the disconnection between the prosthetic head and the connector collar. Therapeutic management relies on bloody reduction through the same skin incision used for the first implant. The two possible options are: repositioning of the radial head prosthesis after replacing the disassembled components or its elimination. At the same time, the reinsertion or re-tensioning of the lateral collateral ligament complex will be an option, in the event that a postero-lateral instability is found during the revision surgery, which was not at the time of the first surgery²⁵. The disassembly of the prosthetic components can also be favored by prosthesis-loosening or overstuffing. Should surgery be unsuccessful, a viable option may be revision using a prosthesis of the radial head, with the inclusion of a long stem and its alignment to the axis of rotation of the forearm. Such event does

however entail well-known intrinsic difficulties linked to revision surgery, mostly determined by the reduction of the bone stock and the breakdown of the soft tissue envelope²⁶.

Conclusions

In conclusion, it is worth noting that the treatment of comminuted radial head fractures entails major complexities. The treatment of choice is generally reduction and synthesis of the fracture. When synthesis is not possible, the implantation of a capital prosthesis may be a valuable alternative. The disassembly of the bipolar radial head prosthesis is a rare but possible event. When it occurs early, surgical intervention is needed to minimize the damage caused by the prosthetic components at the articular cartilage level of the capitulum humeri and the ulnar radial pit.

Authors' Contributions

Conceptualization, G.B., L.B.P and S.F.; methodology, G.B., S.F., R.A., L.B.P.; validation, G.B., S.F., M.B., R.A., S.Z., M.L. and L.B.P.; investigation, G.B., S.F., L.B.P and R.A.; data curation, G.B., S.F. and S.Z.; writing—original draft preparation, S.F., G.B., M.L., S.Z. and L.B.P.; writing—review and editing, G.B., S.F. and S.Z.; visualization, G.B., S.F., M.B. and R.A.; supervision, G.B., S.Z. and S.F.. All authors have read and agreed to the published version of the manuscript.

Conflict of Interest

The authors declare that they have no conflict of interest.

Ethics Approval

This study did not require the approval of the ethics committee and did not entail any damage to the rights, safety, and health of the people involved. This study has pursued as its primary objective, above all others, the well-being of the patient involved.

Informed Consent

The informed consent to participate in the study was obtained from the patient, along with his agreement to publish all the necessary information and data.

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Data Availability

The data presented in this case report are available on request from the corresponding author.

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