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UNIVERSITE DE LAUSANNE - FACULTE DE BIOLOGIE ET DE MEDECINE

Département de l'appareil locomoteur

Service d'orthopédie et de traumatologie

Early aseptic loosening of radial head prostheses – A case series of 6 patients and a biomechanical review

THESE

préparée sous la direction du Docteur Frédéric Vauclair

et présentée à la Faculté de biologie et de médecine de
l'Université de Lausanne pour l'obtention du grade de

DOCTEUR EN MEDECINE

par

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Early aseptic loosening of radial head prostheses – A case series of 6 patients and a biomechanical review

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Résumé en français de l'article

OBJECTIF

La prothèse de tête radiale est le traitement de choix des fractures comminutives de têtes radiales. Une prothèse modulaire monopolaire de type press-fit a été utilisée dans notre institution. La prothèse a par la suite été retirée du marché en raison d'un taux inhabituellement élevé de descellement de la tige. Nous présentons dans cet article le suivi des patients porteurs de cette prothèses et notamment le taux de descellement, le taux de révisions et leur évolution actuelle, ainsi qu'une revue de littérature sur la biomécanique de la tête radiale native et des prothèses de tête radiale.

METHODES

Nous avons collecté rétrospectivement les données des 6 patients porteurs de cette prothèse de tête radiale, données comprenant leur anamnèse, l'examen clinique et leurs radiographies. La durée moyenne du suivi est de 40 mois.

RESULTATS

Cinq des six prothèses se sont descellées. Quatre d'entre-elles furent enlevées, en raison d'un descellement symptomatique. L'ablation de la prothèse a permis une nette diminution de la douleur et une amélioration de la mobilité articulaire du coude.

REVUE DE LITTÉRATURE

La tête radiale est un stabilisateur secondaire du coude, contribuant à la stabilité axiale et en valgus de celui-ci. La mise en place d'une prothèse de tête radiale permet de rétablir la stabilité du coude lors d'une lésion associée des ligaments du coude et d'une fracture comminutive de la tête radiale. Différents types de prothèses sont disponibles, se différenciant par leur mécanique (prothèse monopolaire ou bipolaire), leur fixation dans l'os (press-fit, intentionally loose ou cimentée) et la géométrie de la tête (anatomique ou non-anatomique). Selon les données actuelles, la prothèse probablement la plus recommandée serait une à tête anatomique et à tige press-fit longue. Cependant, c'est aussi la prothèse la plus exigeante du point de vue de la technique chirurgicale, car elle ne permet que très peu de liberté d'erreur lors de la pose. Pour cette raison, le débat sur la prothèse de tête radiale la plus appropriée est toujours en cours.

CONCLUSIONS

La prothèse incriminée (The DePuy Synthes Radial Head Prosthesis System) a présenté un très haut taux de descellement (5/6). La raison d'un tel taux n'a jamais été expliquée par le fabricant. Au vu de la revue de littérature, il est possible de suspecter que la combinaison d'une tête à géométrie non-anatomique associée à une tige courte press-fit ait créé trop de contrainte lors de la mobilisation du coude. Ces contraintes répétées provoquent des micromouvements à la l'interface os-prothèse, qui empêchent l'ostéointégration de la tige dans l'os.

Early aseptic loosening of a press-fit radial head prosthesis – A case series of 6 patients

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journals.sagepub.com/home/imrCorbaz J¹ , Barimani B² and Vauclair F³

Abstract

Objective: Radial head arthroplasty (RHA) is the principal treatment option for comminuted radial head (RH) fractures. Here, we present six cases of failed RHA using a modular monopolar press-fit RHA that was subsequently withdrawn from the market because it was associated with a high incidence of loosening.

Methods: We retrospectively collected data from six patients who had received Radial Head Prosthesis System™ at our centre between July 2015 and June 2016. The average follow-up was 40 months.

Results: Aseptic loosening of the stem affected five (83%) of the six RHA. Four of these were symptomatic and RHA removal was performed. For these patients, the pain subsided and their elbow range of motion (ROM) improved.

Conclusion: While the ideal design for an RHA is still debatable, RHA is an efficient treatment option that restores elbow stability and function after a comminuted RH fracture. Importantly, removal of the prosthesis is an effective remedy following RHA associated elbow pain and decreased ROM.

Keywords

Radial head prosthesis, radial head fracture, loosening, RHA

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Introduction

Radial head (RH) and neck fractures are common and account for approximately one third of all elbow fractures.^{1–3} They typically occur following a fall on an out-stretched arm with the forearm in

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pronation, and fracture of the RH results from impaction on the capitellum.⁴ Conservative treatment is used for nondisplaced fractures, with surgery reserved for more severe cases. The three surgical options are: open reduction and internal fixation (ORIF), excision of the head or radial head arthroplasty (RHA). Mason type III and IV fractures have a poor outcome if treated by ORIF when the fracture has more than three fragments.⁵ RHA improves functional outcomes in complex fractures⁶⁻⁹ and is now commonly used as the primary treatment.

Different designs for RHA are available and can be classified in several ways. For example, one way is to define the RHA by stem fixation, of which there are four groups: press-fit; intentionally loose; cemented; expandable stems.¹⁰ Additionally, RHA prostheses can be monopolar or bipolar, and constructed of cobalt-chromium, pyrocarbon, vitallium, titanium or silicone. Interestingly, there is no evidence to show superiority of one material over another.¹⁰ However, the silastic prosthesis (i.e., the Swanson implant, Dow Corning Corporation, USA) has been found to have a high rate of revision,^{11,12} secondary to its propensity to create wear particles that induce an inflammatory response and synovitis.¹³ The silastic prosthesis is also associated with a high rate of implant fractures¹⁴ and has poor capacity to restore valgus stability because of its low stiffness.^{15,16}

A modular, monopolar press-fit RHA (The DePuy Synthes Radial Head Prosthesis System, DePuy Synthes – Johnson & Johnson, New Brunswick, New Jersey, USA) was used at our centre from 2015 to 2016. The advantage of this implant was related to its modular components. This feature made it easy to use because it was adjustable to the anatomy of the patient and so reduced the risk of overstuffing¹⁷ and residual instability,¹⁸ which are

known causes of RHA failure. However, during patient follow-up, a significant proportion of patients developed osteolysis and aseptic stem loosening. The prosthesis was subsequently withdrawn from the market for this reason. The aim of this article is to present a review of the six patients who received this prosthesis at our institution.

Patients and Methods

Between July 2015 and June 2016, six patients received Radial Head Prosthesis SystemTM at our centre. All the surgeries were performed through a lateral Kocher approach by one surgeon (F.V.). Any associated ligamentous injuries were addressed at the time of surgery. The prosthesis is modular and the radial head locks to the stem by taper locking with a connection screw that allows 10 stem options (i.e., five short straight stems and five long curved stems) and 24 heads (i.e., six different diameters with four different heights) to reconstruct the anatomy of the proximal radius. The heads are round and symmetrical in shape, and are composed of cobalt/chrome. The stems are made of titanium and designed to be press-fit, with a rough coated surface allowing bony ongrowth.

Post operatively, range of motion (ROM) was restricted with the use of a hinged brace or a removable cast with a flexion/extension of 30–130° and full pronation/supination at 90° of flexion. Physiotherapy was adapted according to the associated ligamentous injuries. Follow-up reports were used to evaluate the outcome of each patient, based on history, physical examination and X-rays. Osteolysis was localized on the X-rays and classified according to a modified Gruen¹⁹ classification for the elbow²⁰ (Figure 1).

The reporting of this study conforms to CARE guidelines.²¹ All participants provided written informed consent. Patient data were anonymized prior to analysis. The



Figure 1. Modified Gruen²⁹ classification for the elbow.

study was approved by the hospital ethics committee (Commission Cantonale d’Ethique de la Recherche sur l’Etre Humain – Lausanne, N° 2017-01430).

Results

At the time of surgery, the average age of the five men and one woman was 47 years (range 27–63 years). In four cases, the mechanism of injury was high energy trauma and in two cases it was low energy trauma. For five cases, the indication for RHA was Mason IV fracture and in one case it was Mason III fracture. Five were implanted as primary treatment and one as a secondary treatment following failure of osteosynthesis. Average follow up, defined as the time between the injury and the last available appointment, was 40 months (range, 23–68 months).

Initially, all six patients had a good outcome with minimal pain and improvement in ROM. However, X-rays showed the presence and progression of osteolysis around the stem in five (83%) cases. In two of these cases, osteolysis first started at the tip of the stem (area numbers 3-4-5; Figure 2), in two other cases it started at the proximal part of the stem (area numbers 1-2 and 6-7; Figure 3) and in the remaining case it started all around the stem. First signs of lucency were visible as soon as three months



Figure 2. Osteolysis at the tip of the stem.



Figure 3. Osteolysis at the proximal part of the stem.

post operatively. In these five cases, the osteolysis progressed around the stem, culminating with a loose stem 6–12 months following surgery (Figure 4). Four of the cases were symptomatic (i.e., pain during loading of the elbow) and removal of the prosthesis was conducted in these patients.

Removal of the prosthesis allowed clear regression of elbow pain, and subsequently three patients reported a pain free elbow with the exception of one patient who complained of mild exertional pain when gardening or snow shovelling. All elbows were stable after removal of the prosthesis and none developed wrist pain. The average

ROM in flexion improved from 142° to 148° and the extension deficit decreased from 30° to 16°, which represents a total gain of 20° of motion, and from 78-0-83° to 84-0-94° for pronation/supination, a gain of 15° (Figures 5 and 6).

Discussion

Complex fractures of the RH are frequent among young and active patients and so are a therapeutic challenge because osteosynthesis has a poor result in Mason III or IV fractures.⁵ The two main treatment

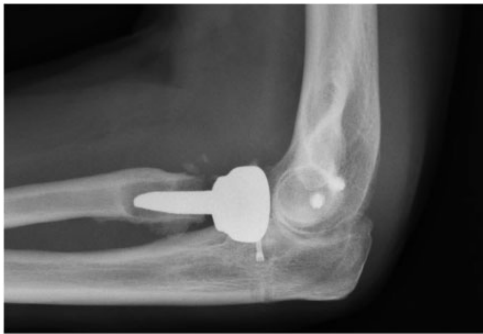


Figure 4. Complete loosening of the stem.

options for complex fractures are removal of the head or RHA. Removal of the RH leads to decreased strength and function.²² Moreover, symptomatic proximal translation of the radius²³⁻²⁶ and generalized instability are seen with associated ligamentous injuries.^{27,28} The implantation of a RHA aims to remedy these shortcomings by restoring a functional, pain-free and stable elbow while avoiding failure of the implant. However, systematic reviews and meta-analyses have found that RHA has a failure rate at four years of 0–29%¹⁰ and loosening has been observed in up to two thirds of the revisions.^{29,30} Therefore, the ideal design for an RHA is an on-going debate. Some surgeons recommend the use of a monopolar prosthesis, focusing on its superior ability to restore stability,^{31,32} while others recommend bipolar or intentionally loose stem prosthesis insertion because of their propensity to diminish the radio-capitellar stress related to their self-centring capacity.³³ Anatomic designs appear to be biomechanically superior,^{34,35} but also less forgiving, rendering their use controversial.^{36,37} When considering press-fit stems,

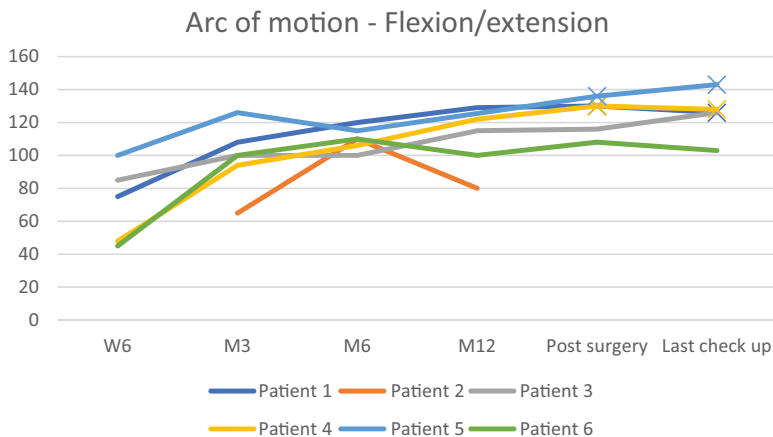


Figure 5. Evolution of the arc of motion in flexion/extension in the six patients.

W6, 6 weeks post operative follow-up; M3, 3 months post operative follow-up; M6, 6 months post operative follow-up; M12, 12 months post operative follow-up. After removal of the radial head arthroplasty (RHA) results are marked with a cross.

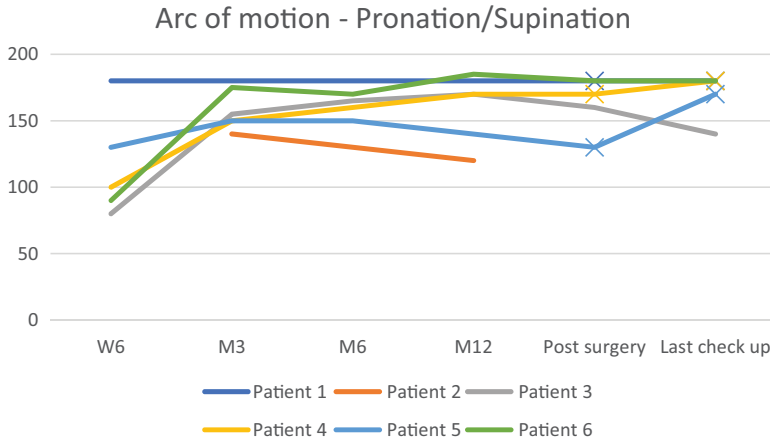


Figure 6. Evolution of the arc of motion in pronation/supination in the six patients.

W6, 6 weeks post operative follow-up; M3, 3 months post operative follow-up; M6, 6 months post operative follow-up; M12, 12 months post operative follow-up. After removal of the radial head arthroplasty (RHA) results are marked with a cross.

long stems appear to perform better than short ones.^{38,39} However, findings from systematic reviews and meta-analyses are inconclusive. One meta-analysis found no difference between different designs in terms of revision rate,⁴⁰ while another found an increased risk of revision among cemented and press-fit stems but no difference in terms of functional outcomes.⁴¹

At our centre, we used the DePuy Synthes Radial Head Prosthesis SystemTM to treat complex RH fractures in six patients. During patient follow up, osteolysis around the stem was noted in 83% of the cases and subsequent stem loosening occurred 6–12 months post-surgery. The reasons behind the early failure of this prosthesis are unclear. Osteolysis following arthroplasty is a known complication, and accounts for up to 75% of revisions in hip arthroplasty⁴² and 30% of RHA.⁴³ Several causes have been suggested among which polyethylene wear, metal on metal reactions (i.e., aseptic lymphocyte-dominant vasculitis-associated lesion [ALVAL]) or modular neck prosthesis are the most common.⁴⁴ Among these complications, only one (i.e.,

modular neck design) was associated with the DePuy Synthes Radial Head Prosthesis SystemTM. However, most of the aforementioned causes take several years to develop. While a reaction to the implant metals (i.e., cobalt, chrome or titanium) could have been the cause, it is highly unlikely because these metals are commonly used for prostheses.

Early loosening suggests a failure of osteointegration. This prosthesis was designed to be press-fit in the radius for primary stability and to undergo bony ongrowth for secondary stability, a process that unfortunately failed. Non-integration has been reported to be caused by micromotion at the prosthesis/bone interface, which results in the formation of fibrous tissue.^{45–47} A recognized cause of micromotion is insufficient primary stability that can occur when an undersized stem has been used in the medullary canal. In the proximal radius, adequate press-fit creates an optimal stem/bone interface but this has been demonstrated to be close to the fracture threshold.⁴⁸ This can lead to apprehension by the surgeon of producing an

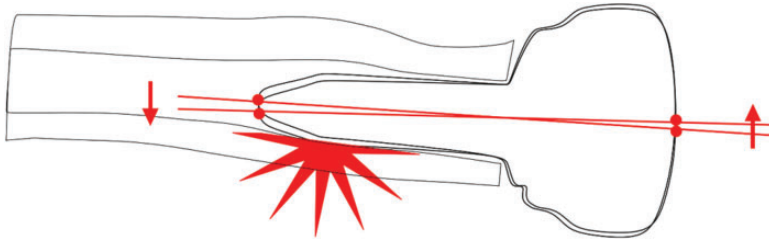


Figure 7. Toggling of the stem due to mismatch between the capitellar and radial head arthroplasty (RHA) centre of rotation during elbow motion.

intra operative fracture and may influence the selection of a slightly thinner stem than the optimal one. Importantly, a direct link between the ratio of stem within the canal to the total length of the RHA and primary stability has been reported.³⁸ This was confirmed by a retrospective study that found a lower loosening rate of longer stems when short vs long press-fit stems were compared.³⁹

Suboptimal design of the prosthesis leading to an increase in constraint level, has also been reported to cause micro-motion.⁴⁹ Non-physiological tracking of the RHA during elbow motion can cause increased levels of constraint. For example, native RHs are slightly elliptical,^{50–52} have an eccentric fovea radialis and an offset between the neck and the head. An RHA with a perfectly round head and centred concavity has been shown to be non-anatomical and prone to create a stress zone.⁵³ The lack of a compensatory mechanism can create eccentric loading of the RHA and varus/valgus constraint along the stem during pronation/supination (Figure 7). Varus/valgus stress on the prosthesis has been shown to create peak micro-motion at the bone/implant interface even under low axial loading conditions.^{48,54} Indeed, loosening of press-fit RHAs has been reported to create severe osteolysis of greater magnitude than caused by intentionally loose stems.^{55,56} One possible explanation for this could be carving of the medullar canal by the roughened surface

of the loose stem after primary stability is lost and secondary stability has failed.

Another cause of non-integration is related to the type of surface of the stem.^{57–61} A grit-blasted chemically etched surface, with a middle roughness, is considered the preferred type.⁶² It provides a balance of primary stability and secondary osseointegration. The exact process used for the DePuy Synthes stem was not clearly specified by the manufacturer and so we cannot conclude definitively that this was the reason for its failure.

In summary, the DePuy Synthes Radial Head SystemTM may have failed because of its amalgamation of a non-anatomic head design with a short press-fit stem. This combination probably imposes high constraints on the stem during elbow motion, facilitating micro-motion at the implant/bone interface, and so preventing osseointegration. Despite the surprisingly high rate of loosening and poor survival of RHA in our case series, restoration of elbow stability was achieved and this permitted the removal of RHA in symptomatic patients. The four patients who had their RHA removed had significant reduction in pain which is consistent with the results of another study that found proximal radial forearm pain to be suggestive of mechanical loosening.⁵⁵


Declaration of conflicting interests

The authors declare that there are no conflicts of interest.

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