Elbow arthroplasty in perspective

Heijink, A.

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Andras Heijink

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ELBOW ARTHROPLASTY IN PERSPECTIVE

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“When your life flashes before your eyes, make sure you’ve got plenty to watch”.

Quoted by Andy Warhol in “From A to B and back again”, author unknow

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1

General introduction

Andras Heijink

INTRODUCTION

Arthroplasty (Gk, *arthron,* an articulation or joint + *plassein*, to form or mold) literally means *plastic surgery of the joint*. Although various types of arthroplasty exist, the term is mostly used for prosthetic replacement of a joint. Arthroplasty and replacement are generally used interchangeably, unless a different type of arthroplasty is specifically indicated.

Outcomes after total joint arthroplasty, both at the level of the individual patient and at the population level, are influenced by systemic factors as well as biological and biomechanical factors at the level of the prosthesis. Biological and biomechanical factors may be related to the patient, to the execution of the operation or to the prosthesis. Biological factors include, but are not limited to, bone ingrowth or ongrowth to the surface of the prosthesis and bone quality. Biomechanical factors include, but are not limited to, bone quality, positioning of the prosthesis and prosthesis design parameters. These factors may interact with one another.

We are interested in the biomechanical factors, prosthesis design parameters in particular, which influence outcome after elbow arthroplasty. We are also interested in partial arthroplasties of the elbow. We performed a number of studies on these topics, a selection of which is published in this thesis: a study on the role of biomechanical factors in the pathogenesis of osteoarthritis of the elbow, a series of studies on outcome after radial head arthroplasty (RHA) with specific interest in implant polarity, and a study on metallosis after total elbow arthroplasty (TEA).

ELBOW ANATOMY

The elbow is a complex joint, formed by the articulation of the distal humerus and proximal ulna and radius. It is considered a tricompartmental joint, composed of the ulnohumeral, radiocapitellar and proximal radioulnar joints. From a kinematic standpoint, the elbow is a trochogynglymoid joint, allowing flexion-extension in the ulnohumeral joint (hinge or ginglymus type of motion) and axial rotation or pivoting in the radiocapitellar and proximal radioulnar joints (trochoid type of motion)[1]. Stability of the elbow joint is secured by interaction of static (osseous congruency, joint capsule and collateral ligaments) and dynamic (tendons and muscles) constraints[1]. For a more detailed discussion of the static and functional anatomy of the elbow the reader is invited to turn to the wide spectrum of anatomical textbooks on the topic.

RADIAL HEAD ARTHROPLASTY

The radial head is an important secondary stabilizer of the elbow for resisting valgus stress when the primary stabilizer against valgus force, the medial collateral ligament, is insufficient[2]. This secondary stabilizing function of the radial head is particularly important following Mason type 3 fractures, because of the high prevalence of associated ligamentous injuries that compromise elbow stability[3-7]. The same is true following more complex elbow injuries such as terrible triad injuries, complex elbow (fracture-) dislocations and longitudinal radioulnar instability. In these situations it is imperative to replace or reconstruct, and not resect, the radial head in order to allow healing of the damaged stabilizing soft tissues about the elbow.

Since the introduction of radial head prostheses in the literature by Speed et al. in 1941, various prosthetic designs have been made available[8]. Those designs have varied in terms of material, fixation technique, modularity, and polarity. Despite the quickly rising number of publications on radial head arthroplasty in recent years, the increasing understanding of elbow anatomy, biomechanics and kinetics, and the evolution of surgical techniques and prosthetic designs, there is currently no evidence to support one type of radial head prosthesis over another. The only exception is that silicone prostheses have shown to be biologically and biomechanically insufficient[9].

TOTAL ELBOW ARTHROPLASTY, AND METALLOSIS

Total elbow arthroplasty (TEA) can be a treatment option for disabling elbow pain resulting from rheumatoid, degenerative, or posttraumatic conditions. Although fairly good results have been reported for TEA, numbers are lower, survival is less favorable and complications are more frequent than after lower extremity arthtroplasty[10].

Total elbow prostheses may be *linked* or *unlinked*, depending on the coupling of the humeral and ulnar components. Total elbow prostheses may also be constrained, semi-constrained or unconstrained, depending on the degree of laxity of the aforementioned coupling. Linked prostheses may be constrained or semi-constrained; and unlinked prostheses may be constrained, semi-constrained or unconstrained.

The first attempts to replace the elbow joint involved hemiarthoplasties. In 1927, Robineau implanted a metal humeral prosthesis covered with rubber and in 1947 Mellen and Phalen reported on implantation of an acrylic prosthesis[11, 12]. In this period of hemiarthroplasty, these procedures were only incidentally performed and the prostheses were often custom made[13]. Interestingly, in recent years distal humerus hemiarthroplasty has regained interest as treatment option for unreconstructable fractures of the distal humerus[14].

The first publication on TEA dates from 1942; Boerema reported the implantation of an uncemented, non-anatomic, rigid hinged prosthesis[15]. The *modern* era of TEA is considered to have begun in the early 1970's with the design from Dee in 1972, followed by a number of other hinged prostheses[16, 17]. The important feature of the Dee prosthesis was that is was the first implant to use cement fixation. High failure rates were observed for these constrained prostheses due primarily to lack of understanding of elbow anatomy, kinematics and biomechanics[13, 16]. Failures resulted from protrusion of the humeral stem, bone resorption, fracture and breakage of the prosthesis caused by the transmission of high leverage and rotational forces onto the prosthesis. As a consequence, constrained prostheses have become obsolete today.

Subsequently, various unlinked designs were developed. In unlinked prostheses, the humeral and ulnar components fit one another, but have no fixed connection. Unlinked prostheses theoretically reduce stresses at the bone-to-cement and cement-to-implant interfaces, but are naturally also less constrained at the articulation[13, 16]. They rely on ligamentous integrity for stability.

It is now recognized that it is not the linkage per se, but the articular constraint that influences loosening. Contemporary prostheses are either semi-constrained or unconstrained. Semi-constrained prostheses, introduced in the 1980's, have a coupling (either linked with a *loose hinge,* or unlinked) that allows 6°-8° of varus-valgus and rotational motion. They theoretically reduce stress at the bone-cement interface, which would result in a lower failure rate, while also providing the necessary degree of articular constraint.

The choice between a semi-constrained prosthesis and an unlinked (i.e. unconstrained) prosthesis depends on indication, patient characteristics and preference of the surgeon.

In recent years, several cases of metallosis after TEA have been reported[18-23]. Metallosis is defined as infiltration of metallic wear debris in periprosthetic soft and bony tissues, resulting in damage of those tissues and possibly formation of pseudotumors and implant failure[24]. Implant failure due to metallosis has been well recognized and extensively studied with metal-on-metal total hip arthroplasty (MoM THA)[24]. Those metal-on-metal articulations have been demonstrated to be subject to corrosion and wear, primarily at the taper and to a lesser extent at the articulation itself[25]. The metallic particles that are thereby formed may give rise to asymptomatic lymphocyte-dominated vasculitis-associated lesions (ALVAL) and adverse reaction to metal debris (ARMD)[26]. Not much is known about metallosis after TEA.

The *Kudo Total Elbow System* (Biomet, Warsaw IN, U.S.A.) is a type of total elbow prosthesis that has been widely used in Japan and Europe. It consists of a cobalt-chromium humeral component, that articulates in an unlinked, but relatively highly constrained, fashion with a polyethylene bearing titanium ulnar component. It has been proposed that the unconstrained coupling of the Kudo prosthesis may lead to excessive polyethylene wear, which could eventually result in metal-on-metal impingement and subsequent formation of metallic particle debris. The mechanism by which metallic particles are formed after Kudo TEA may be different from MoM THA, but the local reactions at the tissue level are likely to be similar.

AIMS OF THIS THESIS

1. To identify biomechanical conditions about the elbow that play a role in the development of osteoarthritis of this joint.
2. (*i*) To report the results of both cemented and press-fit (uncemented) bipolar radial head arthroplasty (RHA), (*ii*) to investigate if specific design characteristics of radial head prostheses are associated with improved outcomes and (*iii*) to evaluate if bipolar radial head prostheses are able to compensate for radiocapitellar malalignment and/or radioulnar instability.
3. (*i*) To investigate the occurrence of metallosis after Kudo total elbow arthroplasty (TEA) and (*ii*) to investigate if metallosis after TEA can be screened for by means of clinical and/or serological parameters.

OUTLINE OF THIS THESIS

The body of this thesis is structured in five sections. The first section is formed by a brief introduction and presentation of the aims and outline of the thesis. The second section focuses on the pathogenesis of osteoarthritis of the elbow, with specific focus on biomechanical considerations in this process. In the third section a series of studies on radial head arthroplasty (RHA), with focus on prosthesis characteristics, implant polarity in particular, is presented. The fourth section holds a clinical study in which metallosis after Kudo total elbow arthroplasty (TEA) is investigated. The fifth section is formed by the general discussion and the English and Dutch summaries.

Section I: Introduction

Chapter 1 provides a brief introduction to elbow anatomy and the concepts of RHA and TEA.

Section II: Do biomechanical factors play a role in the pathogenesis of osteoarthritis?

Osteoarthritis is the most common joint disease. It should be considered a heterogeneous group of syndromes affecting all joint tissues, although the articular cartilage and subchondral bone often show the most prominent changes. Understanding of the early changes in the development of osteoarthritis is important, since these could still be reversible and therefore preventive treatment could be initiated to halt or reverse further progression of these changes.

The etiology of osteoarthritis is multifactorial and to date not fully understood. It is becoming apparent that ageing changes work in conjunction with other factors, both intrinsic and extrinsic to the joint. For the elbow, it is not known if biomechanical factors play a role. Interestingly, the pathophysiology of the process by which joint degeneration leads to the clinical syndrome of osteoarthritis also remains poorly understood. The primary aim of this section is to identify biomechanical factors or conditions about the elbow joint that play a role in the development of osteoarthritis of this joint. In **chapter 2**, the current evidence for pathophysiological mechanisms by which biomechanical factors or conditions about the elbow may result in osteoarthritis is discussed.

The specific research questions for this section is:

1. Do biomechanical conditions about the elbow joint play a role in the development of osteoarthritis the elbow?

Section III: Metallic bipolar radial head arthroplasty, good or better?

The concept and indications of RHA have been introduced earlier. In this section, a series of studies on RHA, in particular on implant polarity and other prosthesis design characteristic, are presented. The aims of this section are (*i*) to report the results of both cemented and press-fit (uncemented) bipolar radial head arthroplasty, (*ii*) to investigate if specific design characteristics of radial head prostheses are associated with improved outcomes and (*iii*) to evaluate if bipolar radial head prostheses are able to compensate for radiocapitellar malalignment and/or radioulnar instability.

In **chapters 3 and 4**, the mid-term results of two case series after cemented and press-fit bipolar RHA, respectively, are presented. **Chapter 5** is a systematic review of the current literature on the outcomes after RHA in relation to prosthesis design parameters. **Chapter 6** reports the outcomes after metallic RHA in the very specific setting of chronic longitudinal radioulnar instability in a small patient series.

The specific research questions for this section are:

1. Is the clinical performance of metallic bipolar RHA favorable?
2. Are there any unforeseen problems when using metallic bipolar RHA?
3. Are the outcomes after unipolar or bipolar RHA different?
4. Do prosthesis design parameters affect outcome after RHA in general?
5. Are bipolar radial head prostheses able to compensate for radiocapitellar malalignment?
6. Can monoblock unipolar radial head prostheses reliably address the functional deficiency from chronic longitudinal radioulnar dissociation?

Section IV: Metallosis after Kudo total elbow arthroplasty, what is the problem?
The concept and indications of TEA have been introduced earlier. The Kudo total elbow prosthesis is an unlinked prosthesis that has primarily been used in Europe and Japan. In recent years, several cases of metallosis after TEA have been reported, as discussed earlier. The aims of this section are (*i*) to investigate the occurrence of metallosis after Kudo total elbow arthroplasty and (*ii*) to investigate if metallosis after TEA could be screened for by means of clinical and/or serological parameters.

In **chapter 7**, the occurrence of metallosis and the value of clinical and serological markers as screening tool for metallosis are investigated in a cohort of 38 patients that had undergone Kudo TEA in the past. To our knowledge, this is the first study to date that primarily focuses on metallosis after TEA.

The specific research questions for this section are:
1. Is metallosis after Kudo TEA a significant problem?
2. Can metallosis after Kudo TEA be screened for by means of clinical and/or serological markers?

Section V: General discussion
Chapter 8 provides a general discussion in which a synthesis of the performed research is put in perspective and is related to other studies on the same topic.

Appendix
In chapter 9, a brief summary of this thesis is provided in both the English and Dutch language.

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Section

II

Do biomechanical factors play a role in pathogenesis of osteoarthritis?

Chapter

2

Biomechanical considerations in the pathogenesis of osteoarthritis of the elbow.

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ABSTRACT

Osteoarthritis is the most common joint disease and a major cause of disability. Distinct biological processes are considered crucial for the development of osteoarthritis and are assumed to act in concert with additional risk factors to induce expression of the disease. In the classical weightbearing joints one such risk factor is an unfavorable biomechanical environment about the joint. While the elbow has long been considered a non-weightbearing joint, it is now assumed that the tissues of the upper extremity may be stressed to similar levels as those of the lower limb, and that forces across the elbow are in fact very high when the joint is extended from a flexed position. This review examined the available basic science, preclinical and clinical evidence regarding the role of several unfavorable biomechanical conditions about the elbow on the development of osteoarthritis: posttraumatic changes, osteochondritis dissecans, instability or laxity and malalignment. Posttraumatic osteoarthritis following fractures is well recognized, however, the role of overload or repetitive microtrauma as risk factors of posttraumatic osteoarthritis is unclear. The natural course of untreated cartilage defects in general, and osteochondritis dissecans at the elbow in particular, remains incompletely understood to date. However, larger lesions and older age seem to be associated with more symptoms and radiographic changes in the long term. Instability seems to play a role, although the association between instability and osteoarthritis is not yet clearly defined. No data are available on the association of malalignment and osteoarthritis, but based on force estimations across the elbow joint it seems reasonable to assume an association.

INTRODUCTION

Osteoarthritis is the most common joint disease. It should be considered a heterogeneous group of syndromes affecting all joint tissues, although the articular cartilage and subchondral bone often show the most prominent changes[1]. The primary changes occur in the articular cartilage, followed by associated changes in the subchondral bone[2, 3]. More recently, the important and maybe even initiating role of the subchondral bone has been the focus of interest[4-7].

Osteoarthritis results from the disruption of the balance between synthesis and degradation of extracellular matrix components by the chondrocyte in combination with increased uncompensated chondrocyte apoptosis[2-4, 8, 9]. Ageing profoundly alters chondrocyte function and matrix structure and function[10]. There is increasing evidence that cell senescence can result in phenotypical alteration of cells, called the *senescent secretory phenotype*[11, 12]. This phenotype is characterized by increased production of cytokines and growth factors. Accumulation of cells expressing this *senescent secretory phenotype* may contribute to tissue ageing, by stimulating matrix degradation and reducing matrix synthesis and repair, and possibly even directly link ageing to joint degeneration[3].

Amongst many, age has been shown to be the major independent risk factor for the development of osteoarthritis. Ageing and osteoarthritis are inter-related, not inter-dependent, cartilage is to some extent part of *normal ageing*. It is increasingly understood that ageing contributes to the development of osteoarthritis by working in conjunction with a variety of other factors, both *intrinsic* and *extrinsic* to the joint[3].
Osteoarthritis has traditionally been classified as *primary* (idiopathic, developing in previously undamaged joints in the absence of a clear causative mechanism or event) or *secondary* (caused by a well-recognized predisposing condition)[13]. With more and more etiologic factors being recognized, the term *primary* osteoarthritis seems to reflect more the incomplete understanding of the etiopathogenesis than that it defines a specific form of osteoarthritis. More recently, a classification into three subsets of primary osteoarthritis (type I genetically determined, type II estrogen hormone dependent, and type III ageing related), based on well recognized and important biological mechanisms, has been proposed[1]. These three distinct biological processes are considered crucial for the development of osteoarthritis and are presumed to act in concert with various risk factors to induce expression of the disease[1]. One such risk factor is a *unfavorable biomechanically condition* about the joint. At present, avoiding or correcting such unfavorable conditions are the only ways through which physicians can influence the development of osteoarthritis.

Normal synovial joints can withstand repetitive loading during normal activities for a lifetime without developing osteoarthritis[9, 14]. Mechanical demand that exceeds the capacity of the joint to repair itself plays an important role in the development and progression of joint degeneration[2, 9]. This *overloading* can take two forms. Excessive mechanical surface stress can directly damage articular cartilage and subchondral bone and adversely alter chondrocyte function[9]. Also, substantial micro-damage can result from impact levels far below the level needed to produce macroscopic fracture. This micro-damage may progress to detectable compromise of the articular cartilage. Loading rate and shear stress are important variables[15-17].

Compared to osteoarthritis of the hip and knee, symptomatic osteoarthritis of the elbow is rare, while radiographic degenerative changes are being noted much more frequently[18-20]. Rheumatoid arthritis is the most frequent form of osteoarthritis at the elbow, followed by posttraumatic arthritis. Men are four times more affected than women. The most common causative factor in primary osteoarthritis of the elbow seems to be related to microtraumata and to sports that put stress on the upper limbs, although studies of these associations have produced contradictory results[21-23]. Based on cadavers studies of the general population it had always been assumed that elbow osteoarthritis starts at the radiocapitellar joint and from there progresses to the ulnohumeral joint[24, 25]. On the other hand, two recent image-based studies suggest that with symptomatic osteoarthritis the ulnohumeral joint is as much or more affected as the radiocapitellar joint[26, 27]. Potentially, the radiocapitellar compartment is affected first, while the ulnohumeral compartment is already involved when the degeneration becomes symptomatic.

In this review, the pathophysiological mechanisms by which biomechanical conditions about the elbow may result in osteoarthritis are discussed.

TRAUMA AND POSTTRAUMATIC OSTEOARTHRITIS

Posttraumatic osteoarthritis of the elbow following fractures is well recognized and primarily affects young males[28, 29]. The mechanisms responsible for the development of osteoarthritis following injury are complex and remain incompletely understood[10]. There seems to be an association between the development of posttraumatic osteoarthritis and the injury pattern and amount of energy absorbed within the joint[30]. Elbow fractures are often the result of a series of complex biomechanical events and therefore frequently involve associated (i.e. non-osseous) injuries[31]. Because these associated injuries and their consequences to the elbow joint may all contribute to the development of osteoarthritis, it is difficult to isolate the role of each individual injury or effect. The role of overload or repetitive microtrauma as risk factor of posttraumatic osteoarthritis of the elbow is not so clear. Surveys in Scotland revealed miners working at the coalface to have a higher prevalence of elbow osteoarthritis[32]. An association of sports-related exercise, in the absence of macroscopic trauma, and increased prevalence of elbow osteoarthritis has never been reported. In addition, radial head resection in case of ulnohumeral degeneration increases stress on the ulnohumeral compartment and is therefore suggested to lead to aggravation of the pre-existing degeneration[33, 34].

OSTEOCHONDRITIS DISSECANS

Osteochondritis dissecans (Figures 1a, b) is a process in which a segment of articular cartilage separates from the subchondral bone[35]. It is an uncommon disorder in the general population and presents typically in adolescent athletes engaged in repetitive overhead or upper extremity weightbearing activities (e.g. baseball, tennis, volleyball and gymnastics). The capitellum of the dominant elbow is most affected, however bilateral involvement is seen in 20%[36]. The etiology is still unclear, but repetitive valgus forces across the elbow joint resulting in high compression loads at the lateral elbow compartment ('valgus overload') are thought to be the primary eliciting factor[37].

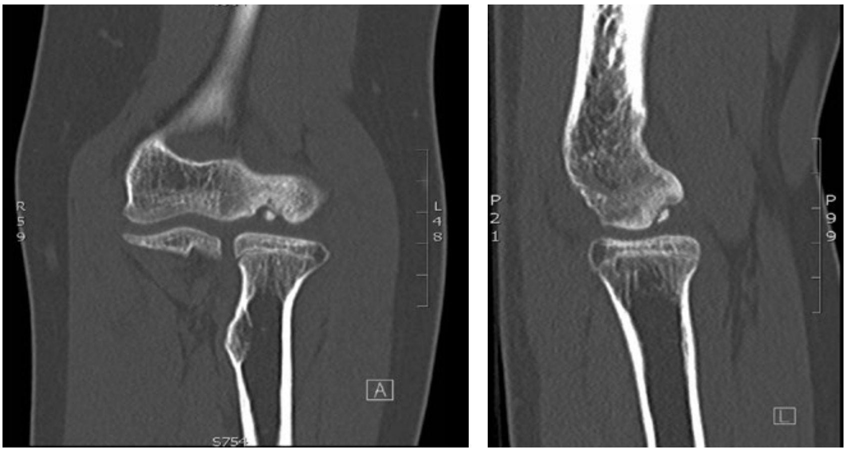

Figure 1A, B. Coronal (A) and sagittal (B) CT-scan images of an osteochondral defect of the capitellum of the *right* elbow in a young girl with osteochondritis dissecans.

The relation to cartilage defects in general and the development of osteoarthritis in the long term is not clear to date. A large body of evidence is available about cartilage lesions in the knee[10]. With regards to the elbow, little is known about the cartilage lesions in osteochondritis dissecans and the risk of development of degenerative changes in the long term. In fact, even the natural course of untreated osteochondritis dissecans of the capitellum is still undefined to date[38]. Bauer et al. observed a high incidence of elbow degeneration amongst 31 patients who had previously sustained osteochondritis dissecans at mean follow-up of 23 years[39]. At end follow-up 42% of patients complained of pain and/or reduced range of motion. One-third had radiographic degenerative changes. It seemed that the younger the patient was diagnosed, the better the odds of having a pain free elbow with no radiographic signs of degeneration at end follow-up. The authors contributed this to better healing conditions at a younger age.

Takahara et al. noted a poorer long-term outcome of patients with larger cartilage lesions as compared to patients with smaller lesions[38]. The authors concluded that this finding suggests that larger lesions may lead to degenerative changes over time and should therefore not be left untreated. However, no data is available whether any of the available cartilage defect repair strategies stop or slow down the development or progression of osteoarthritic changes at all. In conclusion, the natural course of cartilage defects in general and untreated osteochondritis dissecans at the elbow in particular remain incompletely understood to date. However, larger lesions and older age seem associated with more symptoms and radiographic changes in the long-term. No data is available whether any of the available cartilage defect repair strategies stop or slow down the development or progression of osteoarthritic changes at all.

INSTABILITY

The elbow consists of a stable bony construct, surrounded by muscles and strong ligaments. The joint is stabilized by contraction of the muscles surrounding it. The passive ligamentous stabilizers will only be loaded when an external load overcomes the active stabilizing function of the muscles[40]. The ligaments of the elbow can be grossly divided into the *medial collateral ligament complex (MCL)* and *lateral collateral ligament complex (LCLC)*. The LCLC is assumed to be less important, because varus moments about the elbow are primarily resisted by the highly congruent osseous anatomy of the ulnotrochlear join and because the elbow is mostly loaded in valgus due to the valgus carrying angle[41]. Somewhat simplified, three patterns of ligamentous injury are clinically recognized. The first is an injury to the MCL caused by repetitive valgus stress due to overhead throwing type activities or axial compression. The MCL can become attenuated over time or rupture, either acutely or following progressive weakening with attenuation. Secondly, instability can result from injury to the LCLC caused by forced external rotation of the elbow. Usually this is a complete rupture of the ligamentous complex. The third type of instability is caused by simple dislocation of the elbow. Dislocations are mostly posterolateral in direction and LCLC is always involved[42, 43].

A biomechanical study on cadavers by Eygendaal et al. showed that complete rupture of the MCL can result in an increase of 5.9 mm medial joint space opening during valgus stress with the elbow in 90° of flexion[44]. The authors suggested that this would clinically result in damage of the articular cartilage of the radial head. A cadaveric study by Mullen et al. demonstrated 50% loss of valgus stability after sectioning of the MCL[13]. This stability was almost fully recovered (97% of initial stability with the elbow in 90° of flexion) after reconstruction of the anterior bundle of the medial collateral ligament. A cadaveric study by Jensen et al. demonstrated that isolated reconstruction of the anterior bundle in the medial collateral ligament deficient elbow normalized joint varus-valgus and rotatory stability[45]. Only four clinical studies are available in the literature that focus on the association of instability and the development of osteoarthritis[42, 46-48]. A clinical follow-up study by Melhoff et al. of 52 adults who had sustained a simple dislocation of the elbow and were treated conservatively showed no signs of radiographic degenerative changes at average follow-up of 34 months[48]. A similar study by Boris et al., looking at radiographic osteoarthritis after conservatively treated simple elbow dislocations in both children and adults, showed no degeneration in all 28 children at an average follow-up of 7 years[46]. However, 11 out of 28 patients suffered from instability. In the adult group, radiographic osteoarthritis had developed in only one out of 34 adult patients at an average follow-up of 8 years, and eight out of 34 complained of instability. Josefsson et al. observed radiographic degenerative changes or periarticular ossifications in 19 out of 52 patients (i.e. 37%) at an average of 24 years follow-up after conservatively treated simple elbow dislocation[47]. Similar observations were made by Eygendaal et al., who noted radiographic degenerative changes in 21 out of 41 patients (i.e. 51%) at an average follow-up of 9 years[42]. In addition, 19 reported pain, 8 had decreased flexion and 23 had a flexion contracture at end follow-up. They also noted evidence of medial instability on dynamic radiographic examination and found a statistical highly significant association between this medial instability and the development of osteoarthritis on MRI. The much lower incidence of osteoarthritis of the first two studies compared to the latter two could possibly be explained by the short duration of follow-up of the study by Melhoff et al. and the somewhat diffuse inclusion criteria of the study by Boris et al. There are no studies available investigating the effect of surgery on the development of elbow osteoarthritis at the long term.

In conclusion, elbow joint instability seems to play a role in the development of osteoarthritis in the long-term, although the association between the two is not yet clearly defined. The effect of reconstructing elbow stability by ligamentous repair, augmentation or reconstruction on prevention of elbow osteoarthritis has never been investigated.

MALALIGNMENT

Malalignment of the elbow may result from malunion of intra- or extra-articular fractures, or from a combination of the two. Malunion with subsequent angular deformity of the elbow is mostly seen as an adverse sequela of supracondylar fractures in children. Varus deformity (*cubitus varus*) (Figure 2) is more often reported than valgus deformity (*cubitus valgus*). In elbows with open growth plates, some remodeling can be expected, especially in the sagittal plane; no improvement is expected in the coronal plane or in case of rotational deformity[49]. The biomechanical consequences of malalignment of the upper limb relate to the distribution of forces transmitted from the distal humerus acrross the elbow joint to the forearm. The upper limb is often referred to as ‘non-weightbearing’. However, based on calculated loads across the normally aligned elbow joint and their effect on the relatively small bones and joint surface it has been shown that the tissues are stressed to similar levels as those of the lower limb[50]. Forces across the elbow are in fact very large when the joint is extended from a flexed position due to the high forces needed to be generated by the triceps muscle to compensate for its small moment arm. As a result, the joint contact force at the ulnohumeral may be as much as twenty times as large as the external load acting on the hand and wrist[51]. No data are available on the effect of malalignment of the elbow on forces across the elbow joint. Despite the lack of evidence, it nevertheless seems reasonable to assume an association between malalignment and osteoarthritis, much alike the lower extremity[52].

Figure 2. Posttraumatic varus deformity (cubitus varus) of the left elbow, posterior view.

In conclusion, no data are available on the effect of malalignment of the elbow on forces across the elbow joint. However, with the understanding that the tissues of the upper extremity are stressed to similar levels as those of the lower limb and that forces across the elbow are in fact very large when the joint is extended from a flexed position, it seems only reasonable to assume an association between malalignment and osteoarthritis.

CONCLUSIONS

The available basic science, preclinical and clinical evidence regarding the role of several *unfavorable biomechanical conditions* about the elbow on the development of osteoarthritis of the elbow was examined. Posttraumatic osteoarthritis following fractures is well recognized and primarily affects young males. The role of overload or repetitive microtrauma as risk factor of posttraumatic osteoarthritis is unclear. The natural course of cartilage defects in general and untreated osteochondritis dissecans at the elbow in particular remain incompletely understood to date. Instability seems to play a role in the development of osteoarthritis of the elbow in the long-term. No data are available on the effect of malalignment of the elbow on forces across the elbow joint. It is important to realize that many other factors may play a role in the development of osteoarthritis, some of which also via mechanically induced pathophysiological changes to the cartilage and subchondral bone.

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Section

III

Bipolar radial head arthroplasty, good or better?

Chapter

3

Cemented bipolar radial head arthroplasty: mid-term follow-up results

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ABSTRACT

Background

Theoretical advantages of bipolar over monopolar radial head arthroplasty include better accommodation of radiocapitellar malalignment, reduction of capitellar abrasion and reduction of stress at the bone-to-cement and cement-to-implant interfaces. Our purpose was to report the mid-term results of cemented bipolar radial head arthroplasty.

Methods

Twenty-five patients were treated by cemented bipolar radial head arthroplasty for acute fracture of the radial head, failed earlier treatment or posttraumatic sequelae. One patient refused follow-up after surgery. Results are presented for the remaining 24 patients.

Results

At a mean follow-up of 50 months (range, 24-72 months,) one (4%) prosthesis had been removed 2 years after implantation for dissociation of the prosthesis due to failure of the snap-on mechanism. There were 2 (8%) additional radiological failures in the subluxated position; one prosthesis due to malalignment of the radius onto the capitellum and another due to ulnohumeral erosion. The average flexion-extension arc was 129° (range, 80° to140°) and the average pronation-supination arc was 131° (range, 40° to 180°). According to the Mayo Elbow Performance Score, the combined excellent and good results accounted for 83%. In 8 patients, the bipolar design compensated for radiocapitellar malalignment.

Conclusions

The overall mid-term outcome of this series of 25 cemented bipolar radial head arthroplasties can be considered favorable. There was one (4%) revision and 2 (8%) additional radiological failures. The bipolar design was able to compensate for radiocapitellar malalignment. We suggest considering a cemented bipolar radial head prosthesis in case of concerns about radiocapitellar alignment.

INTRODUCTION

It is generally accepted that preserving or restoring the integrity of the native radial head is preferred when treating radial head fractures, but prosthetic replacement should be considered when this is not feasible or not advisable[1]. In general, Mason type I fractures are treated conservatively with early range of motion, Mason type II fractures are treated by open reduction-internal fixation or conservatively and most Mason type III fractures are replaced. In particular, the radial head should be replaced when the secondary stabilizing function of the radial head is required, as is the case with fracture of 25% to 50% of the coronoid process, disruption of the medial collateral ligament (MCL), disruption of the lateral collateral ligament complex (LCLC) or acute longitudinal radioulnar dissociation. Magnetic resonance imaging studies have demonstrated that associated injuries are common[2, 3]. Radial head arthroplasty can also be a salvage procedure after failed osteosynthesis or failed conservative treatment.

Despite the growing amount of data, evolving surgical technique and improving implant design and rationale, prosthetic radial head replacement can be a challenge. Comparing reported results is difficult due to the considerable variation in indications and associated injuries, timing of surgery, implant design, duration of follow-up and outcome surveillance. Satisfactory outcome can generally be expected in approximately 85% of immediately treated isolated radial head fractures, whereas this is, at best, approximately 50% with fractures treated in a delayed fashion[1]. Although associated injuries about the elbow may have a significant effect on prosthetic function and survival, none of the studies available in the literature are of sufficient methodological quality to be able to analyze this effect.

Radial head prostheses may be categorized according to material (silicone, polyethylene, pyrocarbon, metal), modularity (monoblock *vs.* modular), polarity (unipolar or monopolar *vs.* bipolar) or fixation (cemented, uncemented press-fit, intentional loose-fit or fixation with an expandable stem).

A bipolar design is thought to have several theoretical advantages. The bipolar articulation theoretically allows for free rotation and, therefore, reduced abrasion of the capitellar cartilage and reduced stress at the implant-to-cement and cement-to-bone interfaces during forearm rotations as compared with monopolar designs. In addition, the radiocapitellar joint contact area may be increased and, consequently, radiocapitellar contact pressure reduced, which may also reduce radiocapitellar cartilage abrasion[4]. A bipolar prosthesis may also accommodate to some degree to malalignment of the radius onto the capitellum, which may be the case in certain posttraumatic conditions where contraction and scaring have occurred[5]. The cemented prosthesis might be better able to do this than the more recently introduced press-fit version (Figure 3). A disadvantage may be that bipolar prostheses have been shown not to provide as much stability as monopolar prostheses in cadaveric models[4, 6, 7].

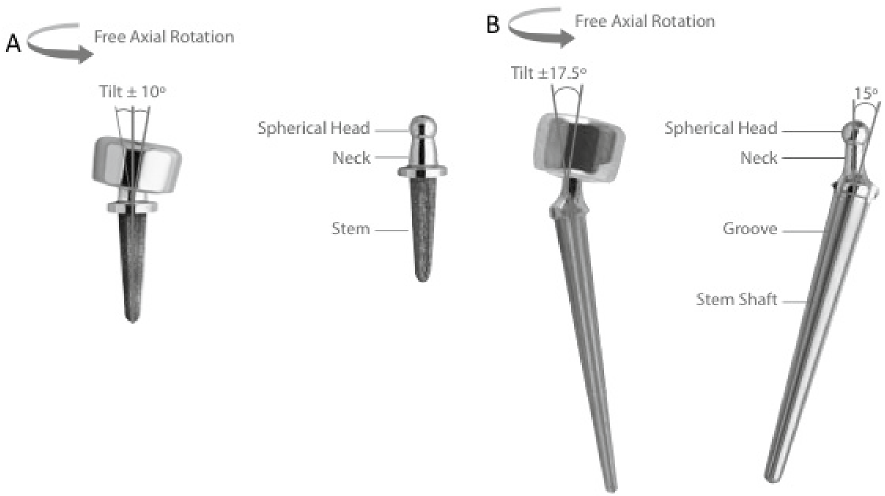

Figure 3 A and B. The press-fit (A) and the cemented (B) RHS (Tornier, Montbonnot-Saint-Martin, France) bipolar radial head prostheses. The design of the cemented prosthesis allows for more tilting of the articular component (i.e. head) than the press-fit design.

The English, peer-reviewed literature on bipolar metallic radial head arthroplasty is limited[8-17] (Table 1). Short-term to mid-term results seem favorable; however, no methodologically sound studies are available to compare bipolar and monopolar prostheses. Long-term results are not available.

The purpose of this study is to report our experience with 25 patients who were treated by cemented bipolar metallic radial head replacement for acute fracture of the radial head, failed earlier treatment or posttraumatic sequelae. We hypothesized that the results would not be different than those reported in the available literature.

METHODS

Between March 2005 and March 2012, 25 cemented bipolar metallic radial head arthroplasties (RHS; Tornier, Montbonnot-Saint-Martin, France; Figure 3, B) were performed in our institution. All were treated for acute radial head fracture, for earlier treatment that had failed or for posttraumatic sequelae. The inclusion period was set to ensure minimum follow-up of 2 years for each patient. The senior author (D.E.) performed all operations.

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Table 1 Overview of the current English, peer-reviewed literature on bipolar metallic radial head arthroplasty.

Author	Year	Country	Level of evidence	Inclusion period	N	Lost to f/u
Current study	2015	Netherlands	IV	2005-2012	25	1 (4%)
Berschback[1]	2013	U.S.A.	IV	2004-2001	21	7 (33%)
Rotini[20]	2012	Italy	IV	2009-2010	19	0 (0%)
Burkhart[4]	2010	Germany	IV	1997-2001	19	2 (12%)
Celli[5]	2010	Italy	IV	2000-2007	16 [(3)]	0 (0%)
Popovic[18]	2007	Belgium	IV	1994-2001	55	4 (7%)
Dotzis[7]	2006	France	IV	1992-2003	14	2 (14%)
Brinkman[2]	2005	Netherlands	IV	1999-2003	11	0 (0%)
Smets[21]	2000	Belgium	IV	1995-1999	18	3 (17%)
Popovic[17]	2000	Belgium	This study reports the short-term results of the first 11 patients of the series reported by Popovic *et al.* in 2007.			
Judet[10 (4)]	1996	France	IV	1988-1995	5 [(5)]	0 (0%)
Judet[10 (4)]	1996	France	IV	1988-1995	7 [(7)]	0 (0%)

[(1)] The RHS bipolar radial head system (Tornier) was previously referred to as CRF II (Capule Radiale Flottante) or simply Judet bipolar radial head prosthesis.
[(2)] The article provides a pooled duration of follow-up of 2 years (range 13-36 months) for a combined group of 19 bipolar and 12 monopolar prostheses. Duration of follow-up for the individual patients or all bipolar prostheses combined is not provided. Likewise for the delay from initial trauma to placement of the bipolar metallic prosthesis.
[(3)] Those 16 were selected from a consecutive series of 73 bipolar radial head prosthesis (see text).
[(4)] Reported as one study.
[(5)] Those were the first 5 patients of a series of 18 patients treated acutely for comminuted, non-reconstructable radial head fracture.
[(6)] One patient was treated within two days with a silicone prosthesis, which was replaced 17 days after trauma with a cemented bipolar metallic prosthesis.
[(7)] Those were the first 7 patients of a series of 20 patients treated in a delayed fashion for complications following radial head excision.

Type, fixation [1]	Follow-up (mean, range)	Delay (mean, range)	Revision (N, %)	MEPS
RHS (Tornier), cemented	50 months (24-72 months)	43 months (0 days-312 months)	0 (0%)	E 14, G 7, F 3, P 1
Katalyst (Integra Life Sciences Coorporation), uncemented	36 months (24-46 months)	Range 1 day-23 years	0 (0%)	E 9, G 3, F 2, P 0
Radial Head Implant (SBi), uncemented	n/a [2]	Range 1-130 days [2]	2 (7%)	E 13, G 5, P 0, F 1
RHS (Tornier), cemented	106 months (78-139 months)	100 days (0-515 days)	1 (5.3%)	E 10, G 6, F 1, P 0
RHS (Tornier), cemented	42 (12-86) months	9 days (0-20 days)	0 (0%)	W 12, G 2, F 0, p 2
RHS (Tornier), cemented	8.4 years (4-13 years)	"All acutely treated"	0 (0%)	E 14, G 25, F 9, P 3
RHS (Tornier), cemented	5.3 years (1-12 years)	Within 8 days, 2 exceptions	0 (0%)	E6, G4, F1, P1
RHS (Tornier), cemented	22.5 months (12-48 months)	8 years (2 weeks -31 years)	2 (18%)	Not provided
RHS (Tornier), cemented	25.8 months (6-48 months)	13 acutely treated, 2 delayed	1 (7%)	E 7, G 3, F 4, P 1
RHS (Tornier), cemented	49 months (24-65 months)	0-2 days [6]	0 (0%)	E 2, G 3, F 0, P 0
Judet CRF II, cemented RHS (Tornier), cemented	43 months (24-72 months)	29 (7-156) months	0 (0%)	E 1, G 4, F 2, P 0

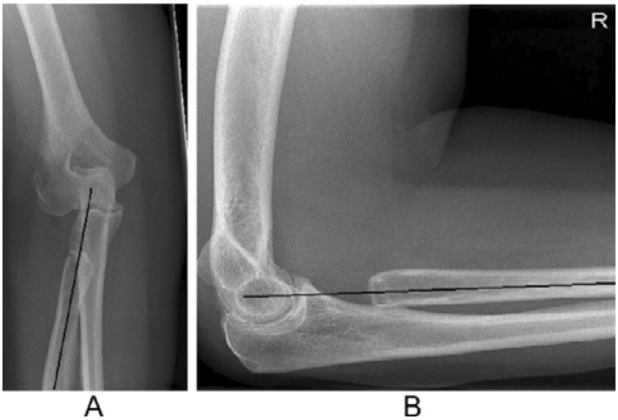
3

We initially treated these patients routinely with a cemented bipolar prosthesis. When press-fit designs became available, we started placing a press-fit prosthesis if bone quality was good and the trial components showed a good press-fit and a cemented prosthesis if there was any doubt about bone quality or fixation of the trial components and also in case of concerns about radiocapitellar alignment, as will be discussed later. This is still the algorithm we use in our clinic today.

The cemented RHS bipolar radial head prosthesis is a 2-part modular system. The smooth stem is made of cobalt-chrome. The head is made of polyethylene encased in cobalt-chrome. The head articulates with the neck of the stem by means of a low friction, snap-on ball-and-socket joint. The stem has a built-in 15º neck angle to reproduce the anatomical offset of the native radial shaft, which, however, has not been formally reported in the literature to date. Stem length varies with diameter: 55 mm or 60 mm for a 6.5 mm or 8 mm, respectively tapered stem width. Neck length options are 19 mm or 22 mm.

The patients were supine during surgery with the arm resting on an arm table. Prophylactic antibiotic coverage consisted of intravenous cefazolin (2000 mg). A tourniquet was used. An extensor split (Kaplan interval) was used. The annular ligament was transected, tagged with a stay suture and repaired at the end of the procedure. The level of the radial neck osteotomy was visually determined and guided by the proximal radioulnar joint. The medullary canal was broached and reamed, a trial prosthesis was inserted to assess the correct size and height of the prosthesis and the elbow was tested for stability and range of motion. When in between sizes, the smaller size was selected. The trial component was removed and a small bone plug was inserted as cement stop and pulse lavage was used to clean the medullary canal. The stem of the definite implant was cemented in place with the angled neck aligned with the radial styloid process and the head was snapped on the neck. At closure, medial collateral ligament injury was tested for, but not encountered in the current series. Post-operatively, a pressure bandage was applied for 48 hours and mobilization was started under guidance of a physiotherapist on the first post-operative day. Continuous passive motion (CPM) was not used. When additional procedures had been performed, this post-operative regimen was adjusted accordingly. Prophylaxis for heterotopic ossification (HO) was not routinely used.

Medical records were reviewed and each patient was seen in the office for a clinical assessment and radiographic evaluation. Post-operative range of motion was determined using a goniometer and elbow function was assessed using the Mayo Elbow Performance Score (MEPS)[18, 19]. Radiographs of the elbow were reviewed for signs of loosening, radiocapitellar alignment, osteolysis of the radial neck, lucency, erosion of the capitellum, periarticular ossifications and ulnohumeral degeneration. Radiocapitellar malalignment was noted to be present if the radius axis did not cross the central third of the capitellum (Figure 4). Osteolysis was evaluated in terms of regions about the radial neck as postulated by Grewal et al[20]. Erosion of the capitellum were noted to be present or absent. Degenerative changes of the ulnohumeral joint were graded as none, slight, moderate or severe as previously described by Broberg et al[21].



Figures 4 A and B. Preoperative anteroposterior (A) and lateral (B) radiographs of patient 19 show malalignment of the ulna on the capitellum (i.e. radiocapitellar malalignment).

Clinical results are reported using descriptive statistics. Prosthetic failure rate was evaluated using a failure rate analysis. Failure was defined as symptomatic radiographic loosening or scheduled or completed revision surgery. Implant failures were assumed to follow a Poisson distribution.

RESULTS

Demographic data and overall clinical outcome data are presented in Tables II and III, respectively. There were 18 women and 7 men. Mean age at surgery was 55 years (range, 31-77 years). The fractures involved16 left and 9 right and 4 dominant elbows. The operations in 8 were for acute fractures and 5 of those underwent an additional procedure at the time of radial head arthroplasty. Operations in 17 were for failed earlier treatment or posttraumatic sequelae and 9 of those underwent additional procedures performed about the elbow at the time of surgery. The average time between the initial trauma and cemented bipolar radial head arthroplasty in those operated were delayed was 64 months (range, 2 to 312 months). One patient (4%) refused post-operative follow-up, thus end follow-up results are presented and calculated for the remaining 24 patients. The patient who refused follow-up was still included in the failure analysis to be able to determine the true failure rate.

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Table 2 Demographic data for all patients treated by cemented bipolar radial head arthroplasty

Case	Sex	Age (years)	Injured side	Dexterity	Indication	Timing
1	F	55	Left	Right	Posttraumatic degeneration RH	Delayed
2	F	53	Right	Left	Posttraumatic degeneration RH	Delayed
3	F	64	Left	Right	Posttraumatic degeneration RH + valgus instability with subluxations	Delayed
4	F	50	Right	Left	Failed silicone RH arthroplasty	Delayed
5	F	50	Left	Right	Nonunion RH fracture + valgus instability	Delayed
6	M	62	Right	Right	Acute Mason 3 RH fracture + diaphyseal humerus fracture + ulna fracture (floating elbow)	Acute
7	F	55	Left	Right	Acute Mason 3 RH fracture + ulnohumeral luxation	Acute
8	F	62	Right	Left	Acute Mason 3 RH fracture + coronoid fracture + LCL rupture	Acute
9	M	51	Left	Left	Overstuffed RH prosthesis with beginning ulnohumeral degeneration	Delayed
10	F	60	Left	Right	Acute Mason 3 RH fracture + ulnohumeral luxation	Acute
11	M	51	Left	Right	Longstanding longitudinal radioulnar dissociation with status after RH resection	Delayed
12	F	56	Left	Right	Acute Mason 3 RH fracture + olecranon fracture	Acute
13	F	70	Left	Left	Overstuffed RH prosthesis (cemented, bipolar)	Delayed
14	F	36	Left	Left	Failed silicone RH arthroplasty + insufficiency LCL	Delayed

Time since fracture (months)	Previous surgical procedures about the injured elbow	Concomitant surgical procedures	Additional comment
17	None	None	
7	None	None	Ulnohumeral and radiohumeral degeneration
10	None	None	
168	Silicone RH arthroplasty (Swanson prosthesis) for fracture	Debridement + microfracturing OCD capitellum	
14	ORIF RH fracture (T-plate)	None	
0	None	None	ORIF ulna fracture 2 days later, humerus fracture conservative
0	None	None	
0	None	LCL reconstruction (triceps graft) + fixation coronoid fracture	
30	Metallic RH arthroplasty (uncemented, bipolar) for fracture with ALRUD	Arthrolysis via lateral column procedure	
1	ORIF RH fracture (K-wire)	Removal K-wire	
16	RH resection for fracture	Arthrolysis via lateral column procedure + ulnar shortening osteotomy + arthrotomy and debridement DRUJ	
0	None	Tension band wiring olecranon fracture	Radial nerve neuropraxia, fully recovered over time
7	Metallic RH arthroplasty (uncemented, bipolar) for fracture, ORIF comminuted olecranon fracture	Removal hardware olecranon + arthrolysis via lateral column procedure	Radial nerve neuropraxia, fully recovered over time
132	Silicone RH arthroplasty (Swanson prosthesis) for fracture	Synovectomy, repair LCL	

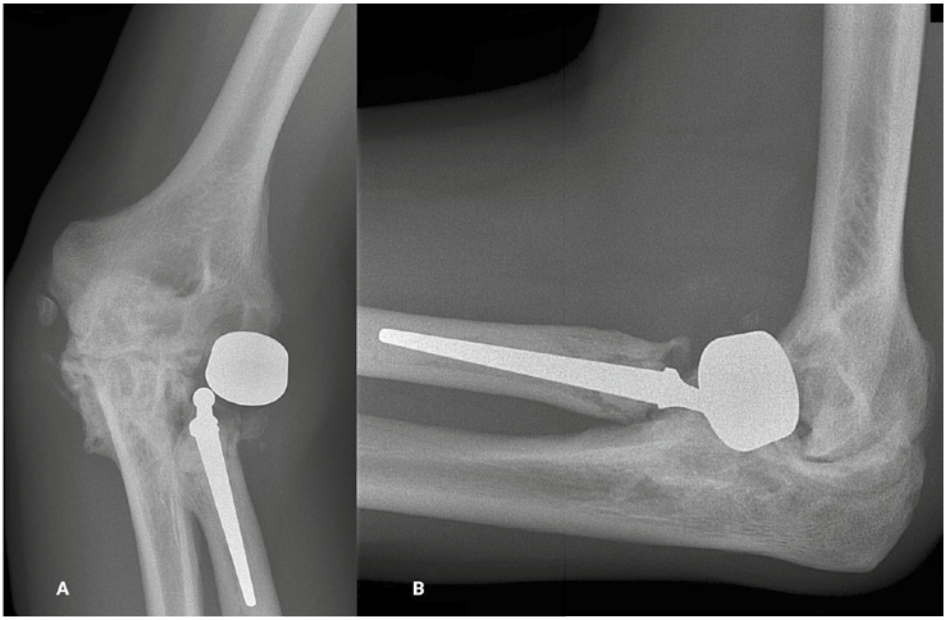
Table 2. Continued

Case	Sex	Age (years)	Injured side	Dexterity	Indication	Timing
15	M	45	Right	Left	Ulnohumeral degeneration secondary to RH resection	Delayed
16	F	55	Left	Right	Acute Mason 3 RH fracture + coronoid chip fracture + LCL rupture	Acute
17	M	50	Right	Left	Nonunion Mason 2 RH fracture	Delayed
18*	F	31	Left	Right	Acute Mason 3 RH fracture	Acute
19	F	63	Right	Left	Longstanding longitudinal radioulnar dissociation with status after RH resection	Delayed
20	F	65	Left	Right	Acute Mason 3 RH fracture	Acute
21	F	65	Right	Left	Longstanding longitudinal radioulnar dissociation with status after RH resection	Delayed
22	F	52	Left	Right	Valgus angulation with lateral elbow pain and traction ulnar nerve neuropraxia, wrist pain and flexion contracture secondary to RH resection	Delayed
23	F	60	Right	Left	Longstanding longitudinal radioulnar dissociation with status after RH resection	Delayed
24	M	77	Left	Right	Acute Mason 3 RH fracture + ulnohumeral luxation + LCL insufficiency	Acute
25	M	40	Left	Left	Failed silicone RH arthroplasty	Delayed

* This patient had refused follow-up after surgery.
ALRUD: Acute longitudinal radioulnar dissociation (*i.e.* Essex-Lopresti type injury).
DRUJ: distal radioulnar joint.
LCL: lateral collateral ligament.
OCD: osteochondral defect.
ORIF: open reduction-internal fixation
RH: radial head.

Time since fracture (months)	Previous surgical procedures about the injured elbow	Concomitant surgical procedures	Additional comment
240	RH resection for fracture	Arthrolysis via lateral column procedure + debridement ulnohumeral joint	
0	None	Reinsertion LCL + debridement and microfracturing OCD capitellum	
24	Arthroscopic debridement.	Arthrolysis via lateral column procedure	
<1	None	None	
19	RH resection for fracture	Debridement and microfracturing OCD capitellum	
0	None	Reinsertion LCL	
180	RH resection for fracture	Debridement and microfracturing OCD capitellum	
12	RH resection for fracture	None	
24	RH resection for fracture	None	
2	None	None.	
180	Silicone RH arthroplasty for fracture	None	Arthrolysis 1 year after RH arthroplasty

At a mean follow-up of 50 months (range, 24-72 months) the prosthesis in one patient (4%; patient 25) had been removed 2 years after implantation for frank luxation due to dissociation of the prosthesis resulting from failure of the snap-on mechanism with poor clinical performance (Figures 5). Two prostheses were subluxated, one (4%; patient 15) due to uncompensated malalignment of the radius onto the capitellum, with excellent clinical outcome and another (4%; patient 17) due to pronounced ulnohumeral erosion, with fair clinical outcome. Altogether, there were three (13%) radiological failures, one of which also was a clinical failure. In the failure analysis, there was then one prosthetic revision (i.e. removal) in 1202 person-months of follow-up. Assuming the number of failures follows the Poisson distribution, there was a 5% probability to find a number of failures of ≤1 with a true failure rate of ≤0.0039 per person-month of follow-up.



Figures 5 A and B. Anteroposterior (A) and lateral (B) radiographs at 24 months of follow-up of patient 25 show dissociation of the prosthesis due to failure of the snap-on articulation between the articulating component and the stem.

Thirteen patients had no pain, 7 had mild pain, 3 had moderate pain and 1 had severe pain. The average flexion was 135° (range, 110°-140°), the average extension deficit was 6° (range, 0°-30°); and the average flexion-extension arc was 129° (range, 80°-140°). The average pronation was 70° (range, 20°-90°), the average supination was 61° (range, 20°-90°) and the average pronation-supination arc was 131° (range, 40°-180°). None had instability. According to the MEPS there were 13 (54%) results, 7 (29%) good results, 3 (13%) fair results and one (4%) poor result. Two patients (8%)

had a radial nerve neuropraxia that fully recovered over time. Two (8%) had ulnar nerve paresthaesia. One (4%) underwent additional open arthrolysis of the elbow for stiffness. There were no post-operative infections.

At final follow-up none of the prostheses showed radiographic signs of loosening. As stated earlier, one (4%; patient 25) had been removed for frank luxation due to dissociation of the prosthesis. In 8 (patients 4, 5, 7, 10, 13, 14, 19 and 22) the bipolar design compensated for malalignment of the radius onto the capitellum. In one (patient 15) it did not and this prosthesis was, as stated before, in a subluxated position. Seven (29%; patients 2, 3, 8, 10, 16, 21 and 23) showed osteolysis of the proximal radius to some degree. One (patient 13) showed lucency around the stem, present and stable since placement of the prosthesis and, therefore, attributed to suboptimal cementing technique, another (patient 8) showed limited lucency at the level of the radial tuberosity and a third (patient 20) showed lucency at the cement-to-bone interface around the stem, with plenty bone formation at the proximal radius. Four (patients 3, 15, 23 and 25) showed erosion of the capitellum. Five (patients 8, 9,15, 24 and 25) developed periarticular ossifications. Eleven (patients 2, 5 thru 7, 12, 15, 16, 19 and 21-23) had developed grade 1, and 2 (patients 17 and 25) had developed severe ulnohumeral degeneration, where on pre-operative radiographs none had ulnohumeral degenerative changes. In one (patient 17) of the 2 patients with severe ulnohumeral erosion, the prosthesis was, as stated earlier, in a subluxated position. Two patients had stable pre-existing mild and 2 had pre-existing moderate ulnohumeral degeneration.

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DISCUSSION

Radial head arthroplasty is indicated when the secondary stabilizing function of the radial head is required and reconstruction of the radial head is not feasible[1]. Generally, this is the case with Mason type 3 radial head fractures and more complex fracture dislocations[1]. Theoretically, the bipolar designs reduce abrasion of the capitellar cartilage and stress at the implant-to-cement and cement-to-bone interfaces due to the free rotation between the stem and articular component. Radiocapitellar contact pressure may also be decreased compared with monopolar designs due to better alignment of the articular component onto the capitellum. In addition, they are thought to be able to accommodate some degree of malalignment of the radius onto the capitellum. All these advantages still need scientific backing and whether bipolar radial head prostheses are associated with superior implant survival and clinical performance than monopolar prostheses also remains to be determined. The current study presents favorable mid-term outcome of a series on 25 patients treated by cemented bipolar radial head arthroplasty for acute fracture of the radial head, for earlier treatment that had failed or for posttraumatic sequelae. There was one

Table 3 Clinical outcome data of all patients treated by cemented bipolar radial head arthroplasty

Case	F/U (months)	Pain	Flexion (degrees)	Extension deficit (degrees)	Flexion-extension arc (degrees)	Pronation (degrees)
1	63	None	140	0	140	80
2	62	None	130	0	130	80
3	72	Mild	130	10	120	70
4	59	Mild	140	10	130	80
5	65	None	120	0	120	20
6	58	None	140	5	135	30
7	66	None	140	0	140	80
8	63	None	140	0	140	70
9	60	None	140	15	125	70
10	60	None	130	5	125	70
11	56	Mild	140	0	140	70
12	61	None	140	10	130	70
13	61	Mild	140	0	140	70
14	42	Moderate	140	5	135	60
15	64	None	130	0	130	70
16	60	Mild	140	3	137	90
17	24	Moderate	130	10	120	70
18*	n/a	n/a	n/a	n/a	n/a	n/a
19	36	None	130	0	130	80
20	37	None	140	0	140	70
21	24	Moderate	140	10	130	70
22	30	Mild	135	0	135	80
23	25	Mild	140	20	120	90
24	24	None	135	5	130	90
25#	24	Severe	110	30	80	60

[1] Valgus instability was graded as none, mild (only tender), moderate or severe.
[2] The Mayo Elbow Performance Score is classified as excellent (>90 points), good (75-89 points), fair (60-74 points) or poor (<60 points).
DRUJ: distal radioulnar joint.
* This patient had refused follow-up after surgery.
# Data at last follow-up before removal (i.e. revision) 2 years after implantation of the prosthesis.

Supination (degrees)	Pronation-supination arc (degrees)	Instability [1]	Mayo Elbow Performance Score [2]	Additional comment
80	160	None	100 / Excellent	
80	160	Valgus, mild	100 / Excellent	
70	140	None	85 / Good	
60	140	Valgus, mild	85 / Good	
20	40	None	100 / Excellent	
20	50	Valgus, mild	100 / Excellent	
80	160	None	100 / Excellent	
45	115	None	100 / Excellent	
30	100	None	100 / Excellent	
70	140	None	100 / Excellent	
40	110	None	85 / Good	
50	120	None	100 / Excellent	
70	140	Valgus, mild	85 / Good	
60	120	None	70 / Fair	
50	120	None	95 / Excellent	
90	180	None	85 / Good	
60	130	None	70/Fair	
n/a	n/a	n/a	n/a	
80	160	None	100 / Excellent	Ulnar nerve dysaesthesia, DRUJ instability
50	120	Valgus, mild	100 / Excellent	
80	150	None	70 / Fair	
60	140	None	85 / Good	Ulnar nerve dysaesthesia
90	180	None	85 / Good	
70	160	None	100 / Excellent	
60	120	None	50 / Poor	Removed

3

(4%) revision in 1276 person-months of follow-up for dissociation of the prosthesis due to failure of the snap-on mechanism. The bipolar design appeared to be able to accommodate radiocapitellar malalignment in 8 patients. Owing to the greater tilt (17.5° vs. 10°) of the head on the stem at the snap-on junction, it may be better able to do so then its press-fit equivalent (Figure 3, A). None of the stems had come loose. In only one (4%) there was lucency around the stem of the prosthesis, but this was attributed to a suboptimal cementing technique.

Several limitations are recognized. The study is retrospective in nature. There is variation in the presence and nature of associated injuries. Although associated injury will have an effect, possibly even profound, on outcome, this effect has not been clarified in the literature to date. Also, owing to the variation in nature, severity and treatment of the associated injuries and because some associated injuries go unrecognized and therefore remain untreated, performing any meaningful analysis stratified for associated injury is extremely difficult, if not impossible. Duration in follow-up varied between patients. Owing to the referral nature of our practice, most of the cases involved delayed reconstructions. This does, however, reflect the population in which a bipolar prosthesis is postulated to be beneficial. Some radiographic parameters that were scored (i.e. osteopenia of the capitellum, post-operative degeneration) are difficult to evaluate and are subjective. The information does, however, reflect concerns that are relevant to outcomes of radial head arthroplasty in general.

At the end of follow-up there had been one (4%) revision for dissociation of the prosthesis and there were 2 (8%) additional radiological failures (subluxations). Revision rates in studies on cemented bipolar radial head arthroplasty have been low so far, but all studies report short- term to mid-term follow-up with no long-term results available to date (Table 1). Also, radial head prostheses are generally not tracked in national joint registries. However, as is very well illustrated in this case series, the revision rate does not necessarily reflect the true treatment failures. The incidence of prosthetic subluxations in the current study is similar to the literature. Berschback et al. report 1 (7%) subluxation in 14 patients, Burkhart et al. report 2 (12%) luxations in 17 patients and Brinkman et al. reported 2 (18%) revisions for subluxations in 11 patients[8-10].

Failure of the snap-on mechanism, as was encountered in patient 25, has been recognized and reported by O'Driscoll et al[22]. The authors attributed this failure to polyethylene wear, allowing slippage of the articular component on and off the stem. On the one hand, whether reduced stability or frankly uncorrectable radiocapitellar malalignment possibly contributes to levering the articular component of the stem remains open to debate. On the other hand, the bipolar design seems to be able to accommodate well for malalignment at the radiocapitellar joint in a significant number of patients (8 patients; 33%). Naturally, how a monopolar prosthesis would have performed in these specific cases is not known.

There were two radial nerve neuropraxias, both of which fully recovered over time. To restore adequate congruency with the lesser sigmoid notch, the osteotomy for the bipolar prosthesis is slightly more distal than for the monopolar prosthesis. This theoretically increases the risk of injury of the deep branch of the radial nerve (i.e. posterior interosseous nerve).

Popovic et al. observed progressive radiolucent lines around the stem of the prosthesis in 27 out of 51 patients (53%)[15]. These remained stable over time in 11 and were attributed to a suboptimal cementing technique. In 16, these were progressive over time and were attributed to mechanical factors, possibly in conjunction with progressive osteolysis. However, the authors did not report any revision. Burkhart et al. reported a radiolucent line around the stem in one of 17 patients (6%), Rotini et al. in one of 19 patients (5%), Dotzis et al. in one of 12 patients (8%), Berschback et al. stated that they were often observed and Celli et al., Brinkman et al., Smets et al. and Judet et al. did not comment on the occurrence of radiolucent lines around the stem[8-13, 16, 17]. In the current study, we observed a radiolucent line around the stem in one (4%) patient. We do not, at this time, have an explanation between the large discrepancy in incidence of radiolucent lines around the stem between the study by Popovic et al. and the other more recent studies[15].

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Popovic et al. reported a moderately high incidence of 31% bone resorption direct under the prosthesis (zones 1 and 7 according to Chanlalit et al. after bipolar radial head arthroplasty[15, 23]. In the current series, a similar incidence (29%) was observed. Rotini et al. also reported a high incidence, although the exact numbers cannot be calculated due to the format in which the data are presented[16]. Others reported a lower rate, narratively discussed osteolysis or did not comment on osteolysis[8-13, 17].
Heterotopic ossifications have been observed following bipolar radial head arthroplasty with variable, but occasionally high incidence (range 0%-76%), but are mostly asymptomatic[8-12, 15, 16].

CONCLUSIONS

The overall mid-term outcome of this series of 25 cemented bipolar radial head arthroplasties can be considered favorable. One revision was performed for dissociation of the prosthesis due to failure of the snap-on mechanism. The bipolar design has shown that it is able to compensate for radiocapitellar malalignment. Radiographic observations are similar to earlier reports on cemented bipolar radial head arthroplasty. We suggest considering a cemented bipolar radial head prosthesis for unreconstructable fractures of the radial head or posttraumatic sequelae after such fractures in case of concerns about radiocapitellar alignment.

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Chapter

4

Press-fit bipolar radial head arthroplasty, mid-term results

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ABSTRACT

Background

Theoretical advantages of bipolar compared with monopolar radial head arthroplasty include better accommodation of radiocapitellar malalignment, reduction of capitellar abrasion and reduction of stress at the bone-implant interfaces. Our purpose was to report the mid-term results of press-fit bipolar radial head arthroplasty.

Methods

Thirty patients were treated by press-fit bipolar radial head arthroplasty for acute fracture of the radial head, failed earlier treatment or posttraumatic sequelae. Three patients were lost to follow-up. Results are presented for the remaining 27 patients.

Results

At mean follow-up of 48 months (range, 28–73 months), there had been 3 (11%) revisions. Two involved conversion to prosthetic radiocapitellar hemiarthroplasty for symptomatic capitellar abrasion, a third involved exchange of the articular component (i.e. head) for instability. In all, the stems appeared well fixed. A prosthesis in a subluxed position accounted for the one (4%) additional radiological failure. The average flexion-extension arc was 136° (range, 120°-145°) and the average pronation-supination arc was 138° (range, 70°-180°). According to the Mayo Elbow Performance Score, the combined excellent and good results accounted for 70%.

Conclusions

The overall mid-term outcome of this series of 30 press-fit bipolar radial head arthroplasties can be considered favorable. Although the revision rate was 11%, the stems were well fixed in all. There was one (4%) additional radiological failure. We suggest considering a press-fit bipolar radial head prosthesis for acute comminuted radial head fractures with limited bone loss of the proximal radius.

INTRODUCTION

The radial head is an important secondary stabilizer of the elbow and forearm and its integrity becomes crucial to elbow stability especially in case of disruption of the medial collateral ligament (MCL), lateral ulnar collateral ligament complex (LCLC) or interosseous membrane and large fractures of the coronoid process[1, 2]. Approximately 36% of all radial head fractures are Mason types 2 to 4 and are frequently associated with injury of the stabilizing structures[3, 4]. Consequently, prosthetic replacement of the radial head is to be considered for comminuted fractures of the radial head that are not amenable to adequate reconstruction[5].

In general, radial head arthroplasty has been associated with about 85% favorable results when it is performed in the acute situation, but with only about 50% when it is performed in delayed fashion[6]. Although associated injuries about the elbow may have a significant effect on prosthetic function and survival, hardly any clinical study is of such methodology that it can contribute to quantifying this.

Radial head prostheses may be categorized according to material (silicone, polyethylene, pyrocarbon, metal), modularity (monoblock vs. modular), polarity (unipolar or monopolar vs. bipolar) or method of fixation (cemented, uncemented press-fit, intentional loose-fit or fixation with an expandable stem).

The rationale of the bipolar prosthesis is the freedom of movement of the articulating component on the intramedullary component. This may theoretically reduce abrasion of the capitellar cartilage and reduce stress at the implant-bone and bone-cement interfaces during forearm rotations. In addition, radiocapitellar contact may be facilitated and consequently contact pressures be reduced during flexion and extension of the elbow[7]. Also, malalignment of the radius onto the capitellum, which may be the case in long-standing injuries with soft-tissue contracture, may be compensated for to some degree.

Initially, the bipolar radial head prosthesis was cemented[8]. Only more recently has a short-stemmed, press-fit design become available. The rationale for the press-fit design is to obtain biological fixation by bone ongrowth onto the stem for optimal long-term fixation. Loosening of cemented implants at the cement-bone interface had been observed in up to 10% of cases with cemented prostheses[7]. In addition, because of the shorter stem, the press-fit prosthesis is easier to implant and may be easier to revise[9]. The literature on bipolar radial head arthroplasty is limited and exists of several mid-term follow-up cases series of cemented arthroplasties[7, 10-14]. To our knowledge, no results have been published on press-fit bipolar radial head arthroplasty.

The purpose of this study was to report our experience with 30 patients who were treated by uncemented (press-fit) bipolar metallic radial head replacement for acute fracture of the radial head, failed earlier treatment or posttraumatic sequelae. We hypothesized that the results would not be different from the results of other types of radial head arthroplasty reported in the literature.

METHODS

This is a retrospective case series of 30 press-fit bipolar radial head arthroplasties that were performed in our institution between September 2007 and June 2011. All were treated for acute fracture of the radial head, failed earlier treatment or posttraumatic sequelae. The inclusion period was set to ensure minimum follow-up of 2 years for each individual case. The senior author (D.E.) performed all surgeries. Initially, we treated these cases with routinely with a cemented bipolar prosthesis. When press-fit designs became available, we started placing a press-fit prosthesis if bone quality was good and the trial components showed a good press-fit and a cemented prosthesis if there was any doubt about bone quality or fixation of the trial components. This is still the algorithm we use in our clinic today.

The press-fit RHS bipolar radial head prosthesis (Tornier, Montbonnot-Saint-Martin, France; Figure 3) is a modular system and consists of 2 parts. The stem is made of cobalt-chrome and is titanium plasma sprayed. The head is made of high-density polyethylene encased in cobalt-chrome. The head is available in 4 sizes and articulates with the stem by means of a low-friction, snap-on ball-and-socket joint with 10° bipolarity. The stem is available in 4 length sizes (21, 22, 23 and 24 mm) and each size available in 5 diameters (6-10mm, with 1-mm increments). Neck length options are 13 mm and 16 mm.

During surgery, the patient was supine with the arm rested on an arm table. Prophylactic antibiotic coverage consisted of 2000 mg cefazolin intravenously. A tourniquet was used. An extensor split approach (Kaplan interval) was used. The annular ligament was transected and tagged with a stay suture; it was repaired at the end of the procedure. The level of the radial neck osteotomy was visually determined and guided by the lesser sigmoid notch of the ulna[15]. The medullary canal was prepared, a trial prosthesis was inserted to assess the correct height of the prosthesis and the elbow was tested for stability and range of motion. The trial components were then removed and the definite implant was pressed-fit in place. In 22 patients it was necessary to perform additional procedures (Table 1). Post-operatively, a pressure bandage was applied for 48 hours and mobilization was started under guidance of a physiotherapist on the first post-operative day. Continuous passive motion was not used. When additional procedures had been performed, this post-operative regimen was adjusted accordingly. Prophylaxis for heterotopic ossifications was not routinely used.

Table 1. Demographic data for all patients treated by press-fit radial head arthroplasty

Case	Sex	Age (years)	Injured side	Dexterity	Indication
1	F	42	L	R	Mason type-3 RH fracture with persistent dislocation.
2	M	53	L	L	Terrible triad injury with forearm instability.
3	F	42	R	R	Failed ORIF RH.
4	F	55	L	R	Failed ORIF RH and lateral humeral condyle.
5	F	48	L	L	Failed ORIF and RH excision.
6	M	61	R	R	Failed RH excision.
7	F	59	L	L	Failed silicone RH arthroplasty.
8	M	48	R	R	Terrible triad injury with OCD of the capitellum.
9	F	39	R	R	Malunion RH with valgus instability.
10	M	54	R	R	Failed ORIF RH.
11	M	51	R	R	Pain and limited ROM after Mason type-2 RH fracture.
12	F	52	R	R	Pain and limited ROM after Mason type-2 RH fracture.
13	F	60	R	R	Failed RH excision.
14	F	24	L	R	Pain and valgus instability after elbow dislocation.
15	F	43	R	L	Pain after elbow dislocation with Mason type-3 RH fracture.
16	F	53	L	L	Mason type-3 RH fracture with valgus instability and positive pivot shift.
17	F	45	L	L	Failed silicone RH arthroplasty.
18	F	57	L	R	Pain and valgus instability after Mason type-2 RH fracture.
19	F	46	L	R	Failed silicone RH arthroplasty.
20	F	49	R	R	Failed RH excision.
21	M	60	L	R	Terrible triad injury with forearm instability.
22	F	45	L	R	Pain and limited ROM after Mason type-2 RH fracture.

Timing	Time since fracture (months)	Previous surgical procedures about the injured elbow	Concomitant surgical procedures
Acute	0	None.	LCL reconstruction.
Delayed	5	External fixation.	LCL reconstruction.
Delayed	27	ORIF RH, debridement and later removal of fixation material.	Debridement capitellum.
Delayed	39	ORIF RH and lateral humeral condyle.	Removal fixation material RH and lateral humeral condyle.
Delayed	29	ORIF ulna, RH excision and later removal fixation material.	None.
Delayed	15	RH excision.	None.
Delayed	156	Silicone RH arthroplasty and later removal of the prosthesis.	Debridement capitellum and arthrolysis.
Acute	0	None.	LCL reconstruction and refixation coronoid fracture.
Delayed	6	Ulnar nerve release.	UCL reconstruction, debridement capitellum and ulnar nerve release.
Delayed	9	ORIF RH.	None.
Delayed	7	None.	Arthrolysis.
Acute	0	None.	None.
Delayed	144	RH excision.	Debridement ulnohumeral joint.
Delayed	10	None.	Arthrolysis.
Acute	1	None.	LCL reconstruction.
Acute	0	None.	LCL reconstruction and debridement capitellum.
Delayed	46	Silicone RH arthroplasty.	None.
Delayed	19	None.	Debridement capitellum.
Delayed	216	Silicone RH arthroplasty.	LCL reconstruction.
Delayed	8	RH excision.	None.
Delayed	9	None.	LCL reconstruction and arthrolysis.
Delayed	3	None.	None.

Table 1. Continued

Case	Sex	Age (years)	Injured side	Dexterity	Indication
23	F	56	R	R	Failed ORIF RH and proximal ulna.
24	M	24	R	R	Terrible triad injury.
25	F	36	R	R	Failed external fixation and debridement after terrible triad injury.
26	M	63	L	R	Failed ORIF RH.
27	M	29	L	R	Failed ORIF RH.
28	F	39	L	R	Failed ORIF RH.
29	F	53	L	R	Failed ORIF and external fixation after open elbow fracture dislocation.
30	F	57	R	R	Pain and valgus instability after Mason type-2 RH fracture.

RH: radial head
ROM: range of motion
LCL: lateral collateral ligament complex
UCL: ulnar collateral ligament complex
DRUJ: distal radioulnar joint
PRUJ: proximal radioulnar joint
OCD: osteochondraal defect
ORIF: open reduction-internal fixation

Timing	Time since fracture (months)	Previous surgical procedures about the injured elbow	Concomitant surgical procedures
Delayed	10	ORIF RH and ulna.	None.
Acute	0	None.	LCL reconstruction.
Delayed	41	External fixation and joint debridement, later LCL reconstruction.	LCL reconstruction.
Delayed	5	ORIF RH.	LCL reconstruction.
Delayed	61	ORIF RH.	LCL reconstruction.
Delayed	5	ORIF RH.	Arthrolysis.
Delayed	16	ORIF ulna and external fixation.	LCL reconstruction.
Delayed	10	None.	Arthrolysis.

Medical records were reviewed and each patient was seen in the office for a clinical assessment and radiological evaluation. Post-operative range of motion was determined using a goniometer and elbow function was evaluated with use of the Mayo Elbow Performance Score (MEPS)[16, 17]. The MEPS is based on 4 items (pain, range of motion, stability, and elbow function) and has a maximum score of 100 points. A score from 90 and 100 is considered an excellent result; from 75 to 89 a good result; from 60 to 74 a fair result; and less than 60 a poor result. Radiographs of the elbow were evaluated for signs of loosening, radiocapitellar alignment, osteolysis of the radial neck, lucency, periarticular ossifications and ulnohumeral degeneration. Osteolysis was evaluated in terms of regions about the radial neck as postulated by Grewal et al. (Figure 6)[18]. Osteopenia and abrasion of the capitellum were noted to be present or absent. Degenerative changes of the ulnohumeral joint were graded as none, slight, moderate or severe as previously described by Broberg et al[16]. The position of the head of the prosthesis on the capitellum was assessed and possible failure of the snap-on mechanism was evaluated as described by O'Driscoll et al[19].

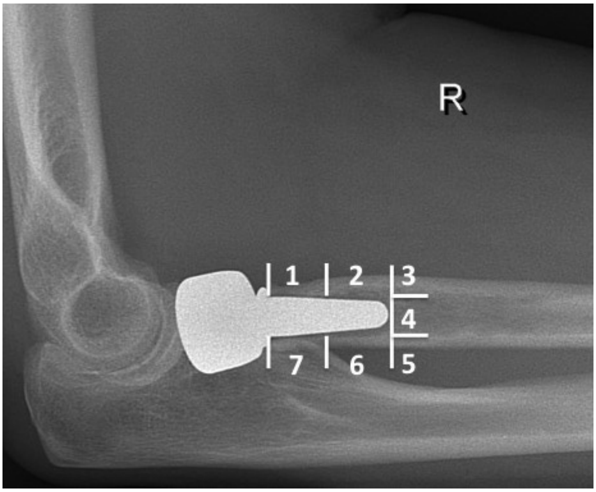

Figure 6. Zones of radiolucency as described by Grewal et al.[18]

Demographic data are presented in Table I. There were 21 women and 9 men. Mean age at surgery was 48 years (range, 24–63 years). There were 16 right and 14 left and 18 dominant arms involved. Six were operated on for acute fracture and 5 of those underwent an additional procedure about the elbow at the time of surgery. Twenty-four were operated on for failed earlier treatment or posttraumatic sequelae and 17 of those underwent an additional procedure at the time of surgery. Eighteen of those 24 had undergone previous surgery about the elbow. The average time between initial trauma and press-fit radial head replacement for the delayed cases was 37 months (range, 3 months to 18 years). Three patients were lost to follow-up. End follow-up results are presented and calculated for the remaining 27 patients.

Although 3 patients did not complete the follow-up of at least 24 months, their follow-up times were still included in the person-months at risk a denominator to obtain a proper estimate of the failure rate.

Clinical results are reported using descriptive statistics (SPSS 21.0; IBM Corp., Armonk, NY, USA). In addition, prosthetic failure rate is evaluated using a failure rate analysis. Failure was defined as symptomatic radiographic loosening of the prosthesis or scheduled or completed revision surgery. Implant failures were assumed to follow a Poisson distribution.

RESULTS

At mean follow-up of 48 months (range, 28–73 months), there had been 3 (11%) revisions (Table II). There was one conversion to a cemented bipolar prosthesis for persistent instability (case 4). Later, a capitellar resurfacing arthroplasty and reconstruction of the lateral collateral ligament complex would be performed in the same patient for persistent instability. There was a second conversion to a cemented bipolar prosthesis, this time with concomitant capitellar resurfacing arthroplasty, for symptomatic abrasion of the capitellum (i.e. pain on the capitellum at palpation with erosion of the capitellum at radiography; case 14). In both, the stems appeared well fixed during the operation, but in the second case it had to be revised because of incompatibility with the capitellar resurfacing arthroplasty. In a third, the articulating component (i.e. head) of the prosthesis was exchanged for a larger size for instability (case 3). The stem was well fixed and left alone. One additional prosthesis was in a subluxated position in relation to the capitellum and was considered a radiological failure (case 29; Figure 7). In the failure analysis, there were then 3 prosthetic revisions in 1207 person-months. Assuming the number of failures follows the Poisson distribution, there was a 5% probability to find a number of failures of ≤3 with a true failure rate of ≤0.0064 per person-month of follow-up.

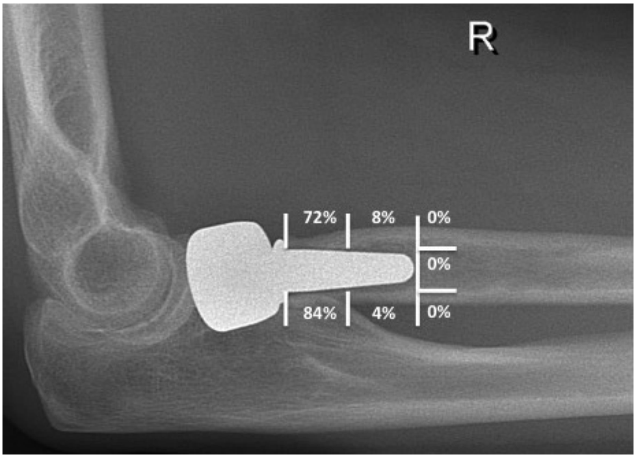

Figure 7. Incidence of radiolucency per zone.

Table 2. Clinical outcome data for all patients treated by press-fit radial head arthroplasty.

Case	F/U (months)	Pain	Flexion (degrees)	Extension deficit (degrees)	Flexion-extension arc (degrees)	Pronation (degrees)
1	47	None	120	40	80	70
2	34	None	130	0	130	70
3	44	None	145	0	145	80
4	74	Moderate	130	0	130	80
5	65	Moderate	140	0	130	80
6	40	Mild	130	5	125	70
7	41	Mild	140	0	140	70
8*	1	-	-	-	-	-
9	73	Moderate	140	0	130	70
10	35	None	135	0	135	60
11	61	None	130	0	120	70
12	49	None	140	0	140	70
13	63	None	140	5	135	70
14	68	None	140	0	140	70
15	68	None	140	0	140	70
16	37	None	140	0	140	70
17*	20	None	130	5	125	70
18	28	None	130	20	110	60
19	40	Moderate	140	10	130	60
20*	15	None	140	0	140	70
21	47	None	140	10	130	60
22	60	None	135	0	135	90
23	37	None	130	0	100	70
24	36	Mild	140	0	140	50
25	36	Moderate	140	0	130	70
26	49	None	140	0	140	70
27	31	None	145	0	145	90
28	45	None	130	20	110	70
29	51	Moderate	120	30	90	80
30	33	Moderate	130	45	85	90

* Lost to follow-up.
[1] Instability was graded as stable, mild instability or severe instability
[2] The Mayo Elbow Performance Score is classified as excellent (>90 points), good (75-89 points), fair (60-74 points) or poor (<60 points).

Supination (degrees)	Pronation-supination arc (degrees)	Instability [1]	Mayo Elbow Performance Score [2]	Complications and treatment.
70	140	Mild	95 / Excellent	None.
80	150	Stable	100 / Excellent	None.
80	160	Stable	100 / Excellent	Instability -> revision head of RHP (good fixation of stem RHP)
70	150	Mild	60 / Fair	Instability -> revision to cemented RHP with capitellum resurfacing and LCL reconstruction.
50	130	Stable	65 / Fair	Pain -> removable splint.
90	160	Stable	70 / Fair	None.
70	140	Stable	80 / Good	None.
-	-	-	-	
70	140	Mild	65 / Fair	Degeneration capitellum and medial epicondylitis.
80	140	Stable	100 / Excellent	Ulnar nerve dysfunction -> ulnar nerve release.
70	140	Stable	100 / Excellent	None.
70	140	Stable	100 / Excellent	None.
70	140	Mild	95 / Excellent	None.
80	150	Stable	100 / Excellent	Proximal osteolysis and degeneration capitellum -> revision to cemented RHP with capitellum resurfacing.
70	140	Stable	100 / Excellent	None.
70	140	Stable	100 / Excellent	None.
70	140	Stable	100 / Excellent	None.
60	120	Stable	100 / Excellent	None.
60	120	Mild	65 / Fair	Ulnar nerve dysfunction -> ulnar nerve release.
50	120	Mild	95 / Excellent	None.
70	130	Mild	95 / Excellent	Forearm instability with degeneration DRUJ -> stabilization with Sauvé-Kapandji procedure.
90	180	Stable	100 / Excellent	None.
0	70	Stable	100 / Excellent	Stiffness -> arthrolysis.
70	120	Stable	85 / Good	None.
30	100	Mild	55 / Poor	Preexistent malalignment radius with degeneration ulnohumeral joint -> LCL repair.
70	140	Stable	100 / Excellent	None.
90	180	Stable	100 / Excellent	None.
70	140	Stable	100 / Excellent	None.
45	125	Mild	60 / Fair	Luxation RHP with degeneration ulnohumeral joint -> patient unfit for reoperation.
60	150	Stable	65 / Fair	Lateral epicondylitis

DRUJ: distal radioulnar joint.
LCL: lateral collateral ligament complex.
RHP: radial head prosthesis

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Average flexion was 136° (range, 120°–145°); average extension-deficit was 9° (range, 0°-45°); and average flexion-extension arc was 126° (range, 85°-145°). Average pronation was 71° degree (range, 50°–90°); average supination was 67° (range, 0°-90°); and average pronation-supination arc was 138° degrees (range, 70°-180°). Seventeen patients had no pain, 3 had mild pain, 7 had moderate pain. None had gross instability. According to the MEPS, there were 17 (63%) excellent results, 2 (7%) good results, 7 (26%) fair results and one (4%) poor result.

At end follow-up, none of the 25 press-fit prostheses that were still in situ showed radiographic signs of loosening. Radiographic osteolysis around the radial neck was observed in 23 (92%) patients (Figure 7). This osteolysis involved both zones 1 and 7 in seventeen patients, only zone 7 in 4 patients, only zone 1 in one patient an only zone 6 in one patient. In 2 patients in which both zones 1 and 7 were involved, zone 2 was also involved. One prosthesis with osteolysis in zones 1 and 7 had been revised (exchange of the articular component, i.e. head; case 3) and appeared well fixed during surgery. Nine patients (cases 6, 18, 21, 23, 25-28 and 30) had developed grade 1 and 4 patients (cases 13, 19, 24 and 29) had developed grade 2 ulnohumeral degeneration. Twelve showed occurrence or progression of osteopenia of the capitellum. Seven showed erosion of the capitellum. Heterotopic ossifications were seen in 5 (20%) patients and were asymptomatic in all. There was pre-existing malalignment of the radius onto the capitellum in one patient (case 25). In none, the snap-on mechanism had failed.

In addition to the 3 revisions, there were 9 additional patients with a complication that required surgical intervention in 5. All complications were in patients who were treated in a delayed fashion. Two had signs of ulnar nerve dysfunction and required ulnar nerve release (cases 10 and 19). One had symptomatic degeneration of the distal radioulnar joint (DRUJ), which was treated by a Sauvé-Kapandji procedure (case 21). One had posttraumatic elbow stiffness and was treated by open arthrolysis (case 23). The one patient with pre-existing malalignment of the radius onto the capitellum underwent additional reconstruction of the lateral collateral ligament complex (LCLC), but the outcome remained fair according to the MEPS (case 25). One patient had subluxation of the prosthesis and degenerative changes of the ulnohumeral joint resulting in persisting elbow pain (case 29, Figure 8). Conversion to total elbow arthroplasty was contemplated, but the patient was unfit for operation. There were no infections. One had persistent pain due to lateral epicondylitis (case 30), one due to medial epicondylitis (case 9) and one for unexplained reasons (case 5).

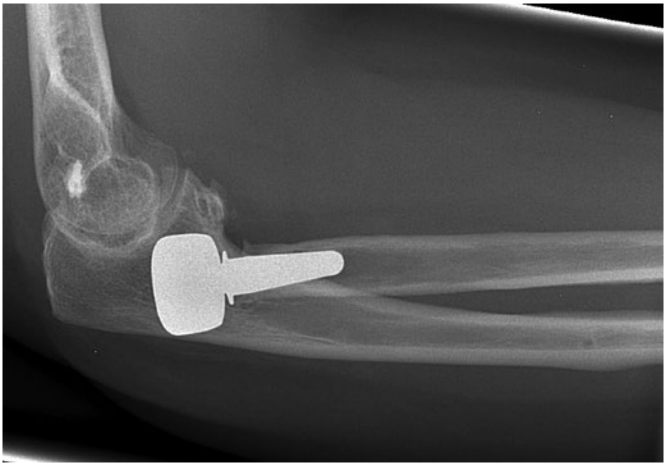

Figure 8. Lateral radiograph of case 29 shows the subluxed position of the press-fit bipolar radial head prosthesis onto the capitellum. There is distinctive proximal osteolysis around the implant.

DISCUSSION

The bipolar radial head prosthesis may theoretically have advantages over the monopolar prosthesis in terms of reduced abrasion of the capitellar cartilage and reduced stress at the implant-bone interface during forearm rotations. In addition, radiocapitellar contact may be facilitated and consequently contact pressures may be reduced during flexion and extension of the elbow[7]. In addition to the cemented bipolar prosthesis, a press-fit design was more recently introduced to obtain biological ongrowth onto the stem for optimal long-term fixation. To date, there are no clinical outcome data on press-fit bipolar radial head arthroplasty in the literature. The current study reports the mid-term clinical and radiographical outcome of a series of 30 patients treated by press-fit bipolar metallic radial head arthroplasty for acute fracture of the radial head, failed earlier treatment or posttraumatic sequelae. Overall, the outcomes can be considered favorable. However, there are concerns of a relatively high revision rate of 11% (one conversion to a cemented prosthesis, one exchange of only the articulating head for instability and one conversion to a cemented bipolar prosthesis that was compatible with the simultaneously performed capitellar resurfacing arthroplasty for abrasion of the capitellar cartilage). It is noted that none of the stems had come loose, suggesting the press-fit fixation with subsequent bone ongrowth results in adequate fixation.

The current study has several limitations. It is retrospective in nature. Although associated injuries almost certainly affect outcome, it has to be recognized that variation in presence, nature, severity and treatment of those associated injuries and the fact that some associated injuries go unrecognized and therefore remain untreated make it difficult if not impossible to perform a meaningful analysis stratified for associated injury. There is variation in duration of follow-up between patients. Because of the referral nature of our practice, the majority of cases involved delayed reconstructions. This does, however, reflect the population in which a bipolar prosthesis is postulated to be beneficial.

Flinkkilä et al. have recently reported the survival of press-fit *monopolar* radial head arthroplasty[20]. They observed loosening of the prosthesis in 12 of 37 (32%) cases at a mean follow-up of 11 months. This was significantly worse than the reported long-term survival of loose-fit and cemented monopolar implants[7, 10, 21, 22]. The authors hypothesized that poor bone ongrowth onto the stem of the press-fit prosthesis due to micromotion of the prosthesis within the medullary canal was one of the factors explaining this inferior implant survival[20, 23]. Possibly, the bipolar design results in reduced stress and micromotion at the implant-bone interface. Van Riet et al. reviewed radial head prosthesis revisions and observed a lower incidence of loosening of fixed-stem bipolar prostheses compared with monopolar prostheses[24]. In the current study, none of the prostheses had come loose.

Popovic et al. extensively reported radiographic changes around bipolar radial head prostheses[7]. They observed 3 different kinds of radiolucency around the prosthetic stem: complete radiolucent lines, balloon-shaped radiolucent zones and proximal bone resorption at the radial neck. Migration of the prosthesis was only observed in 5 out of 51 (10%) cases with obvious balloon-shaped osteolysis and not in the other forms of radiolucency. The authors explained the radiographic changes as the result of stress-shielding or particle disease[7]. Subsequent studies on different types of radial head prostheses found that the progression of radiolucencies tends to stabilize 2 years after implantation[5, 22, 25, 26]. As proximal osteolysis occurs early and has been described for different prosthetic designs (monoblock, modular, bipolar) and diverse fixation techniques (loose fit, press-fit, expandable stem, cemented) it is probably the result of stress shielding rather than an effect of particle wear. In the current study, osteolysis of the proximal radius to some degree was observed in 92%. It was not associated with prosthetic loosening.

The reported incidence of additional elbow or forearm surgery after radial head arthroplasty varies from 0% to 29%[10, 22, 25, 27-29]. In the current series, such secondary surgery was performed in 30% and all patients that required a secondary surgical procedure had the prosthesis implanted in a delayed fashion. The primary indication for secondary surgery was instability; all 3 revisions were related to instability resulting from poor condition of the soft tissues. Moon et al. and Chanlalit et al. found superior stability of monopolar radial head arthroplasty compared with bipolar radial head arthroplasty in biomechanical studies[30-32]. They suggested that monopolar implants mimic the native radial head during compression loading, in contrast to bipolar implants, which may show tilting of the radial head during compression, leading to subluxation of the implant. However, comparative clinical studies by Rotini et al. and Berschback et al. failed to show a difference in stability between monopolar and bipolar implants[25, 28]. Moreover, all elbows were found to be stable at follow-up. Thus, the biomechanical theory has nit been confirmed in clinical studies. We were unable to draw firm conclusions on stability in the current study. Second, in 2 patients, a capitellar resurfacing arthroplasty had been performed for symptomatic abrasion of the capitellum. We consider erosion of the capitellum at radiograph and, in case of instability, a poor quality of the capitellum (i.e. a capitellum that is unable to host the radial head in a stable way) indications for revision to a radiocapitellar implant. Our recommendation is therefore to be prepared to perform a capitellar resurfacing arthroplasty during the index operation if capitellar bone or cartilage quality is poor.

CONCLUSIONS

The overall mid-term outcome of this series of 30 radial head arthroplasties can be considered favorable. The revision rate was 11%, which compares favorably with the only reported series of monopolar press-fit implants in the literature. Despite the revisions, none of the stems had come loose, suggesting that the press-fit stem results in sufficient bone ongrowth and adequate fixation. We suggest considering a press-fit bipolar radial head prosthesis for acute comminuted radial head fractures with limited bone loss of the proximal radius.

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Chapter

5

Radial head arthroplasty, a systematic review

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ABSTRACT

Introduction:

Despite the expanding body of literature on radial head arthroplasty, the increasing understanding of elbow anatomy, biomechanics and kinetics, and the evolution of surgical techniques and prosthesis designs, there is currently no evidence to support one type of radial head prosthesis over another. The purposes of the present report were to review the literature and to explore the association between prosthesis design variables and the timing of surgery and the outcome of modern radial head arthroplasty.

Methods:

The literature search was limited to studies involving skeletally mature patients. Major databases were searched from January 1940 to May 2015 to identify studies relating to functional and subjective outcomes and radiographic results after radial head arthroplasty.

Results:

Thirty articles involving 727 patients were included. Seventy percent of the implants were made of cobalt-chromium, 15% were made of pyrocarbon, 9% were made of titanium and 6% were made of Vitallium. Seventy percent were monopolar and 30% were bipolar. Twenty-one percent were cemented in place, 32% were press-fit, 32% were intentionally loose-fit and 15% were fixed with an expendable stem. The weighted average duration of follow-up was 45 months. The incidence of revision ranged from 0% to 29% among studies. Eight percent of prostheses had been revised during 2,714 person-years of follow-up across all 727 patients, yielding a crude overall revision rate of 2.06 per 100 persons-years of follow-up. The revision rate was not significantly affected by prosthesis polarity, material or technique of fixation, nor was it significantly affected by the delay of treatment. There was also no significant effect of prosthesis polarity, material or technique of fixation on post-operative range of motion. The Mayo Elbow Performance Score was only reported for half of the overall patient population, but, among those patients, the combined excellent and good results accounted for 85%. Seven percent of the overall patient population underwent secondary surgery about the elbow other than revision surgery. Twenty-three percent were reported to have one or more complications.

Conclusions

On the basis of our analysis of the peer-reviewed English literature on radial head arthroplasty from January 1940 to May 2015, there seems to be no evidence to support one type of radial head prosthesis over another. The only exception is that silicone prostheses have been shown to be biologically and biomechanically insufficient.

INTRODUCTION

The radial head is an important secondary stabilizer of the elbow for resisting valgus stress, when the primary stabilizer against valgus force, the medial collateral ligament, is injured[1]. This secondary stabilizing function of the radial head is particularly important following many Mason type III fractures, because of the high prevalence of associated ligamentous injuries that compromise elbow stability[2, 3]. The same is true following more complex elbow conditions such as so-called terrible triad injuries, complex elbow dislocations and longitudinal radioulnar instability. In these situations, it is imperative to replace or reconstruct, and not resect, the radial head, in order to allow healing of the damaged stabilizing soft tissues about the elbow[4].

Since the introduction of radial head prostheses by Speed et al. in 1941, various prosthetic designs have been made available[5]. Those designs have varied in terms of material, fixation technique, modularity and polarity. Despite the quickly rising number of publications on radial head arthroplasty in recent years, the increasing understanding of elbow anatomy, biomechanics and kinetics, and the evolution of surgical techniques and prosthetic designs, there is currently no evidence to support one type of radial head prosthesis over another. The only exception is that silicone prostheses have been shown to be biologically and biomechanically insufficient[6].

The purpose of the present systematic review of the literature was to explore the association between prosthetic design variables and the timing of surgery and the results of modern radial head arthroplasty in order to provide evidence-based clinical recommendations. It was hypothesized that functional outcome is not different for cemented and uncemented prostheses, unipolar and bipolar prostheses and acute and delayed treatment.

METHODS

Study population

This review was intended to include patients with a minimum age of 18 years who were managed with a metallic or pyrocarbon prosthetic radial head prosthesis.

Outcome parameters

The primary outcome measures of interest were (1) the incidence of revision, (2) post-operative ranges of motion and (3) the Mayo Elbow Performance Score (MEPS)[7]

The secondary outcome measures of interest were (1) the incidence of complications, (2) the incidence of additional surgery about the elbow other than revision surgery and (3) patient-reported outcome measures (PROMs), including the Disability of the Arm, Shoulder and Hand (DASH) questionnaire[8], Short Form-36 Health Survey (SF-

36)[9], American Shoulder and Elbow Surgeons questionnaire (ASES)[10], Patient-Rated Elbow Evaluation (PREE)[11] and Oxford Elbow Score (OES)[12].

Inclusion and exclusion criteria

Articles written in the English language and evaluating original clinical data on primary radial head arthroplasties performed with use of metallic or pyrocarbon prostheses were considered, regardless of level of evidence. Only articles with a minimum of 10 cases and a minimum average duration of follow-up of 2 years were considered.

A study was excluded if the type of prosthesis and the duration of follow-up were not reported and were not provided by the author on request.

Search strategy and study selection

A comprehensive literature search was conducted with the assistance of a clinical librarian using the following terms: radius[Mesh], radius fractures[Mesh], arthroplasty, replacement[Mesh], joint prosthesis[Mesh], radial head[tiab], replacement[tiab], arthroplasty[tiab], prosthesis implantation [tiab] and prosthesis[tiab]. The PubMed/ Medline and Embase databases were searched using the filters "English" and "humans" for the period from January 1940 to the date of search (May 27, 2015). The start date was chosen as the first documentation of a radial head replacement by Speed et al. dated back to 1941[5].

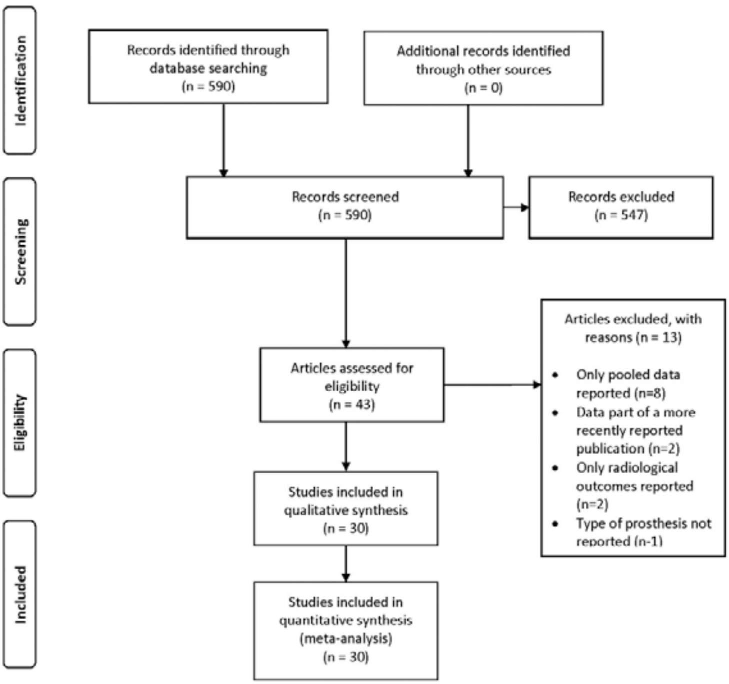

Figure 9. Flowchart of the selection and inclusion of studies.

Table 1: Included studies

Author	Year	Country	N*	Prosthesis	Material	Type
Yan	2015	China	20	Radius Head Comp. (LINK)	Cobalt-Chrome	Monopolar
Schetzke	2014	Germany	30	Evolve (Wright Medical)	Cobalt-Chrome	Monopolar
Allavena	2014	France	22	Guepar (DePuy Johnson & Johnson)	Cobalt-Chrome	Bipolar
Watters	2013	U.S.A.	30	Evolve (Wright Medical)	Cobalt-Chrome	Monopolar
Berschback	2013	U.S.A.	27	Katalyst (Integra), Anatomic RHS (Acumed)	Cobalt-Chrome	Bipolar, monopolar
El Sallakh	2013	Egypt	12	Anatomic RHS (Acumed)	Cobalt-Chrome	Monopolar
Katthagen	2013	Germany	29	Radial Head (Corin)	Cobalt-Chrome	Monopolar
Sarris	2012	Greece	32	MoPyC (Tornier)	Pyrocarbon	Monopolar
Flinkkilä	2012	Finland	31	rHead (Avanta), Anatomic RHS (Acumed)	Cobalt-Chrome	Monopolar, monopolar
Rotini	2012	Italy	31	rHead (SBi)	Cobalt-Chrome	Bipolar, monopolar
Zunckiewicz	2012	U.S.A.	30	Katalyst (Integra)	Cobalt-Chrome	Bipolar
Ricón	2012	Spain	28	MoPyC (Tornier)	Pyrocarbon	Monopolar
Lamas	2010	Spain	47	MoPyC (Tornier)	Pyrocarbon	Monopolar
Chien	2010	Taiwan	13	Evolve (Wright Medical)	Cobalt-Chrome	Monopolar
Burkhart	2010	Germany	17	Judet CRF (Tornier)	Cobalt-Chrome	Bipolar
Celli	2010	Italy	16	Judet CRF (Tornier)	Cobalt-Chrome	Bipolar
Shore	2008	Canada	32	Richards (Smith & Nephew), Evolve (Wright Medical)	Titanium, Cobalt-Chrome	Monopolar, monopolar
Popovic	2007	Belgium	51	Judet CRF (Tornier)	Cobalt-Chrome	Bipolar
Doornberg	2007	U.S.A.	27	Evolve (Wright Medical)	Cobalt-Chrome	Monopolar
Grewal	2006	Canada	26	Evolve (Wright Medical)	Cobalt-Chrome	Monopolar
Chapman	2006	U.S.A.	16	Solar (Stryker Howmedica Osteonics)	Vitallium	Monopolar
Dotzis	2006	France	12	Judet CRF (Tornier)	Cobalt-Chrome	Bipolar
Wretenberg	2006	Sweden	18	Radius Head Comp. (LINK)	Cobalt-Chrome	Monopolar
Brinkman	2005	Netherlands	11	Judet CRF (Tornier)	Cobalt-Chrome	Bipolar
Ashwood	2004	Australia	16	Evolve (Wright Medical)	Cobalt-Chrome	Monopolar
Moro	2001	Canada	25	Richards (Smith & Nephew)	Titanium	Monopolar
Harrington	2001	Canada	20	Richards (Smith & Nephew)	Titanium	Monopolar
Smets	2000	Belgium	15	Judet CRF Tornier)	Cobalt-Chrome	Bipolar
Judet	1996	France	12	Judet CRF (Tornier)	Cobalt-Chrome	Bipolar
Knight	1993	U.K.	31	Osteonics (Stryker Howmedica)	Vitallium	Monopolar

* Total: number of patients followed-up in the study, n/a: not available, HO = Heterotopic Ossifications, CRPS: complex regional pain syndrome, PRUJ = Proximal Radioulnar Joint.

Fixation	Follow-up (months) (mean, range)	Revisions (%)	Complications (number of complications// number of patients wit a complication)
Loose fit	36 (n/a)	5%	(3/3) 1x malposition (revision), 1x dislocation coronoid fracture, 1x resection HO.
Loose fit	36 (13-60)	17%	(14/unclear) 5x overstuffing (5x revision), 1x infection (revision), 1x ossification, 6x ulnar neuropathy, 1x superficial infection.
Cemented	50 (n/a)	23%	(16/14) 6x subluxation (1x revision), 1x loosening (revision), 3x lateral elbow pain (3x revision), 2x CRPS, 4x ulnar neuropathy.
Loose fit	24 (18-53)	10%	(9/9) 3x overstuffing (3x revision), 4x stiffness, 2x nonunion/ malunion coronoid.
Loose fit, press fit	33 (18-57)	0%	(5/5) 5x resection HO.
Press fit	42 (22-58)	0%	None
Press fit	25 (7-54)	3%	(12/11) 1x overstuffing (revision), 6x symptomatic hardware, 3x ulnar neuropathy, 1x CRPS, 1x wound infection.
Expandable stem	27 (21-46)	6%	(3/3) 2x dissociation prosthesis (revision), 1x arthrolysis.
Press fit	53 (12-106)	29%	(15/15) 9x loosening (9x revision), 4x resection HO with arthrolysis, 1x radial neuropathy, 1x superficial infection.
Press fit	24 (13-36)	6%	(3/3) 1x loosening (revision), 1x stiffness (revision), 1x persistent wrist pain. Cases hardware removal excluded.
Loose fit	34 (24-48)	3%	(2/2) 1x overstuffing (revision), 1x instability.
Expandable stem	32 (12-62)	11%	(6/6) 3x subluxation (3x revision), 1x peroperative fracture radial neck due to expansion stem prosthesis, 1x instability, 1x ulnar neuropathy.
Expandable stem	48 (12-60)	11%	(7/7) 2x dislocation prosthesis (2x revision), 1x stiffness (revision), 1x dissociation prosthesis (revision), 1x fracture stem prosthesis (revision), 2x posterior interosseous nerve palsy.
Loose fit	38 (20-70)	0%	(2/2) 1x stiffness, 1x symptomatic hardware.
Cemented	106 (72-139)	12%	(4/4) 2x dislocation prosthesis (2x revision), 1x perforation shaft, 1x re-fracture ulna.
Cemented	42 (12-86)	0%	(4/4) 2x ankylosis, 2x synostosis PRUJ.
Press fit & Loose fit	99 (26-166)	0%	(5/5) 3x ulnar neuropathy, 1x posterior interosseous nerve palsy, 1x CRPS.
Cemented	101 (48-156)	0%	(10/10) 1x subluxation, 1x ulnar neuropathy, 4x posterior interosseous nerve palsy, 1x CRPS, 1x synostosis PRUJ, 2x symptomatic radiocapitellar degeneration.
Loose fit	40 (24-55)	7%	(13/unclear) 1x infection (revision), 1x overstuffing (revision), 1x subluxation. 4x stiffness, 5x ulnar neuropathy, 1x symptomatic hardware
Loose fit	25 (12-48)	0%	(6/6) 2x stiffness, 2x ulnar neuropathy, 1x posterior interosseous nerve palsy, 1x CRPS.
Press fit	36 (23-51)	0%	(4/3) 1x stiffness, 1x ulnar neuropathy, 1x symptomatic hardware, 1x arthrolysis with ulnar nerve release.
Cemented	63 (12-144)	0%	(1/1) 1x stiffness.
Loose fit	36 (12-84)	28%	(5/5) 5x stiffness (5x revision).
Cemented	24 (12-48)	18%	(4/4) 2x subluxation (revision), 2x stiffness.
Loose fit	34 (14-52)	0%	(6/6) 3x ulnar neuropathy, 1x CRPS, 2x superficial infection.
Press fit	39 (26-58)	0%	(8/8) 1x posterior interosseous nerve palsy, 2x ulnar neuropathy, 1x CRPS, 1x mild instability, 2x symptomatic hardware, 1x superficial infection.
Press fit	145 (72-348)	20%	(4/4) 4x lateral elbow pain (4x revision).
Cemented	25 (6-48)	7%	(4/4) 1x stiffness (revision), 1x posterior interosseous nerve, 1x radial neuropathy, 1x synostosis PRUJ.
Cemented	45 (24-72)	0%	(2/2) 1x bony impingement, 1x posterior interosseous nerve palsy.
Press fit	54 (24-96)	6%	(5/4) 2x loosening (2x revision), 2x ulnar neuropathy, 1x synostosis PRUJ.

Four authors independently assessed all titles and abstracts and identified eligible articles. Two authors assessed the full text of all eligible studies and did the final inclusion. The lists of references of all eligible publications were manually checked for additional studies potentially meeting the inclusion criteria, but did not yield any additional eligible studies. Disagreements were settled by discussion. With use of this strategy, 590 articles were identified (Figure 9). After screening of title, abstract and methodology, 43 studies were found to be potentially eligible for inclusion. The full text of all those studies was analyzed and, after application of the inclusion and exclusion criteria, 30 studies were finally included. The additional 13 articles were excluded for various reasons: 8 included only pooled data (5 for radial head arthroplasty and open reduction-internal fixation, 2 for radial head arthroplasty and radial head resection, and one for radial head arthroplasty, open reduction-internal fixation and nonoperative treatment), 2 included data on cases from a larger case series that was presented more recently, 2 assessed only radiographic outcome parameters, and one did not specify the type of prosthesis.

Data analysis

Only 14 of the 30 studies included data on individual patients. The other 16 included only pooled data. As a consequence, analyses covering all 30 studies had to be performed on the aggregated study level, with the data on the individual patients pooled per study. The number of patients who underwent revision surgery was expressed for each study in relation to the total number of patients in that study and in relation to the total number of person-years of follow-up per study. Revision was defined as removal of the prosthesis, or a part of it, regardless of whether a new radial head or other type of prosthesis was implanted and regardless of indication.

The various ranges of motion were expressed as an unweighted average and as a weighted average with the number of patients per study group as weights; the latter equaled the mean across the maximum of 727 patients.

For the analysis of MEPS data, studies were included only if the MEPS had been used as intended. For this analysis, only the interpreted outcome (coded as 1 for poor, 2 for fair, 3 for good and 4 for excellent), and not the numerical outcomes, were used and averaged per study.

Because of the substantial variability in reporting and the nature of the complications, we decided that summarizing the complications data in tabular format would provide the most information (Table I). In addition, the total number of patients with a complication was expressed for each study in relation to the total number of patients in that study. We calculated the number of complications from each individual publication and did not routinely use the number that was stated in the publication for analysis; therefore, there may be differences. Radiographic observations that were considered to be complications included symptomatic loosening of the prosthesis, subluxation of the prosthesis and periprosthetic fractures. Other radiographic findings were only considered to be complications if they required surgical intervention. As a consequence, periarticular ossification was only considered to be complication if a resection was performed. The outcome variable of secondary surgery was analyzed in a similar fashion. Secondary surgery was defined as all surgery about the elbow, including revision surgery, performed after the index procedure.

All outcome parameters were analyzed for dependence on the prosthesis polarities, materials and fixation techniques, both jointly and separately. In 27 of the 30 studies, only one combination of prosthetic modularity, material and fixation technique (i.e. only one type of prosthesis) was used. In 3 studies, 2 combinations (i.e. 2 types of prostheses) were used and were considered as separate groups in the analyses. Therefore, the aggregated pooled data file used for the analyses consisted of 33 study groups rather than 30 studies. All outcome parameters were also analyzed according to delay of treatment as dichotomized in 3 alternative ways: ≤1 week versus >1 week, ≤2 weeks versus >2 weeks, and ≤1 month versus >1 month. For each study, these dichotomized delays of treatment were summarized as proportion of the number of patients. Age (averaged per study) also was used as an explanatory variable.

Statistical analysis

The overall population of all radial head prosthesis was characterized using descriptive statistics on the aggregated level of study group. Unweighted as well as weighted averages across study groups were calculated with use of the number of patients per study as weights. Special attention was paid to the joint outcome of prosthesis polarity, material and fixation technique and the operational interrelationship between these modalities. Revision data, aggregated per study, were analyzed with use of generalized linear modeling. The number of revisions per study was assumed to have a negative binomial distribution, with the logarithm of the number of person-years as offset. For the effect of explanatory variables on the revision rate, a log-link function was used. Rate ratios, the dispersion parameter and mean revision rates per category of the explanatory variables were estimated with use of this model. The dispersion parameter accounted for the extra-Poisson variability across studies. The various ranges of motion and the MEPS were analyzed with use of weighted linear regression, with the number of valid patients per study group as weights. For all analyzes, a p-value ≤0.05 was considered significant. Analyses were performed using SPSS 21.0 (IBM Corp., Armonk, NY, USA) and SAS 9.2 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Population characteristics

Thirty articles involving 727 patients were included (Table 1)13-42. The number of patients per study ranged from 11 to 51. All studies were case series (Level IV, therapeutic studies). Studies originated in Europe (17 articles), North America (9 articles), Asia

(2 articles), Australia (1 article) and northern Africa (1 article). The oldest article was published in 1993 and the most recent was published in 2015. Variability among the studies in terms of reporting of patient and population characteristics was substantial. Data on prosthetic material and modularity was complete, because failure to report these parameters would have resulted in exclusion of the study. The most frequently used prostheses were the Evolve Modular Radial Head System (Wright Medical), the Radial Head System (Tornier) and the MoPyC radial head (Tornier), together accounting for 54% of all prostheses (Table II). Regarding implant material, 506 (70%) prostheses were made of cobalt-chromium, 107 (15%) were made of pyrocarbon, 67 (9%) were made of titanium and 47 (6%) were made of Vitallium. Regarding polarity, 508 (70%) were monopolar and 219 (30%) were bipolar. Regarding fixation, 156 (21%) were cemented in place, 230 (32%) were press-fit, 234 (32%) were intentionally loose-fit and 107 (15%) were fixed with an expandable stem (Table III). Only 8 of the 32 theoretically possible combinations of prosthesis polarity, material and fixation technique were observed (Table III). This relatively small number of observed combinations complies with the operational interrelationship between these 3 prosthesis modalities and reflects the true spectrum of available prostheses. In 3 studies, 2 combinations of prosthesis polarity, material and fixation technique (i.e. 2 types of prostheses) were used15, 24, 37. Descriptive summary statistics of the various other independent and dependent variables are presented in Table IV. For each variable, 2 means were calculated across the 33 study groups: an unweighted average and a weighted average with the number of patients per study group as weights, with the latter equaling the mean across the 727 patients. These means did not differ much from one another, as no systematic relationship should exist between the number of patients and the mean of a variable per study. Sample statistics other than the mean for the total group of patients, such as median, range and standard deviation, are not reported, as they do not bear a proper relationship to underlying population parameters, with 16 studies presenting only pooled data. Age at the tome of surgery was reported for 667 (92%) of 727 included patients. The weighted average age at the tome of surgery was 50 years. Data on delay of treatment were inconsistently and variably reported. It could be determined that 262 (68%) of the 388 patients for whom the delay of treatment could be inferred from the reported data were operated with a delay of ≤1 week, or that 299 (75%) of the 398 for whom the delay could be inferred were operated with a delay ≤2 weeks, or that 424 (83%) of the 508 patients for whom the delay could be inferred were operated with a delay of ≤1 month. Information on delay of treatment was not reported for 47%, 45% and 30% of patients with a delay of ≤1 week, ≤2 weeks and ≤1 month, respectively. The weighted average follow-up was 45 months.

Table 2: List with characteristics of all types of radial head prostheses used in the included studies

Name of prosthesis	Manufacturer	Material	Modularity	Polarity	Fixation	Comment
Anatomic Radial Head System	Acumed	Cobalt-Chrome	Modular	Unipolar	Press-fit	
Evolve Modular Radial Head System	Wright Medical	Titanium	Modular	Unipolar	Loose-fit	
Guepar radial head prosthesis	DePuy, Johnson & Johnson	Cobalt-Chrome	Modular	Bipolar	Cemented	Discontinued
Judet Floating Radial Head (CRF II) (now Radial Head System)	Tornier	Cobalt-Chrome	Modular	Bipolar	Cemented	In text and tables listed as Radial Head System (Tornier) for all occurrences. Currently also available as press-fit.
Katalyst Bipolar Radial Head System	Integra	Cobalt-Chrome	Modular	Bipolar	Loose-fit	
MoPyC radial head	Tornier	Pyrocarbon	Modular	Unipolar	Expandable stem	
Solar radial head	Stryker Howmedica Osteonics	Vitallium	Monoblock	Unipolar	Press-fit	
Radial Head	Corin	Cobalt-Chrome	Monoblock	Unipolar	Press-fit	
Radius Head Component	LINK	Cobalt-Chrome	Monoblock	Unipolar	Loose-fit	
rHead	Avanta	Cobalt-Chrome	Modular	Unipolar	Cemented	Currently Small Bone Innovations (SBi)
rHead	Small Bone Innovations (SBi)	Cobalt-Chrome	Modular	Unipolar	Cemented	
Richards radial head	Smith & Nephew	Titanium	Monoblock	Unipolar	Press-fit	Discontinued

Table 3: Observed combinations of prosthesis polarity, material and technique of fixation.

	Combination of prosthesis polarity, material and technique of fixation	Number of study groups	Studies with 2 combinations	Number of patients
1	Monopolar / cobalt-chrome / press-fit	5	2	97
2	Bipolar / cobalt-chrome / press-fit	1	1	19
3	Monopolar / titanium / press-fit	3	1	67
4	Monopolar / vitallium / press-fit	2	0	47
5	Bipolar / cobalt-chrome ./ cemented	8	0	156
6	Monopolar / cobalt-chrome – intentional loose fit	9	1	190
7	Bipolar / cobalt-chrome / intentional loose fit	2	1	44
8	Monopolar / pyrocarbon / expandable stem	3	0	107
	Total	**33**		**727**

Table 4: Descriptive summary statistics across the aggregated study groups
[The mean presented under ***study groups*** is an unweighted average and the mean presented under ***patients*** is a weighted average with the number of patients per study as weight.]

	Study groups				Patients	
Independent variable	**N**	**Mean**	**Min.**	**Max.**	**N**	**Mean**
Age at surgery (years)	31	48.4	37.0	59.2	667	49.8
Delay of treatment ≤1 week (%)	21	55.6	0.0	100	388	67.5
Delay of treatment ≤2 weeks (%)	21	66.5	0.0	100	398	75.1
Delay of treatment ≤1 months (%)	26	76.4	0.0	100	508	83.5
Follow-up (years)	33	3.6	1.01	8.83	727	3.73
Dependent variable						
Revision surgery (%)	33	7.1	0.0	29.0	727	7.7
Revision surgery (per 100 person-years of follow-up)	33	2.81	0.0	19.83	727	2.1
Postoperative flexion (deg.)	29	130.2	117.0	140.0	609	130.6
Postoperative extension deficit (deg.)	30	15.0	6.0	28.1	625	15.3
Postoperative flexion-extension arc (deg.)	25	115.8	96.4	131.5	523	115.8
Postoperative supination (deg.)	29	72.2	56.8	88.0	610	72.8
Postoperative pronation (deg.)	29	69.7	51.0	84.0	610	69.6
Postoperative pronation-supination arc (deg.)	21	140.3	112.6	168.9	399	141.2
Mayo Elbow Performance Score*	18	3.37	2.92	3.84	358	3.35

* For purposes of statistical analysis coded as 1=poor, 2=fair, 3=good and 4=excellent. See text for explanation.

Primary outcome measures

The percentage of patients who underwent revision surgery ranged from 0% to 29% when expressed in relation to the number of patients in the studies. The number of revisions per 100 person-years of follow-up ranged from 0 to 20 across studies. In total, there were 56 revisions (8%) during 2,714 person-years of follow-up across all 727 patients, yielding a crude overall revision rate of 2.06 per 100 person-years of follow-up. With use of generalized linear modeling, the mean revision rate across all 33 study groups (i.e. for the entire overall population of 727 patients) based on the negative binomial distribution was 2.53 (95% confidence interval [CI], 1.53 to 4.20) per 100 person-years of follow-up. The simultaneous effect of all 8 combinations of prosthesis polarity, material and fixation technique was not significant (p=0.92) (Table V). For combinations with a small underlying number of patients, the imprecision of the estimates was large, as reflected by the wide CIs. Even the largest pairwise difference was not significant. Also, the separate prosthesis modalities of polarity, material and fixation technique had no significant effect on revision rate (p=0.46, 0.69 and 0.98, respectively). The revision rate was also not significantly affected by delay of treatment when dichotomized at 1 week (p=0.52), 2 weeks (p=0.87) or 1 month (p=0.77). It must be noted that delay of treatment was not reported in many studies. In addition, age was found to have no significant effect on the revision rate (p=0.92).

Table 5: Revision rate (per 100 person-years of follow-up) by combinations of prosthesis polarity, material and technique of fixation as estimated using generalized linear modeling

Combination of prosthesis polarity, material and technique of fixation	Mean (95% CI)	
Monopolar / cobalt-chrome / press-fit	2.74 (0.81 - 9.28)	
Bipolar / cobalt-chrome / press-fit	2.63 (0.14 – 51.1)	
Monopolar / titanium / press-fit	4.77 (1.16 – 26.4)	
Monopolar / vitallium / press-fit	0.91 (0.11 – 7.82)	p=0.92
Bipolar / cobalt-chrome ./ cemented	2.10 (0.72 – 6.11)	
Monopolar / cobalt-chrome / intentional loose fit	2.82 (1.16 – 6.85)	
Bipolar / cobalt-chrome / intentional loose fit	0.72 (0.06 – 9.14)	
Monopolar / pyrocarbon / expandable stem	3.10 (0.73 – 13.2)	
Total	**2.53 (1.53 – 4.20)**	

The range of motion variables flexion-extension arc and pronation-supination arc were analyzed with use of weighted linear regression (Table VI). Neither the flexion-extension arc, nor the pronation-supination arc was significant affected by the combination of prosthesis polarity, material and fixation technique (p=0.76 and 0.19, respectively). The flexion-extension arc and the pronation-supination arc also were not significantly affected by the separate prosthesis modalities of polarity (p=0.88 and 0.26, respectively), material (p=0.87 and 0.23, respectively) and fixation technique (p=0.86 and 0.18, respectively). Delay of treatment of ≤1 week or ≤2 weeks resulted in a higher pronation-supination arc than longer delays (130.0° compared with 157.2° [difference 27.2°; 95% CI, 13.1° to 41.2°; p=0.001] and 129.1° compared with 154.2° [difference 25.1°; 95% CI: 9.2° to 41.0°; p=0.004], respectively). A delay ≤1 month had no significant effect on pronation-supination arc as compared with a delay of >1 month (130.8° compared with 146.3° [difference 15.5°; 95% CI -5.0° to +36.0°; p=0.13]). Delay of treatment had no significant effects on the flexion-extension arc (p=0.77, 0.61 and 0.70 for delays of ≤1 week, ≤2 weeks and >1 month, respectively).

Table 6: Mean flexion-extension arc (F/E arc) and pronation-supination arc (P/S arc) by combination of prosthesis polarity, material and technique of fixation as estimated using weighted linear regression analysis

Combination of prosthesis polarity, material and technique of fixation	Flexion-extension arc (degrees)		Pronation-supination arc (degrees)	
	Mean (95% CI)	P-value	Mean (95% CI)	P-value
Monopolar / cobalt-chrome/ press-fit	114.8 (105.3-124.3)	0.76	147.6 (133.1-162.1)	0.19
Bipolar / cobalt-chrome / press-fit	113.9 (92.5-135.4)		112.6 (82.0-143.3)	
Monopolar / titanium / press-fit	119.9 (106.2-133.5)		137.7 (118.2-157.2)	
Monopolar / vitallium / press-fit	115.3 (92.0-138.7)		154.1 (120.6-187.5)	
Bipolar / cobalt-chrome / cemented	113.2 (105.3-121.1)		139.9 (125.6-154.1)	
Monopolar / cobalt-chrome / intentional loose fit	112.9 (103.5-122.2)		129.9 (113.9-145.9)	
Bipolar / cobalt-chrome / intentional loose fit	126.5 (112.4-140.6)		135.4 (99.6-171.1)	
Monopolar / pyrocarbon / expandable stem	118.0 (105.9-130.1)		156.7 (139.4-173.9)	
Total	**116.8 (111.5 – 122.1)**		**139.2 (130.7 – 147.8)**	

Average MEPS was reported for 18 of the 33 study groups (Table IV). The standard deviation (SD) of the average MEPS was 0.26, allowing small mean differences between groups to reach significance. The combination of prosthesis polarity, material and fixation technique had an overall significant effect on the MEPS (p=0.038), meaning that at least one combination differed from the other ones. Testing the difference of each combination with another combination (pairwise comparisons) indicated that the difference between the combinations bipolar/cobalt-chromium/cemented fixation and monopolar/pyrocarbon/expandable stem mainly contributed to this overall significant effect (p=0.003). The p values for the separate effects of the prosthesis modalities on the MEPS were 0.13 for polarity, 0.057 for material and

0.009 for fixation technique. Although the coded interpreted outcome for all 4 fixation techniques was on average between good and excellent, it appeared that, within this small range, press-fit fixation (mean, 3.5) and fixation with an expandable stem (mean, 3.7) resulted in better outcome scores on average than cemented fixation (mean 3.1) (p=0.019 and 0.002, respectively). Fixation with an expandable stem (mean, 3.7) also scored better than intentionally loose-fit (mean, 3.3)(p=0.024). It must be noted that the effect of a separate prosthesis modality is operationally confounded by effects of the other modalities on the MEPS.

Table 7: Mean coded interpreted outcome of the Mayo Elbow Performance Score (MEPS) (coded as 1=poor, 2=fair, 3=good and 4=excellent) by combination of prosthesis polarity, material and technique of fixation as estimated using weighted linear regression analysis

Combination of prosthesis polarity, material and technique of fixation	**Mean (95% CI)**	
Monopolar / cobalt-chrome / press-fit	3.6 (3.1 – 4.0)	p=0.038
Bipolar / cobalt-chrome / press-fit	3.7 (3.2 – 4.0)	
Monopolar / titanium / press-fit	No data reported	
Monopolar / vitallium / press-fit	3.3 (2.7 – 3.8)	
Bipolar / cobalt-chrome / cemented	3.1 (2.9 – 3.3)	
Monopolar / cobalt-chrome / intentional loose fit	3.3 (3.1 – 3.5)	
Bipolar / cobalt-chrome / intentional loose fit	3.6 (3.0 – 4.0)	
Monopolar / pyrocarbon / expandable stem	3.7 (3.4 – 4.0)	
Total	**3.5 (3.3 – 3.6)**	

5

Secondary outcome measures

There was substantial variation between studies in reporting of complications and the definition of complication varied among studies. A particular issue was whether or not radiological observations were counted as complications. Therefore, it was deemed that comparing incidences was of no value. In the overall patient population, 182 complications were reported in 167 (23%) of the 727 patients (Table I).

The incidence of secondary surgery, including revisions, ranged from 0% to 42% when expressed in relation to the valid number of patients in the studies. Altogether, 107 (15%) of the 727 patients underwent secondary surgery including revision surgery and 51 (7%) of the 727 patients underwent secondary surgery other than revision surgery.

PROMs were scarcely reported. Thirteen articles involved use of the DASH questionnaire, 3 involved the SF-36, 2 involved the ASES questionnaire, 2 involved de PREE and none involved the OES.

DISCUSSION

The radial head is an important secondary stabilizer of the elbow {Morrey, 1991 #59}. Replacement of the radial head is advised in cases in which the extent of ligamentous injury calls for this secondary stabilizing function and it is not possible to reconstruct the radial head. This is the case with Mason type III radial head fractures and the more complex elbow traumata. There is currently no evidence to support one type of modern radial head prosthesis over another. The current study showed that the incidence of revision of radial head arthroplasty, regardless of indication, ranged from 0% to 29% among the included studies. Among all patients, 8% underwent revision surgery. For the overall study population, the estimated revision rate was 2.5 per 100 person-years of follow-up. The combination of prosthesis polarity, material and fixation technique had no significant effect on the revision rate or the functional outcome in terms of range of motion. The combination of prosthesis polarity, material and fixation technique appeared to have a significant effect on the MEPS; however, the MEPS was only reported in half of the patients in the overall study population. Twenty-three percent of the overall study population had some complication and 7% underwent secondary surgery other than revision surgery.

Several limitations are recognized. Studies were included regardless of surgical indications. Due to the mixed populations in many studies and limited reporting of associated pathology, it was not possible to perform analyses stratified for indication and/or associated pathology. There was substantial variability among studies in terms of reporting of results. This was particularly true for radiological parameters. Prosthesis polarity, material and fixation technique are not independent of each other. Consequently, there were only 8 possible combinations instead of the maximum of 32 possible combinations (2 different polarities, 4 different materials and 4 different fixation techniques) were the prosthetic design parameters to be completely independent. As stated, these 8 possible combinations reflect the true spectrum of available prostheses. Statistically, prosthesis polarity, material and fixation technique are therefore inextricably operationally confounded with each other. Further, a much larger sample size would be needed to obtain significant effects with sufficient power. Even for the largest pairwise contrast in revision rates between combinations of prosthesis polarity, material and technique of fixation, a sample size at least 3 times larger would be needed.

In the overall population of the current study, there were 56 revisions (8%) among 727 patients, including those with both monopolar (n=44) and bipolar (n=12) prostheses. Thirteen failures (23%) were due to loosening, 11 (20%) were due to overstuffing, 10 (18%) were due to subluxation, 8 (14%) were due to stiffness, 7 (12%) were due to lateral elbow pain, 3 (5%) were due to dissociation of the prosthesis, 2 (4%) were due to infection, 1 (2%)was due to malposition and 1 (2%) was due to fracture of the stem of the prosthesis. One revision for loosening involved a cemented prosthesis and 12 involved a press-fit prosthesis[13, 24, 29, 34]. Osteolysis around the stem has been described in about 50% of all patients with a press-fit radial head prosthesis, with a prevalence of 17% to 100% in the various studies included in this review[15, 19, 23, 24, 26, 29, 31, 34, 37]. In most cases, this osteolysis was deemed asymptomatic It is noteworthy that 9 of the 12 failures of press-fit prostheses occurred in a single case series by Flinkkila et al. and were due to lateral elbow pain and implant loosening[24]. Although the authors attributed this high incidence of implant loosening to poor osseous ongrowth, it is not clear why other studies involving the same or similar prostheses demonstrated substantially lower incidences of failure. Biomechanical studies have suggested that monopolar prostheses better restore elbow stability than bipolar prostheses and, therefore, that monopolar prostheses better resist radiocapitellar subluxation[43, 44]. However, Berschback et al. and Rotini et al. could not confirm this hypothesis in comparative clinical studies[15, 34]. In the overall population of the current study, 5 revisions for subluxation involved a monopolar prosthesis and 5 involved a bipolar prosthesis. When replacing the radial head, restoration of the length of the radius is important. Overstuffing may result in increased radiocapitellar pressure, which may in turn lead to attrition of the capitellar articular cartilage and pain[45]. Conversely, failure to restore the length of the radius may result in instability. It has been proposed to use the proximal edge of the lesser sigmoid notch of the ulna with the forearm in neutral rotation as reference for the articulating surface of the prosthesis[46]. It has been proposed that the proximal edge of the lesser sigmoid notch of the ulna with the forearm in neutral rotation can be used as a reference for the articulating surface of the prosthesis[46]. It has been postulated that restoring radial length may be easier to accomplish with modular prosthesis. This hypothesis could not be confirmed by the current study; of the 11 revisions that were performed because of overstuffing in the overall population of the current study, 10 involved modular prostheses and one involved a monoblock prosthesis.

There was large variation among studies in terms of the quality and quantity of the reported data. Not infrequently, important methodological information or important outcome parameters were lacking. This heterogeneity in data hampers sound comparison of studies and renders it impossible to conduct a formal meta-analysis. This problem has also been recognized for total elbow arthroplasty[47]. It is likely that the peer-review process is falling short in ensuring uniformity and quality in data reporting. A discussion about the institution of guidelines for standardized reportage of clinical outcomes seems appropriate. This also holds true for radiographic parameters. Radiographic findings were reported with too great a variability to allow for a structured analysis and for that reason no radiological outcome parameter was used in this study.

It has been recognized that associated injury about the elbow, forearm or wrist is very likely to affects the outcome after radial head arthroplasty. However, in the current study, it became apparent that associated injuries were so scarcely and variably reported that no reliable analysis could realistically be attempted. It is assumed that such associated injuries are often missed during physical examination. Magnetic resonance imaging studies have shown that 76% to 96% of elbows that had sustained a radial head fracture may have associated injuries about the elbow[45, 48-50]. Also, if adequate reconstruction or replacement of the radial head is performed in a timely fashion, many of these injuries may heal without clinical consequences and may not be diagnosed at all.

CONCLUSIONS

On the basis of our analysis of the peer-reviewed English literature on radial head arthroplasty from January 1940 to May 2015, there seems to be no evidence to support one type of radial head prosthesis over another. The only exception is that silicone prostheses have been shown to be biologically and biomechanically insufficient.

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Chapter

6

Delayed treatment of elbow pain and dysfunction following Essex-Lopresti injury with metallic radial head replacement: A case series

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ABSTRACT

Background
Chronic longitudinal radioulnar dissociation has been associated with unpredictable and generally unfavorable outcomes. Metallic radial head replacement may address this treatment deficiency.

Methods
Eight patients were treated with a metallic radial head replacement for chronic longitudinal radioulnar dissociation. The average treatment delay was 3.3 years. All eight patients were seen for a clinical and radiographic assessment.

Results
Five of the 8 failed after a mean of 3.0 years (range, 1.0 to 5.7 years). Revision to bipolar radial head replacement was successful in the short term in 2 of 3 that failed from aseptic loosening. One of 2 failures due to painful radiocapitellar arthritis was salvaged with a capitellar replacement.

Conclusion
Metallic monoblock radial head replacement did not reliably address the functional deficiency from chronic radioulnar dissociation, due to primarily malalignment and implant loosening. A cemented bipolar radial head implant may provide a better alternative as a long-term solution. Regardless, ligamentous integrity at the elbow should also be addressed at the time of reconstruction.

INTRODUCTION

Concomitant fracture of the radial head, tearing of the interosseous ligament and disruption of the distal radioulnar joint, commonly referred to as Essex-Lopresti injury, causes longitudinal radioulnar dissociation[1-4]. The resulting axial instability of the forearm leads to proximal migration of the radius relative to the ulna, which causes secondary disability at the elbow and wrist due to radiocapitellar and ulnocarpal abutment and altered mechanics at the elbow and wrist[5-7].

With acute treatment, favorable results may be possible[1, 4, 8-10]; however, untreated or delayed treatment of the injury has been associated with unsuccessful results in about 80% of patients[1, 4, 11-18]. With a delay in treatment, the proximal radial migration becomes relatively irreducible, presumably due to scarring and soft-tissue contraction. The combination of injury to the distal radioulnar joint, interosseous ligament and secondary changes at the proximal radioulnar joint further complicates reconstructive surgery options.

Metallic radial head replacement has been employed as a treatment option for chronic Essex-Lopresti injuries. Biomechanical studies have demonstrated that a metallic radial head prosthesis potentially provides the necessary stiffness to withstand the increased axial forces that act on the radius in that condition without adverse biological reaction[9, 19, 20]. To date, only 3 reports with a total of 12 cases with limited surveillance have appeared in the literature in which this injury was treated by metallic radial head replacement[21-23].

The purpose of this study is to report our experience with 8 patients who were treated by metallic radial head replacement for secondary elbow pain and dysfunction in the setting of a chronic Essex-Lopresti injury.

METHODS

Institutional Review Board approval was obtained from the Mayo Clinic on July 16, 2009 (study no. 633-04) and each subject was informed that data concerning their case would be submitted for publication.

Eight patients were treated by metallic radial head replacement at our institution between 1998 and 2002 for a chronic Essex-Lopresti injury with secondary elbow pain and dysfunction, with or without wrist pain. Medical records were reviewed and each patient was seen in the office for a clinical assessment and radiographic evaluation. Post-operative elbow function was graded using the Mayo Elbow Performance Score (MEPS)[24, 25]. Radiographs of the elbow were reviewed for capitellar osteopenia and degenerative changes at the elbow. Degenerative changes were graded as previously described[26].

Table 1. Demographic data for the individual patients. (Information is from all individual patients that were treated in a delayed fashion with metallic radial head replacement for residual elbow pain and dysfunction in the setting of a chronic Essex-Lopresti injury)

Case	Sex	Age	Injured side	Dominant side	Treatment at time of injury	Delay RH excision (wks)	Surgical procedures following RH excision, but prior to metallic RH arthroplasty	Associated ligamentous injury at the elbow at the time of metallic RH arthroplasty (clinical; per-operative findings)
1	Female	51	Left	Right	ORIF	417	Silastic RH arthroplasty; Removal silastic RH arthroplasty	Annular ligament deficiency
2	Male	27	Left	Right	Supportive sling	81	None	None
3	Female	41	Right	Right	RH excision	0	None	MCL deficiency, marked valgus and mild varus instability, PLRI‡
4	Male	54	Right	Right	RH excision	0	Arthroscopic debridement TFCC and partial resection distal ulna	None
5	Male	38	Left	Right	Splint cast	17	Ulnar shortening with allograft RH arthroplasty; Revision allograft RH arthroplasty	None
6	Female	40	Right	Right	Splint cast	9	None	PLRI‡
7	Male	33	Right	Right	ORIF, LUCL reconstruction	31	Cutis interposition RH arthroplasty	MCL deficiency
8	Female	46	Left	Right	RH excision	0	None	MCL deficiency, marked valgus instability, PLRI‡

RH=Radial head; ORIF=Open reduction and internal fixation; LCL=Lateral collateral ligament; MCL=Medial collateral ligament; TFCC=Triangular fibrocartilage complex.
Posterolateral rotatory instability (PLRI) is indicative of lateral collateral ligament (LUCL) deficiency.

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Table 2. Information related to the primary metallic radial head arthroplasty. (Information is from all individual patients that were treated in a delayed fashion with metallic radial head replacement for residual elbow pain and dysfunction in the setting of a chronic Essex-Lopresti injury)

Case	Metallic radial head arthroplasty			Delay from RH excision (wks)	Delay from injury (wks)
	Fixation	Type	Uni-/bipolar		
1	Cemented	Custom Avanta	Unipolar	352	769
2	Cemented	Custom Avanta	Unipolar	12	92
3	Cemented	Wright	Unipolar	88	88
4	Cemented	Avanta	Unipolar	143	143
5	Cemented	Avanta	Unipolar	82	99
6	Uncemented	Avanta	Unipolar	46	55
7	Uncemented	Avanta	Unipolar	76	107
8	Cemented	Judet/ CRFII	Bipolar	37	37

RH=Radial head; LUCL=Lateral collateral ligament; MCL=Medial collateral ligament; PLRI=Posterolateral rotatory instability;
Radiocapitellar hemiarthroplasty consisted of insertion of a custom capitellar resurfacing prosthesis in combination with revision of the articular component of the metallic radial head arthroplasty to a custom metal-backed, polyethylene articular component, while the intramedullary component (*i.e*. the prosthesis stem) was left alone.

Procedures simultaneous to metallic RH arthroplasty	Complications/Further procedures
Repair annular ligament, ulnar head prosthesis, stabilization DRUJ (flexor carpi ulnaris advancement)	Radiocapitellar hemiarthroplasty§; Revision radial head arthroplasty with Avanta bipolar metallic prosthesis
None	LLC repair (palmaris longus graft) and capsular repair (Achilles tendon graft); Removal of reactive bone about the posterior olecranon
MCL and LCL reconstruction (semitendinosus tendon allograft)	Repeat LCL reconstruction, revision radial head arthroplasty with Judet bipolar metallic prosthesis
None	Partial resection distal ulna, radiocapitellar hemiarthroplasty§, ulnar head arthroplasty
None	Open capsular release; Ulnar resection; Repeat open capsular release
LCL reconstruction (palmaris longus tendon)	Revision radial head arthroplasty with Judet bipolar metallic prosthesis
None - especially, MCL deficiency was not addressed.	Removal metallic radial head arthroplasty; Revision radial head arthroplasty with Avanta bipolar metallic prosthesis (delayed)
MCL reconstruction (semitendinosus allograft)	None

There were four males and four females with a mean age at injury of 38 years (range, 25-51 years) (Tables I and II). There were four left and four right and four dominant elbows involved. Mean age at surgery was 41 years (range, 27-54 years). In five patients (63%), the initial injury was work-related. All patients had previously been treated by excision of the radial head, either acute or delayed. The mean delay from the time of injury to the time of insertion of a metallic radial head implant was 3.3 years (rang, 37 weeks to 14.8 years); and from radial head excision to metallic radial head replacement was 2 years (range, 12 weeks to 6.8 years). The spectrum of pathology, which was identified in these patients, is seen in Table I. Specifically, it should be noted that 5 patients had some form of ligamentous instability and 2 had evidence of both medial and lateral ligamentous deficiency. Subsequently, we found that this was an important prognostic finding. Surgical procedures at the elbow and wrist following radial head excision, but prior to metallic radial head replacement are listed (Table II). There was no attempt at reconstruction of the forearm interosseous membrane in any patient. Four different types of prostheses were inserted based on surgical preference and options at the time; these included 4 non-custom monoblock radial head prostheses (Avanta; SBI, New York, NY, USA), two custom Avanta prostheses (SBI), one Swanson design titanium prosthesis (Wright Medical Technologies, Arlington, TN, USA) and one Judet/CRFII bipolar prosthesis (Tornier, Saint-Denis Monbonnot, France). Six prostheses were cemented in place and 2 were press-fit. Surgical procedures at the elbow at the time of prosthesis implantation are presented (Table II).

The Avanta (SBI, http://www.totalsmallbone.com) prostheses initially used in these cases were of monoblock (unipolar), modular design. The radial stem is curved and can be inserted with or without bone cement. The two components (head and stem) are coupled using a Morse taper lock. The Swanson design titanium prosthesis (Wright Medical Technologies, http://www.wmt.com) is a unipolar, modular design and has a straight, sintered stem that is press-fit into place. The Judet/CRFII radial head (Tornier, http://www.tornier.com) is a bipolar, modular prosthesis with an extended intramedullary stem. The radial stem, which is straight and available in two lengths, requires the use of bone cement for prosthesis fixation. A ball-in-socket joint allows a total of 35°of tilt. All arthroplasties were performed according to the manufacturer’s recommendations.

RESULTS

The overall outcome of the treatment of this patient sample is shown in Table II. We have analyzed the outcomes based on stability of the stem, the articular symptoms and malalignment and stability of the ulnohumeral and radiohumeral joints. It is noted that 4 patients (cases 1, 3, 6 and 7) had problems with stem loosening; however, 3 had problems with articulation, alignment and arthritis (cases 1, 3 and 4). All 4 patients

Table 3. Clinical outcome data after the primary metallic radial head arthroplasty. (Information is from all individual patients that were treated in a delayed fashion with metallic radial head replacement for residual elbow pain and dysfunction in the setting of a chronic Essex-Lopresti injury)

Case	F/U (yrs)	Pain elbow§		Instability†		Flexion-extension arc (degrees)		Pronation-supination arc (degrees)		Mayo Elbow Performance Outcome Index*		Result
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
1	2.6	Moderate	Severe‡	Moderate	Stable‡	130	115‡	120	170‡	60/Fair	45/Poor‡	Failure
2	7.4	Moderate	Mild	Stable	Stable	115	85	105	140	70/Fair	80/Good	Success
3	1.5	Moderate	Moderate‡	Moderate	Moderate‡	127	145‡	170	170‡	65/Fair	65/Fair	Failure
4	4.4	Moderate	Mild‡	Moderate	Stable‡	125	110‡	95	105‡	50/Poor	70/Fair	Failure
5	5.4	Moderate	Mild	Mild	Stable	115	110	45	105	55/Poor	80/Good	Success
6	1.0	Severe	Mild‡	Mild	Mild‡	140	150‡	160	145‡	50/Poor	70/Fair	Failure
7	5.7	Moderate	Severe‡	Stable	Mild‡	100	105‡	160	90‡	45/Poor	70/Fair	Failure
8	4.4	Severe	Mild	Gross	Mild	105	130	170	160	25/Poor	80/Good	Success

§ Pain is graded as none, mild, moderate or severe.

† Instability is graded as none (i.e., stable), mild, moderate gross

* The Mayo Elbow Performance Index total scores is graded as excellent (95 to 100), good (80 to 94), fair (60 to 79) and poor (<59). All revisions are considered a poor result, regardless of total score.

‡ These measurements were taken just prior to revision surgery, at the moment that the treatment was already failing, hence may not represent the true postoperative course prior to that specific moment.

6

who had residual instability problems after the primary radial head replacement (cases 3, 6, 7 and 8) had instability before the implant as well. None had excessive lengthening. The outcomes were ultimately influenced by these various parameters.

The primary treatment of metallic radial head replacement failed in five patients (cases 1, 3, 4, 6 and 7) after a mean of 3.0 years (range, 1.0 -5.7 years) and was successful in 3 (cases 2, 5 and 8) at final surveillance after a mean of 5.7 years (range, 4.4-7.4 years)(Tables IV). Two failures were because of the development of painful radiocapitellar arthritis (cases 1 and 4). In both patients, revision surgery was performed to replace the articular component of the metallic radial head prosthesis with a metal-backed, polyethylene articular component, which articulated with a metallic capitellar resurfacing arthroplasty. This revision treatment was successful in one at 25 months of follow-up (case 4). The other had required revision surgery of the metallic radial head replacement for aseptic prosthetic stem loosening, followed by total elbow arthroplasty for continuous pain about the lateral elbow (case 1). Three failures were due to aseptic loosening of the radial head prosthesis (cases 3, 6 and 7). In all 3 patients, revision to a cemented bipolar metallic radial head replacement was performed and included insertion of two Judet/CRFII bipolar prostheses and one Avanta bipolar prosthesis. This revision treatment was successful in one patient 53 months later (case 6). In another, the implant continued to be well fixed at final surveillance; although, the articular component of the prosthesis had required exchange due to due to pistoning of the articular component on the stem as a result of polyethylene wear (case 3). The third patient (case 7) had inadequate follow-up (2 months) after the revision surgery.

Four of the 5 patients in whom the primary treatment had failed had associated ligamentous injury at the elbow at the time surgery. This included the 3 patients with aseptic prosthetic stem loosening (cases 3, 6 and 7), and one of the 2 patients in whom failure was related to symptomatic radiocapitellar arthritis (case 1). In contrast, 2 of the 3 patients in whom the primary treatment was successful had no associated ligamentous injury at the elbow at the time of radial head replacement (cases 2 and 5).

In 2 of the 5 patients in whom the primary prosthesis had failed, the implant was inserted without bone cement. In both patients, failure was due to aseptic prosthetic stem loosening (cases 6 and 7).

Pre-operative radiographs strongly suggest that 7 of the 8 patients had at least some degree of capitellar osteopenia and 3 had mild degenerative changes (grade I) at the capitellum prior to the primary metallic radial head replacement surgery (Figure 10). An important observation is that serial radiographs, a mean of 6.5 years (range, 5.0-8.1 years) after the initial prosthetic reconstruction (thus including follow-up of revisions), revealed that the capitellar osteopenia had resolved in 4 of 7 who had pre-operative osteopenia (Figures 11 and 12). Degenerative changes at the capitellum had developed in 5 additional patients (mild or grade I in 3, and moderate or grade II in 2), while it had worsened in 2 and remained stable in one of the 3 patients with pre-operative changes. Thus, at end follow-up, four patients had mild (grade I), and two had moderate (grade II) degenerative changes at the capitellum; 2 patients had a prosthetic capitellar replacement in place.

Figure 10. Antero-posterior radiographic image of the elbow prior to primary metallic radial head replacement of case 1. Moderate osteopenia of the capitellum without degenerative changes can be noted.

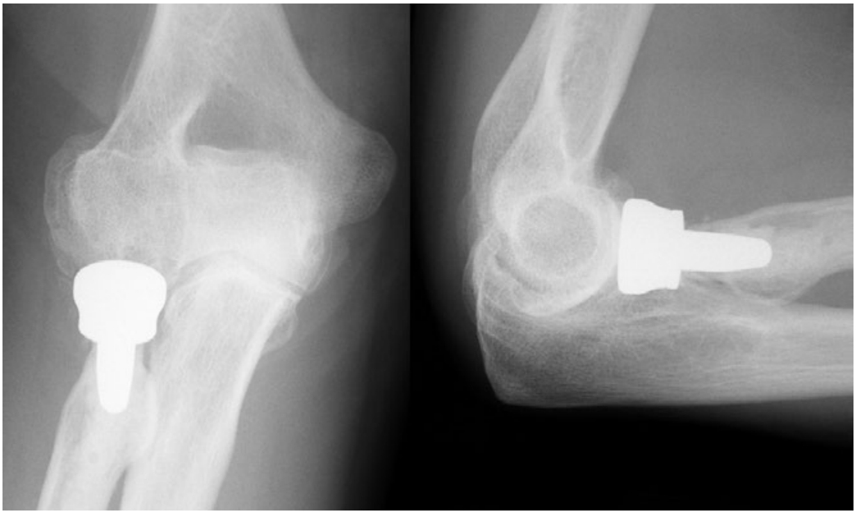

Figure 11. Antero-posterior (A) and lateral (B) radiographic images of the elbow 65 months after the primary metallic radial head replacement (cemented unipolar Avanta prosthesis) of case 5. There are mild degenerative changes, but no signs of prosthetic loosening.

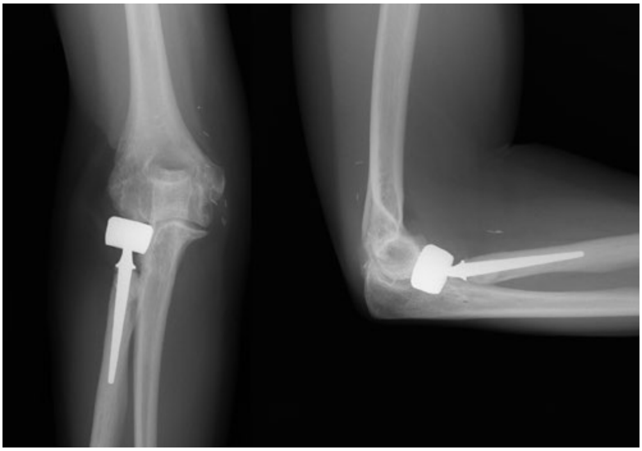

Figure 12. Antero-posterior (A) and lateral (B) radiographic images of the elbow 53 months after revision metallic radial head replacement (cemented Judet/CRFII bipolar prosthesis) of case 3. There are no signs of prosthetic stem loosening. Mild to moderate (grade I-II) degenerative changes at the capitellum can be noted.

Although 6 of the 8 patients are currently considered clinically satisfactory, only 3 of the 8 patients did well with the initial radial head replacement. Of the 5 revisions, 3 are currently considered satisfactory, although for one follow-up is short.

DISCUSSION

Treatment of chronic longitudinal radioulnar dissociation has been associated with unpredictable, but typically unfavorable outcomes[8, 12, 14, 16, 18, 27]. Metallic radial head replacement is an attractive potential treatment possibility to address residual elbow pain and dysfunction in this complex condition[19-21]. To date, only 3 reports with a total of 13 cases have documented metallic radial head replacement as treatment for chronic longitudinal radioulnar dissociation[21-23]. Judet et al. described 2 cases of delayed treatment in which a good result was obtained at 72 and 24 months follow-up, respectively[21]. Van Riet et al. described a case that developed severe capitellar erosion after treatment with a metallic radial head prosthesis 44 months after the initial injury[23]. Jungblut et al. described 10 cases, with treatment delay ranging from one month to 18 years, of which 8 are considered a success[22]. However, follow-up for 4 of those 8 successes is less than 2 years.

In our limited experience, several observations were of note. Aseptic loosening occurred in 3 of the 8 cases and 2 of these were treated initially with non-cemented stems.

The second observation highlights the persistence of symptoms of the radiohumeral joint. This is due to either the high stresses across the radiocapitellar joint resulting in osteoarthritis or malalignment of the radiohumeral joint. Two patients clearly had evidence of osteoarthritis of the radiohumeral joint and these were both successfully treated with a subsequent capitellar replacement. The remaining 4 patients that had evidence of radiohumeral joint symptoms were treated with a bipolar implant, with the thought that this would provide a more accurate articulation at this joint.

Finally, instability was observed in 5 cases. Instability of the ulnohumeral joint is related to the radiohumeral congruity and stability. Our date do not allow any significant comments with regard to the medial collateral ligament and our perspective is that this ligament does not necessarily need to be reconstructed. However, the lateral ulnar collateral ligament (LUCL) is essential and was the most common reconstructive procedure. When stable lateral ligament was realized in the operation, was of benefit to the patient.

In summary, our relatively limited series has resulted in our current approach to reconstructing the Essex-Lopresti lesion consisting of the following features: 1) all radial head implants are cemented; 2) if there is any question about alignment of the radius onto the capitellum, a bipolar device is selected; 3) if the capitellum shows significant cartilage lesion or deformity, it is replaced with a capitellar replacement; 4) the lateral ulnar collateral ligament (LUCL) is specifically addressed and, if the soft-tissue laterally is deficient, it is formally reconstructed.

These features seem to address the major deficiencies encountered in this series and hopefully will provide better outcomes in the future.

CONCLUSIONS

Metallic monoblock radial head replacement did not reliably address the functional deficiency from chronic radioulnar dissociation due to primarily malalignment and implant loosening. A cemented bipolar radial head implant may provide a better alternative as a long-term solution. Regardless, ligamentous integrity at the elbow should also be addressed at the time of the reconstruction.

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Section

IV

Metallosis after Kudo total elbow arthroplasty, what is the problem?

Chapter

7

Identifying metallosis after Kudo total elbow arthroplasty is challenging. A clinical and radiological study

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ABSTRACT

Introduction

Recently, several case reports have reported on metallosis after Kudo total elbow arthroplasty (TEA). Little is known about its occurrence after TEA. The objectives of this study are (1) to determine the incidence of metallosis on CT after Kudo TEA and (2) to explore differences in clinical parameters, Mayo Elbow Performance Score (MEPS), patient reported outcome measures (PROMs) and free cobalt and chromium serum levels between patients with and without metallosis on CT.

Methods

Cross-sectional study with a cohort of 38 patients with 45 Kudo (types 4 and 5) TEA's. Survival analysis was done on the entire cohort. Analyses for differences in clinical outcome measures, MEPS, PROM's and free cobalt and chromium serum levels between patients with and without metallosis on CT were done within the subgroup of 21 living patients with 25 prostheses.

Results

Survival was 95,3% (95% confidence interval [CI]: 89,2-100) at 5 years, 81,3% (95% CI: 68,0-94,6) at 10 years and 56,3% (95% CI: 34,5–77,9) at 15 years. Metallosis on CT was observed in 20%. The MEPS was significantly worse for patients with metallosis on CT than for those without (p=0.018). Clinical outcome measures, PROMs and ion levels were not different for both groups.

Conclusions

Metallosis after Kudo TEA is a serious problem. Although the MEPS was significantly worse for patients with than for those without metallosis on CT, it's screening potential for metallosis seemed poor. Screening by means of physical exam, free serum cobalt and chromium levels and (PROMs) is not sufficient. Screening by means of advanced imaging is warranted.

INTRODUCTION

Total elbow arthroplasty (TEA) can be a treatment option for disabling elbow pain resulting from rheumatoid, degenerative or posttraumatic conditions[1]. Although fairly good results have been reported for TEA, numbers are lower, survival is less favorable and complications are more frequent than after lower extremity arthtroplasty[1].

Total elbow prostheses may be linked or unlinked, depending on the coupling of the humeral and the ulnar components. The first 'modern' total elbow arthroplasty using bone cement (constrained type) was performed in 1972 by Dee[2, 3]. In general, most early attempts to replace the elbow joint using a prosthesis were generally not successful due to insufficient understanding of fixation techniques and elbow anatomy, kinematics and biomechanics[2]. With time, the coupling of the humeral and ulnar components has proven to be a very important variable in implant design. The early rigid-constrained prosthesis showed a high failure rate of up to 27% after 3 years due to loosening at the bone-cement interface[2, 3]. Subsequently, various unlinked designs were developed, which would reduce the stresses at the bone-cement interface, but were naturally also less constrained at the articulation[2]. It is now recognized that it is not the linkage per se, but the articular constraint that influences loosening. Semi-constrained implants, where the ulnar and humeral components are in fact linked, but some varus-valgus laxity is built-in, were introduced in the 1980's. They theoretically reduce stress at the bone-cement interface and consequently result in a lower failure rate, while also providing the necessary degree of articular constraint. To date, both unlinked and semi-constrained prostheses are used and the choice of one design over the other depends on several factors, including indication, bone quality, and certainly also surgeon preference.

The Kudo Total Elbow System is a non-constrained total elbow replacement. It consists of a cobalt-chrome humeral component that articulates in a non-constrained fashion with a polyethylene bearing titanium ulnar component. In recent years several authors have specifically mentioned the occurrence of metallosis about the Kudo prosthesis[4-9]. Likely, metallosis was also present with failures in earlier studies, but was not really appreciated as such at the time. Metallosis is defined as infiltration of metallic wear debris in periprosthetic soft and bony tissues, resulting in damage of those tissues and possibly formation of pseudotumors and implant failure[10]. Implant failure due to metallosis has been well recognized and extensively studied with metal-on-metal total hip arthroplasty (MoM THA)[10]. Those metal-on-metal articulations have been demonstrated to be subject to corrosion and wear, primarily at the taper and to a lesser extent at the articulation itself[11]. The metallic particles that are thereby formed may give rise to asymptomatic lymphocyte-dominated vasculitis-associated lesions (ALVAL) and adverse reaction to metal debris (ARMD)[12]. The unconstrained coupling of the Kudo prosthesis may lead to excessive polyethylene wear, which could eventually result in metal-on-metal impingement and subsequent formation of metallic particle debris. The mechanism by which metallic particles are formed after Kudo TEA may be different from MoM THA, but the local reaction at the tissue level is likely to be similar.

In the evaluation of prostheses with regards to metallosis several imaging strategies are available, such as conventional radiographs, ultrasound, CT-scan and MRI-scan. Even nuclear scans, such as bone scintigraphy and SPECT, could be considered. Recently, Boomsma et al. reported a CT classification (A-C) for the evaluation of MoM THA. The first clinical validation on 48- and 64-multislice systems of this CT-classification showed good intra- and interrater reliability and an independent association with revision surgery. In a multiple logistic regression prediction model this CT-classification was an independent predictor of revision and of all MoM related parameters the one that was most unlikely attributed to chance[13]. CT is generally readily available, dedicated metal artifact reconstruction techniques are increasingly available to provide better image quality and full iterative protocols give the possibility for better images with lower dose[14, 15]. Detection, interpretation and knowledge of pathology of the capsule of a joint after implantation of a prosthesis by means of CT is greatly improved due to the growing experience of screening cohorts of MoM THA with CT. In addition to imaging modalities, free cobalt and chromium serum levels have been used in the evaluation of metallosis after MoM THA[16]. There is no published data of ion levels after TEA.

The complexity and therefore clinical challenge lies in the fact that several factors may play a role in prosthetic failure, including biomechanical conditions, poor bone quality in rheumatoid patients, tissue destruction due to ALVAL/ARMD, individual vulnerability to metal ions or any combination.

The primary goal of this study was to determine the incidence of metallosis on CT-scan after Kudo TEA. The secondary goal was to explore differences in clinical outcome measures, patient reported outcome measures (PROM's) free cobalt or chromium serum levels between patients with metallosis on CT and patients without metallosis on CT.

METHODS

Approval for the study was waived by our institution's Medical Ethical Committee and each patient was informed that data concerning their case would be submitted for publication.

A cross-sectional study was performed with the cohort of 45 Kudo (types 4 and 5) TEA's (Biomet, Warsaw IN, U.S.A.) in 38 patients operated in our institution between November 1991 and June 2008. After that date the Kudo prosthesis was no longer used in our institution. There were 28 males and 10 females. The indication was rheumatoid arthritis in 35 patients (92%) with 42 prostheses (93%), primary degenerative arthritis in 2 patients (5%) and posttraumatic degenerative arthritis in one patient (3%). Six patients had a prosthesis implanted bilaterally. Mean age at surgery was 60 years (range, 36-78 years). Twenty-six patients wit 31 prostheses were alive (Figure 13). Five of those with 6 prostheses had already been revised. The remaining 21 patients with 25 prostheses underwent clinical, laboratory and radiographical evaluation. Eleven patients with 13 prostheses were confirmed deceased. One of those with a single prosthesis had been revised. For one patient with a single prosthesis the life status could not be determined. However, this patient had already been revised and could therefore be included in the survival analyses.

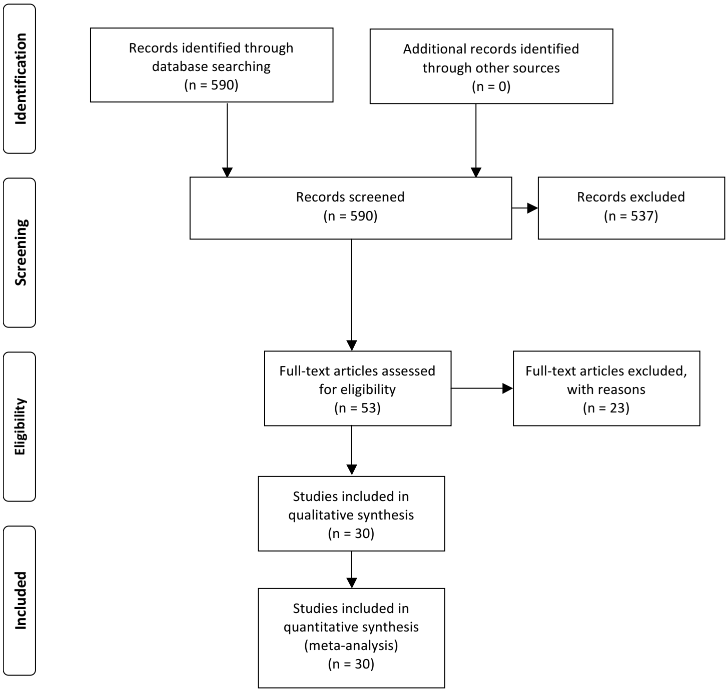

Figure 13. Patient flow chart for the entire cohort (45 arthroplasties in 38 patients).

One orthopaedic surgeon (R.G.T.) performed all operations using the posterior triceps flap approach and following the manufacturer's recommendations. The ulnar component was cemented in place, while the humeral component was uncemented. Prophylactic intravenous antibiotics were given routinely. The ulnar nerve was always identified, but not mobilized. Postoperatively, the elbow was immobilized in a posterior splint at 90° of flexion for 5 days. Then the elbow was mobilized under supervision, avoiding active extension for six weeks.

Two physicians saw all patients and performed a routine physical exam (A.H. and D.E.). Specifically, active range of motion was determined using a hand-held goniometer. Pain was graded as none, mild, moderate or severe; and the degree of valgus instability (in extension and 30° of flexion) was graded as none, mild (pain with valgus stress), moderate (instability, but no subluxation) or severe (subluxation), both in order to allow calculation of the MEPS (MEPS)[17]. For all patients the MEPS was completed and all patients completed the validated Dutch versions of the Oxford Elbow Score (OES)[18], Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire[19] and Short Form-36 Health Survey (SF-36)[20].

Free cobalt and chromium serum levels were determined. The assessments were done by our reference laboratory using inductively coupled plasma mass spectrometry[21]. The reference value for chromium was <40.38 nmol/L and for cobalt <17.0 nmol/L.

Standard orthogonal conventional radiographs were made and reviewed by a board certified musculoskeletal radiologist (M.F.B.) for loosening and/or luxation of the prosthesis, polyethylene wear, periprosthetic fracture, metal particles, periarticular ossifications (PAOs) and presence of anterior and/or posterior fat pads.

A 64-slice CT-scanner was used (Siemens, Erlangen, Germany) to scan the elbow joint. CT parameters were: 100 Kv, mAs 30, slice thickness 0.75mm, CARE dose on. Collimation 16 x 0.6. Pitch 0.85. Rotation 1.0 sec. Reconstructions in the transversal plane were made with slice thickness of 0.75 mm with an increment of 0.4 mm. Reconstructions were processed axial, sagittal and coronal. Reconstructions were made, slice 2 mm with an increment of 2 mm from U70u sharp Filter. Window width to window level values were set at 3200: 700. No dedicated metal artifact reduction software tool was applied. All examinations were reviewed on a workstation running Agfa IMPAX version 6.3.1.4537 with BARCO monitors type MDCC3120-DL, color, resolution 1536 x 2048, display orientation portrait, physical size 31.8 x 42.4 cm / 12.52 x 16.69 inch. One board certified musculoskeletal radiologist (M.F.B.) with extensive experience in reading scans of metal-on-metal total hip arthroplasties (MoM THA) read all the scans. Because of a lack of a classification system for the reactive capsule in the elbow after total elbow arthroplasty all patients were scored with a simplified designed CT classification system used for the evaluation of large head MoM THA, which has shown good inter-rater reliability and significant association with serum ion levels and revision rate[13]. Elbows were scored A or B. Category A is, in concordance with grade A in the CT-classification for the hip mentioned earlier, hereby defined as normal postoperative reactive joint capsule of up to 6mm. Category B, resembling category B and C in the classification for the hip, is defined as extension, either symmetrical or eccentric, of the elbow joint capsule. In our opinion this represent capsular thickening with mass effect due to the inflammatory response to polyethylene and metallic wear of the prostheses. Kaplan-Meier survival analysis was done on the entire cohort with revision for any reason as endpoint. As revision we naturally considered the prostheses that had already been revised at the time of this cross-sectional study, but also the prostheses that were considered a failure and were indicated for revision in the realm of this cross-sectional study and were indeed revised shortly after. Deaths without revision were censored at the date of death. Prostheses that were implanted in the same patient were treated individually. Survival at 5, 10 and 15 years was calculated and presented 95% confidence intervals (CIs).

Differences in clinical outcome measures, free serum cobalt and chromium levels and metallosis between CT-scan groups A and B were explored within the subgroup of living patients using two-sided Student t-tests. Clinical outcome parameters that were considered were flexion-extension and pronation-supination arc, MEPS, Oxford Elbow Score (OES), Disabilities of Arm, Shoulder and Hand questionnaire (DASH) and the Short-Form 36 health survey (SF-36). For all tests a p-value less than 0.05 was considered significant. Analyses were performed using SPSS 19.0 (IBM Corporation, Armonk, NY, USA).

RESULTS

Survival analysis

Three of the 25 elbows in 3 of the 21 patients that formed the group of living patients that underwent clinical, laboratory and radiological evaluation were indicated for revision and indeed revised shortly after (Figure 3). Consequently, there were eventually 11 (24%) of 45 prosthesis failures in 9 (24%) of 38 patients in the total cohort at a total follow-up of 441.3 prosthesis-years (Figure 14). After 5 years there were 40 prostheses remaining, resulting in a 5-year survival of 95.3% (95% CI: 89.2–100). After 10 years there were 20 prostheses remaining, resulting in a 10-year survival of 81.3% (95% CI: 68.0–94.6). After 15 years there were 8 prostheses remaining, resulting in a 15-year survival of 56.3% (95% CI: 34.5–77.9).

Clinical, laboratory and radiological results

Five (20%) of 25 elbows in 5 (24%) of 21 patients that formed the group of living patients that underwent clinical, laboratory and radiological evaluation had evident metallosis on CT-scan (graded as “B”) (Figure 15). Two of those were indicated for revision; the others had no symptoms at the time of the study. Neither the flexion-extension arc (p=0.70), nor the pronation-supination arc (p=0.19) was different between patients without or with metallosis on CT (Table I). Also free cobalt (p=0.54) and chromium (p=0.76) levels were not different between patients without or with metallosis on CT (Table II). The MEPS was significantly worse for patients with compared to patients without metallosis on CT (p=0.018)(Table III). When considering the MEPS with a fair or poor outcome as a negative test-result an with a good or excellent outcome as a positive test result, the sensitivity and specificity of the MEPS for identifying patients with metallosis on CT-scan were 50% and 90%, respectively; and the positive and negative predictive values were 60% and 86%, respectively. Finally, no significant differences between patients with or without metallosis on CT were seen for the OES pain (OES-p), functional (OES-f) and socio-psychological (OES-s) subscales (p=0.06, p=0.13 and p=0.32, respectively), the DASH (p=0.09) and the SF-36 physical component score (SF-36 pcs) and mental component score (SF-36 pcs) subscales (p=0.88 and p=0.98, respectively) (Table III).

Table 1. Range of motion parameters (mean and standard deviation)

	Overall	No metallosis on CT-scan ("A")	Metallosis on CT-scan ("B")	*p*-value
Flexion-extension arc	98 (16.1)	98 (17.6)	95 (8.7)	0.70
Pronation-supination arc	134 (36.6)	130 (38.4)	154 (20.7)	0.19

Table 2. Free ion serum levels (mean and standard deviation)

	Overall	No metallosis on CT-scan ("A)	Metallosis on CT-scan ("B")	*p*-value
Cobalt	45.1 (64.4)	49.2 (71.4)	28.8 (15.6)	0.54
Chromium	41.6 (37.4)	42.8 (41.5)	36.9 (12.9)	0.76

Table 3. Mayo Elbow Performance Score and patient reported outcome measures (mean numerical score and standard deviation)

	Overall	No metallosis on CT-scan ("A)	Metallosis on CT-scan ("B")	*p*-value
MEPS	784.0 (20.6)	88.8 (14.3)	65.0 (31.8)	0.018
OES-p	79.5 (29.0)	85.0 (22.9)	57.5 (42.3)	0.06
OES-f	75.8 (27.9)	80.0 (21.1)	58.8 (45.6)	0.13
OES-s	79.8 (27.0)	82.5 (22.5)	68.8 (42.2)	0.32
DASH	36.2 (23.2)	32,2 (19.9)	52.2 (31.1)	0.09
SF-36 pcs	32.7 (15.4)	32.4 (15.2)	33.6 (17.8)	0.88
SF-36 mcs	53.1 (14.1)	53.0 (15.8)	53.2 (4.3)	0.98

MEPS: Mayo Elbow Performance Score
OES-p, OES-f and OES-s: Oxford Elbow Score; pain, function and socio-psychological subscale, respectively.
DASH: Disabilities of the Arm, Shoulder and Hand questionnaire.
SF-36 mcs and pcs: Short Form (36) Health Survey; mental and physical component score, respectively.

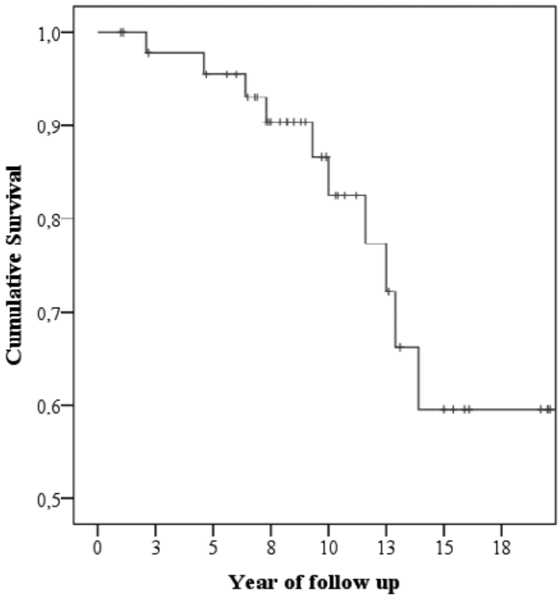

Figure 14. Kaplan-Meier survival curve for the entire cohort (45 Kudo total elbow arthroplasties).

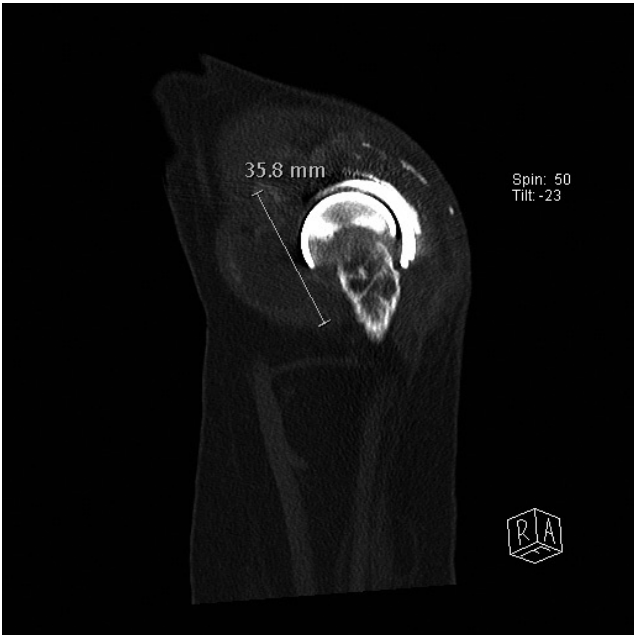

Figure 15. Sagittal reconstruction of a 64-slice CT-scan without metal artefact suppression technique of the elbow after total elbow arthroplasty. There is anterior and posterior bulging of the joint capsule. Different densities can be appreciated. Tissue with higher density, representing a thickened fibrous capsule with calcifications, is seen delineating tissue with lower density, representing tissue with higher water content.

DISCUSSION

To our knowledge this is the first time the occurrence of metallosis after TEA and a possible correlation with clinical, laboratory or patient reported outcome measures were the primary topic of study. Metallosis on CT-scan was observed in 20% of the elbows available for evaluation. There was an association between MEPS and metallosis on CT-scan, but test performance would be poor when used as a screening tool. There was no association between flexion-extension and pronation-supination arc, or between free cobalt and chromium serum levels and metallosis on CT-scan.

Survival of the Kudo TEA in this cohort was in range of what has been reported in the literature[7, 9, 22-24].

Reports of metallosis after Kudo TEA, or after TEA in general for that matter, are few in number. Kudo *et al* were the first to report on fracture of the humeral component with metallosis after TEA. In their series of 32 TEA's in 26 patients they had 2 fair and 5 poor results according to the MEPS[7]. All five elbows with a poor result underwent revision and in all metallosis was observed. Dos Remedios et al. reported 5 cases of metallosis in their series of 41 TEA's in 35 patients[6]. No laboratory tests were done and imaging was limited to conventional radiographs. Outcome after the revisions was not reported. Asahina *et al* reported a case in which metallosis after Kudo TEA became apparent as blue-greyish pigmentation of the forearm[4]. No orthopaedic work-up was done. Although not specifically stated, there did not seem to be any pain and/or dysfunction. Skyttä et al. observed one failure of a Kudo TEA due to excessive polyethylene wear and metallosis in a series of 21 Kudo and 21 Souter-Strathclyde prostheses[9]. No detailed data on the case was provided. De Greef et al. reported twelve revision cases for aseptic loosening of primarily Kudo prostheses, in all of which severe metallosis was noted preoperatively[5]. No laboratory tests were done and only conventional radiographs were obtained. The revisions were challenging. Sayed-Noor and Sjödén reported one case in which extensive polyethylene wear and severe metallosis were noted at revision surgery 6 years after the primary Kudo TEA[8]. A laboratory test was not done and imaging was limited consisted of conventional radiographs. Outcome after the revision was favorable. Although these reports did bring metallosis after TEA under the attention, they do not provide a lot of information on that guides us in dealing with the problem.

Other imaging modalities can be used in the screening and diagnosis of metallosis, such as ultrasound and MARS-MRI, and all have their specific advantages and disadvantages[25].We chose to use CT, because we have large experience with CT and metallosis.

Several limitations are recognized. Due to the cross-sectional nature of the study no preoperative outcome data was available or obtainable on the 9 prostheses in 8 patients that had already been revised. Particularly data on those patients would be needed to explore a possible association between clinical, laboratory and radiological outcome measures and prosthetic failure and true metallosis, which could therefore not be done in this study. In addition, a number of patients had died of unrelated causes. Also for those no outcome data was available or obtainable. Further, no dedicated metal artefact reduction protocol was used for the CT-scans. Such protocols are known to reduce metal artifacts in comparison with conventional scanning and consequently facilitate evaluation of the periprosthetic soft tissues. We felt confident, however, that the distinction between 'metallosis' and 'no metallosis', which was the primary radiological parameter in this study, could be reliably made. Also, the diagnosis of metallosis on a CT-scan was not confirmed by tissue biopsy. However, Bosker et al. have shown at the hip that in the majority of cases of suspected pseudotumor on CT the diagnosis was confirmed on biopsy[16]. Unfortunately, CT findings were not correlated with ultrasound.

Now that the occurrence of metallosis after Kudo TEA is recognized, the question arises what the best follow-up strategy should be. Because so little is known about metallosis after Kudo TEA and the effects of metallosis on periprosthetic soft tissues can be detrimental, routine follow-up seems warranted. The true extent of metallosis in patients that show signs of metallosis on CT-scan is not known. Also, it is not know whether patients with no signs on metallosis on CT-scan indeed don't have metallosis. In other words, the sensitivity and specificity of the various imaging modalities for true metallosis are unknown, as is the true incidence of metallosis. However, since no clinical, laboratory or patient reported outcome measure has been demonstrated to be good screening tool even for metallosis on CT-scan, imaging is the only way to screen the elbow for metallosis. We propose a yearly clinical examination with MEPS and advanced imaging every 5 years. Imaging could be ultrasound, CT-scan or MRI-MARS. Centralizing treatment and follow-up of these patients, possibly even in the setting of a (multicenter) prospective study, seems advisable. Ongoing study of the value of laboratory studies is of interest. At this moment their use as screening tool for metallosis is not supported. Then it is also not clear what to do with patients that are diagnosed with metallosis, but have no symptoms. So far, we have not revised those prostheses; the complication rate is high with revisions in general and outcome unpredictable. Furthermore, there are the concerns about possible toxic effects of prolonged exposure to elevated free chromium and cobalt serum levels[26-29].

CONCLUSIONS

Metallosis after Kudo total elbow arthroplasty (TEA) is a serious problem; it was observed in 20% of the elbows. Although the MEPS was significantly worse for patients with metallosis on CT than for those without, it's screening potential for metallosis seemed poor. Screening by means of physical exam, free serum cobalt and chromium levels and PROMs is not sufficient. Screening using advanced imaging is warranted. A follow-up protocol has been proposed.

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Section

V

General discussion and conclusions

Chapter

8

General discussion and conclusions

Andras Heijink

"DO BIOMECHANICAL FACTORS PLAY A ROLE IN THE PATHOGENESIS OF OSTEOARTHRITIS?"

Osteoarthritis is the most common joint disease. It should be considered a heterogeneous group of syndromes, affecting all joint tissues[1]. The primary changes with osteoarthritis occur in the articular cartilage, followed by associated changes in the subchondral bone[2, 3]. Recently, more focus has been placed on the subchondral bone as the primary cause of symptomatic disease[4-7].

The etiology of osteoarthritis is multifactorial and to date not fully understood. Age is the major independent risk factor of osteoarthritis, however, ageing and osteoarthritis are inter-related, not inter-dependent. Where cartilage senescence is, to some extent, part of normal ageing, the relationship between ageing and the development of osteoarthritis is not fully understood. It is becoming apparent that ageing changes in the musculoskeletal system contribute to the development of osteoarthritis by working in conjunction with other factors, both *intrinsic* and *extrinsic* to the joint[3].

Osteoarthritis results from failure of chondrocytes to maintain the homeostasis between synthesis and degradation of these extracellular matrix components[2-4, 8, 9]. This disruption of homeostasis results in increased water content and decreased proteoglycan content of the extracellular matrix as well as weakening of the collagen network due to decreased synthesis of type II collagen and increased breakdown of pre-existing collagen[2]. Furthermore, there is increase apoptosis of chondrocytes. At first, compensatory mechanisms, such as increased synthesis of matrix molecules and proliferation of chondrocytes in the deeper layers of the cartilage, are able to maintain the integrity of the articular cartilage, but eventually loss of chondrocytes and changes in extracellular matrix predominate and osteoarthritic-changes develop[10].

Compared to osteoarthritis of the hip and knee, symptomatic osteoarthritis of the elbow is rare, but radiographic degenerative changes are being noted more frequently[11-13]. Rheumatoid arthritis has been the most frequent form of osteoarthritis at the elbow, followed by posttraumatic arthritis. With improved treatment of rheumatoid arthritis, these indications are slowly changing. The most common causative factor in primary osteoarthritis of the elbow seems to be related to microtraumata and to sports that put stress on the upper limbs, although studies of these associations have produced contradictory results[14-16].

Clinical experience shows that the development and progression of posttraumatic osteoarthritis is not necessarily due to rapid wear of an irregular articular surface alone[17]. The relationship between residual osseous depression of the joint surface and development of osteoarthritis is very inconsistent. Even when joint congruity, alignment and stability are adequately restored, the joint may degenerate[18]. On the other hand, it is apparent that normal articular surfaces often degenerate following injuries as well[18].

Joint loading can induce a wide range of metabolic responses in articular cartilage. The mechanisms by which chondrocyte-mediated production of extracellular matrix components responds to mechanical stimuli are only beginning to be understood[2, 9]. There are multiple regulatory pathways by which chondrocytes sense and react to mechanical stimuli. These including upstream signaling pathways and mechanisms that may lead to direct changes at the level of transcription, translation, post-translational modifications, and cell-mediated extracellular assembly and degradation of matrix[2, 19, 20]. Also, there are multiple pathways by which physical stimuli can alter not only the rate of matrix production, but also the quality and functionality of newly synthesized proteoglycans, collagens, and other molecules[2].

Normal synovial joints can withstand repetitive loading during normal activities for a lifetime without developing osteoarthritis[9, 21]. However, mechanical demand that exceeds the tolerance, that is the ability to repair and maintain itself, of the articular cartilage plays an important role in the development and progression of joint degeneration in all forms[2, 9]. Excessive mechanical surface contact stress can directly damage articular cartilage and subchondral bone and adversely alter chondrocyte function[9]. In experimental settings, it has been shown that cartilage cannot survive more than 25MPa of impulsive contact stress. Since physiological peak contact stresses are several fold less, there appears to be a built-in 'safety' factor[9]. The in vivo tolerance of human cartilage to surface contact stress is not known, but an association between high mechanical demand and degenerative changes of the hip joint has been observed. In addition, joint apposition and engagement are important determinants of cartilage damage following an impact event. Also, substantial acute micro-damage (e.g. micro-fractures, cartilage fissures, chondrocytes death, proteoglycan release) can result from impact levels far below the level needed to produce a macroscopic fracture. This micro-damage may progress to a detectable compromise of the mechanical integrity of the articular cartilage. Furthermore, loading rate and shear stress are important variables[22-24].

From experimental data it is observed that certain patterns of increased mechanical stress, in particular high levels of shear stress, increase production of free oxygen radicals and decrease synthesis of proteoglycans; and that this increased *oxidative stress* on chondrocytes accelerates chondrocyte senescence[17]. It is thus concluded that chondrocyte senescence contributes to the risk of posttraumatic articular cartilage degeneration by decreasing the ability of the cells to maintain and repair the tissue[17]. This oxidative stress-related damage is in addition to the damage due to chondrocyte senescence resulting from increased metabolic stress resulting from the impact of trauma and following the repair response that was already taking place[17].

In the second section of this thesis **(chapter 2)**, we examine the available basic science, preclinical and clinical evidence regarding the role of *several unfavorable* *biomechanical conditions* about the elbow on the development of osteoarthritis. We focus on posttraumatic osteoarthritis, osteochondritis dissecans, elbow joint instability, and malalignment of the elbow.

Elbow fractures often seem to be the result of a series of complex biomechanical events and therefore frequently involve associated ligamentous injuries. Because these associated injuries and their consequences on the elbow joint may all contribute to the development of osteoarthritis, it is difficult to isolate the role of each individual injury or effect. The role of overload or repetitive microtrauma as a risk factor of posttraumatic osteoarthritis of the elbow is not yet clear. Surveys in Scotland revealed miners working at the coalface to have a higher prevalence of elbow osteoarthritis. An association of sports-related exercise, in the absence of macroscopic trauma, and increased prevalence of elbow osteoarthritis has never been reported. In addition, radial head resection in case of ulnohumeral degeneration increases stress on the ulnohumeral compartment and is therefore suggested to lead to aggravation of pre-existing degeneration. In general, the natural course of cartilage defects and untreated osteochondritis dissecans of the elbow remain, to this day, to be not fully understood. Larger lesions and older age seem associated with more symptoms and radiographic changes in the long term. No data is available on whether any of the available cartilage defect repair strategies stop or slow down the development or progression of osteoarthritic changes at all.

Elbow joint instability seems to play a role in the development of osteoarthritis in the long term, although the association between the two is not yet clearly defined. The effectiveness of reconstructing elbow stability by ligamentous repair, augmentation or reconstruction to prevent elbow osteoarthritis has never been investigated.

There is no data available on the effect of malalignment of the elbow on forces across the elbow joint. However, with the understanding that the tissues of the upper extremity are stressed to similar levels as those of the lower limb and that forces across the elbow are in fact very large when the joint is extended from a flexed position, it seems only reasonable to assume an association between malalignment and osteoarthritis.

Conclusions
Biomechanical conditions about the elbow do indeed play a role in the development of osteoarthritis of the elbow. The pathophysiological mechanisms by which they do so are complex and to this date not fully understood. Posttraumatic osteoarthritis is a well-recognized condition. Posttraumatic osteoarthritis is increasingly acknowledged to be more a mechanically induced biological problem than a biomechanical problem

per se. Instability seems to play a role, but the relation between instability and degenerative arthritis of the elbow is not yet clearly defined. The roles of cartilage defects and untreated osteochondritis dissecans remain unclear to date. It is important to realize that there are many other etiologies that can cause osteoarthritis, some of which are also via mechanically induced pathophysiological changes to the articular cartilage, subchondral bone and other joint tissues.

Clinical implications and lessons learned

It is important to understand and communicate to the patient that even a perfectly reconstructed joint, in terms of joint congruency and stability, may still degenerate over time. The in vivo tolerance of articular cartilage to both acutely or chronically increased stress and the potential to repair and remodel itself remain largely unknown. Chondrocyte senescence, resulting from the combination of both metabolic and oxidative stress related damage, contributes to the risk of posttraumatic articular cartilage degeneration by decreasing the ability of the cells to maintain and repair the tissue. Possibly, a period of non-weightbearing, which has shown to be protective against some types of chemically induced damage to chondrocytes in experimental studies, and biologic interventions, which have shown to decrease mechanical stress-induced chondrocyte damage in experimental studies, will be important adjuncts to fracture treatment in the near future[9, 25-29].

"BIPOLAR RADIAL HEAD ARTHROPLASTY, GOOD OR BETTER?

It is generally accepted that, when treating radial head fractures, preserving or restoring the integrity of the native radial head is preferred, but that when this is not feasible or not advisable, prosthetic replacement should be considered[30]. Generally, Mason type I fractures are treated conservatively with early range of motion, Mason type II fractures are treated by open reduction-internal fixation or conservatively, and Mason type III fractures are replaced in most and reconstructed in some cases. MRI studies have demonstrated a high prevalence of associated ligamentous injuries that compromise elbow stability with Mason type 3 fractures[31-33]. Replacing the radial head is then required, in order to allow healing of those damaged stabilizing soft tissues. Radial head arthroplasty (RHA) can also be a salvage procedure after failed osteosynthesis or failed conservative treatment.

Prosthetic radial head replacement can be challenging. With acutely treated isolated radial head fractures satisfactory outcome can be expected in about 85% of cases, while with cases treated in a delayed fashion this is at best about 50%[30]. Although it is generally assumed that associated injuries about the elbow will have a significant effect on outcomes after RHA, the true effect of such injuries has not yet been established.

Radial head prostheses may be categorized according to material (silicone, polyethylene, pyrocarbon, metal), modularity (monoblock *vs.* modular), polarity (uni- or monopolar *vs.* bipolar) or fixation (cemented, press-fit, intentional loose-fit, or fixation with an expandable stem).

The bipolar design is thought to have several theoretical advantages. The bipolar articulation allows for free rotation and therefore, theoretically, reduced abrasion of the capitellar cartilage and reduced stress at the implant-to-cement and cement-to-bone interfaces during forearm rotation as compared with the monopolar design. In addition, radiocapitellar joint contact area may be increased and consequently radiocapitellar contact pressure reduced, which may also reduce radiocapitellar cartilage abrasion[34]. A bipolar prosthesis may also accommodate to some degree to malalignment of the radius onto the capitellum, which may be the case in certain posttraumatic conditions where soft tissue contraction and scaring have occurred. The cemented prosthesis might be better able to do this than the more recently introduced press-fit (uncemented) version. A disadvantage may be that bipolar prostheses have been shown not to provide as much stability as monopolar prostheses in cadaveric models[34-36]. Also, the polyethylene-articulating surface may be subject to wear. Cemented bipolar prostheses are rotational-dependent and therefor technically more demanding than the press-fit version.

The English, peer-reviewed literature on bipolar metallic RHA is limited[37-46]. Short- to mid-term results seem favorable, however, there are no methodologically sound studies available to compare bipolar and monopolar prostheses. Long-term results are not available either.

Concomitant fracture of the radial head, tearing of the interosseous ligament and disruption of the distal radioulnar joint, commonly referred to as Essex-Lopresti injury, causes longitudinal radioulnar dissociation[47-50]. The resulting axial instability of the forearm leads to proximal migration of the radius relative to the ulna, which causes secondary disability at the elbow and wrist due to radiocapitellar and ulnocarpal abutment and altered mechanics[51-53]. With acute treatment by RHA, favorable results may be possible[47-50, 54-56]. Results are usually unsatisfactory in about 80% when left untreated or treated in delayed fashion[47-50, 57-64]. With a delay in treatment, the proximal radial migration becomes relatively irreducible, presumably due to scarring and soft-tissue contraction. In addition, stresses on the radial head across the elbow are high and unbalanced in the setting of radioulnar instability related to disruption of the interosseous membrane and triangular fibrocartilage complex at the wrist. These high unbalanced stresses tend to cause tilting of the head of the implant and angular displacement of the prosthesis within the medullary canal. The optimum treatment strategy for chronic LRUD is not yet defined.

Metallic RHA has been employed as a treatment option for chronic cases of LRUD, although documentation is limited to 3 reports involving 13 cases.[42, 65, 66]. Biomechanical studies have demonstrated that metallic radial head prostheses potentially provide the necessary stiffness to withstand the increased axial forces that act on the radius in that condition without adverse biological reaction[55, 65, 66].

In the third section of this thesis **(chapters 3, 4, 5 and 6)**, we report our experience with cemented and press-fit bipolar RHA. We also investigate if prosthesis design characteristics influence outcomes after RHA. In addition, we evaluate if bipolar radial head prostheses are able to compensate for radiocapitellar malalignment and chronic longitudinal radioulnar dissociation.

In **chapter 3**, the mid-term (average follow-up 50 months; range, 24-72 months) results are reported of a series of 23 cemented bipolar metallic radial head arthroplasties using the RHS® prosthesis (Tornier, Montbonnot-Saint-Martin, France; Figure 3, B) as treatment for acute radial head fracture, failed earlier treatment or posttraumatic sequelae. There had been one (4%) revision, rendering a failure rate of ≤0.00395 per person-month of follow-up. Interestingly, this revision involved dissociation of the prosthesis, which had only been reported once before in the literature[67]. There were 2 (8%) additional radiological failures in the subluxated position; one due to malalignment of the radius onto the capitellum, and another due to ulnohumeral erosion. Altogether, there were 3 (13%) radiological failures, one of which also was a clinical failure. The overall results of this study compare well with the literature. Twenty percent had a complication other then revision, which required surgical intervention in only one patient (4%). The bipolar design seems to be able to accommodate for radiocapitellar malalignment. We consider these results to be as favorable. **Chapter 4** holds the first peer-reviewed publication on press-fit bipolar metallic RHA (RHS® prosthesis, Tornier; Figure 3, A). Midterm (average follow-up 48 months; range, 28-73 months) results were reported for a series of 30 press-fit RHAs. There were 3 revisions (11%), rendering a failure rate ≤0.0064 per person-month of follow-up. Two revisions involved conversion to prosthetic radiocapitellar hemiarthroplasty; one for instability, and another for symptomatic capitellar abrasion. The third revision involved exchange of the articular component with a larger one for instability. In all revisions the stem was fixed well, suggesting the press-fit fixation performs well. There was one (4%) additional radiological failure. Thirty percent had a complication other than revision, which required surgical intervention in 5 cases (17%). Despite the relatively high mid-term revision rate, we consider these results to be as favorable. The reason being that there was adequate press-fit fixation in all cases and revision surgery for conversion to radiocapitellar prosthetic hemiarthroplasty can be prevented, to some extent, by adding the capitellar component during the initial surgery, when capitellar bone quality is poor. In **Chapter 5**, the results of a systematic review of the English literature on radial head arthroplasty from January 1940 to May 2015 are reported.

The incidence of revision after RHA is 8% in 2174 person-years of follow-up with an estimated crude revision rate of 2.06 per 100 person-years of follow-up. There does not seem to be an effect of prosthesis polarity, material and fixation technique on the revision rate, or post-operative ranges of motion. An additional 7% had needed secondary surgery other than revision and in total 23% had any kind of complication. On the basis of our analysis, there seems to be no evidence to support one type of radial head prosthesis over another. The only exception is that silicone prostheses have been shown to be biologically and biomechanically insufficient. In **chapter 6**, the results of metallic RHA as treatment of chronic LRUD are reported. All, but one, involved a monopolar prosthesis. Five of the 8 prostheses had failed after a mean of 3.0 years (range, 1.0 to 5.7 years). Revision to bipolar radial head replacement was successful in the short term in 2 out of 3 cases that failed from aseptic loosening. One out of 2 failures due to painful radiocapitellar arthritis was salvaged with a capitellar replacement. It was concluded that monopolar metallic RHA did not reliably address the functional deficiency from chronic radioulnar dissociation, primarily due to wear of the capitellar cartilage and implant malalignment and loosening. It was suggested that a bipolar radial head prosthesis, alone or combined with capitellar replacement, may provide a better alternative as a long-term solution.

An important observation related to the studies presented in chapters 4, 5, 6 and 7 is that clinical and radiographic outcome data are reported in the literature with great variability and inconsistency. The peer-review process appears to be falling short in ensuring uniformity and quality in data reportage.

Conclusions

The mid-term results of our series of both cemented and press-fit RHA are considered favorable. However, there certainly were failures, complications and challenges. On the basis of our systematic review, there seems to be no evidence that prosthesis design characteristics affect outcome after RHA. Consequently, there is no evidence that the bipolar design is associated with better outcomes than the unipolar design. It seems that bipolar prostheses are able to compensate, to some extent, for radiocapitellar malalignment. We think that because of the larger permitted neck-shaft angulation of the cemented prosthesis as compared with the press-fit RHS® prosthesis (17.5° and 10°, respectively), the cemented prosthesis may be better capable of compensation for radiocapitellar malalignment than the press-fit prosthesis.

Metallic monoblock RHA, as part of the overall treatment, did not reliably address the functional deficiency from chronic LRUD primarily due to malalignment, implant loosening and the capitellar cartilage wear.

The peer-review process appears to be falling short in ensuring uniformity and quality in data reportage.

Clinical implications and lessons learned

For the treatment of unreconstructable fractures of the radial head or posttraumatic sequelae after such fracture, there is currently no evidence to support one type of radial head prosthesis over another. The only exception is silicone prostheses, which have been shown to be biologically and biomechanically insufficient. We suggest considering a bipolar prosthesis, depending on bone quality either press-fit or cemented, in case of concerns about radiocapitellar alignment. If capitellar bone or cartilage quality is poor, one should be prepared to perform a capitellar resurfacing arthroplasty during the index operation.

The optimal treatment for chronic LRUD remains to be defined. Monopolar RHA, as part of the treatment of chronic LRUD, is insufficient. Whether a bipolar prosthesis, with or without a capitellar component, would perform better is not known. Treatment with a APTIS® distal radioulnar prosthesis (APTIS medical) is a recently introduced alternative with promising short-term results.

With the vastly increasing number of publications in the medical literature, the finding that the peer-review process is seriously falling short in ensuring sound data reportage should prompt *us* (the medical community) to have a discussion about guidelines and formats for data reportage.

"METALLOSIS AFTER KUDO TOTAL ELBOW ARTHROPLASTY, WHAT IS THE PROBLEM?"

Metallosis is defined as infiltration of metallic wear debris in periprosthetic soft and bony tissues. The metallic particles may give rise to asymptomatic lymphocyte-dominated vasculitis-associated lesions (ALVAL) and adverse reaction to metal debris (ARMD), resulting in damage of those tissues and possibly formation of pseudotumors and implant failure[68]. Implant failure due to metallosis has been well-recognized and extensively studied with metal-on-metal total hip arthroplasty (MoM THA)[68]. The unconstrained coupling of the Kudo total elbow prosthesis may lead to excessive polyethylene wear, which could eventually result in metal-on-metal impingement and subsequent formation of metallic particle debris**.** Reports of metallosis after Kudo TEA, or after TEA in general for that matter, are few in number and have been discussed in detail in chapter 8.

In the fourth section of this thesis **(chapter 7)**, we report the results of our investigation of the occurrence of metallosis on CT-scan after Kudo TEA and exploration differences in clinical outcome measures, patient reported outcome measures (PROMs), and free cobalt and chromium serum levels between patients with and those without metallosis on CT. To our knowledge, this is the first study with metallosis after TEA as primary topic.
We found that clinical parameters, PROMs and free serum cobalt and chromium levels were no different between patients with and without metallosis on CT. The MEPS was significantly worse for patients with metallosis compared with patients without metallosis. However, test performance would be poor when used as a screening tool with good or excellent outcomes being considered as a positive test result and fair or poor outcomes being considered as a negative test result.

It is important to realize that, because of the cross sectional nature of our study, we could only collect data on the patients that were still alive and had not yet undergone revision surgery. This unfortunately made it impossible to investigate the relation between metallosis and prosthesis failure rate, which is obviously a key interest when evaluating a specific prosthesis or complication. Also, if data on all patients would been prospectively collected from the time of surgery, our conclusions would have been based on larger numbers and would therefore be stronger. We acknowledge this limitation, but at the same time emphasize that this is the first study focusing on metallosis after TEA and that it is unlikely that any research group has this data available at this time.

It is also important to realize that we used the observation of metallosis on CT-scan (*metallosis on CT*) as the formal diagnosis of metallosis. It would have been very informative to have this diagnosis confirmed by needle biopsy. The risk, albeit small, of infection after such a biopsy and the fact that we collected the data in this old and fragile population as part of routine clinical follow-up have led us to not consider this. However, a study by Bosker et al. has shown that in the majority of cases of suspected pseudotumor at the hip on CT, the diagnosis was confirmed on biopsy[69].

Because metallosis after Kudo TEA is an important problem and the effects of metallosis on periprosthetic soft tissues can be detrimental, our opinion is that routine follow-up of these prostheses is mandatory. Unfortunately, the true extent of metallosis in patients that show signs of metallosis on CT-scan is not known. Also, it is not known whether patients with no signs on metallosis on CT-scan indeed do not have any metallosis. In other words, the sensitivity and specificity of the various imaging modalities for true metallosis are unknown, as is the true incidence of metallosis. However, since none of the evaluated clinical and laboratory outcome parameters, nor any of the evaluated PROMs, appeared to be able to function as a reliable screening tool, advanced imaging seems the only way to screen the elbow for metallosis. We propose a yearly clinical examination with MEPS and advanced imaging every 5 years. This advanced imaging could consist of ultrasound, CT-scan or MRI-MARS. Centralizing treatment and follow-up of these patients, possibly even in the setting of a (multi-center) prospective study, seems advisable.

At this point, it is also not clear how to act with patients that are diagnosed with metallosis, but have no symptoms. So far, we have not revised those patients, since the complication rate after revision surgery is high and outcomes unpredictable. The obvious question is, if ‘early’ revision, when metallosis starts developing and may even still be asymptomatic, would have better outcomes than revision at the time the metallosis becomes symptomatic or secondary complications occur. We need a better understanding of the relation between metallosis and prosthesis failure to guide us with these challenging decisions.

Based on our study, the use of free cobalt and chromium serum levels as screening tools for metallosis after TEA is not supported. However, our study has limitations and our findings will need to be corroborated by others. Ongoing study remains of interest; obviously, a blood test as a screening tool for metallosis would be ideal; it avoids radiation and reduces costs. Furthermore, there are reports of toxic effects of prolonged exposure to elevated free chromium and cobalt serum levels, including neurological symptoms, cardiomyopathy, and hypothyroidism[70]. There is also concern about mutagenic and carcinogenic potential, which remains an active area of research.

There is currently no universally accepted cut-off that defines elevated cobalt or chromium concentrations in patients with metal hip prostheses, although several threshold concentrations have been proposed[70]. In our study we have therefore used the absolute concentrations in order to explore a possible association between metallosis and free cobalt and chromium serum levels.

In our experience, identification of excessive polyethylene wear with subluxation and metal-on-metal impingement of the humeral and ulnar components was very discordant between conventional radiographs and CT-scans, because of variations in position of the arm. The presence of metallic particles on conventional radiographs was, in our experience, an inconsistent parameter; they were not noted on conventional radiographs of patients that showed evident metallosis on CT-scan. Perhaps metallosis has to be advanced before it can be appreciated on conventional radiographs. For these reasons, we find conventional radiographs to be unreliable when confirming the diagnosis of metallosis and would then always obtain advanced imaging.

Conclusion

Metallosis after Kudo TEA is indeed a problem of significance, since it was observed on CT-scans of 20% of the elbows. On the basis of our analysis the use of clinical parameters, PROMs or free cobalt and chromium serum levels as screening tool for metallosis after TEA is not supported. The MEPS is significantly worse for patients with metallosis compared with patients without metallosis, but the MEPS is not a reliable screening tool either. In our experience, ruling out metallosis on the basis of conventional radiographs is not reliable.

Clinical implications and lessons learned

Because metallosis after Kudo TEA is an important problem and the effects of metallosis on periprosthetic soft tissues can be detrimental, our opinion is that routine follow-up of these prostheses is mandatory.

However, screening for metallosis by means of physical exam, free serum cobalt and chromium levels and PROM's is not sufficient. Routine follow-up with advanced imaging is necessary. A follow-up protocol has been proposed.

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Appendix

Summary

Samenvatting

Dankwoord / Acknowledgement

SUMMARY

This thesis originates from our interest in both (*i*) the effect of biomechanical factors, particularly prosthesis design characteristics, on outcomes after elbow arthroplasty and (*ii*) partial arthroplasties of the elbow.

First, we aim to identify biomechanical conditions about the elbow that play a role in the pathogenesis of osteoarthritis of this joint. In **chapter 2** we examine the available basic science, preclinical and clinical evidence regarding the role of several *unfavorable biomechanical conditions* about the elbow in the development of osteoarthritis. We focus on posttraumatic osteoarthritis, osteochondritis dissecans, elbow joint instability and malalignment of the elbow. We conclude that biomechanical factors do indeed play a role in the development of osteoarthritis of the elbow, but that the pathophysiological mechanisms by which they do so are complex and not fully understood to date. Posttraumatic osteoarthritis is a well-recognized condition. It is increasingly acknowledged to be more a mechanically induced biological problem than a biomechanical problem per se. Instability seems to play a role, but the relation between instability and degenerative changes of the elbow is not yet clearly defined. The roles of cartilage defects and untreated osteochondritis dissecans remain unclear to date.

Second, we aim (*i*) to report the results of both cemented and press-fit bipolar radial head arthroplasty (RHA), (*ii*) to investigate if specific design characteristics of radial head prostheses are associated with improved outcomes and (*iii*) to evaluate if bipolar radial head prostheses are able to compensate for radiocapitellar malalignment and/or chronic radioulnar instability. In **chapter 3**, we report the mid-term results of a series of 23 cemented bipolar metallic RHAs (RHS® prosthesis, Tornier) as treatment for acute radial head fracture, failed earlier treatment or posttraumatic sequelae. **Chapter 4** holds the first peer-reviewed publication on press-fit bipolar metallic RHA (RHS® prosthesis, Tornier). Midterm results of a series of 30 press-fit prostheses are presented. In **chapter 5**, the results of a systematic review of the English literature on RHA from January 1940 to May 2015 are reported. In **chapter 6**, our own results of metallic RHA as treatment of chronic longitudinal radioulnar dissociation (LRUD) are reported; all, but one, involved a monopolar prosthesis. Based on the aforementioned case series, we consider that the mid-term results of our series of both cemented and press-fit RHA as favorable. On the basis of our systematic review, there seems to be no evidence that prosthesis design characteristics affect outcome after RHA. Bipolar prostheses seem to be able to compensate, to some extent, for radiocapitellar malalignment. Metallic monoblock RHA does not reliably address the functional deficiency from chronic LRUD, due primarily to malalignment, implant loosening and the capitellar cartilage wear.

Third, we aim (*i*) to investigate the occurrence of metallosis after Kudo total elbow arthroplasty and (*ii*) to investigate if metallosis after TEA can be screened for by means of clinical and/or serological parameters. In **chapter 7**, we report our results of the investigation of the occurrence of metallosis on CT-scan after Kudo TEA (Biomet, Warsaw IN, U.S.A.) and the results of the investigation of clinical outcome measures, patient reported outcome measures (PROMs), and free cobalt and chromium serum levels as possible screening tools for metallosis. We conclude that metallosis after Kudo TEA is indeed a problem of significance, since it was observed on CT-scans of 20% of the elbows. Our analysis does not support the use of clinical parameters, PROMs, the MEPS or free cobalt and chromium serum levels as a screening tool for metallosis after TEA.

SAMENVATTING

Dit proefschrift komt voort uit onze interesse in zowel (*i*) de invloed van biomechanische factoren, prothese eigenschappen in het bijzonder, op de uitkomsten na gewrichtsvervanging van de elleboog als in (*ii*) partiële gewrichtsvervangingen ter hoogte van de elleboog.

Het eerste doel is het identificeren van mogelijke biomechanische condities ter hoogte van de elleboog, die een rol spelen in de pathogenese van osteoartrose van dit gewricht. In **hoofdstuk 2** onderzoeken we het beschikbare wetenschappelijke bewijs betreffende de rol van *biomechanisch ongunstige condities* ter hoogte van de elleboog in de ontwikkeling van osteoartrose. We hebben ons gericht op posttraumatische artrose, osteochondritis dissecans, instabiliteit en malalignement van de elleboog. We concluderen dat biomechanische factoren inderdaad een rol spelen in de ontwikkeling van osteoartrose van de elleboog, alhoewel de pathofysiologische mechanismen via welke dit gebeurt complex en nog niet compleet opgehelderd zijn. Posttraumatische artrose is een erkend probleem. Het wordt in toenemende mate onderkend dat posttraumatische artrose meer een mechanisch geïnduceerd biologisch probleem is, dan een biomechanisch probleem per se. Instabiliteit lijkt een rol te spelen, maar de relatie tussen instabiliteit en degeneratieve veranderingen van de elleboog is nog niet goed bekend. De rol van kraakbeendefecten en onbehandelde osteochondritis dissecans is op het moment niet duidelijk.

Het tweede doel is (*i*) de resultaten na gecementeerde en ongecementeerde radiuskopvervanging te presenteren, (*ii*) te onderzoeken of specifieke prothese eigenschappen van radiuskopprothesen geassocieerd zijn met een betere uitkomst en (*iii*) te evalueren of bipolaire radiuskopprothesen kunnen compenseren voor radiocapitellair malalignement en/of chronische longitudinale radio-ulnaire dissociatie (LRUD. In **hoofdstuk 3** zijn de middellange termijnresultaten gepresenteerd van 23 casussen na bipolaire metalen radiuskopvervanging met een gecementeerde prothese (RHS®, Tornier) als behandeling van acute radiuskopfracturen of de posttraumatische gevolgen hiervan. **Hoofdstuk 4** bevat de eerste *peer-reviewed* publicatie betreffende *press-fit* bipolaire metalen radiuskopvervanging (RHS® prothese, Tornier). De middellange termijnresultaten van een serie van 30 prothesen worden gepresenteerd. In **hoofdstuk 5** zijn de resultaten beschreven van een *systematic review* van de literatuur betreffende radiuskopvervanging van januari 1940 tot mei 2015. In **hoofdstuk 6** zijn de middellange termijnresultaten gerapporteerd van de uitgestelde behandeling van progressief symptomatisch LRUD middels monopolaire metalen radiuskopvervanging. We concluderen dat de middellange termijnresultaten van zowel gecementeerde als press-fit radiuskopvervangingen gunstig zijn. Op basis van onze *systematic review* is er geen effect van polariteit, materiaal en fixatietechniek van de prothese op de revisie *rate*. Bipolaire prothesen lijken tot op zekere hoogte te kunnen compenseren voor radiocapitellair malalignement. Als behandeling van chronische LRUD is metalen radiuskopvervanging ontoereikend, voornamelijk vanwege malalignement en loslating van de prothese, als wel vanwege slijtage van het capitellaire kraakbeen.

Het derde doel is (*i*) het voorkomen van metallose na Kudo totale elleboog arthroplastiek (TEA) te onderzoeken en (*ii*) te onderzoeken of *screening* op metallose na TEA mogelijk met behulp van klinische en/or serologische parameters. In **hoofdstuk 7** zijn de resultaten gerapporteerd van het onderzoek naar het voorkomen van metallose CT-scan na Kudo TEA en de resultaten van de vergelijking van klinische parameters, *patient reported outcome measures* (PROMs) of kobalt en chroom ionenconcentraties in het bloed tussen patiënten met en patiënten zonder metallose op CT. We concluderen dat metallose inderdaad een belangrijk probleem is na Kudo TEA, aangezien er sprake was van metallose van 20% van de ellebogen. We concluderen verder dat, op basis van onze analyse, screening voor metallose na TEA met behulp van klinische parameters, PROMs, de MEPS of kobalt en chroom ionenconcentraties in het serum niet mogelijk is.

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ABOUT THE AUTHOR

Andras Heijink was born in Amsterdam. After attending gymnasium in Amstelveen, he studied one year abroad in Dijon, France. Upon return, he obtained a bachelor in medical biology at the Vrije Universiteit in Amsterdam. He then studied medicine in Antwerp. After getting a little over a year of surgical experience, he has worked as a research fellow for four years at the Biomechanics lab of the Mayo Clinic in Rochester, MN in the USA. He also did the orthopaedic internship there, before returning to The Netherlands to train as an orthopaedic surgeon at the AMC in Amsterdam. Andras has developed a keen interest in and is pursuing a career in upper extremity surgery. He has authored numerous peer-reviewed publications and thrives to remain scientifically active as a clinician. Andras is married to Dilara Savci Heijink. They live in Amstelveen and have two children, Milan and Bente.