Radial head prosthesis with a mobile head

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Radial head replacement is a useful method in the treatment of comminuted radial head fractures. Because such injuries are a common clinical problem and many complications have been reported after radial head replacements, a new radial head prosthesis is proposed. This new design, based on the shape-dimensional identification of the radial head, consists of two parts. The head, made of ultra-high molecular weight polyethylene, is articulated with a Vitallium stem. A series of functional quality and strength tests were conducted on this new prosthetic design. The implant was also examined via the finite element method. General preclinical investigations of clinical cases show that this prosthesis is a very promising design. (J Shoulder Elbow Surg 2004;13:78-85.)

Stability of the elbow joint depends on the capsule, ligaments, and bony constraints. The radiocapitellar joint carries about 40% of the load transmitted across the elbow joint. The radial head (RH) is a secondary stabilizer to valgus stress, whereas the medial collateral ligament is the primary one.[20] Fractures of the RH constitute about 1.7% to 5.4% of all fractures and 30% of fractures around the elbow joint.[21,33] In comminuted fractures of the RH, repair is often impossible, in which case, some surgeons prefer resection or replacement.

After resection of the RH, some complications have been reported, such as limitation of the range of movement, valgus deformity of the elbow, proximal migration of the radial shaft, and as a consequence of this, subluxation of the distal radioulnar joint, decreased grip strength, heterotopic ossifications, and degenerative arthritis.[10,18]

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Prosthetic replacement is recommended when comminuted fractures of the RH are associated with destruction of the ligamentous stabilizers of the forearm or elbow. Speed[26] and Carr and Howard[5] used a metal (Vitallium) prosthesis, whereas Cherry[6] used an acrylic one. Since 1979, a Silastic prosthesis, designed by Swanson et al,[27] has been used. However, the results have not been consistently satisfactory. The most common complications are implant failure, loosening, synovitis, and degenerative arthritis.[15,21,35]

Recently, a bipolar type of RH prosthesis, the so-called floating prosthesis, was introduced by Judet et al.[11] The authors have reported very promising clinical results; however, no experimental study concerning this RH prosthesis has been published. Therefore, one may conclude that there is still a need for a fundamental study of the new RH prosthetic design.

The aim of this study was to develop a new RH prosthesis with features superior to prostheses currently in use. New-generation implants should provide proper matching of the prosthesis itself to the remaining bone elements of the elbow joint.[1,3,14,28] Thus, the process of prosthetic design should be preceded by precise identification of the anatomic features of the RH. This can be performed by use of computed tomography (CT)[30] and a coordinate-measuring machine (CMM)[25] integrated with a computer-aided design (CAD) system.[31] In designing the implant, proper materials should be chosen that ensure joint stability and allow for carrying adequate loads. Following such guidelines and on the basis of experimental research,[25,30,31] we introduce a mobile/bipolar RH prosthesis.[13]

MATERIAL AND METHODS

Analysis of RH anatomic features

To provide the information necessary for the design of the prosthesis, an anatomic study was performed on 17 RHs.[28] Fresh cadaveric specimens were used to analyze the anatomic properties of the RH. Because of its high accuracy (on the order of ±0.01 mm), the CMM method was applied in identifying the RH characteristic parameters. The CT method was also used, despite its low accuracy (on the order of ±0.5 mm, resulting from resolution of the tomograph and the density data recording), because of its ability to produce visualizations and take measurements inside the medullary canal of the radial neck. The results of identifica-

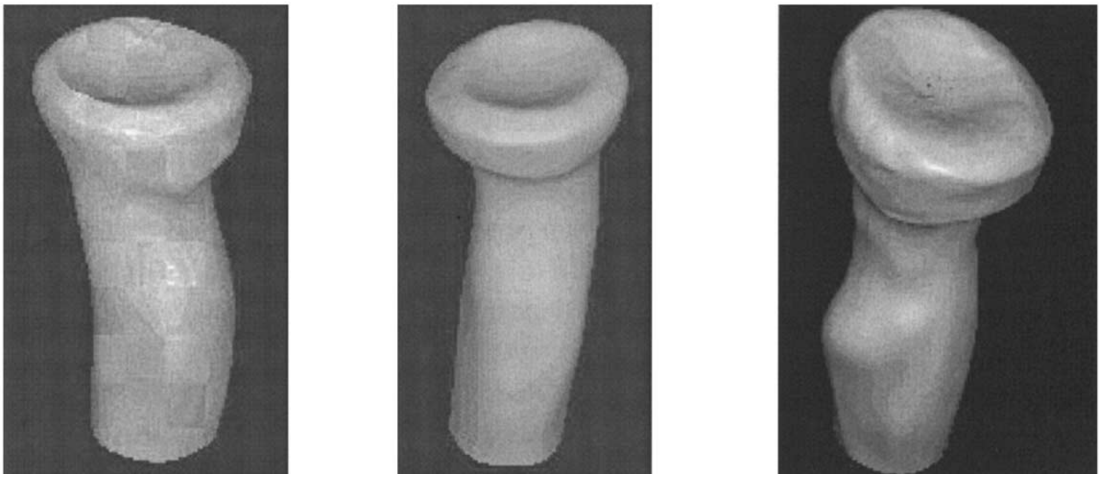

Figure 1 Geometric models of measured radial heads (examples).

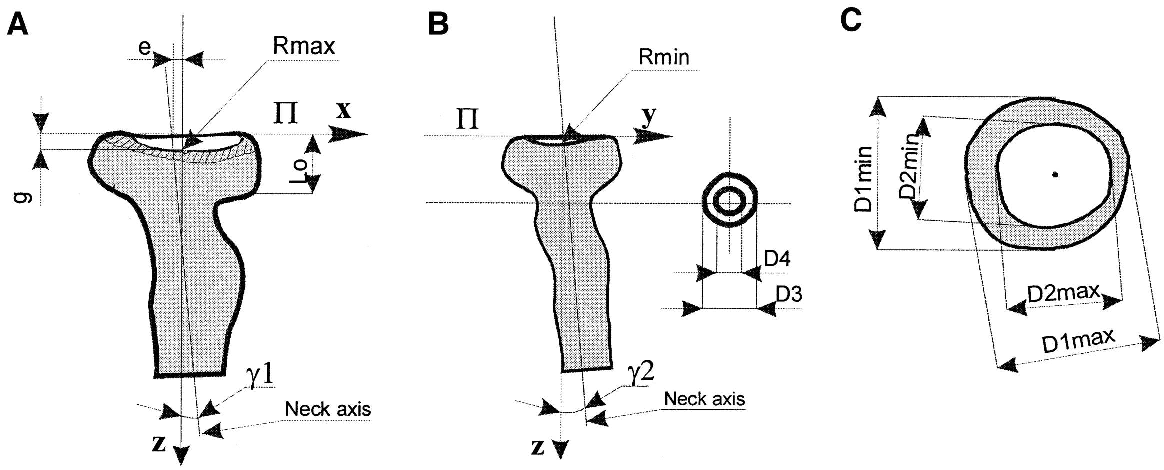

Figure 2 Radial head parameterization: Front view (**A**), side view (**B**), and top view (**C**). *D1max/D1min*, Maximum/minimum diameters of the radial head; *D2max/D2min*, maximum/minimum diameters of the articulate surface; *Rmax/Rmin*, maximum/minimum radii of the articulate surface; *g*, maximum depth of the articular surface; *Lo*, maximum heights of the radial head; $\gamma 1$ and $\gamma 2$, angles at which the head is inclined relative to the neck; *e*, shift of the neck in relation to the head; *D3*, minimum diameter of the neck; *D4*, minimum diameter of the marrow cavity.[28]

tion performed by means of the CMM and CT methods, after adequate formatting of numerical data, were forwarded to a Unigraphics CAD system (Unigraphics Solutions Inc, Cypress, CA). This made it possible to reconstruct the shapes of the examined bone elements—that is, to create geometric computer models of them. It is worth noting that the very complex shape of the RH (as there are no such complex shapes to be found in engineering practice) requires that the most sophisticated methods of 3-dimensional surface description be used. The nonuniform rational B-spline method has been used in the present research. Three-dimensional models reconstructing real shapes of the bones examined (Figure 1) were obtained from the CAD system. Sample representations and their parameters are given in Figure 2. The values of the geometric parameters presented in Table I were determined from a dimensional analysis of the RH models.

From morphologic analysis, it can be concluded that the RH is a solid, very complicated irregular shape. The upper articular surface is concave, whereas the lateral surface is convex, which allows for good articulation with the concave radial notch of the ulna. As a result of differences between the maximum and minimum diameters, its contours are very close to an ellipse. The characteristic anatomic features of the bone (ie, inclination and shift of the RH relative to its neck) must be taken into consideration in the design and selection of an RH prosthesis for a particular patient.

Table I Mean values (SD) of geometric parameters of radial heads (confidence level, α = .05)[28]

Parameter	Left limb	Right limb
D1max (mm)	23.33 (1.25)	23.38 (1.10)
D1min (mm)	21.98 (1.28)	22.54 (1.08)
D2max (mm)	16.48 (1.08)	16.57 (1.01)
D2min (mm)	15.11 (1.18)	14.79 (0.80)
Rmax (mm)	20.99 (5.33)	19.54 (3.99)
Rmin (mm)	15.43 (1.33)	15.52 (1.88)
Lo (mm)	10.04 (1.41)	10.23 (1.44)
g (mm)	1.88 (0.31)	1.96 (0.35)
e (mm)	1.64 (0.32)	1.78 (0.38)
D3 (mm)	12.22 (1.26)	11.89 (1.48)
γ1	2.37° (0.35°)	2.62° (0.44°)
γ2	9.44° (0.42°)	9.56° (0.62°)

D1max/D1min, Maximum/minimum diameters of radial head, *D2max/D2min*, Maximum/minimum diameters of articulate surface; *Rmax/Rmin*, Maximum/Minimum radii of articulate surface; *Lo*, Maximum height of radial head; *g*, Maximum depth of articular surface; *e*, shift of neck in relation to head; *D3*, Minimum diameter of neck; γ1 and γ2, angles at which head is inclined relative to neck.

Prosthetic design

On the basis of the shape-dimensional identification of the radius, a new RH prosthesis (called KPS) was designed.[13] It is a modular prosthesis consisting of two parts: a stem and a head. A ball-and-socket joint between the stem and head allows the head to rotate and tilt. The upper surface of the head is concave to articulate with the spherical capitellum. The radius and depth of this surface correspond to the real dimensions of the replaced head. This surface has smooth rounded edges to avoid irritation of the capsule. The lateral surface of the head, which articulates with the concave radial notch of the ulna, is approximated as a barrel-shaped surface. This allows for good synergy of the ulna with the prosthetic head. The natural RH cannot be regarded as an axisymmetrical solid body (there is both head shift and inclination, respectively, relative to the neck axis). Therefore, the mobile head of the implant allows for proper positioning and matching of the articulating surfaces during the course of movement or load bearing. The shape of the prosthetic stem, as a result of CT measurement of the marrow cavity, is close to being conoidal. Because the stem is cemented in place, there is no need to match the shape of the marrow cavity accurately. The stem collar is designed for correct positioning of the stem. The collar is chamfered to provide surface contact between the head and collar in the most extreme position of head rotation.

This new prosthesis, in which RH anatomic features have been taken into consideration, is made of two different materials. The head is made of ultra-high molecular weight polyethylene (UHMWPE)—Chirulen (Poly Hi Solidur Deutschland GmbH, Vreden, Germany) (ISO 5834)—whereas the stem is made of a cobalt-chromium-molybdenum (Co-Cr-Mo) (Vitallium) alloy—Endocast (gb Implantat Technologie GmbH, Essen, Germany) (ISO 5832/4). The prosthetic materials are biocompatible and comply with international standards. It should be noted that this prosthesis differs from other designs with regard to the anatomic features of its head and its short stem.

Preclinical study: Finite element method analysis

Prosthetic strength was tested via finite element method (FEM) analysis (Figure 3). The geometry of the bones was modeled from CT measurements.[30] The FEM model including the bones, soft tissue, and prosthesis consists of 49,484 eight-noded solid elements (including 1,692 contact elements). The bone, soft tissues, and prosthetic biomaterials were modeled as elastic isotropic materials (Table II). A static loading for 0° of elbow flexion was simulated with joint reaction forces of 457 N, 687 N, and 918 N. Nonlinear numerical analysis was performed with ANSYS 5.3.3 (Swanson Analysis Systems, Inc, Houston, PA). Friction in the contacting elements was neglected. FEM analysis was used to determine the stress distribution in the bone-cement-implant system.

The results of finite element analysis (Figure 4 and Table III) proved that maximum local reduced von Mises stresses appearing in the polyethylene head do not exceed 26 MPa (for 688-N elbow loading) and are, therefore, less than the permissible stress for Chirulen (16-27 MPa depending on the grade). The stresses exceeded 33 MPa only when the joint reaction force was about 918 N. However, this represents an extreme load condition almost impossible for a patient with an implanted prosthesis.

Preclinical cadaveric study

Functional quality assessment was aimed at proving that the new design may replace a natural RH. It was based on radiographic analysis of the elbow joint with a prosthesis prototype implanted. The prosthetic head was supplied with metallic circumferential and longitudinal markers and was implanted (after resection of the RH) into the left elbow joint of the cadaver.[29] From the positions of the prosthetic markers, the position of the prosthetic head during forearm rotation and elbow flexion was analyzed, thus allowing us to make a qualitative evaluation of prosthetic function.

Following the proposed functional method, it was found that during various movements of the elbow joint, the main axis of the prosthesis was always directed toward the geometric center of the capitellum (Figure 5). It was also found that the prosthetic head automatically positioned itself against the capitellum and the concave radial notch of the ulna. In addition, the prosthetic head did not display any tendency toward subluxation or dislocation.

The stabilizing effect of the KPS RH replacement was evaluated in cadaveric elbows. The experimental study showed that the KPS bipolar prosthesis and a Wright monoblock prosthesis (Wright Medical Technology Inc., Arlington, TN) provided equal degrees of elbow stability.[24] On the basis of this finding, it was suggested that in clinical practice, a bipolar prosthesis may be as effective in restoring stability of the elbow joint as a monoblock prosthesis.

RESULTS

Prosthetic design and manufacturing

An assembly drawing of the new prosthesis is shown in Figure 6. Four parameters (diameter of the head *D1e*, diameter of the articulate surface *D2e*, radius of the articulate surface *Re*, and height of the

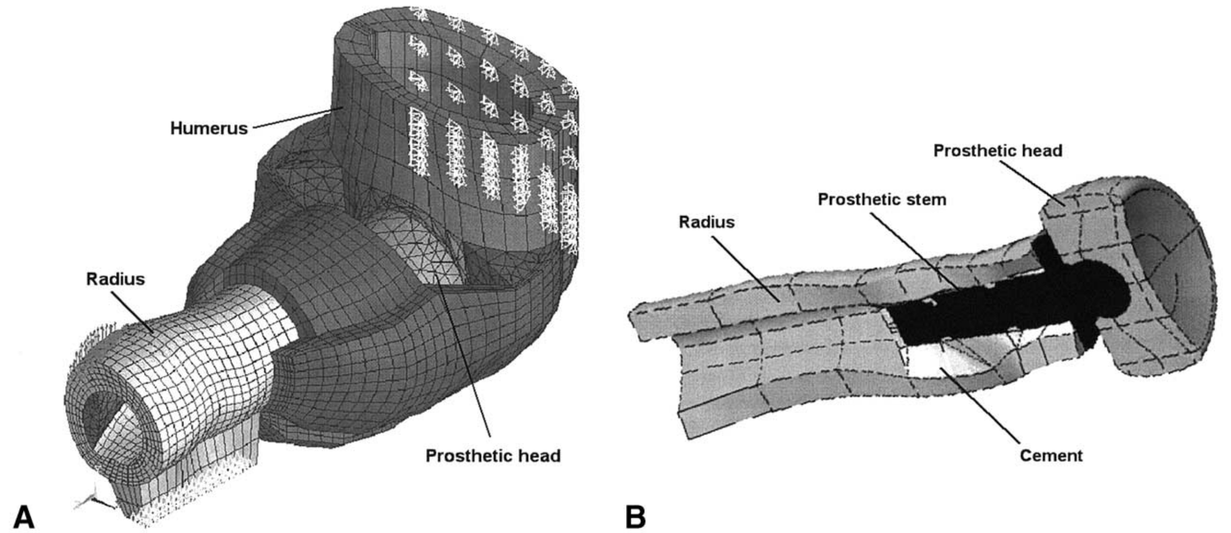

Figure 3 Finite element model: Part of the elbow with prosthesis (**A**) and prosthesis fixed in the radius (**B**).

Table II Material properties[8,10,34]

Material	Young modulus	Poisson ratio
Cortical bone	15,000	0.35
Cancellous bone	1,500	0.35
Ligaments	100	0.49
Prosthetic stem (Co-Cr-Mo)	200,000	0.3
Prosthetic head (UHMWPE)	1,200	0.35
Cement (PMMA)	3000	0.35

Co-Cr-Mo, Cobalt-chromium-molybdenum; *UHMWPE*, ultra-high molecular weight polyethylene; *PMMA*, polymethyl methacrylate.

head *Loe*) and three parameters (diameter of the collar *dk*, diameter of the stem *d*, and length of the stem *l*) have been used for parameterization of the prosthetic head and stem, respectively. The parameterization was performed based on the results for identification of natural bone geometry.[28] The dimensions of the prosthesis were determined from the sizes of anatomic RHs presented by us[28] and by Amis,[1] Gupta et al,[10] Beredjiklian et al,[3] and King et al.[14] Four different prosthetic head sizes are proposed (Table IV), enabling a surgeon to make the proper choice of implant during arthroplasty. For every head diameter, two different head thicknesses are provided to accommodate variable amounts of bone fracture. The head thickness must be such as to restore the length of the radius and prevent dislocation in the implanted head. Moreover, when the prosthetic head is too small, axial translation of the radius can occur and may cause subluxation of the distal radioulnar joint.

Because of the very complex shape of the implant and the high requirements imposed on the ball-and-socket latch joint, a computer numerically controlled machine was applied in manufacturing the prosthesis. The Unigraphics system used in the course of prosthetic design allowed for automatic generation of the machining program to manufacture the prosthesis on a computer numerically controlled machine. The manufactured prosthesis is presented in Figure 6.

Clinical application

Promising preclinical results obtained from overall investigations enabled the prosthesis to be used in clinical practice. The first case was the implantation of a prosthesis into the left elbow joint of a 38-year-old woman who had fallen on her hand. The elbow joint damage can be clearly seen in Figure 7. A comminuted RH fracture (Mason III type[16]) was diagnosed. Clinical examination revealed some degree of valgus instability resulting from additional medial collateral ligament strain, indicating the need for RH replacement.[21] After 4 years, the patient had a full range of movement of the operated elbow. The elbow was free of pain, and the patient had returned to her previous job of nursing. According to the Mayo Elbow Performance Index (Morrey 2000), which takes pain, range of movement, stability, and functionality of the elbow joint into account, the early clinical results were excellent. Radiographic evaluation, which was performed 2 and 4 years after the operation, showed no signs of cartilage degeneration, bone osteoporosis, or loosening of the prosthesis (Figure 8). Radiographs have proved that, generally, the prosthesis functions very well in the joint during different movements of the elbow joint. It can be seen from the radiographs that the prosthetic head positions itself automatically relative to the articulating surfaces of the humerus and ulna (Figure 8). There is no sign of subluxation of the

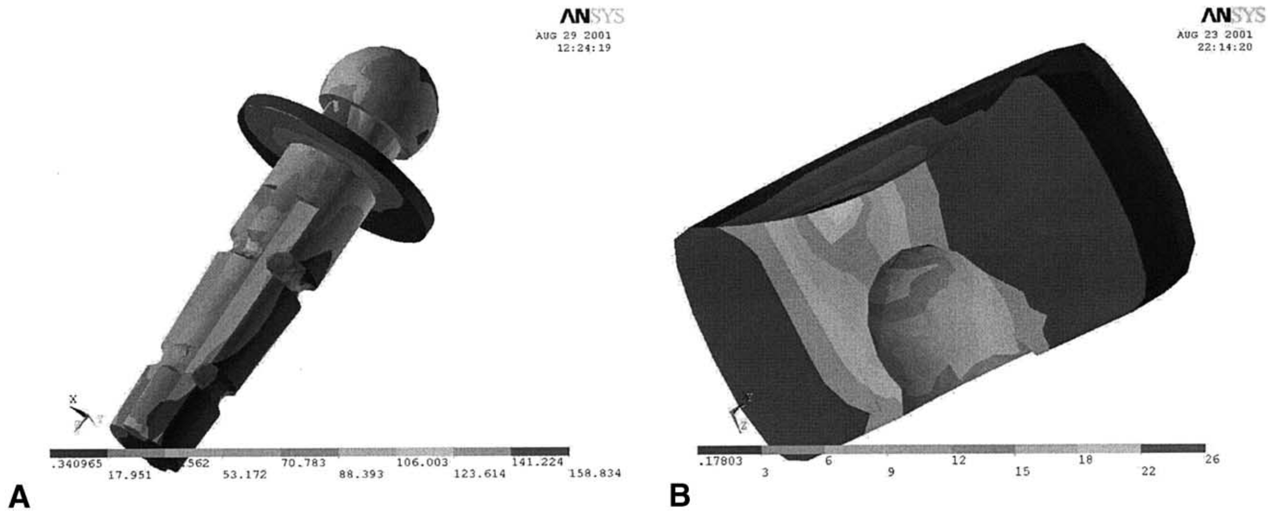

Figure 4 von Mises stress plot in the prosthetic stem (**A**) and head (**B**) for a load of 687.75 N.

Table III Maximal von Mises stresses in prosthesis and bones for three loading conditions of elbow

	Von Mises stress (MPa)		
	458-N elbow loading	**688-N elbow loading**	**918-N elbow loading**
Cortical bone	27.1	43.2	57.2
Prosthetic head	14.5	25.0	33.6
Prosthetic stem	107.2	158.8	204.7
Bone cement	5.6	8.2	11.1

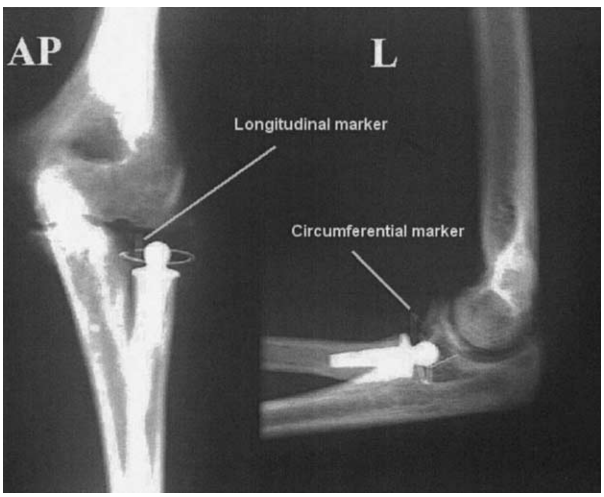

Figure 5 Radiographs of a radial head prosthesis implanted into a cadaver. *AP*, Anteroposterior; *L*, lateral.

prosthetic head. The elbow joint is stable. After this promising result was achieved, 5 more patients were provided with the new type of prosthesis. In all 5 a Mason III–type RH fracture in combination with elbow instability was diagnosed. In these patients internal fixation of the comminuted RH fracture was not possible, and KPS implants were inserted. After a mean follow-up of 18 months (range, 6-36 months), no tendency toward elbow instability, no symptoms of implant loosening, no degenerative changes of cartilage, and no bone osteoporosis have been found in any of the patients. According to the Mayo Elbow Performance Index, the early clinical results were excellent in 3 patients and good in 2 patients. However, further clinical and biomechanical assessment of the functioning of the elbow joint with the new prosthesis is planned before it is introduced into regular clinical practice.

DISCUSSION

Precise reconstruction of the original bone shape might seem to be the ideal solution; however, such a custom-designed prosthesis would be both very expensive (one-off production) and difficult to implant properly into the elbow joint. Thus, a simplified axisymmetric head is proposed. The ball-and-socket joint between the head and stem of the prosthesis allows for prosthetic head revolution about its axis of symmetry, as well as for head inclination relative the stem axis of symmetry. The additional 3 dimensions of freedom introduced by the ball-and-socket joint between the head and stem allow for automatic positioning of the prosthetic head against the capitellum and the radial notch of the ulna. This reduces the possibility of loosening and of damage to the prosthesis during the complex movements of the elbow joint, ensuring at the same time that the distribution of pressures on the articular surface of the humerus is uniform. These considerations should be the object of future study.

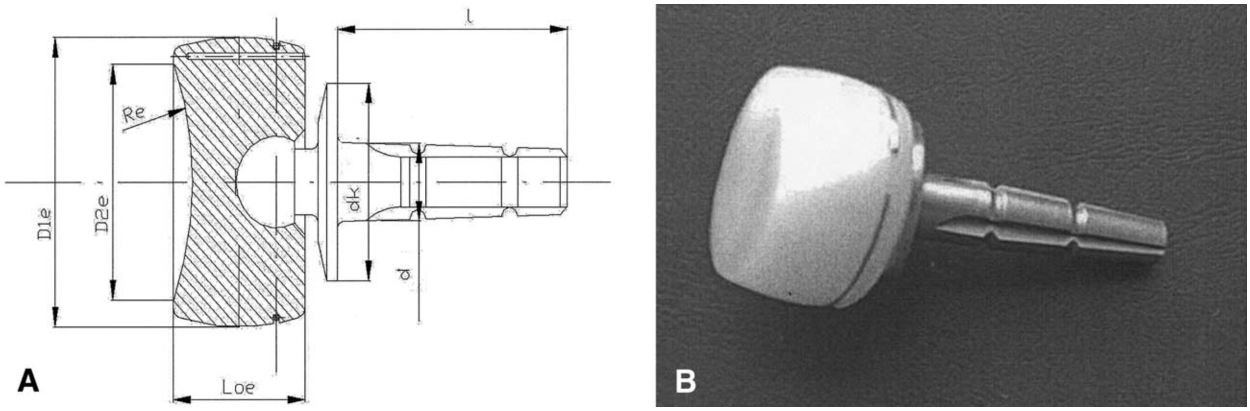

Figure 6 The new prosthesis: Assembly drawing (**A**) and general view of the implant (**B**). *D1e*, diameter of the head; *D2e*, diameter of the articulate surface; *Re*, radius of the articulate surface; *Loe*, height of the head; *dk*, diameter of the collar; *d*, diameter of the stem; *l*, length of the stem.

Table IV Prosthesis sizes

Parameter	Size (mm)							
	I	II	III	IV	V	VI	VII	VIII
D1e	18	18	20	20	22	22	24	24
D2e	14	14	16	16	18	18	20	20
Re	20	20	20	20	25	25	30	30
Loe	10	11.5	10	11.5	10	11.5	10	11.5

D1e, diameter of the head; *D2e*, diameter of the articulate surface; *Re*, radius of the articulate surface; *Loe*, height of the head.

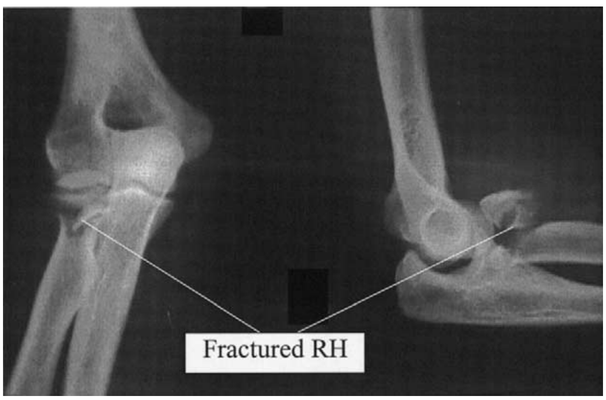

Figure 7 Patient elbow with radial head (RH) fracture.

A short stem is used because implantation of a long stem is very difficult. A long stem must be curved to pass the bicipital tuberosity[1] and must, therefore, be fixed at the correct angular position. The short straight stem avoids this difficulty. However, it cannot be used in a situation in which fragmentation extends far below the RH into the neck. In such a case a long stem or an allograft can be used.[32]

The modularity of the prosthesis and its short symmetrical stem make surgery much easier to perform, because initially, only the stem is implanted into the marrow cavity of the radius, the head being put on afterward. If the size of the implant head is inadequate, a larger or a smaller one can be substituted. This modularity is very important, as there is no correlation between the size of the RH and that of the intramedullary canal of the proximal radius.[14]

One of the most important aspects in prosthetic design is the selection of the correct biomaterials. Biomaterials for prostheses should be characterized by good biocompatibility, high strength, and high durability. They should have good tribological properties qualifying them for long-term functioning in a load-bearing joint with little or no wear particles. It has been proved in several studies that incorrect selection of materials results in postoperative complications after RH replacement. Although stiff metallic implants are able to bear high loads, they cause a nonanatomic stress distribution in the artificial joint.[11] The elastic modulus of titanium or Vitallium is about 10 times greater than that of bone, and this difference often results in a biomechanical incompatibility between the bone of the capitellum and the RH prosthesis. A hard material can cause degradation of the soft cartilage layer of the capitellum.[10,16] When the prosthetic material selected is too soft, it can result in implant fracture. Mayhall et al[17] showed mechanical damages with Silastic prostheses. Morrey et al[19] and

Figure 8 Radiographs of patient's elbow 2 years (**A**) and 4 years (**B**) after operation.

Carn et al[4] confirmed the problem of failure of soft prostheses. Moreover, using Silastic for RH replacements has been shown to cause synovitis and degenerative arthritis.[9,35] Kedzior et al[12] have shown in numerical analysis that the materials currently used for RH prostheses are not properly suited to the task.

In striving for a solution to these problems, UHMWPE (Chirulen) has been used for the prosthetic head. We assume that such a less stiff polymer will allow for better load distribution and protect the articular cartilage from destruction, and this has been confirmed by Gupta et al.[10] Moreover, finite element analysis proved that the maximum local reduced stresses appearing in the polyethylene head do not exceed the elastic limit for polyethylene. The high stresses for a joint reaction force of about 1000 N can be the result of there being no cartilage layer on the articulating surface of the capitellum. When the articulate cartilage layer is added to the model, lower stresses are expected.

Direct contact of UHMWPE with cartilage can be a point for discussion, as poor results have been encountered when using polyethylene in contact with cartilage in knee or hip replacement.[36] However, it should be mentioned that such results were obtained for polymers produced 50 to 60 years ago. Several new kinds of UHMWPE have been developed since then, such as ArCom (Biomet Orthopedics Inc., Warsaw, IN), Crossfire (Stryker Howmedica Osteomics, Mahwah, NJ), Chirulen, Durasul (Sulzer Orthopedics Inc., Austin, TX), and so on, which are characterized by better mechanical and tribological properties than the polymers previously used in prostheses.[23] In addition, the wear of polyethylene depends on the contact stresses and contact area in load-bearing joints.[8] Because the contact stresses in the radiocapitellar joint are much lower than in the hip or knee joint, the wear of a UHMWPE head is also expected to be lower. Some researchers try to mimic the features of cartilage by using polyurethane[34] or hydrogel,[22] materials even softer than UHMWPE, in joint replacement. In their opinion, this allows for better lubrication, less wear, and better long-term postoperative results. In addition, it should be mentioned that in the presented bipolar concept of the RH prosthesis, articulation that occurs between the polyethylene head and the spherical metal head of the prosthetic stem reduces the articulation between the polyethylene head and the cartilage, resulting in less cartilage wear. Finally, when we looked at the results of the articulation of cartilage with metallic alloys, they were not promising at all, as they showed not more than a 20% probability of survival for cartilage.[7] Therefore, the answer to the question of what is the best material to be used in contact with articular cartilage is still unknown and will be the subject of future studies.

Analysis of elbow joint forces shows that a polymeric intramedullary stem will not have sufficient strength to resist bending during joint loading. Therefore, the prosthetic stem was made of a Co-Cr-Mo alloy. This material was also selected because it has been proved by Bankston et al[2] that fewer wear particles appear when polyethylene articulates with a Co-Cr-Mo alloy than with a titanium alloy, meaning lower wear in the ball-and-socket joint of the new prosthesis. Knight et al[15] and Judet et al[11] also used Co-Cr-Mo as the material for the stems in their prostheses. In short, the most suitable biomaterials currently in use have been used for the new prosthesis.

Clinical and radiographic evaluations of the elbow of 1 patient during a 4-year follow-up and 5 other patients over shorter periods show no implant loosening and no signs of polyethylene wear or cartilage changes. However, a short follow-up time does not allow us to give a detailed assessment of the new RH arthroplasty. Moreover, the reaction of the cartilage of the capitellum working against materials such as polymers remains unknown.[21] Future long-term studies should be performed to assess the durability of the ball-and-socket joint and the direct effects of cartilage-UHMWPE contact.

The following advantages of the new RH prosthetic design should be noted: modularity of the prosthetic head makes surgery much easier to perform, and the additional 3 degrees of freedom introduced between the implant head and the stem by means of the ball-and-socket joint ensures automatic positioning of the head against the capitellum and the radial notch of the ulna. This junction should reduce the risk of loosening or fatigue fractures of the prosthetic elements and prevent damage to the cartilage of the capitellum.

Preclinical and early clinical evaluations have shown that this new prosthesis is a very promising design. The limitation of this study is that its conclusions must be verified by following up a larger number of patients who have undergone this type of operation. Long-term results, in particular, will be valuable.

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