Total Knee Arthroplasty Using the S-ROM Mobile-Bearing Hinge Prosthesis

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Abstract: A retrospective study was performed on 15 patients receiving 16 S-ROM mobile-bearing hinge total knee prostheses that were evaluated with at least a 2-year follow-up (range, 27–71 months). Indications for its use included severe instability and bone loss. The average patient age was 63 years (range, 33–83 years). There were 15 revision arthroplasties and 1 primary arthroplasty. Knee Society scores showed notable improvement in pain, motion, and stability (33.6 preoperatively vs 76.5 postoperatively; P < .0001) and approached significant improvement in function (29.2 preoperatively vs 43.5 postoperatively; P = .11). After excluding a patient with a traumatically ruptured patellar tendon, the probability of the latter comparison improved (P < .01). There was no evidence of loosening, and complete bone apposition was seen in nearly all cases. A high percentage of satisfactory results can be achieved when using this mobile-bearing hinge knee prosthesis for these indications. **Key words:** hinge knee arthroplasty, total knee arthroplasty, knee prosthesis, mobile-bearing knee, knee biomechanics.

A hinge total knee prosthesis is valuable in the surgical management of failed total knee arthroplasties (TKAs) and nonresurfaced arthritic knees with marked instability or bone loss. Nearly all early hinge-type total knee prostheses used commonly from the 1950s through the 1970s had high rates of loosening and complications, however [1–9]. Poor results with these early designs were attributed primarily to their highly constrained articulation,

large size (requiring excessive bone resection), all-metal hinges (with direct metal-to-metal transmission of load), nonanatomic position of load-bearing axes, and fixed axis of rotation [6,7,9,10–20]. It has been speculated that these design features produced excessive amounts of particulate wear debris, which resulted in synovitis and osteolysis [7,13,21]. With design improvements, early aseptic loosening or implant breakage (or both) still occurred at a high rate. These complications were attributed to excessive stresses across bone–cement–implant interfaces resulting from the inability of these prostheses to accommodate adequately gait-related flexural and rotational stresses at the knee [7,9,19,22–26].

To eliminate complications associated with deleterious stresses in hinge total knee prosstheses, mobile-bearing tibiofemoral articulations were developed [25,27–29]. An advanced mobile-bearing design was introduced in the mid-1970s—the Kinematic hinge knee (Howmedica, Rutherford, NJ) [7]. This mobile-bearing tibiofemoral articulation allowed axial rotation and distraction between the inner tibial bearing and the outer tibial sleeve. Rand et

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al [26] reported satisfactory results in only 65% to 75% of knees resurfaced with this prosthesis, however; there were high rates of loosening and other complications. Independent investigators more recently have reported similar success rates with this prosthesis [30]. Although mobile-bearing, the Kinematic hinged prosthesis has a curved tibial surface, and transarticular loading is primarily across the hinge. It has been suggested that these and other structural features result in excessive constraint to axial rotation and impart high forces on the hinge [9,26]. These problems prompted some design changes of this prosthesis [9].

Basic design features for the S-ROM mobilebearing hinge total knee prosthesis (DePuy Orthopedics, a Johnson & Johnson Co, Warsaw, IN) were eveloped by Noiles to improve on apparent design deficiencies of past and current hinge prostheses [11,28,31]. Additional design improvements were made in the 1980s and early 1990s. The original Noiles knee now is obsolete. The tibial tray and femoral components of the current S-ROM hinge prosthesis are made of cobalt-chromium alloy, and the patellar dome and tibial-bearing components are ultra-high molecular weight polyethylene. The intramedullary stem of the femoral component is fixed at 7° (physiologic) valgus (Fig. 1). A notable feature distinguishing this prosthesis from most other hinge prostheses is the capacity for adding modular intramedullary sleeves and stems. This feature enhances metaphyseal and diaphyseal fit and fill, facilitating load sharing and load transfer, especially in situations of bone loss and poor bone quality. The sleeves are textured with beads having interbead pore diameters of approximately 200 μ , allowing for the possibility of bone ingrowth. The tibial and femoral stems are slotted and have flutes to enhance diaphyseal fit and rotational stability and match bone stiffness more closely. In contrast to the Kinematic hinge prosthesis [7], the S-ROM hinge prosthesis has a flat tibial tray, and transarticular loading is transmitted across the hinge and polyethylene tibial-bearing surface. In theory, by better accommodating axial rotation and reducing high contact stresses, these features help reduce deleterious stresses across the hinge and bone-cement-implant interfaces [32,33]. Metallic augmentation blocks are available for use with the S-ROM hinge in situations of bone loss of the distal femur or proximal tibia. Although the S-ROM mobile-bearing hinge prosthesis has advanced design features, there are no studies documenting its clinical and radiographic performance. The present study is a retrospective analysis of the clinical and radiographic performance of this prosthesis.

Materials and Methods

Demographics

A retrospective review was performed on a cohort of 18 consecutive patients with 19 S-ROM mobile-bearing hinge prostheses who were evaluated with at least 2-year follow-up from implanta-

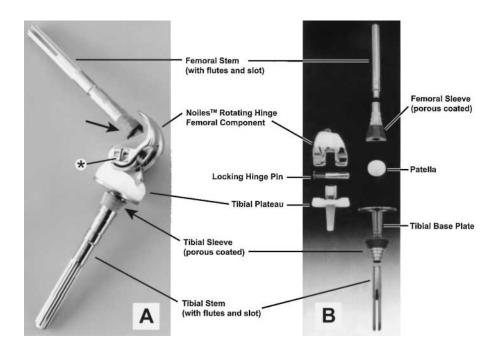


Fig. 1. S-ROM mobile-bearing hinge total knee arthroplasty. (A) Lateral view shows porous-coated sleeves (arrows) and attached intramedullary stems. The locking hinge pin is indicated with an asterisk. (B) Exploded anterior view shows modularity of all components.

tion. Three of these patients had died before the 2-year follow-up and were excluded from the study. Characteristics of the remaining 15 patients (16 knees) and their knees at the time of surgery are listed in Table 1. Surgeries were performed between August 1991 and May 1995, providing a mean follow-up period of 47 (range 27-71 months). Four men and 11 women underwent S-ROM hinge TKA. Mean age at surgery was 63 years (range, 33–83 years). The right knee was involved in 9 patients and the left knee in 7; 1 patient had bilateral hinge TKAs. All of the operative procedures were performed by the senior author (R.E.J.).

The underlying diagnosis was osteoarthritis in 7 knees, rheumatoid arthritis in 6 knees, and posttraumatic arthritis in 2 knees. With 1 exception, all patients had undergone ≥1 surgical procedures on their knees before the TKA (Table 1). The S-ROM hinge prosthesis was used as the initial implant in 1 knee and the revision prosthesis of previously failed TKAs in 15 knees. For these 16 knees, implantation was for aseptic loosening or instability in 11 cases and for septic loosening or instability in 5 cases.

Surgical Technique and Postoperative Rehabilitation

Old incision scars were used in each revision surgery. When possible, an anterior midline surgical approach was used. Bone cuts were made with

intramedullary mounted cutting jigs and alignment rods of the S-ROM TKA system. Cut bone surfaces were irrigated with pulsatile saline lavage. Polymethyl methacrylate cement was applied to the undersurfaces of tibial plateau and femoral condylar components [34]. In 1 patient (No. 2202) who had severe bone loss, cement was applied to the entire tibial sleeve; otherwise the remaining surfaces of the sleeves and stems were not cemented. In all cases, tibial and femoral components were implanted with intramedullary stems and sleeves. Ten knees had femoral augmentation blocks to reestablish the joint line.

Three patients had undergone total patellectomies. Patelloplasty was performed in each of 6 of the remaining 13 knees because the remaining bone stock was insufficient for accommodating a revision patella component. Patelloplasty included reshaping prominent areas of the unresurfaced patellar remnant with an oscillating saw or rongeur and removing any obviously loose fragments of bone. To balance the extensor mechanism, lateral retinacular releases were required in 5 cases. Staged debridements for infected cases were done according to a published protocol [34]. In most cases, the surgical wound was closed and a Robert-Jones dressing was applied with an elevated tourniquet because most procedures were completed in <2 hours. Indwelling drains were not used.

Table 1. Patie	ent Demographics	and	Knee	Data
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Patient Code	Gender/Age (y)	Right or Left	Is S-ROM Hinge a Revision	Previous Infected Total Knee	Contralateral Prosthesis	Knee Before S-ROM	Lateral Retinacular Release	Patelloplasty
2202	F/69	R	Y	N	Kinematic H	Kinematic H	Y	N
5203	F/66	L	Y	N	S-ROM NH	TKA NOS	N	Y
2304	F/59	L	Y	Y	St. Georg H*	Guepar H*	Y	Y
3206	F/69	R	Y	N	S-ROM NH	Miller H(?)	N	N
9507	M/33	L	Y	N	NA	Noiles H*	Y	PP
2308	M/60	R	Y	Y	NA	TKA NOS	N	Y
5109	F/78	R	Y	Y	Kinematic H	TC-III TKA	Y	PP
2110	F/80	L	Y	N	NA	PCA TKA	N	Y
9311	F/54	R	Y	N	TC TKA	TKA NOS	N	N
0512	M/44	R	Y	N	NA	LCS TKA	N	Y
7113	M/76	L	Y	N	TC-II TKA	Spherocentric H*	Y	Y
2316	F/62	L	N	N	NA	NA	N	N
0317	F/64	R	Y	Y	S-ROM NH	PCA TKA	N	N
8318	F/56	L	Y	N	NA	Kinematic H	N	N
8318	F/56	R	Y	N	NA	Kinematic H	N	N
2119	F/83	R	Y	N	LCS TKA	LCS TKA	N	PP

^{*} St. Georg hinge knee [54]; Guepar hinge knee [14,55]; Noiles, early-generation mobile-bearing knee [31]; Spherocentric hinge knee [25]. H, hinge; NA, not applicable; NH, nonhinged; NOS, not otherwise specified, (?), uncertain; LCS, low-contact-stress implant (this is mobile-bearing) (DePuy Orthopaedics, Inc, Warsaw, IN); PCA, porous-coated anatomic implant; PP, previous patellectomy; TC, total condylar; TCII and TCIII, Total Condylar II and III prostheses (although nonhinged, these are relatively more constrained than nonhinged TKAs listed above); TKA, total knee arthroplasty prosthesis (nonhinged).

Knee Function Scores

In most cases, clinical data were collected during clinic visits. In 3 patients (3 knees) minor deficiencies in the database were clarified by telephone and by written survey. Twelve patients (13 knees) had sufficient clinical data for a detailed battery of knee pain and function scoring. Of the 3 patients with insufficient data for comprehensive scoring, 1 was lost to follow-up, and 1 refused follow-up, but function was reported as good at 39 months postoperatively and radiographs were available. The third patient did well until 27 months postoperatively, when a recurrent infection developed, requiring resection arthroplasty. The follow-up data for this patient were tabulated from a clinic visit preceding the clinical symptoms of infection. A total of 15 knees in 14 patients had complete follow-up data.

Preoperative and postoperative status of each patient were quantified in terms of pain, function, deformity, motion, and strength. Three knee rating systems were used: i) Brigham and Women's Hospital and Harvard Medical School score (Harvard score) [35,36]. ii) Hospital for Special Surgery score (HSS score) [37,38], and iii) Knee Society score [39].

Harvard Score. The Harvard score is based on a maximum of 100 points with 50 points allocated for pain, 30 for function, 10 for deformity, and 10 for motion [36].

HSS Score. The HSS score is based on a maximum of 90 points with 30 points allocated for pain; 18 for motion; 12 for function; and 10 each for deformity, strength, and instability. In accordance with Rand et al [26,40], a composite score of a score of \geq 85 placed a knee in an excellent category; 70 to 84, a good category; 60 to 69, a fair category; and <60, a poor category.

Knee Society Score. The Knee Society score is based on a maximum of 200 points [39]. In contrast to the Harvard and HSS scores, the Knee Society score formally provides for a separate function score (100 points) and pain, motion, and stability score (100 points).

Other Scores and Specific Function Measures. The results were evaluated as satisfactory or unsatisfactory according to criteria of Rand et al [26] in their follow-up study of patients with the Kinematic mobile-bearing hinge prosthesis. Their criteria for a satisfactory result were i) no or mild pain, ii) no or mild instability, iii) flexion of the knee to at least 90°, and iv) no extensor lag >10°. A result in any knee that did not meet all 4 of these criteria was judged to be unsatisfactory.

Ten-centimeter visual analog scales were used to evaluate preoperative versus postoperative pain when climbing stairs (ie, ascent and descent), when arising from a chair, and when walking on level ground. All patients were questioned specifically about anterior knee pain during these activities. All patients were questioned about thigh or leg pain that, if present, might be attributable to the presence of the intramedullary stems.

Radiographic Analysis

Radiographs were available for 14 of the 15 patients (15 knees). Radiographs included anteroposterior, lateral, and Merchant views. The mean duration of final radiographic follow-up was 36 months (range, 19-67 months). Radiographs were evaluated for the presence or progression of lucent lines using the methodology described by Ewald [41] and endorsed by the Knee Society. In addition to evaluating the femoral and tibial components, the sleeve and stem regions of the radiographs were evaluated for evidence of bone apposition, mechanical stability, or both, following the criteria of Engh et al [42].

Statistical Analysis

A 2-sample Student *t*-test was used for comparison of paired data. Data are expressed as means \pm 1 SD.

Results

Demographic and knee data are listed in Table 1. The indications for use of the S-ROM mobile-bearing hinge prosthesis were ligamentous instability, bone deficiency, or both in all knees. Because only 1 patient had a primary TKA, scores were not segregated into primary arthroplasty and revision arthroplasty groups. Representative preoperative and postoperative radiographs of 1 patient (No. 2304) are shown in Fig. 2.

Knee-Rating Scores and Other Function Measures

Results of knee scores are shown in Fig. 3. The distribution of preoperative and postoperative pain levels during some activities, measured using visual analog scales, are shown in Fig. 4.

The Harvard scores showed notable postoperative improvement (33.1 preoperatively vs 68.8 postoperatively; P < .0001) (Fig. 3). The HSS scores showed significant improvements (46.3 preoperatively vs 70.8 postoperatively; P < .0001). The Knee Society scores showed notable improvement in pain, motion, and stability (33.6 preoperatively vs

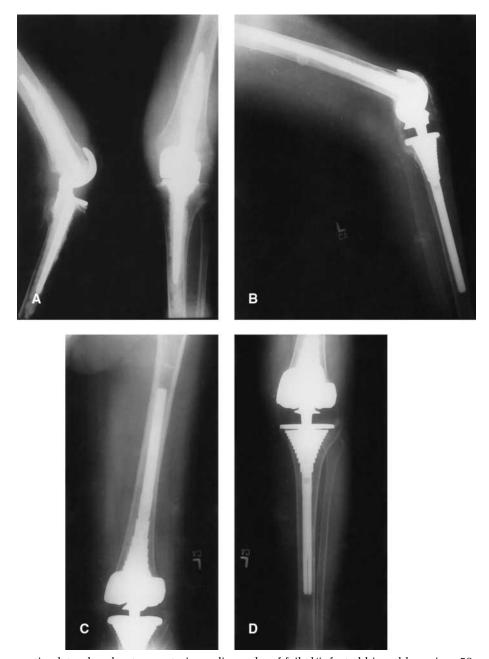


Fig. 2. (A) Preoperative lateral and anteroposterior radiographs of failed/infected hinged knee in a 59-year-old woman (patient No. 2304) with severe periprosthetic osteolysis. (B-D) Seven-year postoperative lateral and anteroposterior radiographs of the revision S-ROM hinge knee. There appears to be complete apposition of bone to the implant. Lucencies are not present.

76.5 postoperatively; P < .0001) and approached significant improvement in function (29.2 preoperatively vs 43.5 postoperatively; P = .11). After excluding data from a patient who had a postoperative traumatic patellar tendon rupture, the probability of the latter comparison improved (P < .01).

In accordance with the HSS score, as used by Rand et al [26,46], no knees were rated good pre-

operatively, 2 were rated fair, and 14 were rated poor. For the knees that could be evaluated, a good or excellent result (≥70 points) was obtained at final follow-up in 9 knees, and a fair or poor result (<69 points) was obtained in 4 knees (scores, 42, 55, 56, and 56).

Using the simplified criteria of Rand et al [26], a satisfactory result was obtained in 11 knees. The

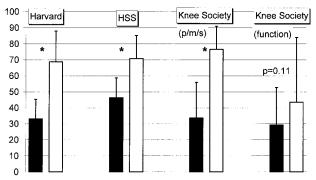


Fig. 3. Results of knee scores (means and SDs); preoperative versus final follow-up. Harvard, Harvard score; HSS, Hospital for Special Surgery Score; Knee Society, Knee Society Score (p/m/s, pain, motion, and stability portion of HSS score). ■, preoperative; □, postoperative.

unsatisfactory results were due to 85° of flexion and occasional moderate pain in 2 patients and an extensor lag $>10^{\circ}$ in 1 patient.

Fourteen knees had moderate-to-severe pain during walking preoperatively, but only 1 knee (7%) had the same degree of pain at final follow-up (Fig. 4). Visual analog scales showed that the pain that occurred preoperatively during walking improved notably at final follow-up (preoperatively 6.6 ± 2.2 vs postoperatively 2.8 ± 3.0 ; P = .0001). Pain that occurred preoperatively during stair climbing was improved notably at final follow-up (visual analog scale, preoperatively 7.6 ± 2.0 vs postoperatively 7.6 ± 2.0 vs

At final follow-up, 10 of 13 patients reported being able to walk equal to or greater than the distance they could walk preoperatively. Of these

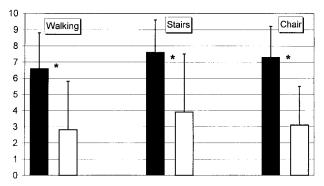


Fig. 4. Visual analog scale representations of pain during walking, stair climbing, and arising from a chair (means and SDs). Preoperative versus final follow-up results. ■, preoperative; □, postoperative.

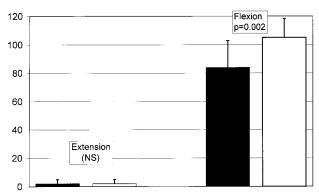


Fig. 5. Range of motion (means and SDs). Preoperative versus final follow-up results. NS, nonsignificant. \blacksquare , preoperative; \Box , postoperative.

13 patients, 9 still required occasional use of supportive devices (eg, cane or walker), however.

Preoperatively, 8 (50%) of the knees had at least 90° of flexion (Fig. 5). At final follow-up, 12 of 13 knees had at least 90° of flexion. The range of motion improved significantly in these knees by final follow-up (preoperative means $2^{\circ}-84^{\circ}$ vs postoperative means $2^{\circ}-105^{\circ}$; P=.002).

Preoperatively, all knees exhibited moderate-to-severe anterior knee pain, which was especially pronounced during stair climbing and when arising from a chair. Anterior knee pain improved postoperatively during stair climbing (visual analog scale, preoperatively 7.6 \pm 2.0 vs postoperatively 3.9 \pm 3.6; P=.0004) and when arising from a chair (Fig. 4) (visual analog scale, preoperatively 7.3 \pm 1.9 vs postoperatively 3.0 \pm 2.4; P=.0001). There was no evidence of patellar instability by evaluation of radiographic (Merchant) views, clinical examinations, or patient reports.

The range of postoperative alignment was 5° to 10° of valgus for all knees. No knee exhibited a varus alignment. No knee exhibited any clinical instability, as would be expected with a well-fixed, constrained knee prosthesis.

Radiographic Analysis

None of the knees showed evidence of loosening or mechanical instability. One patient had a 4-mm lucency beneath the proximal aspect of the anterior flange of the femoral component. This lucency was 2 mm in the immediate postoperative radiographs, and it progressed to 4 mm by 6 months. This lucency did not progress farther, and the patient remained asymptomatic. Three additional knees had localized lucencies that were ≥2 mm. These lucencies were beneath the proximal aspect of the

anterior femoral flange and were seen in lateral radiographs taken in the immediate postoperative period. These lucencies can be attributed to imperfect surgical fit of the prosthesis over this localized area. In all but the 1 case noted previously, examination of lateral radiographs showed that by 6 months postoperatively these localized lucencies were filled completely by bone.

Intramedullary tibial and femoral sleeves and stems were implanted in all cases. In all but 1 patient, analysis of radiographs showed bone apposition in all views of the tibial sleeves. The only exception was minor lucencies at the cement-bone interface in the only patient who had cement placed around the tibial sleeve for severe bone deficiency. There were no radiolucencies at the bone-implant interfaces of any of the femoral sleeves and stems or tibial stems.

Complications

There were 2 intraoperative complications; these were fractures that occurred during implant insertion into notably osteopenic bone. One fracture was of the proximal tibial metaphysis, and the other was of the distal femoral metaphysis. In both cases, intramedullary rods were part of the prefracture implant construct. In 1 case, the intramedullary rods were replaced with longer rods. Both fractures were treated with cerclage wire fixation.

Postoperative complications included i) 1 patient with 2 episodes of ispilateral traumatic quadriceps tendon ruptures and ii) 1 patient with a recurrent infection. The patient with the ruptured quadriceps tendon underwent a surgical repair; however, a rerupture occurred in a subsequent fall. Revision repair was not done because the patient had become a poor surgical candidate for medical reasons. Final treatment included a drop-lock brace and walker. The patient with the recurrent infection was treated with resection arthroplasty. Reimplantation was not done because the patient's medical condition became poor.

Discussion

High complication rates and the inconsistent achievement of successful outcomes with past and some currently available hinge-type prostheses stimulated the development of the S-ROM mobilebearing hinge prosthesis. This prosthesis has several advanced design features, including i) physiologic valgus, fixed at 7° in the femoral component; ii) modular sleeves and stems for accommodating bone deficits and for enhancing stress transfer into

host-bone; iii) porous sleeves, allowing for the possibility of bone ingrowth; iv) fluted tibial and femoral stems for enhanced rotational stability, v) increased contact area between femoral and tibial components for decreasing high contact stresses, which, in theory, reduces wear debris; and vi) a rotating hinge that allows axial rotation and distraction between the inner tibial bearing and the outer tibial sleeve, reducing deleterious stresses at the bone-cement-implant interfaces. These advanced design features may account for the low prevalence of radiolucencies and low incidence of complications reported in this study.

In contrast to findings of the present study, high rates of patellar complications have been reported with the Kinematic hinged knee. In a retrospective review with 53-month average follow-up, Shaw et al [36] reported patellar problems that were identified by examination of radiographs—subluxation being apparent on a Merchant view in 36% of 18 revision knees. In a 50-month average follow-up report of 38 knees receiving the Kinematic hinged knee for primary (15 knees) or revision (23 knees) TKA, Rand et al [26] reported patellar subluxation in 8 knees (21%) and patellar dislocation in 3 (8%). Most of these patellar complications occurred in revision TKAs.

Similar problems with patellar instability did not occur in the present series. The relatively deeper, more anatomic femoral groove of the S-ROM hinge prosthesis may yield more normal kinematics. This design feature is an attempt to improve dynamic tracking of the patellofemoral articulation. A higher degree of support and conformity may result in decreased patellofemoral stresses. In the present series, 50% of the revision cases (without previous patellectomy) required patelloplasty because the bone remaining was insufficient for a revision patellar component (Table 1).

Patelloplasties have been used with success in patients receiving nonconstrained TKA prostheses [43,44]. Significant symptoms can develop during stair climbing in some of these patients, however, [43,45–47]. Stair-climbing activity is the commonest specific activity used to assess function and pain of the patellofemoral joint in TKA [48]. In the present study, anterior knee pain with stair climbing improved notably even in the patients who had had a patelloplasty. Several factors probably contributed to improved anterior knee pain and patellofemoral kinematics in our series of patients, including the design of the femoral component, removal of loose or worn patellar components, and decreased patellofemoral stresses provided by patelloplasty.

In cases in which a TKA requires revision but has medial instability, Rand [40] recommended avoiding revision to a hinged prosthesis. He advocated using the Total Condylar III (TC-III) prosthesis, which is not a linked hinge but has a high intercondylar post that matches a recessed area in the femoral component. This recommendation reflects a philosophy stemming from previous experience with high rates of complications with the Kinematic hinge and other hinged prostheses [26,36,49]. Rand [40] noted that previous reports of radiographic and clinical analyses of the Kinematic rotating hinge prosthesis documented nearly 50% prevalence of radiolucent lines [26,36]. In contrast, data of the present study show the radiolucencies that occurred were beneath the anterior femoral flange, and there were no related complications. These were attributed to imperfect fit of the prosthesis in this region.

In the present study, intramedullary stems were not cemented. This minimal use of cement is supported by several outcome studies showing high percentages of good-to-excellent results of TKA prostheses implanted with press-fit intramedullary stems [50-53]. The near-complete absence of radiolucencies in the present series suggests that the fit and fill provided by the modular sleeves and stems, in addition to their porous-coated sleeves, and fluted and slotted stems allows for clinically beneficial bone modeling and remodeling at the boneimplant interfaces. Additionally, and perhaps most importantly, the rare incidence of radiolucencies suggests that dynamic motion at the tibiofemoral articulation is sufficient to decrease the deleterious stresses that contributed to early failures of previous designs of hinged TKA prostheses. Additional studies are warranted to test this hypothesis specifically.

No specific evidence of pain related to the presence of intramedullary stems was detected in our series. Such pain can be problematic after revision TKA [53]. It is suggested that the absence of stem pain in the present series can be attributed to the slots of the intramedullary stems. This feature may help promote graded transfer of load into the diaphyseal cortex. A similar reduction in the incidence of pain in total hip arthroplasty has been attributed to slotted femoral stems.

Conclusion

Significant clinical improvement and radiographic evidence of bone maintenance and apposition were shown at nearly 4 years' average followup. A high percentage of satisfactory results can be achieved with the S-ROM mobile-bearing hinge knee prosthesis in patients with severe deficiencies in soft tissue stability or hard tissue framework.

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