

# Minimum 5-Year Results With Duracon Press-Fit Metal-Backed Patellae

Anthony K. Hedley, MD, FRCS

## Abstract

Negative outcomes of earlier metal-backed patella designs have overshadowed reports of positive outcomes achieved with careful attention paid to component design, patellar tracking, and surgical technique. Much as reported elsewhere, we found earlier component failures were caused by poor locking mechanisms, thin polyethylene, poor tracking, and minimal femur contact. Over the past decade, however, our outcomes with Duracon metal-backed patellae have been encouraging. We think these positive outcomes, seen over a minimum 5-year follow-up, are largely attributable to the thicker polyethylene and improved articular conformity of this component relative to earlier designs.

The metal-backed patella was originally designed to address the shortcomings of cemented, all-polyethylene patellae: deformation, aseptic loosening, stress fractures of polyethylene, and possible thermal damage from bone cement.<sup>1-3</sup> Several long-term studies have found very good outcomes with use of all-polyethylene patellae.<sup>4-6</sup> However, complications of using an all-polyethylene patella reportedly accounted for up to half of all knee revisions, and during revision surgery patellar bone stock was often found to have been compromised.<sup>7</sup>

The intention behind the design of press-fit metal-backed patellae was to address the shortcomings of all-polyethylene patellae by eliminating the need for bone cement and providing stiffness that would help resist polyethylene deformation while decreasing implant–bone interface stresses.<sup>8</sup> However, early design iterations of metal-backed patellae demonstrated short-term failures—most commonly, local polyethylene wear damaging the locking mechanism and subsequent dissociation or fracture from the metal baseplate; polyethylene delamination from the metal baseplate; and failure of interface fixation.<sup>9,10</sup> On the other hand, good fixation with bony ingrowth was observed in both titanium and cobalt-chromium porous-coated patellae.<sup>1,3,9,11-13</sup> Overall, however, negative outcomes reported for metal-backed patellae led many surgeons

to abandon these components and return to using cemented all-polyethylene patellae.

Negative outcomes of earlier metal-backed patellae designs have overshadowed reports of positive outcomes achieved with careful attention paid to component design, patellar tracking, and surgical technique.<sup>2,3,14</sup> Subsequent design improvements (eg, a third stabilizing peg, thicker polyethylene, improved conformity) produced excellent outcomes.<sup>8,12,15</sup> The advantages of using a metal-backed patella (eg, uniform load sharing, decreased polyethylene deformation, potential for biological fixation) may be unjustly outweighed by the fear of patellar component failure.<sup>3</sup>

Our 30-plus years of experience with metal-backed patellar components reflect the evolving effect of component design on outcome. Much as reported elsewhere, we found earlier component failures were caused by poor locking mechanisms, thin polyethylene, poor tracking, and minimal femur contact. Over the past decade, however, our outcomes with Duracon metal-backed patellae (Stryker) have been encouraging. We think these positive outcomes, seen over minimum 5-year follow-up, are largely attributable to the thicker polyethylene and improved articular conformity of this component relative to earlier designs. We have also found it helpful to adhere to certain criteria when implanting metal-backed patellae, and we think adhering to these criteria, along with improved component design, indicates use of press-fit metal-backed patellae. In this article, we report our failure incidence with use of this device at minimum 5-year follow-up.

## Materials and Methods

In this single-center study, we performed clinical and independent radiographic reviews of 88 primary press-fit metal-backed patellae with minimum 5-year follow-up. All components were the same design (Duracon metal-backed patella) from the same manufacturer (Stryker).

This study, which began in September 2003, was reviewed and approved by the Western Institutional Review Board (WIRB). Either the investigator (Dr. Hedley) or the clinical study coordinator gave study candidates a full explanation of the study and answered any questions. Patients who still wanted to participate in the study signed WIRB consent forms after their index surgery but before minimum 5-year follow-up.

---

**Author's Disclosure Statement:** Dr. Hedley is a paid consultant for Stryker Orthopaedics, which manufactures the device used in the study reported here.

**Device Description**

This Duracon patella has a porous-coated cobalt-chromium metal back intended for press-fit fixation, 3 cobalt-chromium porous-coated pegs, and a preassembled polyethylene anterior surface (Figure 1). Four sizes are available to fit the peripheral shape of the resected patella.

This patella has 3 styles: symmetric, asymmetric, and conversion. In this study, we used only the asymmetric and conversion styles. The design of each style incorporates medial/lateral facets intended to conform to the convex intercondylar radii of the femoral component, thereby allowing the patella to ride deeply in the recessed patellofemoral groove. The asymmetric patella is a resurfacing component with a generous polyethylene thickness (4.6 mm at its thinnest) and a larger lateral facet for more bone coverage. The asymmetric patella naturally medializes component placement. The articulating surface of the conversion patella is identical to that of the asymmetric patella. However, the conversion patella allows for exchange of the polyethylene portion of the implant without revising a stable, well-fixed metal baseplate.

**Patient Selection**

Candidates were recruited from a group of metal-backed patella patients within Dr. Hedley’s medical practice. All candidates had undergone primary total knee arthroplasty and received a Duracon press-fit metal-backed patella. All recruited patients had undergone primary knee arthroplasty at least 5 years before clinical and radiographic evaluation. Patients were

included in the study if they had a diagnosis of noninflammatory degenerative joint disease (eg, osteoarthritis, traumatic arthritis, avascular necrosis). Patients with body mass index higher than 40 were excluded from the study.

**Surgical Technique**

The patella is everted completely or as much as feasible. Debridement is done circumferentially around the patella. Adherent fat and pseudomeniscus are stripped back until the surgeon sees the entry point of the quadriceps tendon fibers above and the patella tendon fibers below. The cut is then made at this level to remove as much bone as needed to restore the normal height of the patella with the implant in place. The cut is usually made by hand—without guides but with the patella stabilized with a towel clip above and below to prevent any movement during the action.

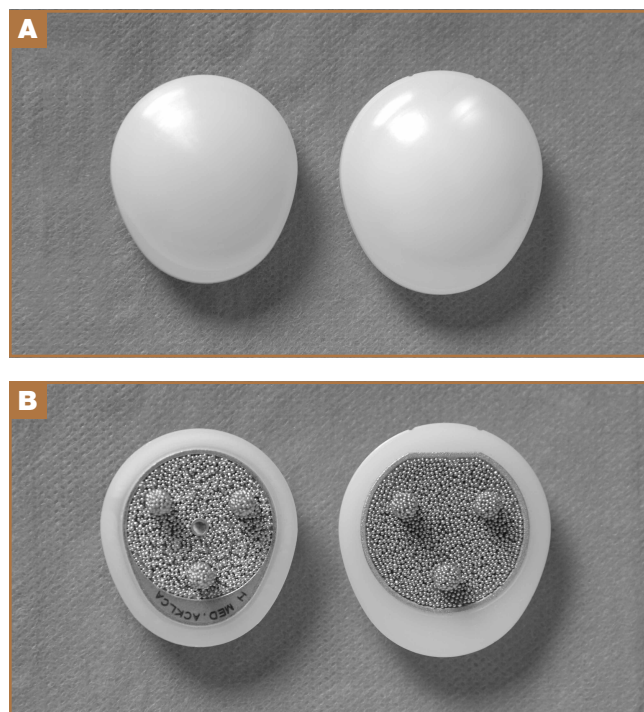
The desired cut must be absolutely planar, and this should be checked by placing the edge of the blade across the interface. Repeated passes with the saw blade are needed if the cut is not 100% planar. Once the cut is made, the patella is sized with the patella sizers and drill guide. After the appropriate size is selected, the patella is drilled with a bit that is slightly undersized from the size of the pegs (1/32 inch smaller than the bit supplied by the manufacturer).

Once the patella is prepared, the rest of the knee arthroplasty is performed. The patella is press-fit as the last component to be inserted.

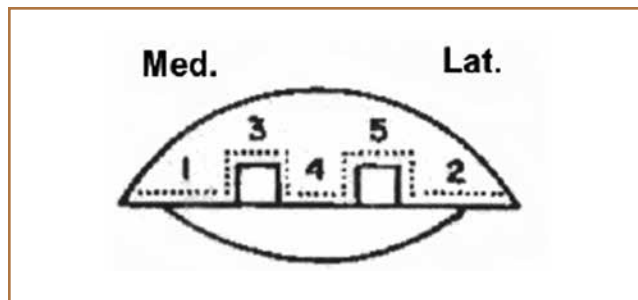
**Radiologic Review**

Radiographic analysis was performed by an independent reviewer according to the current Knee Society total knee arthroplasty roentgenographic evaluation and scoring system (Figure 2).<sup>16</sup> The reviewer was an orthopedist specializing in hip and knee surgery. Radiographs the reviewer deemed questionable were shown to another independent hip and knee surgeon for validation. In all cases, the second reviewer confirmed the first reviewer’s initial recorded observations.

KSS (Knee Society Scale), WOMAC (Western Ontario and McMaster Universities Arthritis Index), and SF-36 (36-Item



**Figure 1.** Duracon metal-backed patella (Stryker), (A) anterior side and (B) posterior side. In each image, asymmetric style is on left, conversion style on right.



**Figure 2.** Effectiveness of press-fit metal-backed patellae for fixation was determined by radiologic analysis of bone–prosthetic interface, according to current Knee Society total knee arthroplasty roentgenographic evaluation and scoring system.

Short Form Health Survey) were also used to evaluate effectiveness in this protocol.

### Survivorship Calculations

Kaplan-Meier survivorship was determined for all metal-backed patellae. For survival analysis, only knees with radiographic data were included (74 knees). Mean follow-up was 75.8 months (range, 60-105 months).

Seventy-four patients (88 knees) met the study criteria (Table). At minimum 5-year follow-up, complete data were acquired for 59 patients (72 knees). Of the total group, 14 knees did not have radiographic data. Those knees were categorized as lost to follow-up and were excluded from the survivorship analysis. The status of patients enrolled in the study at minimum 5-year follow-up is shown in the Table.

Mann-Whitney U test (nonparametric t test) was used to compare WOMAC and SF-36 scores between the “complete” and the “WOMAC and SF-36 only” data groups.

### Statistical Analysis

Kaplan-Meier survivorship probabilities (asymmetric method) were calculated using SAS Version 9.2 (SAS Institute); 95% pointwise confidence limits were used.

The Mann-Whitney U test is a nonparametric analogue to the independent-samples t test. It was used here to compare WOMAC and SF-36 scores of patients with “complete” data with scores of patients with “WOMAC and SF-36 only” data. In either group, for patients who had primary bilateral knee arthroplasty, mean WOMAC and SF-36 scores were used.

Comparisons were made between the unilateral and bilateral knee arthroplasty groups. There were no differences in age, height, or weight (Mann-Whitney U test) or in sex, primary diagnosis, or number of patients lost to follow-up (Fisher exact test). Fisher exact test (vs  $\chi^2$  test) was used for the contingency table analysis because of small cell sizes (eg,  $\leq 10$  females in “both knees” group), suggesting the unilateral and bilateral patients did not differ in demographics.

For all patient-reported questionnaires, bilateral patients were given the opportunity to note any differences between their knee arthroplasties, but none of these patients made any special notations. We interpreted this to mean that all survey responses from bilateral patients were applicable to both knee arthroplasties.

## Results

Seventy-four patients (88 knees) were enrolled in the study: 31 women (41.2%) and 43 men (58.1%). At time of surgery, mean age was 59.7 years (range, 40-86 years), and mean body mass index was 30.6 (range, 19.1-39.6). Eighty-three knees were diagnosed with osteoarthritis, and 5 knees were diagnosed with posttraumatic arthritis. Mean time to follow-up was 74.8 months (range, 60-105 months). Fourteen knees (14 patients) were considered lost to follow-up. However, 8 patients (8 knees) were contacted by telephone about the status of their knee(s), and all 8 completed and returned the minimum 5-year follow-up WOMAC and SF-36 forms; they did not return for their minimum 5-year clinical or radiographic evaluations.

Asymmetric patellae were used in 24 knees, conversion patellae in 64 knees (88 knees total). Forty-nine months after surgery, 1 patella was revised for loosening at its interface with the bone. The 51-year-old active female patient’s asymmetric patella was revised to a conversion patella. The decision to implant another metal-backed device was based on its high density; proper intrusion of acrylic cement would have been questionable. Some early wear was observed on the tibial insert, which was replaced. Sixty-eight months after the revision, the patient was asymptomatic, with a KSS Pain score of 96 and a KSS Function score of 100 (Figure 3). Another revision, for tibial insert exchange only, was performed 48 months after surgery. During this revision, the patella was evaluated and found to be well fixed and functioning normally.

Survivorship of the Duracon metal-backed patella at minimum 5-year follow-up was estimated to be 93.95%, with bounds of 73.61% and 98.74%.

Radiographic analysis revealed no radiolucencies larger than 1 mm (Figure 4). Seventeen 1-mm radiolucencies were recorded: 6 (35.3%) in zone 1, 2 (11.8%) in zone 2, and 9 (52.9%) in zone 4. Twelve (70.6%) of the 17 radiolucencies were in the left knee. Nine radiolucencies were in women and 8 in men. Most (55.6%) of the women’s radiolucencies were in zone 1, and most (75.0%) of the men’s were in zone 4. There were no loose beads other than in the case that was later revised.

KSS, WOMAC, and SF-36 scores and radiographic reviews were used to evaluate effectiveness in accordance with the protocol. At minimum 5-year follow-up, mean KSS Pain score was 94.10 (range, 55-100), and mean KSS Function score was

**Table. Study Knees and Patients at Minimum 5-Year Follow-Up**

	Knees, n	Patients, n
Study initiation	88	74
Minimum 5-year complete data (clinical and radiographic evaluation, KSS, WOMAC, SF-36)	72	59
Minimum 5-year clinical and radiographic evaluation and KSS only	2	1
Minimum 5-year WOMAC and SF-36 only	8	8
Completely lost to follow-up (no data)	6	6

Abbreviations: KSS, Knee Society Scale; SF-36, 36-Item Short Form Health Survey; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

92.67 (range, 60-100). Mean WOMAC score was 2.21 (range, 0-19.70), mean SF-36 Physical score was 83.65 (range, 30.70-100), and mean SF-36 Mental score was 89.41 (range, 1.4-100).

The preceding calculations do not include WOMAC and SF-36 data for the 8 patients (8 knees) who were counted as lost to follow-up but who submitted minimum 5-year follow-up data. We compared these 8 patients with the 60 patients (74 knees) who had complete WOMAC and SF-36 data at the end

of the study in order to determine whether there were any statistically significant differences between the 2 groups' mean scores. No statistically significant differences were detected in any WOMAC or SF-36 category ( $\alpha = 0.05$ ).

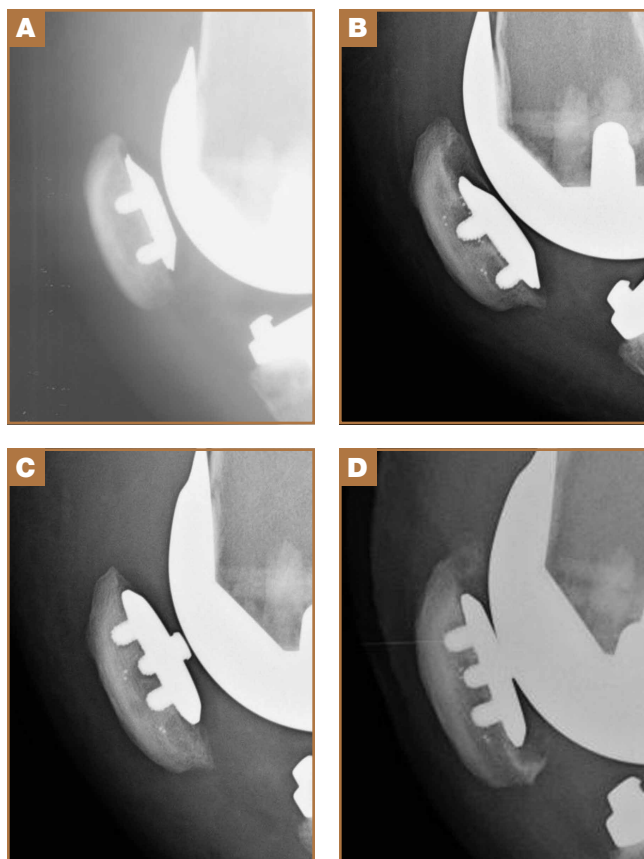
### Discussion

Metal-backed patellar components were originally designed to address the shortcomings (eg, fracture, deformation, aseptic loosening) of cemented all-polyethylene patellae.<sup>1-3</sup> It was thought that the stiffness of the metal could help resist polyethylene deformation and that the press-fit interface with bone might eliminate issues related to bone cement.<sup>8</sup> However, short-term failures were reported with early metal-backed designs.<sup>9,10</sup> At the same time, good fixation with bone ingrowth was observed in both titanium and cobalt-chromium porous-coated patellae.<sup>1,3,9-12,17</sup> Further, reports of poor outcomes with some metal-backed patella designs overshadowed reports of positive outcomes.<sup>2,3</sup> In all reports (of both poor and positive outcomes), component design, patellar tracking, and surgical technique were cited as contributing to implant success.<sup>2,3,14,17,18</sup> Subsequent design improvements (eg, use of a third stabilizing peg, thicker polyethylene, improved conformity) produced excellent outcomes.<sup>8,12,15</sup>

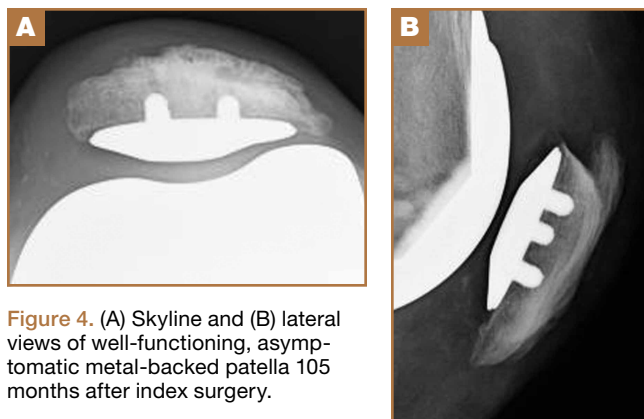
Our early results are similar to those reported in the literature, and we observed markedly better outcomes that we think resulted from component design improvements. Over the past decade, this has been particularly true with our use of the Duracon metal-backed patella, which has thicker polyethylene, better articular conformity, and a third stabilizing peg, all of which were previously noted as contributing to a successful metal-backed patellar component.<sup>2,12,14,15,19</sup> In our study, all 72 knees radiographically evaluated and independently reviewed at minimum 5-year follow-up had well-fixed press-fit metal-backed patellae. Seventeen patellae had 1-mm radiolucencies; the other 59 had no radiolucencies in any zone around the patella-bone interface.

One of the most important aspects of removing a metal-backed patellar component from a patella is that the remaining bone stock is often far superior to the stock available after revision of a cemented patella. Careful removal should leave an excellent bony bed for reimplantation.

We think that surgeons should adhere to certain indications and contraindications when implanting metal-backed patellae and that doing so can contribute to successful outcomes. Type of bone stock available should be considered, as successful biological fixation relies on a good blood supply. A dense (or thin) patella in which intrusion of acrylic cement is improbable or impossible may favor use of a metal-backed patella. Cement is not an adhesive but a grout, so successful cementation requires intrusion of cement into the interstices of the cancellous bone. As adequate intrusion of cement into dense bone is not possible, cementation may not be the best option. Some patellae have failed because of peg "shear-off,"<sup>9</sup> likely caused not by failure of peg strength but by failure of cement fixation at the nonpeg interface.<sup>20,21</sup> Polyethylene pegs fail when used as the sole method of fixation (they were never



**Figure 3.** Progressive loosening of primary metal-backed patella (A) 3 months and (B) 47 months after index surgery, and revised metal-backed patella in same patient (C) 6 weeks and (D) 68 months after revision surgery.



**Figure 4.** (A) Skyline and (B) lateral views of well-functioning, asymptomatic metal-backed patella 105 months after index surgery.



designed for that). In addition, we think younger patients are often indicated for a metal-backed patella because, over the long term, loosening of a cemented patella (and the accompanying stress shielding and osteolysis) may cause severe patellar bone destruction. Last, we have found that abnormally high or small patellae are not good candidates for cement fixation because they tend to work themselves loose riding on and off the superior flange. These types of patellae appear to have a much sturdier and longer lasting interface than cement, once biological fixation has occurred.

In summary, we think the indications for a metal-backed implant are a patella that is dense or sclerotic; a patella that is thin, abnormally high, or small; and a younger patient. In addition, a metal-backed implant is not indicated for soft, osteoporotic bone.

This study had a few limitations. Fourteen knees (14 patients), or 15.9% of all knees in the study, were categorized as lost to follow-up. Comparing the WOMAC and SF-36 scores of 8 patients (8 knees) who completed minimum 5-year follow-up but were not clinically evaluated with the scores of patients who had complete data, we found no statistically significant differences in any category. However, 5-year follow-up clinical data were available for those 8 patients. Nevertheless, 74 knees were available for radiologic evaluation, and during telephone interviews all 8 patients indicated they had their original implant(s) and were asymptomatic.

Our experience with the Duracon metal-backed patella has been encouraging. In the study reported here, there were no failures caused by dissociation of plastic. We think that, because the porous coating is under almost constant compression, biological fixation is likely in most instances, as observed in our minimum 5-year radiologic results. Given our minimum 5-year follow-up results with uncemented metal-backed patellae, we think their use may be a viable alternative to use of all-polyethylene patellae.

Dr. Hedley is Chairman, Hedley Orthopaedic Institute, Phoenix, Arizona.

Acknowledgments: The author thanks Leigh Breslauer for help with data collection, Shane Fitzgerald for statistical analysis, and Kate Matthews for writing assistance.

Address correspondence to: Anthony K. Hedley, MD, FRCS, Hedley Orthopaedic Institute, 2122 E Highland Ave, Suite 300, Phoenix, AZ 85016 (tel, 602-318-5716, 602-667-7956; email, elaine@azibjd.com).

*Am J Orthop.* 2016;45(2):61-65. Copyright Frontline Medical Communications Inc. 2016. All rights reserved.

## References

1. Firestone TP, Teeny SM, Krackow KA, Hungerford DS. The clinical and roentgenographic results of cementless porous-coated patellar fixation. *Clin Orthop Relat Res.* 1991;273:184-189.
2. Laskin RS, Bucknell A. The use of metal-backed patellar prostheses in total knee arthroplasty. *Clin Orthop Relat Res.* 1990;260:52-55.
3. Evanich CJ, Tkach TK, von Glinski S, Camargo MP, Hofmann AA. 6- to 10-year experience using countersunk metal-backed patellas. *J Arthroplasty.* 1997;12(2):149-154.
4. Schwartz AJ, Della Vale CJ, Rosenberg AG, Jacobs JJ, Berger RA, Galante JO. Cruciate-retaining TKA using a third-generation system with a four-pegged tibial component: a minimum 10-year followup note. *Clin Orthop Relat Res.* 2010;468(8):2160-2167.
5. Bisschop R, Brouwer RW, Van Raay JJ. Total knee arthroplasty in younger patients: a 13-year follow-up study. *Orthopedics.* 2010;33(12):876-880.
6. Dixon MC, Brown RR, Parsch D, Scott RD. Modular fixed-bearing total knee arthroplasty with retention of the posterior cruciate ligament. A study of patients followed for a minimum of fifteen years. *J Bone Joint Surg Am.* 2005;87(3):598-603.
7. Brick GW, Scott RD. The patellofemoral component of total knee arthroplasty. *Clin Orthop Relat Res.* 1988;231:163-178.
8. Garcia RM, Kraay MJ, Goldberg VM. Isolated all-polyethylene patellar revisions for metal-backed patellar failure. *Clin Orthop Relat Res.* 2008;466(11):2784-2789.
9. Rosenberg AG, Andriacchi TP, Barden R, Galante JO. Patellar component failure in cementless total knee arthroplasty. *Clin Orthop Relat Res.* 1988;236:106-114.
10. Stulberg SD, Stulberg BN, Hamati Y, Tsao A. Failure mechanisms of metal-backed patellar components. *Clin Orthop Relat Res.* 1988;236:88-105.
11. Sundfeldt M, Johansson CB, Regner L, Albrektsson T, Carlsson LV. Long-term results of a cementless knee prosthesis with a metal-backed patellar component: clinical and radiological follow-up with histology from retrieved components. *J Long Term Eff Med Implants.* 2003;13(4):341-354.
12. Kraay MJ, Darr OJ, Salata MJ, Goldberg VM. Outcome of metal-backed cementless patellar components: the effect of implant design. *Clin Orthop Relat Res.* 2001;392:239-244.
13. Jensen LN, Lund B, Gottfredsen K. Bone growth into a revised porous-coated patellar implant. *Acta Orthop Scand.* 1990;61(3):213-216.
14. Hsu HP, Walker PS. Wear and deformation of patellar components in total knee arthroplasty. *Clin Orthop Relat Res.* 1989;246:260-265.
15. Jordan LR, Sorrells RB, Jordan LC, Olivo JL. The long-term results of a metal-backed mobile bearing patella. *Clin Orthop Relat Res.* 2005;436:111-118.
16. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. *Clin Orthop Relat Res.* 1989;248:9-12.
17. Bayley JC, Scott RD, Ewald FC, Holmes GB Jr. Failure of the metal-backed patellar component after total knee replacement. *J Bone Joint Surg Am.* 1988;70(5):668-674.
18. Lombardi AV Jr, Engh GA, Volz RG, Albrigo JL, Brainard BJ. Fracture/dissociation of the polyethylene in metal-backed patellar components in total knee arthroplasty. *J Bone Joint Surg Am.* 1988;70(5):675-679.
19. Moreland JR. Mechanisms of failure in total knee arthroplasty. *Clin Orthop Relat Res.* 1988;226:49-64.
20. Francke EI, Lachiewicz PF. Failure of a cemented all-polyethylene patellar component of a press-fit condylar total knee arthroplasty. *J Arthroplasty.* 2000;15(2):234-237.
21. Stulberg BN, Wright TM, Stoller AP, Mimnaugh KL, Mason JJ. Bilateral patellar component shear failure of highly cross-linked polyethylene components: report of a case and laboratory analysis of failure mechanisms. *J Arthroplasty.* 2012;27(5):789-796.