Intermediate Outcome of a Cruciate-retaining Tibia

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abstract

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The use of an all-polyethylene tibia in total knee arthroplasty is being revisited as a means to decrease backside polyethylene wear and lessen cost. The Depuy Sigma all-polyethylene tibia (Depuy Orthopedics, Warsaw, Indiana) has been reported with good outcomes at a greater than 10-year interval, whereas the Biomet AGC I beam design (Biomet, Warsaw, Indiana) has had a high failure rate at an early interval. This is a retrospective review of another design. One hundred seventy patients (190 cruciate-retaining total knee replacements) with a Scorpio (Stryker, Mahwah, New Jersey) all-polyethylene implant and tibia were identified in the authors’ registry. This implant was chosen for all octogenarians deemed fit for a cruciate-retaining knee and a few septuagenarians who were deemed likely to remain inactive postoperatively for reasons other than knee arthritis. Mean follow-up was 38 months (range, 24-83 months). Mean patient age was 83.1 years (range, 72.7-93.8 years). Twenty-seven patients (29 knees) were lost to follow-up. Nineteen patients (24 knees) died before 24-month follow-up; all implants were in place, and no deaths were associated with the index procedure. Fifty-one patients (55 knees) were followed by telephone interview only and 75 patients (81 knees) by an office visit with radiograph analysis. One tibia revision was performed 2 months postoperatively for an implant placed in extension and varus. No infections, component wear, radiolucent lines, or impending revisions of the remaining cohort occurred. Lower Extremity Activity Scale scores ranged from 2 to 10 (mean score, 6.8), which demonstrated success even in patients with an active lifestyle. This previously unreported design is a promising all-polyethylene tibia alternative for total knee arthroplasty in older patients.
The modern era of total knee arthroplasty (TKA) dawned in the 1960s with a symmetrical femoral component and an all-polyethylene tibia. Later, an optional all-polyethylene patellar button was offered. Few size options were available for the tibial component; thus, the prosthesis either failed to extend to the margin of the host tibial anatomy or markedly overhanged. In the event of failure, no predictable revision option was available. Increased sizes of tibia and femoral components and a metal-backed tibia option were developed with the intent of improving outcomes for primary and revision TKA. These developments led to a near total abandonment of all-polyethylene components by the early 1980s. However, because retrieval studies of modular tibial components revealed backside polyethylene insert wear and cost containment mandates, a renewed interest arose in all-polyethylene and cost containment mandates, a renewed interest arose in all-polyethylene components. However, the Biomet AGC all-polyethylene tibia (Biomet, Warsaw, Indiana) with a flat-on-flat design demonstrated a high early failure rate. In contrast, reports on a different round-on-round design more closely mimicking early all-polyethylene components had favorable outcomes at intermediate follow-up. This article describes the short-term outcome of a third implant design, the Scorpio (Stryker Orthopedics, Mahwah, New Jersey) all-polyethylene knee arthroplasty.

**Materials and Methods**

The lead author (J.W.M.), who has 10 years of experience with the Scorpio metal-backed cruciate-retaining implant, began using the all-polyethylene tibia in seemingly uncomplicated TKAs in patients older than 80 years. This represented 52% of the 300 TKAs performed in this age group during the study. The decision to use this component came about as a result of concern with backside polyethylene wear in modular tibial bearings as a whole, increasing literature support for the safety and durability of the all-polyethylene tibia in elderly patients, and the desire to have a less expensive prosthesis. Included in this study was an additional randomly selected group of septuagenarians who were deemed likely to continue with sedentary lifestyles postoperatively for reasons other than arthritic knees. The septuagenarians selected for the all-polyethylene tibia represented 17% of the TKAs performed in this age group during this study.

One hundred seventy-two patients underwent 188 TKAs with Scorpio cruciate-retaining all-polyethylene tibial components. Surgeries were performed between July 2003 and August 2009. All data were prospectively collected in the authors’ registry but were retrospectively reviewed after institutional review board approval was granted. Although the manufacturer provided support for the statistical analysis of this material, they had no influence or input in the selection of patients, implants, decisions regarding surgical methods, or postoperative patient care or follow-up intervals.

All knees were approached through a mini-midvastus approach without patellar eversion. All bilateral surgeries were performed in a staged fashion. Before wound closure, 60 cc of 0.25% bupivacaine with epinephrine was injected into the soft tissues. One hundred eighty-seven tibial components were 10 mm thick and 1 was 12 mm. All patellas were resurfaced. For those who went home, outpatient therapy was begun 3 to 5 days after discharge, with 8 sessions spread over 4 weeks. The deep venous thrombosis (DVT) prophylaxis used was an efficient surgical technique with limited tourniquet time, rapid mobilization, warfarin during the hospitalization, and 81 mg of aspirin after discharge for 6 weeks. Ten patients (12 knees) had a history of DVT, a blood relative with a history of a DVT, or were deemed a high risk for developing DVT. These patients were maintained on warfarin after discharge for at least 1 month, with weekly monitoring of their International Normalized Ratio to keep it between 1.8 and 2.5. Six patients (9 knees) were on a chronic anticoagulation protocol before admission and resumed the same treatment after discharge.

Eighteen patients (20 knees; 10.5%), were lost to follow-up despite multiple attempts and pathways used to locate them. Twenty-eight (16%) patients (32 knees) died before a follow-up of more than 24 months occurred. Their deaths occurred between 4 and 77 months (mean, 35 months) postoperatively. An additional 10 deaths (11 knees) occurred after the patients were examined for an at least 24-month follow-up. Their data are included in the calculations below. The latter died between 46 and 94 months (mean, 63 months) postoperatively. No deaths were associated with the index procedure. Deceased patients were identified through newspaper obituaries, family contact, or the Social Security Death Index on Ancestry.com.

The remaining 126 (73%) patients (136 knees) were last seen or contacted by telephone between 24 and 87 months (mean, 49 months) postoperatively and are the group the authors are reporting. All patients were diagnosed with osteoarthritis. Ninety-five patients (105 knees) were women and 31 (31 knees) were men. Seventy-six left and 60 right knees were implanted. Mean patient age at surgery was 82.9 years (range, 78.4-91.9 years). Mean±SD body mass index was 29.9±5.0 kg/m². Patients who were examined in the office had radiographs taken. Information was gathered from patients who did not come to the office by a telephone interview. These patients answered questions regarding their knees and most commonly did not come to the office because their overall medical condition made them unwilling to leave their residence, transportation was too difficult to secure, or they were doing well and saw no point in coming in, even if they were offered a no-cost assessment. Table 1 lists the hospital and surgical details of these patients who responded to at least one telephone interview.
2 groups. Table 2 shows the telephone script used when talking to patients who were unable to come to the office.

Baseline characteristics were compared between the patients with more than 24-month follow-up and more who died or were lost to follow-up before 24-month follow-up using the Wilcoxon rank-sum test or Fisher’s exact test for categorical data. Survival probability was estimated using the Kaplan-Meier method, with revision of any component for any reason as the primary endpoint. All patients were included in the Kaplan-Meier survival analysis. SAS/STAT version 9.1.3 software (SAS Institute, Cary, North Carolina) was used for data analysis. Statistical analysis showed no difference in the distribution of demographics of the lost to follow-up and deceased (without 24-month follow-up) groups compared with the minimum 24-month follow-up group.

**Results**

None of the 75 patients (81 knees) seen in the office reported additional procedures after their index surgeries. Their preoperative Knee Society Scores (KSS) ranged from 33 to 78 (mean score, 53) and improved to a range of 71 to 100 (mean score, 91). Final follow-up Lower Extremity Activity Scale (LEAS) score ranged from 3 to 11 (mean score, 7). The most current radiographs revealed no misalignment, radiolucent lines, or osteolysis about the tibial component. Eight knees had incomplete lucent lines about the posterior feet of the femoral prostheses, and 3 had incomplete lucent lines of the proximal anterior flange. No patellar lucent lines were demonstrated, although 2 knees demonstrated a slight lateral tilt of the patella.

None of the 51 patients (55 knees) contacted by telephone only reported additional knee procedures since their index procedure. Preoperative KSS ranged from 32 to 78 (mean score, 51). The 50-point pain element of the original KSS on the telephone interview was statistically the same as for the patients who were examined in the office. Their LEAS scores ranged from 4 to 11 (mean score, 7.2). Figure 1 graphically illustrates the LEAS scores of either group.

Low LEAS scores rarely reflected the knee function in either group, but rather reflected other musculoskeletal or medical pathologies that limited their ability to engage in more rigorous physical activity. Patients with exceptional LEAS scores in both groups reported activities such as regular swimming, gardening, bicycling, and working out at a gym. Figure 2 includes a preoperative and a 60-month postoperative bilateral knee radiograph of an active 84-year-old patient.

No clinically significant postoperative DVT or pulmonary emboli were noted. No deep infections or manipulations under anesthesia were performed for arthrofibrosis in either group. Three complications occurred, 1 of which resulted in another knee operation. The first patient died before 24-month follow-up on either knee from causes other than the knee surgery. She presented with a left hemiplegia from a previous stroke with bilateral knee valgus deformities. She was primarily on bed rest for 6 months preoperatively because of pain. Her bone was markedly osteopo-

### Table 1

<table>
<thead>
<tr>
<th>Data</th>
<th>2-y Follow-up in Office</th>
<th>2-y Follow-up Via Telephone</th>
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<tbody>
<tr>
<td>Anesthesia, %</td>
<td>Spinal, 75; general, 25</td>
<td>Spinal, 77; general, 22</td>
</tr>
<tr>
<td>Mean operative time, min</td>
<td>94.0</td>
<td>96.7</td>
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<tr>
<td>Discharge disposition, %</td>
<td>Home, 89; nursing home, 6; outside rehab, 1; home health, 4</td>
<td>Home, 75; nursing home, 10; outside rehab, 10; home health, 6</td>
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<tr>
<td>Mean length of stay, d</td>
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### Table 2

<table>
<thead>
<tr>
<th>Questions</th>
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<tr>
<td>1. Are you having any pain with your knee(s)?</td>
</tr>
<tr>
<td>2. If so, how severe and how frequent is the pain?</td>
</tr>
<tr>
<td>3. How far are you able to walk?</td>
</tr>
<tr>
<td>4. Do you use any assistance when walking?</td>
</tr>
<tr>
<td>5. How active would you say you are?</td>
</tr>
<tr>
<td>6. What kind of activities do you do?</td>
</tr>
<tr>
<td>7. How often do you perform those activities?</td>
</tr>
<tr>
<td>8. Have you had any other procedures done on your knee(s)?</td>
</tr>
<tr>
<td>9. Can I convince you to come in to follow up with the doctor for an examination and to get radiographs taken of your knees?</td>
</tr>
<tr>
<td>10. Do you have any questions or concerns?</td>
</tr>
</tbody>
</table>
rotic intraoperatively; additional femur was removed and an extensive posterior capsular release was added to address chronic flexion contracture. No immediately postoperative radiographs were obtained. At 6-week follow-up, the patient and her caregiver were pleased with her pain relief but were concerned about her varus alignment. Radiographs revealed the tibial component to be in an extended, varus position (Figure 3). No overt falls were noted in the recovery process, although the family described a slip and near fall on transferring her 2 weeks postoperatively. This may also have occurred from overly vigorous extension in an effort to resolve her preoperative flexion contracture, which would have led to the osteoporotic proximal tibial bone collapsing at the anterior medial corner. The tibial component was revised to a stemmed metal-backed component with a medial augment with no femoral or patellar revision. She went on to have the contralateral knee replaced with an all-polyethylene tibial component. She and her caregiver were pleased with her pain relief, but her hemiplegia limited her ambulation. She died 48 months postoperatively from causes unrelated to her TKA.

Another patient had multiple spontaneous bleeds into his knee starting 16 months postoperatively. He reported no trauma. Because of her overall poor health, she underwent no surgical intervention, remained in a wheelchair, and learned transfers.

**Discussion**

Early all-polyethylene tibial components were limited in the sizes offered, which was a reason these designs fell short of restoring normal knee function. Despite this shortcoming, the Total Condylar Knee (Zimmer, Warsaw, Indiana) results with 21 to 25 years showed 91% to 87.5% survivorship.11,12 Revision options in that era were more limited in the event of component fixation, and the outcomes were poor, especially in knees with significant tibial bone deficiency.12-14 Early failure was nearly universal in knees with large defects and sizes larger than those offered by the manufacturer. Bartel et al15 used finite element analysis, focusing on mechanical stresses on the proximal tibia comparing an all-polyethylene tibia vs a metal-backed tibia with or without a stem, and a constant tibial component thickness. They modeled anatomic coverage by a theoretical tibial prosthesis and an anatomically sized theortetical femoral component. The study demonstrated that better stress distribution could be realized in a revision setting with the use of a metal-backed tibia covering the entire proximal tibial surface with a tibial stem. Surgeons and manufacturers rapidly switched to new stemmed...
metal-backed tibial components with the hope of greater options for intraoperative decision making in tissue balancing, less inventory, and future revision ease by changing the polyethylene bearing. The potential downsides of the modular tray paradigm were not sufficiently appreciated. Many orthopedic surgeons did not view the all-polyethylene tibia favorably, and thus shifted their tibial implant selection to a metal-backed modular implant. All-polyethylene tibia sales decreased dramatically, and some companies terminated this option in their inventory.

Over time, the problems of modularity in the tibial tray have become apparent. Unintended, yet significant, motion of the polyethylene insert against unpolished metal backing liberated debris, which resulted in proximal tibial osteolysis. Cold flow into screw holes and fretting wear at the locking mechanisms added to polyethylene wear and locking mechanism failures. Polyethylene motion in several older fixed-bearing modular trays led to backside wear in numerous tibial designs that were retrieved and tested. Mobile bearings that intentionally rotate on a polished tibial tray are thought to decrease the amount of backside tibial polyethylene wear. However retrieval studies from 2 centers reported no advantage in a rotating bearing over a fixed bearing with regard to surface polyethylene damage and in several cases discovered greater burnishing, scratching, and embossed third-body debris in some mobile bearings compared with fixed bearings.

Modularity concerns and cost containment have moved many manufacturers to reintroduce the all-polyethylene tibia using improved materials and proportionally sized components to match their metal-backed counterparts. However, these newer generations of implants have not been universally trouble free. Faris et al used the Anatomic Graduated Component (AGC) (Biomet, Warsaw, Indiana) flat coronal design with a central I-beam tibial post with a no backside tibial undercuts mated with a symmetrically flat femoral component and used in nearly all corners at 1 institution. They reported a 10-year tibial component failure rate at 32%. Seventy-three percent
of these failures resulted from the collapse of the medial tibial plateau speculated as a result of greater stress of the unsupported polyethylene on the subchondral bone.\(^1\) Berend et al\(^{23}\) reported that the highest tibial loosening and implant migration in this same cohort occurred in those with higher body mass indexes and smaller tibial component sizes. More positive outcomes were reported for the Sigma (Depuy Orthopedics, Warsaw, Indiana), with its round-on-round coronal geometry.\(^2\)-\(^6\) The Twin Cities community registry noted a 99.7% 14-year survivorship.\(^5\)-\(^9\) Single centers reported 0% to 1% revision rates with up to 10 years of follow-up.\(^2\)-\(^5\),\(^25\)

The Scorpio cruciate-retaining all-polyethylene tibia has a swept-back keel post design (Figure 4). The tibial keel cavity is prepared using a bone-displacing punch that leaves room for a 2-mm cement mantel. Implant fixation enhancers include undersurface peripheral dovetail marginal grooves and post grooves. Implants come in 4 sizes, each in 10-, 12-, 15-, and 18-mm thicknesses. The ultrahigh-molecular-weight polyethylene originates from GUR 1020. It is compression-molded into bar stock and machined to size. It is sterilized by Gamma Irradiation, and packaged in an inert nitrogen environment (N2Vac; Stryker Orthopedics).

![Figure 5](https://via.placeholder.com/150)

**Figure 5:** Sagittal view of the femoral component showing 2 major radii: 15° to 75° of flexion and greater than 75°. The latter radius is smaller to accommodate deep flexion, allowing improved midrange knee stability (A). Coronal view showing the medial lateral radius (B). (Reprinted with permission from Stryker Orthopedics, Mahwah, New Jersey.)

<table>
<thead>
<tr>
<th>Author</th>
<th>Implant</th>
<th>No. of Joints</th>
<th>Follow-up</th>
<th>No. (%) of Failures</th>
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<tr>
<td>Faris et al(^1)</td>
<td>ACG(^a)</td>
<td>536</td>
<td>120 mo</td>
<td>79 (14.7)</td>
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<tr>
<td>Gioe et al(^2)</td>
<td>PFC Sigma(^b)</td>
<td>312</td>
<td>42 mo</td>
<td>10 (3.2)</td>
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<tr>
<td>Gioe et al(^3)</td>
<td>Sigma(^b)</td>
<td>316</td>
<td>115 mo</td>
<td>22 (7)</td>
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<tr>
<td>Gioe et al(^4)</td>
<td>Sigma(^b)</td>
<td>433</td>
<td>120 mo</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Dalury et al(^5)</td>
<td>PFC Sigma(^b)</td>
<td>177</td>
<td>7 y</td>
<td>1 (0.6)</td>
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<tr>
<td>Muller et al(^6)</td>
<td>PFC(^c)</td>
<td>21</td>
<td>24 mo</td>
<td>0 (0)</td>
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<tr>
<td>Berend et al(^23)</td>
<td>ACG(^a)</td>
<td>22 MB, 32 AP</td>
<td>3.1 y</td>
<td>7 (20)</td>
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<tr>
<td>Font-Rodriguez et al(^12)</td>
<td>PS Total Condylar(^d)</td>
<td>265</td>
<td>16 y</td>
<td>16 (5.9)</td>
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<tr>
<td>Rand(^14)</td>
<td>Total Condylar(^d)</td>
<td>61</td>
<td>10 y</td>
<td>4%</td>
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<tr>
<td>Joshi et al(^28)</td>
<td>Howmedica ACG(^e), GPAC(^a)</td>
<td>110</td>
<td>7.9 y</td>
<td>0 (0)</td>
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<tr>
<td>Zicat et al(^29)</td>
<td>MG(^f); Howmedica Kinematic II(^e)</td>
<td>50</td>
<td>2 y</td>
<td>3 (6)</td>
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<tr>
<td>Ranawat et al(^30)</td>
<td>APT-PS(^f)</td>
<td>54</td>
<td>5 y</td>
<td>2 (3.7)</td>
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<tr>
<td>Current study</td>
<td>Scorpio(^e)</td>
<td>188</td>
<td>49</td>
<td>1 (5.5)</td>
</tr>
</tbody>
</table>

Abbreviations: ACG, Anatomic Graduated Component; AP, all-polyethylene; APT, all-polyethylene tibia; MB, metal-backed; PFC, Press Fit Condylar; PS, posterior-stabilized.

\(^a\)Biomet, Warsaw, Indiana.

\(^b\)Depuy Orthopedics, Warsaw, Indiana.

\(^c\)Johnson and Johnson, Leeds, United Kingdom.

\(^d\)Zimmer, Warsaw, Indiana.

\(^e\)Stryker Orthopedics, Mahwah, New Jersey.

\(^f\)DePuy Sigma, Warsaw, Indiana.

Joshi et al\(^28\) reported 110 TKAs in octogenarians using a combination of metal-backed and all-polyethylene cruciate retaining knees and reported that 34% were
alive after 10 years. No revisions were performed as a result of loosening or polyethylene wear.\textsuperscript{28} Zicat et al\textsuperscript{29} reported 50 knees with a 2- to 5-year (mean, 3 years) follow-up with metal-backed tibial components. Patient age ranged from 80 to 95 years (mean, 83 years). No revisions were performed for component loosening, but 2 patients died of unrelated causes, and 3 reoperations were performed for extensor failures or infection.\textsuperscript{29}

The current patients’ LEAS scores revealed typically active patients following their TKA, with a mean activity reflective of walking outside their residence on a regular basis. This knee design allows these patients to have a modestly active lifestyle at the reported intervals. This corroborates well with the success of an all-polyethylene tibia in a higher activity level of a younger age group of patients following posterior-stabilized all-polyethylene tibia as reported by Ranawat et al.\textsuperscript{30}

The efficacy of a well-performed TKA in an elderly individual with late-stage arthritis is well documented.\textsuperscript{28,29,31,32} Delivering this care in a more cost-efficient manner is essential. Less invasive surgery, earlier therapy intervention, less anesthesia use, and postoperative pain management improvements have contributed to decreased inpatient length of stay. An all-polyethylene tibia decreased the overall cost of the TKA by $1200, or a 30% savings in this group. This represented a savings of more than $228,000 in these 190 knees. This correlates with the 20% to 50% savings reported by Gioe and Maheshwari.\textsuperscript{24}

The weaknesses of this study begin with the design of a longitudinal study group without a randomized metal-backed group. Literature control gives no indication of different results with a metal-backed component in this interval in this patient age group.\textsuperscript{23,26} Second, the 27% of patients who were lost to follow-up or died before 24-month radiographs were obtained dilutes the potential effect of these findings, especially if a worst case scenario would assume that these were eventually failed implants. Third, the authors only had 44% of the group with implants for longer than 24 months present to the office for examination and radiograph analysis. However, the lack of statistical difference in the patient-reported element of the pain portion of the KSS and the LEAS score make it reasonable to consider that the radiographs of the 29% the authors spoke to only by telephone would have similar findings with those who were examined in the office. Elderly patients had difficulty getting transportation for follow-up visits, even if the services were provided at no cost. “I am not having any problems with my knee” was a common reason for not coming to the office. Finally, the authors had no comparison group for LEAS scores in either a metal-backed or a no knee arthritis cohort with which to compare the results.

**CONCLUSION**

A group of Scorpio cruciate-retaining all-polyethylene tibia knees had a 99% survivorship rate in an elderly patient population at a mean interval of 49 months, which compared favorably with other studies that reported other all-polyethylene tibia designs (Table 3). The average life expectancy for all individuals who had reached age 75 years was an additional 11.6 years.\textsuperscript{9} Improved quality of life and maintaining independence as a result of a technically well-placed TKA supports the use of this knee design in this age population. Cost savings were realized without compromising the quality of the outcome in this short-term time interval. Ongoing follow-up is necessary to demonstrate whether the Scorpio cruciate-retaining all-polyethylene tibia knee functions comparably with its modular counterpart at a longer-term interval. \( ^{\#} \)

**REFERENCES**

15. Bartel DL, Burstein AH, Santavicca EA, Insall JN. Performance of the tibial compo-


