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ORIGINAL RESEARCH

Polished Cobalt-Chrome *vs* Titanium Tibial Trays in Total Knee Replacement (a Comparison using the PFC Sigma System)

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ABSTRACT

Fixed-bearing total knee arthroplasty components can cause wear debris due to fretting micromotion between the polyethylene insert and the metal tibial tray, possibly leading to osteolysis and implant failure. This study compared the effects of either a highly polished cobalt-chrome (CoCr) or titanium tibial tray in patients receiving the PFC. Sigma® posterior stabilized knee system with a moderately cross-linked polyethylene insert. One hundred five patients with titanium tibial trays and 70 patients with CoCr tibial trays were prospectively enrolled at the time of follow-up of at least 4 years from surgery. There were two revisions with implant removal in each group. On blinded radiographic review, osteolysis was observed in three of 105 knees in the titanium group and three of 70 knees in the CoCr group. Radiolucent lines were categorized in accordance with the Knee Society roentgenographic evaluation system. In the titanium group 18% showed no radiolucent lines, 65% scored four or less (nonconcerning), and 17% scored between five and nine (requires observation for progression). In the CoCr group 24% showed no radiolucencies, 61% scored four or less, and 14% scored between five and nine. None of the knees in either group scored greater than 10 (possible or impending failure). Knee society scores and radiographic alignment were statistically similar between groups. These results suggest that there may not be a difference in clinical or radiographic mid-term outcome between titanium and CoCr tibial trays in total knee arthroplasty.

Keywords: TKA, Cobalt-chrome, Titanium, Osteolysis, Radiolucency.

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INTRODUCTION

Total knee arthroplasty (TKA) is an effective therapy for the treatment of painful and deforming joint diseases.[1] Advances in implant designs and material sciences have helped increase the longevity of implants and improve clinical outcomes for patients. Despite the overall success of TKA, limitations of the procedure certainly exist. Osteolysis associated with polyethylene wear is one major limitation adversely affecting the success and longevity of various knee arthroplasty constructs.[2-8] Polyethylene surface wear produces small particulate debris, which stimulates a foreign-body cellular response that may result in periprosthetic osteolysis and component loosening.[9,10]

In addition to articular surface wear present in both modular and monoblock tibial devices, modular knee systems are subject to wear at the interface between the underside of the polyethylene insert and the metal tibial tray. This phenomenon has been termed backside wear and is caused by fretting micromotion of the polyethylene insert on the tibial tray during normal movement overtime.[11-14] Variables affecting backside wear include polyethylene composition, metal surface finish, alloy, implant design and locking mechanism.[15,16]

Titanium and cobalt-chrome (CoCr) are two metal alloys with different material characteristics commonly used in TKA implants.[17,18] Titanium alloy is softer than CoCr, making it more susceptible to damage and less wear resistant.[19,20] Some authors have observed that implant constructs made from harder metals, such as CoCr may be more scratch-resistant, resulting in a decrease in backside wear.[21] These metals also produce different cell-mediated responses in the periprosthetic environment. CoCr particles are likely to be more toxic to surrounding tissue, but titanium particles are more likely to cause release of inflammatory cytokines implicated in osteolysis.[22-24] The various *in vivo* effects of titanium and CoCr metal debris remain unclear.

Titanium and CoCr tibial tray constructs may have uniquely different impacts on backside polyethylene wear leading to subsequent discrepancies in radiolucency, osteolysis and loosening. The goal of this study, therefore, is to investigate if significant clinical or radiographic differences exist between titanium and CoCr tibial tray designs.

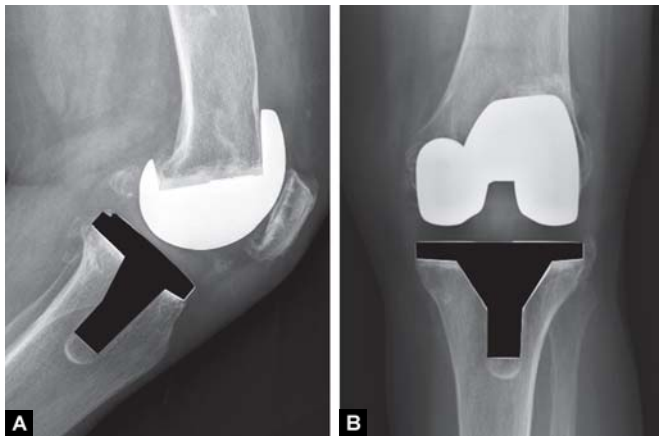
MATERIALS AND METHODS

The senior author (TPV) performed all primary TKAs between November 2001 and October 2005 at a single institution exclusively with the cemented PFC. Sigma® knee system (DePuy Orthopaedics, Warsaw, IN). The Sigma is a modular fixed-bearing prosthesis with a moderately cross-linked, oxidatively stabilized polyethylene insert. Before April of 2004, the Sigma tibial trays were constructed using a standard titanium material. At that time, a highly polished CoCr tibial tray was offered with the hope of providing a

more polyethylene-friendly environment to minimize abrasion and increase long-term durability. All other components (femur, patella, polyethylene insert) were unchanged. Surgery for all patients was performed *via* standard-length medial parapatellar approach. The femoral, tibial and patellar components were implanted with DePuy Endurance® cement. All implants were posterior stabilized devices, and all patellae were resurfaced. A standard post-operative protocol was used in all patients. This consisted of weight-bearing as tolerated 1 day after surgery, typical discharge on the third day after surgery, and 4 to 6 weeks of outpatient physiotherapy. Patients were routinely followed up postoperatively at 2 and 6 weeks, 6 months or 1 year, and periodically in the years thereafter.

All patients returning to clinic who received the Sigma knee system during this time period with at least 4 years of follow-up were enrolled in this study and followed prospectively thereafter. After informed consent, patients were evaluated with a physical examination by one of the senior authors (MPB) and a standard three-view radiographic series of the replaced knee. Radiographs were taken parallel to the component-bone interface in both anterior-posterior (AP) and lateral projections. Knee Society knee and function scores,[25] demographic information, and clinical history were also prospectively collected at the time of follow-up.

Standard AP, lateral and sunrise radiographs were evaluated for radiolucent lines, osteolysis, loosening and femoral-tibial alignment. All radiographs were evaluated by two investigators (BJH and KTH). Titanium and CoCr each produce a uniquely identifiable radiographic shadow. Therefore, a customized graphic template was created to adequately blind the tibial components before radiographic analysis (Figs 1A and B). The evaluators were also blinded from all patient-related demographics and the clinical status of each patient. All length measurements were made using the known diameter of the circular tibial stem as a reference. Radiolucent lines measuring at least 1 mm were categorized using the Knee Society roentgenographic evaluation system[26] with modification of the zonal system for the Sigma construct. The presence of osteolysis was defined as an area of focal radiolucency of at least 1 cm that displayed an absence of cancellous markings and could be visualized on both AP and lateral radiographs.[4] Areas of osteolysis were measured in their most prominent radiographic axis using the formula to calculate the area of an ellipse $[(1/4)\pi(\text{length})(\text{width})]$.[27] The femoral-tibial angle was measured using a 180° coronal system[28] and compared to a goal range of 172.8 to 177.6° (2.4° to 7.2° of valgus).[29] Clinical and radiographic data were compiled into a single database. Continuous variables between the two groups were compared using the Student's t-test, while categorical variables were compared with Chi-square analysis and the Fisher's exact test. A two-tailed p-value of less than 0.05 was considered significant. All statistical analyses were performed using SAS E-Guide Version 4 for Windows (SAS Institute, Cary, NC).



Figs 1A and B: Typical (A) AP and (B) lateral radiographic views of implant position and bone quality at follow-up demonstrating the customized graphic template used to blind the tibial shadow during analysis

RESULTS

Clinical Outcomes

One hundred five patients with titanium tibial trays and 70 patients with CoCr tibial trays were enrolled. The titanium group had a mean age at surgery of 61 (SD 8.05, range 40-77) and was 40% male. The CoCr group had a mean age at surgery of 62 (SD 11.50, range 21-79) and was 47% male. The mean time to follow-up was 72 months (SD 13.95, range 48-102) for the titanium group and 58 months (SD 6.37, range 59-72) for the CoCr group. Preoperative diagnosis for the titanium group included osteoarthritis (87 patients, 83%), inflammatory arthritis (6 patients, 5.5%), post-traumatic arthritis (9 patients, 8.5%) and osteonecrosis (3 patients, 3%). Preoperative diagnosis for the CoCr group consisted of osteoarthritis (59 patients, 84%), inflammatory arthritis (8 patients, 11.5%), post-traumatic arthritis (2 patients, 3%) and osteonecrosis (1 patient, 1.5%) (Table 1).

Two patients from each group received revisions for implant loosening ($p > 0.05$). No revisions with component removal were performed for other indications. Nine procedures without component removal were performed in the titanium group (2 superficial infection, 6 manipulation, 1 arthroscopic debridement of scar tissue) and three

Table 1: Demographic comparisons of the two groups

Parameter	*Titanium (n = 105)*	*Cobalt Chrome (n = 70)*	*p-value*
Gender (n)			NS
Male	42	33	
Female	63	37	
Age, mean ± SD (range)	61 ± 8.05 (40-77)	62 ± 11.50 (21-79)	NS
Diagnosis (n)			NS
Osteoarthritis	87	59	
Inflammatory	6	8	
Posttraumatic	9	2	
Osteonecrosis	3	1	
Follow-up in months, mean ± SD (range)	72 ± 13.95 (48-102)	58 ± 6.37 (59-72)	<0.001

NS: Not significant

Table 2: Clinical and radiographic results

	Titanium (n = 105)	*Cobalt Chrome (n = 70)*	*p-value*
Clinical Results			
Revision (n)	2	2	NS
Procedure (nonrevision) (n)			NS
Manipulation	6	2	
Superficial infection	2	0	
Arthroscopic debridement of scar tissue	1	0	
Quadriceps tendon repair	0	1	
Knee Society Score: Knee, mean ± SD (range)	91.18 ± 12.47 (47-100)	93.21 ± 9.68 (59-100)	NS
Knee Society Score: Function, mean ± SD (range)	85.24 ± 21.88 (10-100)	84.00 ± 21.44 (5-100)	NS
Radiographic results			
Osteolysis (n)	3	3	NS
Radiolucency score (n)			NS
No radiolucent lines	19	17	
1-4 (nonconcerning)	68	43	
5-9 (requires observation)	18	10	
≥ 10 (impending failure)	0	0	
Alignment, mean ± SD (range)	176.0° ± 2.73° (168.3°-181.4°)	175.3° ± 1.90° (169.2°-181.8°)	NS

NS: Not significant

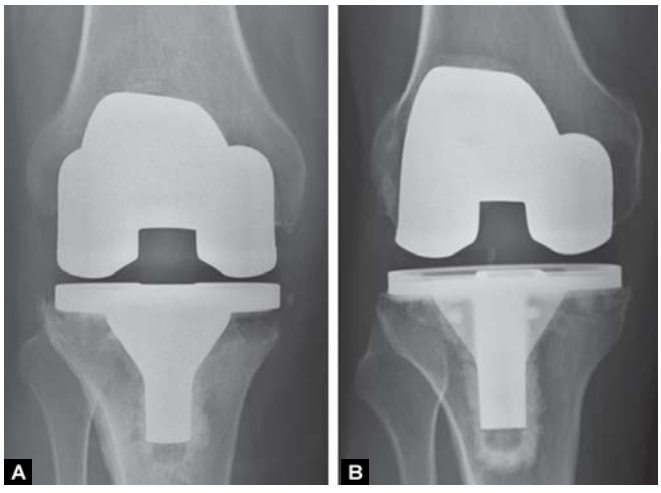
procedures without component removal were performed in the CoCr group (2 manipulation, 1 partial quadriceps tendon rupture) ($p > 0.05$). The mean Knee Society knee scores at follow-up were 91.18 (SD 12.47, range 47-100) in the titanium group and 93.21 (SD 9.68, range 59-100) in the CoCr group. The mean Knee Society function scores at follow-up were 85.24 (SD 21.88, range 10-100) in the titanium group and 84.00 (SD 21.44, range 5-100) in the CoCr group ($p > 0.05$) (Table 2).

Radiographic Outcomes

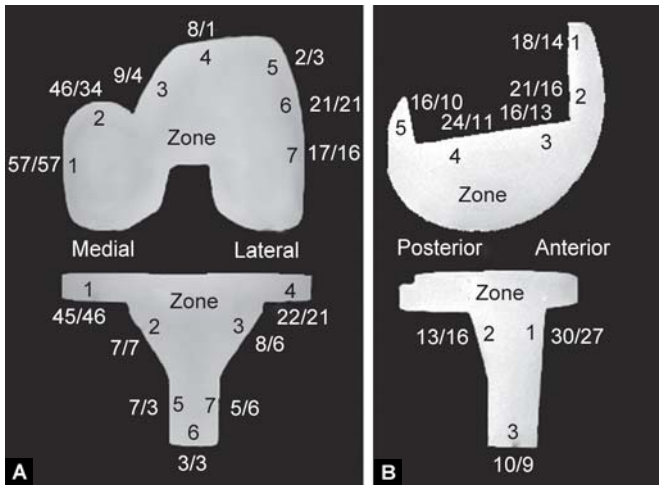
Osteolysis was present in three of 105 knees in the titanium group and three of 70 knees in the CoCr group ($p > 0.05$). The location and area (mm^2) of all osteolytic lesions are outlined in Table 3. Two examples of periprosthetic osteolytic lesions present in the study (Figs 2A and B). Radiolucent lines were categorized with a modified Knee Society roentgenographic evaluation system.[26] In the titanium group 18% showed no radiolucent lines, 65% scored four

Table 3: Radiographic zones of osteolysis

Case	*Alloy*	*AP tibial zone (L × W, mm)*	*Lat. tibial zone (L × W, mm)*	*AP femoral zone (L × W, mm)*	*Lat. femoral zone (L × W, mm)*
1	Titanium	—	—	1 (20 × 8)	3 (6 × 4)
2	Titanium	—	—	1 (23 × 9)	3 (9 × 6)
3	Titanium	—	—	1 (20 × 8)	4 (10 × 5)
4	CoCr	1 (23 × 12)	3 (10 × 6)	—	—
5	CoCr	4 (10 × 4)	1 (6 × 3)	—	—
6	CoCr	—	—	1 (25 × 7)	2 (5 × 7)



Figs 2A and B: AP radiographs demonstrating osteolysis of the (A) medial tibial plateau (Zone 1) and (B) medial femoral condyle (Zone 1). These nonblinded radiographs also exhibit the difference in tibial shadow between (A) CoCr and (B) titanium



Figs 3A and B: A representation of our modified (A) AP and (B) lateral zonal system and a comparison of the presence of radiolucent lines in each radiographic zone (% of titanium/% of CoCr)

or less (nonconcerning), and 17% scored between five and nine (requires observation for progression). In the CoCr group 24% showed no radiolucencies, 61% scored four or less, and 14% scored between 5 and 9. None of the knees in either group scored greater than 10 (possible or impending failure) ($p > 0.05$) (Table 2). The percentage of radiolucent lines present in each radiographic zone for both metal alloy groups (Figs 3A and B). The mean coronal femoral-tibial angle at follow-up was measured at 176.0° (SD 2.73°, range 168.3-181.4°) in the titanium group and 175.3 (SD 2.90°, range 169.2-181.8°) in the CoCr group ($p > 0.05$).

Revision Characteristics

Two revisions were performed for presumed implant loosening in each group based on clinical symptoms, radiographic results and bone scan results. Clinical and radiographic revision characteristics are summarized in Table 4. The revisions in the titanium group occurred after 15 and 60 months. Intraoperatively, one patient was found to have a grossly loose tibial component, minimal bone wear and extensive polyethylene wear on the tibial tray. The other patient had a grossly loose femoral component with significant osteolysis at the anterior flange and substantial polyethylene insert wear. The revisions in the CoCr group occurred after 28 and 66 months. Intraoperatively, one patient was found to have a grossly loose tibial component in the setting of bone loss that was concerning for possible osteolysis in both the distal femur and the tibial plateau. There was minimal polyethylene insert wear. The other patient had a grossly loose tibial component with significant medial tibial plateau osteolysis and polyethylene insert wear. This patient's prerevision radiograph with an obvious osteolytic lesion can be seen in Figure 2A. The observed lesion met our specifications for radiographic osteolysis and represents case 4 in Tables 3 and 4. Two out of the three revisions without radiographic osteolytic lesions had radiolucency scores between five and nine (requires observation for progression). The other revision showed no radiolucencies before revision surgery.

DISCUSSION

Metal alloys used in TKA implants generate both metal wear debris and polyethylene debris from liner wear. In order to understand the effects that titanium and CoCr have on the periprosthetic environment in TKA, both the amount of metal and polyethylene debris as well as their different immunomodulatory properties must be accounted for. There is no clear consensus in the literature on these issues. Titanium alloy is softer than CoCr, leading some authors to believe that it is more susceptible to metal wear.[19,20] La

Table 4: Clinical and radiographic revision characteristics

Case	*Alloy*	*Survival (months)*	*Component loosening*	*Polyethylene wear, intraop*	*Osteolysis, intraop*	*Osteolysis, radiographic*	*Radiolucency score*
1	Titanium	15	Tibial	Yes	No	No	5 to 9
2	Titanium	60	Femoral	Yes	Yes	No	5 to 9
3	CoCr	28	Tibial	No	Yes	No	0
4	CoCr	66	Tibial	Yes	Yes	Yes	n/a

n/a: Not available

Budde et al examined the synovial tissue from 6 CoCr and 6 titanium TKA revisions. The authors demonstrated that titanium alloy knees generated significantly more metallic debris but CoCr knees had more polyethylene debris and a greater number of histiocytes.[30] A recent fretting wear simulator study showed that a CoCr disk produced slightly greater polyethylene fretting wear than a titanium disk. However, the effect of different alloys was smaller than the effect of surface roughness or micromotion amplitude.[31] Rao et al stereoscopically examined retrieved tibial baseplate wear in 10 titanium and 7 CoCr baseplates. No significant differences between alloy type and insert motion, backside polyethylene wear, or baseplate wear were identified.[32] The generated particulate debris likely causes a direct toxic effect on the local soft tissue as well as a cytokine-mediated immunological response. CoCr particles are likely to be more toxic to surrounding tissue, but titanium particles are more likely to cause release of inflammatory cytokines implicated in osteolysis.[22-24] These topics are complex and unclear. For these reasons, some surgeons choose to eliminate the issue of backside wear through the use of monoblock tibial components. Advocates of monoblock implants have demonstrated reduced incidence of osteolysis and revision procedures when compared to modular implants.[33-36] Continued multidisciplinary research is warranted.

This study documents similar clinical and radiographic outcomes between titanium and CoCr tibial trays at a minimum of 4 years postsurgery with the cemented PFC Sigma® posterior-cruciate-substituting knee system. Clinical findings were notable for statistically similar revision rates and Knee Society scores between groups. Radiographic findings were notable for comparable incidences of osteolysis and radiolucency between groups. In this study, we report an implant survivorship of 103 of 105 knees (98.1%) at a mean of 72 months follow-up in the titanium group and an implant survivorship of 68 of 70 knees (97.1%) at a mean of 58 months follow-up in the CoCr group. This rate is comparable to previous studies that have documented implant survivorship within same knee system. Dalury et al reported specifically about midterm results of the PFC. Sigma® implant system and showed a survivorship of 99.6% at a mean of 87 months follow-up.[27] Mikulak et al reported a slightly lower implant survivorship rate of 96.1% at a mean of 56 months follow-up. However, the survivorship rate specific to aseptic loosening and osteolysis was 97.1%.[21]

Osteolysis after TKA is associated with backside wear in modular tibial components[11-14] and wear of the tibial post in posterior stabilized components,[37] but is uncommon in cemented implants.[2,38] On blinded radiographic review, we observed osteolysis in three of 105 (2.9%) knees in the titanium group and three of 70 (4.3%) knees in the CoCr group. This rate is comparable to other studies with cemented, modern knee systems and similar follow-up time. Dalury et al reported a 4% incidence of osteolysis with the Sigma implant.[27] Lachiewicz and Soileau documented osteolysis in eight out of 193 (4.1%) knees at a mean follow-up time of 7 years using the Insall-Burstein II posterior stabilized system.[6] However, their study had a longer maximum follow-up duration of 14 years.

Subgroup analysis of the subjects in our study with osteolysis revealed that all six subjects were younger than the overall mean age at surgery and had an average group age of 48.2. Younger age has been associated with increased risk for osteolysis.[5] A possible explanation for this observation is that younger patients are more likely to live active lifestyles and generate more polyethylene wear.

Additional subgroup analysis revealed that the location of the osteolytic lesions in this study is of particular interest. All four of the AP femoral osteolytic lesions were located in zone 1 (medial femoral condyle). The two AP tibial osteolytic lesions were in zone 1 (medial tibial plateau) and zone 4 (lateral tibial plateau) (Table 3). To our knowledge, Dalury et al is the only other research group to categorize osteolysis in the Sigma implant by radiographic zone. They observed 6 AP tibial osteolytic lesions in zone 1; 2 AP tibial lesions in zone 4; and 2 AP femoral lesions in zone 1.[27] These results suggest that osteolysis in this knee implant system is most likely to occur in the medial and lateral tibial plateaus and the medial femoral condyle. This indicates that providers should be vigilant to concerning radiographic lesions in these areas.

One limitation of this study is that the mean follow-up time of the titanium group is significantly longer than the CoCr group because all of the titanium tibial trays were implanted before the switch was made to CoCr. Radiolucency and osteolysis in TKA are known to progress with time.[39] We found that even though the incidence of radiolucent lines between groups was statistically similar, the percentage of titanium knees with radiolucent lines was consistently higher than the percentage of CoCr knees with radiolucent lines across almost all radiographic zones without reaching the level of significance (Fig. 3). It is unclear whether this observation is related to metal alloy or a result of longer follow-up time in the titanium group.

Another limitation of the present study is the retrospective nature of enrollment. All patients returning to clinic who received the Sigma knee system between November 2001 and October 2005 with at least 4 years of follow-up were enrolled in this study until the enrollment goal of 175

patients was reached. The most likely reason that more patients were enrolled in the titanium group than the CoCr group is because patients received the titanium implant from November 2001 to April 2004 and only received the CoCr implant from April 2004 to October 2005. However, the enrollment in this study does has several notable strengths. Notably, a single surgeon (TPV) performed all of the procedures at a single medical center. Additionally, the two groups consist of patients with statistically identical demographic data and diagnoses (Table 1). This helps to alleviate concern for unaccounted differences between the groups.

In the present study, we used plain radiographs to identify osteolysis around a TKA. Currently, this modality is used almost universally by providers to monitor arthroplasty patients over time. However, it provides only a two-dimensional projection of a three-dimensional osteolytic lesion. Furthermore, the opaque implant shadow can often mask part or all of the osteolysis.[40-42] For these reasons, we required that the osteolysis be observable in both the AP and lateral radiographic views in an attempt to catalog the three-dimensional footprint of the lesion. At this time, three-dimensional imaging modalities are not routinely used for evaluation of osteolysis. In the future, modalities, such as computed tomography and magnetic resonance imaging with scatter reduction technology, may help to more accurately categorize osteolysis in arthroplasty.

This study compared the midterm clinical and radiographic results of highly polished CoCr tibial trays with titanium tibial trays in patients receiving the PFC. Sigma® posterior stabilized knee system. Our results show no difference in revision rate or incidence of osteolysis between these two tibial trays. Further studies with long-term follow-up are needed in order to completely delineate the differences in clinical and radiographic outcome between these two metal alloys in TKA.

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