

Reconstructive REVIEW

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Reconstructive REVIEW

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Orthopaedic Surgeons Specializing in
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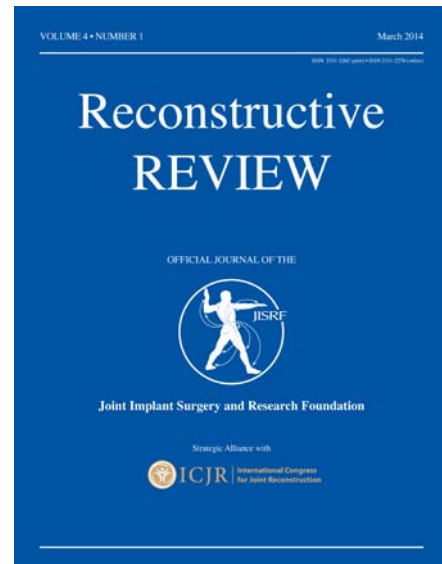
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Reconstructive Review



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Reconstructive Review

A Journal Published by the Joint Implant Surgery & Research Foundation



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- Historical Reviews
- Letters to the Editor
- Surveys

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ORIGINAL ARTICLE

Peri-Prosthetic Infection in the Orthopedic Tumor Patient

Daniel C. Allison MD, MBA, FACS^{1,2}; Eddie Huang, MD²; Elke R. Ahlmann, MD²; Scott Carney, MD²; Ling Wang, PA-C²; Lawrence R. Menendez, MD, FACS²

Abstract

Background: Infection complicates traditional joint reconstruction prostheses in up to 7% of cases, with even higher rates in oncologic cases.

Questions / Purposes: The authors ask if prosthetic infection in bone tumor patients is associated with any epidemiologic, treatment, or outcome variables that could influence management of these difficult conditions.

Patients and Methods: Authors retrospectively reviewed 329 consecutive bone tumor (malignant and benign) patients treated with hip or knee tumor resection and subsequent joint reconstruction, comparing infected and non-infected cases. Patients were followed for a mean of 34 months.

Results: Of lower extremity tumor reconstructions, 13.1% developed periprosthetic infection, with the knee significantly more involved than the hip (20.5% vs 6.1%). The most common organism cultured was *Staphylococcus aureus* (33%). The diagnosis of sarcoma was associated with a higher infection rate, and infections were associated with a two-fold increase in number of total surgeries. Adjuvant radiation alone and chemotherapy alone (but not in combination) was associated with statistically increased infection rates. Debridement with fixed implant retention achieved a 70% infection remission rate, as opposed to 62% with two-staged treatment, and 100% with amputation. The implants tended to survive longer than the patients.

Conclusions: Infection complicates lower extremity prosthetic joint reconstructions in tumor patients more frequently than in non-tumor arthroplasty cases, with eradication rates lower than that of non-tumor patients. Periprosthetic infection correlates with radiation and chemotherapy administration, as well as an overall increase in revision surgery. Single stage debridement procedures result in infection remission rates comparable to two-stage reconstructions.

Level of Evidence Level III, Retrospective comparative study.

Introduction

Periprosthetic joint infection remains a very common cause of failure of hip and knee arthroplasty [12]. The prevalence of infection in total knee arthroplasty ranges from 0.9% [13], to 2.01% [19], to 4.0% [1], while recent studies document the prevalence of infection in total hip arthroplasty at 1.1 – 2.2% [25, 26]. Another study notes a 1 – 7% infection prevalence in all primary joint arthroplasty

cases [12]. The incidence and prevalence of joint arthroplasty infection is increasing, with a two-fold increase in hip and knee prosthetic infections documented from 1990–2004 [17,18,19].

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The clinical impact of periprosthetic joint infection remains severe, with infection noted to be the leading cause of morbidity following joint replacement [22], the #1 cause of joint arthroplasty failure [12], and associated with a statistically increased rate of revision surgery [1]. Periprosthetic infection has been shown to carry a 2.7 – 18% mortality rate [22]. The economic impact of periprosthetic joint infection remains a significant problem, with these cases totaling three to four times the cost of uncomplicated primary arthroplasty [3,4,18]. One study estimates a cost of \$50,000 per periprosthetic infection [12], while another notes that septic revisions cost \$60,000 more than aseptic revision [1].

Peri-endoprosthetic infection for tumor reconstruction has been documented to occur in 5.7 – 15% of cases [8,10,11,23,24,27]. One series of 650 endoprosthesis cases, notes a 9.6% infection rate [7]. Another series documents the infection prevalence to increase to 43% in revision endoprosthesis cases [5], and another notes peri-endoprosthetic infection results in amputation in 23.5% of cases [27]. A thorough review of previous endoprosthesis infection case series was performed in 2010 [2]. The study found staphylococcus was most common organism among multiple case series. Factors associated with infection were myeloma, radiation therapy, poor soft tissue condition, revision surgery, and extra-articular joint resection. These studies yielded mixed recommendations on treatments and outcomes [2].

The current study aims to investigate the incidence, prevalence, risk factors, treatments, and associated outcomes of infection of lower extremity arthroplasty cases performed for the treatment of musculoskeletal tumors in order to help improve their prevention and treatment. The authors post the question: is periprosthetic infection in our bone tumor patients associated with any disease, treatment, or outcome variables that could influence management of these difficult conditions?

Patients and Methods

All musculoskeletal tumor patients treated with lower extremity tumor resection and artificial joint reconstruction over a ten year period at a single institution were retrospectively reviewed, specifically evaluating those who developed deep periprosthetic infection, as determined by the clinical diagnosis of the evaluating surgeon. Non-tumor patients and those with infection prior to reconstruction were excluded.

Table 1 describes relevant patient demographics. Four basic lower extremity reconstructions were performed af-

ter surgical treatment of benign and malignant tumors: standard femoral stem arthroplasty, proximal femoral endoprosthetic reconstruction, distal femoral reconstruction, and proximal tibial reconstruction. Infection cases were then analyzed according to multiple variables, including patient epidemiology, pathology, adjuvant therapy, surgical history, type of prosthesis, previous implant surgeries, presentation time, causative organism, original treatment modality, and subsequent infection treatment. Patients were followed according to standard oncologic protocols for a mean of 34 months (range 4 to 251 months).

Table 1. Patient Demographics

Type of Prosthesis	n	Gender (M/F)	Age (Min - Max)	Follow up (months)
Hip Endoprosthesis	147	69/78	61 (14 - 86)	13 (0.5 to 217)
Hip Standard Prosthesis	16	5/11	59 (23 - 86)	21 (0.75 to 152)
Hinged Distal Femur Endoprosthesis	125	61/64	30 (12 - 90)	87 (1.8 to 251)
Hinged Proximal Tibia Endoprosthesis	41	23/18	31 (11 - 82)	70 (4.4 to 195)
Total	329	158/171	50 (11 - 90)	34 (0.4 to 251)

Variables were then compared within the infection cohort, using the student t-test to compare means and relative risk ratio. Kaplan-Meier survival analysis was performed to evaluate both implant and patient survival. Statistical confidence was set to a 95% interval, and data analysis was performed using Graphpad® statistical software. No power analysis was performed.

Results

The overall prevalence of infection in this tumor prosthetic patient cohort was 13.1%. Proximal femoral endoprostheses demonstrated a 5.4% rate of infection, as opposed to the 12.5% rate of standard hip prostheses, 19.2% in distal femoral endoprostheses, and 22% in proximal tibial endoprostheses (Table 2). Hip prosthesis reconstructions demonstrated a 6.1% infection rate as opposed to the 20.5% rate observed in knee endoprosthetic cases, a difference that was noted to be statistically significant ($p < 0.001$). When looking at infection rates with regard to specific diagnosis, sarcomas demonstrated the highest infection rate (21.7%), which was statistically increased when compared to non-sarcoma cases ($p = 0.001$ [Table 3]). Metastatic disease demonstrated the lowest overall infection rate at 7.4%, which was statistically lower than non-metastatic disease cases ($p = 0.006$ [Table 3]). Table

4 describes the cultured pathogens associated with the infections, with *Staphylococcus aureus* demonstrated in 33% of culture positive specimens, and *Staphylococcus epidermidis* in 17%. 50% of *Staphylococcus Aureus* specimens were methicillin resistant.

Table 2. Overall Infection Rate by Location

Type of Prosthesis	n	Time (mo)	Infection (n)	Infection %
Hip Endoprosthesis	147	12	8	5.4
Hip Standard Prosthesis	16	18	2	12.5
Hinged Distal Femur Endoprosthesis	125	70	24	19.2
Hinged Proximal Tibia Endoprosthesis	41	53	9	22.0
Total	329	28	43	13.1

Table 3. Overall Infection Rate by Disease

Disease	n	Infection Rate (%)	P-value
Sarcoma	106	21.7	0.001
Metastatic Disease	163	7.4	0.006
Benign Bone Tumor	60	15.3	0.64

Table 4. Microbiology

Pathogens	Patients (n)
<i>Staphylococcus Aureus</i>	10 (5 MRSA)
Coag Neg <i>Staphylococcus</i>	5
<i>Diphtheroids</i>	3
<i>Streptococcus</i>	3
<i>Enterobacter</i>	3
<i>Enterococcus</i>	2
<i>Escherichia Coli</i>	2
<i>Candida Albicans</i>	1
<i>Cryptococcus</i>	1
No Growth (gross purulence)	9

The mean total number of surgeries performed (prior to infection) was doubled in the infection group when compared to that of the non-infected group ($p = 0.005$ [Table 5]). The knee endoprosthesis cases demonstrated a consistently stable incidence with time, while hip infections developed earlier, and their incidence decreased with time (Figure 1 & 2). With regard to adjuvant therapy, radiation therapy alone was noted to carry a significantly higher risk of infection ($RR = 3.85$, $p = 0.03$), as did chemotherapy alone ($RR = 1.51$, $p = 0.05$). Interestingly, chemotherapy in combination with radiation was associated with a decreased rate of infection ($RR = 0.66$, $p = 0.05$ [Table 6]). With regard to the results of the final treatment modality, irrigation and debridement procedures alone (without any component exchange) were associated with 42% success at achieving remission of infection, while single stage irrigation and debridement procedures with the addition of

modular component exchange and varying degrees of suppressive antibiotics was associated with a 70% success rate. Formal two-staged implant removal, antibiotic spacer placement with subsequent reimplantation was associated with a 62% success rate, while 100% of infection cases treated with amputation resulted in remission of infection.

Table 5. Number of Associated Surgeries (prior to infection diagnosis)

	Infection		No-Infection	
# of Surgeries	n	%	n	%
1	20	45	224	78
2	15	34	50	17
3	3	7	9	3
4	2	5	1	0
5	2	5	0	0
Mean ($p=0.005$)	2		1	

Table 6. Infection and Adjuvant Therapy

Adjuvant	Patients	Infection Rate	Relative Risk	p-value
Chemotherapy alone	97	0.20	1.51	0.05
Radiation alone	6	0.50	3.85	0.03
Chemotherapy & Radiation	139	0.09	0.66	0.05
No Adjuvant Therapy	87	0.13	1.00	0.81

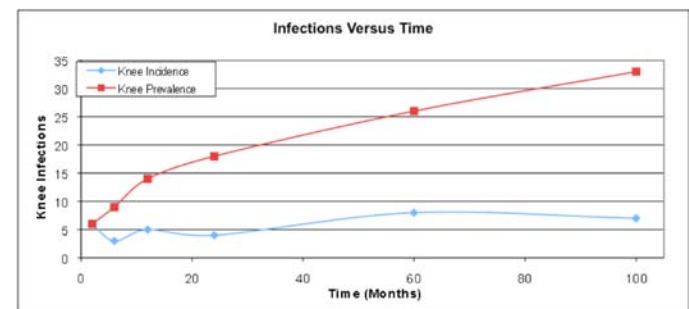


Figure 1. Incidence and prevalence of knee infections with regard to time

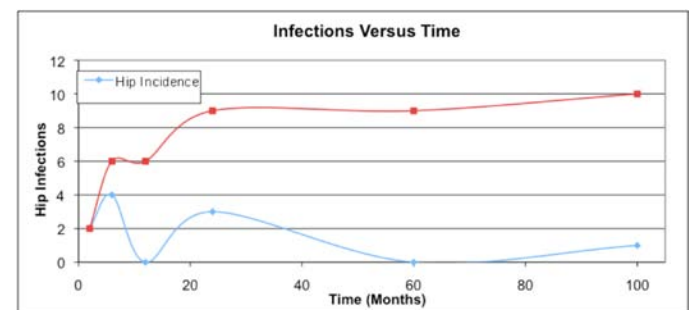


Figure 2. Incidence and prevalence of hip infections with regard to time

Figure 3 describes the overall implant survival in the entire base population, with over 70% of these implants surviving beyond a projected 20 years. Hip implants lasted longer than knee implants, when the subgroups were divided (Figure 4). Overall patient survival in the cohort hovered at roughly 40% for the long term (Figure 5), with

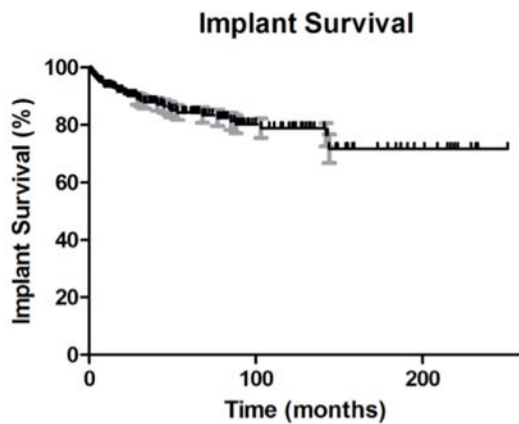


Figure 3. Kaplan-Meier curve describing overall implant survival

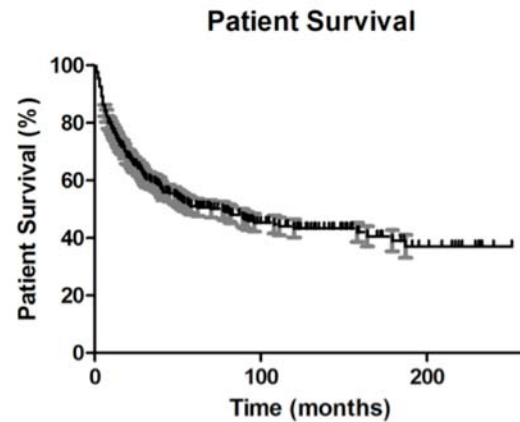


Figure 4. Kaplan-Meier curve describing implant survival with regard to location & type of implant (oncologic [endoprosthesis] vs non-oncologic [standard] implant)

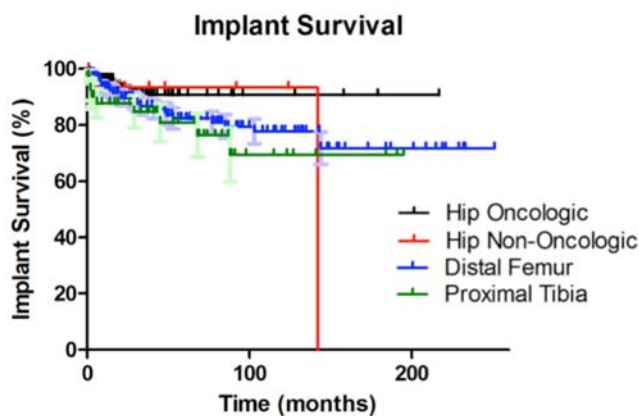


Figure 5. Kaplan-Meier curve describing overall patient survival

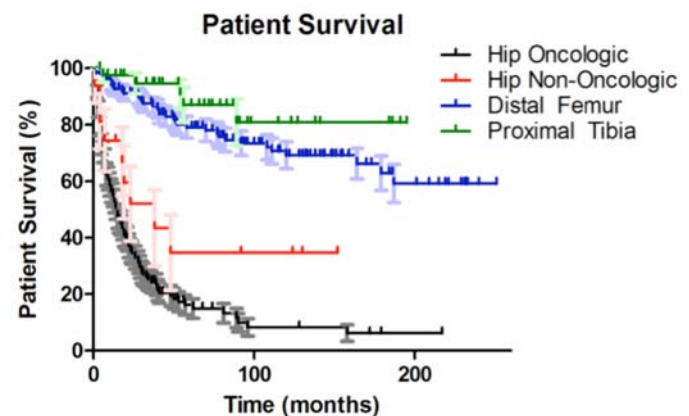


Figure 6. Kaplan-Meier curve describing patient survival with regard to location & type of implant (oncologic [endoprosthesis] vs non-oncologic [standard] implant)

knee patients surviving much longer than the hip counterparts (Figure 6). In all cases, implant survival was greater than patient survival.

Discussion

Periprosthetic infection represents a leading cause of failure, morbidity, and mortality in non-oncologic primary joint arthroplasty. Tumor prostheses are associated with increased infection rates when compared to traditional joint arthroplasty. The current study asks if periprosthetic infection in our bone tumor patients is associated with any epidemiologic, treatment, or outcome variables that could influence the prevention, diagnosis, and treatment of these conditions.

A major weakness of the study includes the lack of control and standardization of patients with multiple confounding variables with regard to their disease and treatment. For example, hip prosthesis were more often used in those with malignant diagnoses, especially metastatic disease. The decreased life expectancy seen in metastatic

disease will influence the prevalence of infection. Despite this lack of control, and relatively small numbers, statistical differences were indeed discovered with analysis of the subgroups in the cohort. The diagnosis of deep periprosthetic infection was based on the clinical judgment of the treating surgeon, and the diagnosis of initial or recurrent infection can often be unclear. The fact that all treating surgeons in the study were well versed in the clinical diagnosis and management of periprosthetic infection may mitigate this weakness.

Disease variables that were associated with infection in this tumor prosthesis series include the location and type of implant, with the knee significantly more at risk than the hip (20.5% vs 6.1% [$p = 0.0001$]). This correlates with a former study finding 23% of proximal tibial endoprosthetic reconstructions became infected [14]. The malignant diagnosis of sarcoma was associated with a statistically higher infection rate ($p = 0.001$), while those with metastatic disease demonstrated a statistically lower infection rate ($p = 0.006$). This finding contrasts previous literature citing increased infection rates with myeloma, as opposed to other tumors [14]. Most hip infections occurred in the first

year, while knee infections with same incidence at 5 years out. Previous publications show that most infections occurred early, but could be seen as late as 210 months after implantation [2]. Staphylococcus species remain the most common pathogen (50% of culture positive cases), a finding which also corresponds to the previous literature review [2].

In this study, radiation alone was associated with significantly higher infection risk (50%, RR = 3.85, $p = 0.03$), and less so chemotherapy (20%, RR = 1.51, $p = 0.05$). Several previous publications demonstrate increased infection rates with adjuvant radiation therapy [9,14,15,20]. A previous review of endoprosthesis infection case series failed to find any studies showing a correlation between chemotherapy and implant infection [2]. In the current study, chemotherapy and radiation in combination demonstrated a statistically decreased overall infection rate, likely due to the fact that their combined use often indicated underlying metastatic disease, with treatments administered at lower doses in those with shorter life expectancies. Infections were associated with significantly increased number of associated prior to development of infection ($p = 0.005$). Previous studies have also indicated infection correlates with revision surgery rates [9,14,20]. In these cases, the increased number of surgeries could be a cause or an effect of the periprosthetic infection. Irrigation & debridement with modular component exchange was noted to have similar success rates when compared to formal, extensive 2-staged procedures (70% vs 62%) in the current study. This contrasts with several studies in previous literature, which often found two stage procedures to have higher resolution rates, with single stage procedure success rates ranging from 6% to 73% [6,7,9,14,16,21].

With regard to survival, the current study's long term (> 10 year projected) implant survival was noted to be well over 70%, which correlates with recent literature regarding modular oncologic endoprostheses [28]. In our study, standard primary hip implants lasted longer than "oncologic" endoprostheses, which also correlates with previous studies. This study's highest survival was documented in proximal tibia and knee cases. This difference occurred presumably because primary tumors (benign and malignant) more commonly occurred in the knee, as opposed to the increased proportion of metastatic disease occurring in the proximal femur.

In conclusion, periprosthetic joint infection in the tumor patient occurs at a higher Incidence and prevalence when compared to traditional primary joint arthroplasty. Staphylococcus Aureus remains the most common cultured organism in these cases. Knee endoprosthetic infections can occur late, and the development of infection is associat-

ed with radiation therapy, chemotherapy, and revision surgery. Irrigation and debridement with modular component exchange may result in infection remission rates comparable to two-staged procedures.

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Surgical Stabilization of the Medial Capsulo-Ligamentous Envelope in Total Knee Arthroplasty

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Abstract

This study will evaluate an alternative method in which a four prong bone staple was used to repair the medial collateral ligament following over-release or avulsion injuries in (#6) cases during a total knee arthroplasty. The use of a four prong bone staple to repair medial collateral ligament injuries status post total knee replacement will provide satisfactory results with respect to post-operative knee stability and range of motion. Our retrospective review revealed that all six patients improved with regards to range of motion following the total knee arthroplasty. We feel that repair of the medial collateral ligament with a four-prong bone staple is a viable option after an over-release or avulsion injury sustained during a total knee arthroplasty.

Introduction

One of the more common complications of total knee arthroplasty is an intraoperative injury to the medial collateral ligament (MCL), in which there is significant loss of collateral ligament tissue with or without damage to the medial femoral condyle/epicondyle [7]. In a thorough review of the orthopedic literature, the overall incidence of this injury during total knee arthroplasty is unknown [7,9,10]. In this study, we describe a new, unreported fixation method of repairing the knee medial collateral ligament status post injury during a total knee arthroplasty using a Smith and Nephew four prong bone staple.

When researching the most current arthroplasty literature, insufficiency of the medial collateral ligament when discovered in the preoperative physical examination with varus and valgus stress testing can be treated with either soft tissue reconstruction using one of the following methods: 1.) hamstring fixation technique, 2.) achilles allograft with a calcaneal bone block and fixation with 6.5mm cancellous screws, 3) or with an implant that provides stability, not only in the sagittal but in the coronal plane as well with the use of a constrained knee construct [2,3,4,5].

The medial collateral ligament is the primary restraint to valgus stability of the knee. At around 30° of flexion, the medial collateral ligament provides 80% of the restraining force [12,13]. While in full extension, it only provides 60% of the restraining force [12,13]. A thorough understanding of the anatomy of the knee medial collateral ligament is crucial before any repair of this ligament can be performed.

The superficial medial collateral ligament otherwise known as the tibial collateral ligament is the largest struc-

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ture of the medial aspect of the knee. This structure consists of one femoral attachment and two tibial attachments. The femoral attachment has been shown to be oval in shape and on average is located 3.2mm proximal and 4.8mm posterior to the medial epicondyle [12,13]. As it courses distally, it has two tibial attachments. The first proximal attachment point is primarily to soft tissue over the semimembranosus tendon. This attachment measures an average of 12.2mm distal to the tibial joint line [11,12,13]. The distal tibial attachment of the superficial medial collateral ligament is broad and attaches directly to the bone approximately 61.2mm distal to the tibial joint line [11,12,13].

The deep medial collateral ligament is comprised of thickened tissue and is found on the medial aspect of the joint capsule. This ligament is divided into menisiofemoral and menisiotibial components. The menisiofemoral portion of the deep medial collateral ligament has a slight convex curve attachment is located 12.6mm distal and deep to the femoral attachment of the superficial medial collateral ligament [12]. The menisiotibial portion is much shorter and thicker. It attaches just distal to the edge of the articular cartilage of the medial tibial plateau and is found 3.2mm distal to the medial joint line and 9.0mm proximal to the proximal tibial attachment of the superficial medial collateral ligament [11,12].

Literature supports the fact that the medial collateral ligament has an excellent capacity to heal after injury. In the opinion of our lead surgeon (JM), the use of a constrained hinged knee construct and/or the implantation of allograft tendon to repair the medial collateral ligament injury is not needed. Our hypothesis is that the use of a four-prong bone staple (Smith and Nephew) to repair the medial collateral ligament injury status post total knee replacement will provide satisfactory clinical results with regards to post-operative stability and range of motion.

Methods and Materials

All demographic and intraoperative data were retrieved, as part of a prospective database, on all patients (758) undergoing total knee arthroplasty at the senior author's (JM) institution since 2008. Our present study included all of the patients who underwent total knee arthroplasty performed by the senior author (JM) between the dates of 08-01-2008 to 02-15-2013 and who sustained an intraoperative injury to the medial collateral ligament as documented in the database with confirmation in the operative report. Patients with prior MCL injuries were excluded. These operative reports were carefully examined and confirmed that the injury to the medial collateral ligament occurred during

over-release or avulsion of the medial collateral ligament in attempts to balance a tight varus/valgus knee.

The same surgical techniques along with cruciate retaining implants were used by the senior author (JM) during each case. All the operations were performed by the senior author or under his direct supervision. The author used a straight midline incision, measuring four fingerbreadths above the superior pole of the patella to the medial aspect of the tibial tubercle. The standard medial parapatellar incision was used as the exposure technique in all the knees.

After eversion of the patella and flexion of the knee, a self-retaining knee strap was used to maintain the knee in flexion. A scalpel was then used to transect and remove the anterior cruciate ligament. Attention was then placed on the tibia, where the subperosteal plane was developed beneath the deep medial collateral ligament. Bovie electrocautery was then utilized to continue the dissection from anterior to posterior. Careful attention was taken as the dissection proceeded in the posterior direction to ensure that the insertion site of the medial collateral ligament is not violated.

Bilateral weight-bearing radiographs were available in the room to assess for varus/valgus deformity. If the knee was neutral to slight varus, the dissection was stopped at the midcoronal plane. If the knee had a more severe varus deformity, the dissection was extended to the posterior medial corner of the knee. Carefully attention was placed on retractor placement during the entire procedure in attempts to decrease iatrogenic injury.

Injury of the medial collateral ligament was identified after insertion of the trial implants and during balancing of the knee in both flexion and extension. At this time, the defect whether at the femoral origin or the tibial insertion point was repaired using a Smith and Nephew four prong bone staple. Medial collateral ligament defects on the femoral side were thought to develop due to the nature of the osteoporotic bone. Here the cortical bone is so thin and the cancellous bone underneath is so soft; the demineralized bone almost fractures off and lifts away during manipulation of the knee. This portion was repaired by first by fully extending the knee joint and localizing the area of liftoff/fracture. The four prong bone staple (Smith and Nephew) was then impacted into the femoral epicondyle. Of note, the staple dimensions are 16mm in width and 22mm in length, therein it does not come into contact with the femoral or tibia component.

If the medial collateral ligament deficiency was noted on the tibial side, it was thought to occur due to over-release during soft tissue balancing. This deficiency was then repaired by first placing a varus stress to the knee followed by flexing the knee to 60°. A Kocher clamp was then used

to advance the ligament distally and laterally to an isometric point on the tibia and the four prong bone staple (Smith and Nephew) was then malleted into place.

The senior author (JM) once again evaluated the balance of the knee with the trial implants in to ensure optimal balance. The final implants were placed and the knee was once again thoroughly evaluated as in all total knee arthroplasty's.



Figure 1. An example of the Smith and Nephew four-prong staple used for repair.



Figure 2. Post-operative radiographs following four-prong staple fixation on the femur side.



Figure 3. Post-operative radiographs following four prong staple fixation on the tibia side.

In the acute post-operative setting, these patients were treated as a normal total knee arthroplasty, with no additional precautions. Each patient was placed in a continuous passive range of motion machine immediately and each proceeded to participate fully with physical therapy with no restrictions on weight-bearing status. All patients received 10mg of Xarelto orally once a day for 3 months for deep venous thrombosis prophylaxis. Upon discharge from the hospital, each patient continued with physical therapy in an outpatient setting or attended a skilled nursing facility for rehabilitation.

The 2011 Insall Modified Knee Society score will also be utilized as a tool to evaluate each patient in the post-operative setting. This system has been developed by the Knee Society to provide a more current and stringent evaluation form. The system is subdivided into a knee score that rates only the knee joint itself and a functional score that rates the patient's ability to walk and climb stairs [1]. The dual rating system eliminates the problem of declining knee scores associated with patient infirmity. This score was obtained before the surgery and after the surgery to assess pain and function following the total knee arthroplasty.

Results

We retrospectively reviewed the medical records of the 758 patients (380 knees) who underwent primary TKA from August of 2008 to February of 2013. Intraoperative medial collateral ligament disruption or stretching was recognized when there was unexpected medial laxity in a patient with no preoperative medial instability. There were (#6) patients with recognized intraoperative medial collateral ligament injury (0.79%). Six knees in six patients were available for follow up at a mean of 75 days following surgery (range 30 days to 120 days). The mean age of each patient was 68 years (range 54 to 76) and the mean age at the time of surgery was 66 years. Two of the patients were male and four were female. Four of six of our patients were considered to be obese according to the body mass index scale with a score of 30 or greater. Three of the knee replacements were right sided and three were left sided. The pre-operative diagnosis for five of the patients was osteoarthritis with the other having traumatic arthritis.

After careful thought and discussion, it was found that all of our injuries occurred secondary to either over-manipulation of the osteoporotic femur or by the sharp osteotomes used for the subperosteal elevation in attempts to balance the varus/valgus knee. Four of the medial collateral ligament injuries were on the tibial side and two were on

the femoral side. No patients in this study were required to wear any bracing devices after the surgery and no patients reported any instability of the knee joint. Each patient ambulated into the clinic at the last follow up visit with no assistance needed. None of these patients had to undergo any form of revision surgery.

In the post-operative setting, each patient was scheduled to follow up at the senior author's clinic for orthopedic and radiographic evaluation. At the first follow up visit, the range of motion of the knee was evaluated and documented with the use of a goniometer along with assessment of standing knee radiographs to determine whether an acceptable overall alignment was achieved. Each of the radiographs was reviewed by the lead surgeon and an upper level orthopedic resident, revealing well aligned knee prosthesis with no presence of radiolucent lines, lytic lesions, or component migration.

The Knee Society clinical rating score was officially performed at the pre-operative visit and at the initial follow-up appointment. Of note, stability of the medial collateral ligament was assessed on physical examination by gently applying a valgus stress to the knee at both 0° and with the knee flexed to 30°. Grading of valgus stress testing was defined as follows: A) 0 defined as 0-3mm of opening, B) +1 defined as 3-5mm of opening, C) +2 defined as 5-10mm of opening and D) +3 defined as >10mm of opening. Failure in our study was defined as >5mm of opening at either 0° or 30° with absence of a firm endpoint with stressing of the knee.

At follow up examination, the senior author (JM) evaluated each of the patients and found that each exhibited an increase in range of motion along with no laxity noted upon varus/valgus stress testing of the affected knee at both 0° and 30°. Table 1 reviews the pre and post-operative knee laxity, range of motion, and Knee Society score.

The average preoperative knee range of motion was 1.6° of extension to 92° of flexion. Upon comparison, the average postoperative range of motion was 3° of extension to 95.6° of flexion. The average grade of preoperative valgus laxity of the affected knee was (+) 1.6, but this decreased to zero laxity after total knee arthroplasty and

tive and postoperative Knee Society scores were 23.6 and 75.8 respectively. Each patient had a significant increase in Knee Society score, with an average score increase of (+) 52.2.

Conclusion

Any disturbance of the medial collateral ligament during a total knee arthroplasty is a serious complication and should be treated with the utmost respect. It has been well documented in the orthopedic literature that all coronal plane instabilities can result in the need for revision total knee arthroplasty with the use of a constrained device [8,9,10]. In addition, these patient's actually function well with respect to the knee society score. The downfall of this treatment option is placing a constrained revision component into a primary total knee. Our study is the first to address this issue with only the use of a small, unconstrained, minimally invasive implant device.

In our study of six patients, four of them who sustained medial collateral ligament injuries were obese according to the body mass index scale. In a past article by Winiarsky, Barth, and Locke, they concluded that the rate of perioperative complications was significantly higher in obese patients. According to their study, 22% of their obese patients had a wound complication, 10% had an infection, and 8% had an avulsion of the medial collateral ligament.

In comparison, 2% of the knees in their non-obese control group had a wound complication, 0.6% had an infection, and none had an avulsion of the medial collateral ligament [15]. This is an important factor to consider when performing a total knee arthroplasty on the obese population in the future.

There are limited studies dedicated to the treatment of intraoperative injuries to the medial collateral ligament without the use of a constrained device [2,3,4,5]. Most of the current literature recommends using a constrained implant instead of direct repair [8,9,10]. In our study, we evaluated (#6) cases in which a four-prong bone staple (Smith and Nephew) was used to repair the medial collateral ligament following either over-release or avulsion injury dur-

Age	BMI	Sex	Injury Side	Pre-operative ROM	Pre-operative laxity	Post-operative ROM	Post-operative laxity	Pre-operative Knee Score	Post-operative Knee Score	Change
72	31	Male	Right Tibia	0-75	(+)2	0-90	0	15	86	(+)71
51	19	Female	Right Tibia	0-75	(+)3	5-100	0	2	77	(+)75
66	44	Female	Left Femur	0-80	(+)1	0-94	0	25	67	(+)42
72	30	Male	Left Tibia	0-125	(+)1	6-105	0	36	68	(+)32
65	26	Female	Left Tibia	10-120	0	3-100	0	27	76	(+)49
72	30	Female	Right Femur	0-90	0	4-103	0	37	81	(+)44
Avg: 66.3				Avg: 92	Avg: 1.2	Avg: 95.6	Avg: 0	Avg: 23.6	Avg: 75.8	Avg: (+) 52.2

medial collateral ligament fixation. The average preopera-

ing total knee arthroplasty.

Two limitations of our case series are 1) the small number of patients (#6) and 2) the lack of a control group of which to compare. Another limitation of our study is the short follow up period, which averaged 75 days post-surgery. This study could be stronger if these patients were followed for a longer period of time to assess function and pain control, which will be an area that this research paper could expand on in the future. However, we remain cautiously optimistic that this mode of fixation will provide adequate fixation over the life of the arthroplasty.

Our retrospective review revealed that all six patients improved with regards to range of motion and Knee Society score following the total knee arthroplasty. Post-operative varus and valgus stress testing of the affected knee found no laxity. Once again, no patients in this study were required to wear any bracing devices after the surgery and no patients reported any instability of the knee joint. None of these patients had to undergo any form of revision surgery. Due to these results, we feel that repair of the medial collateral ligament with a four-prong bone staple (Smith and Nephew) is a viable option after an over-release or avulsion injury during a total knee arthroplasty.

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CASE REPORT

Early Intraprosthetic Dislocation of Dual-Mobility Total Hip Arthroplasty Implant Following Attempted Closed Reduction: A Case Report

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Introduction

Introduced in 1974 by Bousquet, the dual-mobility bearing for use in total hip arthroplasty (THA) confers increased jump distance and improved overall stability relative to conventional THA designs [1-3]. The dual-mobility bearing incorporates a relatively small (22-28mm) metal or ceramic femoral head press fit into a larger polyethylene liner which articulates with the acetabular component. Dissociation of the femoral head from the polyethylene liner (intraprosthetic dislocation) is a known late complication thought to be related to polyethylene liner wear and has been previously reported [2-7]. In a consecutive series of 384 primary THAs employing Bousquet's original design, there were 14 intraprosthetic dislocations over 15 years (3.6%). The authors cited polyethylene wear as causative and mean time to intraprosthetic dislocation was 8.9 years [2].

A recent investigation by Hamadouche et al. reported a 2.4% rate of intraprosthetic dislocation among 168 consecutive primary THAs followed for a minimum of 5-years [5]. The dislocations occurred at a mean 5.9 years and were thought to be secondary to wear at the mobile insert. A case report from the UK describes an intraprosthetic dislocation

of a dual mobility implant occurring 1.5 years after primary THA [8]. There have been no reports in North America of early intraprosthetic dislocation following use of dual mobility implants for primary THA.

Three recent case reports describe early (within 14 months) intraprosthetic dislocation of the dual mobility implants following attempted closed reduction of an ipsilateral hip dislocation [4,6-7]. The reports, however, concern patients in which the dual-mobility head was used in an off-label, mix-and-match fashion to revise an existing THA with retention of either the femoral stem [7] or acetabular cup [4,6].

We present a patient with intraprosthetic dislocation following attempted closed reduction of a primarily-implanted dual-mobility THA. To our knowledge, this is the first case of early intraprosthetic dislocation of a primary dual-mobility implant to be reported in North America. The purpose of the current report is to increase awareness of intraprosthetic dislocation and mitigate its risk by recommending that orthopaedic surgeons be involved with any attempted reduction of dual mobility implants.

Case Report

A sixty-seven-year-old man with a pertinent history of cerebral palsy (CP) presented to an outside hospital after a fall onto his left hip while attempting to rise from a chair. Prior to the fall, the patient was a community ambulator. Roentgenograms revealed a displaced, comminuted femoral neck fracture and the patient was transferred to a trauma

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center for definitive management. The time of orthopaedic consult was twenty-four hours after original injury. Due to the timing and the patient's pre-injury functional status, it was felt a total hip arthroplasty was most appropriate. Due to his history of CP, it was felt that use of a large head with dual mobility would minimize his risk of dislocation. The patient subsequently underwent primary total hip arthroplasty utilizing a posterior approach with implantation of a 56mm press-fit cobalt chrome acetabular shell in anatomic anteversion and a 28mm diameter ceramic femoral head with a 50mm polyethylene insert (Anatomic Dual-Mobility X3; Stryker, Mahwah, New Jersey) (Fig. 1). Grade 3-4 degenerative changes were found anteriorly and superiorly on femoral head. Additionally, two luque wires were placed proximal and distal to the lesser trochanter for fracture prophylaxis per surgeon's routine for hip fracture patients undergoing arthroplasty. The polyethylene and ceramic head were assembled with implant-specific tools according to the manufacture's specifications. The hip was noted to be stable intraoperatively with flexion to 90 degrees, adduction to 20 degrees and internal rotation to 80 degrees with no impingement or subluxation. Both the posterior capsule and short external rotators were repaired. The patient had an uneventful postoperative course and was discharged on hospital day 5.



Figure 1: Post-operative anteroposterior (A) and cross-table lateral (B) views of the hip.

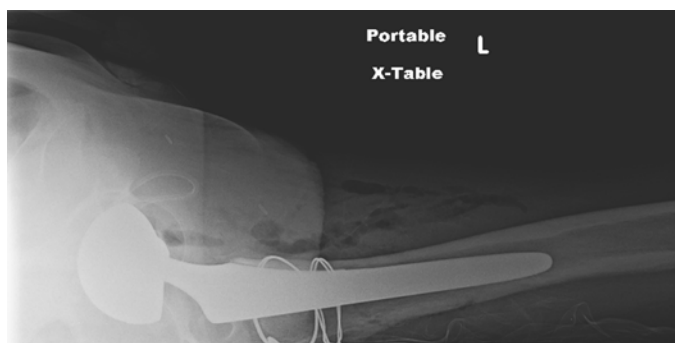


Figure 1B

On postoperative day 26, the patient presented to the emergency department with left hip pain and inability to bear weight subsequent to a fall out of bed onto his left hip. Imaging revealed a posterior dislocation of the left hip. On initial dislocation films the poly head can be visualized in place on the ceramic femoral head (Fig. 2). Emergency medicine physicians performed closed reduction under



Figure 2: Anteroposterior pelvic film after initial dislocation. The poly head can be visualized in place on the ceramic femoral head.

conscious sedation. Postreduction roentgenograms were read as normal. Retrospective review demonstrates an eccentrically located femoral head and a circular radiolucency overlying the left gluteal musculature (Fig. 3). The patient was discharged with instructions to bear weight as tolerated, limiting hip flexion to less than 70 degrees.

Six weeks after the index procedure, the patient again presented to the emergency department with left hip pain and inability to bear weight after attempting to get into a car. Plain imaging revealed a posterior hip dislocation with the prosthetic head superior and posterior to the acetabular component (Fig. 4). The patient underwent closed reduction under conscious sedation with subsequent relocation of the hip in the ER. Post-reduction films were notable for an eccentric position of the femoral head within the acetabular component in addition to a spherical lucency posterior to the acetabulum confirming an intraprostatic dislocation (Fig. 5). The patient returned to the operating theater for revision THA. Intraoperatively, the polyethylene liner was



Figure 3: Anteroposterior hip film after reduction. Note the eccentrically located femoral head and a circular radiolucency of poly head overlying the left gluteal musculature (identified by the arrow).



Figure 4: Anteroposterior pelvic films after the posterior hip dislocation with the prosthetic head superior and posterior to the acetabular component.



Figure 5: Anteroposterior hip films after reduction. Note the eccentric position of the femoral head within the acetabular component in addition to a spherical lucency posterior to the acetabulum confirming an intraprosthetic dislocation (identified by the arrow).

identified within the gluteal musculature, completely dissociated from the femoral head. A trial was done with existing components and the hip was found to be stable with flexion to 90 degrees, adduction to 20 degrees, internal rotation to 70 degrees, with no obvious component failure. Due to concern for damage to the cobalt chrome acetabular shell and ceramic head from articulation over the previous weeks both the femoral head and acetabular components were revised using a 58mm press-fit cobalt chrome acetabular shell and 28mm outer diameter ceramic femoral head with a 52mm polyethylene insert (Anatomic Dual-Mobility X3; Stryker, Mahwah, New Jersey). The CoCr shell was placed with an additional 10 degrees of anteversion and patient had a stable intraoperative exam. He tolerated the procedure well but his postoperative course was complicated by sigmoid volvulus. This resulted in an emergent exploratory laparotomy, a prolonged course in the SICU from which the patient did not recover, and ultimately the death of the patient on post operative day 79 from the index procedure.

Discussion

This is the first case of early intraprosthetic dislocation of a primary dual-mobility implant to be reported in North America. Previous literature has suggested restricting the use of dual-mobility components in primary THA only to patients at increased risk for dislocation (i.e. patients >75 years of age, those with neuromuscular or cognitive disorders, and patients having an ASA score ≥ 3) [9]. A dual mobility implant was therefore chosen for this patient with cerebral palsy who is at higher risk for dislocation. Our institution has flat cap pricing contracts and we occasionally use this device in patients felt to have an increased risk of instability.

The patient's diagnosis of cerebral palsy is material to the current discussion, as the risk of THA dislocation is higher in patients with CP [10]. While there have been no large case series analyzing the incidence of dual-mobility THA dislocation in patients with cerebral palsy, a retrospective cohort of eight patients (10 hips) treated with dual-mobility designs reported no dislocations at an average follow-up of 39 months [11].

The posterior approach was utilized in this patient according to the preference of the primary surgeon. An anterior or anterior lateral approach can be considered in patients with increased dislocation risk. However, in a retrospective review of 228 THA revisions in the Swedish Hip Arthroplasty Register using dual mobility implants 56% were performed through a posterior approach and there was no increased incidence of dislocation in this cohort relative to other approaches [12].

Philippot et al. recently postulated three mechanisms of intraprosthetic dislocation after analysis of 81 such cases from a series of 1960 primary dual-mobility THAs implanted between 1985 and 1998 [13]. Type I "pure" dislocation results from wear of the polyethylene retentive rim in an otherwise functional prosthesis; this accounted for 32% of cases. Type II was secondary to extrinsic blocking of the polyethylene liner, for example, by arthrofibrosis or heterotopic ossification; 51% of dislocations were classified as Type II. Finally, Type III was characterized by cup loosening and accounted for 17% of intraprosthetic dislocations. Notably, each of these mechanisms is a late complication with mean onset of 11, 8, and 9 years, respectively.

In North America there are no randomized controlled trials comparing the rate of dislocation among dual-mobility and conventional THA implants. A single non-randomized, retrospective study compared the rate of dislocation of conventional THA and dual-mobility THAs implanted primarily following femoral neck fracture. Among 98

primary THAs at one year there were no dislocations reported in the dual-mobility group compared with 8 of 56 (14%) of the conventional THAs [11]. Moreover, in a recent retrospective comparison of bipolar hemiarthroplasty and dual-mobility THA the authors reported a significantly increased incidence of dislocation among patients treated with bipolar hemiarthroplasty (14.6% vs. 4.5%) [15].

Analogous to the current case, intraprostatic dislocation of bipolar hemiarthroplasty implants after attempted closed reduction has been described in the French literature [16]. In both cases bipolar hemiarthroplasty was utilized in treating displaced femoral neck fractures. The authors of this report postulate a “bottle-opener” effect where the cup engages the posterior acetabular rim and subsequent limb traction results in dislocation of the intraprostatic joint. It is reasonable to conclude, although no biomechanical studies have been conducted to address this claim, that the “bottle-opener” effect would only be exaggerated when the relatively smooth posterior acetabular rim is replaced with a metal acetabular component.

In contradistinction to postulated mechanisms of late intraprostatic dislocation, the current case was likely a direct result of attempted closed reduction with subsequent impingement of the polyethylene head on the acetabular component. The aforementioned case report by Banzhof et al. describes this impingement mechanism leading to early intraprostatic dislocation following attempted closed reduction [4].

We advise caution with any attempt at closed reduction of dual-mobility implants. In many communities emergency room physicians routinely perform closed reduction of dislocated total hips under sedation without consulting orthopaedics. For patients with a dual-mobility implant and THA dislocation, an orthopaedic surgeon should perform the reduction attempt under general anesthesia with complete muscle relaxation using fluoroscopy. Although an intraprostatic dislocation could still occur in this setting the risk would be reduced, recognition of the complication immediate, and it would allow for an open reduction under the same anesthetic if required. We recommend advising patients with dual mobility implants that orthopaedic surgeons be involved with any attempted reduction in the event their total hip dislocates to mitigate the risk on an intraprostatic dislocation. If similar case reports follow in the literature consideration should be made for advising patients with dual-mobility implants to have dislocations addressed in the manner described above.

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ORIGINAL ARTICLE

Early Results of a Modular Cementless Tibial Component for Total Knee Arthroplasty

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Abstract

Cementless components in TKA have been used for almost 3 decades, despite mixed success rates. However, biologic fixation remains attractive, especially for younger patients, because of the potential of unlimited durability. This paper is the first to report results on a modular tibial base plate using trabecular metal as a fixation surface. Twenty-four primary TKAs were evaluated clinical and radiographically at mean 1.9 year followup. Excellent clinical results were obtained. There was no significant subsidence or change in orientation of any component. One component was probably loose radiographically but was insufficiently symptomatic to warrant revision. Five components showed nonprogressive radiolucent lines. One reoperation was performed for stiffness, at which time the components were well fixed. Thus, it would appear that excellent bony fixation can be achieved with a modular cementless tibial component with excellent short-term clinical results.

Introduction

Cementless components in total knee arthroplasty (TKA) have been used for three decades, with mixed results, especially for fixation. As such, cemented components have continued to be endorsed as the gold standard [1-5]. However, cementless fixation remains attractive, especially for younger and more active patients, in whom cemented fixation may be less durable, with a greater risk of polyethylene wear/osteolysis from third body wear [1,6,7]. Therefore, an optimum implant would be cementless and reliably achieve durable bony fixation.

Previous cementless devices suffered from poor design characteristics such as improper pore size, debonding of the porous coating, and excessively thin polyethylene inserts [8]. Newer technologies such as hydroxyapatite coating have to achieve better osseointegration at early fol-

low-up with limited subsidence [9]. Similarly, nonmodular trabecular metal (TM) tibial components have demonstrated excellent fixation and mid-term durability [10,11].

This study evaluates the early radiographic fixation status and changes and clinical outcomes of a modular tibial component with a TM coating intended for cementless fixation. To the best of our knowledge, this is the first report on this implant.

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Patients/Methods

A total of 24 primary TKAs (16 right sided) indicated for painful OA unresponsive to conservative medical therapy were performed in 21 patients by the senior author (RKS) from 2007 to 2009. The cohort consisted of 5 females and 16 males. The mean age at the time of surgery was 64.78 (range 46.94-74.95; SD 7.00). The mean age of males was 66.39 (range 55.54-74.95; SD 5.69). The average age of females was 59.94 (46.94-68.84; 8.71). Three patients had bilateral TKAs, with 2 patients having simultaneous bilateral TKAs. In no case was a TM tray abandoned for a cemented component. These data are summarized in Table 1.

Table 1: Demographics

Number of Patients	21
Males/Females	16/5
Average Age for cohort in years (range; SD)	64.78 (46.94-74.95; 7.00)
Average Age Males in years (range; SD)	66.39 (55.54-74.95; 5.69)
Average Age Females in years (range; SD)	59.94 (46.94-68.84; 8.71)
Average Follow-up in in years (range; SD)	1.78 (.08-4.14; 1.25)

All of the surgeries were performed using a mini-midvastus approach and used an uncemented Zimmer® NexGen® Trabecular Metal™ Tibial Tray (Figure 1), a cemented posteriorly stabilized Zimmer® NexGen® LPS-flex femur and cemented all-polyethylene patellar components. Post-operatively patients were allowed immediate weight bearing as tolerated status with the use of crutches or a walker. Continuous passive motion was not used with any of the patients. Thromboprophylaxis was achieved with use of aspirin and calf pumps.

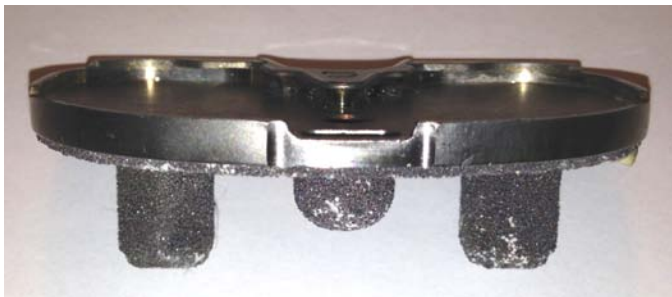


Figure 1: Zimmer® NexGen® Trabecular Metal™ Modular Tibial Tray. The implant has the standard locking mechanism, and has 3 pegs coated in trabecular metal for bone ingrowth.

Fixation status was assessed by retrospectively evaluating serial standard Anterior-Posterior and Lateral radiographs, which were obtained immediately post-operatively and at an average of 1.78 years post-operatively. The presence or absence of lucencies was recorded at 13 coronal zones and 4 lateral zones as illustrated in Figure 2. Ad-

ditionally, immediate postop and latest follow-up X-rays were evaluated for changes in femoral-tibial angle (FTA), coronal femoral component angle (cFCA), coronal tibial component angle (cTCA) and the posterior tibial slope. All Radiographs assessed were digital, with built-in measurement tools and image enhancement features. Finally, a chart review was performed to obtain information on post-op ROM, recovery status, and complications.

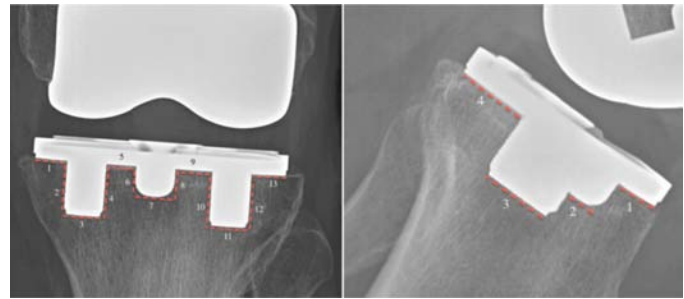


Figure 2: Tibial Zones

Results

Table 2 summarizes the alignment measurement data. The average FTA change from immediate postop to the latest films was 0.33 degrees valgus from 4.25 valgus (range: 10 valgus - 4 varus) to 3.92 valgus (range: 9 valgus - 10 varus) with $t(23)=0.725$, $p=0.476$ showing no significant statistical difference. The average cFCA change from immediate postop to the latest films was 0.59 degrees varus with $t(23)=0.394$, $p=0.697$, showing no significant statistical difference. The average cTCA change from immediate postop to the latest films was 1.21 degrees valgus with $t(23)=0.011$, $p=0.991$ showing no significant statistical difference. The average cFCA change from immediate postop to the latest films was an increase by 0.72 degrees with $t(23)=0.449$, $p=0.658$, showing no significant statistical difference.

Table 2: X-ray measurements

	Average 1st Postop Measurement (range)	Average Most Recent Measurement (range)	Mean Difference (degrees)	Standard Deviation	T-test	P-value
FTA	4.25 valgus (10 valgus - 4 varus)	3.92 valgus (9 valgus - 10 varus)	0.3	4.58	0.725	0.476
cFCA	2.97	3.56	0.59	3.34	0.394	0.697
cTCA	1.24	0.029	1.21	2.14	0.011	0.991
PTS	4.31	5.03	0.72	4.58	0.449	0.658

Figure 3 demonstrates the radiographic appearance of a fully osseointegrated, well functioning component. Immediate post op films showed one knee with one non-pro-

gressive radiolucent line (RLLs) in coronal zone 1 and in one other patient on the lateral view there was another non-progressive radiolucent line in the anterior tray region that both subsequently cleared on the most recent follow-up films. On follow-up A/P films there were 5 components with non-progressive RLLs on AP views: 3 RLLs in zone 1, 2 RLLs in zone 3, 1 RLL in zone 5, 1 RLL in zone 9 and 3 RLLs in 13. On follow-up lateral films there were 6 components with non-progressive RLLs with 6 seen in the anterior tray and 2 in the posterior tray (Table 3). All RLLs were 1 mm or less in thickness.

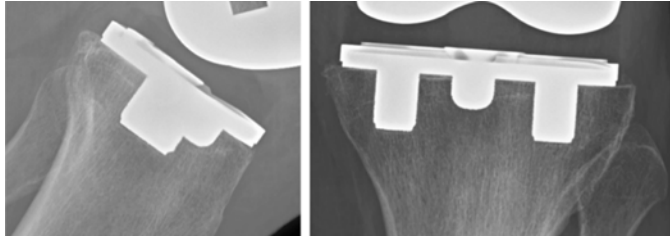


Figure 3: Example of well-fixed component without lucencies

Table 3: Fixation Status

Coronal Zone*	# of RLLs**	
	Immediate post-op	Most recent
1	1	3 (3 new, 1 resolved)
3	0	1
5	0	1
9	0	1
13	0	3

Lateral Zone*	# of RLLs**	
	Immediate post-op	Most recent
Anterior Tray	1	6 (6 new, 1 resolved)
Posterior Tray	0	2

* all unlisted zones had no RLLs present

** all RLLs were non-progressive

On clinical follow-up, one reoperation was done at 7 months post op and was needed due to poor ROM with pain and swelling, stiffness, and startup pain. In this particular case only the polyethylene insert was replaced, as the tibial implant was found to be well fixed intra-operatively. Another patient required fluid aspiration, was experiencing increased quad weakness and had a probable radiographically loose component (Figure 4), but opted not to revise at 18 months post op as pain was tolerable. A third patient at 17 months post op was experiencing knee pain and overactivity-induced pes bursitis and was given a cortisone shot, with symptom relief. Otherwise, generally patients recovered well, with no other notable symptomatic RLLs and with minimal residual pain symptoms. Average ROM post op was 0.6° (range 0-10) to 118.7° (range 80-140). Two

out of 24 patients had a flexion contracture of 5° and 10°, with the rest having full extension. Sixteen out of 24 patients had flexion to 120° or greater postop (data summarized in Table 4).

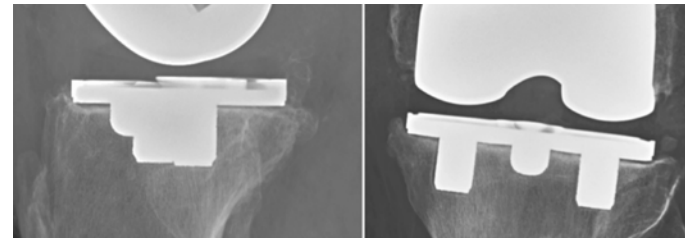


Figure 4: Example of worst appearing x-ray in series. In Zones, 4, 5, 6, 7, 8, 10, 11 and 12, there is evidence of bone ingrowth, despite radiolucent lines in other zones.

Table 4: Final post-op follow-up results

ROM Measurement	Average	Range	SD
Extension	0.625°	0°-10°	2.24
Flexion	118.7°	80°-140°	18.6

Discussion

This is the first report on a modular trabecular tibial component intended for cementless fixation during TKA. In general, this design reliably achieved early bony fixation. No components were revised and 1/24 was probably radiographically loose or fibrous stable. Compared to other cementless designs, this low failure rate compares favorably. For example, Moran et al found a 19% failure rate due to aseptic failure of the tibial component in a series of 108 primary total knee arthroplasties in 96 patients after an average follow-up of 64 months using an uncemented, porous-coated system (PCA designed by Howmedica, Rutherford, NJ) 4. Additionally, Goldberg et al observed a 13% failure rate in 124 TKAs on 99 patients after an average follow-up of 11 years in the surviving knees (Miller-Galante I, designed by Zimmer, Warsaw, IN), although only 1 revision was cited as being due to tibial component loosening. Additionally, Berger et al observed a 19% failure rate (7% due to tibial loosening) in a series of 108 TKAs (Miller-Galante I, designed by Zimmer, Warsaw, IN), performed on 82 patients after follow-up greater than 7 years, and average 11 year follow-up of surviving knees². In addition, this modular version compares favorably to its nonmodular counterpart. Patients did not have prolonged pain post-operatively, and at latest follow-up, behaved like typical TKA patients.

Given the short follow-up, no comments can be made regarding durability of fixation. Longer term study will be needed. In addition, the femoral component was a high flex

PS design, possibly loading the implant posteriorly to a higher degree than a non-high flex or CR design would. Nevertheless, initial mechanical fixation appeared to be adequate to achieve bony ingrowth. Lastly, although the trabecular metal fixation surface has enjoyed success in multiple applications, the data from this study utilizing this particular tibial component design cannot be extrapolated to other tray designs or to femoral components. Nevertheless, use of a modular tibial tray designed for cementless fixation appears to be safe and effective.

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ORIGINAL ARTICLE

No Rationale for Gender Specific Femoral Stems for Total Hip Arthroplasty

Raj K. Sinha, MD, PhD¹; Vangalea Weems, BS, PA-C¹; Margaret J. Cutler, RN¹

Abstract

The purpose of this study was to compare the applicability of two femoral stem systems in male and female populations via preoperative templating. The radiographs of 47 consecutive patients (94 hips) were templated using one of two stem systems by first fixing the acetabular center of rotation. Based upon templating, the result categories were: no obvious advantage of either system, System 1 preferred, System 2 preferred, neither system adequate. Preference was determined based upon having a best-fit stem choice and at least one additional length or offset option, and avoiding the extremes of the system as the best-fit choice. Significantly, there were gender differences in applicability of femoral stems. Specifically, more neck length and offset options seem to be required for females. The potential limitations of the implant systems in applicability could be overcome by adjusting the level of neck resection. Therefore, it would appear that there is a limited role for gender specific implants for total hip arthroplasty.

Keywords: *hip arthroplasty modular stem gender*

Introduction

Variations in femoral anatomy [1,2,3,4] and acetabular anatomy [5] have been partially ascribed to gender differences. Traditionally, femoral stems for THA have been designed across an entire population including both males and females. The purpose of this study was to compare the applicability of two femoral stem systems, one with modular bodies and one with a one piece stem, in male and female populations via preoperative templating.

Methods

All patients seen during a single month who presented complaining of knee pain had screening pelvis x-rays. These x-rays formed a consecutive cohort of hips for the templating study. During templating, the acetabular component was placed in a fully medialized position at 45° of abduction. The center of rotation was marked. The femoral neck osteotomy was set at 15 mm proximal to the top of lesser trochanter, as recommended in the technique guide. Templates of equal magnification were utilized for both systems. System 1 (Figure 1a) had a double tapered wedge body design, a fixed 135° neck-shaft angle with two different offsets (6 mm difference) and two different neck lengths (4 mm difference). There were 7 head options with different lengths. System 2 (Figure 1b) had the same body design with a modular neck offering 20 different offsets/lengths and 7 different neck-shaft angles, with only

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Figure 1. (a) In System 1, there are two neck length and two neck offset choices. The stem on the left is a reduced neck length, standard offset. The stem on the right has standard length and offset. (b) In System 2, multiple neck lengths and offsets can be used with any body. The neck length of the head is always +0.



Figure 2. Template Examples. (a) System 1 applicable as lateralized stem matches center of rotation of the templated acetabular component. (b) System 1 would not be applicable as the stem has too much offset to match the center of rotation of the templated acetabular component.

one head option. Neck length and offset were independent of body size for both systems. Based upon templating, the categories were: No obvious advantage of either system, System 1 preferred, System 2 preferred, Neither system adequate. Preference was determined based upon providing at least one additional length or offset option, and avoiding the extra extended offset option in System 2 based upon the risk of fracture or disassociation due to extremely high moments [6,7]. Examples of templates are depicted in Figure 2.

Fisher exact test was utilized to calculate the probability of a difference in system applicability across groups.

Results

There were 20 female patients contributing 40 hips and 27 males contributing 54 hips. The data are summarized, by gender, in Table I. Among the males, there was no obvious advantage in 20/54 hips (37%), System 1 was preferred in 11/54 hips (20.4%), System 2 was preferred in 15/54 hips (27.8%), and neither system was adequate in 8/54 hips (14.8%). In addition, System 1 could have been used in 33/54 hips (61.1%), while System 2 could have been used in 42/54 hips (77.8%). Overall, 46/54 male hips (85.2 %) could be implanted with either of these stems. There was no statistically significant advantage of one system over the other in applicability ($p = 0.13$). Among the

Table I. Neck Cut 15 mm above lesser trochanter

	Males	Females
No Advantage	20/54	17/40
System 1 Preferred	11/54	1/40
System 2 Preferred	15/54	13/40
Neither Adequate	8/54	9/40
Either Possible	46/54	31/40

Table II. Neck Cut Adjustable

	Males	Females
No Advantage	31/54	30/40
System 1 Preferred	14/54	1/40
System 2 Preferred	4/54	6/40
Neither Adequate	5/54	3/40
Either Possible	49/54	37/40

Table III. Dorr B and C Females, with adjustable neck cut

	Dorr B	Dorr C
No Advantage	15/21	11/16
System 1 Preferred	1/21	0/16
System 2 Preferred	5/21	3/16
Neither Adequate	0/21	2/16
Either Possible	21/21	14/16

females, there was no obvious advantage in 17/40 hips (42.5%), System 1 was preferred in 1/40 hip (2.5%), System 2 was preferred in 13/40 hips (32.5%), and neither system was adequate in 9/40 hips (22.5%). In addition, System 1 could have been used in 22/40 hips (55%), while System 2 could have been used in 31/40 hips (77.5%). Neither system was appropriate in 9/40 (22.5%) of the female patients. Overall, 31/40 female hips (77.5 %) could be implanted with either of these stems. There was no statistically significant advantage of one system over the other in applicability ($p = 0.07$).

We then changed the level of the neck cut to a position that could accommodate either of the stem systems, with no neck resection less than 5 mm above the lesser trochanter. These data are summarized in Table II. Among the males, there was no obvious advantage in 31/54 hips (57.4%), System 1 was preferred in 14/54 hips (25.9%), System 2 was preferred in 4/54 hips (7.4%), and neither system was adequate in 5/54 hips (9.3%). In addition, System 1 could have been used in 49/54 hips (90.7%), while System 2 could have been used in 44/54 hips (81.5%). Overall, 49/54 male hips (90.7 %) could be implanted with either of these stems. Importantly, the availability of System 2 did not increase the applicability of the stem family for THA ($p=0.31$). Among the females, there was no obvious advantage in 30/40 hips (75%), System 1 was preferred in 1/40 hip (2.5%), System 2 was preferred in 6/40 hips (15%), and neither system was adequate in 3/40 hips

(7.5%). In addition, System 1 could have been used in 35/40 hips (87.5%), while System 2 could have been used in 37/40 hips (92.5%). Overall, 37/40 female hips (92.5 %) could be implanted with either of these stems. Again, the addition of System 2 slightly increased the utility of this stem family, but not significantly ($p=0.38$).

Because women are purported to have larger diameter canals (so-called Dorr B and C bone), we next assessed the applicability of the stem systems as a function of bone geometry. Among the female patients, there were 3 Dorr A femurs, 21 Dorr B femurs and 16 Dorr C femurs. The templating data are summarized in Table III. With flexible neck level resections, among the Dorr B hips, there was no obvious advantage in 15/21 hips (71.4%), System 1 was preferred in 1 hip (4.7%), System 2 was preferred in 5/21 hips (23.8%), and neither system was adequate in 0/21 hips. In addition, System 1 could have been used in 19/21 hips (90.4%), while System 2 could have been used in 21/21 hips. The enhanced modularity of System 2 increased the utility of this product line for 10% of the female Dorr B hips, but there was no statistical significance in applicability ($p=0.12$). Among the Dorr C hips, there was no obvious advantage in 11/16 hips (68.8%), System 1 was preferred in 0/16 hips, System 2 was preferred in 3/16 hips (18.8%), and neither system was adequate in 2/16 hips (12.5%). In addition, both systems could have been used in 14/16 hips (87.5%). In Dorr C femurs, the enhanced modularity of System 2 did not increase the applicability ($p=0.80$).

Discussion

Bone atlas and CT scan data suggests that women have larger canals, relatively shorter necks, more varus necks, greater anteversion [2,3,4], less acetabular abduction and more acetabular anteversion [5]. As a result, it has been suggested that a gender specific implant is needed to adequately address such gender-related anatomical variations when considering cementless femoral stems in THA [8]. Significantly, there appear to be gender differences in applicability of femoral stems. Whether these differences translate into poorer outcomes is debatable [9,10].

According to this study, with a fixed level of neck resection, more neck length and offset options seem to be required for female patients. However, by individualizing the level of neck resection, fewer stem options would be required to reconstruct most hips. Similarly, center of rotation of the acetabular component can be adjusted to overcome shortcomings in available stem sizes, although biomechanically, that may be less desirable. With appropriate preoperative planning, it would be expected that an experi-

enced surgeon should be able to successfully perform THA regardless of patient gender, obviating the need for gender specific implants.

Increased stem modularity has also recently been implicated in pain and bone loss due to increased crevice corrosion [11]. Further, there have been several reports of modular neck disassociation and fracture [6,7], requiring additional surgeries with all of their associated morbidity. In these reports, excessive offset has been one associated factor with both modes of modular neck failure. In this study, we specifically avoided the extremes of the product line, thereby likely reducing the risk of such failures. Nevertheless, recent data compels the surgeon to use caution when planning a hip arthroplasty with enhanced modularity stems.

There are some limitations of this study. We did not account for appropriateness of stem as a function of variation in anteversion. In addition, this study included both normal and arthritic hips, which may affect the results. Further investigation is necessary to determine the role of neck-shaft angle, bone quality and adjustment of neck osteotomy height on stem design and patient outcome as a function of gender. Nevertheless, it would seem that no single stem product line can account adequately for all the anatomical variations encountered in routine arthroplasty practice, fur-

ther underscoring the importance of preoperative templating and planning when choosing an implant.

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Smart PEEK Modified by Self-Initiated Surface Graft Polymerization for Orthopedic Bearings

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Abstract

Poly(ether-ether-ketone) (PEEK)s are a group of polymeric biomaterials with excellent mechanical properties, chemical stability, and nonmagnetism. In the present study, we propose a novel self-initiated surface graft polymerization technique, using which we demonstrate the fabrication of a highly hydrophilic and biocompatible nanometer-scale layer on the surfaces of PEEK and carbon fiber-reinforced PEEK (CFR-PEEK) by the photoinduced graft polymerization of 2-methacryloyloxyethyl phosphorylcholine (MPC) without using any photoinitiators. The thus formed hydrophilic and smooth 100-nm-thick PMPC-grafted layer caused a significant reduction in the sliding friction of the bearing interface because the thin water film and hydrated PMPC layer acted as extremely efficient lubricants (so-called fluid-film lubrication or hydration lubrication). Fluid-film lubrication suppressed the direct contact of the counter-bearing surface with the PEEK substrate and thus reduced the frictional force. A PMPC-grafted layer is therefore expected to significantly increase bearing durability. Furthermore, the PMPC-grafted layer shows unique phenomena, e.g., it prevents damage of the metal counter surface regardless of the carbon fiber content of CFR-PEEK. Smart PEEK using the self-initiated surface graft polymerization of MPC should lead to development of novel orthopedic bearings.

Keywords: poly(ether-ether-ketone), 2-methacryloyloxyethyl phosphorylcholine, surface modification, photopolymerization, joint replacement, wear mechanism

Introduction

In recent years, joint reconstruction surgeries ranging from minor repairs to damaged joints to total hip arthro-

plasty (THA) have become increasingly important with the increasingly aging population worldwide. THA has emerged as one of the most successful of such surgeries, and it has been demonstrated to dramatically relieve patients' pain and to improve their quality of life. The most popular artificial hip joint is a bearing couple composed of polyethylene (PE, specifically cross-linked PE (CLPE)) and a cobalt–chromium–molybdenum (Co–Cr–Mo) alloy. However, the implantation duration and clinical outcome of THA is significantly limited by the incidence of osteolysis [1]. Osteolysis is triggered by various inflammatory responses to wear particles produced from a PE articular

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surface [2]. These undergo phagocytosis by macrophages, in turn inducing the secretion of bone resorptive cytokines [3]. Although osteolysis is one of the most common reasons for late revision surgery, the major short-term complication is dislocation. As a solution to this problem, a large femoral head increases not only the range of motion prior to the impingement of the femoral stem neck on the liner but also the jump distance. Therefore, larger femoral heads involving a thin acetabular liner have been frequently used in recent times to improve the stability of the bearing surface.

To reduce wear particles, improve stability, and increase the longevity of artificial hip joints, studies have focused on various bearing alternatives and the improvement of bearing materials [4–10]. Recently, studies have shown that poly(ether-ether-ketone) (PEEK) might be useful in reducing wear debris and improving stability. PEEK consists of an aromatic backbone molecular chain interconnected by ketone and ether functional groups (i.e., its molecular structure contains a benzophenone (BP) unit). It is well known that PEEK is chemically inert, insoluble in most conventional solvents, and compatible with several reinforcement agents (such as carbon fibers, i.e., carbon fiber-reinforced PEEK (CFR-PEEK)); furthermore, it exhibits excellent mechanical properties and nonmagnetism. PEEK and CFR-PEEK are therefore considered potential high-performance plastic replacements for conventional implant materials. Consequently, PEEK and/or CFR-PEEK bearing materials are being increasingly utilized in various applications [11, 12]. However, both PEEK and CFR-PEEK do not satisfy certain properties required in an artificial joint, such as low friction, high wear resistance and biocompatibility [11]. CFR-PEEK acetabular cups, e.g., MITCH PCR Cup (Stryker SA, Montreux, Switzerland) [13] and ABG II acetabular liner (Stryker SA) [14, 15], have been clinically used to a limited extent in several hospitals; the available early clinical results support the short-term efficiency of CFR-PEEK but do not yet demonstrate a long-term clinical advantage over other well established orthopedic bearings [12]. In this light, surface modification has emerged as one of the most important techniques for developing new multifunctional biomaterials for joint reconstruction in order to satisfy various requirements.

Herein, we propose a new and safer methodology for constructing a nanometer-scale functional layer on PEEK and CFR-PEEK substrates by the self-initiated photoinduced graft polymerization of functional vinyl compounds at the surface. It is well known that when BP is exposed to photoirradiation such as ultraviolet (UV) irradiation, a pinacolization reaction is induced [8]. This results in the formation of semi-benzopinacol-containing radicals that act

as photoinitiators. We therefore focused on the BP units in PEEK and developed a self-initiated surface graft polymerization technique that uses these units [6–8]. The polymerization reaction involving free radicals is photoinduced by UV irradiation. This technique enables the direct formation of a functional polymer layer on the PEEK surface in an aqueous medium without any photoactive low-molecular-weight compounds, making this an easy and human-friendly process. Additionally, we prepared a biocompatible polymer layer, i.e., poly (2-methacryloyloxyethyl phosphorylcholine (MPC)) (PMPC). MPC is a methacrylate monomer bearing a phosphorylcholine group, and it can provide various types of polymers upon copolymerization with other vinyl compounds [16–25]. MPC polymers show great potential for applications in the fields of biomedical science and bioengineering because they possess beneficial properties such as excellent antibiofouling ability and friction suppression. Thus, numerous medical devices, including intravascular stent [24], soft contact lenses [25], artificial heart [19], and artificial hip joint [22, 23] have been developed from MPC polymers and applied clinically. The biomedical efficacy and safety of MPC polymers are therefore well established.

Toward finding a solution, we investigated the surface characteristics of surface modified PEEK and CFR-PEEK samples, including the wettability, lubricity, and wear resistance. Such investigations are of great importance for designing life-long artificial hip joints and for obtaining a better understanding of the limitations resulting from the use of this material. During our studies, we sought answers to two questions: (1) Will the PMPC grafting affect the lubrication characteristics of PEEK and CFR-PEEK surfaces? (2) Will the modifications affect their wear resistances?

Materials and Methods

Self-initiated graft polymerization of MPC

The preparation of PMPC-grafted PEEK is schematically illustrated in Fig. 1. PEEK (450G; Victrex PLC, Thornton-Cleveleys, UK) and CFR-PEEK (Sumiploy CK4600; Sumitomo Chemical Co., Ltd., Tokyo, Japan) specimens were machined from extruded bar stocks, and then finished by surface-polishing. CFR-PEEK was blended with discontinuous polyacrylonitrile (PAN)-based carbon fiber of 30 mass%. The surfaces of the PEEK and CFR-PEEK specimens were ultrasonically cleaned in ethanol for 20 min, and then dried in vacuo. MPC (NOF Corp.; Tokyo, Japan) was dissolved in degassed water to obtain 0.50-mol/L MPC aqueous solution. The PEEK and CFR-PEEK specimens were then immersed in these solutions. Photoinduced

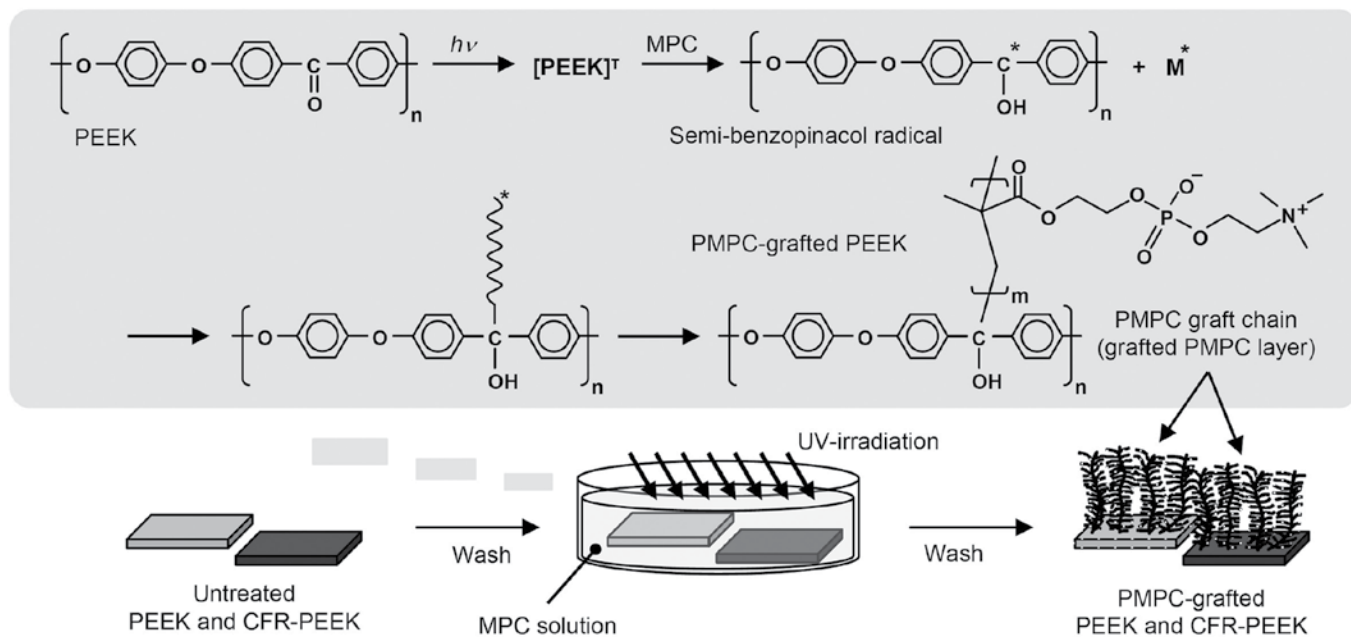


Figure 1. Schematic illustration of the preparation of PMPC-grafted PEEK and PMPC-grafted CFR-PEEK.

graft polymerization was subsequently carried out at 60°C for 90 min on the PEEK and CFR-PEEK surfaces under UV irradiation (UVL-400HA ultra-high pressure mercury lamp; Riko-Kagaku Sangyo Co. Ltd., Funabashi, Japan) with 5 mW/cm² intensity. A filter (UV-D35; Toshiba Corp., Tokyo, Japan) was used to restrict the incident UV light to wavelengths of 350 ± 50 nm. After polymerization, the PMPC-grafted PEEK and CFR-PEEK specimens were removed from the MPC solution and washed with pure water and ethanol to remove the unreacted monomers and ungrafted polymers.

Surface morphological observation by atomic force microscopy and transmission electron microscopy

The surface morphologies of the PMPC-grafted PEEK and CFR-PEEK were analyzed by atomic force microscopy (AFM; Nanoscope IIIa; Nihon Veeco, Tokyo, Japan) in the tapping mode. The measurements were performed under dry conditions using a monocrystal silicon cantilever. A scan rate of 0.25 Hz, tip velocity of 5 μ m/s, and imaging size of 50 μ m \times 50 μ m were used for all samples.

Transmission electron microscopy (TEM; JEM-2010F; JEOL Ltd., Tokyo, Japan) at acceleration voltage of 200 kV was used to observe the cross section of the PMPC layer on the PMPC-grafted PEEK and CFR-PEEK surfaces. A thin film of the samples was prepared by the focused ion beam (FIB) technique (FB-2100; Hitachi High-Technologies Co., Tokyo, Japan) at an acceleration voltage of 40 kV. Untreated and PMPC-grafted CFR-PEEK specimens were precoated with a carbon film before the FIB process.

Wettability and friction evaluation

The static water contact angles on the PMPC-grafted PEEK and CFR-PEEK surfaces were measured by the sessile drop method using an optical bench-type contact angle goniometer (DM300; Kyowa Interface Science Co., Ltd., Saitama, Japan). Drops of purified water (1 μ L) were deposited on the PMPC-grafted PEEK and CFR-PEEK surfaces, and the contact angles were directly observed by a microscope after 60 s of dropping. Fifteen points were measured for each PEEK and CFR-PEEK sample, and the average values were used.

A unidirectional friction test was performed using a pin-on-plate machine (Tribostation 32; Shinto Scientific Co. Ltd., Tokyo, Japan). Six specimens were prepared for each of the PMPC-grafted PEEK and CFR-PEEK surfaces. A 9-mm-diameter Co-Cr-Mo alloy pin was also prepared. The surface roughness (R_a) of the pin was <0.01 μ m, which was comparable to that of femoral head products. The friction test was performed for each specimen at room temperature using a load of 0.98 N, sliding distance of 25 mm, frequency of 1 Hz, maximum of 100 cycles, and pure water for lubrication. The mean coefficients of dynamic friction were determined by averaging the measurements for five data points from 96–100 cycles.

Pin-on-disk wear test

Multidirectional wear tests were conducted using a POD testing machine (Ortho POD; AMTI, Watertown, MA, USA). Untreated PEEK, untreated CFR-PEEK, and PMPC-grafted CFR-PEEK pins with 10-mm diameter were used for the wear tests and control soak tests to cor-

rect the water-absorption increments ($n = 3$). As the control, untreated CLPE pins ($n = 3$) with 10-mm diameter were prepared; these were machined from a compression-molded bar stock of PE (GUR1020 resin; Quadrant PHS Deutschland GmbH, Vreden, Germany) irradiated with a 50-kGy dose of gamma-rays in N₂ gas atmosphere and annealed at 120 °C for 7.5 h in N₂ gas to facilitate cross-linking. The Co–Cr–Mo alloy disks had a surface roughness of $R_a < 0.01 \mu\text{m}$. A mixture of bovine serum with a protein content of 30 g/L, 20 mM ethylenediamine-N, N, N', N'-tetraacetic acid (EDTA), and 0.1 mass% sodium azide was used at 37°C as the lubricant. The multidirectional wear test was conducted on a rectangular sliding surface. The test conditions were specified as a static load of 213 N, sliding distance of 30 mm, and frequency of 1 Hz for a maximum of 1.0×10^6 cycles, according to the ASTM F732 standard. Gravimetric wear was determined by weighing the pins and disks. Soak controls were used to compensate for fluid absorption by the specimens.

Hip simulator wear test

A 12-station hip simulator (MTS Systems Corp., Eden Prairie, MN) using untreated PEEK and CFR-PEEK, and PMPC-grafted PEEK and CFR-PEEK cups ($n = 3$) with inner and outer diameters of 26 and 52 mm, respectively, was used for the wear test according to the ISO 14242-3 standard. A Co–Cr–Mo alloy ball of 26-mm diameter (K-MAX® HH-02; KYOCERA Medical Corporation, Osaka, Japan) was used as the femoral head. A mixture of 25-vol% bovine serum, 20 mM EDTA, and 0.1 mass% sodium azide was used as the lubricant. The lubricant was replaced every 0.5×10^6 cycles. Gait cycles were applied by simulating a physiological loading curve (Paul-type) with double peaks at 1793 and 2744 N and a multidirectional (biaxial and orbital) motion of 1Hz frequency. Gravimetric wear was determined by weighing the cups at intervals of 0.5×10^6 cycles. Load-soak controls ($n = 2$) were used to compensate for fluid absorption by the specimens according to the ISO 14242-2 standard. Testing was continued for a total of 3.0×10^6 cycles.

The wear particles were isolated from the bovine serum solution used for lubrication and observed using a scanning electron microscope (SEM). Isolation was accomplished by incubating the lubricant in a 0.4 g/mL sodium hydroxide solution for 1 h at 60°C and then adding methanol to it. The mixture was sonicated for 10 min to digest the degraded and precipitated adhesive proteins and then sequentially filtered through a 0.1- μm membrane filter. The membrane was directly observed under an SEM (S-3400N; Hitachi Ltd., Tokyo, Japan) using an acceleration voltage of 15 kV after gold deposition.

To evaluate the wear conditions, the features of the bearing surfaces of the femoral heads were observed after 3.0×10^6 cycles of the hip simulator wear test using a confocal laser scanning microscope (OLS1200; Olympus Corp., Tokyo, Japan) and a fluorescence microscope (Axioskop 2 Plus; Carl Zeiss AG, Oberkochen, Germany). For the fluorescence microscope observation, an appropriate exposure time (~ 0.2 s) was allowed to obtain best-quality sample images. The arithmetic mean of the surface roughness of the contact and non-contact areas of the retrieved femoral heads was determined using a surface roughness tester (Surftest SV-3100; Mitutoyo Corporation, Kawasaki, Japan) according to the ISO 7206-2 standard.

Statistical analysis

The mean values of the four groups (untreated and PMPC-grafted PEEK, and untreated and PMPC-grafted CFR-PEEK) were compared by one-factor analysis of variance (ANOVA) and the significance of differences was determined by post-hoc testing using the Bonferroni method. All statistical analyses were performed using an add-on software (Statcel 3; OMS Publishing Inc., Tokorozawa, Japan) for a computerized worksheet (Microsoft Excel® 2010; Microsoft Corporation, Redmond, WA).

Results

The preparation of the PMPC-grafted layer on the surface affected the morphologies of the PEEK and CFR-PEEK substrates. Nanometer-scale scratches (attributed to the surface finishing (polishing)) and pits (attributed to the removal of carbon fibers) were observed on the surfaces of the untreated PEEK and CFR-PEEK (Fig. 2). In contrast, the surfaces of the PMPC-grafted PEEK and CFR-PEEK were smooth; scratches and pits were hardly observed. For both PMPC-grafted PEEK and CFR-PEEK, an approximately 100-nm-thick PMPC layer was clearly observed on the surface of the PEEK substrate, and neither cracks nor delamination were observed on the PEEK substrate or at the interface between the PMPC layer and the PEEK substrate.

PMPC grafting affected the hydration and friction characteristics of the PEEK and CFR-PEEK surfaces. The contact angles of untreated PEEK and CFR-PEEK were $\sim 90^\circ$ (PEEK; mean = 92.5° , 95% CI = ± 1.0 , and CFR-PEEK; mean = 88.3° , 95% CI = ± 1.6) and decreased to their lowest values of $< 10^\circ$ after PMPC-grafting on the surfaces (PEEK; mean = 6.8° , 95% CI = ± 0.9 , $p < 0.01$ and CFR-PEEK; mean = 5.5° , 95% CI = ± 0.8 , $p < 0.01$) (Fig. 3). The coefficient of dynamic friction of untreated CFR-PEEK

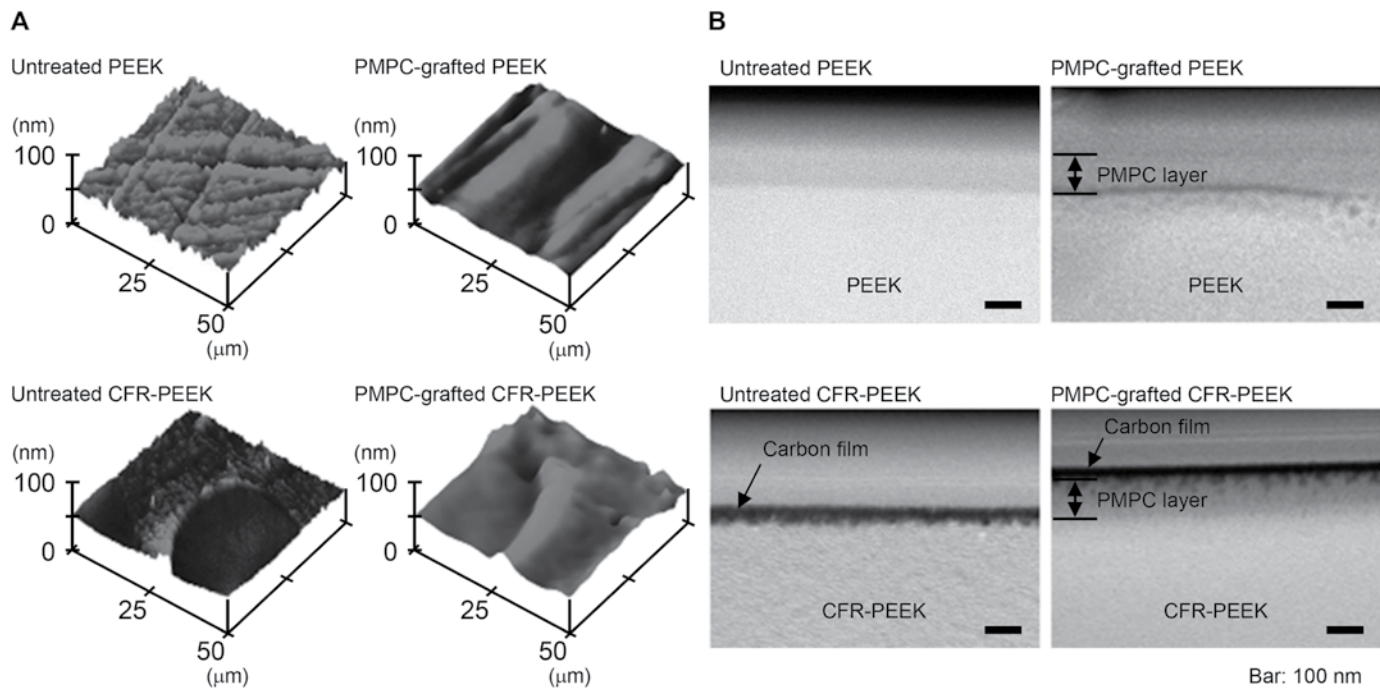


Figure 2. (A) Surface AFM images and (B) cross-sectional TEM images of untreated PEEK, PMPC-grafted PEEK, untreated CFR-PEEK, and PMPC-grafted CFR-PEEK.

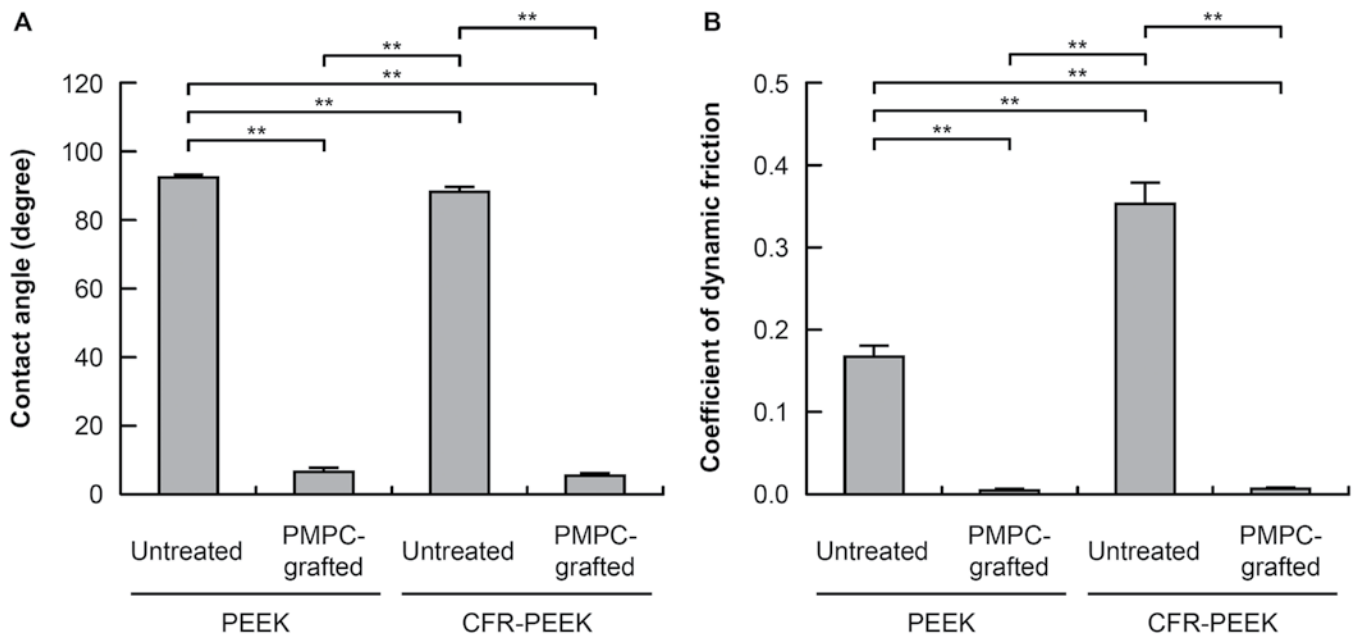


Figure 3. (A) Static water contact angle and (B) coefficient of dynamic friction of untreated PEEK, PMPC-grafted PEEK, untreated CFR-PEEK, and PMPC-grafted CFR-PEEK. Data are expressed as mean \pm 95% confidence intervals. **: One-factor ANOVA and post-hoc test, significant differences ($p < 0.01$) were observed in the comparison between four groups.

(mean = 0.354, 95% CI = ± 0.025) was two times that of untreated PEEK (mean = 0.167, 95% CI = ± 0.013 , $p < 0.01$). However, regardless of the carbon-fiber reinforcement, the lowest values of both coefficients of dynamic friction were < 0.01 after PMPC grafting on the surfaces and were 97% lower (PEEK; mean = 0.005, 95% CI = ± 0.001 , $p < 0.01$ and CFR-PEEK; mean = 0.007, 95% CI = ± 0.001 , $p < 0.01$) than those of untreated PEEK and CFR-PEEK.

In the multidirectional pin-on-disk wear test, untreated CFR-PEEK (mean = -0.18 mg/106 cycles, 95% CI = ± 0.10) and PMPC-grafted CFR-PEEK (mean = 0.01 mg/106 cycles, 95% CI = ± 0.01) pins were found to undergo significantly less ($p < 0.01$) gravimetric wear rate than untreated PEEK (mean = 9.50 mg/106 cycles, 95% CI = ± 4.14) pins (Fig. 4). On the other hand, the gravimetric wear rate of the counter Co–Cr–Mo alloy disks against the

untreated CFR-PEEK pins (mean = 0.61 mg/106 cycles, 95% CI = ± 0.46) exhibit higher wear ($p < 0.05$) than the CLPE pins (mean = 0.02 mg/106 cycles, 95% CI = ± 0.02).

In the hip simulator wear test, the characteristics of the PMPC grafted surface affected the durability of the PEEK and CFR-PEEK cups. During 3.0×10^6 cycles of the hip simulator wear test, the PMPC-grafted PEEK cup (mean = 31.60 mg/106 cycles, 95% CI = ± 19.54) was observed to experience less gravimetric wear rate than the untreated PEEK cup (mean = 216.97 mg/106 cycles, 95% CI = ± 181.02) (Fig. 5A). However, the difference was not statistically significant owing to the wide deviation of the gravimetric wear of the untreated PEEK cups. The untreated and PMPC-grafted CFR-PEEK cups (untreated: mean = -2.46 mg/106 cycles, 95% CI = ± 0.24 ; PMPC-grafted: mean = -5.49 mg/106 cycles, 95% CI = ± 1.62) were found to undergo significantly less ($p < 0.05$) gravimetric wear than the untreated PEEK cups. Remarkably, fewer wear particles were isolated from the lubricants of the PMPC-grafted PEEK cups than from those of the untreated PEEK cups after 3.0×10^6 cycles ($2.5\text{--}3.0 \times 10^6$ cycles) of the hip simulator test (Fig. 5B). Moreover, extremely small and barely observable wear particles were produced by the untreated CFR-PEEK and PMPC-grafted CFR-PEEK cups. The wear particles of the untreated PEEK and PMPC-grafted PEEK cups were micrometer-sized fibrils and sub-micrometer-sized granules. In contrast, those of the untreated CFR-PEEK and PMPC-grafted CFR-PEEK cups were only sub-micrometer-sized granules. PMPC grafting did not affect the morphologies of the PEEK or CFR-PEEK wear particles. In the confocal laser scanning microscope images shown in Fig. 6A, the surfaces of the Co-Cr-Mo alloy femoral heads against the untreated and PMPC-grafted PEEK cups and the PMPC-grafted CFR-PEEK cups were smooth. However, that against the untreated CFR-PEEK cups had a different morphology; the surface was worn and slightly roughened by scratches. In the fluorescence microscope image of only the femoral head against the untreated PEEK cup, fluorescence of the adhesives was observed (Fig. 6B). This is primarily attributed to the PEEK. The mean of the surface roughness of the worn femoral heads against the untreated CFR-PEEK cups (mean = 0.019 μm , 95% CI = ± 0.005) was significantly higher ($p < 0.05$) than those of the other bearing couples (untreated PEEK: mean = 0.009 μm , 95% CI = ± 0.004 ; PMPC-grafted PEEK: mean = 0.006 μm , 95% CI = ± 0.001 ; PMPC-grafted CFR-PEEK: mean = 0.010 μm , 95% CI = ± 0.003) (Fig. 6C). There were no differences among the mean surface roughness of the other three bearing couples.

Discussion

In this study, we developed the novel self-initiated surface graft polymerization technique, by which we demonstrate the fabrication of a highly hydrophilic and biocompatible 100-nm-thick smooth layer on the surfaces of PEEK and CFR-PEEK by the photo-induced graft polymerization of MPC without using any additional low-molecular-weight photoinitiators. Furthermore, we investigate the surface characteristics of PMPC-grafted PEEK and CFR-PEEK. We considered two research questions: (1) Will the PMPC grafting affect the lubrication characteristics of PEEK and CFR-PEEK surfaces? (2) Will the modifications affect their wear resistances? The results suggested that it was possible to improve the durability of orthopedic bearing materials.

It is important to optimize the water-wettability and lubricity of the bearing surface to improve wear resistance. The wettabilities of PMPC-grafted PEEK and CFR-PEEK surfaces are considerably greater than those of the untreated PEEK and CFR-PEEK surfaces (Fig. 3A). This is because of the presence of a smooth 100-nm-scale PMPC layer resulting from the polymerization of highly hydrophilic MPC monomer (Fig. 2). Fig. 3B shows that the coefficients of dynamic friction of the PMPC-grafted PEEK and CFR-PEEK surfaces were significantly lower than those of the untreated PEEK and CFR-PEEK surfaces. The wettabilities of the PMPC hydrated layer clearly affected the frictional properties of the PEEK and CFR-PEEK surfaces. The higher friction of untreated PEEK and CFR-PEEK surfaces is one of their disadvantages because it results in greater wear and the seizure of bearing couples. The higher frictional properties of untreated PEEK and CFR-PEEK surfaces actually affected the wear properties determined by the hip simulator wear test.

The wear properties of PEEK and CFR-PEEK when used as bearing materials in hip joint articulations have been reported in previous studies [26–30]. To the best of our knowledge, the wear resistances of these materials are not completely satisfactory. Scholes et al. reported that the wear rate was 1.16 mm³/106 cycles [28], and Brockett et al. reported that the wear rate was 0.30 mm³/106 cycles [30] for CFR-PEEK cups against alumina or zirconia-toughened alumina (ZTA) ceramic femoral heads, respectively. In the hip simulator wear test, the significant improvements in the water-wettabilities, frictional properties, and/or carbon-fiber-reinforced properties of the PMPC-grafted PEEK and CFR-PEEK cups resulted in substantial improvements in their wear resistances. The wear rate of the PMPC-grafted CFR-PEEK cups was almost zero (–3.81 mm³/106 cycles, as calculated using a specific gravity of

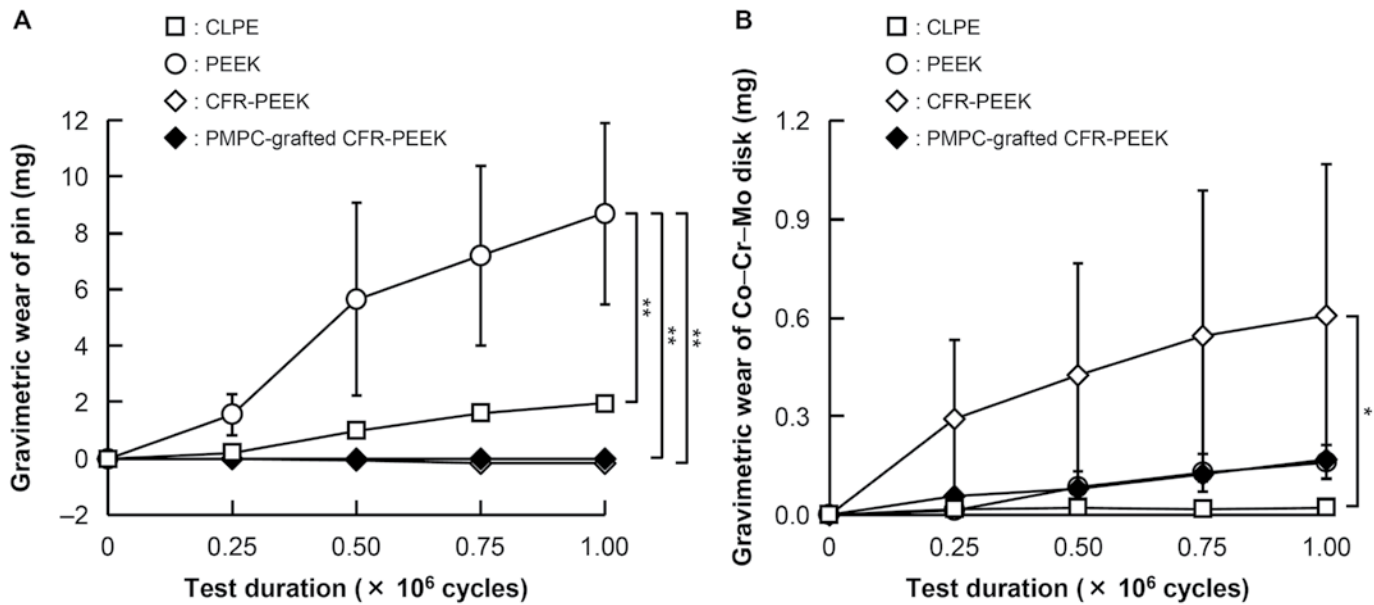


Figure 4. Time courses of the gravimetric wear of the (A) untreated PEEK and untreated and PMPC-grafted CFR-PEEK pins, and (B) counter Co-Cr-Mo disks during the multidirectional POD wear test. Data are expressed as mean \pm 95% confidence intervals. One-factor ANOVA and post-hoc test, significant differences (* $p < 0.05$, ** $p < 0.01$) were observed in the comparison between four groups.

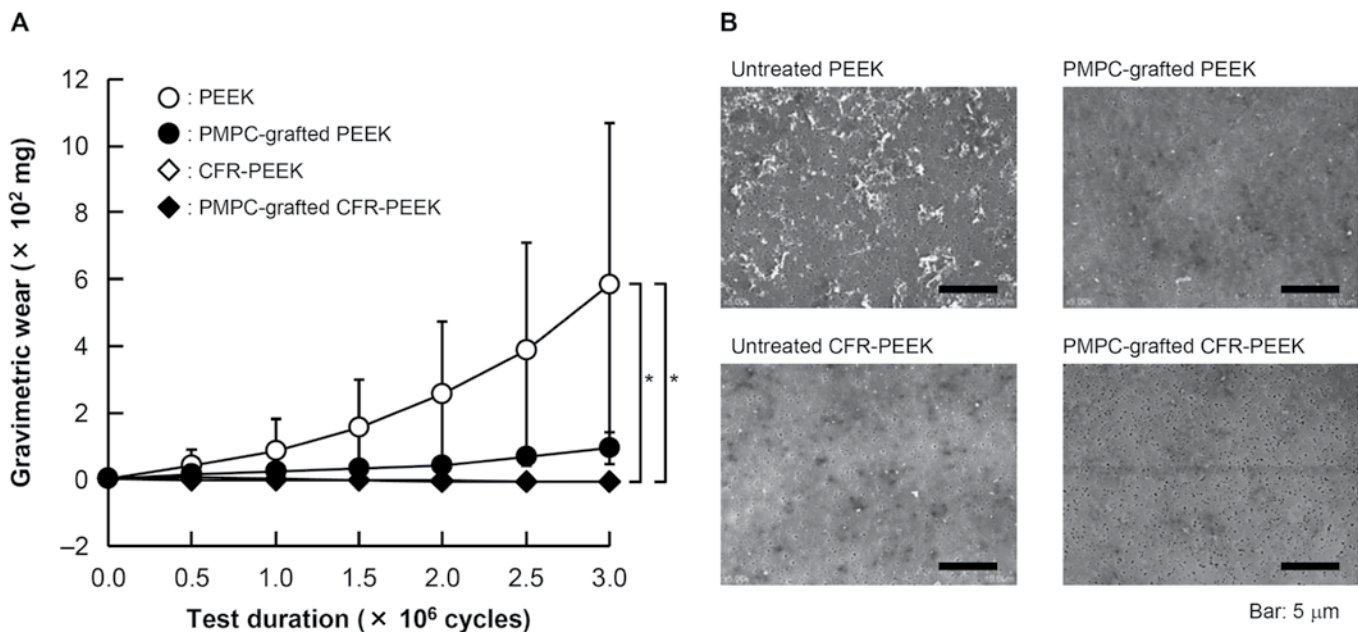


Figure 5. Time courses of the gravimetric wear of the (A) untreated and PMPC-grafted PEEK and untreated and PMPC-grafted CFR-PEEK cups, and (B) SEM images of wear particles isolated from lubricants of the hip simulator wear test. Data are expressed as mean \pm 95% confidence intervals. One-factor ANOVA and post-hoc test, significant difference (* $p < 0.05$) was observed in the comparison between four groups.

1.44 g/cm³) even when articulated to Co-Cr-Mo alloy femoral heads. As noted earlier, PMPC is water-soluble because MPC is highly hydrophilic. Fluid-film lubrication (or hydration lubrication) with the PMPC-grafted surface was therefore afforded by the hydrated layer. It can be affirmed that an orthopedic bearing using PMPC mimics natural articular cartilage. The bearing surfaces of a natural synovial

joint are covered by a specialized type of hyaline cartilage (i.e., articular cartilage) that protects the joint interface from mechanical wear and facilitates smooth movement of the joints during daily activity [31]. Articular cartilage consists of surface-active phospholipids, chondrocytes, and surrounding matrix macromolecules, such as proteoglycans, glycosaminoglycans, and collagens. Because of

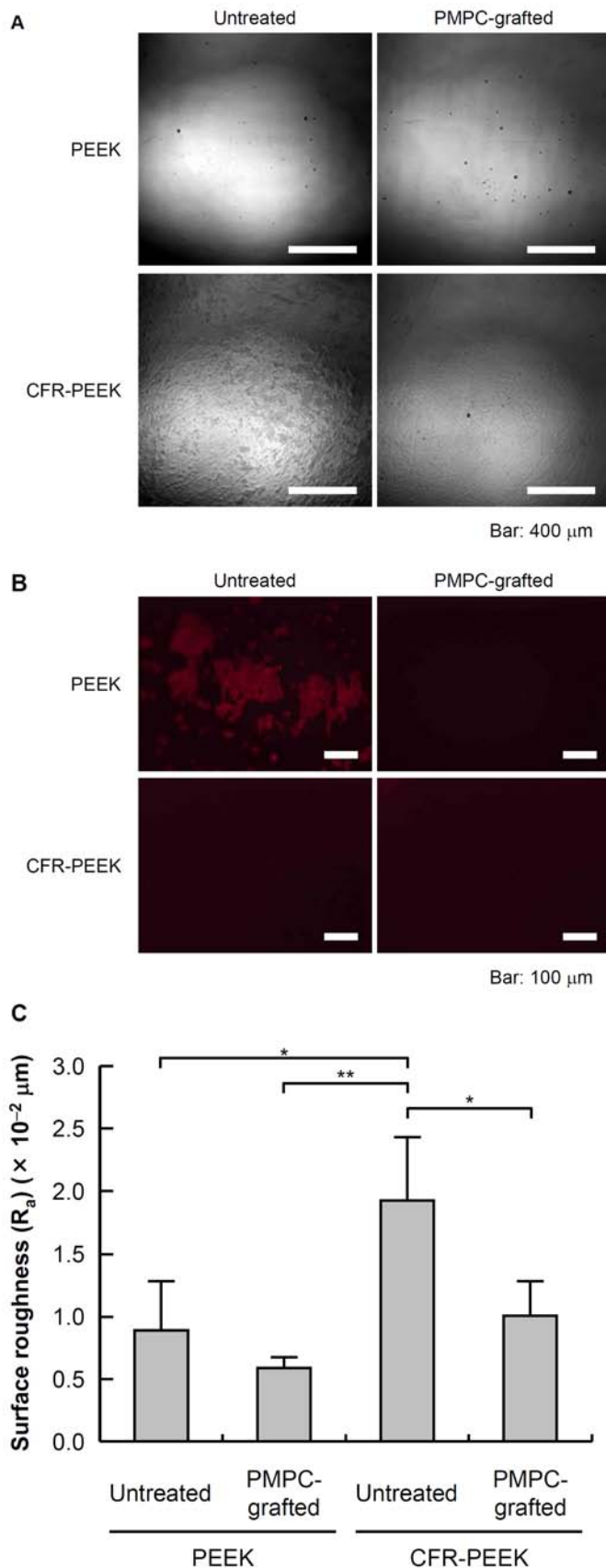


Figure 6. Surface conditions of Co–Cr–Mo alloy femoral heads against PMPC-grafted PEEK and CFR-PEEK cups after 3.0×10^6 cycles. (A) Confocal laser scanning microscope images, (B) fluorescence microscope images, and (C) surface roughness of Co–Cr–Mo alloy femoral heads. Data are expressed as mean \pm 95% confidence intervals. * indicates $p < 0.05$, ** indicates $p < 0.01$.

their charge, they can trap water to maintain the water-fluid and electrolyte balance, which provides hydrophilicity and affords effective boundary lubrication [32]. The thin-film fluid lubrication of the hydrated layer of articular cartilage is essential to the smooth movement of natural synovial joints. Considering that the study and mimicking of nature has been widely successful in science and technology, an investigation of the bearing surfaces of artificial joints with the purpose of mimicking cartilage by surface modification appears promising [32].

There was a significant difference between the wear of PEEK and CFR-PEEK in both the multidirectional pin-on-disk wear test and hip simulator wear test. CFR-PEEK exhibited extremely low wear compared to PEEK. The PAN-based carbon fiber content of the composite must be sufficient to achieve high wear resistance, and it scratched the counter surfaces that exhibited high metal wear [27]. In contrast, the counter surfaces against PMPC-grafted CFR-PEEK were smooth. It is assumed that the fluid-film and/or hydrated layer produced by the PMPC graft suppressed direct contact between the counter-bearing face and the hard carbon fibers of the CFR-PEEK substrate (Fig. 7). This prevented the damage of the metal counter surface, regardless of the carbon fiber content of CFR-PEEK. Evans et al. reported that wear of the metal counter surface proved to be of little concern because it is one-hundredth-thousandth that of CFR-PEEK [33]. Similarly, in the multidirectional pin-on-disk wear test in this study, the wear of the metal counter is only a few percent that of CFR-PEEK or CLPE. However, we should focus on the increasing concern about the adverse local and systemic effects of elevated metal ion release (and electrochemical corrosion), which could cause serious problems such as local soft-tissue reaction and pseudotumor formation [34].

Brockett et al. reported that CFR-PEEK cups exhibited step-like wear with periods of higher wear rate (approximately 0.4–1.4 mm³/106 cycles) and lower wear rate (approximately <0.4 mm³/106 cycles) owing to the composition of the material [30]. The two wear phases were related to the loss of carbon fiber and PEEK matrix, a phenomenon that has been reported previously as well [28]. In contrast, the CFR-PEEK cups exhibited linear low wear [29]. It is assumed that the stepwise wear observed in previous studies was due to the polishing of the worn surface or removal of carbon fibers during the hip simulator wear test. Surface wear of the CFR-PEEK cups was hardly observed during the hip simulator wear test. Because of the surfaces, resulting in relatively linear low wear of carbon fibers and PEEK matrix and a smooth bearing surface, had been polished before the test.

Careful observation of wear particles for PEEK and

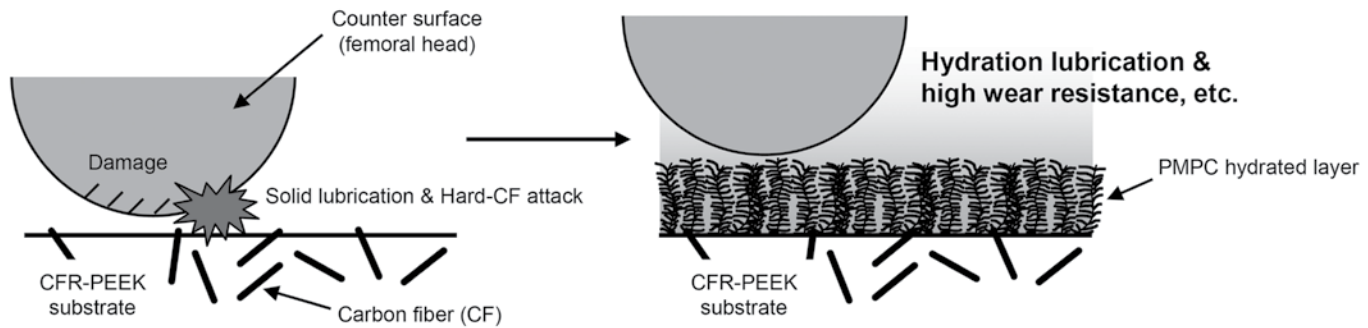


Figure 7. Schematic illustration of advantages of PMPC-grafted PEEK and PMPC-grafted CFR-PEEK.

CFR-PEEK is necessary because the production of wear particles in THA is recognized as the main factor that initiates periprosthetic osteolysis and aseptic loosening [1–3]. These wear particles are not biodegradable *in vivo*, and their deposition in the periprosthetic tissue activates macrophages and the subsequent release of cytokines, which stimulate bone resorption. The inflammatory cellular response to particles is thought to be dependent upon factors such as particle number, size, and shape; surface area; and material chemistry. In the wear particle analysis, remarkably fewer wear particles were isolated from the lubricants used for the PMPC-grafted PEEK and CFR-PEEK cups than from those used for the untreated cups. The wear particles from the PMPC-grafted PEEK and CFR-PEEK cups were almost sub-micrometer-sized. However, the procedure used for isolating the wear particles cannot entirely capture particles of diameter less than 0.1 μm . Moreover, because the amount of wear particles produced by the PMPC-grafted PEEK and CFR-PEEK cups was extremely small, the procedure could not separate them from those produced by the PEEK matrix and the blended carbon fiber. Considering the results of the wear particle analysis, we expect the biological response of the PMPC-grafted PEEK and CFR-PEEK cups *in vivo* to be comparable with those of PE or CLPE [12, 35]. This is supported by the cell culture experiments performed by Howling et al., who reported that CFR-PEEK wear particles had no cytotoxic effects and could not possibly cause adverse cellular (L929 and U937 cells) reactions [36]. Jones et al. reported that wear particles of CFR-PEEK cups exhibited no cytotoxic or mutagenic potential in the Ames test and the evaluation of chromosome aberration in human lymphocytes [12]. On the other hand, Lorber et al. suggested an increased proinflammatory potential of CFR-PEEK in the evaluation of cytokine (TNF- α , IL-1 β , and IL-6) expression tests [37]. Additionally, no *in vivo* biocompatibility studies using an appropriate animal have been published on this subject. Therefore, we think that careful consideration for wear particles of PEEK and CFR-PEEK is neces-

sary, regardless of PMPC grafting.

The design of a new implant with a well-characterized surface and substrate is a very important but difficult task. At present, the possibility of using PEEK and CFR-PEEK as orthopedic bearings in artificial hips is being earnestly investigated globally. The results do not yet demonstrate a clinical advantage of PEEK and CFR-PEEK over other well-established orthopedic bearings, such as CLPE and alumina or ZTA ceramics. The novel self-initiated surface graft polymerization technique proposed in this study, namely, the simple and innovative photoinduced graft polymerization technique would be very suitable for the surface modification of PEEK and CFR-PEEK orthopedic bearings. Indeed, smart PEEK and CFR-PEEK surfaces could usher in a new generation of orthopedic bearing implants.

Conclusions

In the present study, we successfully demonstrate the fabrication of a highly hydrophilic and biocompatible nanometer-scale layer on the surfaces of PEEK and CFR-PEEK by the photo-induced graft polymerization of MPC using self-initiated surface graft polymerization. The wettability of the PMPC-grafted PEEK and CFR-PEEK surfaces was considerably greater than that of the untreated surfaces. The coefficient of dynamic friction depended on the wettability. The PMPC-grafted layer was expected to significantly improve the wear resistance of the bearings; smart PEEK using the self-initiated surface graft polymerization of MPC should lead to the development of novel orthopedic bearings.

Acknowledgments

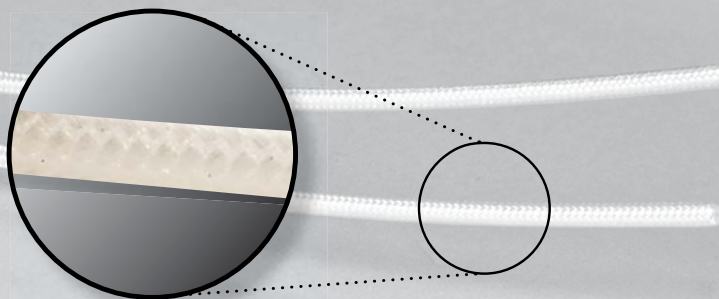
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COURSE CHAIRMEN: Jean-Noël Argenson, MD, PhD, Aix-Marseille University Hospital Sainte-Marguerite • W. Norman Scott, MD, FACS, Insall Scott Kelly Institute for Orthopaedics and Sports Medicine • Giles R. Scuderi, MD, Insall Scott Kelly Institute for Orthopaedics and Sports Medicine



World Arthroplasty Congress | April 16 – 18, 2015 • Paris, France • icjr.net/2015paris

The World Arthroplasty Congress is the first-ever meeting dedicated to the exchange of surgical innovation, cutting-edge science, and practical knowledge related to joint reconstruction on a global scale. While societal, political, and economic climates, as well as surgical environments, may vary drastically from one country to the next, this congress aims to put aside these differences so we can learn from one another with a common goal of advancing the field of reconstruction and improving patient care.

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Tissue Sparing Total Hip Arthroplasty Study Group

The Joint Implant Surgery and Research Foundation has a long history in the study of THA. It began back in 1971 when Professor Charles O. Bechtol, M.D. established JISRF as a nonprofit scientific and educational foundation.

JISRF continues this study with the formation of a new study group of international surgeons and scientists. Findings will be posted on the foundation's web site at www.jisrf.org.

Joint Implant Surgery and Research Foundation

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Surgeons interested in learning more contact the Executive Director at www.JISRF.org



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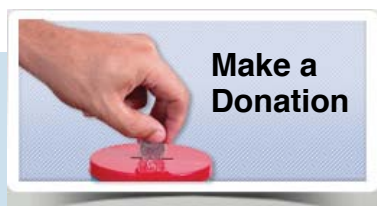
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JISRF Creates Institutional Review Board

JISRF's Board of Directors have approved the formation of an Institutional Review Board (IRB).

JISRF has a long rich history of conducting clinical/surgical research projects. There has been considerable interest in JISRF establishing a formal IRB Committee. The specific purpose of this IRB Committee is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. JISRF's IRB Committee will attempt to ensure protection of subjects by reviewing research protocols and related materials. IRB protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices and seeks to maximize the safety of subjects.

JISRF has lectured and published on ethics and full disclosure since 1993. The Board sees the IRB Committee as a next logical step in interdisciplinary research and education while protecting the individual patients rights on full disclosure with regard to decision making of new technologies and potential conflict of interest in an ever changing health care environment.

Research grants, charitable contributions and revenue from our general fund support the IRB's work.



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Partnering the European Knee Associates (EKA) with ICJR's global affiliates and in combination with the 3rd Best Current Practice in Europe of EKA, the World Arthroplasty Congress is the first-ever global meeting dedicated entirely to hip and knee arthroplasty.

PLAN FOR PARIS!

- Transcend societal, political, and economic differences as well as variances in surgical environments for the benefit of learning from one another to advance the field of arthroplasty and improve patient care
- Develop a global understanding of key issues in orthopaedics, surgical innovation, cutting-edge science, and practical knowledge through a dynamic and engaging 3-day agenda
- Gain insight from and interact with a faculty of orthopaedic experts from around the world
- Submit your abstract for consideration for the scientific poster sessions featuring global advances in hip and knee arthroplasty
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FOR REGISTRATION/INFO VISIT

www.icjr.net/2015paris

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Disclosure for Authors

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This phase will include an expansion of our world renowned executive health and wellness practice, The Greenbrier Clinic, which will be bolstered by a world-class sports medicine program, including an orthopedic surgery center and athletic performance/rehabilitation facility, all led by the Founder of the American Sports Medicine Institute, Dr. Jim Andrews and Chair of Cleveland Clinic Innovations, Thomas Graham. Rounding out the Institute's services will be a first-



in-class plastic and cosmetic surgery and Lifestyle Enhancement Academy, helping people look and feel their best. Physicians, universities, research foundations, medical journals and other healthcare industry leaders, all of whom are on the cutting edge of medical technology, research and care, have committed to join the project and establish an international research and education destination or "think tank" to stimulate research, drive innovation, force change and redefine how the world approaches health, wellness and longevity.

The Institute's facility, designed by Willie Stokes, will feature Georgian architecture similar to the resort's façade, a replica of the Springhouse, the site of the famous sulphur springs and special guests suites for patients and their families. Jack Diamond, President and CEO, and Mark Krohn, COO, are leading the development of this exciting project and are actively looking for other physicians and medical thought leaders to be involved.

For more information, please contact:

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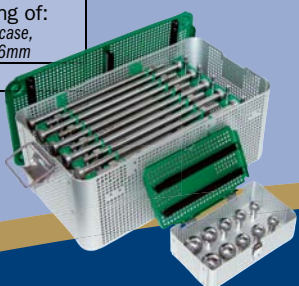
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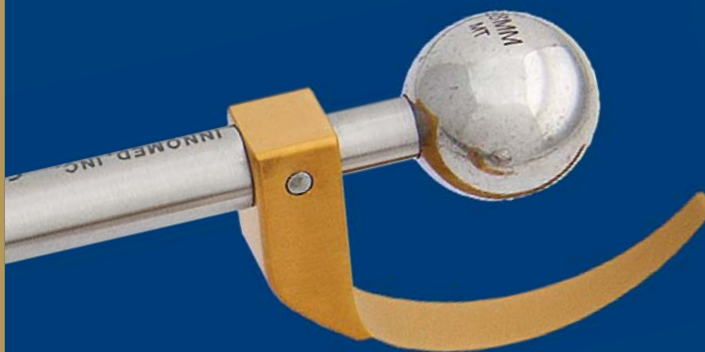


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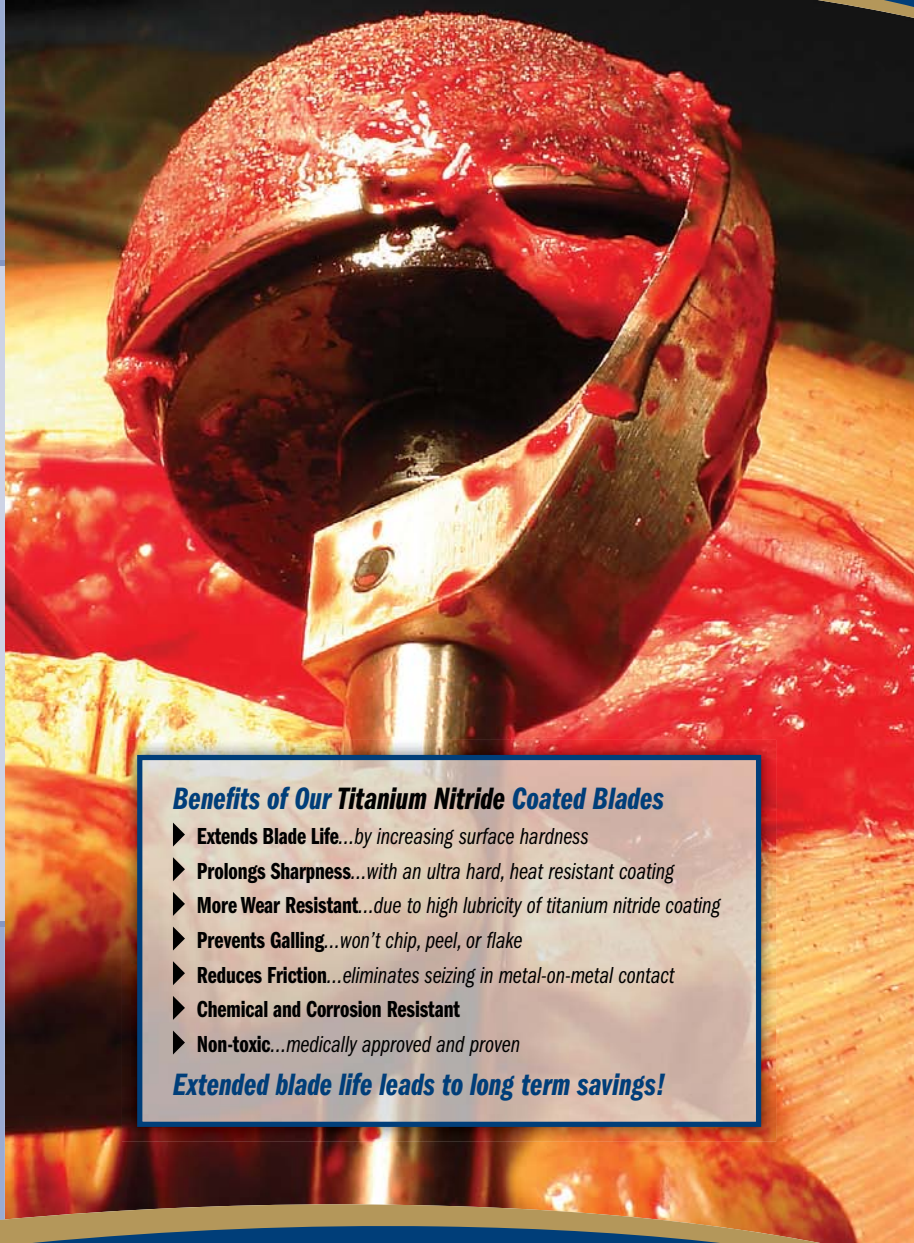
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