BioMed Research International

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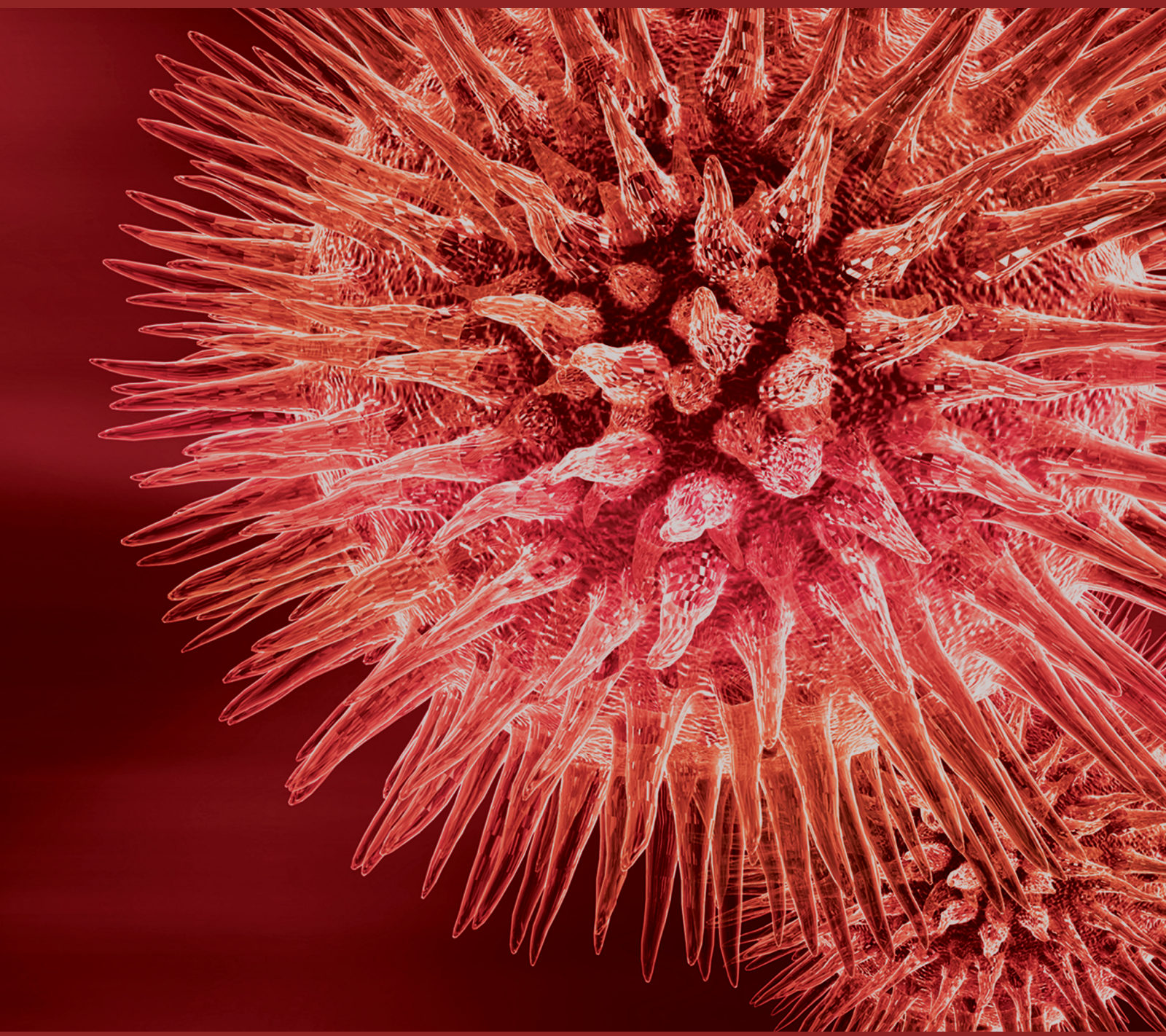
Guest Editors: Thomas M. Grupp, Sandra Utzschneider, and Steven M. Kurtz



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Editorial

Retrieval Research in Hip and Knee Arthroplasty

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During the last two decades, improvements in hip and knee designs, bearing materials, sterilisation techniques, oxidation stabilisation, and articulating surface treatments have led to superior performance of total hip and knee arthroplasties by reducing the prevalence of wear, delamination, and structural material fatigue. These advances are expected to show substantial benefits in decreasing wear, osteolysis, and improved joint function in the coming decades.

In contrast to that new implant designs, articulating bearings, implant modularities, kinematic concepts, and surgical treatments came up, but not all of them were as beneficial in regard to their expected service in vivo in the 2nd and 3rd decade, patient satisfaction, and clinical outcomes.

As total hip and knee arthroplasty today is being increasingly performed on younger, heavier, and more active patients, it appears desirable to further improve implant designs, modular connections, bearing materials, and implant fixation methods to allow for a higher degree of function, patient satisfaction, and long-term survivorship. Dedicated retrieval research programs are a main source to gain more knowledge about the complex surgeon-implant-patient interactions and a deeper understanding on material degradation and potential adverse side effects in vivo to create sustainable arthroplasty technologies for the future.

This special issue presents 7 articles with original research papers and clinical study findings showing different dimensions of implant revision and retrieval research in hip and knee arthroplasty.

In retrieval analysis on polyethylene inlays of an open acetabular screw ring cup design showing a high clinical failure rate, U. Mueller et al. examine the specific failure mechanism and concluded that ongoing creep deformation due to insufficient cup support leads to substantial backside wear, collar fatigue, and decreased clearance.

To understand the wear process of polyethylene inlays from acetabular cup systems with a cone press-fit locking mechanism A. L. Puente Reyna et al. evaluate the backside wear characteristics in a direct comparison of wear simulator testing and retrievals. Similar wear scores for in vitro tested specimen and retrievals (in situ) were found with insertion and removal of the inlay as main source of backside wear.

Using an artificial neural network approach the research paper of D. A. Orozco Villasenor and M. A. Wimmer describes a new method to identify wear scar similarities and discrepancies between retrieved and simulator tested polyethylene gliding surfaces and suggested that current ISO knee testing protocols were not fully representative for in vivo behaviour.

J. A. Eckert et al. performed a retrieval analysis about tribocorrosion in modular shoulder arthroplasty taper junctions using a modified Goldberg score and found the prevalence of fretting and corrosion with titanium stems being more susceptible to tribocorrosion damage than cobalt-chromium stems.

A. C. Paulus et al. have undergone a histopathological analysis of wear particle effects on the synovial tissue achieved during knee revision surgery of a rotating hinge knee design with CFR-PEEK implant components and found differences to previous animal studies. Furthermore they describe

specific differences between the agglomeration behaviour of polyethylene and PEEK in human synovial tissue.

Periprosthetic infection is a remaining major complication in orthopaedic oncology limb salvage surgery procedures of pathologic fractures due to bone metastases. By F. Donati et al., a retrospective clinical study on bone tumor patients (follow-up of 46.5 months) treated with a silver coated or uncoated proximal femur replacement hip hemiarthroplasty was presented, demonstrating good antimicrobial activity with a lower rate of early infection in the silver coated group and low toxicity.

As 10 to 20 percent of TKA patients are dissatisfied with their clinical outcome this is a main reason for early knee revision. A. Giurea et al. studied the impact of personality traits in a cohort of computer navigated TKA patients based on 12 personality traits tested by the Freiburg Personality Inventory (FPI-R). Within this TKA cohort with optimal alignment, 16% of patients were dissatisfied and the FPI-R showed a substantial influence of the personality traits life satisfaction, performance orientation, somatic distress, and emotional stability on clinical outcome and patient satisfaction after TKA.

Finally the guest editors would like to thank all authors for contributing their excellent work to this special issue and all the reviewers for their thoughts and suggestions on the manuscripts.

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Research Article

Backside Wear Analysis of Retrieved Acetabular Liners with a Press-Fit Locking Mechanism in Comparison to Wear Simulation In Vitro

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Backside wear due to micromotion and poor conformity between the liner and its titanium alloy shell may contribute to the high rates of retroacetabular osteolysis and consequent aseptic loosening. The purpose of our study was to understand the wear process on the backside of polyethylene liners from two acetabular cup systems, whose locking mechanism is based on a press-fit cone in combination with a rough titanium conical inner surface on the fixation area. A direct comparison between in vitro wear simulator tests (equivalent to 3 years of use) and retrieved liners (average 13.1 months in situ) was done in order to evaluate the backside wear characteristics and behavior of these systems. Similar wear scores between in vitro tested and retrieved liners were observed. The results showed that this locking mechanism did not significantly produce wear marks at the backside of the polyethylene liners due to micromotion. In all the analyzed liners, the most common wear modes observed were small scratches at the cranial fixation zone directly below the rough titanium inner surface of the shell. It was concluded that most of the wear marks were produced during the insertion and removal of the liner, rather than during its time in situ.

1. Introduction

Aseptic loosening of the implant is the main reason for revision in total hip arthroplasty (THA), with over 50% of the cases [1–3]. The main stimulator of periprosthetic osteolysis and subsequent aseptic loosening is the particulate debris generated by the wear at the articulating surface between the acetabular polyethylene liners and the femoral heads [2, 4–6]. However, there are also other sources of particulate debris generation, such as wear due to impingement, the presence of third-body particles, or micromotion between an insert and its metallic acetabular shell, also known as backside wear [7]. Hence, different implant designs and materials used in hip arthroplasty have been developed in order to decrease the polyethylene wear particle generation.

Currently, the most widely used components in THA are the modular metal-backed acetabular components. Since their development in the 1970s [8], the modular components showed some advantages such as intraoperative flexibility, multiple options for screw placement, and the opportunity to exchange the polyethylene liner during revision surgeries without removing the metallic shell. However, these types of components also brought disadvantages, like an altered stress transmission and micro- and macromotion between the liner and its metallic shell. Creep and wear on the backside of the polyethylene liner are thus generated, therefore an additional

(a) (b)

Figure 1: (a) P-Cup and (b) P-Fit metallic shell with grit blasted rough titanium conical inner surface at the rim ① and milled-drilled smooth surface on the concave area ②.

source of particulate debris that increases the risk of osteolysis and eventual aseptic loosening of the prostheses [9–11].

Particularly high backside wear has been associated with micromotion between the liner and its shell due to an unstable locking mechanism and a poor conformity between both components [11–13]. This type of wear was implicated in the high rates of retroacetabular osteolysis observed in liners that were locked to their metallic shell by means of a titanium locking ring or using a hexagonal thin polyethylene rim at the base of the liner, which fitted to a complementary groove in the metallic shell [9, 14–16]. Moreover, if there is a dissociation of the liner from the shell, the debris generated at the articulating surface can migrate between the liner and the shell and the screw holes can act as conduits for a further migration of the debris into the pelvic bone stock with the risk of inducing osteolysis [17].

Different designs have been developed in order to reduce backside wear and prevent the migration of wear debris into the acetabular bone stock [18]. These designs include improving the locking mechanism between the liner and the shell, polishing the inner surface of the shell, or sealing the screw holes with modular caps. The purpose of our study was to understand more of the wear process on the backside of polyethylene liners from two acetabular cup designs with long- and short-term clinical history, whose locking mechanism is based on a press-fit cone in combination with a rough titanium inner surface at the rim of the metallic shell. A direct comparison between in vitro tested and retrieved liners was done in order to evaluate the backside wear characteristics and behavior.

2. Materials and Methods

An optical analysis of polyethylene liners from two different cup systems (Plasmacup® and Plasmafit®, Aesculap AG, Tuttlingen, Germany) was performed (Figure 1). Both cup designs present the same locking mechanism between the liner and the shell, which is based on a press-fit cone with a large surface area and through a contact with the base of the shell, which will be achieved after the load in service. A grit blasted rough titanium inner surface (Rz = 20–32 μm) along the rim of the shell intends to stabilize the liner to it. Furthermore, the conical fixation surface of the liners intends to form a seal against the migration of wear particles from the articulation joint. The screw drill holes of the Plasmacup (further referred to as P-Cup) are located in the cranial region of the shell. The Plasmafit liners (further referred to as P-Fit) analyzed did not have screw drill holes. The polyethylene liners of the two different cup systems can have either a symmetrical (Sym) or a posterior wall (PW) design. In the symmetrical design, the liners fit symmetrically in the shells, whereas the posterior wall liners contain a polyethylene hood that extends outside the shell in the luxation direction in order to increase luxation stability.

Liners from three different polyethylene materials were analyzed for backside wear. The conventional standard polyethylene liners (STD) were packed under nitrogen atmosphere and sterilized by gamma-irradiation (30 ± 2 kGy). The highly cross-linked polyethylene liners (XPE) were cross-linked by γ-irradiation (75 kGy) and sterilized by ethylene oxide. The highly cross-linked and Vitamin E (0.1%) blended polyethylene liners (VitE) were cross-linked by an electron beam (80 kGy) and sterilized by ethylene oxide. The polyethylene liners were tested in combination with acetabular shells made out of Ti6Al4V alloy and modular heads made out of ceramic or cobalt-chromium (Tables 1 and 2). Large femoral head and shell diameters were chosen, as these produce a high amount of wear at the articulation surface but with a low risk of luxation. Furthermore, as there is no worst case size reported for backside wear, we have chosen the most common clinically used diameters (32 and 36 mm). All the polyethylene liners for the in vitro wear tests were subjected to artificial aging according to ASTM F2003-02 at 70°C in pure oxygen at 5 bar for two weeks (Millipore Corp., 6700P05,

Table 1: Summary of in vitro tested implants.

In vitro group (n = 3 each)	Model	Polyethylene material	Femoral head	Head diameter (mm)	Shell diameter (mm)
P-CupD$_{\text{Sym VitE}}$*	Plasmacup DC symmetrical	VitE	CoCr	36	52
P-CupD$_{\text{Sym VitE}}$	Plasmacup DC symmetrical	VitE	Ceramic	36	52
P-CupD$_{\text{Sym XPE}}$*	Plasmacup DC symmetrical	XPE	CoCr	36	52
P-Fit$_{\text{Sym VitE}}$	Plasmafit Poly symmetrical	VitE	Ceramic	36	50
P-Fit$_{\text{Sym STD}}$*	Plasmafit Poly symmetrical	STD	CoCr	32	46
P-Fit$_{\text{Sym STD}}$	Plasmafit Poly symmetrical	STD	Ceramic	32	46

Table 2: Summary of retrieved implants and demographic data of patients.

Retrieval	Model	Polyethylene material	Femoral head	Head diameter (mm)	Shell diameter (mm)	Time in situ (months)	Gender (age in years at revision surgery)	Weight (kg)	Reason for revision
P-CupD$_{\text{Sym VitE}}$	Plasmacup DC symmetrical	VitE	Ceramic	32	50	11	F (74)	—	Luxation
P-CupD$_{\text{Sym XPE-1}}$	Plasmacup DC symmetrical	XPE	Ceramic	32	56	0.5	N/A (77)	—	Infection
P-CupD$_{\text{Sym XPE-2}}$	Plasmacup DC symmetrical	XPE	Ceramic	32	54	15	M (64)	92	Stem loosening
P-CupD$_{\text{PW VitE}}$	Plasmacup DC posterior wall	VitE	Ceramic	32	52	2	M (69)	109	Stem subsidence
P-CupS$_{\text{PW STD}}$*	Plasmacup SC posterior wall	STD	CoCr	32	58	37	M (69)	110	Stem fracture

Merck KgaA, Darmstadt, Germany). All liners were soaked prior to wear simulation in serum-based test medium until the incremental mass change over 24 h was less than 10% of the previous cumulative mass change to allow for saturated fluid absorption.

In vitro wear simulation was performed on a customized 6 + 2 (reference) stations servo hydraulic hip simulator (EndoLab GmbH, Thansau, Germany) with kinematic and load patterns according to ISO 14242-1:2012 (E). The liners were tested through 5 million cycles with a frequency of 1 Hz in a lubricant of newborn calf serum (Biochrom AG, Berlin, Germany) diluted with deionized water to achieve a target protein content of 30 g/L. The lubricant was incubated at 37°C, pH-stabilized with ethylene diamine tetraacetic acid, and replaced at intervals of 0.5 million cycles. Patricin was added to prevent fungal decay. Every 0.5 million cycles, the polyethylene liners were removed from the acetabular shell in order to perform gravimetric wear measurements and image documentation [18]. It is estimated that the 5 million cycles required in the ISO 14242-1:2012 (E) represent a mean in vivo service life of 2.9 years [19], as several studies that have estimated the gait cycles per year in patients before and after total hip or knee arthroplasty measured an average of 1.76 million gait cycles per year (range of 0.9–3.2 million gait cycles) [20–24].

Retrievals, all Plasmacup liners, were explanted during hip arthroplasty revisions in various hospitals in Germany for various reasons. P-CupD and P-CupS refer to Plasmacup DC and SC acetabular shells, which have no significant design difference. Three of the five explants that were harvested and sent to Aesculap stem from a prospective randomized study to investigate clinical and radiological differences in behavior of two different polyethylene types [25]. Between removal and optical analysis, these liners were cleaned through an ultrasonic bath in mild detergent, individually vacuum packed under nitrogen atmosphere, and stored on a freezer at −20°C. The two other liners were cleaned, individually packed under air atmosphere, and stored at room temperature. The mean survival time for all implants was 13.1 months (from 0.5 to 37 months). The liners were implanted between 2006 and 2014 and their reasons for removal were luxation (20%), infection (20%), and stem related reasons like loosening, fracture, and subsidence (60%).

The backside surface of the acetabular liners was inspected using a stereo light microscope (Leica MZ 16, Bensheim, Germany) up to a 25x magnification. Additional images

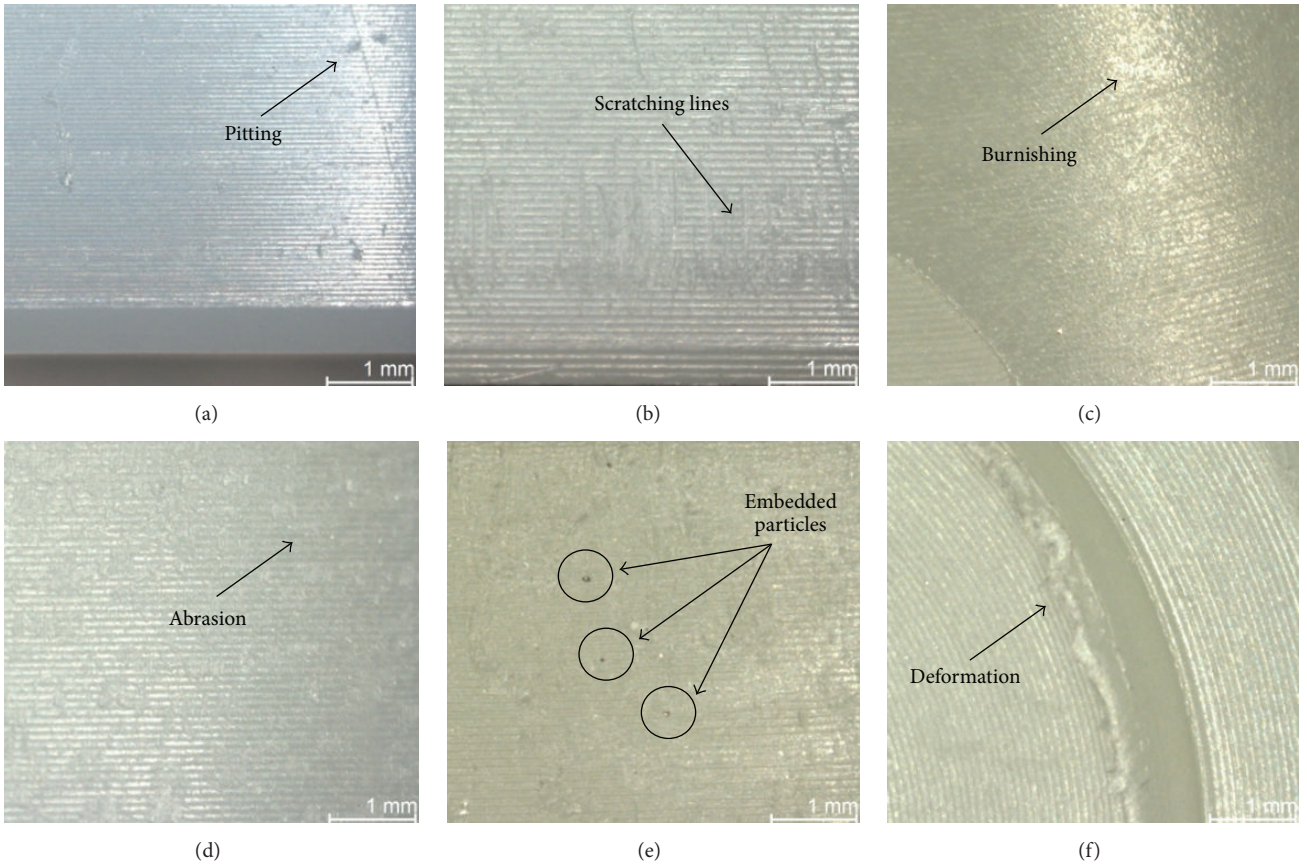

Figure 2: Images from each wear mode: (a) pitting, (b) scratching, (c) burnishing, (d) abrasion, (e) embedded particles, and (f) deformation. No image of delamination was taken, as this wear mode was not present in any of the inserts.

were obtained through Scanning Electron Microscope (SEM) (Zeiss EVO 50, Oberkochen, Germany) equipped with energy dispersive spectrometer (EDX) (Oxford Instruments X-Max, Wiesbaden, Germany) in order to analyze the composition of embedded particles. A semiquantitative method developed by Hood et al. [26] and modified for hip implants was used to assess the damage on the backside of the liners. Seven different modes of damage were defined (Figure 2). Deformation was used to describe the evidence of permanent deformation from the original shape due to cold flow and/or creep. Pitting described small circular indentations. Embedded particles were defined as particles embedded in the polyethylene and were recognized by the color and/or texture difference within the polyethylene surface. Scratching described straight lines that cut into the polyethylene. Burnishing described areas that had become highly polished and thus machining marks were worn off. Abrasion was defined as an area with roughened texture due to repeated rubbing. Finally, delamination described areas where a large section of polyethylene had been lost. Care was taken to differentiate the wear marks that were thought to have occurred during insertion and removal of the liner from the wear marks generated due to the liner's micromovement in service.

On basis of its in situ orientation, the backside section was divided by a superior/inferior line and 7 different sections were determined (Figure 3(a)). Sections 2 and 3 correspond to the convex surface below the milled-drilled area of the shell, whereas Sections 4 to 7 correspond to the rim below the rough titanium inner surface of the shell. Damage scores for the backside surface of each liner were determined. For each section, a score between 0 and 3 was given for each of the seven damage modes, giving a maximum possible damage score of 21 per section. Following Hood's method [26], a score of 0 meant no damage; a score of 1 meant damage to less than 10% of the surface area, 2 meant damage to 10–50% of the surface area, and 3 meant that more than 50% of the area had been damaged. The grading system also combined the severity of the damage with its extent. For example, if several large scratches cover less than 50% of the section, it would be graded as 3, the same grade that would be given if small scratches cover most of the area. Each component was given a total damage score based on the sum of the scores from all its seven sections. Thus, the maximum possible damage score was 147. In case of the in vitro tested liners, a total of three liners were analyzed per group and their scores were averaged.

Moreover, the presence of creep on the backside of the liner into the screw drill holes of the metallic acetabular shell was evaluated for the P-Cup liners. Applying the grading system used by Schroder et al. [27], the liners were divided into two sections (Figure 3(b)) and each was graded according to the presence of screw holes. A grade of 0 was given if no visual

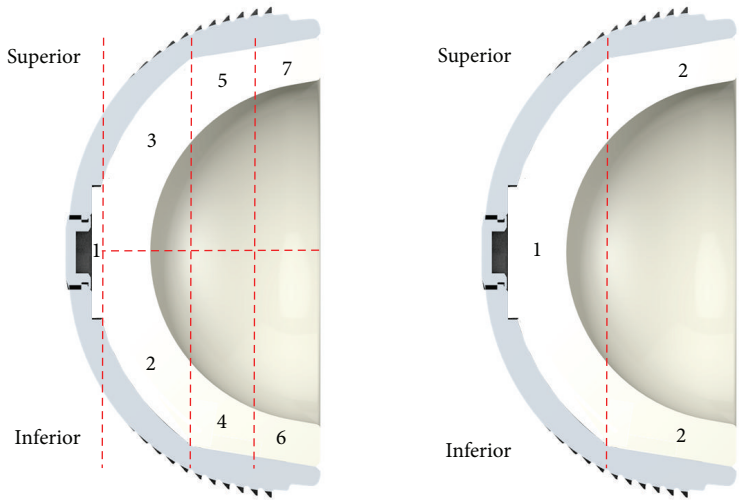

Figure 3: Sketch from a cross section of a P-Fit liner with its titanium alloy shell; (a) backside sections for wear analysis; (b) backside sections for screw indentation analysis.

evidence of creep was observed, a grade of 1 when visual evidence was observed but no palpable step could be felt, and a grade of 2 when both visual evidence and a palpable step were noted.

Two sets of observations were performed by one author (ALPR) in a time distance of one month and the scores were averaged. The intraobserver reliability of this method was between "substantial" and "almost perfect," with kappa measures ranging between 0.72 and 0.88 for retrieved liners and between 0.69 and 0.91 for in vitro tested liners.

To differentiate between the inserts' manufacturing materials (STD versus VitE and XPE versus VitE), the metallic shell model (P-Cup versus P-Fit), and the articulating femoral heads (CoCr versus ceramic) of the in vitro tested groups, an analysis of variance was carried out ($p = 0.05$) followed by a post hoc test (Scheffe $p = 0.05$). Prior to the analysis, the normal distribution (p-p plots) and the homogeneity of variance (Levene test) were verified (Statistica 10, StatSoft Europe GmbH, Hamburg, Germany). A p value less than 0.05 is considered as significant.

3. Results

3.1. General Results. The most common wear modes observed on the backside of in vitro tested and retrieved liners were scratching, abrasion, burnishing, and embedded particles (Table 3). Scratching, with an average score of 1.62 (±1.62) for in vitro tested liners and 1.36 (±0.83) for retrieved liners, had the highest score. No delamination and practically no deformation nor pitting was found in any of the in vitro tested and the retrieved liners. The highest score difference on the wear modes between the in vitro tested and the retrieved liners was found on the embedded particles, as in the in vitro tested liners just a few particles were found in comparison with the retrieved liners (score of 0.07 (±0.24) and 0.70 (±0.82), resp.). Scanning electron microscopy and EDX confirmed that the embedded particles were titanium particles (Figure 4).

Table 3: Average score per wear mode of all backside sections from in vitro and retrieved liners (maximum possible score per wear mode = 3).

Wear mode	In vitro	Retrievals
Pitting	0.00 (±1.04)	0.03 (±0.17)
Scratching	1.62 (±1.62)	1.36 (±0.83)
Burnishing	0.23 (±0.47)	0.13 (±0.41)
Abrasion	0.67 (±0.95)	0.32 (±0.65)
Embedded particles	0.07 (±0.24)	0.70 (±0.82)
Deformation	0.01 (±0.11)	0.03 (±0.17)
Delamination	0.00 (±0.00)	0.00 (±0.00)

3.2. In Vitro Wear Simulated Liners. After the 5 million gait cycles' simulation, the average total backside wear score for the in vitro tested liners ranged from 13.17 (±0.75) to 21.83 (±2.23). The maximum total backside wear score possible was 147. As it can be seen in Figure 5, regardless their design, liners manufactured with STD or XPE showed a statistically higher total backside wear score compared to the liners manufactured with VitE. In case of the P-CupD liners articulated against CoCr femoral heads, the XPE group had a significantly higher average total backside wear score, with 20.17 (±0.75), in comparison with the VitE group, which had 15.83 (±1.33) ($p = 0.0014$). In case of the P-Fit liners articulated against ceramic heads, the STD group had an average total backside wear score of 21.83 (±2.23) compared to 16.50 (±1.52) of the VitE group ($p = 0.0001$).

In a direct comparison between the liners' models, when these were manufactured with VitE and articulated against

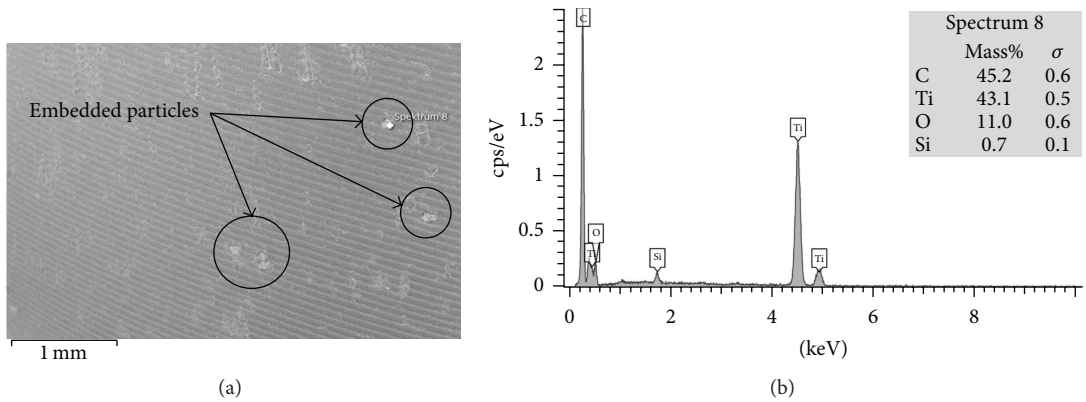

FIGURE 4: (a) SEM image with embedded particles in Section 5 from P-CupD$_{PW\ VitE}$ retrieval; (b) EDX analysis of the selected particle, which apparently consists of titanium alloy. The carbon spectrum corresponds to the surrounding polymer of the liner.

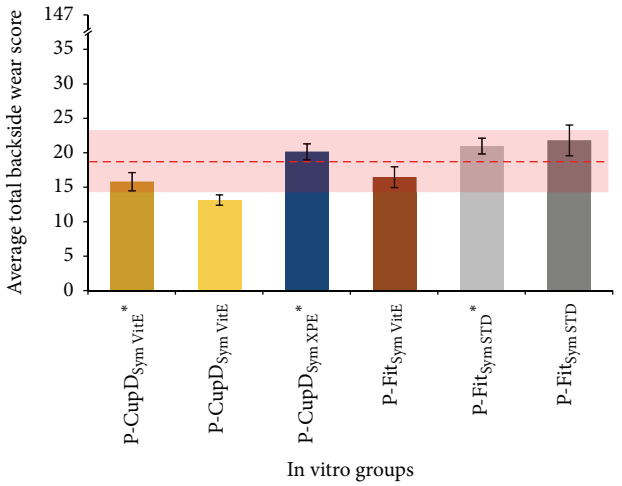

FIGURE 5: Summary of the average total backside wear score for in vitro tested liners. The dashed red line represents the average total backside wear score for the retrieved liners, while the red shadow shows the 95% confidence interval. The groups with "∗" were articulated against CoCr femoral heads and the others against ceramic femoral heads. Maximum total backside wear score possible = 147.

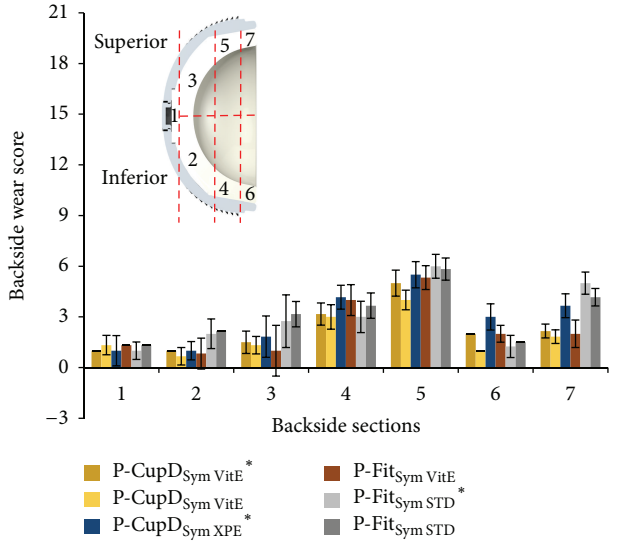

FIGURE 6: Backside wear score per backside section for in vitro wear tested liners. The groups with "∗" were articulated against CoCr femoral heads and the others against ceramic femoral heads. Maximum backside wear score per zone = 21.

ceramic femoral heads, the P-Cup group (13.17 ± 0.75) showed a significantly lower average total backside wear score than the P-Fit group (16.50 ± 1.52) ($p = 0.0215$). However, no significant difference ($p = 0.9755$) was found if the liners were manufactured with XPE or STD and articulated against CoCr femoral heads (20.17 ± 0.75 for P-Cup versus 21.00 ± 1.15 for P-Fit). Finally, no statistically significant difference in the average total backside wear score was found regarding the material of the articulating femoral head. For the P-Cup liners with VitE, the group articulated against CoCr had an average total backside wear score of 15.83 (±1.33), while the group articulated against ceramic had 13.17 (±0.75) ($p = 0.1049$). In case of the P-Fit liners with STD, the group articulated against CoCr had an average total backside wear score of 21.00 ± 1.15, while the group articulated against ceramic had 21.83 (±2.23) ($p = 0.9755$).

The most damaged areas were Sections 4 through 7 (Figure 6), corresponding to the area against the roughened titanium surface of the acetabular metallic shell, with backside wear scores between 1.00 (±0.00) and 6.00 (±0.71) from a maximum score of 21. In these sections, the mode of wear mostly observed was multiple small scratches produced by the roughened inner surface during the repeated insertion and removal of the polyethylene liner in the acetabular shell (Figures 7(c), 7(e), and 8(a)). Section 5, corresponding to the limit between the roughened and milled-drilled section of the metallic acetabular shell on the superior orientation, showed the most wear marks overall, with a backside wear score between 4.00 (±0.58) and 6.00 (±0.71). It was observed that, in this section, the multiple scratches produced abrasion of the liner and the machining marks were not more seen in some areas of the section (Figures 7(d) and 8(b)). However,

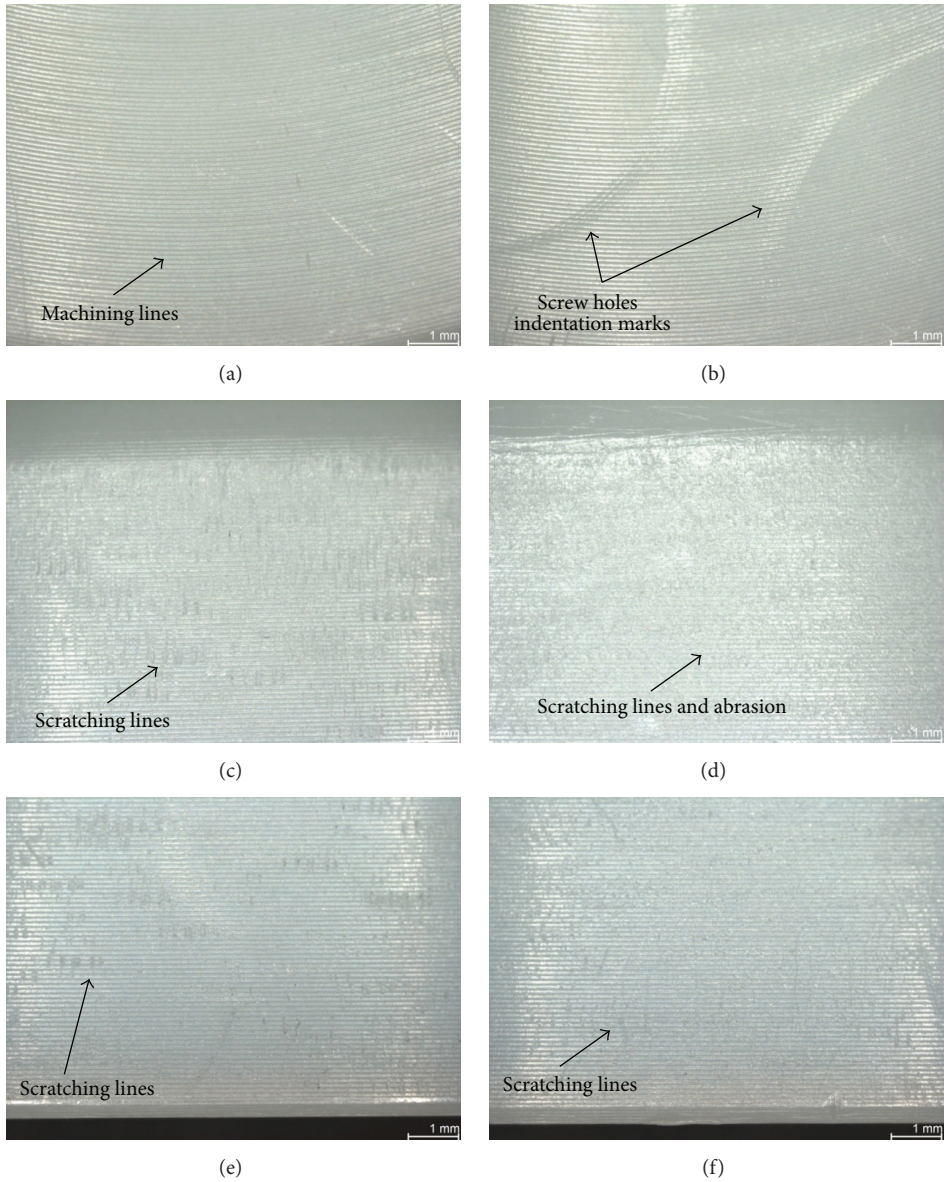

Figure 7: Photographs with microscope from in vitro wear tested liners. (a) P-CupD$_{\text{Sym VitE}}$ group, Section 2, machining lines clearly visible with no wear marks; (b) P-CupD$_{\text{Sym VitE}}$ group, Section 3, screw holes indentations marks and machining lines still visible; (c) P-CupD$_{\text{Sym VitE}}{}^{*}$ group, Section 4, small scratching lines; (d) P-CupD$_{\text{Sym VitE}}{}^{*}$, Section 5, scratching lines and slight abrasion; screw hole is visible; (e) P-CupD$_{\text{Sym VitE}}{}^{*}$, Section 6, small scratching lines; (f) P-CupD$_{\text{Sym VitE}}{}^{*}$, Section 7, small scratching lines.

it was also observed that even if a section in the superior orientation was damaged, its corresponding inferior section could be almost free of wear (Figures 7(a), 7(b), 7(e), and 7(f)). In the sections under the milled-drilled acetabular inner surface, mainly in Section 3, only a few scratches and a slight flattening/burnishing were observed, having low backside wear scores between 1.00 (±0.00) and 2.75 (±1.56).

In all the P-Cup liners, creep due to the screw holes of the metallic acetabular shell was visible but not palpable (score of 1). Near the creep produced by the screw holes, several indentations were observed due to the repeated removal every 0.5 million cycles of the liners (Figures 7(b) and 8(c)). In both the area inside and outside the screw hole creep marks, the machining marks were still clearly visible over the milled-drilled surface. In some cases, particularly on the STD and XPE liners, the machining lines appeared to be slightly flattened or burnished.

3.3. Retrieved Liners. The average total backside wear score for the retrieved liners, whose implantation time varied from 0.5 to 37 months, ranged from 14.50 (±0.71) up to 29.00 (±1.41) (Figure 9). The maximum total backside wear score possible was 147. All the retrieved liners were P-Cup implants. In general, P-CupD liners showed less total average backside wear score, between 14.50 (±0.71) and 17.00 (±0.71), than the P-CupS liner, which had a score of 29.00 (±1.41). The two

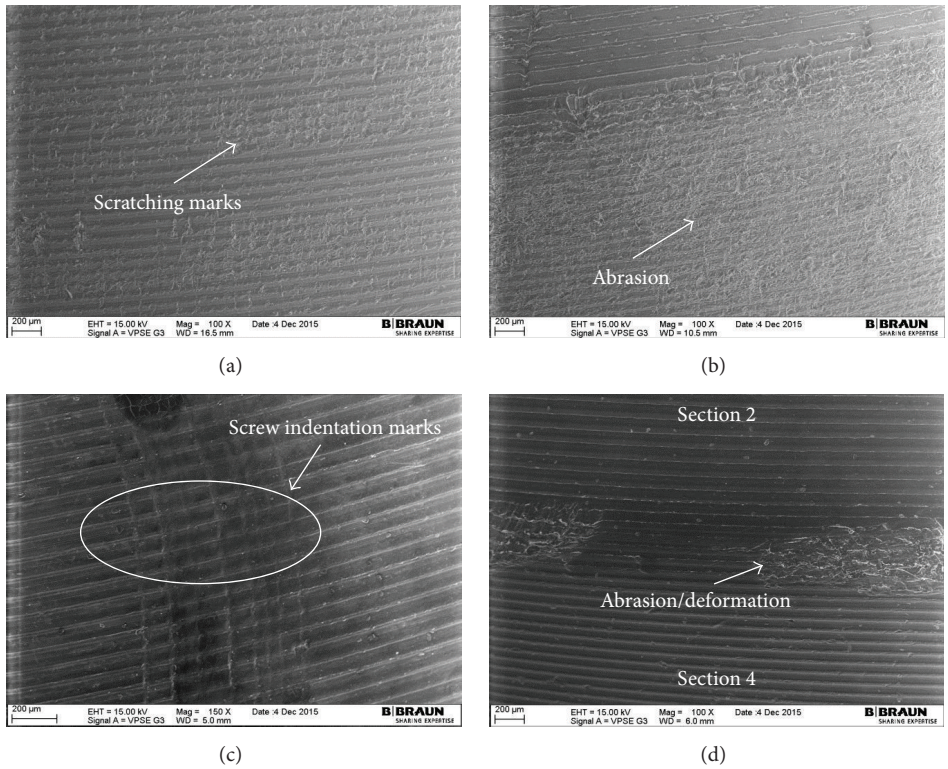

Figure 8: SEM images from the backside of the liners. (a) In vitro tested liners P- $Fit_{Sym\ VitE}$, Section 7 with scratches and visible machining marks; (b) in vitro tested liner P-$Fit_{Sym\ VitE}$, Section 5 with apparently considerable abrasion but with machining marks still visible; (c) in vitro tested liner P-$CupD_{Sym\ VitE}$, Section 3 with multiple screw indentations and clear machining lines on both sides of the hole; (d) retrieval P-$CupD_{PW\ VitE}$, edge between Sections 2 and 4 with small abrasion/deformation.

retrieved liners manufactured with Vitamin E, one P-Cup DC symmetrical and one P-Cup DC posterior wall, had a total average wear score of 17.00 (±0.71).

Figure 10 shows that the P-CupD liners had their highest wear score in Section 5, with an average backside wear score between 4.00 (±1.00) and 6.00 (±1.00). In case of the P-CupS liner, the highest score was found in Section 3, a superior located section, with a score of 9 (±1.00). The high score presented in this section was due to the presence of multiple embedded particles as well as a considerable scratching, abrasion, and moderate burnishing (Figure 11). Overall, the wear modes mostly seen were small scratches produced during the insertion and removal of the liner in the metallic shell (Sections 4–7), generating some degree of abrasion on Sections 5 and 7, and embedded particles (Figures 11(d) and 11(f)).

In all the P-CupD liners, no creep due to the screw holes could be seen in the section below the milled-drilled shell, whereas, below the roughened section, the screw hole could be seen but was not palpable. Regarding the P-CupS liner, the screw holes were visible but not palpable in both sections.

4. Discussion

The purpose of our study was to understand more of the wear process on the backside of polyethylene liners. This was done via optical analysis of the backside of two acetabular cup designs with long- and short-term clinical history, whose locking mechanism is based on a press-fit cone in combination with a rough titanium inner surface at the rim of the metallic shell. A direct comparison between in vitro tested and retrieved liners was done in order to evaluate the backside wear characteristics and behavior. To the best of our knowledge, this is the first study to analyze backside wear on acetabular liners with this particular locking mechanism.

Because of their nature, implant retrieval analysis studies are in general limited and imperfect in study design, as they usually deal with specimens that have been removed due to a clinical failure [28]. Moreover, there is often a broad heterogeneity among the analyzed specimens, such as implant size, articulation material, implant positioning, patient loads and activity level, and time in vivo. One of the biggest limitations of the current study was the limited number of retrievals available for analysis ($n = 5$).

On the other hand, the current study had the strength that all the liners were machined from a single resin depending on their group (GUR1020 for conventional PE, GUR1020X for highly cross-linked PE, or GUR1020E for highly cross-linked and Vitamin E blended PE). Furthermore, the in vitro tested liners within each group had the same batch number and all the liners underwent the same testing and handling procedures. Besides, the in vitro tested liners were selected from batches intended for commercial sale; thus, they had the same manufacturing procedure as the retrieved liners.

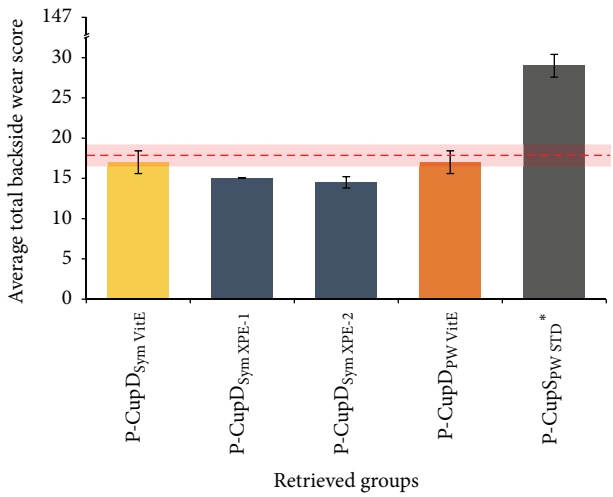

Figure 9: Summary of the total average wear score for retrieved liners. The dashed red line represents the total average backside wear score for the in vitro tested liners, while the red shadow shows the 95% confidence interval. The liner with "∗" was articulated against a CoCr femoral head; the others were articulated against ceramic femoral heads. Maximum total backside wear score possible = 147.

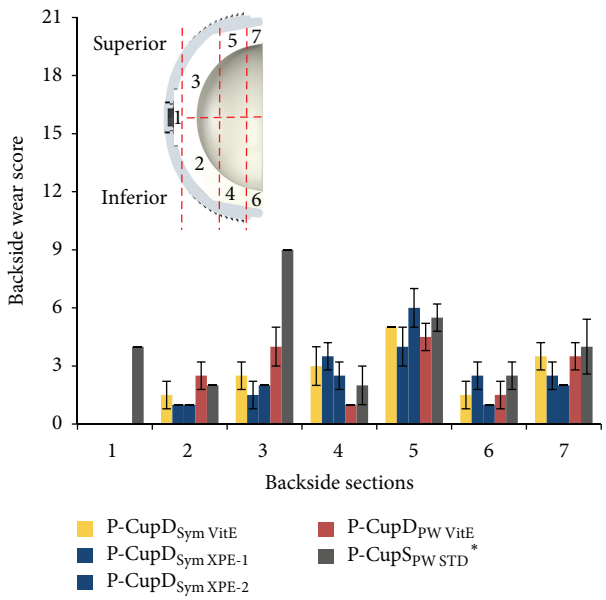

Figure 10: Wear score per backside section for retrieved liners. The liner with "∗" was articulated against a CoCr femoral head; the others were articulated against ceramic femoral heads. Maximum backside wear score per zone = 21.

Moreover, the wear rates produced by the ISO hip simulator during 5 million cycles are in the clinically observed range for ceramic heads coupled with polyethylene liners [29] and represent approximately 2.9 years of in vivo service life [19–24], in comparison to the average 1.09 years of the retrieved liners (range from 2 weeks to 3 years).

Minimizing polyethylene wear is an important goal in the design of total joint replacements, as a mechanical wear of the polyethylene liner may lead to implant failure and the need for revision surgery [11]. Several locking mechanisms have been designed to prevent micromotion and backside wear, obtaining different results [8, 15, 16, 30]. The present study showed that the press-fit locking mechanism of the Plasmacup, which has proven itself successful in clinical practice since 1997 [31], and Plasmafit did not significantly influence the backside of the analyzed polyethylene liners, as most of the small wear marks were limited to the fixation area. In all the analyzed liners, the most common mode of wear observed was small scratches at the zone directly below the rough titanium inner surface of the shell. No major difference regarding the wear modes and patterns was observed among the different liner sizes. These scratches were produced during the insertion of the liner into the shell. In case of the in vitro tested liners, these were repeatedly removed and inserted every half million cycles through 5 million cycles due to the test protocol. For this reason, more scratches and several screw indentations marks (Figure 8(c)) were observed.

It could be observed that the total average backside wear score of the P-CupS$_{PW\ STD}$ * retrieval was higher than the P-CupD retrievals and in vitro tested liners. This higher score was mainly influenced by the higher scores obtained in Sections 1 and 3, which had a high amount of embedded titan particles and a higher score on scratching and burnishing. The rest of the sections had a similar score to the other liners. Wear is influenced by several factors other than a liner or shell design, such as the experience of the surgeon, method of implantation, femoral head size and cup orientation [32], and the patient gait characteristics, activity level, weight, and postoperative range of motion [33]. For these reasons, different wear scores and wear patterns could be observed even within the same liner designs. Moreover, a previous in vitro wear simulation study from Grupp et al. [18] showed that Plasmacup liners machined with conventional PE and aged for two weeks had approximately seventeen times more cumulative wear than aged liners machined with Vitamin E. Thus, the reason for the higher backside wear score from this retrieval could be attributed to the manufacturing material, longer in situ time, the patient's weight and activity level, or damage produced during the fracture of the stem.

Several facts helped to determine the micromotion between the liner and the shell. First, the small scratches produced during insertion were clearly seen and no big abrasion due to movement was observed in most of the rim area. Second, the machining marks on the convex surface beneath the milled-drilled area of the metallic shell were still clearly visible in most of the in vitro tested and retrieved liners (Figures 7(a), 8(c), 8(d), and 11(a)). Third, even though the screw drill hole edges produced indentations, the machining lines in the periphery just appeared to be flattened and were not blurred (Figures 7(b) and 8(c)). Fourth, the P-CupD$_{Sym\ XPE-1}$ retrieved insert that was implanted just for two weeks had a total backside wear score similar to the rest of the retrieved P-CupD liners that were longer in situ and similar to the in vitro tested liners. This could demonstrate that most of the backside wear produced on the liners occurred during their insertion and not during the period

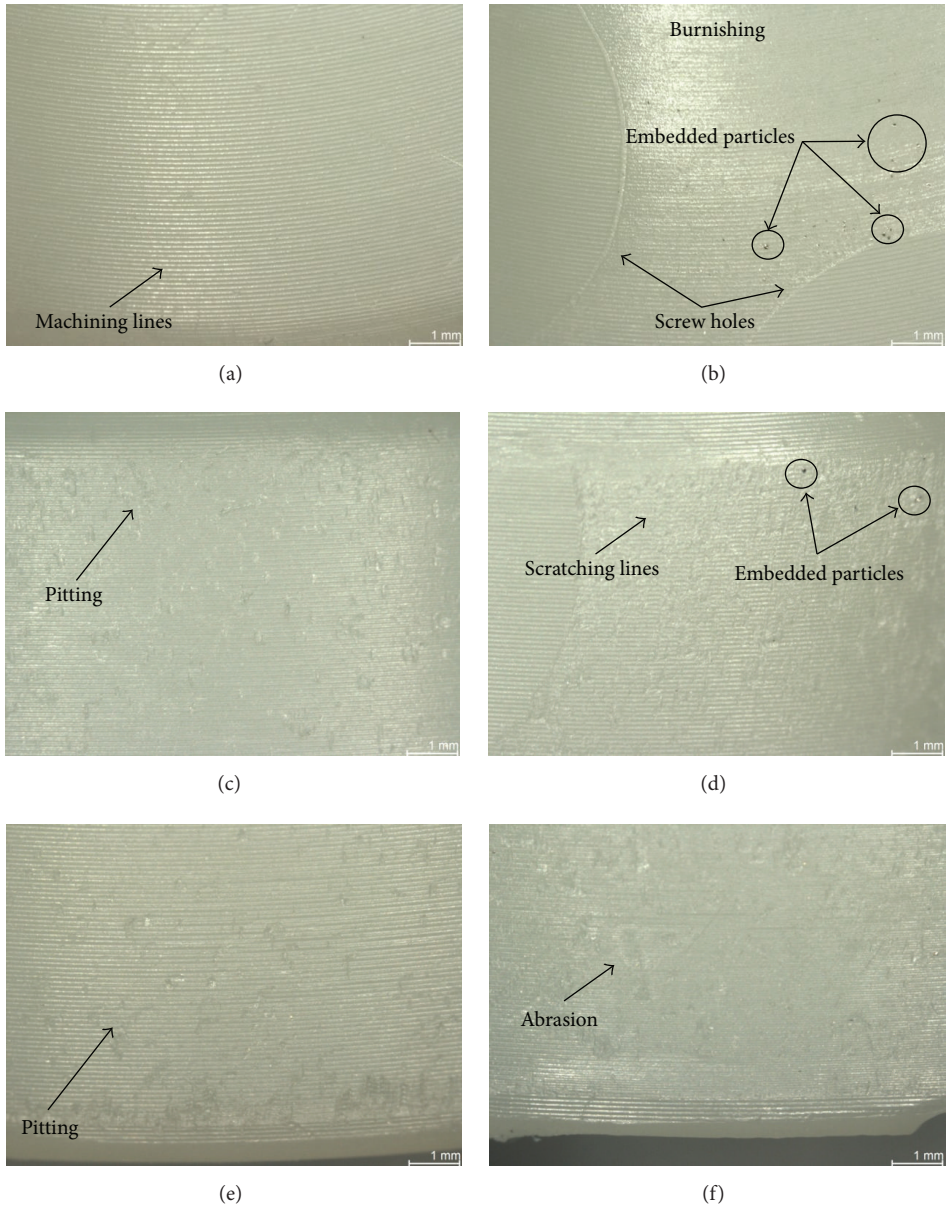

Figure 11: Photographs with microscope from P-Cup$S_{PW\ STD}$* retrieved liner after 37 months in situ; (a) Section 2: machining lines clearly visible with no major wear marks; (b) Section 3: screw holes visible but not palpable, with machining lines clearly visible and the periphery scratched and burnished with embedded particles; (c) Section 4: pitting and machining marks still visible; (d) Section 5: area with embedded particles and covered with scratches, machining marks partially visible; (e) Section 6: small pitting visible; (f) Section 7: area with abrasion marks.

in situ. Further studies should be done in order to quantify the backside wear produced solely during the insertion and removal of the liner. Finally, as mentioned before, the in vitro wear simulation study from Grupp et al. [18] showed a seventeen times difference in the cumulative wear between conventional PE and Vitamin E liners. However, even though our results also showed a higher backside wear score for the liners manufactured with conventional PE in comparison with those manufactured with VitE, this difference was not as high as that found in the previous study. The fact that the average total backside wear scores between the two materials were not as significantly different as the cumulative wear confirms that backside wear is produced during the insertion and removal of the liner and does not have a substantial contribution to overall wear.

The only zone where abrasion could be observed was at the edge along a small zone between the rim and the convex area (Figures 7(d), 8(b), 8(d), and 9(d)). However, a closer analysis with scanning electron microscopy (Figure 8(b)) confirmed that the machining marks were still visible. Several studies have proven through a heat-treatment of conventional PE liners that not all deep scratches necessarily mean loss of

material but small deformations or cold flow, as machining lines reappear after the mentioned treatment [34–36]. Deformation of the liner at the edge between the milled-drilled and roughened sections can be expected due to the change of surface characteristics in this zone.

Moreover, it was observed that the anatomically superior located zones had the higher backside wear scores, and, in some cases, its corresponding inferior zone had a considerably lower backside wear score (Figure 11). Kawaji et al. [9] performed a retrieval analysis of polyethylene liners for backside wear and also found that the most changed surface area was the superior-anterior quadrant followed by the superior-posterior quadrant. The reason for a higher wear score in these sections is the orientation of the axial joint load transmitted to the liner. Kligman et al. [11], who performed an optical analysis on retrieved hip liners, observed creep at the superior-lateral quadrant on the convex surface of the polyethylene liner and associated this creep and its location due to the cyclical axial loading, which is transmitted mostly to the superior-lateral part of the acetabulum. This orientation was also confirmed by Bergmann et al. [37], who measured the in vivo acting loads at the hip joint in four patients and determined the contact force vector in the hip joint.

Insufficient locking mechanism, the amount of micromotion, and the metal surface finish have been well accepted factors for backside wear [14]. Several studies have shown that suboptimal conformity between the shell and the liner could be the major influence factor on liner instability causing backside wear and subsequent osteolysis [3, 12, 14, 16]. The reason for this is that synovial fluid with debris particles from the articulation surface could occupy this empty backside space and a piston pumping mechanism generated during gait could push the debris solution into the iliac bone through the screw holes and create osteolysis [10, 16].

Proven that the locking mechanism and the liner-shell connection is stable, backside wear of polyethylene liners does not substantially contribute to the overall wear rate of polyethylene liners. Using three-dimensional finite element models, Kurtz et al. [12] showed that backside linear wear rates were three orders of magnitude less than the wear rate estimates at the articulating surface. Furthermore, the wear rates between two hole and eight hole cups designs were not substantially different. In another study with a different cup design, Krieg et al. [13] showed that only 2.8% of the rate of volumetric articular wear corresponded to the rate of backside volumetric change. As Krieg's study included creep and wear for the volumetric change, this might be the reason for their higher backside wear proportion found. Moreover, the so-called "monoblock" cups, whose polyethylene liners and cups are factory-preassembled into a single solid construct, theoretically eliminate backside wear of polyethylene liners. Nevertheless, a systematic review performed by Halma et al. [3] as well as a study by González Della Valle et al. [38] showed that there was no difference in the polyethylene wear rate between monoblock and modular acetabular components at intermediate-term follow-up.

Finally, midterm clinical studies have shown very good results of the Plasmacup system, with a low revision rate due to aseptic loosening at a minimum follow-up of eight years [31, 39]. As the retrievals from the present study were at an average of 13.1 months in situ, further long-term studies with a sufficiently large number of retrievals should be performed in the future in order to analyze the backside wear behavior in the long-term as well as in vitro tests with longer testing times.

5. Conclusion

In general, the total average backside wear score was approximately the same for in vitro tested and retrieved liners. The same wear modes of damage and their patterns were observed in both types of liners. More importantly, our observations confirmed the low backside wear of the liners and confirmed that the wear marks were mainly initiated during their insertion and removal rather than during their time in situ. Even though retrieval analysis may show different results among the specimens and may not always coincide with in vitro tests, they still help tracking the performance of implant materials and designs. Further tests with long-term in vivo retrievals and corresponding in vitro test periods could support the results observed, as the simulation and mean retrieval times of the current study were in the short-term range.

Competing Interests

Three of the authors (Ana Laura Puente Reyna, Christoph Schilling, and Thomas M. Grupp) are employees of Aesculap AG, Tuttlingen, a manufacturer of orthopaedic implants.

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Research Article

Failure of Polyethylene Inlays in Cementless Total Hip Arthroplasty: A Retrieval Analysis

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A retrieval analysis has been performed on 50 polyethylene inlays of cementless screw ring implants (Mecring, Mecron, Berlin, Germany) to investigate the failure mechanism of this specific open cup hip arthroplasty design that has shown a high clinical failure rate. Design-specific damage modes like rim creep, collar fatigue, and backside wear were assessed. Furthermore, the inlays were measured using a CMM to determine deformation. In 90% backside wear was observed and collar fatigue occurred in 68% of the cases. Rim creep was present in 38% of the polyethylene inlays. In 90% of the cases the cup opening diameter was 32.1 mm or less and 46% had a diameter less than 32 mm. It seems that creep and deformation of the polyethylene leads to a reduced diameter at the cup opening and consequently decreased clearance. To avoid this type of failure, polyethylene inlays should be supported at the back by the cup to reduce the risk of ongoing creep deformation.

1. Introduction

In total hip arthroplasty cementless cups were introduced into the European and North American markets in the early 1980s to overcome the high failure rates of cemented acetabular components in young and active patients.

The Mecring (Mecron, Berlin, Germany) was introduced as a cementless threaded cup, made of titanium alloy with a relatively smooth surface. It was designed as a metal ring open at the back of the cup. The polyethylene (PE) inlay was fixed in the ring using a snap-fit mechanism additionally supported by a collar.

After encouraging early clinical results [1] high failure rates became obvious in the middle and long term [1–10]. The cup frequently showed migration, instability, and tilting which consequently lead to aseptic loosening [1–3, 5–7, 9, 10]. Clinical studies showed revision rates due to aseptic loosening of 35% after 14 years [2] and more than 50% after 17 years [6]. Such implant failures may be related to polyethylene wear, missing primary stability, surgical preparation, cup positioning, surface structure, postoperative loading, and the pattern of mechanical stress distribution within the implant-bone-interface potentially leading to stress shielding during functional loading [11, 12].

In this study a retrieval analysis has been performed on the polyethylene inlays aiming to assess potential failure mechanisms related to the specific design of the Mecring. It was suggested that the polyethylene inlay is unfavourable supported by the cup leading to creep and deformation and consequentially to narrowing of the cup opening due to the clinical use.

2. Materials and Methods

For the consecutive retrieval analysis 55 Mecring components consisting of the cup and the polyethylene inlay were available. Five components were excluded because two of them were heavily damaged during the explantation and in

Table 1: Patient demographics and implant related data of the 50 Mecring components.

	Parameter	Value
Patient	Number of patients*	49
	Age (at the time of implantation), in years	53 ± 12 (21–70)
	Age (at the time of revision surgery), in years	62 ± 13 (26–79)
	Time to revision, in years	9.1 ± 3.3 (3.0–18.5)
	Sex	
	Female	30 (61%)
	Male	19 (39%)
	Side	
	Left	27 (54%)
	Right	23 (46%)
	BMI, in kg/m^2	26.4 ± 4.3 (17.7–35.3)
Implant	Design, *n* (%)	
	Mecring A (Type A)	42 (84%)
	Mecring B (Type B)**	8 (16%)
	Cup size	46–62 mm
	Head size	32 mm in all cases
	Head material	
	Ceramic (BIOLOX forte)	45 (90%)
	CoCr	5 (10%)

*One patient underwent bilateral hip replacement.
**Type B is a newer design of the acetabular component with an increase in thread width and depth.

three cases all clinical data was not available. In all cases, the reason for revision surgery was aseptic loosening. Patient demographics and implant related data are given in Table 1.

To evaluate the material deterioration a qualitative damage assessment was performed followed by geometric measurements of the components.

The retrieved polyethylene inlays were visually examined for the evidence of damage or alterations. Three major parameters were identified:

(1) Deformation and fatigue at the collar of the polyethylene inlay in the area, where the collar (outer rim) is in contact with the titanium acetabular shell: this has been defined as *collar fatigue*. An example is given in Figure 1 (red arrows).

(2) Creep and deformation at the inner rim of the polyethylene inlay, leading to narrowing at the cup opening: this has been defined as *rim creep*. An example is given in Figure 1 (blue arrows).

(3) Wear at the protruding back of the polyethylene inlay: this has been defined as *backside wear*. An example is given in Figure 2.

These three signs were graded depending on the severeness and extent of the damage by two independent observers (UM, JPK). Hereby the extent was graded on a 0–5 scale. A score of 0 means that no damage was detected at the corresponding region of the polyethylene liner. The score 1 corresponds to less than 20% of the surface area and the score 5 to more than 80%. Hereby, the extent of the damage was evaluated along with the severeness on a 0 (none) to 5 (severe) scale.

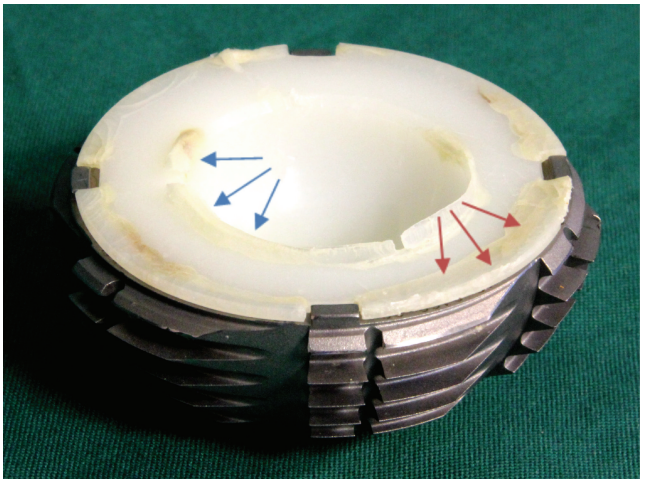

Figure 1: Examples for the design-specific damage modes: rim creep at the cup opening (blue arrows) and collar fatigue at the flanges on the outer rim (red arrows).

Both numbers were added to calculate a combined score (0 to 10). The interrater reliability between both observers has been evaluated using Kappa statistics and the average score of both was used for the final score. Furthermore, the intrarater reliability has been calculated based on 15 samples for one observer.

For some components it was noticed that the head moved easily in the polyethylene insert, whereas others got stuck in it. To evaluate this effect, the equatorial diameter of

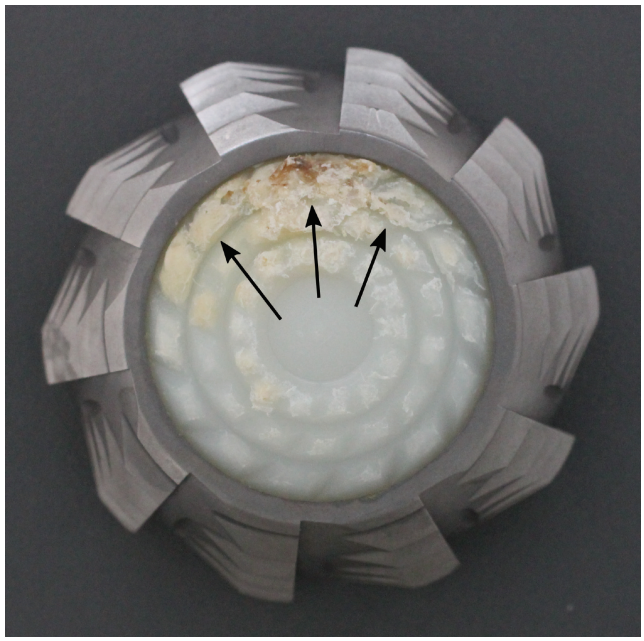

Figure 2: Example for backside wear at the underside of the inlays (black arrows).

the retrieved inserts was measured optically based on an edge detection algorithm, using a 3-dimensional coordinate measuring machine (Mahr, Multisensor, MS 222, Goettingen, Germany). The CMM was accurate within ±3 μm. The equatorial diameter of the inlays was measured at the cup opening. Each polyethylene inlay was measured three times and the mean was calculated.

To determine the equatorial diameter three different circle approximation methods are available: the minimum circumscribed circle (MCC), the maximum inscribed circle (MIC), and the least-square circle (LSC) (Figure 3).

The minimum circumscribed circle (MCC) is defined as the smallest circle which encloses all measuring points of the measured profile (all measuring points are in the inside of the circle; see Figure 3(a)).

The maximum inscribed circle (MIC) is defined as the largest circle which fits in the measuring profile (all measuring points are outside the circle; see Figure 3(b)).

The least-square circle (LSC) determines a best fit circle that is located mostly in the middle between the measuring points (Figure 3(c)).

The observed motion inhibition of the head in the polyethylene inlay was assumed to be related to deformation at the inner rim of the inlay. Because the MIC represents the smallest possible equatorial diameter, it has been chosen as most relevant for further analysis.

To consider the clinical data the damage scores were correlated to time to revision and BMI using Spearman's correlation. The diameter of the cup opening was also correlated to time to revision and BMI. The cup opening diameter was classified into four groups and a group-wise comparison was performed for each damage score using Kruskal-Wallis test.

Table 2: Spearman correlation coefficients for the damage scores correlated to clinical data ($n = 50$).

	Time to revision		BMI	
	R	p	R	p
Rim creep	0.291	0.040	0.165	0.262
Collar fatigue	0.248	0.083	0.097	0.513
Backside wear	0.367	0.009	0.119	0.421
Total damage	0.359	0.011	0.183	0.212

3. Results

3.1. Reliability. Cohen's kappa statistic revealed agreement between both observers (interrater reliability) in any case ($p < 0.005$). Substantial strength of agreement was found for backside wear ($\kappa = 0.755$), whereas the agreement for rim creep ($\kappa = 0.593$), collar fatigue ($\kappa = 0.570$), and total damage ($\kappa = 0.420$) was moderate. The intrarater reliability also showed moderate to substantial agreement ($\kappa = 0.442$–0.840, $p < 0.005$).

3.2. Damage Scores. Rim creep was present in 38% of the polyethylene inlays, whereas backside wear was seen in 90% of the inlays and collar fatigue occurred in 68% of the cases. The total damage score ranged from 1 to 27 (14.5 ± 7.2). Examples for a severe damaged inlay (damage score = 26.5) and an inlay with low damage (damage score = 1) are shown in Figure 4. The assessed damage scores for each type of damage are given in Figure 5.

3.3. CMM. In 11 cases CMM measurements were not feasible because the inner rim of the cup was widely damaged. Therefore 39 of 50 retrieved inlays were included in CMM analysis.

Depending on the analytical approach the diameters varied between 31.997 ± 0.127 mm (MIC), 32.166 ± 0.163 mm (LSC), and 32.334 ± 0.253 mm (MCC). Regarding the MIC diameter, 35 of the 39 inlays (90%) had a diameter of 32.1 mm or less, and 18 inlays (46%) had a diameter less than 32 mm (Figure 6).

Rim creep and backside wear showed a weak but significant correlation to time to revision. No correlation was found for the BMI and the damage scores (Table 2). Also, the cup opening diameter did not correlate to the time to revision ($R = 0.103$, $p = 0.532$) and to BMI ($R = 0.183$, $p = 0.270$).

In Figure 7 the damage scores are compared depending on the cup opening diameter. Lower damage scores are obvious if the cup opening is equal to or greater than 32.1 mm. For rim creep this difference was statistically significant ($p = 0.008$).

4. Discussion

The Mecring was a popular first generation uncemented, threaded cup for arthroplasty of the hip. But this implant showed unacceptably high failure rates in the middle and long term [1–10].

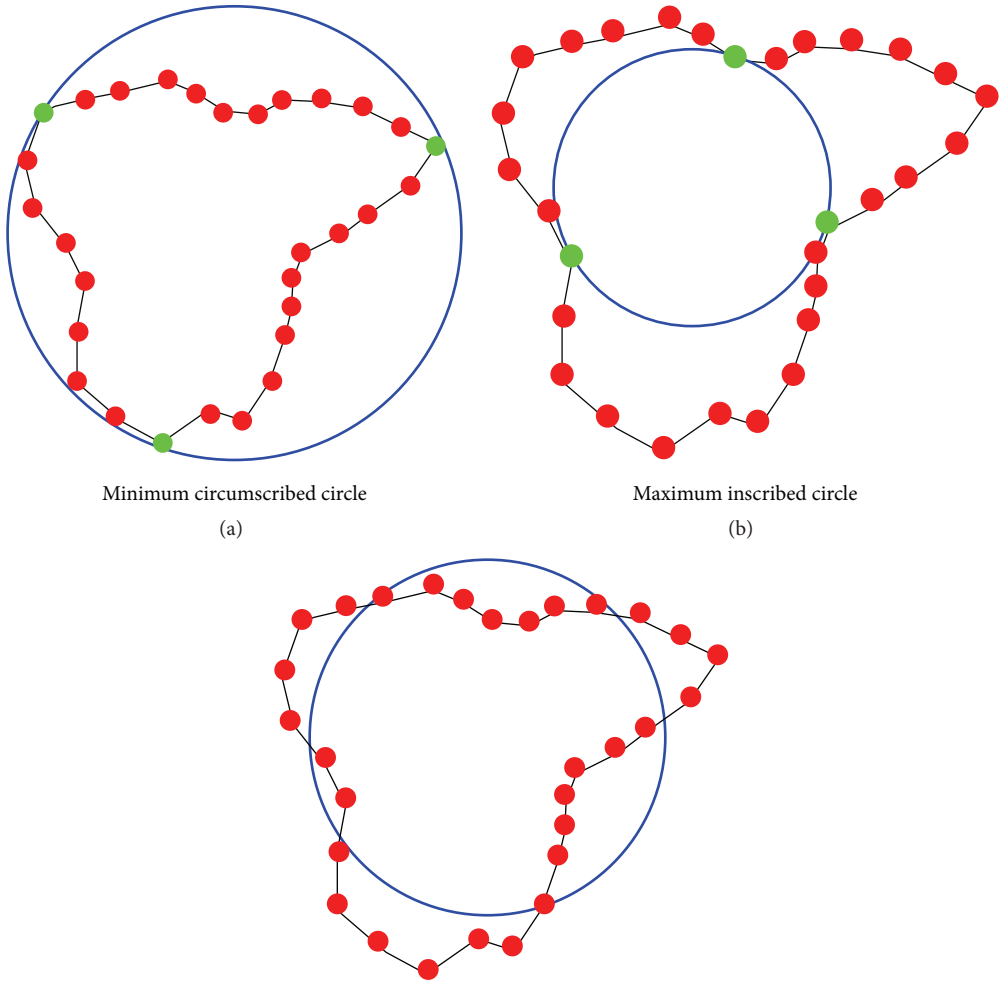

Figure 3: The three circle approximation methods to calculate the equatorial diameter.

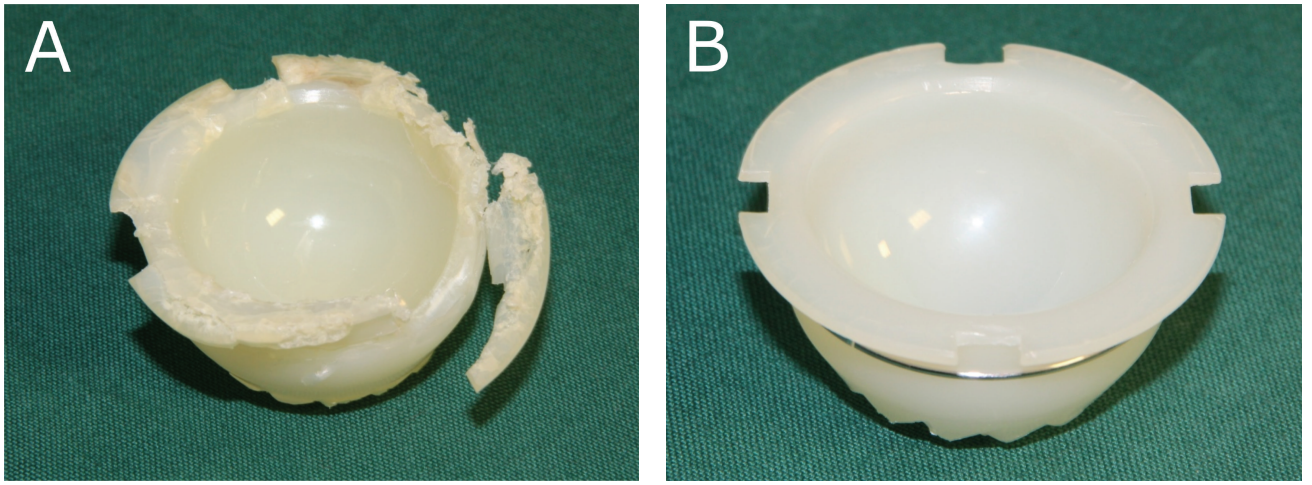

Figure 4: Two examples of the polyethylene inlays: severe damage in terms of backside wear, rim creep, and collar fatigue is obvious after 18.5 years in situ (a) and a mild case whereas only minimal backside wear occurred after 7.6 years in situ (b).

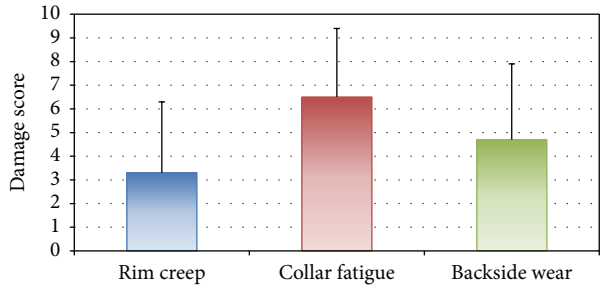

Figure 5: The scores are given for each type of damage. The mean and the standard deviation are shown.

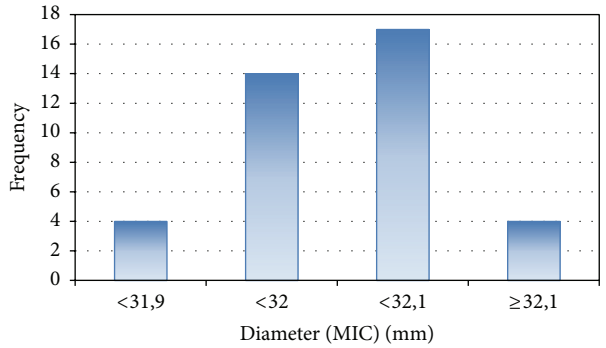

Figure 6: Distribution of the cup opening diameter of the 39 inlays.

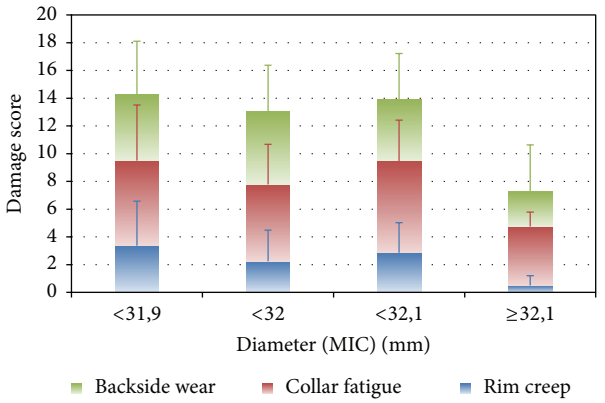

Figure 7: Comparison of the damage scores depending on the cup opening diameter. The total height of the bars corresponds to the total damage score. The mean values and the standard deviations are shown.

This retrieval analysis on 55 failed Mecring components revealed different findings. Creep, fatigue, and backside wear were frequently observed and increased over time. These are typically findings for polyethylene degradation in joint replacement [13–15]. However, the specific localization and type of damage support the suggestion that the implant design takes part in the damage formation and failure of the implants. It was observed that the clearance between head and inlay was too small in many cases. This becomes obvious, firstly because several heads were hard to rotate in the polyethylene inserts by hand and secondly because the CMM measurements revealed that the cup opening diameter was frequently below the head diameter. In 90 percent of cases, the cup opening diameter was smaller than 32.1 mm, whereas in the ISO 7206-2 a clearance of 0.1 to 0.3 mm is recommended for polyethylene inserts [16].

The following mechanism may explain these observations: it is assumed that the inlays were originally manufactured with a sufficient clearance that allows free articulation of the head in the insert. Thus, the inlay geometry might have changed over time in situ. This geometrical alteration is related to a missing support on the back of the inlay and overloading of the collar over time. Initially the inlay is well fixed based on the snap-fit mechanism and the collar is equally supported by the cup (Figure 8(a)). Due to in vivo loading the polyethylene begins to creep and this causes a flow of the material into the cup. As the cup is open, creep will not be limited to a certain extent. Consequently, the polyethylene gets into contact with the bone behind the cup and backside wear may occur (Figure 8(b)(1)). Simultaneously, increased stresses are acting at the back of the collar leading to deformation and fatigue (Figure 8(b)(2)). In progress the deformation will lead to narrowing of the inner rim of the polyethylene inlay (Figure 8(b)(3)). This will result in a reduced diameter at the cup opening and decreased clearance. Increased friction between the head and the inlay will cause higher stresses at the bone implant interface and may contribute to loosening of the implant.

This assumption is supported by the observation that the damage scores were smaller if the cup opening diameter was above 32.1 mm (Figure 7).

Typically creep occurs within the first one or two years after implantation [17, 18]. If the polyethylene is not sufficiently supported at the back, creep may continue to occur. In this study, the analyzed retrievals have been in situ for at least three years and creep progression has been observed over time, although the correlation was not strong. Another possible explanation for the deformation and creep of the polyethylene could be that the screw ring was not stiff enough to withstand acetabular loading.

However, the described mechanism remains an assumption as several limitations have also to be considered. To exactly determine the creep deformation the original geometry of the inlays would have been essential. These data have not been available. Furthermore, the damage score grading has been subjective although good agreement between different observers was found. Regarding the damage, potential oxidation has not been quantified although it takes part in degradation process. The inner rim was frequently damaged. Therefore, an optical measurement method has been chosen to better assess the rim of the polyethylene inlay in comparison to a tactile method. However, in 11 cases the rim was severely damaged leading to excluding them for the measurements of cup opening diameter. Beside these limitations the relatively smooth surface of the cup has also been discussed as another reason for the high incidence of revisions [2, 10].

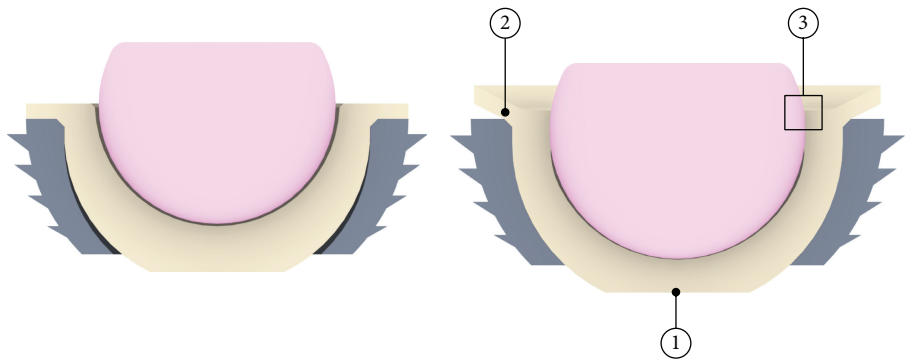

Figure 8: Assumed failure mechanism of the Mecring: the correct function of the PE inlay in the cup as initial state is shown in (a) whereas (b) shows the deformed inlay with narrowing at the inner rim and backside wear caused by cold flow of PE.

5. Conclusion

In conclusion, a polyethylene inlay should be supported at the back to avoid ongoing creep deformation. This is of particular importance if the inlay has a collar. The combination of both may compromise the joint articulation leading to failure of the implant which should be avoided.

Competing Interests

The authors declare that there is no conflict of interests regarding the publication of this manuscript.

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Clinical Study

Silver-Coated Hip Megaprosthesis in Oncological Limb Savage Surgery

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Silver coating has demonstrated good antimicrobial activity and low toxicity. Silver-coated megaprostheses have been introduced in oncological musculoskeletal surgery considering the high rate of infection. We conducted a retrospective analysis on 68 cases of primary or metastatic bone tumors, affecting the proximal femur, treated between 2005 and 2016 with wide margins resection and tumor implants reconstruction. All patients were treated by the same surgeon, with antibiotic prophylaxis according to a standard protocol. In 55.9% of patients silver-coated hip hemiarthroplasty was implanted; in the remaining 44.1% uncoated megaprostheses were implanted. Patients were reevaluated recording the complications and focusing the analysis on infective complications. The average follow-up was 46.5 months. No patient has shown any sign of local or general silver toxicity. A SEM analysis was conducted on the 3-silver-coated hip hemiarthroplasty explanted confirming a severe degradation with a small amount of residual silver on the coating surface. Silver-coated hip prostheses have a lower rate of early infection than traditional implants but showed a reduction of antimicrobial activity for silver coating wear. We recommend using silver-coated prosthesis as primary implants for limb salvage surgery, in primary or metastatic bone tumors affecting the proximal femur, considering the absence of signs of toxicity and the lower rate of early infection.

1. Introduction

Limb salvage surgery following primary or metastatic bone tumors is the treatment of choice in young and old patients with an acceptable life expectancy. Thanks to improved surgical technique and implanted devices, prosthetic reconstruction achieves the best possible level of function in patients who need a wide resection for malignant tumor. Proximal femur is often involved in this kind of surgery with good survival and functional results but many complications are described: dislocations, deep infections, implant failures, periprosthetic fractures, and tumor relapses are among the most common possible severe complications [1, 2].

The infection rate in hip tumor hemiarthroplasty ranged from 10% to 40%, with great variability depending on the age, the resection size, and the primary malignant tumor involved. Preventing periprosthetic infection is one of the main issues, considering that when there are concomitant poor soft tissue conditions, secondary amputation is sometimes inevitable.

Oncological patients are often debilitated by tumor itself, chemotherapy, or concomitant illnesses regarding other organs and the large implants surface predisposed to bacterial colonization; for these reasons many options were proposed to prevent infections in this kind of surgery. Surely systemic treatments have a significant role and many intra- and perioperative antibiotic prophylaxes have been proposed [3, 4]. It is not easy to demonstrate a statistically significant supremacy among antibiotic prophylaxis proposed but is mandatory to choose one according infectious disease specialist indications. Among the metal with antimicrobial activity, silver has gained much interest due to its excellent antimicrobial activity coupled with low toxicity [5]. Only few case reports showed local sign of toxicity, like dermal argyria [6]. Silver-coated hip megaprostheses have been introduced

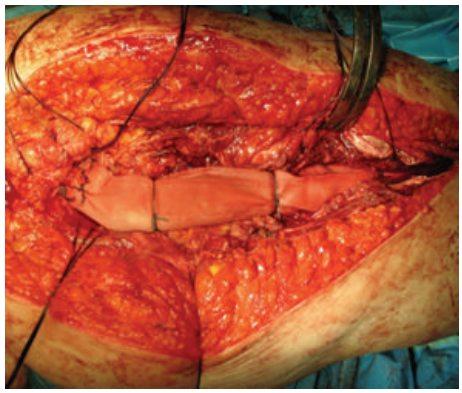

Figure 1: Soft tissue reconstruction using Trevira Tube after proximal femur resection and silver-coated implant.

in medical practice almost 25 years ago initially with the aim of treating local periprosthetic infections and have been recently proposed as first implant in patients with an acceptable life expectancy, in order to prevent the infections onset [7].

In the Division of Orthopedic and Traumatology of "A. Gemelli Hospital" (Catholic University of the Sacred Heart, Rome) the use of silver-coated hip megaprosthesis as first implant in this kind of surgery began, in selected case almost 15 years ago, and involved in the last years more and more patients showing good functional and survival results. To improve functional results and faster recovery, reducing the dislocation rate, our surgical technique involves the use of Trevira Tube® in order to guarantee soft tissue and capsular reconstruction as described by other authors [8] (Figure 1).

Purpose of the study is to evaluate the results of silver-coated hip hemiarthroplasty compared to patients treated with uncoated hip megaprosthesis.

2. Materials and Methods

A retrospective study was performed, analyzing all patients affected by primary or metastatic proximal femur tumors, treated with wide margins resection and megaprostheses reconstruction by the same surgeon between 2005 and 2016 in our Department with a minimum of 12-month follow-up. All patients received the same antibiotic prophylaxis consisting in 2 mg of Cefazolin administered 30 minute before surgery followed by 1 mg each 12 hours in the three postoperative days. The main surgeon considered the implantation of a silver-coated prosthesis when technically available and when not contraindicated according to infectious disease specialist evaluation, considering the high risk of infection for this type of surgery. In other cases standard titan megaprostheses were implanted.

All the patients were periodically evaluated in our outpatients clinic recording complications and functional outcomes. Infection was diagnosed with a clinical evaluation showing a sinus tract communicating with the prosthesis or in presence of purulence in the affected joint or in case of bacterial isolation and identification from at least two separate tissue or fluid sample obtained from the affected prosthetic joint. Elevated CRP and ESR were used as marker of infection if associated with specific clinical signs. When necessary, the patients undergone antibiotic treatment based on microbiological exams and following the indication of an expert infectious disease doctor. The cases managed only with conservative treatments were defined as superficial or transitory infections and were not included in this analysis considering the high rate of such short antibiotic treatment and the objective difficulties in obtaining trustable information in a retrospective study protocol. The patients not responsive to antibiotic treatment were considered affected by a severe deep infection and required surgical revision. We differentially analyzed early infections (defined as an infection that required a second surgery before 6 months after the first surgery) and late infections.

In the data analysis, we considered the data recorded in the last follow-up available. The primary objective of the study was to compare the infection rate in the group in which hip silver-coated prostheses were implanted versus the group in which the standard titan megaprostheses were implanted. The two groups were homogenous for gender, age, resection size, time of infection, associated therapy (radio/chemotherapy or other surgeries), second surgery for other complications, and use of Trevira Tube.

Assuming a reduction of silver activity, a macroscopic visual analysis (MVA) and a scanning electron microscopy (SEM) analysis on the explanted silver-coated prostheses were performed to detect the degradation level of the silver coating. The macroscopic visual analyses were performed by 3 different authors that classified the level of degradation in 4 groups (1: no degradation, 2: initial degradation, 3: advanced degradation, and 4: coating absence) and measured the percentage of the prosthetic surface involved in degradation processes.

After macroscopic analyses, selected sections were cut following a standard laboratory procedure designed to avoid surface damages during preparation and then analyzed by field emission gun scanning electron microscopy (FEG-SEM) (LEO 1520, Oberkochen, Germany) with backscatter Centaurus detector (KE Developments, Cambridge, UK). Grain size was measured by SEM-coupled image analysis using the linear intercept method.

Close clinical surveillance was observed at each follow-up to monitor the risk of local or general silver toxicity.

3. Results

The overall population counted 68 patients, treated with limb salvage surgery: 31 males and 37 females. The average age was 61.6 years (range 21–78 years). In 23 cases the disease for which the patients had been treated was a primary bone tumor; in the remaining 45 cases it was secondary to a metastatic disease. The primary bone tumors were in 9 patients osteosarcoma; 7 Ewing sarcoma/primitive neuroectodermal tumor; 4 chondrosarcoma; 2 malignant fibrous histiocytoma of the bone; 1 locally advanced stage III giant cell tumor of the bone. Seven patients had pathologic fractures.

In 38 cases (55.9% of patients) silver-coated modular hip hemiprostheses (MUTARS® Implantcast Ltd., Buxtehude,

Table 1: Main characteristics of the analyzed population. The two groups were homogeneous for the considered parameter.

	Uncoated prosthesis	Silver-coated prosthesis	Overall population
Number of patients (male : female)	30 (14 M : 16 F)	38 (17 M : 21 F)	68 (31 M : 37 F)
Age at first surgery	60.1 y (23–75 y)	62.8 y (21–78 y)	61.6 y (21–78 y)
Primary bone tumor (PBT) : metastatic lesion (ML)	9 PBT : 21 ML	14 PBT : 24 ML	23 PBT : 45 ML
Bone resection size (cm)	14.7 cm (12–22 cm)	18.3 cm (12–28 cm)	16.7 cm (12–28 cm)
Use of Trevira Tube	93.3%	94.7%	94.2%
Follow-up (months)	51.2 (12–114 months)	42.8 (12–97 months)	46.5 (12–114 months)
Death (time of death)	20.0% (34.7 months)	18.4% (35.8 months)	19.2% (35.3 months)
Complications requiring surgery	7 (23.3%)	7 (18.4%)	14 (20.6%)

Table 2: Early infection, considered as evidence of infection which occurred before 6 months after first surgery, was lower in silver-coated prosthesis group. No difference was demonstrated between the two groups for late infection risk.

	Early infections	Late infections	Total
Silver-coated hip megaprostheses	1 (2.6%)	2 (5.3%)	3 (7.9%)
Titan uncoated hip megaprostheses	3 (10%)	2 (6.6%)	5 (16.7%)

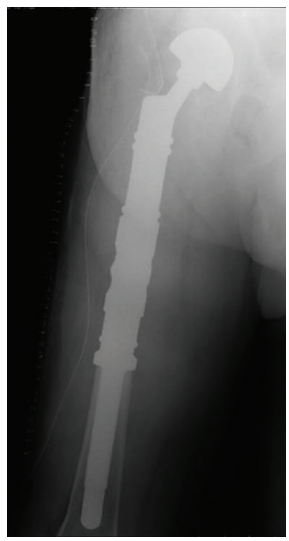

Figure 2: Postoperative X-ray after proximal femur resection and reconstruction with silver-coated modular prosthesis (MUTARS Implantcast Ltd., Buxtehude, Germany).

Germany) were implanted (Figure 2); in the remaining part (30 cases, 44.1%), uncoated titan modular tumor hip prosthesis (MUTARS Implantcast Ltd., Buxtehude, Germany) was implanted.

The two groups were homogeneous for all the considered characteristics (Table 1). The dimension range of the bone resection was between 12 cm and 28 cm (average 16.7 cm). All patients underwent radio and/or chemotherapy when indicated.

The average follow-up was 46.5 months (range 12–114 months). 19.2% of patients died on average 35.3 months after operation. The case of death was equally distributed in silver-coated and silver-uncoated group.

Complications that required performing a second surgery were recorded in 14 cases (20.6% of the population); 2 local relapses, 4 endoprosthesis dislocations, and 8 infections (11.8%) were registered.

The overall rate of infection was 11.8%, in onsets at an average time of 25 months after first surgery. The infection rate in silver-coated prosthesis was 7.9% (3 cases). In the uncoated prosthesis group, the infection rate was 16.7%. Considering early infection cases silver-coated prosthesis group showed 1 case of infection (2.6%) versus 3 cases verified in the control group (10%). The difference between the two groups was not relevant for late infection rate (5.3% versus 6.6%) (Table 2). The differences between the two groups were not statistically significant for the small number of cases.

MVA and SEM analyses were carried out on the 3 silver-coated prostheses explanted. The two proximal femur megaprostheses affected by late infection were explanted 27 months and 18 months after surgery. In both cases an important degradation of the coating surface compared with the silver-coated megaprosthesis explanted for early infection was confirmed (4 months from first implantation).

The MVA for the first case (27 months post-op) showed a grade 4 degradation for <30% of the prosthesis surface and a grade 3 degradation for >50% of prosthesis surface (Figure 3).

The second case (18 months post-op) showed a grade 3 degradation for 50% of the prosthesis surface and a grade 2 degradation for 25% of prosthesis surface.

The third case (4 months post-op) had a grade 2 degradation for less than 30% of his surface.

SEM analyses confirmed severe disruption of prosthetic surface in both explanted prostheses for late infection. In the second case (Figure 4) few, small silver grains on the surface were present which were not found in the first case analyzed (Figure 5) where silver was almost completely absent.

No difference between silver-coated prosthesis and uncoated tumor prosthesis group was recorded for functional scores considered. No patient ever showed local or general sign of toxicity secondary to silver exposition at each time considered, even in wider resection (Figure 6).

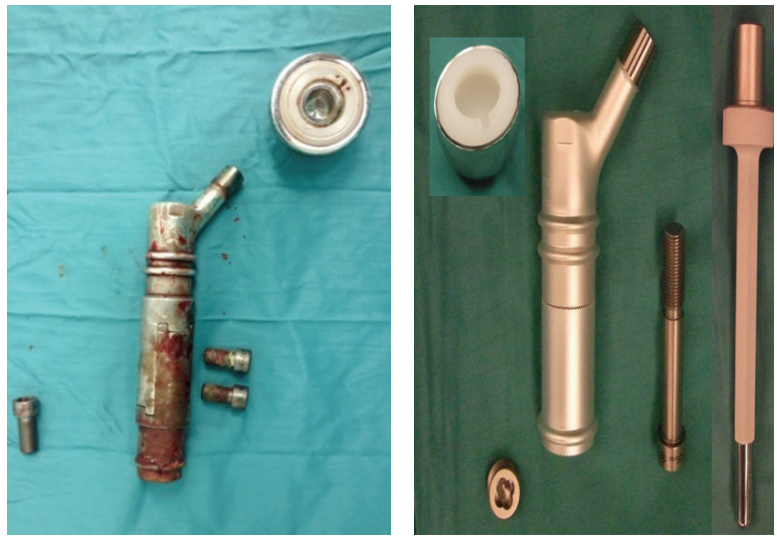

Figure 3: Silver-coated proximal femur prosthesis explanted 27 months after surgery compared with a new silver-coated prosthesis.

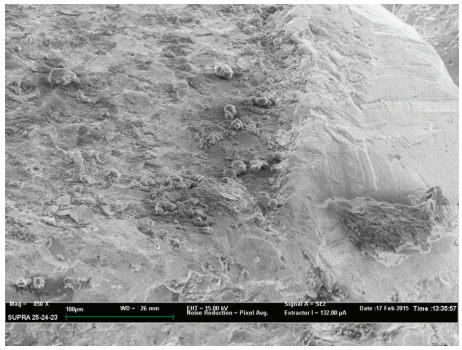

Figure 4: SEM analysis in a silver-coated proximal femur endoprosthesis explanted 18 months after surgery showed evident sign of wear; few, small silver grains were found.

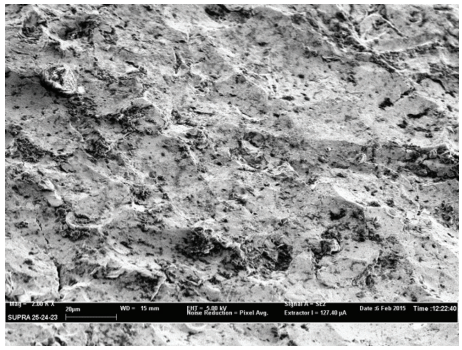

Figure 5: SEM analysis in a silver-coated proximal femur endoprosthesis explanted 27 months after surgery. Coating wear appears more evident: silver particles were almost disappeared.

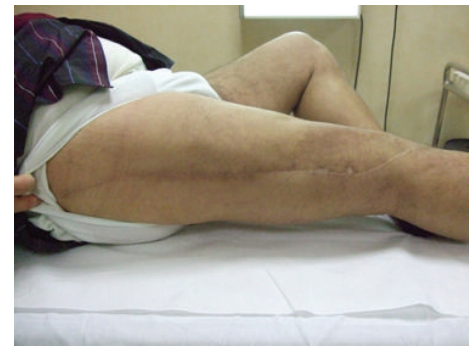

Figure 6: Long term clinical follow-up did not show general or local sign of silver toxicity, even in wider resection and at each time considered.

4. Discussion

Life expectancy of oncologic patients with bone metastases has remarkably increased over recent years; this has led to a higher risk of pathologic fractures and to an increased incidence of limb salvage surgery procedures [9]. Periprosthetic infection in this kind of surgery is still a common and major complication in orthopedic oncology.

It is currently impossible avoiding completely periprosthetic infections, despite the use of operating rooms with laminar airflow, systemic antibiotic treatment, and routine screening for multidrug-resistant bacteria that are becoming more and more common causes of infection. The production of an effective zone of inhibition by an antimicrobial silver-coated surface may be useful to prevent the adherence of organisms (in a manner that allows leaching of silver off the coated surface) [10, 11], not only to the coated surface but also to a variety of host-derived adhesins, such as fibronectin, fibrinogen, fibrin, and laminin that exist within the biofilm layer [12, 13].

Many authors have previously demonstrated that the silver coating of a prosthetic implant can decrease the reinfection rate, due to the release of silver ions, which produces

a zone of inhibition, and the resulting coated prostheses are more likely to be infection-resistant in vivo [14–16].

The present study confirmed the protective role of silver coating compared with standard titan megaprosthesis, especially in the first 6 months after surgery. We observed that the silver coating has partially lost his full effect by the time, due to his physiological mechanical erosion. It is currently unknown what factors influence the silver coating wear in vivo, but in our experience the residual silver, present on prosthetic surface 27 months after his implant, is apparently no more sufficient in producing an effectiveness antimicrobial activity.

The most important bactericidal mechanism of the silver ions is the interaction with the thiol groups of the L-cysteine residue of proteins and its inactivation of bacterial enzymatic functions [17, 18]. Another antimicrobial mechanism is the release of potassium [19], bonding to DNA [20], and generation of intracellular reactive oxygen species (ROS). All this activity is correlated with silver ions density released by prosthetic surface. Considering the demonstrated severe degradation of the coating surface, with almost complete absence of silver, a drastic reduction of free silver ions around prosthesis is predictable. It could explain why infection risk between silver-coated prostheses and titan one is comparable for late infection.

It remains unclear if silver coating may lead to other characteristics of infection (e.g., time of infection and virulence) or to more frequent soft tissue infections. In literature, leukocyte scintigraphy has demonstrated an increased uptake, particularly in the superficial soft tissues. In our view, this may be explained by the fact that active free silver ions bind to proteins and become inactivated (silver ions may build complexes with serum albumin) [16]. In these areas, the silver coating is unable to develop an adjuvant effect as demonstrated by Schierholz et al. [17]: free silver ions may precipitate in albumin-containing environments (e.g., hematoma), leading to concentrations that are too low for bactericidal effects to be achieved. In our study rate of infection was not significantly related to this kind of complication or to the dimension of the resection, probably because of the small number considered, but we feel free to confirm the suggestion that surgeon has to avoid hematoma and poor muscle coverage of the prosthesis, resulting in superficial wound healing problems, which can cause a bacterial colonization. For this reason we routinely use from one to three wound drainages up to 2 days after surgery.

Hussmann et al. [21] analyzed mass spectrometry of the wound fluid of the Redon bottles, at 7th and 14th days postoperatively to find silver concentration and CRP level. Patients with a relatively large amount of released silver ions showed a faster decrease in the inflammatory marker CRP, even if it is unclear whether the concentration of released silver ions in the immediate surroundings of the prosthesis has an influence on the clinical course.

In comparison to other metals with antimicrobial activity (like copper, cadmium, and mercury) [5], silver has shown good antimicrobial activity and low toxicity. Silver toxicity has been reported to occur at serum levels as low as 0.3 mg/mL and manifests as argyria, leukopenia, and alterations in renal, hepatic, and neural tissues. Thus, it is prudent to incorporate silver onto the surfaces of the prostheses in concentrations that are adequate to reduce bacterial adherence but not high enough to cause systemic toxicity [22, 23]. Different kinds of silver coatings have been developed and introduced for clinical practice, following accurate in vitro studies and animal testing that showed a tolerable release of silver ions and no problem in prosthetic osseous integration [14, 24]. We must underline the fact that different industrial procedures used for producing different kinds of silver coatings would probably have a different kinematics in silver ions release. Comparative studies regarding possible differences in local and general silver ions concentration and consequently different efficacy and timing of coating wear in vivo have never been performed. However no general side effects in silver-coated megaprostheses implanted in humans have ever been demonstrated for all the different silver coatings tested, with silver blood level well beyond the threshold level of toxicity [6, 21]. Few cases of local argyria have been described especially as cutaneous manifestation apparently not related to blood, urine, or aspiration fluids silver levels and without concomitant signs of renal, liver, or neurologic sufferings, concluding that the short-term surveillance of blood silver levels in these patients is not required [25, 26].

In the present study and in our previous experiences [7], no patient had ever shown any significant local or general sign of toxicity secondary to silver ions exposition.

At last, the economic factor has to be considered. Silver-coated megaprostheses are admittedly 5–7% more expensive than the other tumor prostheses [14], but considering the significant decrease in the period of hospitalization and in revision surgeries, following an overall lower infection rate, we actually adopt silver-coated prostheses as first choice implant in all primary and revision limb salvage surgery procedure in oncological patients.

5. Conclusions

Silver-coated hip megaprostheses are safe and useful to improve the clinical outcome in limb salvage surgery, considering the lack of toxicological signs and the lower rate of early infections. Therefore, we recommend to use silver-coated hip hemiarthroplasty as primary implants in all the primary or metastatic bone tumors involving the proximal femur.

The analyses performed on the explanted prostheses suggest a reduced antimicrobial activity of the silver coating after 6–18 months from prosthetic implantation, probably due to his degradation. In the future more studies are necessary to confirm these results and to analyze and to compare the in vivo action of different silver-coating manufactures.

Competing Interests

The authors declared that there are no competing interests.

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Research Article

Wear Scar Similarities between Retrieved and Simulator-Tested Polyethylene TKR Components: An Artificial Neural Network Approach

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The aim of this study was to determine how representative wear scars of simulator-tested polyethylene (PE) inserts compare with retrieved PE inserts from total knee replacement (TKR). By means of a nonparametric self-organizing feature map (SOFM), wear scar images of 21 postmortem- and 54 revision-retrieved components were compared with six simulator-tested components that were tested either in displacement or in load control according to ISO protocols. The SOFM network was then trained with the wear scar images of postmortem-retrieved components since those are considered well-functioning at the time of retrieval. Based on this training process, eleven clusters were established, suggesting considerable variability among wear scars despite an uncomplicated loading history inside their hosts. The remaining components (revision-retrieved and simulator-tested) were then assigned to these established clusters. Six out of five simulator components were clustered together, suggesting that the network was able to identify similarities in loading history. However, the simulator-tested components ended up in a cluster at the fringe of the map containing only 10.8% of retrieved components. This may suggest that current ISO testing protocols were not fully representative of this TKR population, and protocols that better resemble patients' gait after TKR containing activities other than walking may be warranted.

1. Introduction

Wear performance evaluation has become an important preclinical tool for the assessment of materials and designs of total knee replacement (TKR) components. To date, the International Organization for Standardization (ISO) has established two wear testing protocols to evaluate the long-term wear performance of TKR components [1, 2]. Both ISO protocols aim at replicating load and motion characteristics of a natural knee during level walking, which is considered to be the most frequently performed physical activity of daily living [3]. As with any simulation tool, the ultimate goal of wear simulations is to recreate in vivo conditions as closely as possible. For knee wear simulation, this means recreating wear damage characteristics (wear rates, wear modes, wear patterns, damage appearances, particle sizes, and morphologies) that are similar to those generated in vivo. However, reproducing in vivo wear damage characteristics of the knee has proven to be very challenging because simulators generate tibial liner wear scars that are less variable in size and location compared to those observed in retrievals of the same design type [4, 5].

Several factors, such as the characteristics of the prosthesis (materials and designs), the patient (height, weight, joint loading during daily activities, and activity level), and the surgical technique (alignment and soft tissue balancing), influence the wear of a TKR polyethylene tibial liner. Discrepancies between simulated and in vivo worn components can be identified by comparing their wear scar characteristics, which are substantially influenced by the kinetics and kinematics of the knee joint. Hence, wear scars are useful indicators of the physiological load and motion spectrum applied to the tibial insert during daily physical activity. However, a detailed analysis of wear scars is very complex.

Table 1: Demographic information of liner hosts (revision and postmortem).

Implant source (*N*)	Gender (*N*)	Side (*N*)	In situ time (mo.)	Cause of failure (*N*)
Revisions (54)	Females (22) Males (26) Unknown (6)	Left (24) Right (23) Unknown (7)	Range (1–108) Mean (26) Unknown (16)	Infection (10) Maltracking (9) Loose (9) Instability (5) Synovitis (2) Fracture (1) Osteolysis (1) Failed liner (1) PE wear** (1) Unknown (15)
Postmortem (21)	Females (13) Males (8)	Left (11) Right (10)	Range (19–144) Mean (79)	Autopsy (21)
Simulator (6)	Not applicable	Left (6)	60 months*	Not applicable
Heavily delaminated (10)	Females (5) Males (4) Unknown (1)	Left (7) Right (3)	Range (24–130) Mean (73) Unknown (3)	Instability (2) Polyethylene wear (2) Tibial subsidence (2) Painful tibial component (1) Unknown (3)

*1 million cycles representing 12 months of level walking.
**PE = polyethylene.

The mathematical description of wear scar patterns is nonlinear and multidimensional, which makes it very difficult or even impossible to model these patterns using traditional mathematical or statistical methods. For instance, different geometric parameters, including area, perimeter, or centroid of a wear scar, could be used to form the basis for a specific model. However, even multiple geometric parameters may not sufficiently explain the overall wear scar generation process, which is why we propose to analyze in vivo and in vitro generated war scars as a whole using bitmap images.

In this study, an artificial neural network (ANN) model based on image information is implemented as a data mining tool to differentiate wear scars that originate from different loading histories. ANNs have been successfully used for similar models because of their ability to handle nonlinear behavior, to learn from experimental data, and to generalize solutions [6–11]. From the pool of ANN models, the self-organizing feature map (SOFM) was selected for this study because it is an unsupervised neural network (i.e., no a priori knowledge of the data structure and classification is used). It is frequently used for the visualization of high dimensional data and for data mining and knowledge discovery [7–10, 12–14]. SOFMs are particularly useful because of their ability to map nonlinear statistical relationships between high dimensional data onto a convenient and easily comprehendible two-dimensional map. This type of mapping preserves the topology of the data, meaning that points within close proximity in the high dimensional space are mapped to neighboring map units in the output space. While this modeling technology has been used for image mapping since the early 2000s [15], to the best of our knowledge, it has not been used for applications in orthopedic tribology.

The purpose of the present investigation was to create a clustering structure of wear scar images based on similarities between retrieved (revision and postmortem) and simulator-tested components of the same design type. Wear scars from the retrieved group were used to create a clustering structure, whereas the wear scars from simulator-tested components were then assigned to the existing clustering structure based on their similarities. Subsequently, data mining was performed to understand the similarities among wear scars clustered together as well as to explain the differences between wear scars of different clusters. Two hypotheses were tested: (1) wear scars from retrieved components will generate several clusters of wear scars because of the variability of wear scar size and location that characterizes retrieved components and (2) all simulator components, regardless of the testing standard used, will be clustered together, reflecting the comparability of the two ISO testing standards and their limitation in generalizing the greater variability observed in retrieved components of the same design type.

2. Materials and Methods

An overview of the materials and methods used in this investigation is presented in Figure 1.

With approval from the Institutional Review Board (#L03072801), twenty-one postmortem- and fifty-four revision-retrieved tibial liners were selected from the Retrieval Repository at Rush University Medical Center (Table 1). Before being included in the study, components were screened for missing demographic information and for signs of heavy delamination. All retrieved components were manufactured by a single company (Zimmer, Inc., Warsaw, IN, USA) and were of the posterior cruciate retaining MG-II design, a fixed bearing prosthesis with a flat tibial polyethylene plateau.

Wear testing was performed using eight tibial liners, which were of the same design type and company as the

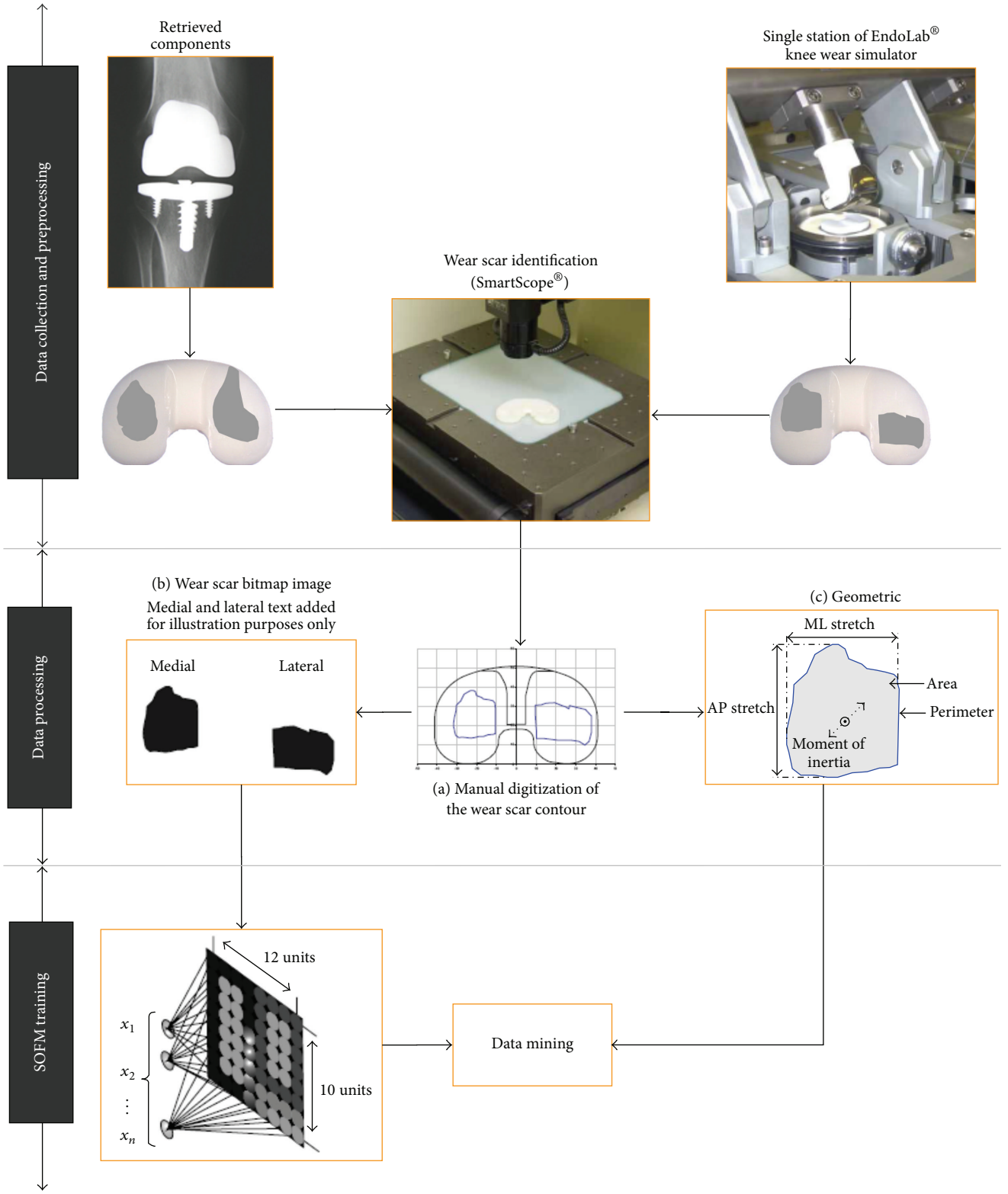

Figure 1: Flow diagram providing the methodology applied in this investigation. The methodology was divided into three main sections: (1) data collection and preprocessing; (2) data processing; and (3) SOFM training.

retrieved components (MG-II, Zimmer, Inc., Warsaw, IN, USA). Testing components were randomized into two equal groups. In each group, three samples were tested for wear performance and one sample served as a loaded soak control. The tibial plateaus were machined from ultra-high molecular weight polyethylene (UHMWPE), gamma sterilized, and packaged in a nitrogen environment by the manufacturer. The boxes were opened immediately prior to testing.

Wear performance tests were carried out in a four-station knee simulator (EndoLab, Rosenheim, Germany). The simulator met ISO standards [1, 2] and could be set up to run either in load control mode or in displacement control mode. The simulator motions were hydraulically actuated and closed-loop controlled. The difference in control mode refers to two degrees of freedom (anterior-posterior and internal-external, resp.) that were either load or displacement controlled, resulting in different implant articulations that were determined by the specific design aspects of the artificial joint.

The wear tests were conducted prior to 2009 following the original ISO standards and have been published elsewhere [16]. Briefly, each simulator station was comprised of a temperature-controlled chamber that maintained the test lubricant at 37°C. The lubricant was based on a buffered mixture of bovine serum (Hyclone Inc., Logan, UT, USA) mixed with a physiological salt solution to achieve a final protein content of 30 g/L and a pH of 7.4. In order to sequester metal ions, 200 mg/L ethylenediaminetetraacetic acid (EDTA) was added. All chambers were closed and sealed during the entire test to minimize fluid evaporation and contamination. The simulator was connected to a computer equipped with a user interface for machine control, test supervision, and data acquisition.

The first simulator group was tested in load control mode (LCM) and the second group was tested in displacement control mode (DCM). The LCM and DCM tests followed the same general protocol and testing parameters stated in the original 2002 and 2004 versions [1, 2]. Tests were conducted at 1.0 Hz cycle frequency and lasted for five million cycles (Mc). Load and displacement input represented one full walking cycle per test cycle and were taken from the respective ISO standards. The experiment was interrupted every 0.5 Mc to dismount, clean, and weigh the specimens according to the ISO standard [17]. Wear scars on the tibial UHMWPE plateaus that developed during the test were analyzed after test completion.

Medial and lateral articulating surfaces were visually analyzed using a video-based microscope (SmartScope, OGP NY, USA). Wear scars were digitized by manually tracking their contours (i.e., the boundary between worn and unworn areas) on the liner surface (Figure 1(a)) [18]. Since the goal of this study was to compare wear scar patterns using images rather than discrete geometric parameters, black and white wear scar bitmap images (220 × 170 pixels) were generated for each component (Figure 1(b)). Each bitmap image contained medial and lateral wear scar shapes with black pixels representing worn areas and white pixels representing unworn areas. Each bitmap image was converted to a 220 × 170 matrix with "1" representing white pixels and "0" representing black pixels. Each matrix was then reshaped to a single row vector and used as input for the SOFM model. While the component border was not kept in the image, the length and height of the image were adjusted to match the component size. All components were normalized to an equal size and right implantation side. Components with unknown implantation side (~7%, Table 1) were normalized after side determination with ANN. Geometric wear scar parameters, including area, perimeter, centroid, bounding box, anterior/posterior stretch, medial/lateral stretch, moment of inertia, and multiple shape factors, were computed for each component (Figure 1(c)) and used for statistical analysis.

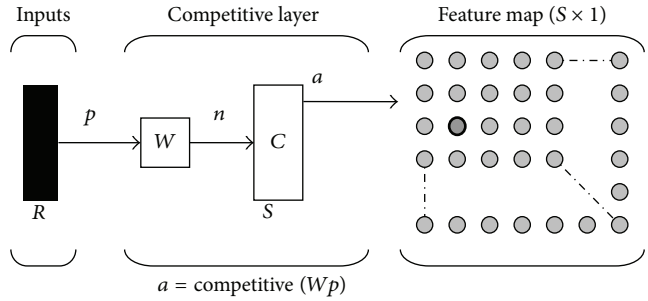

Figure 2: Self-organizing feature map (SOFM) neural network structure. In the competitive layer, input vectors are assigned to the neuron with the shortest Euclidean distance. Similar input vectors will be assigned to neighboring neurons.

The SOFM network was designed and trained using the Matlab SOM Toolbox 2.0 (Helsinki University of Technology, Finland). A sensitivity analysis was conducted to identify ideal training parameters generating best mapping results. The networks consisted of an input layer of 37,400 neurons (from image dimensions of 220 × 170 pixels = 37,400), a competitive layer, and an $n \times m$ neurons map or output layer (Figure 2). Five different networks with different map dimensions were generated. Map size and neighborhood radius were the only parameters tuned during the sensitivity analysis. The learning rate was linearly adjusted for all networks and the presentation of training samples was done in a random order. Training was performed using postmortem-retrieved components only. Subsequently, simulator- and revision-retrieved components were assigned to already existing clusters. No network learning occurred from the simulator wear scar patters. Training was done using the batch algorithm based on the Euclidean metric. Statistical analysis of the clustering structure was performed only from the map providing the smallest quantization error (which is a measure of "fit" between input and output mapping) and a well-defined cluster structure.

The u-matrix method was used to visualize the distance of each map neuron to its neighbors. The shorter the distance between neurons, the smaller the difference between them [19, 20]. This method was used to visually uncover the clustering structure in the SOFM. Commonly, a two-dimensional color coded u-matrix is used to identify cluster boundaries. Component planes (another commonly used visualization tool) were not created because the type of input data used

in this study would have produced 37,400 component planes (one for each dimension).

Clustering robustness was evaluated by producing multiple versions of the map with the best mapping results. The goal of this process was to detect mapping irregularities caused by the inherent mapping error meaning that data from a high dimensional space mask a significantly smaller dimensional space. To detect clustering irregularities, three network versions were created and trained until they converged. The networks were created and analyzed by an independent investigator. The networks' map size, learning rate, and neighborhood radius were left unchanged. The only training parameters that differed between networks were the initial values of the map neurons and the presentation of the training samples, which were both randomly chosen. The clustering structure was visualized and compared between network versions. The map neurons assigned to each wear scar in each of the networks were recorded and used for comparison. Cohen's kappa analysis was carried out to investigate if each component was consistently clustered with the same group of components.

SOFM mapping configurations were evaluated based on quantization errors. To test the interrater reliability of the network, intraclass correlation coefficients (ICC) were computed. An analysis of variance (ANOVA) was conducted to detect differences within and among clustered wear scar images. The geometric parameters, computed for medial and lateral wear scars separately, were used as output variables in the statistical analysis. The associations between two available input variables ("time in host" and "age at surgery") with output variables were evaluated using regression analysis. Only clusters with available input on more than three retrieved components were included. The chance probability that five of six simulator components would land in a single cluster was estimated using the binomial distribution. The probability of "success" (i.e., landing in cluster "X") was estimated from the proportion of revision and postmortem components that landed in that cluster. All statistical analyses were performed in SPSS 16.0 for Windows (SPSS Inc., Champaign, IL, USA).

3. Results

A network with a map size of 12×10 and initial to final neighborhood radii of 4 to 1 was found to provide the lowest quantization error ($q_e = 11.14$) and a well-defined clustering structure. The other network configurations evaluated were $20 \times 10/4$ to 1, $20 \times 10/4$ to 1, $10 \times 10/4$ to 1, $10 \times 10/5$ to 3.5, and $7 \times 7/4$ to 1. The 20×10 network had a lower quantization error ($q_{e(20\times10)} = 10.9$) than the network selected for the final analysis; however, its cluster boundaries were not easily identifiable. The remaining networks evaluated had higher quantization errors: $q_{e(10\times10/4\text{ to }1)} = 12.7$; $q_{e(10\times10/5\text{ to }3.5)} = 15.3$; and $q_{e(7\times7)} = 17.1$.

The clustering robustness analysis showed substantial interrater reliability for the different SOFMs created with a kappa value of 0.69 ($p < 0.001$) and 95% CI (0.667, 0.712). Despite the random initial values of map neurons and the random presentation of the training samples, tibial inserts that were clustered together in the first round stayed mostly in the same cluster during the second round. On average 84% (SD ± 19%) of all components were consistently mapped with the same components.

Using the u-matrix visualization method, eleven clusters became evident, each containing at least one postmortem-retrieved component and a maximum of 18 retrieved components (Figures 3 and 4). While 54 revision-retrieved components were assigned to nine of eleven clusters, all but one of the six simulator-tested components were placed in cluster 1. The chance probability that five or more of the simulator components would land in cluster 1 was estimated to be $1.6E-4$ using the binomial distribution. It is worth mentioning that cluster 1 contained only 10.8% of retrieved components and was one of the more isolated clusters at the fringe of the map.

The geometric features of the wear scars are summarized in Table 2. There was no single geometric variable that could have explained the differences between all clusters. Thus, it was found that cluster 1 was not significantly different from the other clusters based on wear scar geometric parameters alone, although the SOFM network had established cluster 1 as one of the most dissimilar clusters. Interestingly, the largest number of significant differences was found in cluster 11. For simulator components only, medial and lateral wear scars were more anteriorly located and more symmetrical than for the retrieved components in the cluster. However, only the anterior location differed significantly from all other cluster-retrieved components ($p < 0.05$), whereas the wear scar symmetry did not. The associations between two available input variables (i.e., "time in host" and "age at surgery") and geometric output variables differed between the various groups (Table 2).

4. Discussion

In this study, the relationship between wear scar images of simulator-tested and retrieved TKR tibial components was investigated. A nontraditional qualitative modeling approach was used to project nonlinear relationships of a high dimensional data set (wear scar images) onto a two-dimensional map. The SOFM algorithm was used as a data mining and knowledge discovering tool and served as visual aid in the discovery of wear scar characteristics.

After successfully training with wear scars from postmortem-retrieved components, eleven clusters were created. Purposefully, postmortem-retrieved inserts were used for this training purpose since they count as well-functioning at the time of retrieval and as such may be considered a "gold standard" for TKR wear simulation. As hypothesized, several clusters of wear scars were generated, mimicking the variability of wear scar patterns that characterizes retrieved components [4, 5]. Further, wear scars generated through mechanical simulation were clustered together, suggesting that the clustering process is meaningful in that wear scars of a similar loading history are recognized by the SOFM. It must be stressed that this cluster contained wear scars from both load and displacement control tested inserts, which showed distinct differences in wear scar size in an earlier study [17].

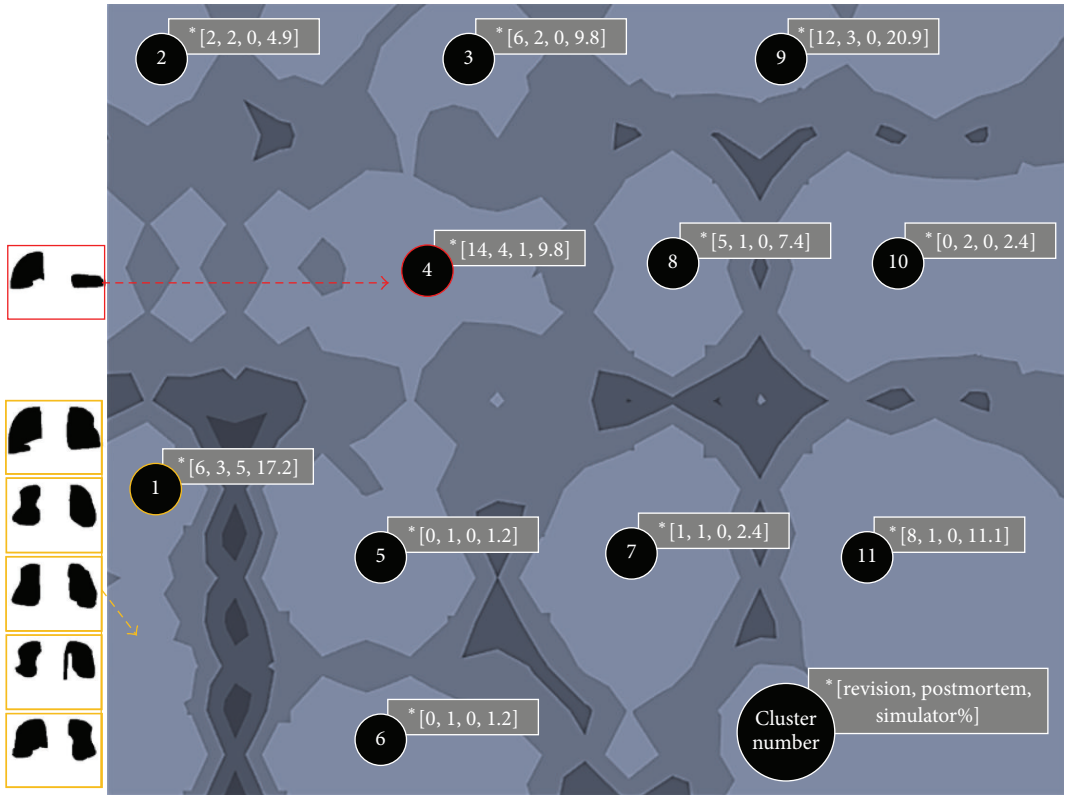

Figure 3: U-matrix visualization of the SOFM after training. Eleven wear pattern clusters were identified. Five out of six in vitro tested components were assigned to cluster "1". *The number of revised (R), postmortem (P), and simulator (S) components and the total percentage (%) of components assigned to each group are noted in brackets [R, P, S, %]. Light map colors represent cluster areas (valleys), while darker colors represent cluster boundaries (hills).

Hence, there must be other important wear scar features that render them similar.

All but one of the simulator-tested components were clustered together. The simulator-tested component assigned to cluster 4 clearly differs visually from the other simulator components (see Figure 3). We were aware of this difference because one of the AP actuators of the simulator became faulty during one of the wear tests. However, this information was not used as input into the SOFM. The only data and information used as input into the network was the medial and lateral wear scar images from both retrieved and simulator-tested components, which were all presented to the network in a random order during the training process. Hence, it appears that the SOFM network is capable of identifying subtle differences in loading history.

Based on the clustering results, the load and displacement control tested inserts account only for about 11% of the wear scar characteristics found in retrieved components. Cluster 1 is at the fringe of the cluster map and relatively isolated from other components (as indicated by the high ridge around it; see Figure 3). Ideally, the cluster containing the simulator components establishes itself in the center of the map to have shorter distances to all components and, thus, be more representative. The sole application of ISO gait cycles may not be sufficient in mimicking the greater variability of wear scar patterns observed on retrieved components. Ngai et al. reported that not only do the motion patterns of TKR patient differ from the motion pattern applied by the displacement [21] and/or load control [22] standard, but they are also highly variable between patients [23]. Also, these findings may indicate that it is important to consider other activities of daily living for knee wear testing. Both Benson et al. [24] and Cottrell et al. [25] found that the inclusion of one cycle of stair descent or ascent for every seventy cycles of level walking during wear testing produced more in vivo-like wear scars than those generated by walking alone. Thus, the variability of wear scars observed in retrieved components may not just be the result of different walking patterns but may reflect the range of physical activities performed by the patient, raising the need for a more representative TKR motion testing pattern.

There are limitations to using the SOFM. The network does not identify variables that characterize each cluster and best discriminate between the clusters [7]. Hence, the user is left in ambiguity. In this study we were unable to explain wear scar clustering by geometric characteristics. Since the clustering created by the SOFM is a projection of a nonlinear and high dimensional input space, the clustering results may not be fully explained by traditional linear statistical models. Perhaps, future mathematical means may resolve this issue.

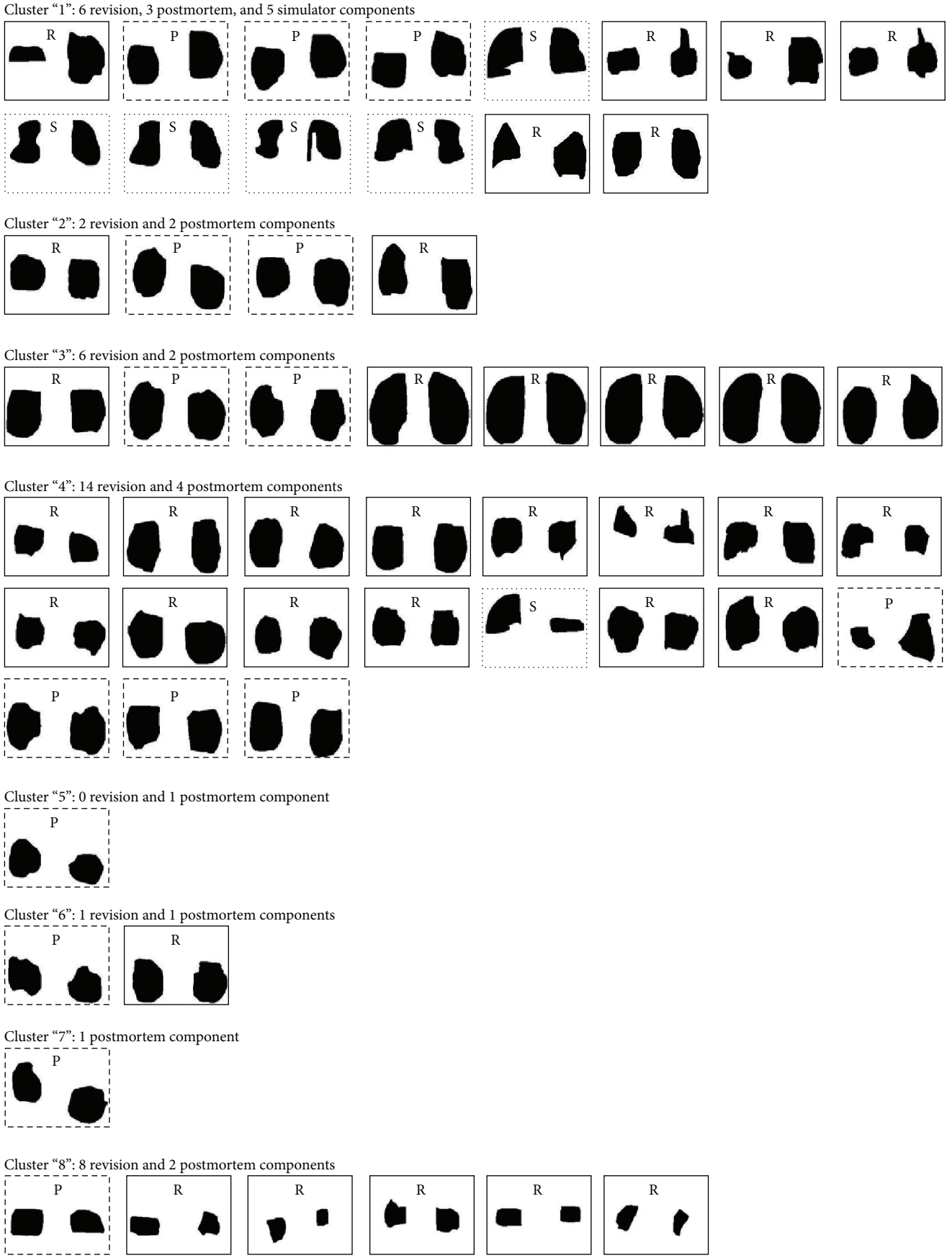

Figure 4: Continued.

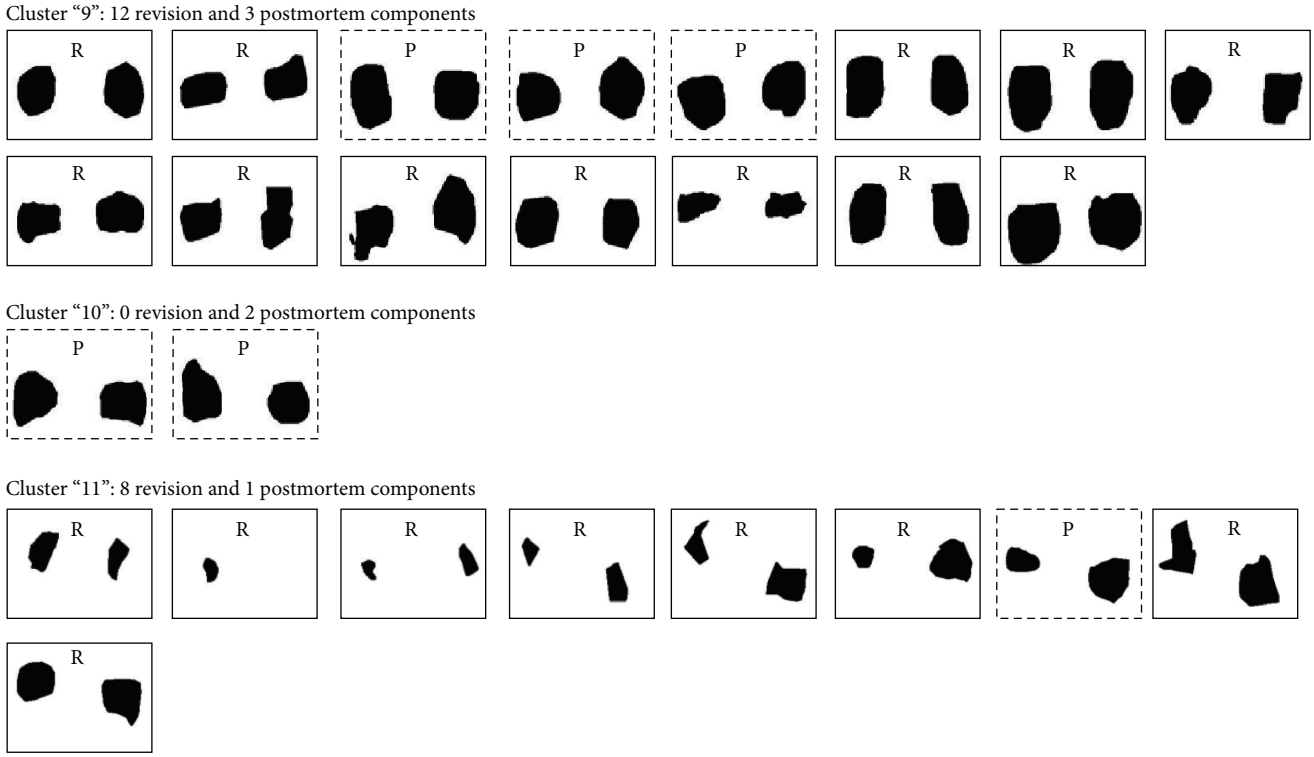

Figure 4: Eleven Clusters were established. Except for one, all simulator components fell in Cluster "1" together with six revision and three postmortem components.

Because of the nature of the clustered data of this study, the issue was amplified. Typically, cluster correlations created by a SOFM are performed using component planes; however, our data sets were based on pixel information and this analysis was not applicable. A second limitation was that the high dimensionality of the input data set affected the training time of the SOFM, ranging from four hours to almost a full day until convergence, depending on the map size. Smaller bitmap images or a different representation of the wear scar pattern may be used to limit the computational time spent on training the SOFM. Smaller bitmap images may also reduce the quantization error because this error depends directly on the dimensionality of the input space and the output map where a greater dimensionality reduction will result in a greater quantization error. On the other hand, a coarser, more pixilated wear scar may result in loss of sensitivity and a threshold has yet to be established. Finally, there were also limitations with the study design. The simulator tests were executed according to the original knee wear testing standards and should be repeated following the updated protocols. Our retrieval collection was small in size, with modest and partially incomplete patient information. This resulted in underrepresented clusters with few components and prevented a thorough data mining. Both "time in situ" and "patient age" are only auxiliary variables for prosthetic use and patient activity. Knowledge about the number of individual walking steps, the specific gait mechanics, and activity profile of each patient may have provided important clues in identifying associations and differences within and between clusters.

5. Conclusions

In conclusion, an artificial neural network approach has been applied for the comparison of wear scar images of simulator and retrieved TKR tibial inserts. This modeling approach proved to be robust and repeatable. The model, which was based on the self-organizing feature map network, can be used to directly compare wear scars from simulator and retrieved tibial liners. The SOFM network analysis revealed that (1) wear scars from retrieved components are highly variable, generating multiple clusters, (2) wear scars generated through wear testing using two different ISO standards were clustered together and are, thus, deemed comparable, and (3) wear scars from simulator components were clustered away from the center of the map and, therefore, are not representative of the whole retrieval collection. In the future, we may check if a new multiactivity testing protocol is capable of generating wear scars that more closely resemble retrieved components. The SOFM model may also be used for data mining of very large retrieval cohorts and search for associations and differences beyond physical context. For example, the input could contain surgical factors and/or socioeconomic factors. In the summary, the SOFM established in this study provides a unique and versatile platform for future discovery analysis.

Table 2: Summary of geometric parameters for retrieved and simulator components. Bold values denote a significant ($p < 0.05$) and meaningful ($R^2 > 0.4$) association with input variables "time in host" and "age at surgery."

Mean (StDev)	Medial				Lateral			
Cluster number	Area (mm^2)	Perimeter (mm)	ML stretch (mm)	AP stretch (mm)	Area (mm^2)	Perimeter (mm)	ML stretch (mm)	AP stretch (mm)
1	**391.84** (135.11)	**79.18** (13.54)	23.59 (3.51)	**21.87** (6.03)	460.96 (166.04)	84.25 (12.78)	−12.77 (20.80)	25.64 (4.97)
2	498.21 (78.26)	83.56 (4.40)	24.39 (4.66)	26.15 (3.32)	566.35 (80.80)	89.47 (2.84)	12.25 (28.34)	27.06 (1.99)
3	712.27 (185.35)	100.02 (12.20)	26.87 (2.88)	32.92 (5.23)	754.24 (180.98)	**102.73** (11.72)	0.93 (29.67)	**33.26** (5.72)
4	416.07 (146.55)	78.78 (1.51)	23.12 (3.37)	23.68 (4.87)	421.97 (165.74)	79.01 (12.56)	−3.67 (26.80)	22.86 (6.32)
5*	283.47	62.59	22.63	16.71	337.01	67.39	−20.51	21.38
6	418.87 (101.98)	77.46 (6.04)	21.78 (0.63)	24.22 (3.62)	412.37 (121.97)	76.86 (10.95)	−23.54 (2.06)	22.74 (3.61)
7*	355.69	71.44	19.39	23.58	436.42	76.99	−26.19	21.71
8	179.84 (34.29)	54.08 (6.05)	17.21 (1.75)	14.83 (3.31)	143.83 (76.49)	46.72 (12.10)	3.17 (15.72)	13.87 (3.19)
9	374.52 (108.82)	75.28 (9.46)	23.33 (3.76)	21.05 (4.33)	392.90 (124.16)	74.99 (10.18)	3.62 (23.54)	21.97 (5.55)
10	363.73 (15.08)	73.69 (0.83)	22.83 (3.82)	21.21 (5.66)	308.54 (46.11)	68.10 (6.71)	−7.98 (28.02)	16.16 (3.08)
11	129.36 (88.82)	45.12 (18.78)	13.76 (5.50)	13.53 (6.04)	**241.70** (136.61)	58.06 (26.35)	8.61 (15.45)	16.62 (7.67)

StDev = standard deviation, ML stretch = medial-lateral stretch, and AP stretch = anterior-posterior stretch.
*StDev not available, n (cluster) = 1.

Competing Interests

The authors declare that they have no competing interests regarding the publication of this paper.

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Research Article

Histopathological Analysis of PEEK Wear Particle Effects on the Synovial Tissue of Patients

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Introduction. Increasing interest developed in the use of carbon-fiber-reinforced-poly-ether-ether-ketones (CFR-PEEK) as an alternative bearing material in knee arthroplasty. The effects of CFR-PEEK wear in *in vitro* and animal studies are controversially discussed, as there are no data available concerning human tissue. The aim of this study was to analyze human tissue containing CFR-PEEK as well as UHMWPE wear debris. The authors hypothesized no difference between the used biomaterials. *Methods and Materials*. In 10 patients during knee revision surgery of a rotating-hinge-knee-implant-design, synovial tissue samples were achieved (tibial inserts: UHMWPE; bushings and flanges: CFR-PEEK). One additional patient received revision surgery without any PEEK components as a control. The tissue was paraffin-embedded, sliced into 2 μm thick sections, and stained with hematoxylin and eosin in a standard process. A modified panoptical staining was also done. *Results*. A "wear-type" reaction was seen in the testing and the control group. In all samples, the UHMWPE particles were scattered in the tissue or incorporated in giant cells. CFR-PEEK particles were seen as conglomerates and only could be found next to vessels. CFR-PEEK particles showed no giant-cell reactions. In conclusion, the hypothesis has to be rejected. UHMWPE and PEEK showed a different scatter-behavior in human synovial tissue.

1. Introduction

Aseptic loosening after total joint arthroplasty is still the main reason for failure of the prostheses and subsequently for revision surgery [1, 2]. The complex mechanism of the aseptic loosening is to this day not understood in detail, but wear particles play an important role in this process [1–3]. Several *in vitro* studies could proof the influence of material, particle number, size, and shape, and the extent of an inflammatory process, which finally leads to an osteolysis [4–6]. Ultra-high-molecular-weight-polyethylene (UHMWPE) is still the bearing material of choice especially in knee arthroplasty, but in regard to the development of a significant amount of wear particles inducing aseptic loosening, there exists a growing demand for alternative bearing materials [7, 8]. Lately, increasing interest developed in the use of carbon-fiber-reinforced-poly-ether-ether-ketones (CFR-PEEK) [7, 9, 10]. PEEK became more and more interesting for the use as biomaterial in trauma and orthopaedic applications, as it has already been successfully employed in spinal surgery [11, 12]. While there is a lack of data concerning the effects of CFR-PEEK particles on human tissue, the effects of this wear debris in *in vitro* and in animal studies are controversially discussed [7, 9]. In a previous study, PEEK particles, generated in a knee simulator testing unicondylar knee replacements, seemed to provoke an elevated biological reaction *in vivo* in a balb/c mice model [7].

Nevertheless, it seems impossible to draw conclusions from a mouse model on humans. In this context, it was the aim of this study to investigate the histologic effect of

Table 1: Size and shape parameters of the UHMWPE and CFR-PEEK particles of a prior *in vitro* simulator based study [13].

Material	Aspect ratio (mean) Original	Roundness (mean) Original	Form factor (mean) Original	Size (mean diameter) Original (μm)
UHMWPE	1,77	0,54	0,56	0.52 ± 0.67
CFR-PEEK PAN	1,65	0,62	0,6	0.96 ± 1.76

CFR-PEEK and UHMWPE wear particles on human synovial tissue. For this reason, synovial tissue, achieved from revision surgery of total knee prostheses containing CFR-PEEK as well as UHMWPE components, was investigated histologically.

The authors hypothesized no different findings between the used biomaterials because of similar size parameters of the wear particles in a prior knee simulator study of this implant [13].

2. Materials and Methods

Revision surgery in 10 patients with a rotating-hinge-knee-implant-design (Enduro®, Aesculap, Germany) was performed (mean age 71.3 ± 10.7 a.; 8 patients were female and 2 were male). During these operations, synovial periprosthetic tissue samples (test group) were achieved. The implant survival until revision surgery was 22 months (2.5 min.–48 max.). Reasons for revision surgery were aseptic loosening, dislocation of the tibial stem, and a patella fracture.

The tibial inserts of this knee implant design were made from UHMWPE (GUR 1020), whereas the bushings and flanges are made from CFR-PEEK containing 30% polyacrylonitrile (PAN) based carbon fibers (PEEK-Optima LT1, Invibio Ltd., Thornton-Cleveleys, UK). In a prior *in vitro* test, most of the released CFR-PEEK particles showed in a scanning electron microscope analysis a size range between 0.1 and 2 μm [13] (Table 1).

For a control, periprosthetic tissue samples were gained during revision surgery of one patient (control group). The implant contained no PEEK components; the articulating surfaces were invariably made from conventional UHMWPE.

The tissue was fixed with 4% paraformaldehyde, embedded in paraffin, and sliced into 2 μm thick sections stained with hematoxylin and eosin in a standard process. A modified panoptical staining (preincubation in propylenglycol; >3 h; 35°C) was also performed, in order to mark the wear particles by staining them turquoise.

All work was conducted in accordance with the Declaration of Helsinki (1964). The study was approved by the ethics committee of the local university.

3. Results

Throughout all samples, histologically a typical "wear-type" reaction was seen in the test as well as in the control group (Figure 1) [14, 15]. These findings were expectedly similar as described for other biomaterials in the common literature regarding wear particle associated biological reactions *in vivo*.

Without exception, the UHMWPE particles in all samples of the test group were scattered in the tissue similar to the control (Figures 1 and 2). Larger UHWMPE particles

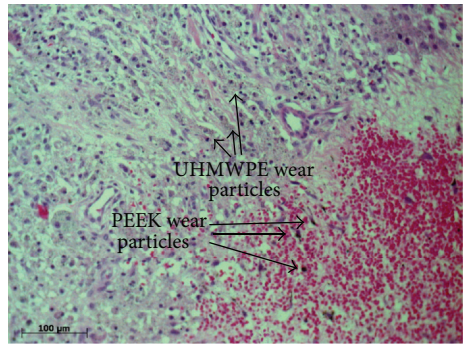


Figure 1: Histologic overview representing a "wear-type" [14, 15] reaction showing UHMWPE and CFR-PEEK particles stained with hematoxylin and eosin.

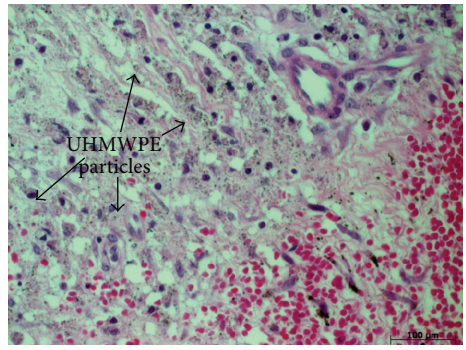


Figure 2: UHMWPE particles were randomly scattered in the periprosthetic tissue. The sample is stained with hematoxylin and eosin.

were incorporated in giant cells (Figure 3). In contrast, the CFR-PEEK particles were not randomly scattered in the periprosthetic tissue but located only as conglomerates. In addition, these conglomerates have been found exclusively near to or in vessels (Figure 4). Furthermore, CFR-PEEK particles were incorporated by macrophages (Figure 4), but no giant-cell reactions could be seen. This characteristic applies to all size ranges of the CFR-PEEK particles.

4. Discussion

The initial hypothesis has to be rejected. A completely different behavior between the UHMWPE and the CFR-PEEK particles in human tissue could be found.

The biological activity of wear particles plays an important role in the pathway of the aseptic loosening process and therefore is a key factor for the survival rate of implants used for joint arthroplasty [1, 2]. There are several *in vitro* studies that examine the effect of UHMWPE wear particles

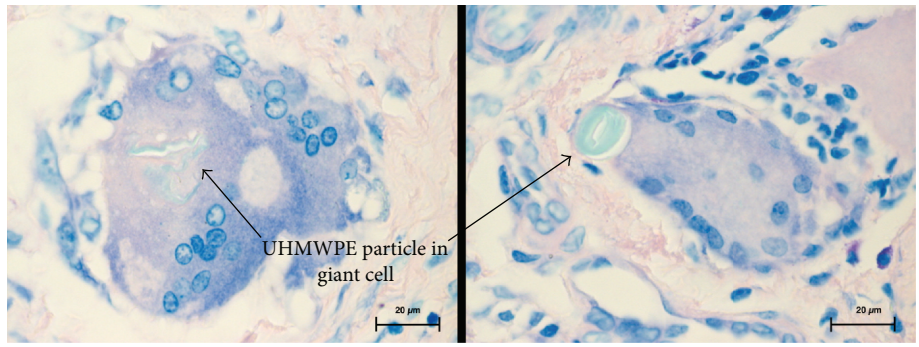
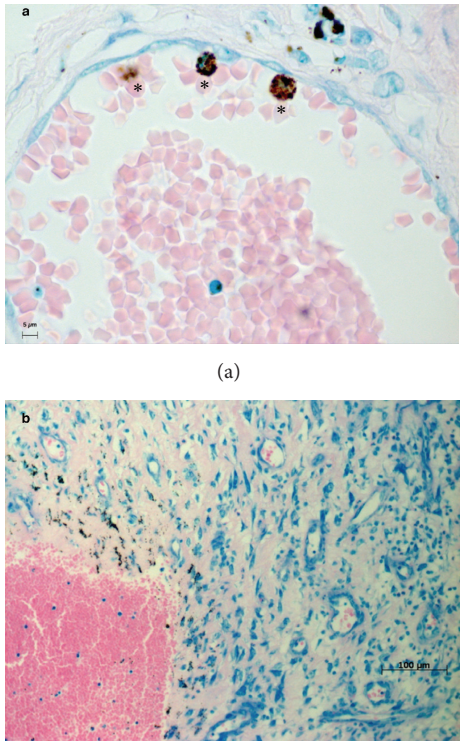


Figure 3: Large UHMWPE particles were incorporated in giant cells. Hematoxylin and eosin staining, 1000x magnified.



(a)

(b)

Figure 4: CFR-PEEK particles only could be found in or next to vessels. Giemsa staining. ∗ = in macrophages incorporated PEEK particle conglomerates.

on different cells, mainly macrophages [4, 6, 16]. In contrast, there are only a few studies concerning the biologic activity of PEEK [17–19]. A recent study compared CFR-PEEK pitch to PEEK-PAN and UHMWPE particles in a murine model and found rather negative effects for the PEEK variants [7]. But still there are data missing that show the biologic effects of PEEK particles in human tissue.

Thus, this is the first study that examines periprosthetic human synovial tissue from patients who underwent revision surgery. To the knowledge of the authors, there are no comparable data in the common literature.

In order to allow the comparison of PEEK and UHMWPE particles in each sample, patients with the Enduro knee system (Aesculap, Germany) were chosen, as this system uses UHMWPE as common bearing material and PEEK for the bushings and flanges in one system. To reduce prosthesis-dependent side effects, only tissue samples from this type of prosthesis were accepted for the test group. Therefore, the sample size was reduced to overall 10 patients. For a control, one patient was selected with a common knee revision system without any PEEK components. The absence of PEEK was the only desired control parameter; thus, it was not necessary to include more patients to the control group.

The results are very homogenous and conclusive, as the proven facts are verifiable in all tested samples: UHMWPE particles are scattered randomly throughout the whole tissue sample without any detectable conglomerates. In addition, small UHMWPE particles are phagocytized and larger particles are incorporated by giant cells. This phenomenon is well described in the common literature [1, 2, 20]. But in contrast, the PEEK particles of all size ranges were incorporated by macrophages; giant-cell reactions could not be seen at all. And interestingly, the PEEK particles are only findable in conglomerates; solitary particles were not detectable. These conglomerates were findable heaped next to or even in vessels that lie in the synovial membrane. It has to be stated that giant-cell reactions around UHMWPE particles were detected rarely, so it cannot be concluded that giant-cell reactions around PEEK particles do not exist, as they were not seen in the analyzed slices.

From this point it is nearly impossible to forecast an eventual biologic activity, especially as the data in the literature concerning the activity of PEEK particles are very controversial. In a recent study, the biological effects of PEEK compared to UHMWPE were analyzed using intravital fluorescence microscopy and a histological evaluation [21]. The authors could not detect any differences between UHMWPE and PEEK [21]. Later on, in an immunohistochemical study with two PEEK varieties, the data showed that the wear particles of CFR-PEEK pitch provoked a significantly more intense inflammatory reaction in the articular cartilage and the bone marrow than the used control group and UHMWPE wear particles [7]. The CFR-PEEK-PAN wear particles induced a higher cytokine release in the bone marrow and synovial

membrane [7]. Compared to the actual study, the PEEK varieties elicited biological activity in certain tissue areas [7]. This might be a consequence of the conglomeration behavior next to certain anatomical structures, which could be found in this study. Summarizing the results of these two consecutive studies [7, 21], the primary results seem to be antithetic. In detail, complementary testing was necessary to prove the complex effects of PEEK particles *in vivo*. In addition, these mice test-specific results cannot be transferred to humans directly.

Howling et al., for instance, did not find cytotoxic effects of CFR-PEEK wear particles *in vitro* [17]. In comparison to CoCr particles, there was less cytotoxicity on fibroblasts and monocytic cells [17]. Morrison et al. examined the effects of CFR-PEEK particles on fibroblasts and osteoblasts [18]. They did not describe any cytotoxic effects [18]. Furthermore, Rivard et al. tested the biocompatibility of CFR-PEEK in an *in vivo* rabbit model and noticed that the particles are harmless to the spinal cord of the animals [22]. Jockisch et al. found *in vivo* a foreign body reaction to CFR-PEEK plates that were implanted into rabbit muscles, but there was no difference compared to an UHMWPE implant [19]. Moreover, there was an *in vivo* study in rats comparing the effects of CFR-PEEK particles to polyethylene particles that were injected into a prepared pouch. The PEEK group seemed to be histologically less inflamed, but there was no significant difference [23].

These studies support the biocompatibility of CFR-PEEK and suggest a comparable biological activity of CFR-PEEK and other implant devices like UHMWPE. Reflecting the noticeable results of the present study, the controversial discussion about PEEK as an alternative bearing material in arthroplasty has to go on. The migration behavior of the CFR-PEEK particles in the synovial tissue remains unclear. Concerning the mechanism of migration or transport of wear particles, there exist different theories [24–27], but there is certainly need for further investigation. Overall, it can be assumed that the adjacency of the PEEK particles to vessels might lead to a vessel-bound transport mechanism. In this situation, the particles can be actively transported to adjacent tissue such as the femoral or tibial bone along an interface membrane or even lead to further systemic reactions. On the other hand, it has to be discussed if vessel-bound transported particles might decrease the local biologic reaction. Further possible reactions are definitely throughout hypothetic and thus further conclusions cannot be drawn based on the present findings.

Overall, these controversial effects of PEEK with a huge amount of open questions definitely need more investigation, especially as now a complete different migration and agglomeration behavior of CFR-PEEK compared to conventional UHMWPE could be proven. In particular, the particle surface texture as well as the surface charge of the UHMWPE and CFR-PEEK particles as a possible factor for this specific particle migration behavior has to be taken into account. And it remains unclear whether the UHMWPE or the PEEK particle migration behavior is accompanied with more negative biologic reactions.

As a limitation of the study, the low number of the tissue samples has to be named, even if the results are quite clear. A statistical analysis was not performed due to the descriptive study design, as there was no quantitative evaluation of the microscopic results.

In this study setup, CFR-PEEK was not the bearing material. Therefore, different wear mechanisms lead to the present CFR-PEEK wear debris. These mechanisms differ from the actual bearing situation of the UHMWPE insert. But in a prestudy, a comparable size range of the found particles was found, so the wear producing factors were neglected. It has to be mentioned that another wear particle analysis of the tissue bound particles was not performed in order to preserve as much tissue as possible for histologic analysis. Different size and shape parameters of the wear particles compared to the preexisting wear simulator study are thoroughly possible.

Additional immunohistochemical analyses are necessary and will be subject of following projects. Further investigations on the adjacent bone and the interface membrane might support the present findings.

5. Conclusion

This is the first study that compares CFR-PEEK and UHMWPE particles in human tissue. Interestingly, a complete different agglomeration behavior of UHMWPE and PEEK particles has been found in human synovial tissue. In addition, large PEEK particles are not incorporated by giant cells, as it is common with large UHMWPE particles. This aspect needs further investigation concerning the cytokine expression and also the surface texture of particles.

Competing Interests

The authors declare that there are no competing interests.

Authors' Contributions

The authors Sandra Utzschneider and Thomas Grupp contributed equally to this work.

Acknowledgments

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Research Article

Fretting and Corrosion in Modular Shoulder Arthroplasty: A Retrieval Analysis

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Tribocorrosion in taper junctions of retrieved anatomic shoulder arthroplasty implants was evaluated. A comparison of the tribocorrosion between cobalt-chromium and titanium alloy stems was conducted and the observations were correlated with the individual's clinical data. Adverse effects caused by metal debris and subsequent elevated serum metal ion levels are frequently reported in total hip arthroplasty. In total shoulder arthroplasty, to date only a small number of retrieval analyses are available and even fewer address the issue of tribocorrosion at the taper junctions. A total of 36 retrieved hemiarthroplasties and total shoulder arthroplasties were assessed using the modified Goldberg score. The prevalence of fretting and corrosion was confirmed in this cohort. Titanium stems seem to be more susceptible to damage caused by tribocorrosion than cobalt-chromium stems. Furthermore, stemless designs offered less tribocorrosion at the taper junction than stemmed designs. A weak correlation between time to revision and increased levels of tribocorrosion was seen. Whether or not tribocorrosion can lead to adverse clinical reactions and causes failure of shoulder arthroplasties remains to be examined.

1. Introduction

Shoulder arthroplasties for primary osteoarthritis of the shoulder are used in steadily increasing numbers [1, 2] with good results [3, 4]. Historically, monoblock designs have been used. As interindividual anatomy of the glenohumeral joint varies immensely, modular designs have been established. Modular implant designs are well known in the hip, where they allow for an optimal restoration of biomechanics. In hip arthroplasty damage at the modular taper connection has been described as a cause for postoperative complications like the so-called trunnionosis [5, 6]. This complication is caused by corrosion and a release of metal debris. Consequently, tribocorrosion can lead to local and, in extreme cases, systemic reactions [7]. Although the effect of head-neck taper junction is generally considered to be benign, some authors describe the percentage of complications in hip replacements caused by corrosion to be as high as 20%; for certain designs some studies describe up to 30% revision rate [8]. In hip arthroplasty corroded tapers often present surface irregularity like fretting scars, worn areas, pits, and etch marks [9, 10]. In this regard several different factors are associated with tribocorrosion, including material combination, head size, offset, implantation time, and flexural rigidity [7]. Whereas multiple retrieval studies regarding hip implants are available, only a small number of retrieval studies for modular shoulder arthroplasty exist [11, 12].

In shoulder arthroplasty common stem materials are cobalt-chromium alloys (CoCr) and titanium alloys (Ti). Furthermore, different shoulder arthroplasties exist with regard to stem design. Regular long stems utilize diaphyseal fixation, whereas "stemless" designs with corolla or cage screw are anchored in metaphyseal manner. There are also different materials (like Ti, CoCr, or ceramics) for the heads available.

The purpose of this study was to assess and analyze tribocorrosion of modular taper junctions of the retrieved shoulder arthroplasty implants and describe them with

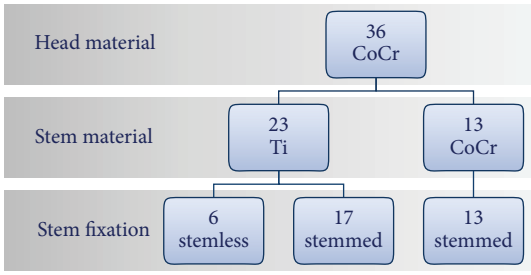


Figure 1: Distribution of material and fixation among the retrieved components.

regard to severity, extent, and frequency. Tribocorrosion was compared in mixed metal (head: CoCr, stem: Ti) and the same metal (head and stem: CoCr) implants as well as in stemmed and stemless fixation. It was hypothesized that there is a higher incidence of corrosion in mixed metal implants whereas no difference regarding stem fixation was expected. Furthermore, it was planned to correlate the findings with clinical data and to assess whether increased tribocorrosion causes earlier failure of anatomic shoulder arthroplasty.

2. Materials and Methods

2.1. Epidemiology. A total of 38 consecutively retrieved anatomic implants were available for analysis. All explants were revised at the Clinic for Orthopedics and Trauma Surgery of the Heidelberg University Hospital. Two of the retrieved implants had a Ti head and a ceramic head, respectively, which were excluded. Out of the 36 retrieved implants, 30 had a stem fixation, whereas 6 had a stemless fixation. In all cases, CoCr heads were used. Twenty-three of the analyzed implants (64%) had a Ti stemmed or stemless fixation, and 13 implants (36%) featured a CoCr stemmed or stemless fixation (Figure 1). All implants were used in anatomical total shoulder arthroplasty (TSA; $n = 7$) or hemiarthroplasty (HA; $n = 29$). The mean time to revision was 3.7 ± 4.1 years (0.03–13.5 years), 10 patients were male, and 27 patients were female. Manufacturers included Tornier ($n = 14$), Zimmer ($n = 7$), Arthrex ($n = 7$), Depuy ($n = 3$), Biomet ($n = 2$), Exactech ($n = 1$), Plus Orthopedics ($n = 1$), and Synthes ($n = 1$). In 4 cases, the stem had a female taper, whereas, in all the other cases, the stem had a male taper (Figure 2). Among the four female tapers, three were made of CoCr and one of Ti. All the stemless implants had a male taper on the humeral component. Patient demographics are given in Table 1. The reasons for revision and distribution are given in Table 2. Inclusion criteria were as follows: explantation of the entire humeral component and availability of all clinical data (dates of primary surgery/revision surgery, age, body weight, body mass index (BMI), and indication for revision).

2.2. Qualitative Damage Assessment. Tribocorrosion was graded on a scale from 1 to 4 depending on the extent and the magnitude of the damage as described by Goldberg et al. [9] and modified by Cusick and colleagues [11] (Table 3). This classification is the most commonly used damage scoring system to identify tribocorrosion on retrieved implants. The taper interfaces were macroscopically evaluated by two independent observers (JAE, UM). Any damage caused during implantation and explantation, respectively, was excluded from the assessment. Both male and female tapers were observed; hence, for each implant, a total of 2 scores were obtained: one for the stemmed/stemless fixation and one for the head. No postoperative cleaning procedure was performed on the components in order to avoid removal of corrosion products. As superficial corrosion products might cover fretting marks, a real distinction between fretting and corrosion is difficult to be achieved macroscopically. Therefore, the term "tribocorrosion" was chosen.

Table 1: Patient demographics of the 36 retrievals.

Parameter	Value
Number of patients	36
Age, in years	68 ± 11 (45–86)
Sex	
Female	26 (72%)
Male	10 (28%)
Time to revision, in years	3.7 ± 3.9 (0.03–13.5)
Side	
Left	13 (36%)
Right	23 (64%)
BMI, in kg/m^2	28.7 ± 5.8 (18.4–43.6)

Table 2: Reasons for revision and distribution.

Reasons for revision	Total	TSA	HA
Infection	9 (25%)	1 (14%)	8 (28%)
Instability	15 (42%)	2 (29%)	13 (45%)
Aseptic loosening	5 (14%)	2 (29%)	3 (10%)
Progression of osteoarthritis	5 (14%)	1 (14%)	4 (14%)
Periprosthetic fracture	2 (6%)	1 (14%)	1 (3%)

2.3. Statistics. The interrater reliability between both observers was evaluated using kappa statistics and the score of the primary observer (JAE) was used for statistical analyses. Furthermore, the intrarater reliability was calculated based on 13 samples for one observer (JAE). Descriptive statistics were calculated for all measurements.

A Shapiro-Wilk test revealed a nonnormal population for the study cohort ($p = 0.05$); hence the nonparametric Mann-Whitney U test was conducted to test for statistical significance. To analyze correlations between tribocorrosion and clinical data, the Spearman rank correlation coefficient was used. A value of $p < 0.05$ was considered statistically significant. All statistical analyses were performed using SPSS software (version 23.0; SPSS Inc., Chicago, IL).

Table 3: The modified Goldberg score [9] according to Cusick et al. [11].

Damage	Score	Criteria
Minimal	1	Fretting on <10% of the surface and no corrosion damage
Mild	2	Fretting on >10% of the surface and/or corrosion attack confined to one or small areas
Moderate	3	Fretting on >30% of the surface and/or aggressive local corrosion attack with corrosion debris
Severe	4	Damage over the majority (>50%) of the surface with severe corrosion attack and abundant corrosion debris

(a) (b)

Figure 2: Analyzed types of shoulder implants: two different stems types were analyzed: retrieved stems had either a male (a) or a female (b) taper.

3. Results

3.1. Reliability. Cohen's kappa statistic revealed agreement between both observers in any case ($p < 0.001$). Substantial strength of agreement was found for the stem ($\kappa = 0.682$), whereas the agreement for the head ($\kappa = 0.553$) was moderate.

The intrarater reliability tested with Cohen's kappa showed a substantial agreement for the stems and the heads, respectively ($\kappa > 0.750$, $p < 0.001$; JAE).

3.2. Assessment of Tribocorrosion. Tribocorrosion (score ≥ 2) was present on 27 of the 36 heads (75%) and 29 of the 36 stems (81%). Seven of the 36 implants (19%) showed at least moderate tribocorrosion (score ≥ 3 for both tapers), three of which (8%) showed severe tribocorrosion (score = 4 for both tapers). One of the severely affected cases is shown in Figure 3 and one of the minimally affected implants is seen in Figure 4.

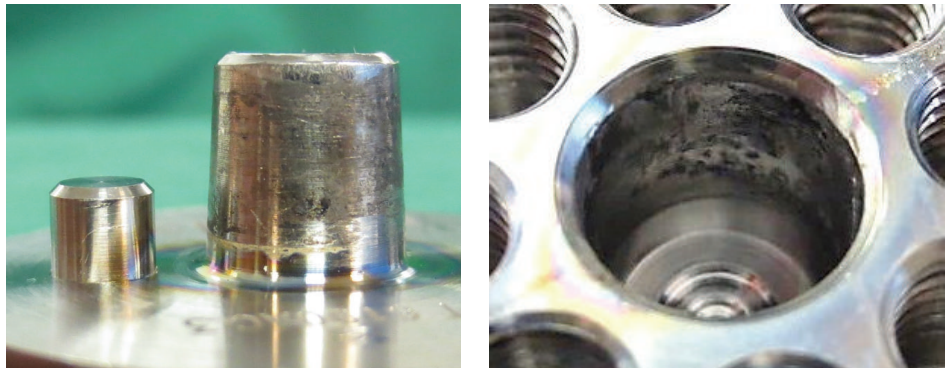
Significantly greater tribocorrosion ($p < 0.001$) was seen in mixed metal combinations where Ti stems were used (2.88 ± 0.78) compared to the same metals using CoCr stems (1.69 ± 0.48). For the CoCr heads there was a tendency of increased tribocorrosion when combined with Ti stems (2.53 ± 0.87) compared to the combination with CoCr stems (1.85 ± 0.90), although this difference was not statistically significant ($p = 0.072$; Figure 5).

Of the 36 retrieved implants, 30 (83%) had a stemmed and 6 (17%) a stemless fixation. All stemless implants were made of Ti alloy. In designs with a stem, the stem material was Ti in 17 (57%) cases and CoCr in 13 (43%) cases. To compare the effect of the stem fixation, only Ti tapers were included (Figure 1). The stemmed designs showed significantly higher tribocorrosion ($p = 0.002$) for the stem tapers (Figure 6). Time to revision of stemless (2.3 ± 1.4 years) and stemmed (3.4 ± 3.6 years) designs was comparable. For the head tapers, stemless designs showed a tendency for less tribocorrosion ($p = 0.052$), although the differences were not statistically significant.

3.3. Correlations with Clinical Data. Correlations between clinical data and the observed damage scores were evaluated (Table 4). Increased tribocorrosion was seen in retrieved implants with a longer period *in situ*; however, the correlation was weak ($R = 0.460$, $p = 0.005$). Apart from that, no correlation with clinical data was found.

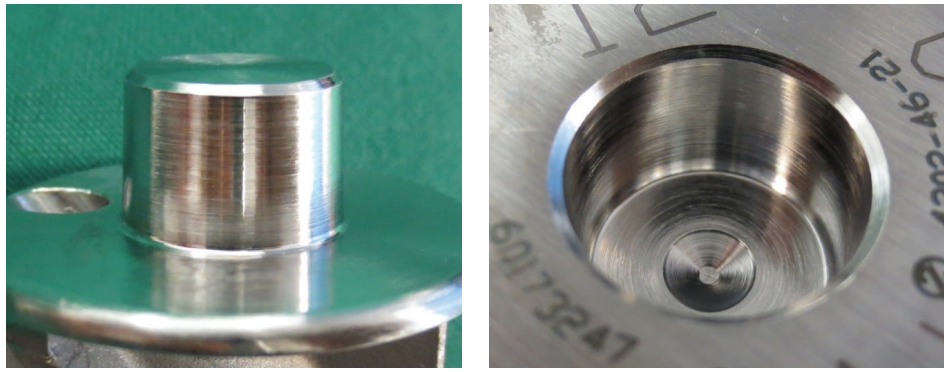
4. Discussion

In this retrieval study, tribocorrosion was seen in the majority of the retrieved implants. However, only a small subset of 16% showed moderate to severe corrosion for both tapers; most prostheses featured only mild tribocorrosion. Generally, there was a higher incidence of tribocorrosion in mixed metal implants as hypothesized although it was only significantly higher for the stem components. Interestingly, retrieved implants with Ti stems showed greater corrosion than the CoCr stems. Furthermore, stemmed Ti implants exhibited



(a) (b)

Figure 3: Severe tribocorrosion on male (a) and female (b) taper of a retrieved prosthesis. The time to revision was 9.2 years.



(a) (b)

Figure 4: Minimal tribocorrosion on male (a) and female (b) taper of a retrieved prosthesis. This prosthesis was implanted for 8.8 years.

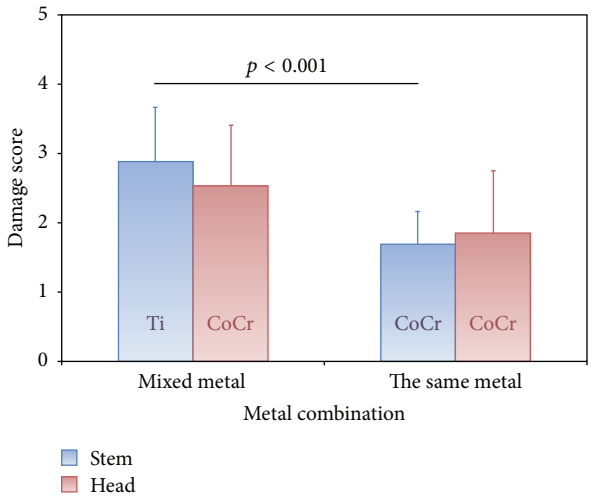


Figure 5: Comparison of the damage scores for the head and stem taper depending on stem material. Heads are all made of CoCr.

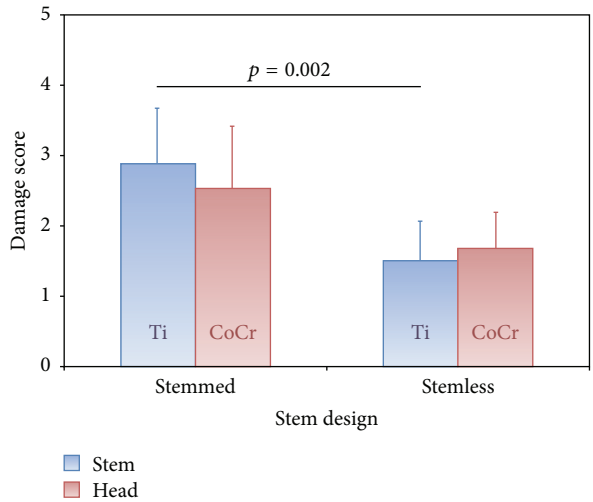


Figure 6: Comparison of the damage scores for the head and stem taper depending on stem design. Only titanium stems are included.

increased corrosion scores than stemless Ti implants. Therefore, the hypothesis regarding the fixation has to be rejected.

Only two other retrieval studies on tribocorrosion in shoulder arthroplasty have been published [11, 12] and only one of those examined anatomic implants. Teeter and colleagues [12] also reported tribocorrosion in their cohort, albeit at a much lower level (38% of the stems and 32% of the heads, compared to 81% and 75%, resp., as found in this

Table 4: Spearman's correlation coefficients for the damage scores depending on clinical data ($n = 36$).

	Stem taper		Head taper	
	R	p	R	p
Time to revision	0.165	0.335	0.460	0.005
BMI	0.038	0.827	0.154	0.371
Age	0.089	0.606	−0.175	0.309

study). They found tribocorrosion to be only prevalent in stemmed designs, whereas no tribocorrosion was seen in the stemless implants. In the current study a similar tendency was observed; however, some tribocorrosion was also found in the stemless implants. The effect of material combinations was not compared in the study by Teeter et al. [12]. The differences regarding the severity of corrosion might be explained by variations in the retrieval cohorts.

With the establishment of modular junctions in endoprostheses in the 1980s, numerous studies were published analyzing the risk of corrosion for modular hip prostheses. As early as 1991, Mathiesen and colleagues described corrosion in a cohort of retrieved hip implants, with the junctions between the modular components being regarded as the source for corrosion processes [13]. Corrosion processes of various kinds are seen in 10 to 40% of retrieved implants [9, 14–17]; some authors reported the rate of corrosion to be as high as 84% in their retrieval cohort [18] (nearly matching the 81% found in this study). Most authors described a risk of metal ion and particle release associated with tribocorrosion at taper junctions and, thus, a higher risk for third-body wear, particle-induced osteolysis, and aseptic loosening.

Possible reasons for the vulnerability of the taper junctions in modular prostheses have been described. For example micromotions between two components may lead to fretting and corrosion [19, 20], augmented by disruption of the passive surface oxide layer [21].

The mixed metal combination (Ti-CoCr) may exhibit higher tribocorrosion than the same metal combination because of the potential for additional galvanic corrosion. Galvanic corrosion may occur intergranularly or if metals of different electrochemical potential are combined [14, 22]. Comparable observations have been reported for mixed metal hip implants [23, 24]. Corrosion was observed in mixed metal couples (Ti-CoCr) but also in the same metal combinations (CoCr-CoCr and Ti-Ti). However, corrosion has been frequently described to be higher in mixed metal hip implants [9, 14, 16, 17].

However, in this study mixed metal implants were only available for the Ti stems in combination with CoCr heads. Thus, these findings should not be generalized for any kind of material or combination.

Stemmed implants might show higher torque levels at the modular interface due to their diaphyseal anchorage than the stemless implants which are anchored in metaphyseal manner. This might offer an explanation for the described findings of lower tribocorrosion levels for stemless implants. Also, stemless implants should only be used in patients with good bone stock in order to secure a suitable fixation in the bone. Hence, patient specific factors (like patient activity and muscle strength among others) might generally have an influence on tribocorrosion.

In the present cohort, implants with a longer time to revision exhibited slightly higher tribocorrosion levels than implants with a shorter time. This correlation, however, was only weak. Whether or not the described findings correlate with serum ion levels or clinical findings is impossible to assess in the retrospective setting of a retrieval analysis. For this purpose, additional prospective long-term studies need to be conducted. In hip prostheses, the effects of increased cobalt, chromium, and titanium levels on pseudotumor formation as well as other adverse clinical findings and subsequent revisions have been described multiple times [25–31]. In total knee arthroplasty, elevated serum metal ion levels have been described in experimental settings [32] as well as clinically [33]; however, it remains debatable whether they have any clinical implications [34]. In shoulder arthroplasty, to our knowledge no study has shown elevated metal ions or pseudotumor formation thus far. It remains unclear whether or not the tribocorrosion in shoulder arthroplasty is of similar clinical importance as it is in hip arthroplasty.

The relevance of retrieval studies has increased as they allow an assessment of the interaction between implant and patient anatomy. Furthermore, *in vitro* testing often cannot fully predict the *in vivo* behavior of implants [35, 36]. Due to regulations and quality control, retrieval management is getting more important and has become mandatory in Germany [37].

This study has some limitations: As it is a retrieval study, the design is retrospective, and as mentioned before tribocorrosion cannot be correlated to acute clinical findings such as blood results. This would be necessary to highlight adverse clinical reactions but can only be achieved in a prospective setting. The terms fretting and corrosion, while clearly defined, are used in different ways in retrieval analysis. While some authors distinguish between fretting and corrosion, we found it hard to classify the differences in this study cohort. Also, whether it actually makes a difference if an implant shows fretting or corrosion or even if corrosion might be the result of fretting is yet to be examined. Thus, the term tribocorrosion was used throughout this publication.

The subgroup of stemless implants was small (Figure 1). As such, further research is necessary to support the observation of less tribocorrosion in stemless implants. Furthermore a comparison between male and female tapers has not been performed due to the limited number of female tapers. Also, prostheses from eight different companies were included in this study. Thus, the high number of different designs and the partially low numbers for the respective prostheses make it impossible to assess the effect of design factors on tribocorrosion.

The retrieved implants were implanted for a number of reasons in a diverse study cohort that features patient ages between 45 and 86 years. Furthermore, they were revised for different reasons and do not necessarily represent a cross section of the normal shoulder arthroplasty population.

5. Conclusion

Tribocorrosion takes place in modular junctions of anatomic shoulder arthroplasties. In our cohort, titanium stems showed significantly more tribocorrosion than cobalt-chromium stems. Also, stemmed designs showed increased tribocorrosion than their stemless counterparts, even though stemless designs represent only a small proportion of the study population. High corrosion scores at the stem correlated with high corrosion at the head tapers. Further studies will be needed to assess clinical implications for trunnion wear in shoulder arthroplasty.

Competing Interests

The authors declare that there are no competing interests regarding the publication of this paper.

Authors' Contributions

Johannes A. Eckert and Ulrike Mueller contributed equally to this study and share the first authorship.

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Clinical Study

The Impact of Personality Traits on the Outcome of Total Knee Arthroplasty

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Ten to twenty percent of patients with total knee arthroplasty (TKA) are dissatisfied with their clinical outcome. Aim of this study was to investigate the impact of personality traits on the subjective outcome of TKA. We investigated 80 patients with 86 computer navigated TKAs. We asked for patients satisfaction and divided patients into two groups (satisfied or dissatisfied). 12 personality traits were tested by the Freiburg Personality Inventory (FPI-R). Postoperative examination included Knee Society Score (KSS), Western Ontario and McMaster University Osteoarthritis Index (WOMAC), and the Visual Analogue Scale (VAS). Radiologic investigation was done in all patients. 84% of our patients were satisfied, while 16% were not satisfied. The FPI-R showed statistical significant influence of four personality traits on patient satisfaction: life satisfaction ($p = 0.006$), performance orientation ($p = 0.015$), somatic distress ($p = 0.001$), and emotional stability ($p = 0.002$). All clinical scores (VAS, WOMAC, and KSS) showed significantly better results in the satisfied patient. Radiological examination showed optimal alignment of all TKAs. There were no complications requiring revision surgery. The results of our study show that personality traits may influence patients satisfaction and clinical outcome after TKA. Therefore patients personality traits may be a useful predictive factor for postoperative satisfaction after TKA.

1. Introduction

Total knee arthroplasty (TKA) is one of the most commonly used procedures for treatment of knee osteoarthritis [1]. Although there have been several improvements in design and implantation technique over the years, there are still a respective number of patients dissatisfied with the clinical outcome after TKA [2–4]. Literature shows a dissatisfaction rate between 10 and 20 percent, although objective examinations cannot show any reasons for dissatisfaction or complications [2–4]. Computer navigated implantation techniques result in improved positioning and alignment of TKAs [5–9] and provide us with a patient cohort with defined alignment of TKAs. Malalignment, range of motion (ROM) [9], patient's age [10], socioeconomic factors [11], and preoperative severity of osteoarthritis [12] are factors influencing patients' satisfaction after TKA but some factors still remain unknown. A former study has shown that the patient's satisfaction following foot surgery may be influenced by individual personality traits [13]. The aim of our study was to investigate if personality traits have an impact on patient's satisfaction and clinical outcome after navigated TKAs.

2. Material and Methods

We performed a prospective controlled clinical study. The study received ethical approval from the regional institutional review board (ref. number 382/2011). An informed consent was given by every patient.

2.1. Patients and Type of Prosthesis. We included 80 patients who received 86 navigated e.motion® UC (Aesculap AG, Tuttlingen, Germany) knee prostheses between 2009 and 2011. The e.motion® UC endoprosthesis is CE-marked, cruciate retaining knee prosthesis with a rotating polyethylene (PE) and high congruency. Mean age at operation was 66 years (54–81) and gender distribution was 48 females and 32 males. Minimum follow-up period was two years. Only patients without psychic disorder and with no psychopharmacal medication were included. Further inclusion criterions were

stability of the TKA and good range of motion (ROM) with a minimum of 100° and the absence of complications.

2.2. Surgical Procedure. All surgical procedures have been carried out through a medial parapatellar arthrotomy. Patients were given a perioperative antibiotic prophylaxis with cefazolin (3 × 2 g) or clindamycin (3 × 600 mg). Thrombotic prophylaxis was used with low-molecular weight heparin (40 mg–60 mg/day) starting 12 hours before surgery continuing for 6 weeks postoperatively. A tourniquet was used before osteotomies have been carried out and released after implant fixation. All implants were cemented using gentamycin containing cement (Palacos® R + G, Heraeus, Hanau, Germany) and vacuum cementing technique. The patella was routinely resurfaced and a lateral release was undertaken when necessary to achieve satisfactory patellar tracking. The postoperative management was similar for all patients with the use of crutches for 6 weeks postoperatively.

2.3. Navigation. All implantations were carried out by the use of the Orthopilot® (Aesculap AG, Tuttlingen, Germany) navigation system. Navigation was used in order to ensure alignment of the prosthesis in a defined position [5, 7, 8, 14, 15]. For inclusion the TKA has to be implanted in a defined range of alignment in all patients: mechanical femorotibial axis of 0° ± 3° and coronal orientation of the femoral and tibial component of 90° ± 2° and sagittal position of femur component 90° ± 2° and tibia component 90° − 4°.

2.4. Clinical Outcome and Patients Satisfaction Measures. To get the actual patients' satisfaction we decided to simply ask by a yes or no question if the patients are satisfied with their TKA or not. Clinical outcome was assessed using the Knee Society Score (KSS, clinical and function scores) and the Western Ontario and McMaster University Osteoarthris Index (WOMAC) [16, 17]. For pain assessment the Visual Analogue Scale (VAS) was used in order to estimate intensity of pain from 1 to 10 [18]. Minimum follow-up period was two years, and none of our patients was suffering from any kind of psychiatric disease, alcohol problems, psychopharmacal medication, or drug addiction. There was no further invasive treatment of the surveyed knee or any obvious complication of the respective knee prosthesis until the time point of follow-up. All TKAs were rated stable and with a minimum range of motion (ROM) of 100°.

2.5. Radiological Examination. Long leg standing X-rays and plain knee radiographs were performed in anterior-posterior (a.p.) and lateral view in all patients and were evaluated by 2 independent observers assessing alignment as well as signs of loosening such as radiolucent lines and osteolyses (Figures 1 and 2). Alignment was measured by the use of integrated radiologic measurement tool Agfa® Impax client (Agfa, Mortsel, Belgium). In the long standing a.p. radiographs the mechanical axis, the distal lateral femur angle, and the proximal medial tibial angle of the TKA were measured. In the lateral long leg radiography the femoral flexion/extension angle and tibial slope of the prosthesis were determined (Figure 2). Radiologic examination was done in all patients to investigate if the defined alignment of TKA implantation was achieved by navigation.

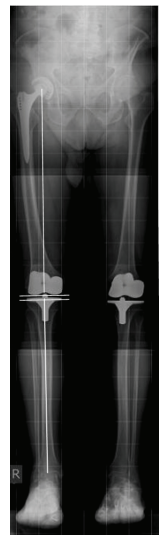

Figure 1: Long leg standing X-ray performed in anterior-posterior (a.p.) view. The mechanical axis, the distal lateral femur angle, and the proximal medial tibial angle of the TKA were measured.

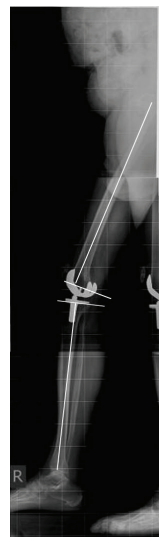

Figure 2: Long leg standing X-rays were performed in lateral view. The femoral flexion/extension angle and the tibial slope of the prosthesis were determined.

2.6. Freiburg Personality Inventory. To investigate the personality parameters we used the Freiburg Personality Inventory-Revised (FPI-R) [13, 19–23]. This multidimensional validated personality form consists of ten traits and two dimensions of personality. Testing is done answering 138 questions by self-evaluation. The scales are life satisfaction, social orientation, performance orientation, inhibition, excitability, aggressiveness, strain, somatic distress, health worries, openness,

Table 1: Preoperative data of satisfied and dissatisfied patients.

Preoperative values	Satisfied patients ($N = 72$)	Dissatisfied patients ($N = 14$)	p value
Age at operation	66.2 (±12.1)	62.3 (±11.3)	0.252
BMI	28.6 (±5.7)	28.0 (±4.9)	0.716
Gender distribution	f/m (41/31)	f/m (10/4)	0.318
Knee score, KSS	46 (±15)	52 (±11)	0.164
Function score, KSS	51 (±14)	50 (±16)	0.899

Table 2: Clinical results of satisfied and dissatisfied patients.

	Satisfied patients ($N = 72$)	Dissatisfied patients ($N = 14$)	p value
VAS	1.1 (±1.5)	6.7 (±1.8)	<0.001
WOMAC	0.86 (±1.3)	5.76 (±2.2)	<0.001
Knee score, KSS	92 (±13)	65 (±17)	<0.001
Function score, KSS	88 (±16)	59 (±22)	<0.001
ROM	118° (±11.4)	117° (±18.3)	0.262
Stability (KSS, max. 25 pts.)	25 (±0)	25 (±0)	1

extraversion, and emotional stability. The norms of the FPI-R are derived from a representative sample of population, which includes 2.035 probands. Higher scores represent higher expression of the items.

2.7. Statistical Analysis. To compare scores revealing physical functioning with quality of life, pain intensity, and personality traits we used SPSS 21 for statistical analysis. For describing data we used contingency tables and chi-square distribution. Whenever variances were heterogeneous and data were interval scaled t-tests and variance analysis (ANOVA) were used due to the fact that our population was independent. Whenever variances were not heterogeneous rank sum test or Kruskal-Wallis analyses were performed. Level of significance was 95%. Main null hypothesis: there were no significant differences in personality traits in satisfied and dissatisfied participants. Alternative hypothesis: satisfied and dissatisfied participants have different levels of personality traits. Knee society scores and the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) were compared using a t-test a variance analysis.

3. Results

3.1. Patient's Satisfaction and Clinical Outcome. From 86 TKAs 84% ($n = 72$) of patients were declared satisfied with the result, whereas 16% ($n = 14$) were dissatisfied. Preoperative demographic data and preoperative KSS showed now difference between satisfied and dissatisfied patients (Table 1). Satisfied patients showed significantly better clinical outcome postoperatively, although there was no difference in ROM and knee stability between the two groups (Table 2).

Visual Analogue Scale (VAS) in satisfied patients was 1.1 (SD ± 1.5) compared to 6.7 (SD ± 1.8) in dissatisfied patients ($p < 0.001$). WOMAC score in the satisfied group was 0.86 (SD ± 1.3) and 5.76 (SD ± 2.2) in the dissatisfied group ($p < 0.001$). Knee Society Score (KSS) and the Knee Society Function Score were statistically significantly better in satisfied patients ($p < 0.001$) than in dissatisfied patients. The respective scores were 92 (SD ± 13) and 88 (SD ± 16) in the satisfied group and 65 (SD ± 17) and 59 (SD ± 22) in the dissatisfied group (Table 2). ROM showed no difference between satisfied, 118° (SD ± 11.4), and dissatisfied patients, 117° (±18.3) ($p = 0.262$). Both groups had 25 (±0) pts. for stability evaluated from the KSS (Table 2).

3.2. Personality Traits. Evaluation of personality traits using the FPI-R revealed statistically significant difference between the two groups in 4 scales (Table 3).

Satisfied patients showed significantly higher scores for life satisfaction ($p = 0.006$) and performance orientation ($p = 0.015$), whereas dissatisfied patients showed significantly higher scores for somatic distress ($p = 0.001$) and emotional instability ($p = 0.002$). With the numbers available no significant differences were found in the other personality traits of the FPI-R (Table 3).

Thus our alternative hypothesis turned out to be confirmed: dissatisfied and satisfied participants showed different levels of personality traits. They were significantly different in performance orientation, life satisfaction, somatic distress, and emotional stability.

3.3. Radiologic Results. Radiological results showed that all alignment parameters were within the desired range for exact alignment. The mean mechanical axis was 1.3° varus (SD ± 1.6), the mean LDFA was 90.3° (SD ± 1.3), and mean MPTA was 89.5° (SD ± 1.3). In the sagittal plane mean femoral flexion was 90° (SD ± 1.5) and a mean tibial slope was 88.1° (SD ± 1.5).

3.4. Complications and Radiology. There were no obvious clinical complications requiring any revision or intervention of the TKA in both groups. Radiologic examination showed

Table 3: Personality traits in satisfied and dissatisfied patients after total knee arthroplasty—as assessed by Freiburg Personality Inventory-Revised (FPI-R).

FPI scales	Satisfied patients ($N = 72$)	Dissatisfied patients ($N = 14$)	p value
Life satisfaction	9.5 (±2.3)	7.4 (±3.3)	0.006*
Social orientation	7.8 (±2.3)	7.4 (±2.8)	0.56
Performance orientation	8.3 (±2.5)	6.5 (±2.7)	0.015*
Inhibition	4.5 (±2.5)	5.5 (±4)	0.23
Excitability	3.8 (±2.9)	4.9 (±2.9)	0.19
Aggressiveness	35 (±2.9)	4.5 (±3.3)	0.27
Strain	4.3 (±3.3)	5.4 (±4.7)	0.3
Somatic distress	3.4 (±2.5)	6.1 (±3.2)	0.001*
Health worries	6.8 (±2.7)	7.3 (±2.6)	0.5
Openness	4.5 (±2.5)	4.6 (±2.2)	0.89
Extraversion	7.4 (±2.8)	6.1 (±2.9)	0.1
Emotional stability	4.4 (±3.3)	7.6 (±4)	0.002*

*A statistically significant difference.

no sign of wear or loosening of the respective TKA in satisfied and dissatisfied patients.

4. Discussion

Aim of every TKA is to reach highest possible physical functioning and a reduction of pain. We assumed that successful knee arthroplasty without any obvious complication goes along with patients' satisfaction. Nevertheless the rate of unsatisfied patients after TKA is high and goes up to 20% [2–4]. Therefore we compared satisfied with dissatisfied patients after standardized navigated total knee arthroplasty. Computer navigation provided us with a group of patients with their TKAs implanted in a defined range of coronal and sagittal alignment. As alignment and ROM may play a certain role in patient's satisfaction [9] both groups showed desired alignment and good ROM two years postoperatively.

Satisfied patients showed significantly better clinical outcome, although there was no difference in ROM and knee stability between the two groups. So we conclude that inferior clinical results in the unsatisfied group are due to higher pain scores and lower function. Both groups had to be in a situation with no medical problems after arthroplasty and all patients received the same kind of prosthesis in the same implantation technique and the same postoperative protocol. As malalignment, range of motion [9], patient's age [10], socioeconomic factors [11], and preoperative severity of osteoarthritis [12] are factors influencing patients satisfaction after TKA; some factors still remain unknown. Aim of our study was to determine if psychological aspects affect patients' satisfaction after TKA using the FPI-R, one of the most used standardized personality tests [19]. These aspects were life satisfaction, social orientation, performance orientation, inhibition, excitability, aggressiveness, strain, somatic distress, health worries, openness, extraversion, and emotional stability. The main result was that 4 personality traits had a significant impact on patient's satisfaction. These 4 traits were life satisfaction ($p = 0.006$), performance orientation ($p = 0.015$), somatic distress ($p = 0.001$), and emotional stability ($p = 0.002$). Personality traits are considered to be stable. This means that life events do not harm personality. Previous studies have shown even after amputation stable parameters in personality traits, although their behaviour pattern changed. The finding in our study is consistent with results in different surgical procedures [13]. There is a group of people remaining dissatisfied after successful surgical knee arthroplasty. In our study those patients had in common that they had a low emotional stability, a high level of somatic complains, a low life satisfaction, and a bad performance orientation. To our knowledge there has never been a study describing the influence of personality traits on the patient's satisfaction after total knee arthroplasty before.

With these results our alternative hypothesis turned out to be confirmed: dissatisfied and satisfied participants showed different levels of personality traits. Therefore we recommend already before surgical procedures to focus on emotional stability, somatic complaints, life satisfaction, and performance orientation. Beside age and severity of osteoarthritis and socioeconomic factors we think that personality traits may be useful as predictive factors for postoperative satisfaction after TKA.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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