

Orthopädische Klinik und Poliklinik, Universitätsmedizin Rostock

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**Experimentelle Analyse des
Verschleißverhaltens künstlicher
Hüftendoprothesen unter dem Einfluss von
Drittkörperpartikeln**

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1 Einleitung

1.1 Hintergrund zur Hüftendoprothetik

Im Zuge des demografischen Wandels und einhergehend mit einer weniger aktiven Lebensweise steigt die Zahl der muskuloskelettalen Erkrankungen [1]. Eine dieser Krankheiten stellt die Arthrose dar, welche sich in einer degenerativen Veränderung des Gelenkes zeigt, beginnend mit einem sukzessiven Verlust des Gelenkknorpels bis hin zur Freilegung der Knochenoberfläche und Veränderungen an der Gelenkkapsel [2,3]. Die Patienten leiden dabei an Schmerzen, Steifheit und Funktionsverlust des betroffenen Gelenks, vorwiegend an Händen und Füßen, an der Wirbelsäule sowie an Knie oder Hüfte [2]. Ist bei einer fortgeschrittenen Arthrose der großen Gelenke nach einer konservativen Therapie der Leidensdruck der Patienten zu hoch, wird meist das betroffene Gelenk operativ durch eine Endoprothese ersetzt [4]. In Deutschland werden jährlich über 400.000 Endoprothesen implantiert. Dabei stellt der Einsatz von Hüftenprothesen mit ca. 227.000 operativen Eingriffen den größten Anteil dar [5,6].

Durch verschiedene Komplikationen kann eine Revision der Hüftendoprothese erforderlich sein. Die Hauptursache stellt hierbei die partikelinduzierte aseptische Lockerung dar [7]. Daher stellen die Minimierung des Abriebs und die Verbesserung der tribologischen Eigenschaften zwei der Hauptziele bei der Entwicklung neuer Hüftendoprothesen-Designs dar [8]. Der Abrieb der künstlichen Gelenkflächen ist dabei unter anderem abhängig vom Design und der Positionierung des Implantatsystems sowie von den verwendeten Materialien der Gleitpaarung. Als Goldstandard hat sich die Verwendung von Gleitpaarungen aus Keramik mit ultrahochmolekularem quervernetztem Polyethylen etabliert [9312]. Dabei zeigen sich keramische Materialien in Gleitpaarungen als abriebbeständiger als metallische Werkstoffe [13316].

Der Eintrag von Drittkörperpartikeln in die Gleitpaarung kann den Abrieb deutlich erhöhen und führt zu einem Anstieg der Oberflächenrauheit der artikulierenden Oberflächen und höheren Gelenkkraften [17,18]. Durch die Übertragung auf die verankernden Implantatkomponenten führt dies zudem zu einer höheren Beanspruchung der Knochen-Implantat-Grenzfläche [19]. Bei den Drittkörperpartikeln kann es sich unter anderem um Abriebpartikel aus dem Interface Knochen-Implantat oder Knochenzement-Implantat handeln. Jedoch sind finden sich auch freigesetzte Partikel von OP-Instrumenten [20323].

Durch Kontakt des Prothesenkopfes mit der metallischen Pfannenschale, beispielsweise durch Luxationen oder Lockerung, kann es zu einem Materialauftrag auf der Oberfläche des Kopfes kommen, wodurch ebenfalls Drittkörperpartikel in die artikulierende Gelenkfläche eingetragen werden [15,243 29]. Das Ausmaß, die Zusammensetzung und das Erscheinungsbild des Auftrages können stark variieren. Der Auftrag wurde innerhalb mehrerer Studien an explantierten Hüftköpfen dokumentiert und untersucht [8,29338]. Ein detaillierter Zusammenhang von Auftragsmuster, Auftragsmaterial und Entstehung konnte dabei bis heute noch nicht vollständig geklärt werden.

1.2 Verschleißanalyse von Implantatwerkstoffen

Für die Weiterentwicklung von Implantaten und Implantatmaterialien bzw. für deren Etablierung in der Klinik müssen diese auf ihre Eignung untersucht werden. Dafür stehen präklinische Untersuchungen unter möglichst physiologischen Bedingungen im Labor zur Verfügung. Für Endoprothesen wird unter anderem das Reibungs- und Verschleißverhalten untersucht. Man unterscheidet dabei zwischen einfachen Screening- und komplizierten Abriebsimulatortests [19]. Screeningtests dienen der Ersteinschätzung neuer Materialien oder Systeme und betrachten nur die Kontaktfläche einfacher Geometrien unter standardisierten, reproduzierbaren Bedingungen. Dabei können größere Probenzahlen schnell und kostengünstig getestet werden. Pin-on-Disc-Tests zählen zu den häufig angewandten Screening-Methoden. In Abriebsimulatortests sollen die Kontaktbedingungen *in vivo* möglichst physiologisch nachgebildet werden. Dazu werden Komponenten mit komplexen Geometrien mit gelenkspezifischen Bewegungsabläufen und Lasten dauerhaft beansprucht [19]. Bei Abriebsimulatortests sind die Bewegungen, Belastungen, die Schmierung, die Belastungsfrequenz und Dauer sowie die Prüftemperatur ebenso wie die Handhabung und Analyse der Prüfkörper zumeist standardisiert [39,42]. Dies soll eine Vergleichbarkeit der Ergebnisse zwischen verschiedenen Prüflaboren und den getesteten Implantatsystemen ermöglichen. Nach dem Versuch wird das Verschleißverhalten zunächst gravimetrisch analysiert, sodass eine Abriebrate pro Millionen Zyklen angegeben werden kann [39,40]. Optische Analysen, beispielsweise mittels Mikroskopie können weiterführend Aufschlüsse über den Verschleißhergang geben, wie z. B. Scratching, Pitting, Delamination, Polishing [43,44]. Weitere Rückschlüsse über das Verschleißverhalten kann eine Analyse der Abriebpartikel aus dem aufgefangenen Prüfmedium leisten.

Trotz der Darstellung aller Freiheitsgrade und Lasten bieten Abriebsimulatortests nur eine begrenzte Darstellung der Situation *in vivo*. In vielen Studien wird die Abriebrate pro Millionen Zyklen mit der Abriebrate pro Jahr gleichgesetzt [45,46]. Jedoch wurden *in vivo* bereits Aktivitäten von mehr als einer Million Bewegungszyklen pro Jahr nachgewiesen [47,48]. Außerdem bilden die Tests meist nur Standardbedingungen und keine worst-case-Szenarien ab. Bei Hüft- und Knieabriebsimulatoren wird beispielsweise nur der normale Gangzyklus bei einer Prüffrequenz von 1 Hz realisiert. Die Lasten sind dabei auf einen Patienten mit einem Körpergewicht ca. 70 kg ausgelegt [39,40,49]. *In vivo* liegt eine höhere Vielzahl von Belastungssituationen vor. Neben dem normalen Gang muss das Gelenk höheren Belastungen wie Laufen, Treppensteigen oder Stolpern standhalten. Auch werden verschiedene Implantationswinkel, Alterung oder Varus-/ Valgus-Fehlstellungen im Hüftgelenk bei der Testung nach Norm nicht berücksichtigt. Des Weiteren wird in den Labortests der Einfluss von Drittkörperpartikeln oftmals außer Acht gelassen. Daher dienen standardisierte Abriebsimulatortests einer vergleichenden Bewertung. Zudem ist die Lebensdauer der Implantate *in vivo* oft anders als im Test angenommen [19,50352].

Neben diesen präklinischen Untersuchungen kann die Analyse von Explantaten unter Berücksichtigung deren Revisionsgrundes viele wertvolle Informationen zur Versagensursache und somit für die möglichen Ansätze zur Verbesserung eines Implantatsystems und seiner Handhabung liefern.

2 Zielsetzung und Fragestellung

Drittkörperpartikel können auf verschiedensten Wegen zwischen die artikulierenden Gleitpartner gelangen, beispielsweise durch Mikrobewegungen im Knochen-Implantat- bzw. auch im Implantat-Knochenzement-Interface. Auch Abriebpartikel von OP-Werkzeugen während der Implantation oder Revision sind nicht auszuschließen [20323]. Zahlreiche Studien berichten von metallisch schimmernden Verfärbungen auf explantierten Hüftköpfen, welcher unter anderem durch den Kontakt der Gleitfläche mit dem umliegenden Implantatsystem entstehen können. Auch diese stellen eine Art von Drittkörperpartikeln dar. Bekannt ist, dass Fremdkörper im Gelenkspalt künstlicher Endoprothesen zu einer erhöhten Oberflächenrauheit der Gleitpartner und einem deutlich höheren Verschleiß führen können [8,17,18]. Eine Quantifizierung dieses Verschleißes in Langzeitstudien erfolgte bisher nur vereinzelt [8].

Das Ziel dieser Arbeit war es daher, den Einfluss von Drittkörperpartikeln über Langzeitabriebversuche zu quantifizieren und die Herkunft der Fremdpartikel sowie deren Entstehung zu ermitteln. Dazu wurden in einer ersten Studie ionenbehandelte Hüftköpfe aus CoCr und Aluminiumoxid-Keramik (Al_2O_3) unter Hinzugabe von Knochenzementpartikeln über fünf Mio. Zyklen im Hüftabriebsimulator untersucht [I]. In einer zweiten Studie im Hüftabriebsimulator wurden sechs explantierte keramische Köpfe mit deutlichem Material-Auftrag ebenfalls über fünf Mio. Zyklen getestet [II]. Die Ergebnisse beider Studien wurden mit den Ergebnissen aus der Testung fabrikneuer Implantate verglichen. In einer dritten Studie wurden 96 explantierte Hüftendoprothesenköpfe aus verschiedenen Materialien mit metallisch schimmerndem Auftrag hinsichtlich einer Korrelation des Auftragsmaterials, des Auftragsmusters, dem Ort des Auftrages und ihres Revisionsgrundes untersucht, um Rückschlüsse auf die Herkunft und Entstehung des aufgetragenen Materials zu gewinnen [III].

3 Material und Methoden

3.1 Analyse des Verschleißverhaltens von Hüftendoprothesen unter dem Einfluss von Drittkörperpartikeln [I]

Für den Abriebtest wurde das Hüftimplantatsystem Trident® PSL (Stryker GmbH & Co. KG, Kalamazoo, MI, USA) mit neuen vorgesättigten und hochvernetzten X3® Polythetylen-Inserts (PE-Inserts) verwendet. Diese wurden kombiniert mit jeweils vier 36 mm Hüftköpfen aus Aluminiumoxid (Alumina Ceramic C-Taper Femoral Head) und vier mit Sickstoff-Ionen bestrahlten Köpfen aus CoCr (LFIT™ Anatomic C-Taper Femoral Head).

Der Abriebtest wurde in einem Standard-Hüftabriebsimulator (C6/2-08, EndoLab GmbH, Rosenheim, Deutschland) durchgeführt. Dabei standen für jede Materialkombination je drei Stationen für die dynamische Testung zur Verfügung. Auf diese wurden die durch die ISO 14242-1:2014 [39] vorgegebenen fünf Mio. Last- und Bewegungszyklen des normalen Ganges bei 1 Hz aufgebracht (siehe Abbildung 1).

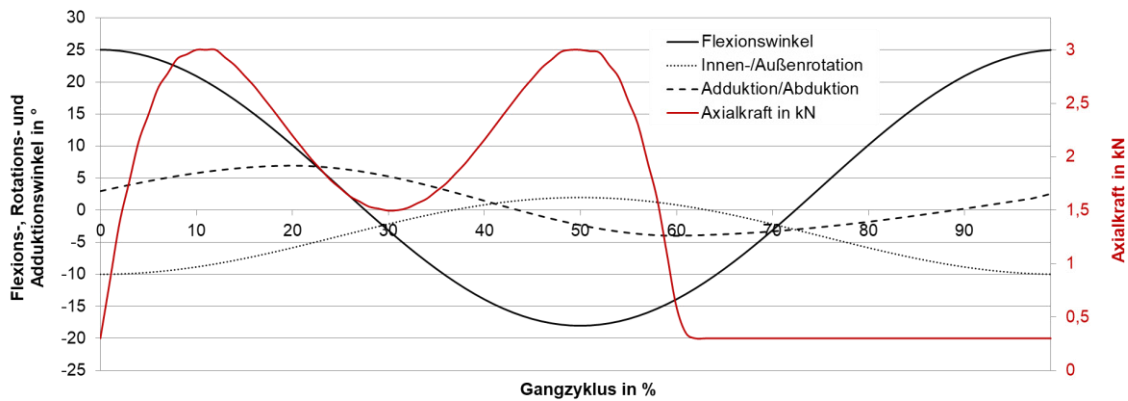


Abbildung 1: Bewegungen und Belastungen im Abriebsimulator nach ISO 14242-1 [39].

Zur Kontrolle der Flüssigkeitsaufnahme wurde pro Materialkombination eine Station lediglich axial statisch belastet (Referenz). Die Testung erfolgte in separaten Testkammern bei 37 ± 2 °C in Rinderserum mit einem Proteingehalt von 30 g/l und mit Zusätzen von Natriumazid (NaN_3) und Ethylendiamintetraessigsäure (EDTA). Alle 0,5 Mio. Zyklen erfolgte ein Mediumwechsel sowie die gravimetrische Messung der PE-Inserts nach ISO 14242-2:2016 [40] mittels Feinanalysewaage (Sartorius ME235S, Sartorius AG, Göttingen, Deutschland).

Zur quantitativen Analyse des Drittkörperverschleißes wurden Knochenzementpartikel (PalacosR®, Heraeus Medical GmbH, Wehrheim, Deutschland) mit einer Kugelmühle (MM2, Retsch GmbH, Haan, Deutschland) hergestellt und die Partikel mit einer Größe von 100 μm bis 200 μm herausisoliert. Diese wurden in einer Konzentration von 5 g/l bei jedem Mediumwechsel in die Gleitpaarung eingebracht. Da die Prüfung im Abriebsimulator unter der gleichen Implantatausrichtung wie *in vivo* durchgeführt wurde, ließ sich eine Sedimentation der Partikel am Grund der Prüfkammer nicht verhindern. Daher wurden 10 % der Zementpartikel vor der Prüfung mit einer konstanten axialen Last von 300 N in die PE-Inserts gedrückt. Die Ergebnisse der gravimetrischen Messungen wurden mit Ergebnissen aus vorhergehenden Studien des gleichen Designs ohne Drittkörperpartikel verglichen [53].

Nach dem Test im Hüftabriebsimulator erfolgte die optische Verschleißanalyse mittels Digitalmikroskop (VHX-900F, Keyence Deutschland GmbH, Neu-Isenburg, Deutschland) und die Messung der Oberflächenrauheit mittels Laser-Scanning-Mikroskop (VK-X250, Keyence Deutschland GmbH).

3.2 Analyse des Verschleißverhaltens von Hüftendoprothesen unter dem Einfluss von Materialauftrag [II]

Für die Analyse des Einflusses den Materialauftrages auf den Abrieb von Hüftendoprothesen wurden jeweils drei explantierte keramische Hüftendoprothesen-Köpfe mit 28 mm Durchmesser und drei mit 36 mm Durchmesser mit ähnlich ausgeprägtem Materialauftrag (siehe Abbildung 2) in Kombination mit neuen passenden und vorgesättigten X3[®] PE-Inserts des Trident[®] PSL Hüftendoprothesensystems im Hüftabriebsimulator über fünf Mio. Zyklen getestet. Die Belastung und gravimetrische Messung erfolgte dabei wie in Kapitel 3.1 beschrieben nach ISO 14242-1:2014 und ISO 14242-2:2016 [39,40]. Die Ergebnisse der gravimetrischen Messungen wurden mit Ergebnissen aus vorhergehenden Studien des gleichen Designs ohne Materialauftrag verglichen [54].

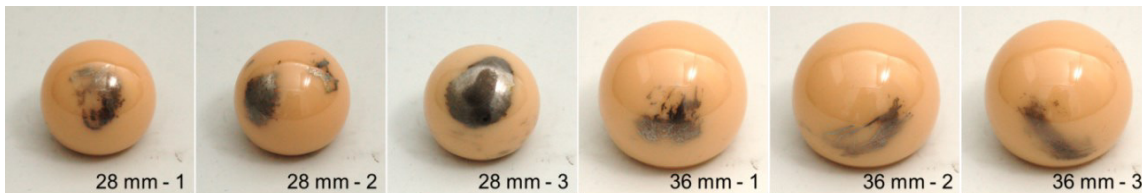


Abbildung 2: Ausgewählte explantierte Femurköpfe mit Materialauftrag für die Testung im Hüftabriebsimulator.

Nach dem Test erfolgte die Messung der Oberflächenrauheit mittels Laser-Scanning-Mikroskop. Die Fläche des Materialauftrages wurde vor und nach Belastung mittels Digitalmikroskop vermessen und verglichen.

3.3 Untersuchung des Materialauftrages auf explantierten Hüftendoprothesen-Köpfen [III]

Um Rückschlüsse über die Herkunft und Entstehung des aufgetragenen Materials zu gewinnen, wurde der Auftrag von 96 explantierten und desinfizierten Hüftköpfen aus CoCr, TiN- bzw. TiNbN beschichtetem CoCr, Aluminiumoxid, ZTA (Zirconia-Toughened Alumina) und anderer Oxidkeramik (ATZ (Alumina-Toughened Zirconia) oder Zirkonoxid (ZrO_2)) untersucht. Von allen Köpfen wurden die zugehörigen Implantatsysteme fotografisch dokumentiert, die Revisionsgründe aufgenommen und von einem erfahrenen orthopädischen Chirurgen bewertet. Durch Auflegen eines Rasters wurde der Ort des Materialauftrages auf dem Kopf bestimmt. Die Einteilung erfolgte dabei in Pol, Äquator und konusnah (siehe Abbildung 3). Die auftretenden Auftragsmuster wurden in die Klassifizierung nach der Studie von Fredette et al. [55] in die Klassen Solid Patch (deckender Flecken), Directional Scratches (gerichtete Kratzer),

Longitudinal Stripe (longitudinaler Streifen), Random Stripes (stochastische Streifen), Random Patches (stochastische Flecken), Patterned Coverage (flächige Maserung) und Miscellaneous (Sonstiges) eingeordnet.

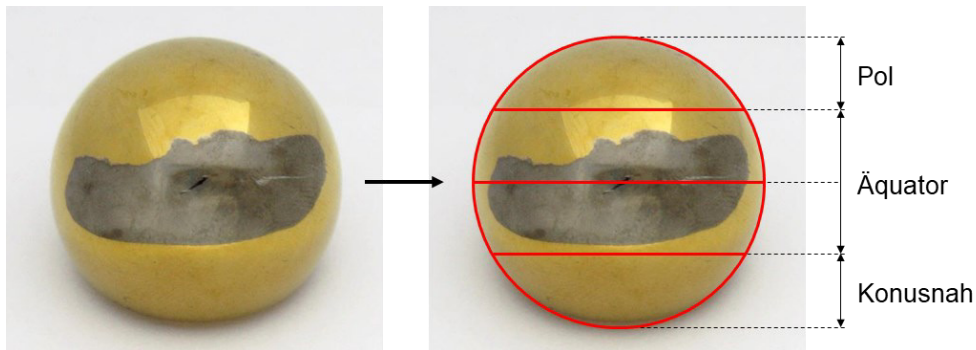


Abbildung 3: Einteilung der Bereiche auf einem TiN-beschichteten explantierten Femurkopf.

Um die Zusammensetzung des Auftragsmaterials zu ermitteln, wurden die Köpfe im Rasterelektronenmikroskop (REM, FESEM, MERLIN® VP Compact, Co., Zeiss, Oberkochen, Deutschland) mittels energiedispersiver Röntgenspektroskopie (EDX, XFlash 6/30) untersucht. Dabei wurden nur Materialien als Transfer definiert, welche im Mapping eindeutig als Auftragsmaterial zugeordnet werden konnten. Beispielsweise wurden Elemente, welche nur als Rausch-Signal erfasst wurden, nicht als Auftragsmaterial in der Studie berücksichtigt.

Die Ergebnisse aller drei Studien wurde mit der Statistik-Software SPSS® Statistics (IBM Corporation, New York, NY, USA) ausgewertet. P-Werte < 0,05 wurden als signifikant angenommen.

4 Ergebnisse

4.1 Verschleißverhalten von Hüftendoprothesen unter dem Einfluss von Drittkörperpartikeln [I]

Die Abriebsdaten der PE-Inserts nach Abzug der Gewichtszunahme durch die Flüssigkeitsaufnahme sind in Abbildung 4 dargestellt. Abbildung 4 (B) zeigt die Abriebrate im Vergleich zu den gleichen Gleitpaarungen ohne Drittkörperpartikel [53]. Die Abriebrate der CoCr-PE Gleitpaarung ist mit $16,57 \pm 5,98$ mg pro Millionen Zyklen (Gesamtabrieb: $82,84 \pm 6,40$ mg) leicht höher als die der Al_2O_3 -PE Gleitpaarung mit $15,14 \pm 3,30$ mg pro Millionen Zyklen (Gesamtabrieb: $75,69 \pm 7,82$ mg). Die Ergebnisse unterscheiden sich jedoch nicht signifikant. Durch den Einfluss der Drittkörperpartikel konnte eine achtfach höhere Abriebrate ermittelt werden, als in der Vergleichsstudie [53]. Zum Vergleich wurde in der

Studie von Fabry et al. [53] gleichsam kein signifikanter Unterschied zwischen der Gleitpaarung CoCr-PE ($2,02 \pm 0,75$ mg) und Al_2O_3 -PE ($2,04 \pm 0,38$ mg) festgestellt.

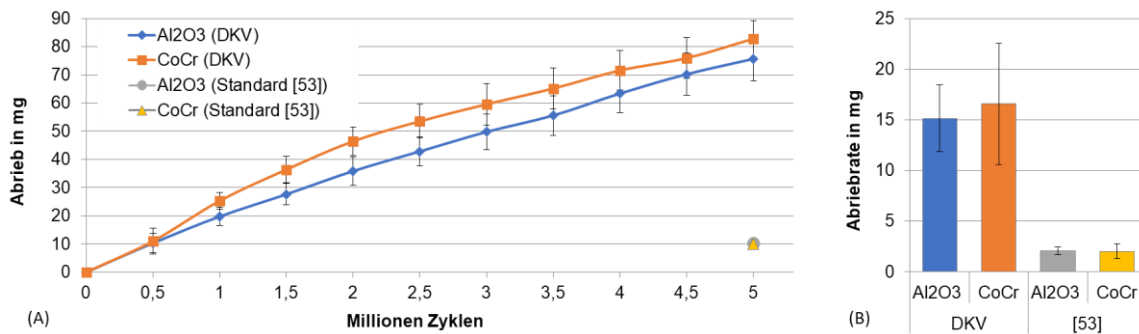


Abbildung 4: Gravimetrischer Abrieb über 5 Millionen Zyklen (A) und Abriebrate pro Millionen Zyklen (B) der PE-Inserts gegen 36 mm Köpfe aus Al_2O_3 und ionenbehandeltem CoCr.

Nach den Versuchen mit Drittkörperpartikeln zeigte die mikroskopische Untersuchung der PE-Gleitflächen zahlreiche Riefen, Kratzer, elliptische Laufspuren in Bewegungsrichtung sowie polierte Flächen und Pitting. Auf den PE-Oberflächen konnten keine Unterschiede zwischen den Gleitpaarungen festgestellt werden. Im Gegensatz dazu zeigten sich auf den Femurköpfen deutliche Unterschiede. Während auf den metallischen Femurköpfen tiefe und lange Kratzer in Bewegungsrichtung zu verzeichnen waren, zeigte sich auf den keramischen Köpfen nur leichtes Pitting in Form von Kornausbrüchen entlang einer Linie (Abbildung 5).

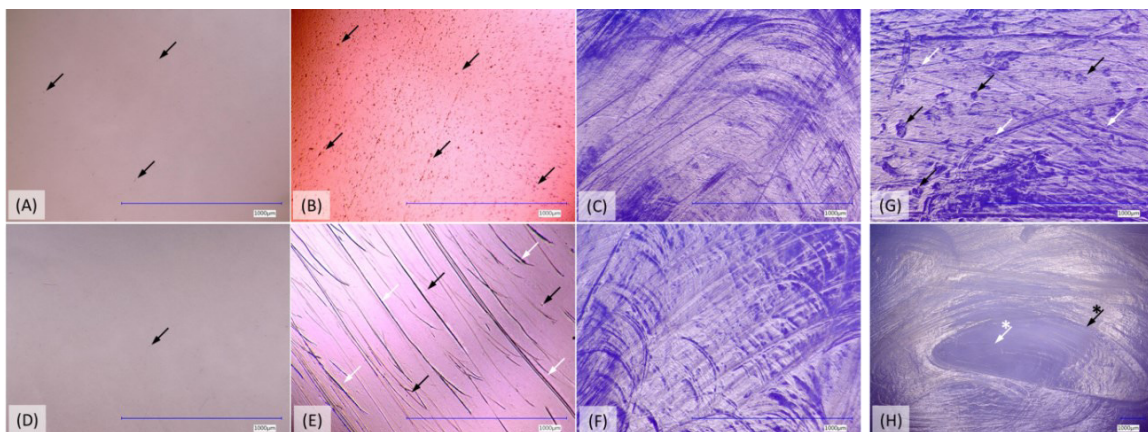


Abbildung 5: Oberfläche eines keramischen Kopfes vor Belastung (A), nach Belastung (B) und des zugehörigen PE-Inserts nach Belastung (C); Oberfläche eines metallischen Kopfes vor Belastung (D), nach Belastung (E) und des zugehörigen PE-Inserts nach Belastung (F); typische Verschleißspuren der Inserts nach Drittkörper (G, H): Pittings (schwarze Pfeile), Kratzer (weiße Pfeile), Polierte Bereiche (weiße Pfeile mit Stern), Elliptische Laufspuren (schwarze Pfeile mit Stern).

Die Oberflächenrauheiten der Gleitpaarungen nach 5 Mio. Zyklen sind in Tabelle 1 dargestellt. Die Ergebnisse der metallischen und keramischen Köpfe zeigten keine signifikanten Unterschiede der Rauheitswerte vor und nach Belastung, jedoch

zeigten die Köpfe eine leichte Abnahme der Rauheit nach der Artikulation. Die in Anwesenheit von Drittkörperpartikeln getesteten PE-Inserts zeigten einen signifikanten Anstieg der gemittelten Rautiefe Rz und einen tendenziell höheren Mittenrauwert Ra im Vergleich zu den unbelasteten Referenzinserts. Die Schiefe Rsk der Inserts wechselte nach der Belastung vom Positiven ins Negative. Eine Rauheitsmessung vor dem Versuch, wurde nicht durchgeführt, da der Energieeintrag des Lasers sich auf die Verschleißigenschaften des PEs ausgewirkt hätte.

Tabelle 1: Durchschnittliche Rauheitsparameter Rz, Ra und Rsk in μm der getesteten Köpfe und Inserts.

		Kopf		PE-Insert	
		Referenz	Belastete Probe	Referenz	Belastete Probe
Rz	Keramik	2,096 ($\pm 0,788$)	1,163 ($\pm 0,124$)	4,463 ($\pm 1,826$)	6,396 ($\pm 3,852$)
	Metall	2,091 ($\pm 0,787$)	1,360 ($\pm 0,335$)		9,690 ($\pm 7,776$)
Ra	Keramik	0,374 ($\pm 0,110$)	0,307 ($\pm 0,045$)	0,942 ($\pm 0,387$)	0,995 ($\pm 0,815$)
	Metall	0,377 ($\pm 0,110$)	0,329 ($\pm 0,047$)		1,732 ($\pm 1,672$)
RsK	Keramik	1,463 ($\pm 0,615$)	0,848 ($\pm 0,144$)	0,906 ($\pm 0,418$)	-0,451 ($\pm 0,449$)
	Metall	1,462 ($\pm 0,613$)	0,860 ($\pm 0,123$)		-0,421 ($\pm 0,691$)

4.2 Verschleißverhalten von Hüftendoprothesen unter dem Einfluss von Materialauftrag [II]

Der gravimetrische Abrieb der Inserts, welche in Kombination mit den neuen [54] bzw. explantierten Köpfen getestet wurde, ist in Abbildung 6 dargestellt. Die 36 mm Köpfe erzielten dabei stets höhere PE-Abriebraten, als die Köpfe mit 28 mm Durchmesser. Des Weiteren erreichten die explantierten Köpfe mit Materialauftrag (36 mm: $2,42 \pm 0,82$ mg pro Mio. Zyklen, $12,09 \pm 4,12$ mg Gesamtabrieb; 28 mm: $1,57 \pm 1,36$ mg pro Mio. Zyklen, $7,86 \pm 6,79$ mg Gesamtabrieb) einen deutlich höheren PE-Abrieb, als die neuen Köpfe (36 mm: $2,04 \pm 0,46$ mg pro Mio. Zyklen, $10,21 \pm 2,28$ mg Gesamtabrieb; 28 mm: $-0,06 \pm 0,89$ mg pro Mio. Zyklen, $-0,29 \pm 4,45$ mg Gesamtabrieb).

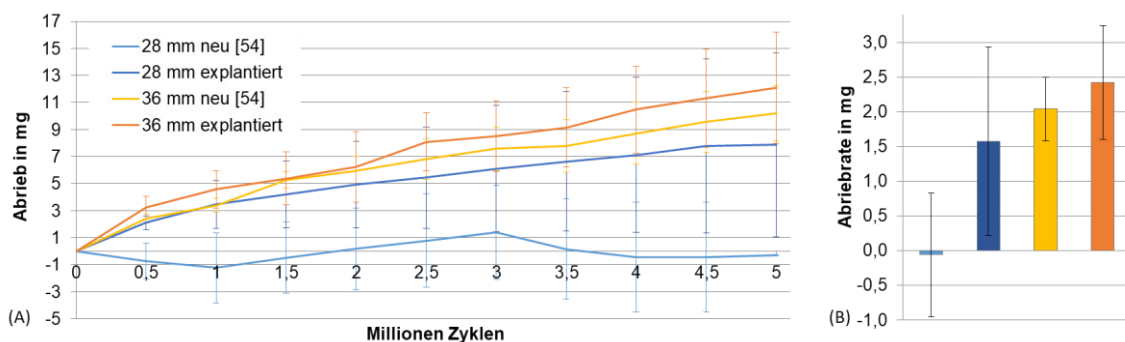


Abbildung 6: Gravimetrischer Abrieb der PE-Inserts über 5 Millionen Zyklen (A) und Abriebrate pro Millionen Zyklen (B) der PE-Inserts gegen neue [54] und explantierte 28mm und 36 mm Al_2O_3 -Köpfe.

Die Fläche des metallischen Auftrages auf den explantierten Köpfen verringerte sich nach der Belastung im Abriebsimulator leicht ($p = 0,188$). Die Änderung der Auftragsfläche ist in Abbildung 7 dargestellt.

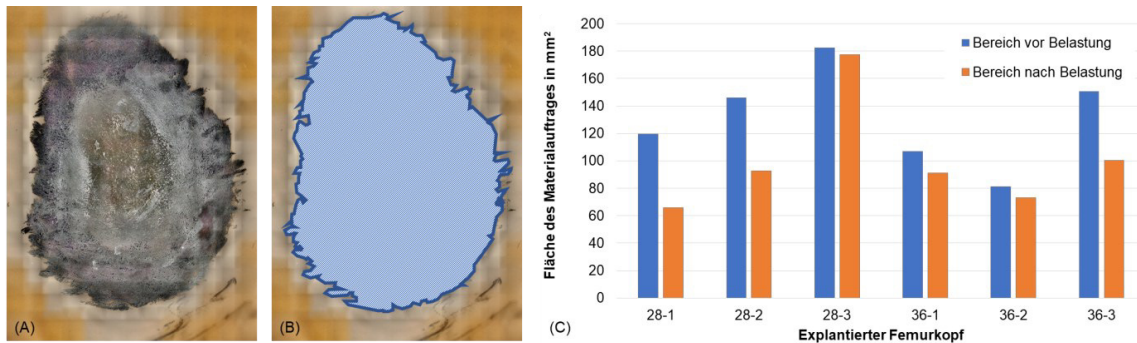


Abbildung 7: Bestimmung der Fläche des Materialauftrages; (A) Materialauftrag, (B) Markierter Bereich für die Messung, (C) Gemessene Flächen des Auftrages vor und nach Belastung.

Bei allen Köpfen konnten signifikant höhere Rauheitsparameter Ra und Rz auf dem Materialtransfer gegenüber der originalen Kopfoberfläche ermittelt werden ($p < 0,001$). Die ermittelten Daten sind in Abbildung 8 dargestellt.

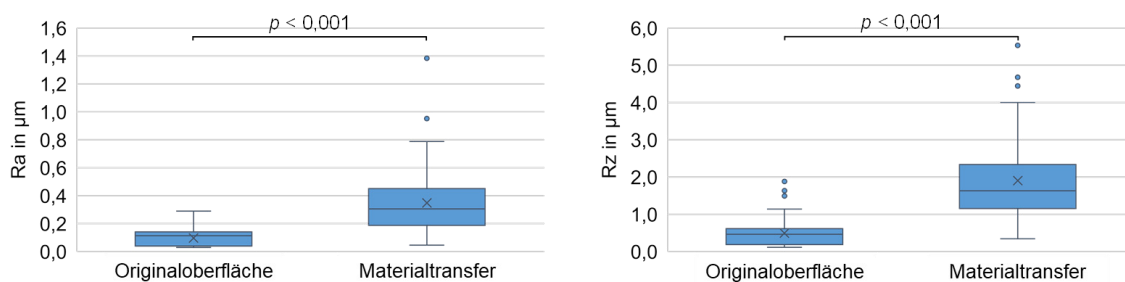


Abbildung 8: Vergleich der Oberflächenrauheit der Köpfe auf und neben dem Materialauftrag.

4.3 Untersuchung des Materialauftrages auf explantierten Hüftendoprothesen-Köpfen [III]

Bei der Auswahl der Köpfe und der Fotodokumentation wurde festgestellt, dass der Materialauftrag nicht nur auf den Köpfen zu finden war, sondern teilweise auch auf anderen Komponenten des Implantatsystems. Die Revisionsgründe sind in Tabelle 2 dargestellt. Am häufigsten mussten die Implantatsysteme aufgrund von Polyethylenabrieb, Impingement und aseptischer Lockerung explantiert werden.

Tabelle 2: Revisionsgründe der 98 explantierten Köpfe (Mehrere Revisionsgründe pro Implantat möglich).








Revisionsgrund	Häufigkeit H	Absolute H
	in %	(n = 98)
Polyethylenabrieb (inkl. Dezentralisation, Delamination, Linearer Abrieb)	43,9	43
Impingement	40,8	40
Aseptische Lockerung (davon 25,5% globale Lockerung, 11,2% Pfannenlockerung, 1% Stiellockerung)	37,7	37
Dislokation (einfach und mehrfach)	20,4	20
Partikelerkrankung (durch Abriebpartikel aus Metall oder PE)	17,3	17
Septische Lockerung	11,2	11
Sepsis (ohne Lockerung, inkl. DAIR ¹)	8,2	9
Implantatmigration	5,1	5
Glutealinsuffizienz	3,1	3
Osteolyse	3,1	3
Periprothetische Fraktur	3,1	3
Implantatversagen	3,1	3
Subluxation	2,0	2

¹ DAIR [engl. Debridement, antibiotics and implant retention] = Gelenkprotheseninfektion

Auf den explantierten Köpfen wurde am häufigsten Materialauftrag in Form von Random Patches und Random Stripes sowie Solid Patches gefunden. Die Random Patches traten dabei fast ausschließlich auf Hart-Hart-Paarungen auf. Der Auftrag wurde dabei am häufigsten in der Äquatorregion beobachtet. Die Verteilung der Auftragsmuster (eingeteilt nach Fredette et al. [55]) insgesamt und in den einzelnen Regionen sind in der Tabelle 3 und Abbildung 9 dargestellt.

Es zeigte sich, dass Solid Patches vermehrt im Zusammenhang mit Dislokationen und hauptsächlich im Bereich des Äquators auftraten. Mögliche Zusammenhänge zeigten sich auch beim Auftreten von Random Stripes bei Glutealinsuffizienz und Implantatbruch.

Tabelle 3: Auftragsmuster auf den 98 explantierten Köpfen (mehrere Muster pro Kopf möglich).

Auftragsmuster	Random Stripes	Random Patches	Solid Patch	Longitudinal Stripe	Directional Scratches	Patterned Coverage	Miscellaneous
Häufigkeit	44,9	41,8	35,7	27,6	20,4	11,2	2,0
Absolute Häufigkeit	44	41	35	27	20	11	2
							

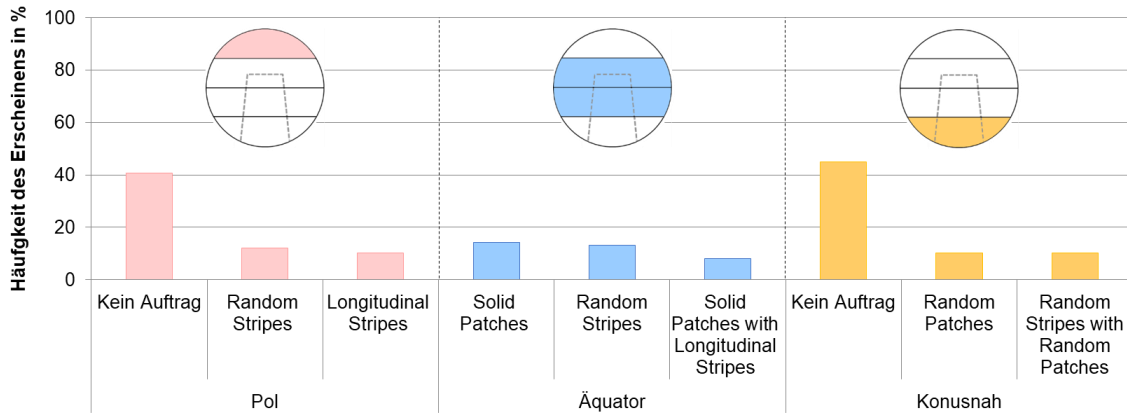


Abbildung 9: Häufigste Auftragsmuster auf den explantierten Köpfen in den Bereichen Pol, Äquator und konusnah.

Die Elemente, welche klar als Auftrag definiert werden konnten (siehe Abbildung 10), sind in Tabelle 4 aufgelistet. Titan zeigte sich dabei als das am häufigsten transferierte Material auf 76,5 % der Köpfe, gefolgt von Kohlenstoff, welches auf nahezu der Hälfte aller Köpfe zu finden war. Es konnten keine Zusammenhänge zwischen dem detektierten Auftragsmaterial und dem Grundmaterial des Kopfes gefunden werden, jedoch einige signifikante Korrelationen zwischen einigen Auftragsmaterialien und Revisionsgründen. Im Zusammenhang mit PE-Verschleiß wurde vermehrt Eisen auf den Köpfen gefunden (24 von 34 Köpfen, $p = 0,035$), ebenso bei Implantatfrakturen (3 von 3 Köpfen, $p = 0,039$). Bei Partikelerkrankung, d. h. einer inflammatorischen Reaktion des Gewebes auf Abriebpartikel, wurde vermehrt Sauerstoff im Auftragsmaterial detektiert (5 von 7 Köpfen, $p = 0,002$). Bei septischer Lockerung konnte Schwefel im Auftragsmaterial gefunden werden (3 von 4 Köpfen, $p = 0,004$), während bei einer Sepsis vorwiegend Kohlenstoff zu finden war (8 von 9 Köpfen, $p = 0,015$). Bei periprothetischen Frakturen lagerte sich signifikant Calcium auf den betroffenen Hüftköpfen ab (1 von 3 Köpfen, $p = 0,031$).

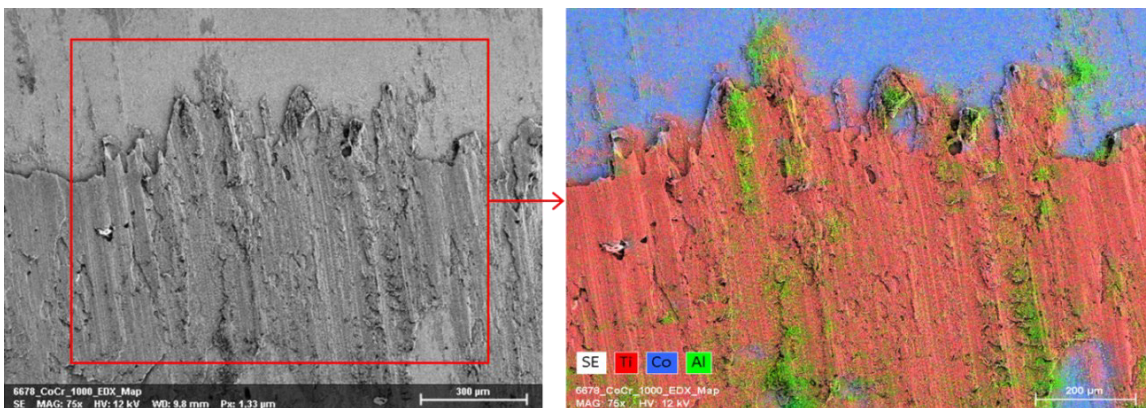


Abbildung 10: EDX Mapping auf einem explantierten CoCr-Kopf mit Auftrag aus Titan und Aluminium.

Tabelle 4: Detektierte Auftragsmaterialien (mehrere Elemente pro Kopf möglich).

Element	Häufigkeit H in %	Absolute H (n = 98)
Titan (Ti)	76.5	75
Kohlenstoff (C)	49.0	48
Eisen (Fe)	34.7	34
Chrom (Cr)	31.6	31
Niob (Nb)	23.5	23
Cobalt (Co)	16.3	16
Aluminium (Al)	12.2	12
Vanadium (V)	9.2	9
Nickel (Ni)	8.2	8
Sauerstoff (O)	7.1	7
Stickstoff (N)	6.1	6
Silizium (Si)	5.1	5
Molybdän (Mo)	4.1	4
Schwefel (S)	4.1	4
Magnesium (Mg)	3.1	3
Phosphor (P)	2.0	2
Kupfer (Cu)	1.0	1
Zirkon (Zr)	1.0	1
Calcium (Ca)	1.0	1

5 Diskussion

Drittkörperverschleiß kann in verschiedensten Formen auftreten und in der Gleitpaarung zu erheblichen Schädigungen führen. Dabei kann dieser während der Operation beispielsweise in Form von Abriebpartikeln von Knochen oder oszillierenden Sägen erzeugt werden oder auch im Körper durch Abrieb bei Mikrobewegungen oder ungewöhnlichen Belastungen des Gelenks (z. B. Dislokation) entstehen. Bei der Entwicklung neuer Gleitpaarungen bzw. neuer Materialien für künstliche Gelenke sollten diese daher möglichst resistent gegen den stärkeren Verschleiß im Falle von Fremdpartikeln sein. In den vorgelegten Arbeiten zur kumulativen Dissertation wurden Untersuchungen zur Quantifizierung des Verschleißes unter dem Einfluss von Drittkörperpartikeln im Hüftabriebsimulator durchgeführt. Dazu wurden sowohl neue Implantate genutzt [I] sowie Explantate, welche *in vivo* bereits Drittkörperverschleiß ausgesetzt waren [II]. Außerdem wurde Materialauftrag auf explantierten Hüftköpfen analysiert, um die Entstehung *in vivo* präziser beurteilen zu können [III].

5.1 Verschleißverhalten von Hüftendoprothesen unter dem Einfluss von Drittkörperpartikeln [I]

Keramische Gleitflächen gelten in der Hüftendoprothetik als abriebbeständiger als Gleitpaarungen mit metallischen Komponenten. Durch eine

Oberflächenbehandlung beispielsweise durch die Bestrahlung mit Stickstoffionen können die tribologischen Eigenschaften deutlich verbessert werden, sodass ähnliche Abriebraten wie bei keramischen Köpfen erreicht werden können [53]. Die Zugabe von Drittkörperpartikeln aus Knochenzement erhöhte den Abrieb der genutzten PE-Inserts, gepaart mit ionenbehandelten CoCr-Köpfen und Köpfen aus Al₂O₃-Keramik, um das Achtfache. Es zeigte sich kein signifikanter Unterschied zwischen den Abriebraten der beiden Gleitpaarungen. Auch bei der mikroskopischen Betrachtung der Inserts zeigten sich die gleichen Abriebspuren. Bei der mikroskopischen Analyse der Köpfe wiesen die CoCr-Köpfe eine deutlich zerkratzte Oberfläche auf, während auf der Keramik nur leichte Ausbrüche entlang einer Linie zu sehen waren. Daher sind die Keramikköpfe trotz ähnlicher PE-Abriebraten als resistenter gegen Drittkörperverschleiß einzuordnen. Die Rauheitsmessung ergab eine leichte Glättung der Kopf-Oberfläche unter dem Einfluss der Drittkörperpartikel. Dies unterstützt auch die Aussagen aus der Studie von Heuberger et al. [56]. Die PE-Inserts zeigten bei erhöhtem Verschleiß auch eine erhöhte Oberflächenrauheit, vermutlich verursacht durch ein Pflügen der Partikel in die weiche Oberfläche. Der Wechsel des Rauheitsparameters R_{st} ins Negative weist auf Entfernung der herstellungsbedingten Rillen durch die Abriebpartikel hin. Manche Studien berichten über ein Implantatversagen infolge eines starken Verschleißes durch eingebettete Partikel [57359]. Im Zusammenhang mit den Ergebnissen dieser Studie kann geschlussfolgert werden, dass Drittkörperverschleiß die Lebensdauer eines Implantates *in vivo* deutlich herabsetzen kann.

In einer Studie von Grupp et al. [60] wurde in einem ähnlichen Versuch auch ein erhöhter Abrieb durch Drittkörperverschleiß festgestellt. Jedoch wurde dort ein dreimal höherer Abrieb als in dieser Studie erzielt, welcher durch Abweichungen im Studiendesign zu erklären sein könnte. Viele Studien untersuchten den Abrieb unter dem Einfluss von Drittkörperpartikeln. Jedoch wurden bei fast allen Tests unterschiedliche Prüfbedingungen gewählt. Da die Tests nicht genormt sind, wäre eine Offenlegung aller Testparameter wünschenswert. Ein Problem bei der Prüfung mit Drittkörperpartikeln stellt die Sedimentation der Partikel am Boden dar, welche bei der konventionellen Testung (nicht invers) am Hüftabriebsimulator nicht zu vermeiden ist. Daher wurden die Partikel durch ein vorheriges Einpressen in die PE-Gleitpaarung eingebracht (I). In anderen Arbeiten wird das Vorgehen oft nicht beschrieben. Daher sollte in zukünftigen Studien zum Drittkörperverschleiß neben denen durch die ISO 14242-1 [39] geforderten Informationen auch

Angaben zur Art, Größe und Konzentration sowie zur Einbringung der Drittkörperpartikel in den Abriebsimulator gemacht werden.

Des Weiteren ist zu erwähnen, dass die im Gelenkspalt vorkommenden Drittkörperpartikel aus einem Mix verschiedenster Materialien bestehen und nicht in reiner Form vorkommen [21] sowie eine stärkere Größenvariation zeigen, als die in Studien verwendeten Partikel [57,61]. Dabei hat jedes Material unterschiedlichen Einfluss auf den Verschleiß. Ebenso ist anzunehmen, dass die Partikel im Gelenkspalt verbleiben und dort unter der dauerhaften Belastung stetig kleiner gemahlen werden. Auch dies konnte in der vorliegenden Studie nicht berücksichtigt werden.

5.2 Verschleißverhalten von Hüftendoprothesen unter dem Einfluss von Materialauftrag [II]

Zur quantitativen Analyse des Verschleißverhaltens von Köpfen mit Materialauftrag wurden explantierte Köpfe mit aufgetragenem Material ähnlichen Ausmaßes und an ähnlicher Position verwendet. Um leichte Unterschiede in Expansion und Dichte auszugleichen, wurden die Köpfe im Abriebsimulator so platziert, dass sich der Auftrag stets in der Mitte des artikulierenden Bereiches befand. In dieser Studie konnte gezeigt werden, dass, auch unter dem Einfluss von Materialauftrag, größere Köpfe zu einem höheren Verschleiß der Gleitpaarung führen, was größtenteils mit der größeren Reibdistanz zu erklären ist [62]. Die PE-Inserts, welche gegen Köpfe mit Materialauftrag artikulierten, zeigten eine leicht erhöhte PE-Abriebrate mit deutlich höheren Standardabweichungen. Neben leichten Unterschieden der Dichte, des Auftragsmusters und der Ausbreitung des Auftrages können diese auch durch eine unterschiedliche Zusammensetzung des Auftragsmaterials bzw. der Auftragsschichten entstehen. Die nicht signifikante Abnahme des Auftragsbereiches während der Prüfung weist auf ein Abreiben der Schicht hin. Somit kann von einer weiteren Verteilung von freien Drittkörperpartikeln in der artikulierenden Gleitpaarung ausgegangen werden. Um dies zu überprüfen, könnten in zukünftigen Studien die Ionenkonzentration im Medium überprüft oder die Abriebpartikel mittels EDX-Analyse auf Drittkörper untersucht werden. Die Rauheitsmessung zeigte signifikant höhere Reibwerte der Oberfläche des Auftrages im Vergleich zur originalen keramischen Oberfläche. Auch hier sind wieder hohe Standardabweichungen zu verzeichnen, welche durch die oben genannten Gründe bedingt sein könnten. Diese Erkenntnisse werden durch die Studie von Kim et al. [8] bestätigt, welche bei größeren Auftragsbereichen eine Erhöhung der Oberflächenrauheit einhergehend mit einer

Erhöhung des Abriebs feststellten. Laut Kim et al. [8] und Dorlot et al. [27] hat die Anamnese der Patienten keinen Einfluss auf das Ausmaß des Auftrages. In nachfolgenden Studien sollte untersucht werden, welche Parameter Einfluss auf den Bereich des Materialauftrages haben. Da sehr dünne Schichten von Materialauftrag mit bloßem Auge kaum sichtbar sind, kann dieser, besonders bei gleichfarbigen metallischen Köpfen, nicht ausgeschlossen werden. Daher sollten bei jeder Revision von Pfanne oder Insert auch der Kopf gewechselt werden und umgekehrt [63,64].

5.3 Untersuchung des Materialauftrages auf explantierten Hüftendoprothesen-Köpfen [III]

In zahlreichen Studien wurde ein dunkel schimmernder Materialauftrag auf explantierten Hüftköpfen dokumentiert, aber nur in wenigen Studien detailliert für verschiedene Kopfmaterialien untersucht [8,15,17,18,24,32,28]. In vorliegender Explantat-Studie wurden nur Köpfe mit makroskopisch eindeutigem Materialauftrag untersucht und das zugehörige Implantatsystem, wenn möglich, mitbetrachtet. Dabei wurde der Auftrag nicht nur auf Köpfen verschiedenen Materials gefunden, sondern auch auf verschiedenen zugehörigen Implantatkomponenten. Für die Analyse wurden nur die explantierten Köpfe untersucht. Anders als in der Studie von Fredette et al. [55] wurde der Materialauftrag in dieser Studie hauptsächlich im Bereich des Äquators mit Ausläufern in die umliegenden Bereiche detektiert. In diesem Bereich wurde häufig ein Solid Patch beobachtet, welcher im Zuge wiederkehrender Dislokation durch Schaben des Kopfes über den Pfannenrand und anschließendem Verteilen der Abriebpartikel im Hauptbelastungsbereich entsteht. In Verbindung mit Keramik-Keramik-Gleitpaarungen wurden signifikant Random Patches gefunden. Diese bilden sich wahrscheinlich durch das Zermahlen von Drittkörperpartikeln zwischen den härteren Gleitoberflächen. Random Stripes konnten mit den Revisionsgründen Glutealinsuffizienz und Implantatbruch in Verbindung gebracht werden. Hierbei kann der Hüftkopf in der instabilen Gelenksituation in linearen Kontakt zum Pfannenrand treten.

Bei der EDX-Analyse konnten zahlreiche Elemente als Bestandteil des Auftrages detektiert werden. Auffallend war hierbei, dass es sich dabei nicht nur um Metalle handelt, wie vielen Studien zu finden [25,35,36,65]. Als häufigstes Auftragselement wurde Titan detektiert, welches eines der am häufigsten verwendeten Legierungselemente für endoprothetische Implantate darstellt. Bei nahezu der Hälfte aller untersuchten Köpfe wurde Kohlenstoff im Auftrag

nachgewiesen. Auch dies ist Teil verwendeter Legierungen in medizinischem Edelstahl und Bestandteil des Knochens sowie des umliegenden Gewebes. In Zusammenhang mit den Revisionsgründen konnten signifikante Zusammenhänge festgestellt werden. Beispielsweise trat Eisen in Zusammenhang mit Polyethylenverschleiß auf. Dabei zeigten die Gleitpaarungen oft einen stark vergrößerten Gelenkspalt, wodurch das Eindringen von Partikeln in die Gleitpaarung erleichtert wird. Bei einem untersuchten durchgeriebenen Insert könnte der Hüftkopf auch in Kontakt mit Fixierschrauben gekommen sein, bei welchen Eisen ein Legierungsbestandteil war. Im Zusammenhang mit der Partikelkrankheit wurde Sauerstoff im Auftrag nachgewiesen, welcher von freien Radikalen bei der biologischen Fremdkörperreaktion oder auch von oxidierten Metallpartikeln herrühren kann. Schwefel zeigte sich vermehrt bei septischer Lockerung. Hierbei kann der Schwefel aus Biofilm-bildenden Bakterien sowie aus deren mikrobiellem Schwefelkreislauf [66371], von Defensinen [72] oder aus dem Knochenzement [73] kommen. Vermehrt vorkommender Kohlenstoff auf Köpfen im Rahmen einer Sepsis kann aus den Biomolekülen der Entzündungsreaktion des umliegenden Gewebes stammen. Bei einem Fall mit periprothetischer Fraktur wurde Calcium als signifikantes Auftragsmaterial auf dem Hüftkopf nachgewiesen. Calcium kann durch Knochenfragmente als Drittkörperpartikel in den Gelenkspalt bzw. auf den Kopf gelangen. Wegen der hohen Probenvariabilität konnten viele dieser Zusammenhänge trotz der großen Gesamtanzahl untersuchter Hüftköpfe nur innerhalb sehr kleiner Gruppen festgestellt werden, weshalb in weiterführenden Studien eine größere Anzahl an Köpfen in die Untersuchung einfließen sollten. In der EDX-Analyse konnten lediglich einzelne Elemente detektiert werden, aber keine Verbindungen. Da das Material Schicht für Schicht aufgetragen wird, könnten tiefere Schichten eine andere Materialzusammensetzung aufweisen und somit weitere Aufschlüsse über den Vorgang des Materialtransfers liefern. Bei vielen der untersuchten Explantate liegen keine vollständigen Informationen beispielsweise über die Patientendaten, Implantationszeit, vorangegangene Implantate oder das Implantatmodell vor, weshalb diese Daten nicht in die Auswertung dieser Studie einfließen konnten. In der Studie von Fredette et al. [55] wurde nachgewiesen, dass es keinen Einfluss von Alter, Geschlecht, Gewicht oder Aktivität des Patienten auf das Ausmaß des Materialtransfer gibt. In vorliegender Studie wurden Explantate verwendet, bei welchen keine Informationen über das Erscheinungsbild der Auftragsmuster vor der Explantation vorlagen. Ein möglicher Materialauftrag während der

Explantation durch OP-Werkzeuge konnte nicht ausgeschlossen werden. Daher wäre bei weiterführenden Analysen eine intraoperative fotografische Dokumentation der Implantate vor deren Ausbau wünschenswert.

Hüftabriebsimulatorversuche sind als Testverfahren etabliert, um den Verschleiß neuer Implantatsysteme und Materialien präklinisch zu bewerten. Standardisierte Prüfparameter erlauben eine Vergleichbarkeit zwischen verschiedenen Implantatsystemen und Prüflaboren. Die Bedingungen *in vivo* können aufgrund der sehr komplexen Belastungen und Bewegungsabläufe jedoch nicht immer exakt abgebildet werden. Die Bewertung des Verschleißes *in vivo* kann jedoch durch die Analyse von Explantaten unterstützt und mit den *in vitro* Versuchen korreliert werden. Die durchgeführten Arbeiten belegen die Relevanz, den Drittkörperverschleiß in der präklinischen Implantatanalyse zu etablieren. Gerade die Analyse der Explantate macht deutlich, wie häufig Drittkörperpartikel *in vivo*, beispielsweise in Form von Materialauftrag, auftreten kann und bei Verschleißvorgängen im Körper berücksichtigt werden muss.

6 Zusammenfassung

Durch die steigende Zahl der muskuloskelettalen Erkrankungen steigt auch die Anzahl der Patienten, welche mit einer Endoprothese versorgt werden müssen. Von über 400.000 implantierten Gelenkendoprothesen pro Jahr beanspruchen Hüftendoprothesen mit ca. 227.000 Operationen den größten Teil. Die Hauptursache für eine Revision stellt die partikelinduzierte aseptische Lockerung dar. Daher ist das Ziel bei der Entwicklung neuer Gleitpaarungen die Minimierung des Abriebs. Der Eintrag von Drittkörperpartikeln *in situ* kann die Oberflächenrauheit sowie die auftretenden Gelenkkräfte und somit den Verschleiß der Gleitpaarung deutlich erhöhen. Diese können auf verschiedensten Wegen zwischen die artikulierenden Flächen gelangen, z. B. durch Mikrobewegungen in der Grenzfläche Knochen-Implantat bzw. Knochenzement-Implantat oder durch Abtragungen am OP-Werkzeug während der Implantation. Eine Art von Drittkörperpartikeln im Gelenkspalt stellt der Materialtransfer dar, welcher meist in Form von dunkel schimmernden Verfärbungen der Gleitfläche beschrieben wird. Dieser kann durch den Kontakt der Gleitfläche mit dem umliegenden Implantat beispielsweise bei einer Luxation der Hüftendoprothese entstehen. Versuche zur Quantifizierung des Verschleißes unter Drittkörperpartikeln bzw. unter Materialauftrag erfolgten bisher kaum standardisiert und über die Herkunft und die genaue Zusammensetzung des Materialauftrages ist bislang wenig bekannt.

Abriebsimulatorversuche stellen eine etablierte Methode zur präklinischen Bewertung dar. Dabei werden Implantate unter möglich physiologischen Bedingungen in einem Langzeitversuch getestet, um deren Verschleißbeständigkeit abzuschätzen. Hierbei wird unter Standardbedingungen getestet, welche das Gangbild widerspiegeln sollten.

Das Ziel der vorliegenden Arbeit war es, den Einfluss verschiedener Drittkörperpartikel auf Abrieb und Verschleiß von Hüftendoprothesen in standardisierten Abriebsimulator-Untersuchungen zu evaluieren und die den Materialtransfer auf explantierten Implantaten zu charakterisieren. Hierzu wurden in der ersten Studie ionenbehandelte CoCr- und Al₂O₃-Köpfe mit Drittkörperpartikeln aus Knochenzement in einem Abriebsimulator über fünf Mio. Zyklen belastet. Unter dem Einfluss der Knochenzementpartikel wurde ein achtfach höherer Abrieb erreicht als unter Standardbedingungen. Durch die Behandlung der CoCr-Köpfe mit Stickstoff-Ionen konnte eine erhöhte Beständigkeit gegen Drittkörperverschleiß ermittelt werden, jedoch zeigten sich die Keramiken als kratzresistenter gegenüber den Drittkörperpartikeln (I). In einer

weiterführenden Hüftabriebsimulator-Untersuchung wurden jeweils drei explantierte keramische Köpfe mit ähnlichem Materialauftrag mit jeweils 28 mm und 36 mm Durchmesser unter Standardbedingungen getestet. Auch hierbei zeigte sich eine deutlich höhere Abriebrate als unter Standardbedingungen. Die Gleitflächen zeigten auf den Transferflächen eine signifikant höhere Oberflächenrauheit. Zudem konnte nachgewiesen werden, dass der Auftrag im Laufe der Belastung abgetragen wird, was einen Eintrag von Drittkörperpartikeln in den Gleitpaarungspartner Polyethylen bedeutet (II). Um die Herkunft und die Zusammensetzung des Materialtransfers zu ermitteln, wurde die Zusammensetzung des Auftrages mittels EDX untersucht und die Ergebnisse mit den Auftragsmustern, dem Ort des Auftrags, der Art der Gleitpaarung und dem Revisionsgrund statistisch ausgewertet. Der Materialauftrag wurde hauptsächlich in der Äquatorregion des Auftrages lokalisiert. Die meisten Köpfe mit Materialauftrag wurden mit dem Revisionsgrund Polyethylenabrieb explantiert, welcher aufgrund erhöhten Verschleißes durch die Präsenz von Drittkörperpartikeln hervorgerufen werden könnte. Der Auftrag zeigte sich hauptsächlich in Form von Random Stripes, Random Patches und dem Solid Patch, welcher meistens in der Äquatorregion und signifikant bei Dislokationen zu finden war. Random Patches waren typische Auftragsmuster bei Keramik-Keramik-Gleitpaarungen. Die EDX-Analyse zeigte eine große Variation von Auftragsmaterialien. Dabei wurde Titan am häufigsten detektiert, wobei es sich dabei auch um das häufigste Legierungselement von hüftendoprothetischen Implantatsystemen handelt. Neben metallischen Bestandteilen, wurden auch nichtmetallische Elemente wie Kohlenstoff (auf 49 % der Köpfe) und Schwefel (auf 4,1 % der Köpfe) gefunden. Dabei konnten allen Elementen eine mögliche Herkunft zugeordnet werden. Da mittels EDX jedoch nur eine Analyse einzelner Elemente möglich ist, sollte eine zukünftige Untersuchung zur Ermittlung der Elementverbindungen weitere Erkenntnisse liefern. Weitere Informationen könnten zudem durch die Durchführung von Langzeitstudien mit Dokumentation der Patientendaten, des Implantationszeitraumes, des Implantationsprozesses sowie der Revision liefern (III).

In dieser Arbeit wurde der gesteigerte Verschleiß von Gleitpaarungen im Hüftsimulator unter dem Einfluss verschiedener Drittkörperpartikel deutlich. Daher wird die Untersuchung neuer Gleitpaarungsmaterialien unter dem Einfluss von Drittkörperpartikeln im Rahmen der präklinischen Abriebtestung empfohlen.

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Abkürzungsverzeichnis

Al ₂ O ₃	Aluminiumoxid
ATZ	Alumina-Toughened Zirconia (Aluminiumoxid verstärkte Zirkonoxidkeramik)
CoCr	Kobalt-Chrom-Legierung
EDTA	Ethylendiamintetraessigsäure
EDX	Energiedispersive Röntgenspektroskopie
Mio.	Million
NaN ₃	Natriumazid
PE	Polyethylen
Ra	Arithmetischer Mittenrauwert
Rsk	Schiefe
Rz	Rautiefe
REM	Raster-Elektronen-Mikroskop
ZrO ₂	Zirkonoxid
ZTA	Zirconia-Toughened Alumina (Zirkonoxid verstärkte Aluminiumoxidkeramik)

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Wear analysis of cross-linked polyethylene inserts articulating with alumina and ion-treated cobalt-chromium femoral heads under third-body conditions

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ABSTRACT

Aseptic implant loosening due to wear debris is the main cause of revision of total hip replacement. Since the presence of third-body particles in the joint gap can lead to highly increased amount of wear, the aim of this study was to evaluate wear of hard-on-soft couplings under third-body wear conditions.

For this, alumina ceramic and nitrogen ion-treated cobalt-chromium femoral heads were coupled with sequentially cross-linked polyethylene inserts in a hip joint simulator following ISO 14242-1. Bone cement particles containing zirconium dioxide were added. After 5 million cycles, the amount of wear on the inserts was determined gravimetrically and compared to the amount of wear without third-body particles. The abrasion at the joint components was evaluated by digital microscope.

The mean gravimetric wear rates of the polyethylene inserts under third-body wear conditions measured 16.57 ± 5.98 mg per million cycles when coupled with nitrogen ion-treated CoCr heads and 15.14 ± 3.30 mg per million cycles with alumina ceramic heads. The results revealed no significant differences between the material pairings. The amount of wear was approximately eight times higher in both cases than that resulting under standard wear test conditions. In the microscopic analysis, the ceramic femoral heads showed higher resistance against abrasive third-body wear.

1. Introduction

The main cause of total hip revision is aseptic implant loosening due to particle-induced osteolysis, which is initiated by abrasive wear particles [1,2]. Third-body wear in particular increases the amount of wear of the polyethylene components and accelerates the effect of osteolysis [3]. Moreover, the third-body particles directly transfer increased frictional forces to the artificial implant junction, which leads to a higher loading at the implant-bone interface [4]. One possible method of reducing wear debris is to use low-wear bearings like hard-on-soft bearings, as successfully proven in experimental studies in recent years [5,6]. These studies revealed better frictional properties and less wear when using ceramic-on-polyethylene bearings compared to metal-on-polyethylene bearings [7,8]. Moreover, by using biologically inert and scratch-resistant materials like ceramic implants, the incidence of allergic reactions to metallic, abrasive wear particles can also be reduced [7–11].

By increasing the surface hardness of cobalt-chromium femoral heads, the amount of wear debris can be reduced [12]. In a wear simulator study by Fabry et al. [13], similar amounts of wear were reached when analysing ion-treated CoCr vs. Al₂O₃ ceramic heads,

both articulating with polyethylene inserts.

Due to third-body particles in the joint gap, there is likelihood of abrasion of the joint being highly intensified [9,14,15]. The third-body particles can originate from different materials, mainly from bone and bone cement, but also from metallic or ceramic components, and be induced by different causes [16–18]. For instance, these particles can be generated during implantation of the total hip endoprosthesis, by implant fractures or by relative motion between the bone-implant interface [17–19]. The size of the bone cement particles found during total hip revision and removing is rarely examined, and varies from a few microns to over 1 mm [20]. Lundberg et al. [21] found third-body particles of approximately 50–500 μm or more embedded in explanted acetabular polyethylene inserts.

There are many standard hip simulator tests, but only a few under third-body conditions [8,13,22]. Mostly, the studies are not comparable, since they work with different particles, materials or loads [15,23–25]. One major problem is introducing and keeping the third-body particles between the bearing surfaces [16]. To prevent sedimentation of the particles on the floor of the testing chambers, contaminated lubricants or roller pumps were used [24–27]. All studies show an increase in abrasion [15,24,27]. Some studies provide only

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limited information about how and where exactly the third-body particles were introduced into the artificial hip joint. In the present study, therefore, the application of these particles and its influence on the test results shall be elaborated upon. Furthermore, abrasion behaviour of ion-treated CoCr heads under third-body conditions has not been investigated so far.

Hence, the aim of the present study was to measure the amount of wear of cross-linked polyethylene inserts under third-body conditions, i.e. bone cement containing zirconium dioxide was added to the articulating surface with ion-treated CoCr as well as to that with Al₂O₃ ceramic femoral heads.

2. Material and methods

2.1. Test specimens

For the wear test, Trident® PSL uncemented acetabular cups (Stryker GmbH & Co. KG, Duisburg, Germany) were used. Acetabular cups with an outer diameter of 56 mm and suitable sequentially cross-linked polyethylene inserts were combined with 36 mm femoral heads made of ceramic (Alumina Ceramic C-Taper Femoral Head) and nitrogen ion-treated Co28Cr6Mo (LFIT™ Anatomic C-Taper Femoral Head). The polyethylene inserts (Trident® X3®) were sequentially cross-linked with compression-moulded resin sheets out of GUR 1020 by irradiating with 3 MRads, followed by annealing the components below the melting point. The process of irradiating and annealing was repeated three times [28]. The inserts were pre-soaked in the test fluid bovine serum (Biochrom GmbH, Berlin, Germany) with a protein concentration of 30 g/l, ethylene diamine tetra acetic acid (EDTA) and sodium azide (NaN₃), for eight weeks. The implants used and their respective quantity are shown in Fig. 1.

2.2. Hip simulator test and wear measurement

The wear tests were performed in a standard hip simulator (Endolab GmbH, Rosenheim, Germany) using three dynamic stations for each material combination, and one additional axial loaded soak control in order to validate the liquid absorption of the inserts. The soak control is loaded only statically with the axial load of the ISO standard. The change of the weight is only due to the fluid absorption from the lubricant of the insert. No wear occurs to the soak controls. The recorded saturation of the fluid is subtracted from the gravimetric measurement of the dynamically loaded inserts. Hence, the weight loss of the dynamically loaded inserts is only caused by abrasive wear. The loading and motion were applied on the test inserts according to ISO 14242-1 (2014) [29]. The standard defines the kinematics of the hip joint during

normal gait, containing axial loading between 0.3 and 3 kN and movements of extension/flexion between - 18° and 25°, of abduction/adduction/ between - 4° and 7° and of external and internal rotation between - 10° and 2°. As described in the standard [29], the samples were articulated in bovine lubricant with a protein content of 30 g/l for 5 × 10⁶ cycles at a frequency of 1 Hz and in temperature controlled (37 ± 2 °C) chambers. Every 500,000 cycles, the lubricant was changed and the wear of the inserts was gravimetrically detected with a high precision balance (Sartorius ME235S, Sartorius AG, Göttingen, Germany) according to ISO 14242-2 (2016) [30]. Along with the measured weight of wear and the density of the sequentially cross-linked polyethylene (0.9392 g/cm³ [28]), the volumetric wear of the insert was also calculated. The test implants were changed periodically between the running stations to prevent station-conditioned influences.

In contrast to the standard test conditions described in ISO 14242-1 [29], in this study, third-body particles of bone cement were added to the articulating surface. Sedimentation of the third-bodies was prevented by slight indentation into the liner before wear testing. The results of this study were compared with the wear rates determined by our previous study [13], in which the same implants were tested under standard test conditions without third-body particles.

2.3. Third-body wear particles

The third-body wear particles used, were made of bone cement PalacosR® (Heraeus Medical GmbH, Wehrheim, Germany), which consists of 84.5% methylmethacrylate copolymer, 0.5% benzoylperoxide and 15% zirconium dioxide [31]. For manufacturing the particles, the liquid and the powder components were mixed and spread out thinly at room temperature. After 10 min, the bone cement was completely polymerised and subsequently smashed for one minute in an oscillating mill (MM2; Retsch GmbH, Haan, Germany). To get the desired particle size of 100–200 µm, the resulting powder was sifted through two metal grids with 0.1 mm and 0.2 mm mesh openings. This range of particle size was chosen in accordance with the studies of Grupp et al. [15] and Affatato et al. [25]. Finally, the particle sizes were verified with a laser scanning microscope (LSM VK-X250, Keyence Deutschland GmbH, Neu-Isenburg, Germany). Furthermore, investigations with energy dispersive X-ray spectroscopy (Fig. 2) proved that no metallic wear particles of the oscillating mill were mixed with the bone cement ones (Field Emission Scanning Electron Microscope Merlin V compact; Carl Zeiss AG, Oberkochen, Germany).

According to Grupp et al. [15], a particle concentration of 5 g/l was added to each testing cycle, leading to a total weight of 1.75 g of third-bodies in each 350 ml testing chamber, as determined with a high precision balance (Sartorius ME235S, Sartorius AG, Goettingen,

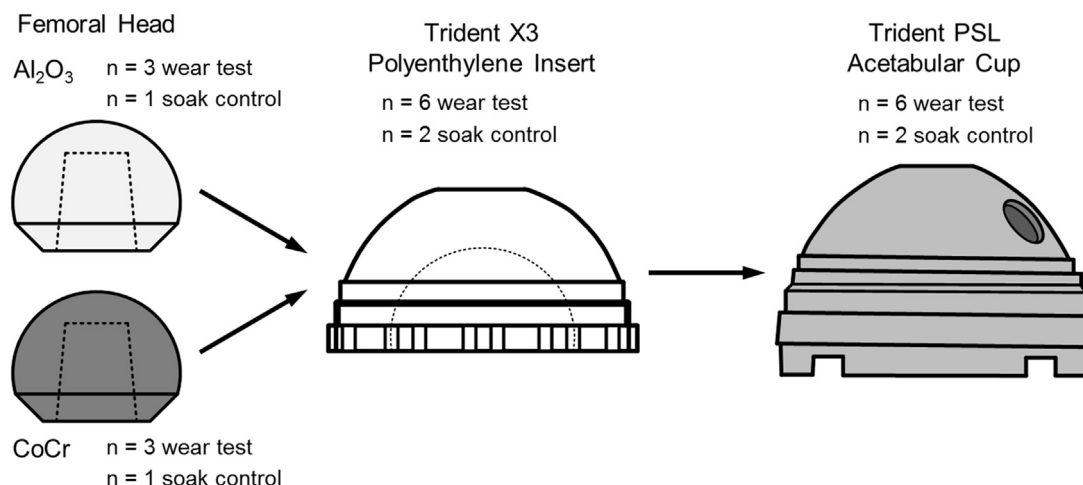


Fig. 1. Implant components used for hip simulator test.

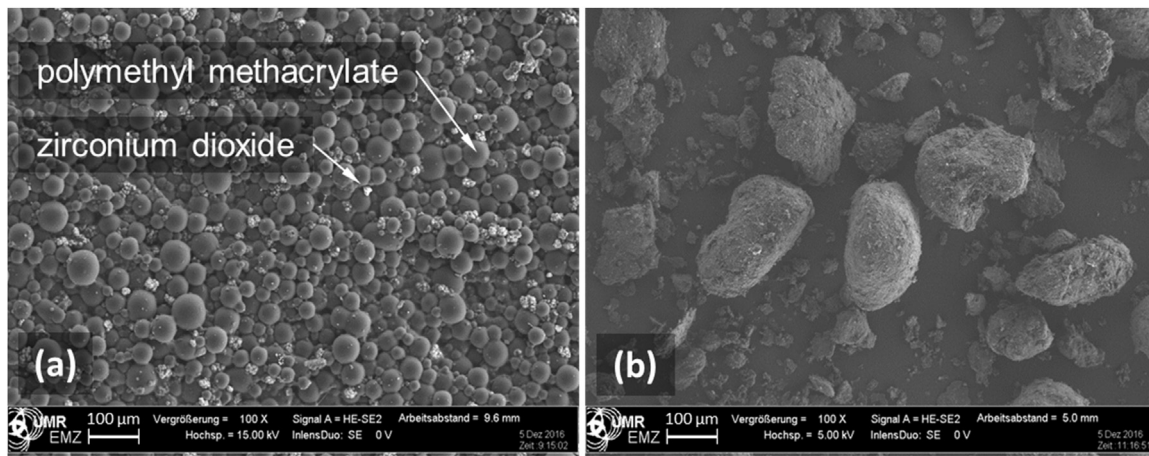


Fig. 2. Third-body particles; (a) surface of polymerised bone cement with zirconium dioxide, (b) third-body particles after grinding and sifting; magnification 100x.

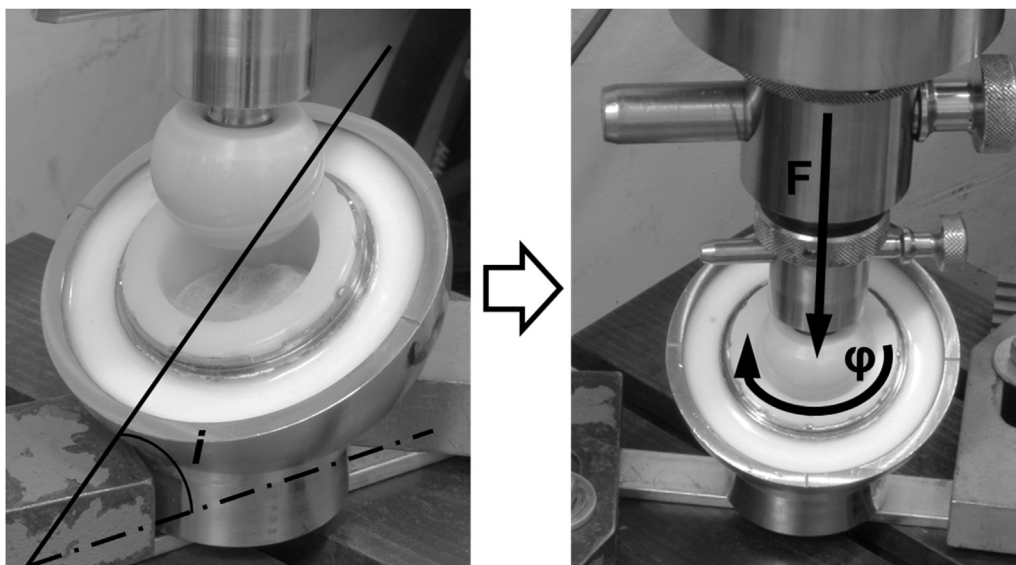


Fig. 3. Application of the third-body particles between the bearing surfaces; inclination $i = 30^\circ$, axial load $F = 300$ N with 30° rotation ϕ .

Germany) [15]. To prevent sedimentation in the testing chambers, the particles were lightly rubbed into the inserts before wear simulator test by using a dynamic testing machine (Instron 8874, 40 Nm (30 lb-ft), Instron GmbH, Darmstadt, Germany). Therefore, 10% of the third-body particles (0.17 g) were placed in the inverse positioned insert with an inclination of 30° and loaded axially with a ceramic head applying 300 N. This force value corresponds to the lowest force to be applied to the testing, as defined by ISO 14242-1 [29] (Fig. 3). Simultaneously with the axial loading, a rotation movement of 30° was applied to the system. The inserts were positioned in the acetabular cup at an inclination angle of 30° , corresponding to the high loaded position during the wear simulator test. The remaining third-body particles were scattered into the articulation surfaces during assembly of the testing chamber. The third-body particles were changed simultaneously with lubrication every 500,000 cycles.

2.4. Surface analysis

After 5 million test cycles, the implant components were cleaned and analysed optically with a digital microscope (VHX – 900F, Keyence Deutschland GmbH, Neu-Isenburg, Germany).

The roughness measurement of the surfaces was done with a confocal laser scanning microscope (LSM, VK-X250, Keyence Deutschland GmbH) and in accordance with DIN EN ISO 4288:1998 [32] and DIN

EN ISO 3274:1998 [33]. For the evaluation, the articulating surface was selected. The maximum height R_z , the arithmetic average roughness R_a and the skewness R_sK were determined. For roughness measurement, four sections of measurement on the areas of wear were used on each of the four samples respectively. In the soak controls the measurements were made on peripheral sample areas. The roughness values of the test samples were measured.

2.5. Statistical analysis

The statistical analysis was conducted with IBM® SPSS® (Statistics version 20, IBM Corporation, New York, USA). To compare the wear rates of the inserts articulated against metal and ceramic heads as well as the roughness values, the independent t -test was applied. P-values of < 0.05 were considered significant. The presented data are shown as mean values and standard deviation.

3. Results

3.1. Wear rates

The mean amount of gravimetric wear from third-body particles and standard test conditions for the sequentially cross-linked polyethylene combined with metallic and ceramic heads are presented in Fig. 4. Both

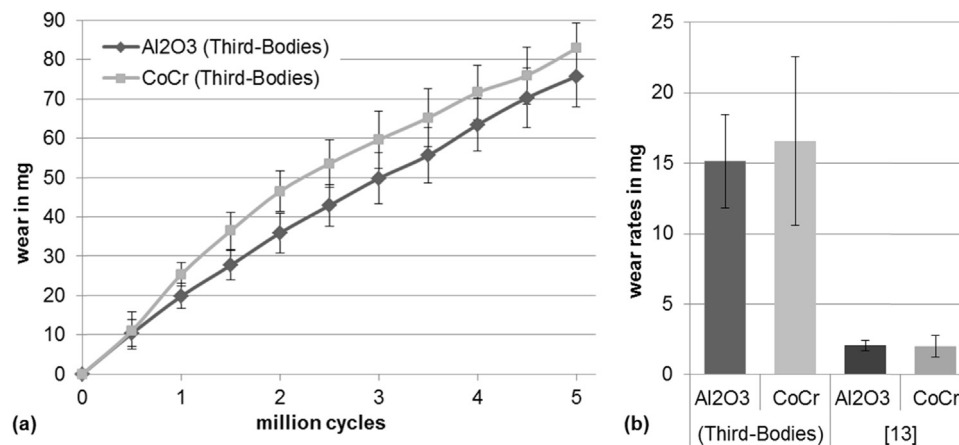


Fig. 4. Mean gravimetric wear of the sequentially cross-linked polyethylene inserts combined with 36 mm diameter femoral heads of alumina ceramic and CoCr modified with nitrogen treatment; (a) under third-body conditions, (b) wear rates per million cycles with and without third-body particles.

graphs increase almost linearly every 500,000 cycles (Fig. 4(a)), whereby the wear of the inserts articulated against CoCr heads (total wear of 82.84 ± 6.4 mg after 5 million cycles) is slightly higher than the wear of the inserts articulated against ceramic heads (total wear of 75.69 ± 7.82 mg after 5 million cycles). The wear rate of the polyethylene inserts using CoCr was 16.57 ± 5.98 mg per million cycles in comparison to the wear rates inserts using the ceramic heads, which was 15.14 ± 3.30 mg. The differences were not statistically significant ($p = 0.433$). Also, in our previous work [13], no significant differences between the two hard-soft bearings could be determined. The influence of the third-bodies is clearly shown. The abrasive wear with third-body conditions is eight times higher in both material couplings. Because bone cement particles could not be detected in the polyethylene inserts after the cleaning process, any influence of third-bodies on the gravimetric wear measurement can be excluded.

3.2. Microscopic analysis of the implant components

At the end of the hip simulator test, the CoCr and the ceramic femoral heads as well as the polyethylene inserts showed matted surfaces consisting of very small scratches on the articulating surfaces.

All test inserts of cross-linked polyethylene showed ridges, scratches and elliptical tracks along the direction of movement of the femoral head, as well as pitting and polished areas (Fig. 5). There is no distinct difference between the inserts articulated with CoCr or ceramic, as seen in Fig. 5(a) and (b). In contrast to the inserts, the femoral heads show different traces of abrasion. While the metallic femoral heads mainly have deep and wide scratches along the direction of movement (Fig. 6(d)), the ceramic heads only show some pitting in the form of grain outbursts along a line (Fig. 6(b)). In general, the ceramic heads have the least damage under third-body wear conditions, whether at a microscopic or macroscopic level.

3.3. Roughness analysis of femoral heads and hip inserts

The roughness parameters R_z , R_a and R_sK of the articulating surfaces of heads and inserts in the loaded and unloaded state after 5 million cycles are shown in Table 1 and in Figs. 7 and 8.

There are no statistically significant differences in the determined parameters of the ceramic and metal femoral heads. However, the diagrams show a significant decrease in all roughness parameters between the unloaded and loaded areas after 5 million cycles (Fig. 7).

The inserts also show a significant increase in maximum height R_z after dynamic loading in the hip wear simulator. The arithmetical average roughness R_a also tends to rise, but not significantly. The skewness R_z changes from the positive to the negative range. The

inserts articulated with metallic heads show higher values of all parameters than insert articulated with ceramic femoral heads. The differences found are not statistically significant (Fig. 8).

4. Discussion

Femoral heads made of ceramic or metal are established bearing materials in total hip arthroplasty [7,34]. In general, the ceramic-on-polyethylene pairing is considered to interact with lower friction than the metal-on-polyethylene pairing, and hence produce less abrasive wear [7]. However, a surface treatment of the metallic femoral heads can improve the frictional force and also reduce abrasive wear [13,35]. This also applies to surface treatment with ions [7,8]. For the pre-clinical evaluation of new implants and to determine the influence of different parameters on the implant system to be tested, standard hip wear simulator tests are suitable [36,37]. It is easy to realise the direct comparison of implant systems or external influences on the system via the standard test [37,38]. Although the basic conditions of such studies are determined by the ISO standards, variations within those limits are possible.

The aim of the present study was to determine the influence of third-body particles made from bone cement on the abrasion of total hip replacements. Fabry et al. [13] have shown that there was no significant difference between the emerging wear rates of sequentially cross-linked PE-inserts articulating with nitrogen ion-treated CoCr heads (2.02 ± 0.75 mg per million cycles) or with alumina ceramic heads (2.04 ± 0.38 mg per million cycles). Since an identical simulator and the same test conditions were used in the present study and in the study of Fabry et al. [13], comparability of both studies is given. Therefore, we applied third-body particles for wear testing using identical bearing materials and designs as described in Fabry et al. [13]. Due to the influence of third-particle bodies, the amount of abrasion wear increased eight-fold to 16.57 ± 5.98 mg per million cycles for metal-on-polyethylene and 15.14 ± 3.30 mg per million cycles for ceramic-on-polyethylene.

Other studies revealed an enormous increase of wear under third-body conditions [15,16,25,27,39]. Grupp et al. [15] researched similar test conditions and third-body conditions (bone cement PalacosR®, 5 g/l per testing chamber). In their study, substantial influence of the bearing materials was shown. They determined a wear rate of metal-on-polyethylene of up to three times higher (35.8 mg per million cycles) than in this study. On the other hand, there was a lower level of abrasion on ceramics (5.9 mg per million cycles).

Many third-body wear studies had a similar experimental test setup, but used different test parameters [15,16,25,27,39]. A major problem is sedimentation of the third-body particles on the bottom of the testing

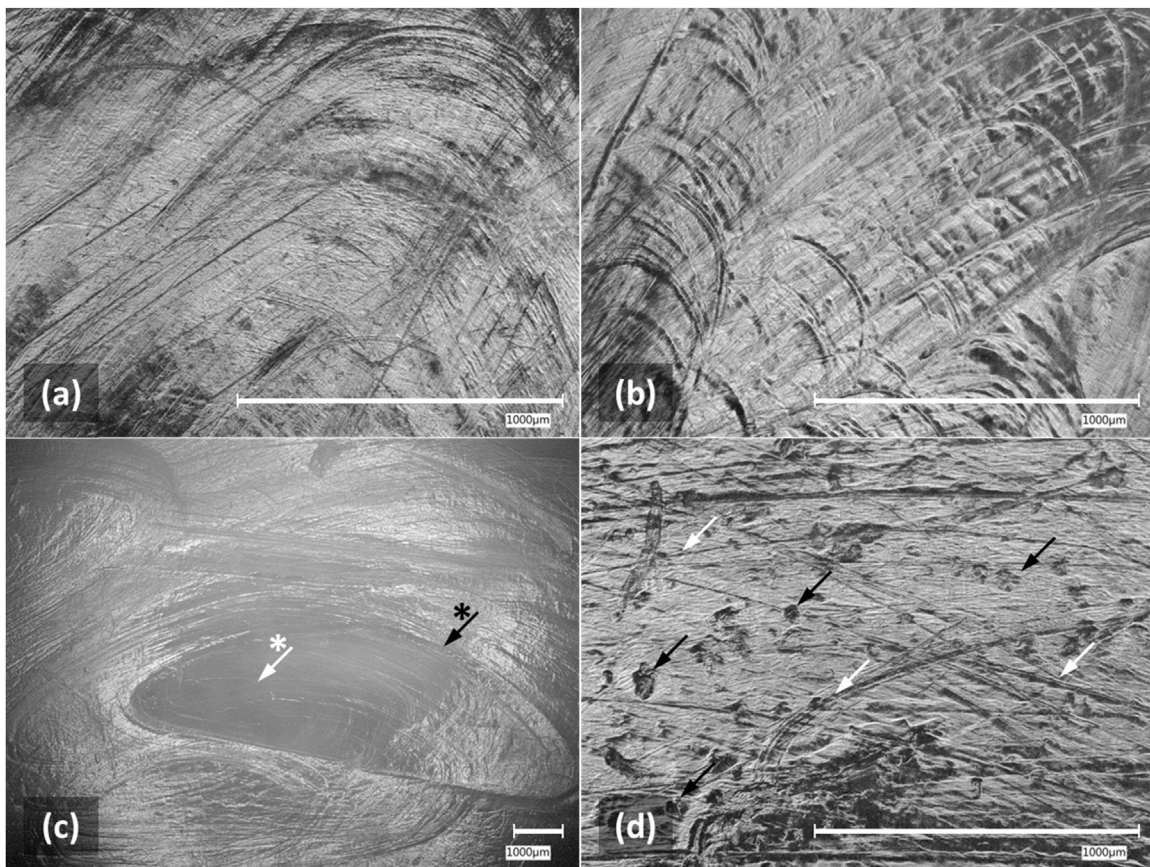


Fig. 5. Signs of wear of the inserts; (a) insert articulated against ceramic femoral head, (b) insert articulated against metallic femoral head, (c) white arrow with asterisk shows a polished area in an elliptical track (black arrow with asterisk), (d) surface with pitting (black arrows) and scratches (black arrows).

chamber. In conventional (non-inverse) hip wear simulators the sedimentation must be prevented, because particles that have settled cannot contribute to wear propagation. In order to enable comparability of the results of our third-body wear study, the third-body conditions were adapted to the study of Grupp et al. [15]. Compared to our study, Grupp et al. [15] used the same bone cement with similar particle size and particle concentration and the experimental trials were carried out according to ISO 14242-1 for 5 million cycles in a hip wear simulator. Similar particle size and similar experimental design according to the standard were also used in the study of Affatato et al. [25]. Certainly, this study used a different particle concentration as well as a shorter running time of the simulator. Therefore, direct comparison of our results with the results of the study of Affatato et al. [25] is not possible. The particle concentration in clinical setting has not been determined so far. Hence, an investigation would be worthwhile, for standardisation of the test parameters and better comparability of third-body studies with each other.

However, the study of Grupp et al. [15] did not describe in detail how the third-body particles were applied into the joint gap. In the study of Affatato et al. [25] the third-body particles were added to the bovine calf serum. Neither study described how sedimentation of the third-body particles was avoided. In our present study sedimentation was prevented by slight embedding of the particles in the PE-inserts. The large differences in the wear rates found between our study and the study of Grupp et al. [15] can be attributed to the application of the third-body as well as to the bearing materials used.

A limitation of our study was that wear tests using CoCr heads with same design without nitrogen ion treatment were not performed. Therefore, we were not able to point out the differences in wear propagation under third-body conditions between CoCr heads with and without nitrogen ion treatment. A retrieval study of McGrory et al. [35]

shows a higher surface hardness and lower friction parameter of retrieved ion treated CoCr femoral heads. This leads to the conclusion that material pairings with ion treated CoCr heads are more wear-resistant than CoCr heads without ion treatment [35].

A second limitation of the present study is the chosen particle size of 100–200 µm, because there is a different size distribution (5 to over 500 µm [20,21]) in vivo. As required in ISO 14242-1 [29], the lubricant was changed every 500,000 cycles. For comparability of the results over 5 million cycles and for better comparison with Grupp et al. [15], the particles were also renewed with the liquid. It is to be assumed that the particles are further reduced in size by the friction forces in the joint gap. This effect is prevented by the substitution of the particles. Studies show that the size of the third-body particles has an influence on the wear of the friction partners. Larger particles cause greater damage [19,45]. It can be assumed that existing third-body particles in the joint space become smaller over time due to continuous friction. Therefore, further investigations to determine the influence of the loading duration on the third-body particle size and on wear are recommended.

Another limitation is the material of the third-body particles used. As described by De Baets et al. [17] and Niki et al. [18], third body particles generated during total knee arthroplasty are mainly a mixture of bone, bone cement and metal. Similar studies which investigate the particles in the lavage after a total hip arthroplasty are difficult to find. Accordingly, there is also a lack of information about the size distribution of the particles generated during hip surgery. In this study, third-body material was restricted to bone cement to maintain comparability to the study of Grupp et al. [15].

The same limitation of using only a single type of particle is realised in every study investigating the influence of third-body particles. Furthermore, even studies using third-body particles of the same material are often not comparable, because of the different size

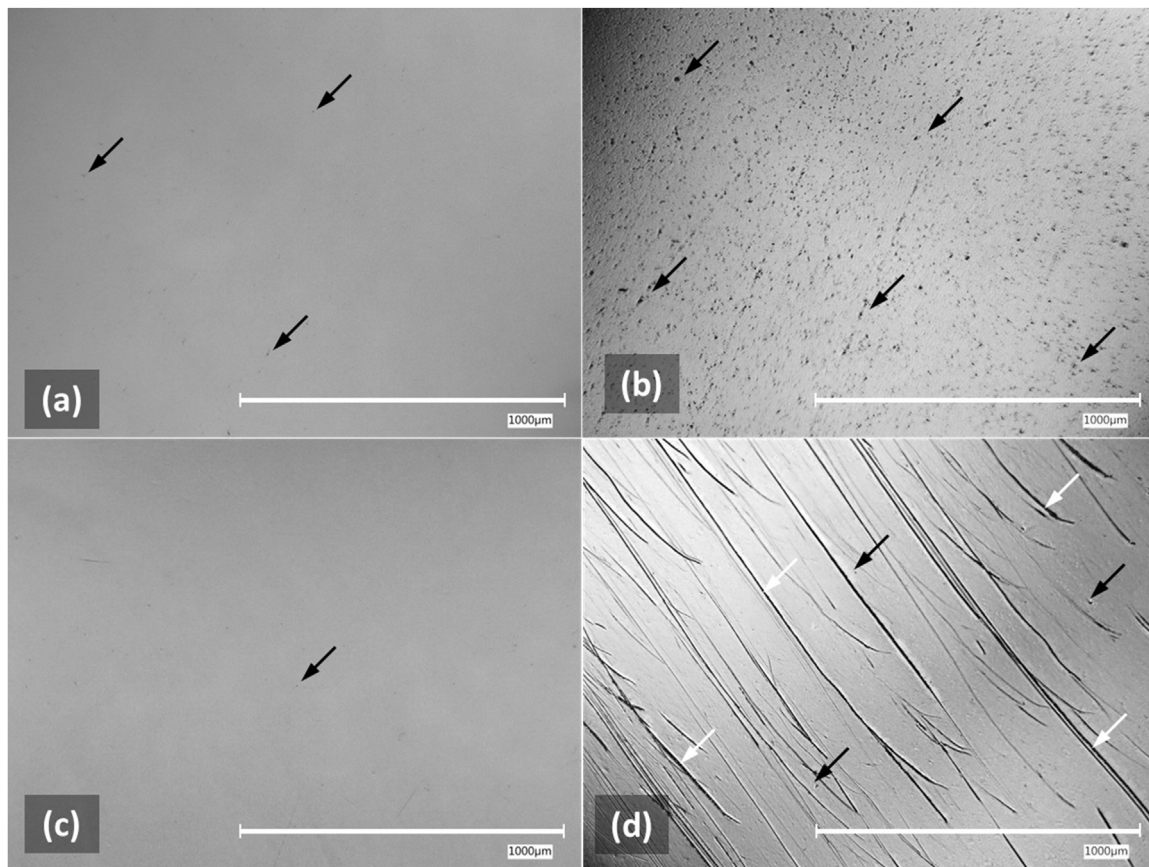


Fig. 6. Surfaces of the femoral heads: (a, b) surfaces of the ceramic femoral heads, (c, d) surfaces of the metallic femoral heads, on the left heads articulated with the soak control, on the right heads articulated with the dynamic loaded test inserts with wear pattern of pitting (black arrows) and scratches (white arrows).

Table 1
Averages of roughness parameters Rz, Ra and Rsk in micrometres for heads and inserts.

		femoral heads		polyethylene inserts	
		soak control	test samples	soak control	test samples
Rz	ceramic	2.096 (± 0.788)	1.163 (± 0.124)	4.463 (± 1.826)	6.396 (± 3.852)
	metal	2.091 (± 0.787)	1.360 (± 0.335)	9.690 (± 7.776)	0.995 (± 0.815)
Ra	ceramic	0.374 (± 0.110)	0.307 (± 0.045)	0.942 (± 0.387)	1.732 (± 1.672)
	metal	0.377 (± 0.110)	0.329 (± 0.047)	0.906 (± 0.418)	−0.451 (± 0.449)
RsK	ceramic	1.463 (± 0.615)	0.848 (± 0.144)	−0.421 (± 0.691)	
	metal	1.462 (± 0.613)	0.860 (± 0.123)		

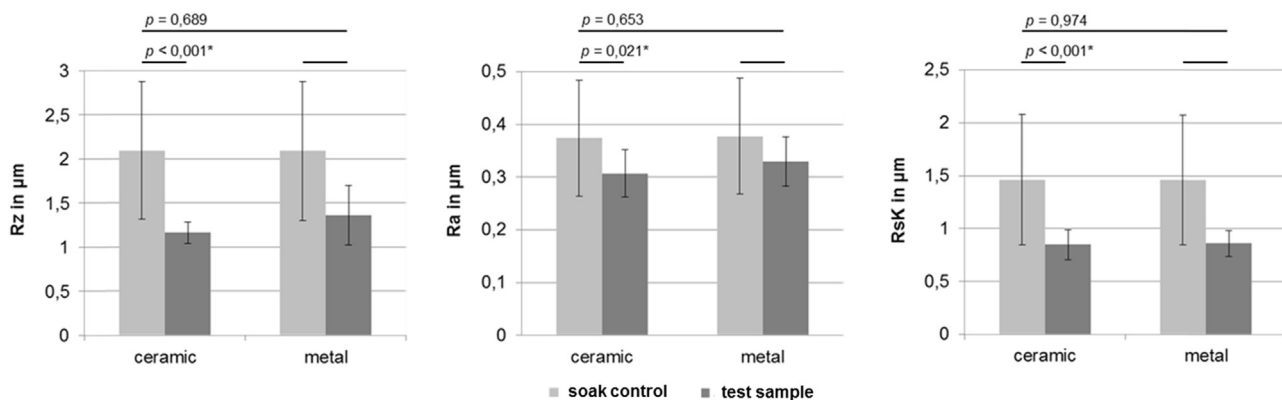


Fig. 7. Mean values of Rz, Ra and Rsk of the articulating surfaces of the heads; the measurements of the soak controls were made on four new heads per material with four measuring sections respectively. The roughness values of the test samples were determined with four measurements each on the wear areas of all three samples.

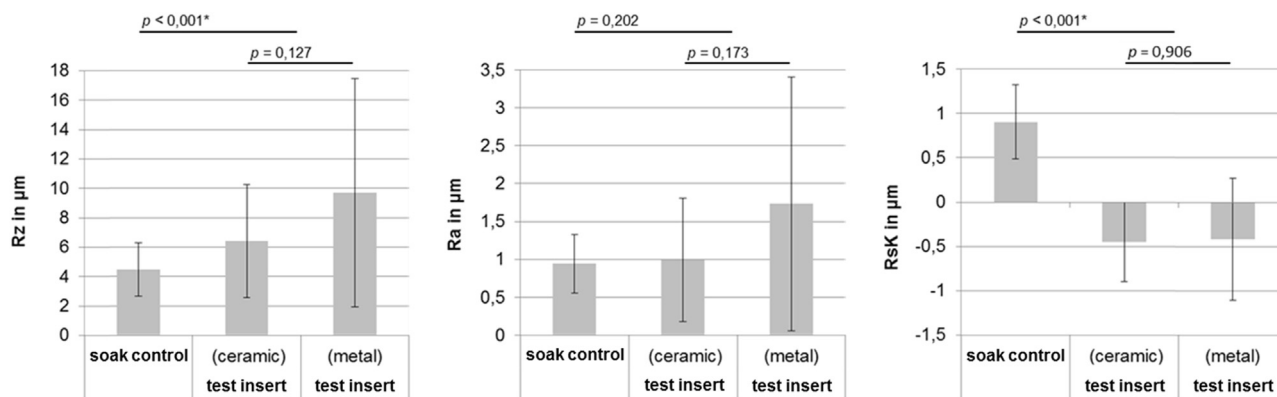


Fig. 8. Mean values of Rz, Ra and RsK of the articulating surfaces of the inserts; for the control, sixteen measurements were performed on an unused insert. The roughness values of the tested implants were determined with four measurements each on the wear areas of all three inserts.

distribution and quantity of the particles, other applied loads or the different application of the particles [15,19,23,24].

Although we could not show a significant influence of the material coupling on wear rate in our present study, the data from optical examination revealed large differences. The femoral heads made of ceramics only had pitting, whereas the surfaces of the ion-treated metallic heads were significantly damaged, with deep scratches and ridges. This means that the metallic femoral heads may show more abrasive wear in the long-term. In contrast, ceramic femoral heads are more resilient against scribing stress under third-body wear conditions. However, roughness measurement with laser scanning microscope can change the surface structure of the measured objects due to laser radiation.

Therefore, the investigation of the articulating surfaces could only be carried out after finishing the wear test over five million cycles. Soak control samples were used as comparative surfaces. Since no particles could be found on the surfaces with the microscope, it is assumed that all particles could be removed by cleaning. All femoral heads show reduced values of roughness parameters after five million cycles. This indicates smoothing of the surfaces by polishing ceramic and metal heads. There are no significant differences between the metal and ceramic femoral heads after the wear test. This leads to the conclusion that the scratches detected with the digital microscope on the metallic heads are not relevant for the increased wear values. The inserts show a significant increase in maximum height Rz after five million cycles, which indicates a roughening of the articulated surface of the inserts. The change in the RsK value from positive to negative indicates the reduction of roughness peaks, and is caused by the removal of milling structures of the inserts during the manufacturing process.

Most retrieval studies show a significant roughening of the articulating surfaces, especially of CoCr femoral heads, by the addition of third bodies [40–43]. This is mainly caused by ploughing of the particles [42]. According to Zietz et al. [16], the cyclic motion of the surfaces may lead to roughening or, as in this work, to smoothing of the bearing surfaces. Furthermore, in the study of Heuberger et al., smoothing of the surfaces of the femoral heads and inserts was detected [44]. However, this is also an experimental study, in which other influences can lead to smoothing of the upper surfaces.

In clinical settings, third-body particles are a major problem cause of wear propagation in total joint arthroplasty. Retrieval studies showed prevalent failure of hip endoprostheses due to embedded particles [21,46,47]. Therefore, more experimental studies with third-body particles should be conducted to simulate the clinical situation and to predict wear performance of the implants in vivo. In this context, standardisation of preclinical third-body studies should be attempted.

5. Conclusions

In the present study, the influence of third-body wear particles (bone cement containing zirconium oxide) on two different hard-on-soft bearings in the hip wear simulator was investigated. The following conclusions could be drawn:

1. The presence of third-body particles between the implant components significantly increases abrasive wear, which in turn can reduce the durability of the endoprosthetic implant.
2. Scratch resistance and wear resistance of metallic femoral heads can be increased by hardening the CoCr surface using nitrogen ion treatment.
3. Due to the higher resistance to scratch stress, ceramic femoral heads are less susceptible to third-body wear conditions.

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Article

Influence of Metallic Deposition on Ceramic Femoral Heads on the Wear Behavior of Artificial Hip Joints: A Simulator Study

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Abstract: Several retrieval studies have reported on metallic depositions on ceramic femoral heads, but the effect on the wear behavior of artificial hip joints has not been investigated in wear simulator studies. In the present study, retrieved ceramic heads with metallic depositions as third particles were tested against cross-linked ultra-high-molecular-weight polyethylene (UHMWPE) liners in a hip wear simulator. The amount of liner wear and expansion of metallic depositions on the heads were determined before and after wear testing with digital microscopy. The surface roughness of the heads was investigated in areas with and without metallic depositions by laser scanning microscopy. After five million load cycles, a non-significant reduction in the metallic formation on the retrieved heads was found. The metallic areas showed a higher surface roughness compared to unconcerned areas. The liners showed a higher wear rate of 1.57 ± 1.36 mg/million cycles for 28 mm heads and 2.42 ± 0.82 mg/million cycles for 36 mm heads with metallic depositions, in comparison with new ceramic heads with a 28 mm size (-0.06 ± 0.89 mg/million cycles) and 36 mm size (2.04 ± 0.46 mg/million cycles). Metallic transfer on ceramic heads can lead to an increased surface roughness and higher wear rates at the UHMWPE liners. Therefore, metallic contact of the ceramic femoral head should be avoided.

Keywords: retrievals; hip wear simulator; total hip replacement; third-body wear; metallic deposition; metallic transfer; ceramic head

1. Introduction

The main cause of total hip revision is aseptic loosening caused by wear particles [1,2]. In order to increase the durability of artificial hip joints, the amount of wear debris has to be minimized and the tribological properties of the articulating surfaces have to be optimized [3]. Tribological properties of ceramic bearings have been proven to be advantageous over metal bearings [4,5]. Therefore, the ceramic femoral head has become a low-friction standard material [6–9] and combined with polyethylene (PE) as a bearing couple, it is an established low-abrasion bearing in total hip replacement [9,10].

In retrieval studies of ceramic femoral heads, authors have reported dark shiny metallic formations on the surface, mainly at the equator of the head [2,3,11,12], due to the transfer of metallic material to the surface of the ceramic head [11–15]. Such formations were also described in a simulator study during the testing of ceramic-on-metal bearings [13,16] and they can appear linear and planar. The metallic transfer can occur in the smallest contact area of the ceramic head with the rim of the metallic cup [3,17,18]. According to Luchetti et al. [11], these effects can result from total hip subluxation or dislocation, since this area is within the articulating surfaces during a normal gait. Most studies indicate that metallic transfer is caused by the malpositioning, loosening, or dislocation of implant

components [3,6,17]. Dorlot et al. [17] found an average area of 67 mm² (5–850 mm²) for metallic transfer on the retrieved ceramic heads. In a recent study, metallic transfer areas in the same size range were found [15]. A correlation between the extent of metallic transfer and the age, sex, weight, and activity of patients could not be detected [3,17]. Furthermore, an increase in the surface roughness in the areas with metallic depositions was reported [3,8]. An increased surface roughness of the femoral head led to enhanced polyethylene wear of the liner and to elevated third-body wear [3,8,11,13,15,19]. In a retrieval study by Kim et al. [3], higher wear of the polyethylene liner with increasing contamination of the heads was found. So far, research on metallic depositions on ceramic heads has only focused on macroscopic and microscopic analyses of retrievals.

The aim of the present study was to determine the influence of metallic depositions on ceramic femoral heads on the wear behavior of ceramic-on-PE bearings under standardized test conditions using a hip wear simulator. Several clinical studies have reported an increase in wear by metallic transfer on the femoral head [3,11]. Experimental investigations using ceramic-metal bearings also showed metallic depositions on the femoral component [13,16]. Nevertheless, standard wear test setups with ceramic-on-PE bearings with metallic depositions have not been performed thus far. In addition, the influence of metallic transfer on different head sizes was determined. The data were compared to the results of a previous study using new ceramic-on-PE bearings with an identical design.

2. Materials and Methods

2.1. Test Specimens

Retrieved alumina femoral heads with shiny metallic areas were used (Figure 1) for a hip wear simulator test. Three femoral heads that were 28 mm in diameter and three femoral heads that were 36 mm in diameter, made of alumina (Al₂O₃) with metallic markings, were selected. In order to ensure comparable ceramic femoral heads for the study, heads with similar distributions and areas of metallic depositions were selected from the retrieval archive of our hospital. The retrieved ceramic heads were part of uncemented implant systems combined with polyethylene liners used as a bearing partner. The implantation period of the 28 mm heads was between 303 and 4769 days and between 51 and 192 days for the 36 mm heads. For the hip wear simulator, the selected retrieved ceramic heads (Figure 1) were combined with new cross-linked ultra-high-molecular-weight polyethylene liners in combination with uncemented acetabular cups (Trident X3, Stryker GmbH & Co. KG, Duisburg, Germany) with an outer diameter of 56 mm. The study was approved by the Ethics Committee of the University of Rostock (registration number A 2017-0141).

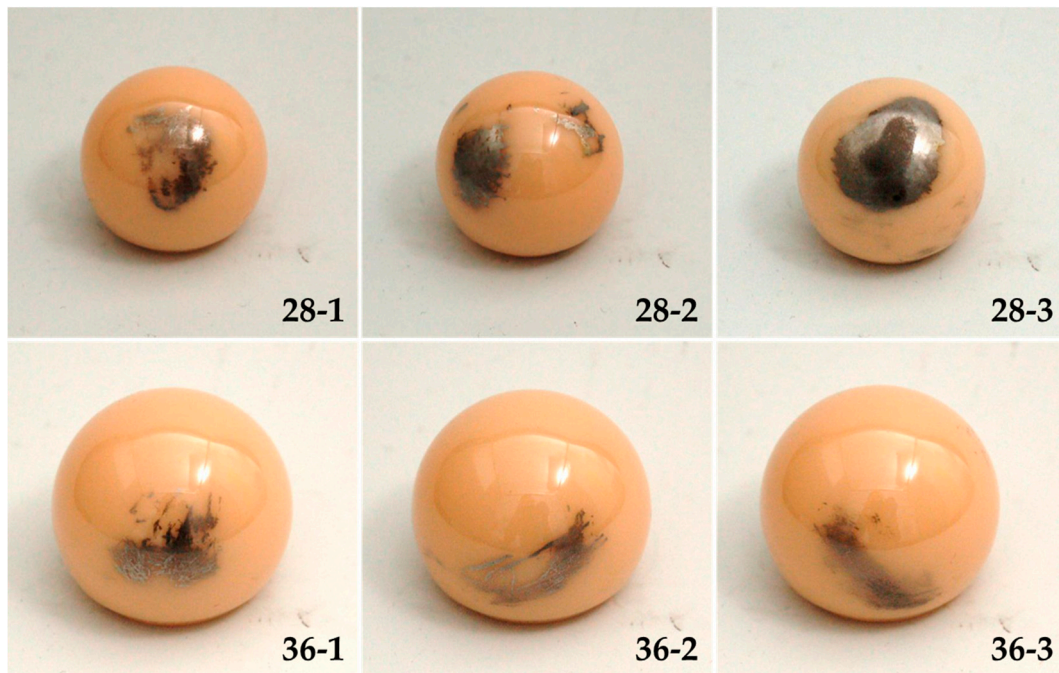


Figure 1. Retrieved femoral heads made of alumina (Al_2O_3) with metallic transfer, 28 mm ($n = 3$) and 36 mm ($n = 3$) in diameter.

2.2. Hip Simulator Test and Wear Measurement

In order to investigate the influence of metallic transfer on the wear rate of ceramic-on-PE bearings, a wear test using a standard hip wear simulator according to ISO 14241-1 [20] was performed. For saturation, the PE liners were stored in the test fluid until saturation for eight weeks at room temperature. Bovine serum (Biochrom GmbH, Berlin, Germany) with a protein content of 30 g/L, including 7.44 g/L ethylene diamine tetra acetic acid (EDTA) and 1.85 g/L sodium acid (NaN_3 , 0.2%), was used as the test fluid.

For wear simulation, the selected retrieved heads (Figure 1) were aligned, so that the surfaces with metallic depositions were in the articulating area and, consequently, in the mainly loaded area. The wear test was conducted in a hip wear simulator (Endolab GmbH, Rosenheim, Germany), in accordance with ISO 14242-1 [20]. Three dynamic loaded stations and one axial loaded soak control to validate fluid absorption were used for each head size (28 and 36 mm). Since the soak control does not produce any abrasion, the weight change of the PE liners can be directly linked to the amount of fluid absorption. By subtracting the fluid adsorption from the mass change of the dynamically loaded liners, the abrasion was determined. The measured wear data are shown as the average and standard deviation.

In the hip wear simulator, the tested specimens were loaded according to the movements and forces of a normal gait defined by ISO 14242-1 [20]. This includes an axial load of between 0.3 and 3 kN and movements between 18° and 25° extension/flexion, -4° and 7° abduction/adduction, and -10° and 2° external/internal rotation. The movements and loads of the bearing surfaces were applied in isolated and tempered with $(37 \pm 2)^\circ\text{C}$ test chambers with 1 Hz for five million cycles. Every 0.5 million cycles, the bovine lubricant was changed and the weight of the liners was measured gravimetrically using a high-precision balance (Sartorius ME235S, Sartorius AG, Göttingen, Germany, sensibility 0.01 mg, uncertainty 0.03 mg), in accordance with ISO 14242-2 [21]. In order to exclude station-conditioned influences, the test implants were changed periodically between the running stations. The measured wear data were compared to the wear rates from our previous studies [22,23].

2.3. Measurement of the Expansion of the Metallic Area

The total areas of the metallic deposition of the alumina femoral heads used in the hip wear simulator (Figure 1) were measured with a digital microscope before and after the wear test in the hip simulator (VHX-900F, Keyence Germany GmbH, Neu-Isenburg, Germany) using 3D images of the surfaces. The recorded values were compared after the abrasive wear test.

2.4. Analysis of Surface Roughness

The roughness measurements were performed for all femoral heads shown in Figure 1 after five million cycles in the hip wear simulator. The maximum height (Rz) and arithmetic average roughness (Ra) were determined optically with a laser scanning microscope (LSM, VK-X250, Keyence Germany GmbH, Neu-Isenburg, Germany), according to DIN EN ISO 3274: 1998 [24] and DIN ES ISO 4288: 1998 [25]. For comparison, the roughness of each ceramic head was examined at three different locations on the unaltered surface without visible metallic deposition and at three areas with metallic depositions on the same retrieved head. Four roughness measurements were obtained for each location and the roughness values of the unaltered and altered surface were compared.

2.5. Statistical Analysis

Statistical analysis was performed using IBM® SPSS® software (Statistics version 20, IBM Corporation, Armonk, NY, USA). The Gaussian distribution of the values for PE wear rates with new ceramic heads and heads with metallic depositions, the metallic transfer area on the femoral heads before and after loading in the hip wear simulator, and the roughness of the head surface with and without metallic depositions were analyzed with the Kolmogorov–Smirnov test. For statistical comparisons, *P*-values of <0.05 were considered significant. The statistical tests performed are explained in further detail in the respective result section.

3. Results

3.1. Wear Rates

The gravimetric wear of the PE liners combined with new and retrieved ceramic femoral heads with metallic transfer (28 and 36 mm diameters) is shown in Figure 2. The graphs show an almost linear increase in wear over five million cycles (Figure 2a), whereby the wear of the liners articulated against the retrieved femoral heads (36 mm head size) was the highest across all five million cycles (MC), with a total wear of (12.09 ± 4.12) mg ((2.42 ± 0.82) mg per MC). This was followed by liners articulated against the new femoral heads (36 mm head size), with a total wear of (10.21 ± 2.28) mg ((2.04 ± 0.46) mg per MC) and by liners articulated against retrieved 28 mm femoral heads with metallic depositions, with a total wear of (7.86 ± 6.79) mg ((1.57 ± 1.36) mg per MC). The combination of PE liners with new 28 mm femoral heads from the standard test showed nearly no change in gravimetric weight, with a total wear of (-0.29 ± 4.45) mg ((-0.06 ± 0.89) mg per MC). For determination of all wear rates, the zero value was included.

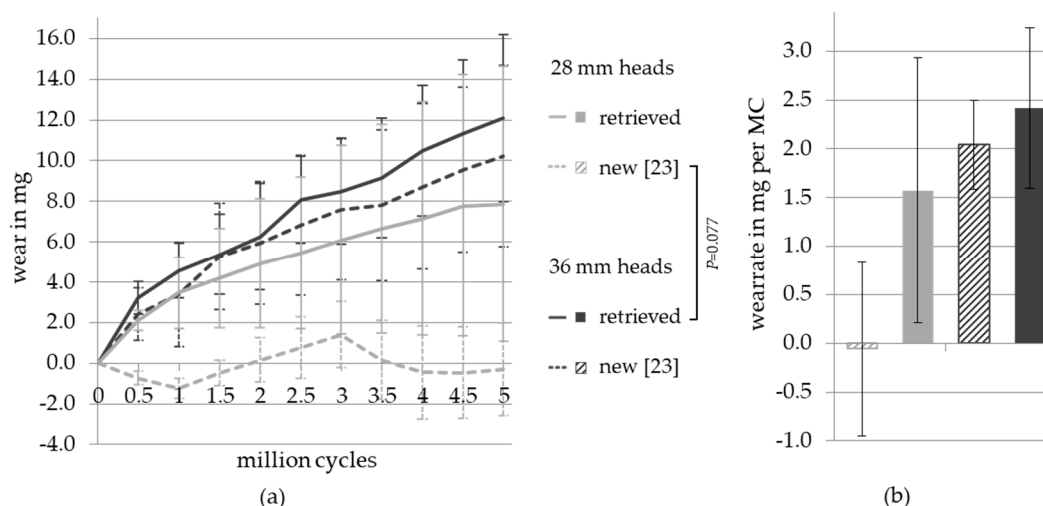


Figure 2. Mean gravimetric wear of the sequentially cross-linked polyethylene (PE) liners combined with new [23] and retrieved 28 and 36 mm alumina femoral heads. (a) Total wear over five million cycles and (b) wear rates per million cycles.

Figure 2b shows the wear rates of the four bearing couples per MC. The wear values were not normally distributed. The standard test surface was compared to the metallic deposition surface by a two-way analysis of variance (ANOVA), with the head size and surface area as variables. The wear values of the PE liners, articulated against the 36 mm femoral heads, were significantly higher than the wear values of the bearings with the 28 mm femoral heads ($p = 0.047$). The difference between the wear values of the new and retrieved femoral ceramic heads with metallic depositions was not statistically significant ($p = 0.150$). Moreover, the interaction between the variables head size and condition of femoral head (new or retrieved) showed no significant influence on wear rates ($p = 0.350$).

The change in abrasive wear over time shown in Figure 2a was statistically analyzed for all four groups in a Repeated Measures two-way ANOVA (mixed model) with Tukey's post hoc test and Greenhouse–Geisser correction. The analyzed variables were the time and different groups. The increase in wear values over time was significant ($p = 0.001$). When comparing all groups, there was a trend for groups differing from each other ($p = 0.079$). The highest difference was found between the new femoral heads with a diameter of 28 mm and the retrieved heads with a diameter of 36 mm ($p = 0.077$).

In summary, Figure 2 shows that the PE liners articulated against heads with metallic depositions tended to exhibit higher wear. The distinctly higher standard deviations in bearings with metallic transfer probably contributed to the fact that the observed differences did not reach significance.

3.2. Measurement of the Expansion of the Metallic Area

The area of metallic depositions was determined on all six femoral ceramic heads before and after the hip simulator test. The measured values were normally distributed. For comparisons of the area before and after the wear test, an unpaired t-test was used. The recorded areas are shown in Figure 3. Before wear simulator testing, the average area of the metallic depositions for all heads was $(131.09 \pm 35.93) \text{ mm}^2$ (81.16 mm^2 – 182.45 mm^2). After the wear test, the average area decreased to $(100.08 \pm 40.01) \text{ mm}^2$ (65.99 mm^2 – 177.41 mm^2). The total area of metallic depositions on the femoral heads before and after the articulation of bearings in the wear simulator was not significantly different ($p = 0.188$). However, Figure 3 shows a slightly reduced metallic deposition area after articulation of the surfaces. The difference was particularly evident in femoral heads 28-1 and 28-2.

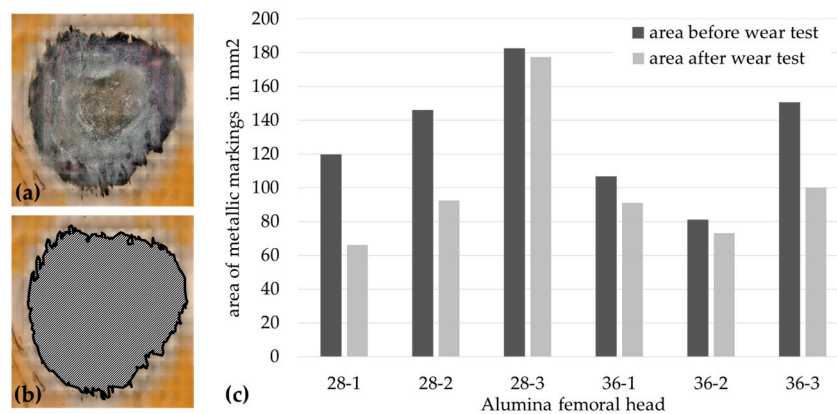


Figure 3. Measurement of metallic deposition areas. (a) Metallic depositions, (b) marked area for evaluation, and (c) recorded values for metallic depositions on retrieved alumina ceramic heads.

3.3. Analysis of Surface Roughness

Since the head size did not significantly influence the roughness Ra ($p = 0.643$) and the maximum height Rz ($p = 0.689$), the comparison of the original surface and metal transfer was based on all six retrieved heads. The Mann–Whitney U test was used for statistical evaluation, as the recorded roughness values for Ra and Rz did not show a Gaussian distribution.

Surfaces with metallic depositions displayed significantly higher ($p < 0.001$) Ra (mean \pm SD: $(0.35 \pm 0.23) \mu\text{m}$) than the unaltered surfaces of the retrieved femoral heads (mean \pm SD: $(0.09 \pm 0.06) \mu\text{m}$). Rz was also significantly higher ($p < 0.001$) in the areas with metallic depositions (mean \pm SD: $(1.90 \pm 1.04) \mu\text{m}$) than on the unaltered surface of the retrievals (mean \pm SD: $(0.49 \pm 0.42) \mu\text{m}$). The distribution of the roughness parameters is shown in Figure 4.

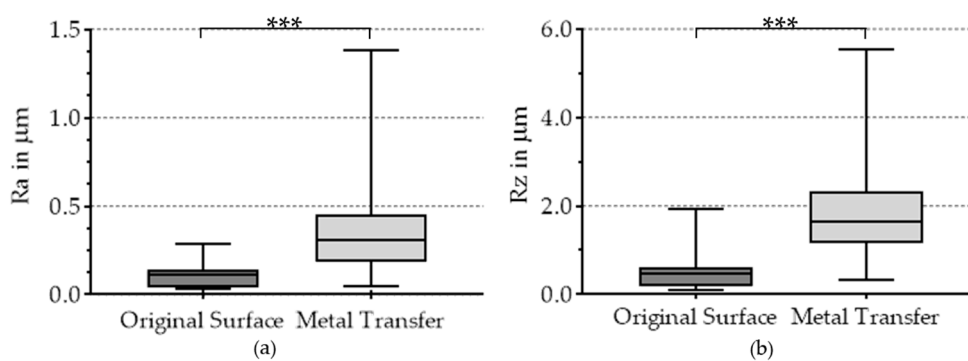


Figure 4. Results of the surface analyses of the ceramic heads with (a) arithmetic average roughness Ra and (b) maximum height Rz; highly significant differences marked with three asterisks.

4. Discussion

In order to investigate the influence of metallic deposition, a wear test using a standard hip wear simulator according to ISO 14241-1 [20] was performed in the present study. The physiological conditions in the human hip joint cannot be completely simulated by such standard tests; however, for a comparison of different bearings, the wear test method with standardized testing conditions has been successfully established and validated [26]. The same applies to bovine serum used as a norm-compliant lubricant for the standard wear testing of artificial joints.

The area of the metallic depositions was measured with a digital microscope. It should be noted that the measurements could be affected by reflections on the smooth surface. This undesirable effect was largely minimized by the use of diffusers. Nevertheless, the smallest metallic deposition could not be included in the survey of the transferred areas, and only the areas around the main articulated area

were included. Another limitation was the selection of the femoral ceramic heads. Although care was taken to use heads with the same amount of metallic contamination, not all ceramic heads showed the same expansion or thickness distribution of metallic depositions. Furthermore, femoral heads from left and right total hips were used. The influence should be minimized by aligning the metallic depositions in the mainly loaded area. To obtain complete comparability, wear simulations with unused ceramic heads after standardized metallic deposition might represent a suitable alternative. Since the material composition of the metallic deposition was not known, this should be determined in further investigations by means of energy-dispersive X-ray spectroscopy (EDX). The measured extent of the metallic depositions was similar to the extent already described by Dorlot et al. [17], which ranged from 5 to 850 mm², and by Affatato et al. [15], which ranged from 29.6 to 573.6 mm², on ceramic heads. The measured areas on the heads before and after wear testing are not significantly different. However, the statistical significance of this test is only partially meaningful, because the thickness or volume of the metallic depositions could not be measured in this study. Furthermore, the non-significant decrease in the deposition area indicates that the removal of the metallic volume could have a significant influence on the wear rate. The reduction of metallic depositions was apparent (Figure 3), especially for heads 28-1 and 28-2. One explanation for the difference could be the thinner metallic deposit on both heads as opposed to head 28-3. A reduction in the deposited metallic amount on the head surface causes the release of metallic depositions in the form of metal particles and metal ions, which indicates the presence of third-body particles in the joint space and surrounding tissue. The correlation between the volume deviation of the metallic depositions and the wear rate of the polyethylene liner may confirm this relationship. Furthermore, the thickness and extent of the metallic depositions may depend on the lifetime of the implant in situ.

For roughness measurements on the retrievals, an LSM was used. Four perpendicular roughness measurements per analyzed area were obtained in order to exclude the influence of one directional pattern on the determined roughness parameters. Significantly higher roughness values for Ra and Rz were detected in the areas with metallic depositions than on the unaltered ceramic surface. Thereby, high standard deviations in roughness values for the metallic deposition were noted. This is probably due to the different deposition thicknesses, the different materials, or the residence time of the implant before retrieval. A limitation is the roughness measurement on the unaltered surface, since the measurement of invisible thin metallic deposits cannot be excluded. It should also be noted that the roughness of the bearing surfaces in general increases with the retention time in the human body. The measured roughness values for Ra were similar to measured data on ceramic femoral heads from Affatato et al. [15], who determined a value of $(0.3 \pm 0.1) \mu\text{m}$ in areas with metallic deposition and $(0.03 \pm 0.1) \mu\text{m}$ on unaltered surfaces.

By aligning the areas with metallic deposition in the mainly loaded articulation surface, the influence of the metallic deposition should be increased as much as possible to simulate a worst-case scenario. Nevertheless, no significant differences in wear rates of ceramic-on-PE bearings with and without metallic deposition could be determined. In Figure 2, the total wear over five million cycles, as well as the wear rate per million cycles, show a slightly higher wear of PE on heads with metallic deposition than on the new heads. As described, the size of the femoral heads exhibited a significant influence on the wear rate of PE liners in the present study. It is well-known that larger femoral heads lead to a higher wear rate of the bearing [22,23,27] due to an increased sliding distance, reduced contact pressure with larger heads [28], and different clearances [29]. It should be emphasized that the bearings of the 28 mm heads with metallic deposition produced significant wear, which was almost in the order of the wear rates of the bearings with 36 mm heads, while in the standard test with new 28 mm ceramic heads, nearly no gravimetric wear could be measured [23]. Zietz et al. [23] found a higher level of fluid absorption than gravimetric wear for alumina-on-PE bearings with a 28 mm head size. Yan et al. [30] showed that wear rates decreased after the end of a running-in phase and the beginning of the steady state phase; thus, the zero point should be excluded from the calculation. This is also required by ISO 14242-2 [21]. However, in order to ensure comparability with the study of Zietz et al. [23], the zero

point was also taken into account in the calculation of wear rates in this study. Since the same hip wear simulator was used in both studies, the inclusion of the zero point presents no disadvantage. Another point to consider is the high standard deviations in the wear data of the PE liners. These may be due to the different extents and thicknesses of the metallic depositions on the retrieved femoral heads. Another possible reason may be the different ablation of the metallic film under cyclic loading of the heads. This would be an indication that the increased wear rates are caused by third-body particles released from the depositions. However, since similar high standard deviations occurred in the comparative study of Zietz et al. [23], the test appears to be very robust and comparable, even with the low number of samples. An important limitation of our study was that the wear rate of retrievals with metallic deposition was not compared to retrievals without metallic deposition, and only with new femoral ceramic heads. However, in the study of Kim et al. [3], no significant differences in surface roughness between retrieved and new ceramic femoral heads could be detected. Furthermore, the same new PE liners were used in combination with both the new and retrieved femoral ceramic heads, and nearly linear wear over five million cycles was achieved. Even though the exact influence of metallic deposition could not be determined, the dynamic load of normal walking still leads to abrasive wear of the metallic deposition. According to a study by Kim et al. [3], the surface roughness increases with the grade of contamination by metallic deposition, which leads to an increase in the wear rate. Due to the movement and friction on the metallic deposition, metallic particles are released from the surface and reach the joint space, where they may lead to increased wear, acting as third bodies. The increase in wear rates by third-body particles has already been investigated and confirmed in several studies [19,31,32]. Therefore, metallic depositions, for instance, caused by subluxation, dislocation, and reposition of the artificial hip joint or any contact of the ceramic components with metallic components intraoperatively and postoperatively, should be avoided [2,7,17]. Moreover, in total hip revision, ceramic heads with metallic depositions should be exchanged.

According to Kim et al. and Dorlot et al., patient history has no influence on the extent of metallic transfer, but a link between undergoing total hip revision and the extent of metal transfer cannot be excluded [3,17]. Luchetti et al. [11] suggested that metallic transfer on femoral cobalt-chromium (CoCr) heads cannot be excluded. Therefore, further retrieval studies on metallic transfer on femoral heads are needed. Investigational studies of metallic transfer on the retrieved ceramic heads for determination of the material composition are currently planned. This may clarify the origin of the metallic deposition, which can be derived from the acetabular cup after subluxation or dislocation, surgical instruments, screws, or other implant materials. The most commonly expected materials are titanium, cobalt-chromium, and stainless steel, since these are often used as implant materials or surgical instruments [11–13]. Since the metallic depositions occurred in femoral heads with an implantation period of only 51 days (femoral head 36-1, see Figure 1), the probability is high that the metal application was caused during implantation. The reason for the retrieval was not recorded and could not be discussed in this study.

Furthermore, an analysis of wear particles from the bovine lubricant of the simulator study could provide detailed information on the origin and shape of the third-body particles from the metallic transfer, as well as their abrasive behavior.

5. Conclusion

When studying the influence of metallic depositions on ceramic femoral heads on PE inserts using a hip wear simulator, heads with metallic depositions exhibited a significantly increased surface roughness and led to an increase of wear rates compared to new ceramic femoral heads. Therefore, metallic depositions, for instance, caused by subluxation, dislocation, and reposition of the artificial hip joint or any contact of the ceramic components with metallic components intraoperatively and postoperatively, should be avoided. Moreover, in total hip revision, ceramic heads should be exchanged, as metallic deposition cannot be ruled out.

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Article

Experimental Investigation of Material Transfer on Bearings for Total Hip Arthroplasty—A Retrieval Study on Ceramic and Metallic Femoral Heads

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Abstract: Metallic deposition is a commonly observed phenomenon on the surface of revised femoral heads in total hip arthroplasty and can lead to increased wear due to third bodies. In order to find out the origin and composition of the transfer material, 98 retrieved femoral heads of different materials were examined with regard to the cause of revision, localization, pattern and composition of the transfer material by energy dispersive X-ray spectroscopy. We found that in 53.1%, the deposition was mostly in the region of the equator and the adjacent pole of the femoral heads. The most common cause for revision of heads with metallic deposition was polyethylene wear (43.9%). Random stripes (44.9%), random patches (41.8%) and solid patches (35.7%) were most prevalent on retrieved femoral heads. Random patches were a typical pattern in ceramic-on-ceramic bearing couples. The solid patch frequently occurred in association with dislocation of the femoral head (55%). The elemental analysis of the depositions showed a variety of different materials. In most cases, titanium was an element of the transferred material (76.5%). In addition to metallic components, several non-metallic components were also detected, such as carbon (49%) or sulfur (4.1%). Many of the determined elements could be assigned with regard to their origin with the help of the associated revision cause. Since the depositions lead to an introduction of third-body particles and thus to increased wear, the depositions on the bearing surfaces should be avoided in any case.

Keywords: material transfer; total hip arthroplasty; deposition pattern; femoral head



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1. Introduction

Nowadays, aseptic loosening due to wear particles is still the main cause for total hip revisions [1,2]. Numerous retrieval studies reported dark shimmering areas on the surface of explanted femoral heads [2–5]. These areas were proven to be transferred metallic deposits [6–9], which are mainly localized at the equator of the heads [10]. Although studies reported the occurrence of deposits mainly on ceramic heads, metallic transfer was also detected on numerous retrieved metallic heads [11]. Independent from the material of the head, it did not matter whether the bearing partner was made of ceramic, polyethylene (PE) or metal [11,12].

Subsequently, the metallic deposit on the surfaces of the bearing couples leads to a change in the wetting behavior [13] and an increase in surface roughness and thus to significantly increased abrasion and wear in total hip replacement, especially with PE as a bearing partner [8,14,15]. In addition, metallic particles can be embedded in the

PE surface [6]. These metallic particles can be released when the metallic deposition on the femoral heads is abraded [14,16]. Chevillotte et al. [17] report that disruption of the lubricating film between the bearing surfaces by metal transfer could be a reason for squeaking in ceramic-on-ceramic bearing couples of hip arthroplasties.

Different motion sequences result in different stress distributions in the hip joint [18]. This can lead to various wear mechanisms but also to a variety of deposition patterns. The most common pattern of deposition was described as scattered and longitudinal stripes, sometimes also randomly distributed areas, and in rare cases a completely patterned coverage of the femoral head [11]. The striped patterns are caused by line contact of the head and acetabular rim, which may occur during final repositioning while primary implantation [19,20] or due to edge loading of the hip arthroplasty [12]. Other possibilities of occurrence are during normal gait due to microseparation or unexpected activities such as stumbling [21]. Other causes for metallic deposition are mainly malpositioning, loosening or migration of implant components as well as metallic contacts during surgery [3,4,7,15,20,22,23]. The entry of wear particles from the taper connection into the articulating joint surface during prosthetic impingement can also cause metallic deposition on the head [24]. Several studies report that metallic transfer can occur with slight metallic contact [7,15,20,23,25].

The amount of total wear correlates with the extent of the deposited area [3,9,26,27]. In studies of Dorlot et al., Fredette et al. and Müller et al. [3,11,23], areas from 5 mm² up to 850 mm² of the transfer with a maximum height of 30 µm were determined. In some studies, energy dispersive X-ray (EDX) analysis in combination with scanning electron microscopy (SEM) was used to determine the composition of the metallic deposit on the femoral heads. In most cases, CoCr or titanium alloys were identified as transferred material. However, EDX has been performed only on small numbers of samples and only on ceramic heads, often searching for explicit materials [3,6–8].

In numerous studies, retrieved femoral heads are examined with regard to their abrasion and wear behavior. Thereby, the metallic deposition was often documented as well. However, a detailed examination of the transferred material mostly did not follow [28–30]. Studies that analyzed the depositions in more detail usually had a very small number of samples or examined only one head material [31–33]. There are just a few studies known to date that have investigated metallic deposition in a meaningful number of samples [10,11,26]. However, of these, only the study of Fredette et al. [11] included metallic heads in addition to ceramic heads. Most studies only investigate the influence of the metallic application but not its origin. So far, only the origin of the striped patterns was explained [12]. The formation of other deposition patterns such as solid or random patches is not yet clear. The knowledge of the cause of formation may help to develop new designs that might prevent the formation of the metallic deposition, such as the use of dual mobility systems to reduce dislocations [34]. Hence, the aim of our present study was to investigate the metallic transfer in terms of its composition and origin. For this purpose, retrieved femoral heads made of different materials with metallic depositions were collected (heads with a minor grade of depositions were neglected) and the composition of the transfer material was determined by means of SEM-EDX analysis. The results of the study together with the data regarding the type of bearing as well as the cause of revision in combination with the large number of samples should allow the origin of the deposited material to be determined. The results of this study are of great importance, since there is no study with a large number of samples and with such a wide variety of femoral head materials and designs that investigates the correlation of the parameters deposition material, cause of revision, type of bearing, localization and pattern of the deposition.

2. Materials and Methods

The workflow and methods used are summarized in Figure 1.

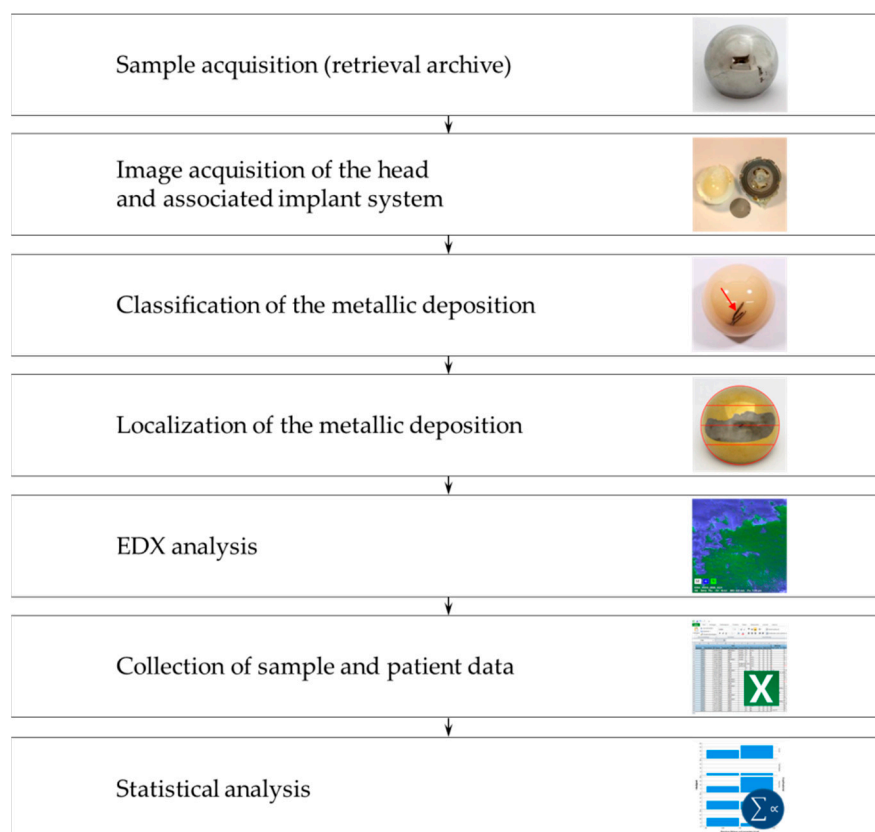


Figure 1. Workflow of the present study.

2.1. Specimens

For this study, retrieved femoral heads of various designs with metallic deposition localized on the surface were selected from the retrieval archive of our hospital. Patients signed a consent statement for the safekeeping and examination of the explants. The data protection regulations were observed. The study was approved by the local Ethics Committee (registration number A 2019-0103). The selected 98 heads consisted of five different materials. The numbers of heads per material group are listed in Table 1.

The patient data collected in reference to the selected explants were anonymized. Since many of the collected samples were not implanted at our Orthopedic Hospital, the implantation period is mostly unknown and was therefore not investigated in this study. The type of bearing materials as well as the cause for revision were considered for the evaluation of the results. After revision, all implant systems were sanitized at 95 °C. Furthermore, all femoral heads were cleaned in deionized water in an ultrasonic bath (SONOREX, BANDELIN electronic GmbH & Co., KG, Berlin, Germany) and dried with nitrogen to remove loose wear debris before examination.

An experienced and board-certified orthopedic surgeon, specially trained and approved in total joint arthroplasty at a center of excellence (Endocert-Certification Germany), was consulted for all subsequent examinations.

2.2. Classification and Localization of the Metallic Deposition

The deposition patterns were classified according to the study of Fredette et al. [11]. The patterns were recorded as follows: solid patch, directional scratch, longitudinal stripe, random stripe, random patch, patterned coverage and miscellaneous. The images were scored by two independent experts based on the above detailed classification. Scorings were compared and if findings differed, a third, joint assessment of the deposits was performed to obtain a consistent result.

In order to standardize the mapping of the localization of the metallic contamination, a grid was drawn on the acquired images of the analyzed femoral heads. The grid was used to divide the head surface into the areas pole, equator and near taper. An example image of the adopted segmentation is shown in Figure 2.

Table 1. Selection of femoral heads with metallic depositions on original surface and associated bearing partners (MoM = metal on metal, MoPE = metal on PE, CoC = ceramic on ceramic, CoPE = ceramic on PE, unknown = unknown bearing partner).

Femoral Head Material	Bearing Partners	Elements Included in Original Surface	Example Image
Metal <i>n</i> = 28	MoM (<i>n</i> = 8) MoPE (<i>n</i> = 19) Unknown (<i>n</i> = 1)	Co, Cr, Mo	
Coated Metal TiN/TiNbN <i>n</i> = 6	MoM (<i>n</i> = 6)	Ti, N, Nb (Co, Cr, Mo beneath coating)	
Alumina Ceramic <i>n</i> = 28	CoC (<i>n</i> = 1) CoPE (<i>n</i> = 26) Unknown (<i>n</i> = 1)	Al, O	
ZTA Ceramic (Zirconia-Toughened Alumina) <i>n</i> = 21	CoC (<i>n</i> = 1) CoPE (<i>n</i> = 20)	Al, O, Zr, Y	
Other oxide ceramics ATZ/ZTA/ZrO (Zirconia-Toughened Alumina) <i>n</i> = 15	CoC (<i>n</i> = 1) CoPE (<i>n</i> = 13) Unknown (<i>n</i> = 1)	Al, Zr, O, Y	

During a revision, the implants are removed, cleaned and stored in single parts (unassembled) in the retrieval archive. The position in which the femoral head was mounted on the femoral stem was not documented. Therefore, an exact determination of the contact surface cannot be made for most heads.

2.3. EDX Analysis of Femoral Heads

To analyze the metallic coating, all femoral heads were examined by field emission scanning electron microscope (FESEM, MERLIN[®] VP Compact, Co., Zeiss, Oberkochen, Germany) equipped with a detector (XFlash 6/30) for EDX spectroscopy and analysis software (Quantax400, Co., Bruker, Berlin, Germany). Representative areas of the samples

were analyzed and mapped to determine the elemental distribution on basis of the EDX-spectra data by the QUANTAX ESPRIT Microanalysis software (version 2.0).

Measurements were made in the transition area from the original surface to the metallic deposition in order to show the difference between the materials. For the investigation by means of EDX, a conductive surface is necessary for the conduction of the electron beam, which is normally ensured by sputtering the sample with gold or carbon. However, in order not to contaminate the retrievals by sputtering, the ceramic heads were placed on a carbon tape in a holder made of aluminum foil and the area to be examined was made accessible with aluminum tape (see Figure 3). It was searched for many known implant and surgical tool materials (exemplary Fe, Co, Cr, Mo, V, Ti, N, Nb, Al, Zr, Y, Sr). The method was used to determine the composition and localization of the transfer material and therefore to deduce the source of the deposited material. However, an exact quantitative analysis of the material composition was not possible by EDX analysis.

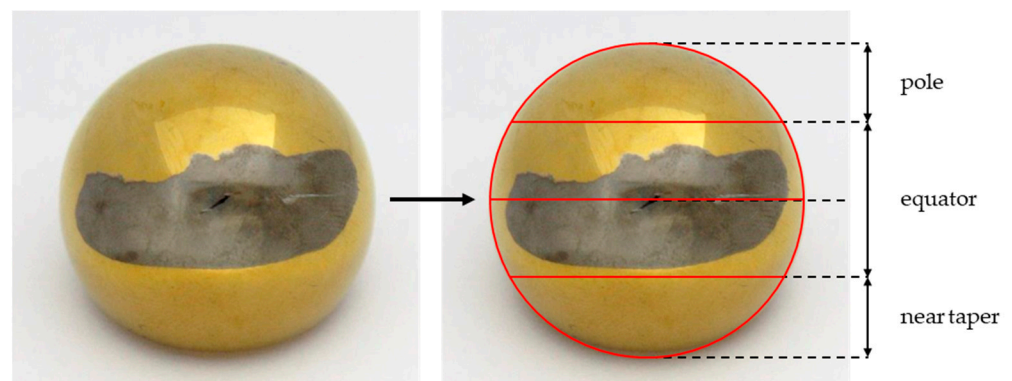


Figure 2. TiN-coated femoral head with metallic deposition in the equatorial area.

2.4. Statistical Analysis

Statistical analysis was performed using the IBM® SPSS® Statistics (version 27, IBM Corporation, New York, NY, USA). For the selected femoral heads, the absolute frequencies of the transfer materials, the deposition patterns and the cause for revision were analyzed. Cross tables with Chi-square test and Fisher's exact test (two-sided) were used to determine associations in deposited material and deposition pattern due to the cause of revision or the localization of the depositions on the femoral head. *p*-values of <0.05 were considered significant.

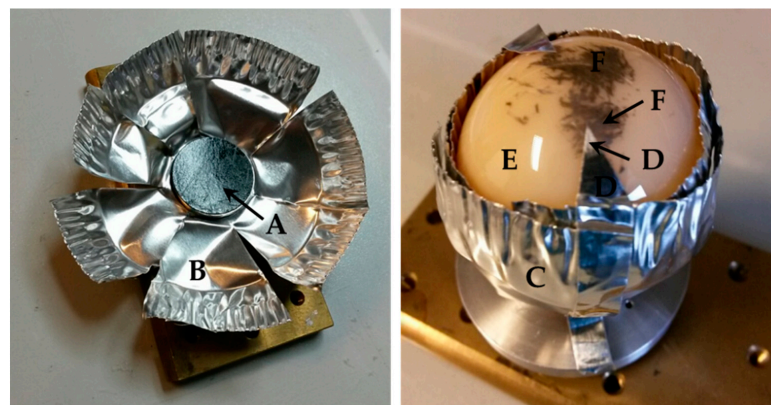


Figure 3. Double-sided carbon adhesive tape (A) in aluminum sample holder (B). Right: inserted ceramic femoral head in closed aluminum sample holder (C) with aluminum adhesive tape (D) on original head surface (E) and deposited area (F).

3. Results

3.1. Cause of the Revision of the Examined Femoral Heads

In order to determine the cause of the revision, revised total hip implant systems (if available) were also examined in addition to the retrieved heads (see Figure 4).



Figure 4. Examples of revised total hip implant systems.

The metallic deposition can also be found in part in the associated metallic or ceramic bearing surfaces (see Figure 5). However, the more noticeable contamination is found on the femoral heads.

The frequencies of the cause for revision of the retrieved heads are listed in Table 2. The most common cause for revision was wear of the polyethylene insert followed by impingement and aseptic loosening. Septic revisions and dislocations amounted to approximately 20% each. Several causes for revision may occur for the same retrieval.



Figure 5. Ceramic-on-ceramic bearing couple with globally distributed metallic deposition on femoral head and insert.

Table 2. Occurring causes for revision of the examined retrievals.

Cause for Revision	Frequency of Occurrence in %	Absolute Number (Total n = 98)
Polyethylene wear (includes decentralization, delamination, linear wear)	43.9	43
Impingement	40.8	40
Aseptic loosening (with 25.5% global loosening, 11.2% cup loosening, 1% stem loosening)	37.7	37
Dislocation (includes single and multiple dislocation)	20.4	20
Particle disease (due to PE and metallic wear particles)	17.3	17
Septic loosening	11.2	11
Septic, without loosening (includes DAIR ¹)	8.2	9
Implant migration	5.1	5
Gluteal insufficiency	3.1	3
Osteolysis	3.1	3
Bone fracture	3.1	3
Implant failure	3.1	3
Subluxation	2.0	2

¹ DAIR = debridement, antibiotics and implant retention.

3.2. Classification and Localization of the Metallic Deposition

Random stripes, random patches and solid patches were most prevalent on retrieved femoral heads (see Table 3). The random patches were located almost exclusively on hard-hard pairings ($p = 0.022$). A further significant correlation of the pattern or the localization of the deposition with the different bearing partners could not be found. In total, 11.2% of the heads showed global patterns distributed over the entire head.

The metallic deposition occurred most frequently in the area of the equator. In 53.1% of the heads, metallic deposits were found in the equator and pole regions without contamination of the taper-near area. However, there was no case in this study in which metallic contamination occurred exclusively in the pole area. A total of 40.8% of the heads had no metallic depositions in the pole area at all. The most prevalent deposition patterns on the pole area were random stripes (12.2%) and longitudinal stripes (10.2%). In the equatorial area, the three most recurrent deposition patterns were solid patches (14.3%), random stripes (13.3%) and a combination of solid patches and longitudinal stripes (8.2%). In the near taper area, the majority of heads also showed no deposition (44.9%). The most prevalent patterns of deposition were random patches and a combination of random stripes and random patches (10.2% each, see Figure 6).

In a statistical comparison, Fisher’s exact test (two-sided) was used to analyze whether there was an association between the metallic patterns and the cause for revision. It was found that a solid patch was detected in more than half (55%) of the femoral heads that were retrieved due to dislocation and thus a direct association cannot be excluded ($p = 0.066$).

When solid patches were present, they were always localized in the equator area (11.4% of heads with solid patches) or in the equator and adjacent area (88.6% of heads with solid patches). In nearly half of the femoral heads with solid patches, it occurred in the equator and pole region ($p = 0.028$). It was also shown that in case of dislocation, there were no random patches in 80% of the cases ($p = 0.041$) and no patterned coverage in 70% of the cases ($p = 0.008$).

A possible association exists for the occurrence of random stripes in gluteal insufficiency as well as implant fracture, which may include a fracture of the acetabular cup as well as a fracture of the surrounding bone cement ($p = 0.087$ in each case). While in both cases all heads showed random stripes, the total number of heads for these specific causes was limited with only three retrieved heads each. This makes it difficult to draw a conclusion from the results.

Table 3. Occurring deposition patterns on femoral heads.

Deposition Patterns on Femoral Heads According to Fredette et al. [11]	Frequency of Occurrence in %	Absolute Number (Total <i>n</i> = 98)	Exemplary Deposition Pattern on Heads of This Study
Random Stripes	44.9	44	
Random Patches	41.8	41	
Solid Patch	35.7	35	
Longitudinal Stripe	27.6	27	
Directional Scratches	20.4	20	
Patterned Coverage	11.2	11	
Miscellaneous	2.0	2	

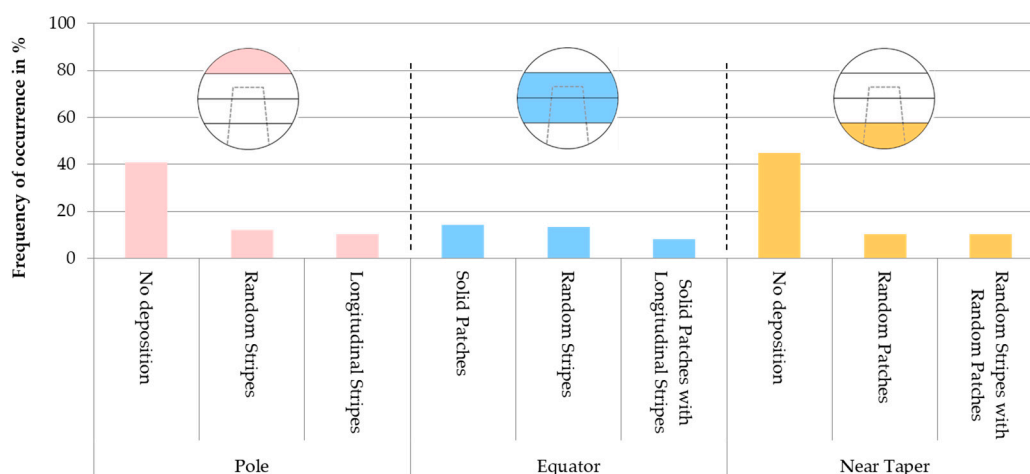


Figure 6. Most frequent deposition patterns on the femoral heads in the areas pole, equator and near taper.

3.3. Material Analysis of Femoral Heads and EDX Analysis

By means of EDX analysis and mapping, individual elements could be assigned to the metallic deposition. Metallic deposit, which consisted of the same material as the original surface of the head, was only included in the analysis if it could be clearly defined as a deposition. Figure 7 shows an example of the composition of the metallic deposit based on a mapping on a CoCr and an alumina head.

The elements that were clearly detected as depositions by EDX are listed in Table 4. Titanium was detected as the most common deposition material on the retrieved femoral heads, amounting to 76.5%. Nearly half of the heads showed carbon deposition. Iron and chromium were found on approximately one third of the retrievals. Other elements were only detected with lower abundance. The bearing materials given in Table 1 were examined for correlations with the detected deposition materials. However, no correlations could be found.

Many elements, often including carbon and silicon were only detected as background noise and could not be directly defined as a deposition material. It was hypothesized that this was background noise caused by remaining material from previous revision surgeries. However, this hypothesis could not be confirmed statistically ($p = 0.374$).

In order to determine the origin of the transferred and deposited materials, it was verified whether there were statistical associations between the transfer materials and the cause for revision of the retrievals. The detailed analyses showed that some of the elements that were detected by EDX occurred more often after specific causes of revision. Only the significant associations in Chi-square test between certain elements and specific causes are described in detail. Of 34 femoral heads with depositions including Fe, 24 heads were retrieved due to PE wear ($p = 0.035$). All heads ($n = 3$) which had to be revised due to implant fracture had depositions of Fe on the head surface ($p = 0.039$). Five out of seven heads with deposition involving oxygen were retrieved due to particle disease ($p = 0.002$). Out of four heads with sulfurous deposit, three had septic loosening as the cause for revision ($p = 0.004$). It should be mentioned here that all three cases were bearing couples of alumina-on-PE. In the first case, the bacterial strains *Finexgoldia magna*, *Bacillus cereus*, *Corynebacterium* species, *Staphylococcus aureus* and *Neisseria* species were detected. The second case infection was again caused by *Staphylococcus aureus*, while in the third case *Enterococcus faecalis* was the causative pathogen. For the revision cause septic (without loosening), eight out of nine heads showed carbon deposition ($p = 0.015$). One out of three heads with revision due to bone fracture (including trochanteric major contact) showed deposition of calcium ($p = 0.031$).

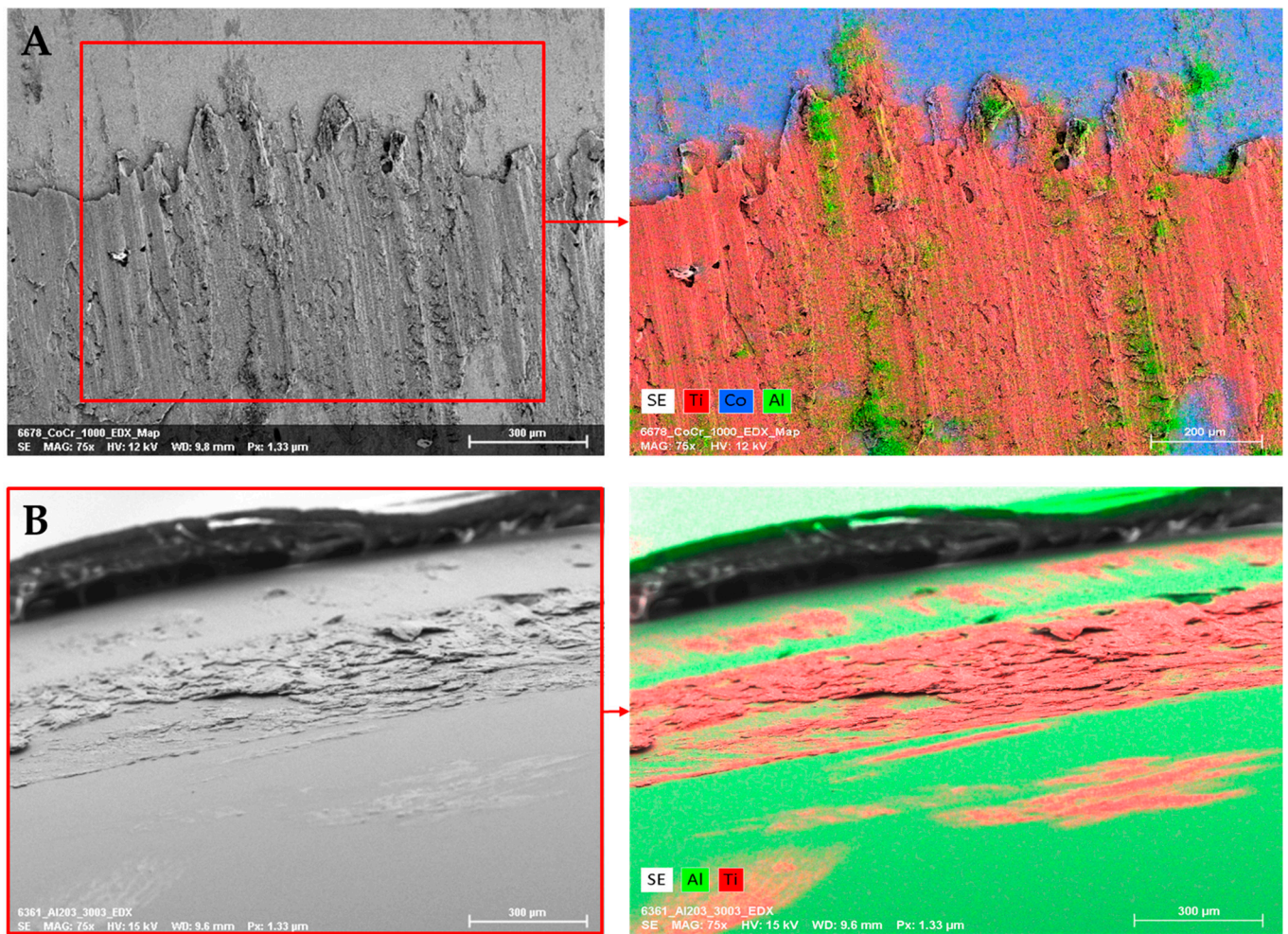


Figure 7. EDX mapping on retrieved femoral heads; (A) metallic deposit containing Ti and Al on CoCr femoral head and (B) metallic deposit containing Ti on alumina ceramic head.

Table 4. Detected deposition materials on femoral heads.

Element	Frequency of Occurrence on Femoral Heads %	Absolute Number (Total <i>n</i> = 98)
Titan (Ti)	76.5	75
Carbon (C)	49.0	48
Iron (Fe)	34.7	34
Chromium (Cr)	31.6	31
Niobium (Nb)	23.5	23
Cobalt (Co)	16.3	16
Aluminum (Al)	12.2	12
Vanadium (V)	9.2	9
Nickel (Ni)	8.2	8
Oxygen (O)	7.1	7
Nitrogen (N)	6.1	6
Silicon (Si)	5.1	5
Molybdenum (Mo)	4.1	4
Sulfur (S)	4.1	4
Magnesium (Mg)	3.1	3
Phosphorus (P)	2.0	2
Copper (Cu)	1.0	1
Zircon (Zr)	1.0	1
Calcium (Ca)	1.0	1

4. Discussion

Metallic depositions on retrieved femoral heads were commonly observed in total hip arthroplasty. Some experimental studies showed that the deposited material can lead to increased third body wear [6,7,14]. The appearance and extent of the transfer varies for each revision [6,11]. Slight deposits are often difficult to detect but can still have an effect on the wear behavior of the articulating surfaces. Especially on metallic heads of the same color, deposits are barely visible [12] and their existence cannot be excluded. The aim of our present study was to determine the composition and emergence of metallic deposition in order to identify indications and strategies on how metallic deposition can be avoided. For this purpose, 98 retrieved femoral heads with material transfer on the surface were analyzed. It should be mentioned that heads with only minor contamination were not included in the study. Since all of the heads were from revisions and in many cases the first implantation did not take place in our hospital, some data could not be recorded and no information about the implantation period or any previous implants could be provided. In some cases, this includes exact data of implant design used. Therefore, for femoral heads with the bearing partner PE, a subdivision into conventional and crosslinked or mixed with additives (e.g., vitamin E) was omitted. For the same reason, in many cases the exact composition of the ceramic could not be determined. For instance, in the case of the other oxide ceramics, it was unknown in some cases whether they were made of zirconia, ATZ or ZTA and whether yttrium had been added. The influence of patient age, sex, weight, or activity on the extent of transfer cannot be found in the study by Fredette et al. [11]. Furthermore, it cannot be excluded that some marks of deposition may have been caused during the implantation or revision, for example due to surgical instruments. It is also unknown which depositions may have been created by contact during storage in the explant archive. To address these limitations, the bearing partners, cups and remaining revised parts (if available) were included in the analysis. In connection with the surgery reports, this provided information about the cause of revision. During examination of the retrievals, it was found that metallic transfer was not only present on femoral heads. It was also present on the surface of the bearing partners in hard-hard bearing couples and, in some cases, also on the associated retrieved implant systems.

A study of Brand et al. [19] reported that mainly stripe-shaped patterns were seen on retrieved femoral heads, while predominantly smear-typed patterns were seen on retrieved acetabular cups. In the study of Fredette et al. [11], the transfer patterns on the femoral heads were classified for the first time. As this classification scheme was also used in this study, a similar distribution of the deposition patterns was observed as compared to the one described by Fredette et al. [11]. A significant association was found between the occurrence of random patches and ceramic-ceramic bearing couples. One reason for this is that particles were ground by the harder ceramic after entering the bearing surfaces and were distributed in the entire joint space during articulation. This could also have resulted in patterned coverage as it is shown in Figure 4. No further association of the occurring transfer patterns and the type of bearing couple was found. Contrary to the study of Fredette et al. [11] where the transfer was mainly located in the upper hemisphere (equivalent to pole), the transfer patterns in our present study were mainly located in the equatorial region, but especially in the transitional region from the equator to the pole region. A distinctive pattern often found in this region was the solid patch. This pattern was associated with a recurrent dislocation. The dislocation patch could be caused by scraping the head on the rim of the metallic acetabular cup and distributing the generated metallic particles on the articulating surface after repositioning, which is also described in the case report of Patten et al. [33]. There were also significantly more occurrences of random stripes in revisions due to gluteal insufficiency and implant fracture. The pattern could occur in these unstable situations due to the linear contact of the femoral head with the rim of the acetabular cup. A study by Walter et al. [12] reported that striped transfer could be caused by edge loading. However, due to the wide variety of causes there were often only a small number of samples available per group in this study to test for associations.

Since the articulating joint is surrounded by a joint capsule, it is likely that the transferred material originates from wear particles of the implant as well as the bone and the surrounding tissue. The main components of metallic acetabular cups and stems are Ti alloys (mainly Ti-6Al-4V) and CoCrMo alloys. Thereby, Ti alloys are the softer material and are often associated with tissue discoloration and the release of wear particles [35]. Additionally, in this study, as well as in the study of Tikekar et al. [31], titanium is most frequently found transfer material on the retrieved femoral heads. The second most common material was carbon, which probably originates from bone wear particles that may be generated during the implantation process or by micromotions between bone and implant. Sources for the other detected elements could be ceramic particles from ceramic heads, in which mixed ceramics of Al₂O₃ and ZrO₂ with added yttrium are often used [36]. Wear particles from bone cement would also be conceivable. This consists primarily of polymethyl-methacrylate (C₅O₂H₈), but may also contain components of ZrO₂, BaSO₄ (barium sulfate), Na, P, Ca, Si and Cl. The elements Na, P, Ca and Cl are also components of the blood plasma and can diffuse into the bone cement over time [37]. Wear particles from surgical tools, which were introduced during implantation or revision, cannot be excluded. Residues of previous implants in case of multiple revisions can remain in the body for a long time and could be an explanation for the background noise that was observed on some heads during EDX analysis. It is assumed that, especially in the case of pronounced depositions, several transfer layers are present, between which tissue and synovial residues have become embedded. In the present study, iron was found to be a transfer material in total hip revisions associated with polyethylene wear. This represents delamination and also decentralization, in which the femoral head ploughs into the liner out of the center of rotation. This enlarges the artificial joint gap and enables the generated wear particles to migrate more easily within the articulating surfaces. In the case of heavily abraded bearings, the femoral head can also come into contact with the outer cup as well as additional fixation screws. These screws are often made of stainless steel and could be a reason for the transferred Fe. Furthermore, the significant occurrence of Fe as a deposit after implant fractures may originate from contact with additional fixating implants. In case of revision due to wear particle disease, the deposit of O was significantly detected. Since only elements can be detected by EDX, but not element compounds, the origin cannot be clarified. A conceivable cause may be the formation of free oxygen radicals, which often occur in wear particle disease due to their biological response [38–40]. Oxidized metal particles are also a possible cause. An advanced analysis method represents X-ray photoelectron spectroscopy (XPS), which can provide information about the elemental compounds on the surface transfer. This could allow for a more precise delimitation of the origin of the transferred material.

In the case of septic loosening, a significant occurrence of sulfur was found in the transferred materials on the femoral heads. A possible source could be in the biofilm formed by colonizing bacteria [41]. The bacterial pathogens detected in the revisions *Staphylococcus aureus* and *Enterococcus faecalis* are among the most common pathogens in septic revisions [42]. Some studies showed that sulfide is an important component of the microbial sulfur cycle and *S. aureus* can use hydrogen sulfide to protect against cationizing molecules from antibiotics [43–45]. *E. faecalis* is also known to produce sulfur-containing radicals to reduce oxidative stress [46]. Alternatively, the sulfur could originate from defensins. These small, disulfide-rich, cationic peptides are known for their antimicrobial activity and represent the first defense of the innate immune system against Gram-positive and Gram-negative bacteria, fungi, viruses and parasitic protozoa [47]. In septic loosening an abundance of these cysteine-rich peptides in the local environment of the infected implant is therefore highly likely. Another source of the sulfur could be bone cement spacers that were used as a temporary placeholder in case of implant-associated infections [37]. Carbon was another detected element that was significantly higher on femoral heads revised due to sepsis. As carbon is the main element in all organic compounds including biomolecules, the inflammatory reaction and tissue destruction in sepsis might explain

why carbon is more abundant in septic revision. On heads revised due to bone fractures, the significantly detected calcium can be explained by contact with bone fragments. Due to smaller group size in the associations, these observations should be confirmed in further studies. In addition, future studies should include femoral heads with slight transfer, which were excluded from present study. In future studies, accurate visual assessment during revision will also help to distinguish existing deposits from intraoperatively generated metallic transfer.

The limitations of the study are summarized below. Due to the high variability of head materials and deposition forms, the group sizes differ remarkably. For example, a very large number of heads made of alumina were examined ($n = 28$), but only comparatively few coated metallic heads ($n = 6$). A critical limiting factor is the patient data. Because the primary surgeries often took place in other clinics, the implantation period and some other data could not be collected and thus could not be included in the correlation. After revision, specimens must be initially stored for one year before examination, as the patient is allowed to recall the retrieval within this time. During storage, additional metallic deposition by the enclosed implant system cannot be excluded. Therefore, heads with very slight deposition were excluded in the sample acquisition. In addition, only single elements could be detected by EDX analysis. The advantage of the EDX analysis is the non-destructive measurement. Nevertheless, a detailed investigation of the chemical composition is desirable. Furthermore, it is assumed that the metallic deposit is formed layer by layer on the surface. Therefore, an erosive analysis to investigate the individual layers of the metallic deposition would be of interest.

5. Conclusions

Material deposits are not only found on femoral ceramic heads. They can also occur on metallic heads and on the surface of the rest of the revised implants parts, such as acetabular cups or hip tapers. Our study showed that titanium is the most commonly transferred material. However, the deposition materials were not limited to metallic elements, and non-metallic materials such as carbon or sulfur were also transferred. Some possible sources of the deposition materials could be identified; for example, random patterns due to implant system contact in unstable joint situations. It was further shown that the deposition pattern solid patch results from dislocations of the femoral head. Random patches were identified as a typical pattern on ceramic-on-ceramic bearing couples. In general, depositions on bearing surfaces should be avoided, as they lead to an introduction of third-body particles and increased wear. Further long-term studies, with complete information on the implantation period and photo documentation during revision, are recommended. An examination of the metallic deposition with XPS to determine the complete elemental composition can provide more precise information on the origin of the deposition. In order to better comprehend the origin and formation of the metallic deposition and to better assess its influence on abrasive wear, the use of simulation models would be a promising option [21]. Investigation of the formation processes by means of multi-body simulation can also provide a lot of information in the future.

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Preise und Auszeichnungen

2022	<p>Heinz Mittelmeier Forschungspreis 2022 der Deutschen Gesellschaft für Orthopädie und Orthopädische Chirurgie e.V. (DGOOC)</p> <p>Hembus J, Rößler L, Springer A, Frank M, Klinder A, Bader R, Zietz C, Enz A. „Experimental Investigation of Material Transfer on Bearings for Total Hip Arthroplasty4 A Retrieval Study on Ceramic and Metallic Femoral Heads“</p> <p>(Dotiert mit 5.000 €)</p>
2018	<p>Posterpreis im Rahmen des 26. MSB-Netzwerk Treffen. Magdeburg: DGOU - Forschungsnetzwerk Muskuloskelettale Biomechanik</p> <p>Dammer R, Crackau M, Hembus J, Lohmann CH, Bader R, und Bertrand J. „Rheologische Untersuchung natürlicher und künstlicher Synovialflüssigkeiten“</p> <p>(Dotiert mit 250 €)</p>

Liste der Originalarbeiten, Buchbeiträge und Konferenzbeiträge

Originalarbeiten und Buchbeiträge

1. **Hembus J**, Rößler L, Springer A, Frank M, Klinder A, Bader R, Zietz C, Enz A. „Experimental Investigation of Material Transfer on Bearings for Total Hip Arthroplasty4A Retrieval Study on Ceramic and Metallic Femoral Heads“. *J. Clin. Med.* 2022, Nr. 11, (Juni 2022): 3946. <https://doi.org/10.3390/jcm11143946>

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2. **Hembus J**, Ambellan F, Zachow S, und Bader R. „Establishment of a Rolling-Sliding Test Bench to Analyze Abrasive Wear Propagation of Different Bearing Materials for Knee Implants“. *Applied Sciences* 11, Nr. 4 (Januar 2021): 1886. <https://doi.org/10.3390/app11041886>.
3. Vogel D, **Hembus J**, Henke P, und Bader R. „Verhalten unterschiedlicher Implantatwerkstoffe unter mechanischer Belastung“. In *Orthopädie und Unfallchirurgie*, 1318. Springer Reference Medizin. Springer, Berlin, Heidelberg, 2021. https://doi.org/10.1007/978-3-642-54673-0_44-1.
4. Vogel D, **Hembus J**, Jackszis M, Bolte V, und Bader R. „Influence of Different Damage Patterns of the Stem Taper on Fixation and Fracture Strength of Ceramic Ball Heads for Total Hip Replacement“. *BioMed Research International* 2020 (14. Mai 2020): e7542062. <https://doi.org/10.1155/2020/7542062>.
5. **Hembus J**, Rößler L, Jackszis M, Klinder A, Bader R, und Zietz C. „Influence of Metallic Deposition on Ceramic Femoral Heads on the Wear Behavior of Artificial Hip Joints: A Simulator Study“. *Materials* 13, Nr. 16 (Januar 2020): 3569. <https://doi.org/10.3390/ma13163569>.
6. **Hembus J**, Lux L, Jackszis M, Bader R, und Zietz C. „Wear Analysis of Cross-Linked Polyethylene Inserts Articulating with Alumina and Ion-Treated Cobalt-Chromium Femoral Heads under Third-Body Conditions“. *Wear* 4023403 (15. Mai 2018): 216323. <https://doi.org/10.1016/j.wear.2018.02.017>.
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 2. **Hembus J**, Gierschner S, Ambellan F, Zachow S, und Bader R. „Tribological investigations of polymer materials on a rolling-sliding knee wear simulator“ In 30th Annual Conference of the European Society for Biomaterials, Biomaterial characterisation: PS1-14. Dresden: ESB, 2019.
 3. **Hembus J**, Rößler L, Zietz C, Jonitz-Heincke A, und Bader R. „Generierung und Charakterisierung von Abriebpartikeln aus Gelenkspacer-Implantaten auf Polyurethan-Basis mit unterschiedlicher chemischer Zusammensetzung“ Bd. Postersession 2 • Implantate/Tribologie, P 10. Berlin: Deutsche Gesellschaft für Biomechanik e.V., 2019.
 4. Vogel D, **Hembus J**, Thalhauser L, Lehner R, und Bader R. „Evaluierung der Computertomografie als Methode zur Abriebanalyse an Polyethylen-Inserts für künstliche Hüftgelenke“ Bd. Session 4-Implantate/Tribologie/Biomaterialien I, V 28. Berlin: Deutsche Gesellschaft für Biomechanik e.V., 2019.
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7. **Hembus J**, Lux L, Jackszis M, Bader R, und Zietz C. „Der Einfluss von Drittkörpern auf das Abriebverhalten von Hart-Weich-Gleitpaarungen im Hüftabriebsimulator“ In Reibung, Schmierung und Verschleiß, Bd. Biotribologie & Life Science, V44. Göttingen: Gesellschaft für Tribologie e.V., 2017.
 8. **Hembus J**, Lux L, Jackszis M, Bader R, und Zietz C. „Experimentelle Untersuchung des Abriebverhaltens von hochvernetzten Polyethylen-Inserts in Kombination mit keramischen und metallischen Hüftköpfen unter Drittkörperverschleißbedingungen“, Bd. Session 12-Tribologie, V 82. Hannover: Deutsche Gesellschaft für Biomechanik e.V., 2017.

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Erklärung

Hiermit erkläre ich, dass ich mich bisher keinem Promotionsverfahren unterzogen oder um dessen Zulassung beworben habe. Die eingereichte Dissertation wurde an keiner anderen Hochschule eingereicht.

Rostock, den 18.10.2022

Unterschrift: _____

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