Ceramics in Orthopaedics

JAMES A. D' ANTONIO
MARTIN DIETRICH
Editors

Bioceramics and Alternative Bearings in Joint Arthroplasty

10th BIOLOX® Symposium
Proceedings

STEINKOPFF DARMSTADT

Springer

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10th BIOLOX® Symposium

Washington D.C., June 10-11, 2005
Proceedings

with 69 Figures
and 31 Tables

STEINKOPFF DARMSTADT

ISBN 3-7985-1518-2 Steinkopff Verlag, Darmstadt

Cataloging-in-Publication Data applied for
A catalog record for this book is available from the Library of Congress.
Bibliographic information published by Die Deutsche Bibliothek
Die Deutsche Bibliothek lists this publication in the Deutsche Nationalbibliografie, detailed bibliographic data is available in the Internet at <http://dnb.ddb.de>.

Steinkopff Verlag Darmstadt
a member of Springer Science+Business Media

http://www.steinkopff.springer.de

Cover Design: TOP DESIGN, Thomas Schuster, Waiblingen

Production and Typesetting: druckerei justus kuch GmbH, Nürnberg

SPIN 11431688 105/7231-5 4 3 2 1 0 - Printed on acid-free paper.

Preface

Dear Colleague and Participant in Bioceramics and Alternative Bearings in Joint Arthroplasty: 10th International BIOLOX® Symposium

We are once again very proud that we are able to present to you the proceedings of the Symposium as part of your registration materials. This group accomplishment has been made possible by the superb cooperation received from the speakers in sending us their manuscripts on a timely basis as well as by the supporting staff at both CeramTec and at the Publishing House in executing all of the details needed. We specially extend our most heartfelt thanks to the Scientific Committee for their assistance in evaluating and selecting the submissions as well as developing the Symposium program.

We are more convinced than ever that the proceedings of this Symposium are a continuation of CeramTec's tradition of providing all members of the orthopedic surgical community with a valuable addition to your reference libraries. We hope that this book will present you with the latest and most up to date source of scientific and clinical information regarding the use of ceramics and other alternative bearings in joint replacement surgery.

The Symposium pays tribute and recognition to the long anticipated awakening of the American Markets to ceramics and alternative bearing technologies as well as to an American City with a strong heritage dedicated to education and to international interaction. We are convinced that the excellence of the presentations, the fruitful discussions, the depth of knowledge of the participants, the quality of the organization and even the City of Washington will all work together to make this a very special event in the pursuit of increased recognition of the benefits of Ceramic Bearing technology by the Orthopedic Surgical community.

James A. D'Antonio
Symposium President

Martin Dietrich
Managing Director
CeramTec Medical Products Division

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BEARING SURFACES – 2005

J. Black

Bearing Surfaces - 2005

I. Black

The mammalian synovial joint is truly a remarkable structure and mechanism. After maturation, guided both by a genetic blueprint and by functionally driven adaptation, its behavior exceeds that of all simple engineered bearings; it is self-lubricating and, to a degree, self-repairing and capable of a service life exceeding 75 years. However, when damaged by trauma, disease or extended use, its repair and replacement has proven to be both one of the most challenging and rewarding of all aspects of human medicine. For when a painful joint, especially in the lower limb, is successfully replaced, the patient has not simply had pain relieved but has been restored to full life, often to such an extent that the permanent presence of an implant is essentially forgotten.

Painful joints, such as the knee or hip, those that historically restricted patients to sedentary existences and consequent shortened life spans, posed problems of enormous magnitude for early healers. Our cultural history is replete with accounts of balms, potions, and liniments, of manipulation, prayer and pilgrimage all directed towards alleviating this terrible affliction. The 20th century combination of anesthesia, antisepsis and, after World War II, blood transfusion, made surgical approaches possible. Early efforts involved interposition of various materials in an effort to replace damaged or missing articular cartilage reaching a culmination in the widely used "mould" arthroplasty introduced by Dr. Marius Smith-Petersen [1]. Other approaches involved surgical resection of the joint surfaces as well as their partial or total replacement with a variety of materials but most usually metal alloys of various compositions.

The modern age of joint replacement, or more commonly arthroplasty, was ushered in in 1961 by the publication by Mr. John Charnley, M.B., B. Sc. Manc., F.R.C.S. of a short paper entitled, "Arthroplasty of the Hip. A new operation" [2]. This paper is notable on two grounds:

First, it lays out the fundamental principles of what Charnley was later to refer to as "low friction" arthroplasty: a metal/polymer bearing, a small ("no bigger than 7/8") diameter metal femoral ball stabilized by an intramedullary stem articulating with a polymeric monobloc acetabular component, both held in place by "cement", the now familiar cure in place poly (methyl) methacrylate (PMMA).

Second, it reports the apparently successful use, over a three-year period involving 97 patients, of poly (tetrafluoro) ethylene (PTFE) for the acetabular component.

As we are now all well aware, by 1962, after some 300 implant procedures, all of which were subsequently revised, Charnley had replaced the unsuccessful PTFE with a high molecular weight polyethylene (HMWP) [3]. With the subsequent evolution of HMWP to a variety of 2 to 6 million molecular weight "ultra high" molecular weight polyethylenes (UHMWPE), Charnley's technological synthesis has been applied to essentially all synovial joints in the human body. It is this approach to which we compare all others, which we thus term "alternate", as in the title of this symposium.

There can be no question of the success of this approach to arthroplasty of the hip and, later, the knee. Some of the most successful, long-lived and durable clinical total arthroplasty series, with reports extending over 2 to 3 decades, utilize

only very modest evolutionary improvements of Charnley's original developments. However, it is worth reflecting on two points from the introduction to his 1961 paper: "In considering how arthroplasty of the hip can be improved, two facts stand out:

1. After replacement of the head of the femur by a spherical surface of inert material, the failures are essentially long-term. At first the patient may notice no difference between the artificial head and the living one, which preceded it. Our problem is to make this temporary success permanent.
2. Objectives must be reasonable. Neither surgeons nor engineers will ever make an artificial hip-joint which will last thirty years and at the some time in this period enable the patient to play football" [4].

Making Temporary Success Permanent

Charnley originally believed that by replacing PTFE with HMWP (and later UHMWPE) he could avoid the adverse lytic response to wear debris that he encountered in his first several hundred cases. Alas, that was not to be so; while the time of onset was delayed and the clinical failure rate was reduced, what we now generally call osteolysis, the loss of bone near implanted components and associated pain secondary to the presence of particulate debris and cytokines generated by macrophages, remains a clinical concern today. The development of alternate bearings and adjunctive fixation technologies can be said to be the primary consequence of attempts to deal with this "disease".

Today the surgeon can make choices among the following engineering options when selecting components for hip arthroplasty:

Structural elements: Components are now fabricated from a wide variety of cobalt and titanium base alloys, as well as advanced stainless steels, and, very occasionally, polymer based composites.

Fixation elements: In addition to variants of the traditional PMMA type "cements", with radio-opacifiers and frequently antibiotic additions, components can be anchored to the supporting bone by direct tissue apposition to a wide variety of ongrowth and ingrowth surfaces, some with bioactive adjuncts to encourage incorporation.

Bearing elements: As this symposium illustrates, the simple metal/polymer interface has expanded to include a wide range of UHMWPE variants with different degrees of cross-linking as well as various surface treatments of the metallic counter face to improve hardness and lubricity. Other, so-called alternate, approaches include a variety of ceramic/polymer. metal/metal and ceramic/ceramic wear pairs.

I shall not recount all the possible combinations, or their relative benefits and risks. There are ample papers elsewhere that allow the reader to make these comparisons and, perhaps, draw conclusions on what may be superior in a specific application or, even possibly, on a global basis. Instead, I would like to make another point, drawing from Charnley's first comment: the challenge is to make temporary success permanent.

With respect to Charnley's original or classical synthesis, improvements in fabrication, sterilization and storage of UHMWPE have so far reduced current wear rates, and subsequent particulate challenge to local biology, that at least one leading orthopaedic surgeon, Dr. W. H. Harris, has declared the problem solved, the disease of osteolysis conquered [5].

In the meantime, research, development and clinical use of alternate approaches has flourished, as judged by this 10th symposium. However, despite the sophistication of in vitro material and simulator testing modalities now available, we are still occasionally surprised, even in the short term. Some early retrievals of modern ceramic components show localized, anomalous wear, termed "stripe" wear [6]. Not only did we not expect this, but we are still not confident in being able to produce in vitro conditions that sufficiently mimic those in patients to permit controlled study of this phenomenon. Additionally, some patients with modern alternate bearing arthroplasties "squeak" when they ambulate. Again, we did not predict this nor do we yet understand its origin or implications, even in isolated cases [7].

More disturbingly, we still lack short-term proxies for long-term outcomes. Most surgeons and engineers believe that lower volumetric wear rates will lead to less osteolysis and more durable long-term outcomes. Correlative studies strongly suggest that this is the case for arthroplasties of both the hip and the knee with classical metal/polymer articulations. But will it be the case in the long-term for those patients receiving the newer UHMWPEs or metal/metal or ceramic/ceramic bearings? We hope for the best but simply do not know.

One thing we should now recognize is that innovation has gone from being an enabler of progress to a barrier to further improvement. Extensive clinical experience both in the US and other countries, with classical metal/polymer bearings in a wide variety of designs, involving different structural materials and fixation systems, suggests that failure rates achievable for lower limb joint replacement arthroplasty are very low. This assertion may come as a surprise to active clinicians, especially in secondary or tertiary referral centers, where revision, as a proportion of current clinical burden, represents between 10 and 20% of all procedures. However, we can now be fairly certain that annual revision rates of 0.5% for hip and 0.4% for knee arthroplasties can be achieved in large clinical populations for periods exceeding 10 years. Furthermore, no more than 1/2 to 3/4 of these revisions can be fairly ascribed to issues associated with bearings, suggesting that bearing "failure", either direct or indirect, should result in no more than 1 patient in each 300 hip or knee arthroplasty patients requiring revision each year in their first post-operative decade. And these estimates do not include the impact of the newer, evolved UHMWPEs that, if they prove as promising as early results suggest, will produce significant further reductions in revision rates.

The high clinical burden constituted by revision arthroplasty is merely reflective of the very large installed clinical bases, due to an annual implantation rate in the US probably now exceeding 700,000, with a similar additional total worldwide. For instance, in Norway, a relatively small country with a population of 4 1/2 million, 2003 saw some 7000 primary hip arthroplasties performed and a national register, in use since 1987, has recorded over 100,000 primary and revision procedures in the hip [8].

These data and other similar ones suggest the following conclusions:

- For "all comers", large improvements in clinical outcome, related to newer (alternate) bearing technology, are not likely.
- Even if such improvements can be inferred from laboratory studies, the tyranny of large numbers and limited resources will prevent their demonstration in prospectively randomized clinical trials.

- Improvements proposed for at risk sub populations, such as younger over weight males with avascular necrosis as the primary diagnosis, will require prolonged, large scale, multi-center clinical studies for demonstration of efficacy (such as reduction in revision rate).
- Finally, it would be a good and ethical idea for surgeons, engineers and companies to agree on maximal acceptable annual revision rates for arthroplasty of major joints duribg evaluation of newer technological approaches, recognizing that procedures that are less successful than more traditional ones in the short-term are unlikely to be better in the long-term.

Let me make a suggestion concerning this last point: the large scale availability of national results for all comers now makes it clear that clinical performance of total joint arthroplasty may be divided into three eras for virtually any patient population: immediate (< 2 years); intermediate (>2 < 7 years) and long-term (> 7 years). Thus it would be reasonable to adopt the following conservative rule for evaluation of newer technological approaches:

Any implant system that shows a cumulative failure (revision) rate of greater than 2% in general populations or 5% in selected at risk sub populations at two-year maximum follow-up should be withdrawn from clinical trial or general use.

The real challenge may not lie, as Charnley suggested, in making temporary success permanent, but in preventing short-term enthusiasm from eroding long-term success.

Objectives must be Reasonable

Engineers and surgeons, as able collaborators, have long looked to technology to improve clinical outcomes of arthroplasty. That is, the devices, their materials of fabrication and, to a lesser degree, the surgical and clinical technology associated with their implantation have been seen as the keys to long-term clinical success. To a great degree, this approach has been responsible for getting us to the admirable situation we find ourselves in today, as measured by revision rates. I would like to suggest that this approach, which has served so well in the past, will not lead us forward.
Instead, I summarize the road ahead, the future of joint arthroplasty, in ten words:

De-skill the procedure.
Re-emphasize the patient.
Regenerate rather than replace.

De-skill the procedure. One of the nasty and poorly kept secrets of orthopaedic surgery is that practice perfects. That is, surgeons who perform low annual volumes of arthroplasty procedures and who work in treating institutions that in turn have few arthroplasty patients do not enjoy these favorable revision rates, even in the short-term [9]. I believe that much of the effort now being devoted to "high-tech" approaches to device design and procedural change should be redirected to providing appropriate technology for the more typical ower volume surgeons and institutions, where the majority of arthroplasties are still performed, to enable them to improve their results towards those already achieved in higher volume situations. Such technology should be low in monetary and training cost,

have minimal associated learning curves and not extend operating time. It should be directed to reduction or elimination of "outliers" in technique rather than to optimization; that is, towards making all procedures good enough.

Re-emphasize the patient. Too often, in the pressure of contemporary orthopaedic practice, the patient has come to be seen as a mal-functioning mechanism and the surgeon as the technician who locates and replaces the defective part. Traditionally orthopaedic surgery has been patient and quality of life oriented. I think that a great improvement in quality of outcomes, reflected by greater patient satisfaction if not by further reduction in revision rates, could be achieved by re-emphasizing the patient. This effort, which must of necessity be multi-disciplinary, should include further development of the current interest in outcomes analyses based upon patient satisfaction, preparation of self-paced educational material to help patients and their families understand the capabilities of contemporary arthroplasty procedures as well as studies of arthroplasty outcomes that focus more on patient pre-operative condition and expectations and on surgical approach, procedures and post-operative rehabilitation and management, rather than on the choice of bearing technology in the implant itself, as study variables.

Regenerate rather than replace. Marius Smith-Petersen had as an original goal the reformation of damaged articular cartilage rather than its removal and replacement. Unfortunately, we know that unaided, the reparative tissue that results is fibrous rather than hyaline in nature and inadequate to the functional requirements of the joint. However, over the five decades since his death, enormous strides have been made and are continuing to be made in understanding and manipulating cartilage and bone repair processes. Much remains to be done but the burgeoning field of tissue engineering suggests a possible future in which even our alternate bearings may come to be seen as parts of aids to in situ repair or bridges to replantation of in vitro cultured cells and tissues, as the left ventricular assist device (LVAD) is increasingly being used as a bridge to heart transplantation [10].

Conclusion

The situation concerning arthroplasty bearing surfaces in 2005 can be summed up as follows:

- Evolutionary change has rendered Charnley's original polymer/metal approach to prosthetic joint articulation durable, reliable and economical.
- Alternate approaches hold great promise, which may be difficult to demonstrate or realize in general clinical experience.
- The future may well see the focus of arthroplasty technology development turning away from traditional concerns about materials and design to a broader involvement of biological and social sciences.

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SESSION 1

New Developments in the Basic Science of Ceramics and other Alternative Bearings

1.1 Severe Simulation Test for run-in wear of all-alumina compared to alumina composite THR

I. C. CLarke, G. Pezzotti, D. D. Green, H. Shirasu and T. Donaldson

Summary

Four combinations of Biolox-forte and Biolox-delta implants (36mm diameter; 70μm diametral clearance) were subjected to a severe microseparation simulator wear model to 1.1 million cycles duration (run-in phase). With Biolox-forte THR, the stripe wear produced during run-in averaged 4.7 mm^3 per million cycles. With the hybrid combinations of Biolox-forte/delta THRs, the wear rates were reduced 5-fold to an average of 0.9 mm^3/million cycles. The delta-ball/forte-cup and forte-ball/delta-cup combinations performed equally well. With Biolox all-delta THRs, the stripe wear averaged a low of 0.45 mm^3 per million cycles, reduced by half from the hybrid combinations. These data were in a good agreement with published simulator studies. The Raman spectroscopy studies of the severely worn stripe regions in delta-balls showed that up to 30% of the surface tetragonal zirconia had transformed to the monoclinic phase as part of the wear process. Comparison of Biolox-forte and delta wear debris from the run-in phase showed similar morphology.

Introduction

From the first retrieval studies of alumina implants used in total hip replacements (THR), the phenomenon of 'stripe' wear has been recognized on both ceramic femoral balls and ceramic acetabular cups [1-3]. Such stripe wear was seen visually, generally as a less highly polished, lunar shape on the femoral ball and a circumferential stripe adjacent to the cup bevel [4-6]. Stripe wear has been attributed to negative clearance between ball and cup to vertically inclined or migrating/tilting cups that loosened [7-9]. Clarke et al [10] suggested that this was also likely to be a natural consequence of using rigid cup materials such as CoCr and alumina ceramic as opposed to the much more flexible polyethylene cups, i.e. a stress concentration effect of the rigid cup rim wearing on the femoral ball [11]. The latest simulator studies incorporating microseparation test modes have illustrated this stripe wear phenomenon in vitro [12-17].

While wear-rates with alumina ceramic THR have been extremely low [18], the stripe wear was a more 'severe' damage mechanism with the consequence of > 20-fold wear elevation in laboratory studies [9,19,20]. It was therefore interesting that microseparation studies with the recently introduced composite ceramic (Biolox-Delta™) revealed up to 12-fold reduction in average wear rates compared to conventional alumina ceramic [18,19]. While Biolox-Forte™ has the highest hardness, the Biolox-Delta™ with significantly smaller grain size provides superior mechanical properties, including almost double the strength. The fracture 'toughening' mechanism of Biolox-delta, i.e. the dispersion in an alumina matrix of small zirconia grains (approximately 24% by weight) and the addition of a small fraction of strontium-hexaluminate platelets provides for an approximately 30%

increase in toughness. Thus from the point of view of a composite ceramic, the alumina phase provides the ideal bearing surface while the zirconia phase contributes to increased strength and toughness.

The microseparation simulator study by Stewart et al [19] examined three forte (f) and delta (d) combinations, i.e. f-ball/f-cup, d-ball/f-cup and d-ball/d-cup. Compared to Biolox-Forte™, the delta-ball/delta-cup combination reduced the roughness 5-fold and also reduced average wear > 10-fold [19,20]. The concomitant wear rate for delta/delta THR was 0.32 mm^3 (0 to 1 million cycles). While the authors studied the ceramic grain size, they did not study the f-ball/d-cup hybrid combination or the phase-transformation dynamics of the zirconia component in the composite ceramic.

Our first microseparation simulator study examined two combinations of ceramic (36mm: f-ball/f-cup and d-ball/d-cup) [17]. This run-in, wear evaluation showed > 11-fold wear reduction with the delta-delta THR combination. The objective of our 2nd microseparation study was to subject four combinations of Biolox-forte and Biolox-delta ceramic (36 mm diameter THR) to a 'severe' microseparation test mode and examine the wear-rates, surface roughness and zirconia morphology during the run-in wear phase (0-1 Mc duration). The X-ray diffraction (EDAX) studies have demonstrated high amounts of tetragonal to monoclinic transformation in femoral balls made entirely of the metastable zirconia ceramic [21-23]. We have confirmed up to 80% monoclinic phase change using the raman spectroscope (1 μm spot size) [16,24,25]. This high-resolution method can detect zirconia transformations that are too small to be measured by standard (EDAX) techniques (200 μm spot size) [24-26]. Thus at the end of 1 million cycles duration, we incorporated high-resolution, raman spectroscopy into our simulator study of Biolox-delta balls and cups.

Materials and Methods

The 36mm Biolox-forte™ and Biolox-delta™ balls and liners were provided by CeramTec AG (Plochingen, Germany). The delta composite contained alumina (Al_2O_3 75% by weight), zirconia (ZrO_2 24%) and mixed oxides (1% CrO_2 and SrO). the volume ratio of zirconia corresponds to 17%. The microstructural characteristics of this composite ceramic have been extensively documented. The salient features can be summarized as follows: (i) no porosity in the composite microstucture; (ii) sizes of the alumina and zirconia grains were typically < 1.0 and 0.3 μm, respectively; (iii) included a small fraction of platelet-shaped strontium hexaluminate with typical aspect ratio between 3 and 6. The addition of strontium oxide (SrO) as elongated platelets greatly adds to the strength and toughness of the composite matrix.

The ball and cup sets with a range of tolerances were diametrically matched to average 70 ± 4 μm. The implants were mounted anatomically with a cup angle of 50° to the horizontal on an orbital hip simulator (Shore Western Manufacturing, Monrovia CA) modified for micro-separation. A spring force provided a latero-medially directed load during a segment of negatively loaded swing phase with the result that the ceramic liner migrated medially and superiorly relative to the femoral head. The spring force was adjusted at each installation to provide a nominal translation of < 2 mm. A Paul load curve (max. load 2 KN) was run at frequency 1 Hz. Diluted alpha-calf serum (Hyclone®, Ogden, UT) was used as a lubricant (10mg/ml protein concentration).

Weight-loss of each implant due to wear was determined at 100,000 cycles intervals up to 1.1 million cycles (1-Mc) duration and the average trends determined by linear regression for conversion to volumetric wear-rates. As a measure of variance the minimum and maximum wear values were normalized to the mean wear-rate and compared to the estimate for 95% confidence limits [Max scatter% = (Max-Avg)x100/Avg]. The peripheral wear scars also referred to as 'stripes' were inspected at each event and logged by macro-photography. Serum was stored frozen for later debris analysis under SEM. Post analysis of ball and cup involved SEM for topographical analysis, surface roughness and wear modes, EDAX for determination of crystal structure of zirconia and raman spectroscopy for determining zirconia phase transformations.

Raman spectra were collected with a triple monochromator spectrometer (T-64000, ISA Jovin-Ivon/Horiba Group, Tokyo, Japan) equipped with a charge-coupled detector (high-resolution CCD camera). The laser power was 400 mW at the laser head and the excitation frequency was the blue line at 488 nm of an Ar-ion laser. A confocal configuration for the Raman probe was selected by placing a pinhole aperture in the optical train of the spectrometer and using it to regulate the rejection of out-of-focus light. The content of monoclinic polymorph in the zirconia phase contained in partially transformed zones could be quantitatively evaluated from the relative intensities of selected Raman bands belonging to the tetragonal (145 and 260 cm^{-1} bands) and to the monoclinic (178 and 189 cm^{-1} bands) polymorphs. Each data point represented the average of 625 Raman measurements on the implant surface. The technique was judged accurate to about 0.2% by volume.

The serum solutions containing the wear debris were digested in dilute hydrochloric acid and then diluted with alcohol followed by ultrasound washes and then centrifuged. Further washings with acetic acid and again centrifugation followed this step. The resulting purified debris was extracted using polycarbonate filters, weighed and then studied by SEM.

Results

In microseparation test mode, the resulting wear damage on the ceramic surfaces was evident as peripheral stripe-like scars at the first measurement event of 100,000 cycles (0.1 Mc) duration. These were seen visually as narrow stripes of dull appearance located approximately 90° from the pole of the femoral ball. On the ceramic cup inserts there was a corresponding wear stripe located adjacent to the cup bevel. By 1.01 Mc duration the stripes had extended to a broad region of wear that extended from the equator up into the polar region (Fig. 1).

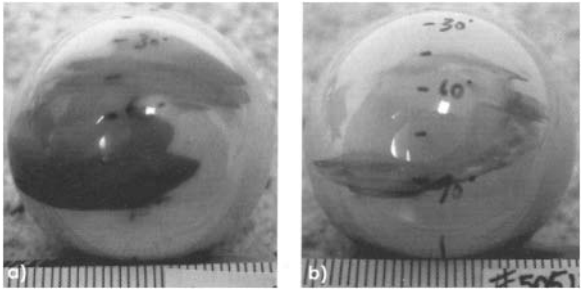

Figure 1a, b:
Extension of stripe wear regions seen marked on 36 mm diameter ceramic femoral balls at 1.1 million cycles duration:
a) broad stripe and extended area of surface damage on Biolox-forte ball
b) stripe damage evident on Biolox-delta ball

For all THR sets, the run-in wear performance, as represented by 11 weight-loss measurements to 1.01Mc duration, appeared as fairly linear trends with all regression coefficients > 0.86 (Table 1). There was also some cyclical variation evident in each wear trend (Fig. 2). This made it difficult to determine whether there was any reduction in wear rate as would be expected at the onset of a steady-state wear phase. The maximum data variance (± 60%) was seen in the forte-forte combinations due to one THR exhibiting a uniquely high wear rate of 7.4 mm^3/Mc (Table 1). Variance in the other ceramic THR sets was typically < 24%. Overall, the forte-forte combinations produced the highest wear (Fig. 2a) averaging 4.7 mm^3/Mc, with cup wear represented 52% of that total.

Ball	Cup	Ball mm^3/Mc	Cup mm^3/Mc	THR mm^3/Mc	Wear ratio	1/ratio	Cup Wear%
forte	forte	2.25	2.46	4.71	100%	1.0	52%
forte	delta	0.35	0.59	0.94	20%	5.0	63%
delta	forte	0.56	0.32	0.87	19%	5.4	36%
delta	delta	0.20	0.25	0.45	10%	10.4	55%

Table 1:
Summary of volumetric wear averages for 4 combinations of ceramic (36 mm Biolox-forte; delta) run under microseparation wear mode to 1.1 million cycles. [cup% = ratio of cup to THR wear]

The least wear was evident with the delta-delta THR sets averaging 0.45 mm^3/Mc. This represented a 10-fold wear decrease compared to the forte-forte sets with the delta-cups representing 55% of total (Table 1). The hybrid ceramic sets represented a 5-fold wear decrease, averaging 0.9 mm^3/Mc. With the forte-ball/delta-cup hybrid, the delta-liner produced the greater amount of wear (Fig. 2b). With the delta-ball/forte-cup hybrid, the delta-ball produced the greater amount of wear (Fig. 2c). Thus the ratio of cup to total wear varied from 36% with delta-forte hybrid to 63% with forte-delta hybrid.

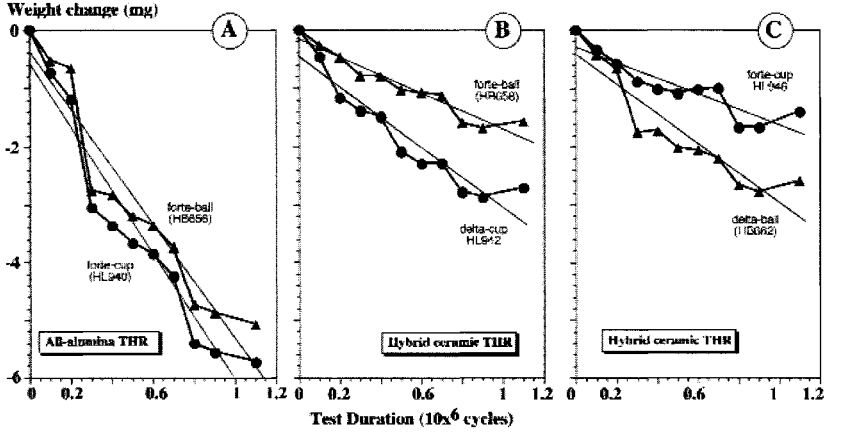

Figure 2a,b,c:
Linear-regression wear trends for run-in phase of 36 mm CeramTec ball and cup pairs (with same y-scale): a) forte ball on forte cup (ball wear < cup). b) forte ball on delta cup (ball wear < cup). c) delta ball on forte cup (ball wear > cup).

On the delta-balls at 1.1Mc duration, the zirconia monoclinic fractions ranged from 15 to 30% by volume in polar and equatorial regions, respectively. The partially transformed structure was clearly recognized from the concurrent presence of Raman bands belonging to both monoclinic and tetragonal polymorphs (Fig. 3). The relative intensity of the Raman bands was always observed to increase in equatorial regions of severe stripe wear compared to the polar regions that had fine burnishing. Similarly the monoclinic fraction detected in the bevel region of the cup were always greater than that detected in the polar region. The monoclinic fractional values in cup-bevel and polar regions were 10 to 16%, respectively, conspicuously lower than detected on femoral balls.

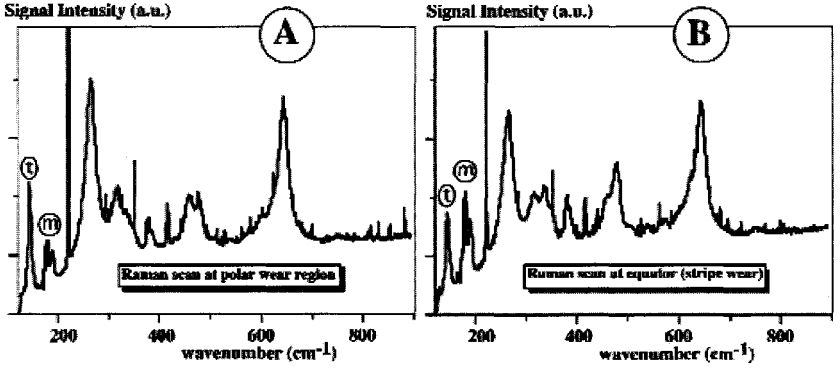

Figure 3a,b:
Raman spectroscope scans by laser (spot size 1 μm) was used to evaluate the quantitatively zirconia phase change from tetragonal (t) to monoclinic (m), using relative intensities of Raman bands at 145 and 260 cm^{-1} belonging to tetragonal polymorph and at 178 and 189 cm^{-1} belonging to monoclinic polymorph:
a) scan of Biolox delta-ball at polar region (mild wear) showing presence of monoclinic peak but still smaller than tetragonal peak
b) scan of Biolox delta-ball at equatorial region (severe stripe wear) showing monoclinic peak now larger than tetragonal peak

While wear debris from the current studies are still under investigation (Fig. 4), the distribution of Biolox-forte and Biolox-delta appeared similar (Fig. 5). The alumina phase was easily detected by EDAX. Overall the delta material showed a wider distribution (larger outliers) but the mean values were similar.

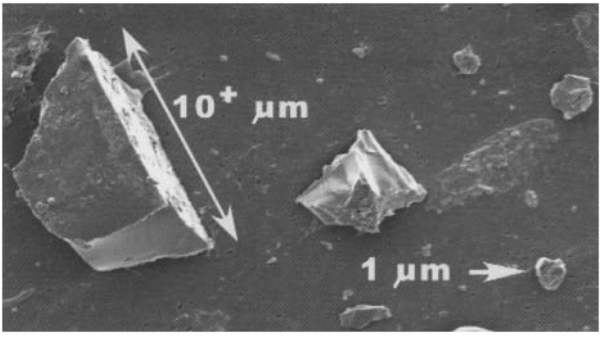

Figure 4:
Comparisons of ceramic wear debris recovered on filters as sub-micron to 10μm size particles. This sample was from 36 mm forte-ball/delta-cup study at 500,000 cycles duration (with microseparation). These were identified as alumina by EDAX but no zirconia phase was detected.

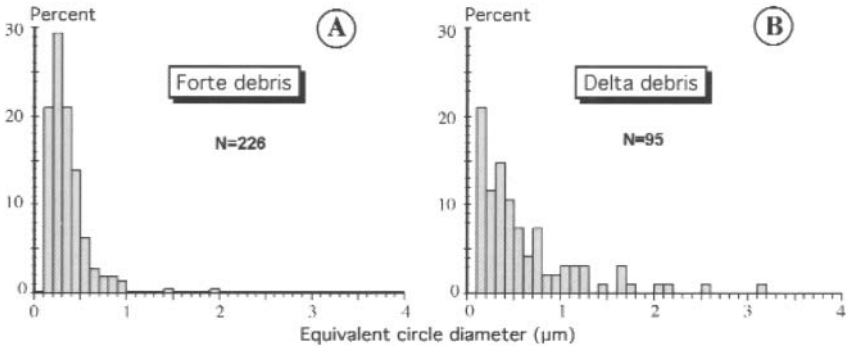

Figure 5a, b:
Similarity in distribution for BIOLOX® forte and BIOLOX® delta.

Discussion

This is the first description for run-in wear for combinations of 36mm diameter forte and delta-implants and also the first description of the tetragonal to monoclinic phase change in the zirconia constituent of the composite matrix. This transformation toughening mechanism is a fundamental characteristic of a metastable zirconia and is responsible for its greatly increased mechanical performance. Thus we were not surprised to find that raman spectroscopy detected the monoclinic phase in the delta-matrix at 1.1 million cycles duration. As ceramic wear progresses, the exposure of tetragonal zirconia grains on the articular surface will naturally result in some zirconia transformation to monoclinic phase due to the action of compressive and shear stresses combined with frictional heating of the lubricant and adjacent surfaces (Fig. 6). Zirconia as the distributed 2nd phase in Biolox-delta, represents 24% by weight but only 17% by volume. Thus a 30% monoclinic volume represented approximately 5% of the articular surface. The volume expansion of the monoclinic phase would also contribute to a desirable compressive stress field on the bearing surface. In addition, the internal ceramic matrix still contains tetragonal zirconia distributed within the more rigid and constraining alumina phase (Fig. 6). Thus the delta-implants retain an optimized combination of high-strength composite core with a hardened alumina articular surface for maximum wear resistance.

The lesser amount of monoclinic transformation at the cup rims was likely due to the fact that it was not possible to focus the laser sufficiently exactly on the stripe, i.e. the geometrical configuration of the acetabular cup interfered with the microscope lens. It was not also possible to section the cups at this point because the microseparation wear study is continuing to 5 million cycles duration,

With gradual burnishing type of wear, both monoclinic zirconia and alumina grains will be eroded as fine ceramic wear debris [4,15,27]. Thus the worn delta-surface will have micron-size craters formed by erosion of both zirconia and the harder alumina grains. The large and sharp-edged ceramic fragments (Fig. 4) that had been chipped of the surface attested to the violence of our micro-separation wear mode. Using this severe impact test mode, the superior toughness of the delta-material was clearly demonstrated by a 5-fold wear reduction in hybrid combinations and 10-fold reduction in the all-delta combination. It was interesting

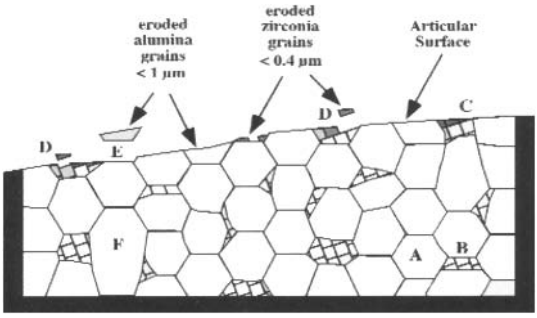

Figure 6:
Schematic representation of the articular cross-section in Biolox-delta. The alumina grains ('A') are indicated as white hexagons measuring less than 1 μm [20]. These enclose a distributed zirconia tetragonal phase indicated by white squares ('B') averaging 0.35 μm or less. For the zirconia grains exposed on the articular surface, the shear stresses and thermal gradients in the joint's moist environment will transform some tetragonal phase to monoclinic (grey squares'C'). As wear progresses these expanded monoclinic grains will become ceramic debris (D). Similarly the alumina grains will either be worn down or suffer trans-granular fracture (E) and be ejected from the surface as potentially larger ceramic particulates. The addition of strontium oxide (SrO) as platelets (F) greatly adds to the strength and toughness of the delta-composite.

that not only were the wear rates very low for all ceramic combinations but the hybrid combinations of delta and forte (ball-liner: f-d, d-f) resulted in the same 5-fold wear reduction. Thus the Biolox-delta implants reduced the THR wear rates in the three combinations studied. This suggested that ball or cup design optimization with Biolox-delta would produce equivalent wear performance.

Stripe wear has been visualized by a quite narrow region of surface damage in simulator studies [15,19] and also short-term clinical retrievals [6]. The stripes can also become very broad, as identified in our SEM mapping of alumina balls retrieved after 17 to 22 years in vivo [27]. In our microseparation study the Biolox-forte balls showed the most extension of the peripheral stripes up into the polar regions and represented far more wear than seen under pristine test conditions [18].

While our microseparation studies are continuing, there appeared to be encouragingly good agreement with the Leeds University study (Table 2). This was especially interesting given the many differences in simulators, test protocols and implant diameters. There was also agreement that forte/forte and delta-delta combinations produced wear equally in both balls and cups whereas with d-ball/f-cup combination, the delta-implants produced comparatively more wear in their THR pairings (Table 2). The question had been raised whether the hardness or toughness of the ceramic hybrid controlled this wear response [20]? Therefore it would appear that the superior hardness of the alumina was responsible for lower wear in each hybrid pairing, whether present as a ball or cup insert.

As well as the usual cyclic variations in wear trends [18], we anticipated additional data variance due to the addition of our spring-loaded, micro-separation mechanisms. Nevertheless, the run-in wear variance in three ceramic sets (ball-cup: d-d, d-f, f-d) was considered adequate at $< \pm 24\%$. The $\pm$ 60% variance in one forte-forte set was due to one ball and cup initiating high wear after 300,000 cycles, which continued linearly to 1.1 Mc duration. It was not clear to us why this variation occurred. Possibly the mounting of this f-f ball/cup had been changed at 300,000 cycles or perhaps this microseparation mechanism was set more severe than for the other stations.

THR	LU study	LLUMC study	Leeds Ratio	LLUMC ratio
forte-forte	4.1	4.71	100%	100%
delta-forte	1.20	0.87	29%	18%
delta-delta	0.32	0.45	8%	10%

Table 2:
Four combinations of ceramic THR (forte; delta) run under microseparation test conditions at LLUORC compared to data from Institute of Medical and BioEngineering (IMBE, Leeds University) [20]. NS = not specified; Pr = protein concentration; * = IMBE study reported majority of ceramic debris predominated around nanometer size.

Conclusions

1. All Biolox-delta THR combinations (36mm ball-cup; d-d, d-f, f-d) resulted in significantly reduced run-in wear compared to Biolox-forte THRs.
2. Use of the delta-ball/forte (d-f) cup combination or alternatively the forte-ball/delta (f-d) cup combination reduced the run-in wear-rate equally to 5-fold less than the historical Biolox forte-forte combination.
3. With the delta-delta combination, the corresponding wear reduction was 10-fold less than the historical Biolox forte-forte combination.
4. At 1.1 million cycles duration, zirconia transformation from tetragonal to monoclinic was detected by raman spectroscopy at 10-30% levels on the surfaces of delta-cups and balls
5. Biolox-forte and Biolox-delta wear debris appeared comparable from sub-micron to micron-sized particles.
6. There was good agreement with our severe microseparation study of 36mm Biolox THRs to previous work from Leeds University with smaller ceramic ball diameters.

Acknowledgements

Our grateful thanks to S. Brown and P. Williams (Orthop. Dept., LLUMC) for editorial assistance.

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1.2 Comparison of the Functional Biological Activity and Osteolytic Potential of Ceramic on Ceramic and Cross Linked Polyethylene Bearings in the Hip

J. Fisher, A. Galvin, J. Tipper, T. Stewart, M. Stone and E. Ingham

Introduction

There is considerable interest in the use of the ceramic on ceramic bearing couple in hip replacement as an alternative to conventional or cross linked polyethylene bearings. Ceramic on ceramic bearings are particularly attractive for younger and more active patients, who have the potential to generate more wear and wear debris, and are at risk of earlier failure due to osteolysis with polyethylene bearings. Highly cross linked polyethylene acetabular cups have been introduced into clinical practice in recent years, and some laboratory studies with these new materials have shown extremely low wear. In some cases it has not been possible to measure the wear of highly cross-linked polyethylene, due to moisture absorption artefacts. Extremely low wear has also been recorded in simulator studies and in vivo for ceramic on ceramic bearings. In this case accurate measurements of low wear can be made.

When selecting bearings for young and active patients, there is a need to understand the relative functional osteolytic potential of the bearing couples. The osteolytic potential of the bearing couple is not only dependent on the wear volume, but also on the biological activity of the wear particles. In this paper we summarise our recent research on the wear, wear debris and functional biological activity of conventional polyethylene, highly cross linked polyethylene and Biolox Forte alumina ceramic on ceramic bearing couples.

Methods

The wear of the bearing couples was investigated in the Leeds physiological hip joint simulator in the anatomical position [1,2]. Prostheses (n >3) of each type of prosthesis was tested to five million cycles under standard walking cycle conditions in 25% (v/v) new born calf serum. In addition, ceramic on ceramic bearings were studied under microseparation conditions, which have been shown to represent more clinically relevant stripe wear [3]. The wear rate was measured every one million cycles. The wear particles were isolated and characterised using SEM and TEM [4,5]. The biological activity of the wear particles and functional biological activity and osteolytic potential was predicted using the methods described by Fisher et al [6]. The biological reactivity of the wear particles was also confirmed by direct cell culture with macrophages and determination of osteolytic cytokines [7,8].

Four different types of polyethylene acetabular cups were studied articulating against polished metallic femoral heads and these were compared to Biolox Forte ceramic on ceramic bearings. All bearing couples were size 28 mm diameter. Polyethylene acetabular cups were manufactured from two different

resins, GUR1020 and GUR1050 which were sterilised with low levels of gamma irradiation (4 and 2.5 MRad respectively). In addition GUR 1050 acetabular cups that were highly cross linked with 10 MRad irradiation and re melted were studied. Ceramic acetabular cups were also sterilised with gamma irradiation.

Results

The volumetric wear rates, specific biological activity per unit volume of wear (SBA), and the functional biological activity (FBA) or osteolytic potential for all four bearing combinations are shown in (Table 1). The volumetric wear rate was four times lower for the highly cross linked polyethylene compared to the conventional polyethylene sterilised with a low dose of irradiation. Under standard conditions the wear of the ceramic on ceramic bearing was reduced by more than one hundred times compared to the highly cross linked polyethylene material. Under more severe microseparation conditions the wear of the ceramic on ceramic bearing was six times lower than the highly cross linked polyethylene.

Bearing type	Wear Volume [$mm^3/10^6$ cycles]	SBA	FBA
GUR1020 polyethylene; 4 MRad GVF*	35	0.49	17
GUR 1050 polyethylene; 2.5 MRad	45	0.93	40
Highly cross linked GUR 1050 polyethylene; 10 MRad	9	0.92	8
Biolox Forte ceramic on ceramic	0.04		
Biolox Forte ceramic on ceramic (microseparation)	1.5	0.2	0.3

Table 1:
Wear rate, Specific biological activity (SBA) and functional biological activity (FBA) for the different bearing materials.
*GVF; Gamma vacuum foil

The wear particles generated by the different bearing couples had different specific biological activities, associated with differences in the volumetric concentrations in different size ranges. This was confirmed with direct cell culture studies [7]. In particular the GUR1050 resin produced a greater proportion of the wear volume as sub micron size particles and higher levels of biological reactivity. Similarly, the highly cross linked polyethylene wear particles also showed high levels of biological activity associated with most of the volume of the particles being sub micron in size. There were insufficient wear particles generated from the ceramic on ceramic bearing under standard conditions to determine their biological reactivity. Under microseparation conditions, the ceramic on ceramic bearings produced particles with a bimodal size distribution and these particles had the lowest specific biological reactivity.

Combining the wear volume and specific biological activity allowed the prediction of the functional biological activity and osteolytic potential. Differences between the conventional polyethylenes were found, with the less

lreactive GUR1020 resin having the lowest osteolytic potential. The highly cross inked polyethylene showed a four fold reduction in wear rate, but only a two fold reduction in osteolytic potential compared to the conventional GUR1020 resin material. The ceramic on ceramic bearing had a fifty fold reduction in osteolytic potential compared to the highly cross linked polyethylene, due to a reduction in both wear volume and reactivity of the wear particles.

Discussion

In this study we have determined finite wear rates for highly cross linked polyethylene in a hip joint simulator, which has allowed direct quantitative comparison with the wear of ceramic on ceramic bearings. A substantial reduction in wear was found with the ceramic on ceramic bearings. Analysis of the wear particles and direct cell culture with macrophages revealed major differences in the reactivity of the wear particles as measured by the release of osteolytic cytokines. Higher molecular weight polyethylene resin and highly cross linked polyethylene were found to produce smaller and more reactive particles compared to the lower molecular weight GUR1020 polyethylene. Ceramic on ceramic bearings generated particles with the lowest level of reactivity due to their, size and shape and chemical composition. The predicted osteolytic potential (FBA) showed the considerable advantage that can be achieved by the clinical use of ceramic on ceramic bearings.

Acknowledgments

This work was supported by EPSRC, ARC, DePuy international and Stryker Howmedica.

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1.3 Allergic reactions to metal implants: Influence of wear debris

P. Thomas and B. Summer

Introduction

The immunological biocompatibility of implant materials depends on the site of implantation, the proinflammatory effects of implant components and the individual reactivity of the host [1,2,3,4]. Cytotoxic, genotoxic and allergological effects of wear debris and metal ions [1,5,6,7,8] are mostly investigated. It is however unclear to which extent allergic (hyperergic) mechanisms lead to implant intolerance reactions. In some patients, localized or generalized eczema, local swelling, recurrent urticaria or even aseptic implant loosening have been described as result of hypersensitivity to implant components [2,4,9,10,11,12,13]. This seems to be a rather rare event as compared to the nickel, cobalt or chromium sensitisation rates in the general population ranging between 2 – 10% [14,15,16]. T-lymphocytes activated by T cell receptor interaction with antigens, e.g. peptide-associated metal ions mediate delayed type hypersensitivity reactions (DTH). Thus, factors influencing antigen presenting cells like macrophages or dendritic cells may direct the subsequent lymphocyte function. Clinical outcome of lymphocyte reactivity is studied by patch testing. As in-vitro-approach specific proliferation and/or DTH characteristic T helper 1 (Th1) phenotype and mediator production, e.g. interferon-γ secretion may be assessed. Examples are: A patient with impaired fracture healing upon osteosynthesis, in whom a dichromate allergy was proven with concomitant periimplantar oligoclonal (antigen driven) T-cell infiltrate and DTH-characteristic IFN-γ production [17]; a patient with intolerance of knee arthroplasty linked to periimplantar immune hyperreactivity of cobalt specific lymphocytes [18]. In this article potential mechanisms of hypersensitivity reactions and the role of wear debris are discussed.

Facilitating factors for hypersensitivity reactions

An inflammatory response at the metal implant site may result among others from wear formation, action of metal ions upon tissue components and potential (subclinical) infection.

The immunogenic / allergenic potency of a given substance. This is often linked with its capacity to provoke irritation or to penetrate the (muco)cutaneous barrier. In arthroplasty, irritative properties may be exerted by not polymerized acrylates or additives like benzoyl peroxide in bone cement or some metal ions. High levels of nickel, chromium and cobalt are rather immunosuppressive or toxic. In contrast, exposure to low amounts of nickel, chromium and cobalt – at least in vitro - may directly induce expression of adhesion molecules on vascular endothelium. Thus proinflammatory cells are attracted into the tissue [19]. Nickel ions may also influence the phenotype of dendritic cells and thus alter/favour the immune response to it [20]. It has been speculated that nickel (hapten) modified

proteins are "seen" by the T-cell receptor (TCR) in the context of MHC class II molecules [21]. In the case of particular phenotype, e.g. accessory molecule expression of antigen presenting cells a preferential induction of DTH-characteristic Th1-responses with production of IFN-γ and TNF-α may result. The individual reactivity and clinical outcome is further controlled by regulatory T-cells [22], mostly maintaining a "non-apparent/transient" inflammation in healthy individuals [23].

Properties of implant materials and particles. The release of potential allergens like nickel, chromium or cobalt depends on composition, surface modification and chemical or physical corrosion factors. Low pH and low oxygenation of adjacent tissue may influence metallic surface – even leading to titanium release in surrounding tissue [24]. "Hidden" nickel contamination of titanium materials may result from manufacturing processes [25]. Particulate debris may greatly enhance the contact surface to metals contained in it and phagocytosis will favour the persistance in the tissue [6]. Articulating surfaces depending on different material combinations are linked with more or less wear formation. Amount, composition and size of different particulate species – for example biologically more active small size particles of < 0,5µm - will lead to a varying degree of macrophage, fibroblast and osteoblast response [1,8,26,27,28,29,30, 31]. An inflammatory bone resorbing environment results from activated macrophages producing IL-6, TNF-α and PGE_2. Additional mechanisms may contribute to wear-dependent osteolysis: Further inflammation due to macrophage derived reactive oxygen species; impaired periimplantar bone formation; suppressed bone regeneration in response to cytotoxic effects [32]. In addition, the formation of a vascularized granulomatous tissue in response to wear debris seems to be mediated by enhanced expression of vascular endothelial growth factor (VEGF) [33]. This is suggested by a dose and time dependent release of VEGF from particle exposed monocytes/ macrophages. In addition, potential antigens are processed by tissue macrophages and presented to T-cells. In Figure 1 particle-loaded macrophages and T-lymphocyte infiltrate are shown in periimplantar tissue of a patient with arthroplasty failure.

Particle-protein interaction, namely by albumin binding, may enhance particle-dependent macrophage activation and their antigen presenting capacity [34].

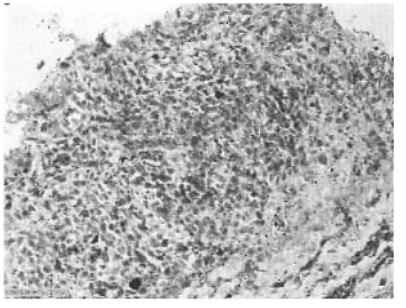

Figure 1:
Periimplantar T-cell infiltrate (antiCD3-stain) in association with wear debris in a patient with implant loosening.

The tissue milieu. Antigen presenting cells (APC) in the tissue first need to be activated by "alarm" or proinflammatory signals (Fig. 2) in order to then take up the potential antigen and transport it to regional lymph nodes. Then, activation of T-lymphocytes, recirculation and reentry into inflamed tissue by preferential

expression of homing receptors will follow. In the periimplantar tissue, it is only partly known which signals induce local APC-activation for primary sensitisation of T-lymphocytes: "Pseudo-lymph follicles" have been observed in periimplantar tissue [35]; particle-loaded macrophages have been seen in proximity to lymphocytes but also in regional lymph nodes; dense T-lymphocytic infiltrates have been observed. With regard to already metal-allergic patients, particles may represent an enlarged metal contact surface for lymphocytes, that are attracted into the tissue. However homing receptors and chemoattractants (like CLA or CCL27) are only well characterized for cutaneous reactions.

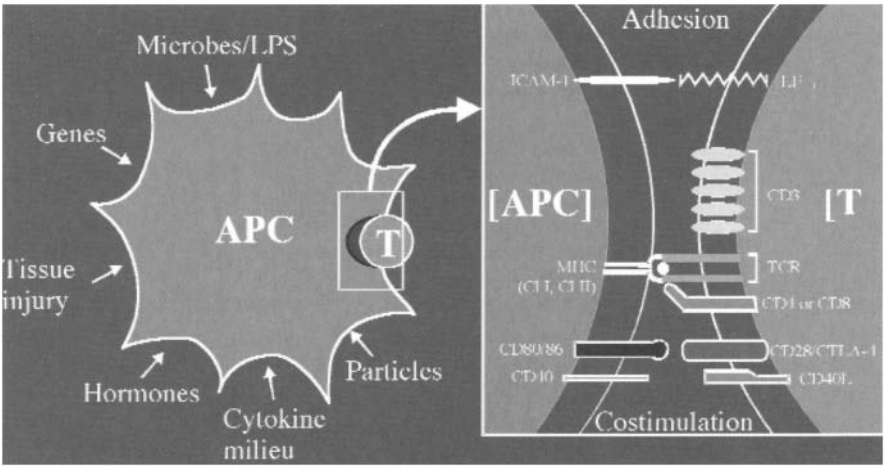

Figure 2:
Factors influencing interactions between antigen presenting cells (APC) and T-lymphocytes.

Adjuvans factors. Again, macrophages are major targets for proinflammatory signals mediated by particles or microbial constituents like lipopolysaccharide or DNA fragments [36]. Thus, allergic reactions could be facilitated through altered phenotype and activation of antigen presenting cells [37]. This is also modulated by the anatomic site, e.g. by tolerance favouring gastrointestinal tract. Other preexisting allergic sensitisations, like allergy to disinfectants, to antibiotics or natural rubber latex may cause inflammation and facilitate sensitisation to implant constituents.

Patient derived factors. However atopy (history of allergic rhinoconjunctivitis, asthma or atopic eczema) seems not to be a risk factor for development of contact eczema [38]. A genetical background for development of metal allergy or granulomatous foreign body reactions is discussed by some authors [39,40]. Interindividual differences in the apoptotic response to cytotoxic effects under exposure to metal ions, e.g. nickel, have been reported recently for T-lymphocytes [41]. Who out of a series of nickel allergic patients may develop also reactions to nickel containing implants cannot be determined before implantation [42,43].

Clinical picture and diagnostics

Internal or "hematogenous" exposure to the relevant allergen may cause a systemically induced contact dermatitis. This was reproducibly proven by oral challenge studies [44,45]. In patients reacting to oral provocation with nickel, a higher frequency of circulating specific T-cells has been found [46]. Alimentary uptake but also metal release from implanted devices may maintain this hyperreactivity. The possible link between amount of metal ions released from the implant over time and incidence of metal implant allergy still needs to be investigated. There are several clinical reports of eczema reactions, both local and remote, to metallic implants [10,47,48,49,50]. In a series of patients with intolerance reactions to knee arthroplasty (eczema, swelling, pain) and no infection or mechanical failure, a strongly increased contact allergy rate to nickel, chromium, cobalt and / or bone cement components was found [51].

The actual incidence of allergic responses to implanted metallic devices cannot be estimated, since there is no overall data collection and allergological testing is not always performed. The authors of this article actually build up a central register for implant related allergic reactions in Munich ("Implant allergy register", e-mail: Implantatallergie.Derma@ med.uni-muenchen.de). Up to now, case reports underline the existence of patients with local or systemic intolerance reactions [52]. However, rather low incidence of allergy-mediated cutaneous or orthopedic complications are reported [10,12,53]. Carlsson and Möller for example retrospectively examined patients with contact allergy to metals proven before implantation of metallic devices [11]. Out of the 39 patients, one had developed eczema of the feet and papular itching eruption of the trunk, both subsiding only after removal of the osteosynthesis material used to treat an ankle fracture. Being deceased at the time of retrospective analysis, this patient like others could not be included. Out of the 18 remaining patients, three had developed eczema reactions, but also had preexisting eczema. In two patients mechanical loosening of the implanted devices was seen. Some patients even showed no more cutaneous reactivity upon renewed skin testing at the time of follow-up. Thus, as conclusion, an overall good implant tolerance was reported.

However, some questions remain: Unusual manifestations of allergic reactions like seroma formation or recurrent pain may not always be recognized as such [13,54]; only a part of implant componentscan be assessed by skin test; epicutaneous testing may not always detect allergic reactions in deeper, periimplantar tissue; additional analysis of the periimplantar tissue or peripheral blood cell reactivity can not always be performed. In the case of a patient with implant loosening and local discomfort, the demonstration of periimplantar oligoclonal (antigen-driven) T-cell infiltrate together with Th1-type mediator production helped to link the intolerance to a proven dichromate allergy [17]. With regard to clinical allergological diagnostics, history and clinical picture are supplemented by epicutaneous testing. The use of aliquots of implant material for skin testing is under investigation by the author of this article. The testwise subcutaneous implantation of aliquots of the material in question is, however, still under discussion. In vitro methods like lymphocyte activation assays do not prove an allergy, but rather indicate "sensitisation" and thus have to be interpreted with caution. However, lymphocyte transformation assays using peripheral blood mononuclear cells (PBMC) of nickel-allergic individuals can demonstrate specific in vitro reactivity to nickel [55]. Despite no preferential association with HLA-DR,

-DQ or –DP specificity has been proven, a restricted use of T-cell-receptor (TCR) phenotype has been shown in nickel reactive lymphocytes [56,57].

Summary

Components of most implants can be released into the tissue [6,55,56,57]. In some conditions a specific immune response may arise against these components and create clinically apparent intolerance reactions. Particles play a central role as proinflammatory stimulus and as a source of enhanced metal exposure. Furthermore, the role of systemically distributed particles needs to be assessed [61]. An interdisciplinary approach including cellular and molecular biology in vitro and clinical follow up will help to optimize implant materials and to identify patient derived allergy predisposing conditions.

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1.4 Can Metal-Metal Total Hip Arthroplasty induce Hypersensitivity reactions?

C. H. Lohmann

Abstract

Metal/metal articulations made from Cobalt-Chromium-Molybdenum (CoCrMo) alloys have been re-introduced more than 15 years ago. The clinical mid term outcomes as well as the in vitro-testing results are very encouraging. Since the mid nineties of the last century lymphocytic infiltrations in the retrieval tissues around metal/metal arthroplasties have been observed. This phenomenon occurs at a low incidence around different metal systems.

Introduction

Metal/metal total hip arthroplasties made from Cobalt-Chromium-Molybdenum (CoCrMo) have been re-introduced in the late eighties of the last century. Compared to metal-metal articulations in endoprostheses (type McKee-Farrar, Huggler, and Müller made from CoCrMo alloys) that had been implanted in the 60s and 70s, a second generation of metal-metal bearings made from CoCrMo-alloy with improvements of the material, manufacturing and prosthetic design showed encouraging low wear rates in tribological laboratory tests [10,12,13]. Different manufacturers produce metal-on-metal articulation with modifications in material composition, manufacturing, and design. These technologies are used in different head sizes as well as for femoral head resurfacing.

Aseptic loosening of endoprostheses is a cascade of cellular events ultimately leading to bone resorption and loosening of the implant [16,17,18,20]. This is initiated by the release of wear products from the articulating surfaces and the subsequent tissue response. At the time of revision, the wear rates of the articulating surfaces of metal/metal arthroplasties were low even after long times of duration [10,11,19]. In the retrieval tissues of the "first generation" metal/metal endprostheses (type McKee-Farrar, Huggler, and Müller) the predominant tissue reaction observed, was a foreign body granuloma formation due to bone cement particles [3,18,19].

Several investigators have analysed if metal/metal total hip arthroplasties can induce hypersensitivity reaction. From cadaver studies it is well known that metal wear products are distributed in mesenchymal organs and lymphatic organs [7]. However, the local adverse reaction

In a previous study [22], a large series of retrieval tissues was investigated and a potential hypersensitivity response to metal-metal prostheses was observed. 19 cases were thoroughly analysed with respect to clinical appearance, histological morphology and linear wear [22]. The tissues were characterized by vasculitis with perivascular and intramural lymphocytic infiltration of the postcapillary vessels, swelling of the vascular endothelium, recurrent localized bleeding and necroses.

In addition to high endothelial venules (HEV), bleeding, and necroses, also fibrin exudation and accumulation of macrophages with drop-like inclusions were frequent findings [8,22].

The present investigation tests the hypothesis that different carbide content in the CoCrMo alloys of the articulating bearings does not alter the tissue response and clinical predictability.

Therefore, we analysed retrievals from 17 revision surgeries of aseptic loosened metal-metal hip arthroplasties from low carbide alloy. The tissues were analysed for the presence of lymphocytic reactions and metal content. Prosthetic components were examined for linear, gravimetric and volumetric wear.

Materials and Methods

The retrieved metallic components and retrieval tissue from 17 consecutive revisions of second generation metal-metal articulations were analysed. There were 16 patients with 17 revisions. The implants were manufactured by Plus Endoprothetik AG (Rothkreuz, Switzerland) and had a low carbide metal content in the CoCrMo alloy. The results were then compared to previously published data [8,22]. In the previously published data, there were 16 Metasul® articulations (Centerpulse, Winterthur, Switzerland) with high carbide content in the CoCrMo alloy [22].

Patients' Profile

16 patients with 17 revisions were included in the study. Infection was ruled out by blood laboratory analyses and aspiration of joint fluid and microbiological testing at the time of surgery. The patients' age was 46 -78 years. There were 2 males and 14 females. The duration of implantation was 54 – 86 months. The recurrence of symptoms occurred 5 – 30 months postoperatively. 1 patient had 2 dislocations before revision.

Histomorphology

Tissue were collected at the time of surgery and fixed in 5% formalin. If necessary, samples were decalcified and then embedded in paraffin. Samples were processed with general histological conditions. 5 –10µm microtome sections were routinely stained with H/E, Giemsa, van-Gieson, Prussian-Blue, and Perjod Acid Schiff (PAS) method. The amount of metal particles stored in the tissue was estimated according to a rating system as previously described [19]. Infiltration of lymphocytes was assessed by cell counts per field of view as previously described [21,22].

Element Analysis

For identification of metallic debris the content of Co, Cr, Ni was determined in the tissue from the revision tissues (17 specimens) using Inductively Coupled Plasma-Mass Spectrometry.

Examination of Retrieved Implants

The retrieved articulating components were inspected for loss of material from the articulating surfaces. Area measurements were performed on a 3D co-ordinate system. More than 5.000 measurements were performed per sample.

The linear wear per year (µm/year) was obtained by relating the maximum total linear wear to the time of function. The measurements and calculation were performed according to a proprietary system of Precision Implants AG (Aarau, Switzerland).

Results

Clinical Data

The metal-metal components had been implanted as cementless arthroplasties. In all cases, the reason for primary total hip replacement was degenerative osteoarthritis (without an underlying inflammatory arthropathy). The duration of symptoms before revision lasted 5 – 24 months. The patients complained about groin or femor pain. 1 patient had a recurrent dislocation, 1 patient sensed metallic clicking

Intraoperative Findings

The intraoperative findings were without a specific loosening pattern: 8 stems and cups were fixed, however in 3 cases osteolyses in the proximal femur were observed. In 2 cases the cup was fixed but the stem loose. In 5 patients, the cup was loose and the stem fixed. In 2 cases, both the stem and cup were loose. Extensive bursa formation anterior of the joints was observed in 5 joints.

The patients received again cementless revision endoprostheses. The articulations were revised to articulations from ceramic-UHMWPE (6x), metal-UHMWPE-(10x), ceramic-ceramic (1x). Intraoperatively, 12 patients had macroscopically a pronounced metallosis. After revision, the patients were free of symptoms.

Retrieval analysis

The 16 periprosthetic tissues showed only a mild foreign body reaction to wear particles from the implant materials. Nevertheless, varying numbers of mono- and multinuclear macrophages were found mainly next to vessels in all cases. The amount of Co, Cr, and Ni in the tissue ranged from 1.4 – 4604.0 µg/g tissue.

Diffuse, perivascular infiltrations of T- and B- lymphocytes and plasma cells were observed in cases with an average metal content of 210 µg/g tissue. The infiltrates mostly surrounded post-capillary vessels and interspersed also the walls of these vessels which could be identified as high endothelial venules (HEV). The macrophage dominated histologies were seen in the retrievals with an average metal content of 3,1.

Examination of retrieved implants

The average linear wear at the articulating surfaces was 2.0 µm/year (range 1 – 3 µm/year). The volumetric wear was 0.31 + 0.26 µm/year, the gravimetric wear was 2.55 + 0.16 µm/year.

Summary and Conclusion

17 revision cases of metal-metal articulations containing low carbide CoCrMo alloys were analysed with respect to clinical symptoms, histological morphology and metal content of the retrievals tissues, and wear of the prosthetic

components. The results were compared to a group of retrievals from a previously published study [8,22].

The revision tissues of low carbide alloys showed similar tissue reactions to wear like the retrieval samples from the high carbide cases that were previously published. In both cohorts, the low carbide and the high carbide group, there were typical signs of a lymphocytic infiltration indicating a local hypersensitivity reaction. Moreover, fibrin exudation and low numbers of particles and macrophages were also seen with lymphocytic reaction.

The wear of the femoral heads measured is lower than in the classic metal-metal joints of the "first generation" and it is comparable to other current endoprostheses from high carbide metal alloys. Laboratory tests have shown that the low carbide alloy prostheses have similar wear rate as the high carbide alloy prostheses.

The amount of metal in the periprosthetic tissues is a distinct finding. The metal content had a wide range (1.4 – 4604 µg/g tissue) and it reflects the wear at the components. Patients with very low metal content in the tissue and one patient with a high metal content did not show lymphocytic infiltrations in the tissues, whereas patients with an average amount of 200 µg/g of metal in the tissue showed lymphocytic reactions. This may lead to assumption that a medium release of wear product may induce a hypersensitivity reaction but we feel that this conclusion is too early and requires a larger series of retrieval analyses to support this hypothesis.

There is no difference in clinical predictability since the symptoms are similar in all documented cases – either in high carbide or in low carbide. Further, the metal content in the tissues and the 3-D wear of the components is comparable in the groups as well as the tissue response is comparable.

All patients were free of pain after revision. None of the patients was revised to a metal-metal articulation again. In the previous study, 5 five patients receiving a second metal-on-metal articulation had similar symptoms than before revision [22]. Two of these patients were free of symptoms only after re–revision 4 months and 5 years after first revision. This supports the recommendation that in revisions due to potential hypersensitivity reaction, an alternative bearing than metal-metal should be used.

Acknowledgments

The contributions of Hans-Georg Willert, MD, Göttingen, Gerald Pflüger, MD, Vienna, Hans Schmotzer, PhD, Aarau, and Mr. Omar Yazigee, Hamburg, are gratefully acknowledged.

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1.5 Blood Analysis for Trace Metals in Patients with Different Bearings in Total Hip Arthroplasty

K. Knahr, L. Karamat and O. Pinggera

Introduction

After failure of the first metal-on-metal articulations [1,2], there has been a revival since 1988 and many studies have reported significant better wear behaviour compared to metal-on-polyethylene bearings [3,4,5]. Based on the experiences of the last decades we know that metallic ions are being released in patients with total hip arthroplasty with a metal-on-metal articulation [6,7]. The greater part of metallic debris generation is presumed at the articulating surfaces. Other sources of metallic ion release such as corrosion, component impingement or dissociation of ions are reported as well [8]. Modularity and carbon content of the articulating metal-alloy components also seem to play a major role. While low carbide metal articulations are faced with high revision rates up to 9% [9], high carbide metal pairings show better clinical performance [10].

Ceramic-on-ceramic articulations have now a history of more than 30 years in total hip arthroplasty since Boutin implanted the first all ceramic articulation. Due to improper material and unfavourable designs in the 70's and early 80's the mechanical performances of ceramic articulations were not fully satisfactory thus leading to a poor reputation for ceramic as material for total joint arthroplasty [11,12,13]. Nevertheless in the last decades materials and manufacturing processes have improved significantly. Simulator tests confirmed the excellent wear behaviour of ceramics [14]. As the risk of fracture of a ceramic component still exists, it is mandatory that surgeons using this material acknowledge the importance of a precise surgical technique [15,16,17].

To improve the wear characteristics of ultrahigh molecular weight polyethylene (UHMWPE), cross-linked-polyethylene was developed. There are basically three different methods to achieve cross-linking [18]. So far laboratory data present excellent wear behaviour of this new material. Clinical data available include only short term experiences, allowing no conclusion about its effectiveness in the long-term [19].

The aim of this study was to assess and evaluate the blood concentrations of Co, Cr, Mo, Ti, Al and Nb in patients with a well functioning primary total hip arthroplasty.

Materials and Methods

Patients with unilateral noninflammatory joint disease who have had primary total hip arthroplasty between January 1998 and December 2000 at our institution were considered for this retrospective single time point study. All subjects were treated with a tapered rectangular Ti-6Al-7Nb alloy stem and a pure Ti threaded cup (VARIALL™, ZIMMER, Switzerland) and a 28mm femoral head.

	METASULTM	CERASULTM	DURASULTM
Femoral head	wrought Co-28Cr-6Mo alloy with 0.20-0.25% C	Alumina (Al_2O_3)	wrought Co-28Cr-6Mo alloy with 0.05-0.08% C
Liner	wrought Co-28Cr-6Mo alloy with 0.20-0.25% C	Alumina (Al_2O_3)	UHMW cross-linked polyethylene
Femoral head size	28 mm	28 mm	28 mm

Table 1:
Characteristics of the bearings

We used three different types of articulations (Fig. 1): metal-on-metal (METASUL™), ceramic-on-ceramic (CERASUL™) and metal-on-cross linked ultra high molecular weight polyethylene (DURASUL™), allocation was done with a randomisation list.

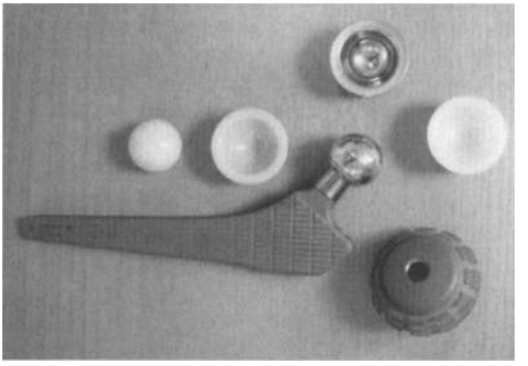

Figure 1:
The Alloclassic Variall Hip System - 3 different types of articulations: metal-on-metal, ceramic-on-ceramic and metal-on-cross linked polyethylene.

Patients with noninflammatory osteoarthritis, osteonecrosis or congenital hip dysplasia and normal renal function (i.e. normal level of creatinine in the serum) showing excellent postoperative clinical results (HHS=100) were invited for blood sample collection. Exclusion criteria were implantation of any other arthroplasty or metallic implant, previous dislocation or infection of the hip device and revision arthroplasty.

Standard radiographs (anteroposterior and lateral) were also obtained to ensure proper functioning and fixation of the artificial hip device. Participants confirmed they were not exposed to the trace metals, occupationally or environmentally.

Sampling and Analysis of Specimen

Venous blood was obtained from all patients through a polypropylene canula discarding the first 5ml to exclude possible metal contamination from the needle. The samples were then stored in plastic tubes at –20°C until sent to assay (LGC Laboratory, Specialized Techniques, Teddington, U.K.).

The aluminum, chromium, cobalt, molybdenum, niobium, and titanium concentrations in whole blood were measured after a 1:10 dilution with a solution of 10ml/l Triton X-100, 0.0002mol/l EDTA, and 0.01mol/l ammonium hydroxide. Analysis was performed by a double-focusing magnetic sector inductively coupled mass spectrometer [20].

The lowest detectable concentration was 0.2ng/ml for cobalt, chromium, niobium and molybdenum, and 2.0ng/ml for aluminum and titanium.

Statistical evaluation was done using the student T-test for follow-up time and creatinine concentration (level of significance: 0.05). Statistical differences of metallic blood-concentrations were analysed with the Mann-Whitney U-test (level of significance: 0.05). The blood concentrations of Co, Cr and Mo below detection limit were defined as 0.19ng/ml for statistical calculations.

Results

25 patients out of each articulation group were evaluated. The follow-up examination was done at least 24 months after surgery to avoid blood collection during the so called running-in-period of the prostheses.

There were no statistically significant differences between all three groups regarding sex distribution, age, follow up and median preoperative serum levels of creatinine.

	Metal-on-Metal	**Ceramic-on-Ceramic**	**Metal-on-cross linked PE**
Gender	12 males 13 females	13 males 12 females	15 males 10 females
Median age at OP in years	62.50 yrs. (range 38 – 75)	63.50 yrs. (range 36 – 80)	68 yrs. (range 39 – 82)
Median follow up in months	25 mths. (range 23 – 38)	27 mths. (range 23 – 36)	28 mths. (range 24 – 34)

Table 2:
Patient's characteristics

The blood levels of Cobalt, Chromium and Molybdenum in the three patient groups are shown in Table 3.

	Cobalt (range)	**Chromium (range)**	**Molybdenum (range)**
Metal-on-Metal n=25	0.69 (0.19 – 3.70)	0.47 (0.19 – 6.38)	0.50 (0.19 – 0.86)
Ceramic-on-Ceramic n=25	0.19 (0.19 – 0.36)	0.19 (0.19 – 2.90)	0.43 (0.19 – 0.80)
Metal-on-cross-linked PE n=25	0.19 (0.19 – 1.07)	0.19 (0.19 – 1.44)	0.52 (0.19 – 1.58)

Table 3:
Median blood concentrations in ng/ml

Patients in the metal-on-metal group had statistically significant higher median Co blood levels than patients in the ceramic and cross-linked PE group (p= 0.0001 and p=0.001). Median Cr blood levels in the all-metal group were also significantly higher than in the other two groups (p=0.003 and p=0.0002).

There were no statistically significant differences in Mo blood concentrations comparing the metal-on-metal with the ceramic-on-ceramic and metal-on-cross-linked PE groups (p=0.07 and p=0.31).

The Al, Ti and Nb blood-levels were all below their detection limits.

Discussion

Our results confirm that metallic wear particles are released in active patients with well functioning THA's with metallic articulation components. The time-point of sampling was chosen at minimum two years after total hip replacement. This was done to avoid collecting blood-concentrations of the trace metals during the so-called running-in period in the first six months after surgery [21]. The metabolic behaviour of the trace metals analysed in this study is not yet clearly understood, especially possible local or systemic effects. We do know however that cobalt is rapidly eliminated in the urine and preferably accumulates in the periprosthetic tissue whereas chromium is not rapidly excreted and can disseminate in many organs of the body [22,23].

Bioavailability and the chemical form of the degradation products are actually unknown. Brodner et al. have reported elevated cobalt serum concentrations in patients five years after THA with metal-on-metal bearings with a median value of 0.7µg/l [24]. Comparing these figures with our data is difficult since we analysed whole blood samples.

Kreibich et al [25] evaluated long term results of uncemented porous-coated THA's and found in cases of aseptic loosening of a component significantly elevated serum Co concentrations ($p<0.05$). However, in another study Lewis et al. [26] report elevated Co-levels in periprosthetic tissue samples from patients with failed cobalt–alloy total hip devices but no elevation in the serum.

The total body concentration of cobalt of 1200µg is much higher than the overall daily release from metallic implants [27] but in the long term any additional metallic release into the body or renal diseases of the patient [28] could cause problematic levels in body fluids and organs.

Molybdenum is a relatively non-toxic mineral because it is under tight homeostatic control by the body and excess amounts are rapidly excreted by the kidneys and the bile. Normal whole blood molybdenum levels vary greatly and are reported ranging from 0.6 to 13.1 ng/ml [29]. There is limited data on molybdenum toxicity in the literature but extremely high levels of intake of Mo have been associated with gout or inflammatory joint disease [30]. In our samples we have found no statistically significant differences in median Mo blood concentrations between all three articulation groups.

Biologic reactions of alumina particles in patients with total hip implants were reported by Lerouge et al. and Böhler et al. [31,32]. They found that the usual reaction of alumina particles is of a fibrocytic type with few macrophages and no giant cells. Alumina and metallic debris were found only when impingement between stem and socket led to loosening of the implant. In these cases true foreign body reactions could be seen and were related to the presence of a larger amount of alumina ceramic particles [32,33,34]. At the end of the last century concerns arose that release of alumina ions leading to an elevated serum level of aluminum could contribute to the occurrence of Alzheimer disease [35,36]. So far this theory could not be confirmed. In all our samples alumina ions were not detectable.

Short term data reporting on cross linked polyethylene inlays are promising but these articulations are still faced with the concern of polyethylene wear particles and their influence on osteolysis and remain to be evaluated in long term studies.

Summary

Based on the evaluation of trace metals in our patients, both hard-on-hard bearings and the metal-on-cross linked polyethylene articulation achieved favourable results in clinical and radiological symptom-free total hip arthroplasty. Although cobalt and chromium blood concentrations were elevated in the metal-on-metal group they did not reach pathologic levels.

The median molybdenum blood levels were similar in all three articulation groups. In all cases titanium, aluminum and niobium blood concentrations were below their detection limits.

Correct surgical technique and continuously improving material properties as well as selecting the appropriate articulation for each patient individually are still the basis for a good performance of artificial hip devices.

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SESSION 2

Alternative Wear Couples

2.1 Metal-on-Metal Total Hip Arthroplasty: The Concerns

S. J. MacDonald

Abstract

The metal-on-metal bearing couple is having a resurgence in clinical applications seen in both total hip and hip resurfacing technologies. The most noteworthy advantage of a metal-on-metal implant is the improved wear characteristics seen both in vitro on wear simulators and in vivo with retrieved implants. All bearings have disadvantages, and a metal-on-metal bearing is no exception. Concerns exist regarding the generation of metal ions seen in both the blood and urine of patients with metal-on-metal implants. These elevated metal ions have theoretical, although not proven, risks related to carcinogenic and biologic concerns. Additionally, concerns exist regarding hypersensitivity, increased incidence of instability and increased costs. Specific patient selection issues arise with metal-on-metal implants. The current generation of implants has only early and mid-term results available, with no long-term series yet published. Therefore, although a metal-on-metal bearing may be considered a viable alternative to either polyethylene or ceramic implants, outstanding and unresolved issues continue to exist with this bearing, as they do with the alternatives.

2.2 Clinical Performance of a Highly Crosslinked Polyethylene at Four to Five Years in Total Hip Arthroplasty: A Randomized Prospective Trial

J. M. Martell, J. J. Verner and S. J. Incavo

Introduction

Highly crosslinked polyethylene demonstrates 80-90% wear reduction by hip simulator testing, however clinical data on this new polyethylene has been limiited. We report the four to five-year results for a prospective randomized trial comparing highly crosslinked to standard polyethylene.

Methods

88 hips were available for radiographic analysis. All cases were performed using the Secur-Fit™ HA acetabular component and the Secur-Fit™ or Secur-Fit Plus™ HA femoral components (Stryker/Howmedica/Osteonics). Femoral bearings were 28 mm cobalt chrome with low friction ion treatment (L-Fit). The polyethylene insert was randomized at the time of implantation to highly crosslinked polyethylene (Crossfire™), or standard polyethylene that was gamma sterilized and packaged in nitrogen (N_2/Vac™). Polyethylene wear rates were measured based on AP and lateral pelvis radiographs at six weeks and yearly intervals using a validated computer assisted edge detection method. Wear rates between the two groups were compared using the non-parametric Mann-Whitney U-test at the 95% level.

Results

There were no device related failures in this group. The 2D volumetric wear rate was 67% lower in the highly crosslinked group (19.8 mm^3/yr.), than in the standard group (61.5 mm^3/yr.).

Conclusions

This follow-up on highly crosslinked polyethylene shows no device related failures and a 67% wear reduction compared to standard (N2-Vac) polyethylene. Follow-up beyond five years will be needed to determine whether in-vivo oxidation impacts wear performance in the long term.
At this time these results are encouraging, given the widespread use of highly crosslinked polyethylene.

2.3 Co-Cr Head Roughness and its Effect on Wear of UHMWPE and XLPE Cups

T. Donaldson, A. Massihi, J. G. Bowsher and I. C. Clarke

Abstract

Crosslinked polyethylene appears to be a better hip bearing material than conventional polyethylene, but will it take us past the expected 20-year survival and into the anticipated need for 30-year survivorships? Knowing that a sizeable percentage of Co-Cr femoral heads roughen in the patient, and that XLPE is sensitive to roughening, there are many doubts over the long-term clinical use of Co-Cr heads with XLPE cups. Wear studies at LLUMC suggest there is a likely cost for using larger Co-Cr head sizes in young and active patients, i.e. those requiring a larger femoral head to increase stability and reduce dislocation. Therefore, we believe that these higher activity patients with extended expectations will better benefit from alternative bearing surfaces such as ceramic on ceramic. In addition, there are four modes of wear generation, i.e. impingement, backside wear etc., however, we still know very little about these processes for XLPE, especially understanding changes in wear particle sizes and concentrations.

Introduction

Total Hip Arthroplasty is the treatment of choice for degenerative arthritis of the hip. With the increased rate of technology exchange we are now faced with many decisions that may significantly affect longevity of the procedure. No longer do we look at total hip arthroplasty articulation as a metal ball inside a generic polyethylene liner. Our options today include metal or ceramic heads with crosslinked polyethylenes of many different types, Co-Cr on Co-Cr [1] in a multitude of diameters, and now more than one kind of ceramic on ceramic bearings [2]. In addition, our patients today are presenting for total hip arthroplasty at a younger age, thus requiring longer-lasting articulations. These same patients are also much more demanding and hence may require larger diameter femoral heads to allow greater range of motion to minimize impingement problems and also increase their joint stability, i.e. more resistance to dislocation [1]. The combination of both of these demands creates serious conflicts in the surgeon's list of choices [3]. The use of larger diameter femoral heads may also create concern over longevity issues [4]. The crosslinked polyethylene appears to be a better bearing than conventional polyethylene [5]. The question is will it take us past the expected 20 year survival and into the required 30 year survivorship? A strong consensus has developed that contemporary highly crosslinked polyethylene (XLPE) will produce almost 'zero' wear [6-10]. However, this laboratory phenomenon has still to withstand the true test of long-term clinical evaluation.

A) Head-size effects on Co-Cr/UHMWPE wear

The advent of the cemented total hip replacement (THR) in the 1960's ushered in a new paradigm of joint reconstruction. Sir John Charnley introduced to the world his concept of a uniquely small head (22.25 mm) in a cemented polyethylene (UHMWPE) cup [11]. From clinical and revision observations of his original polytetrafluoroethylene series (PTFE), Charnley noted that progressively downsizing the femoral ball (41.5 down to 22.25 mm) led to noticeably less wear *in vivo*, even with his inferior PTFE material. However his teaching on the 'small head' wear paradigm was lost in time with the progression of larger head development in the USA, due to the perceived need for balancing the risks of dislocation against the wear issues. The resurfacing concepts launched in the 1970's and 80's used even larger diameter heads (Fig. 1) and also introduced the thin-walled, UHMWPE cup. Unfortunately, the 'big head' paradigm of this resurfacing era produced significant UHMWPE wear debris with concomitantly higher revision rates [12]. Thus use of UHMWPE cups restricted the surgeons' choices to the original 'small head' paradigm of Charnley.

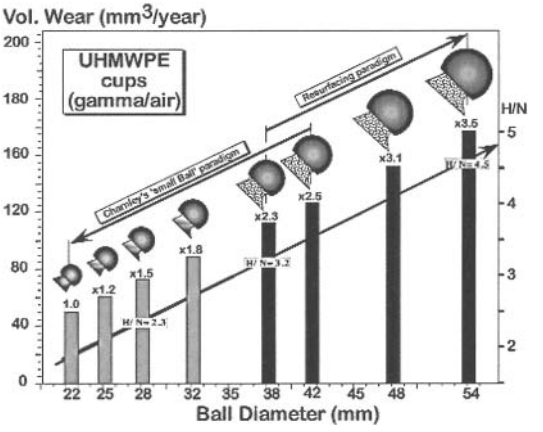

Figure 1:
Dramatic scaling evident in range of THR head sizes (22-32 mm) compared to large diameter resurfacing shells (38-54 mm). Wear rates increased 1.5-fold with the 28 mm diameter and 1.8-fold with 32 mm diameter. Assuming a 12 mm diameter neck used in THR, the head/neck (HN) ratio controlling range of motion increased from 2.5 (28 mm head) to 4.5 (arrow at 54 mm) thereby providing desirable range of motion and stability. However the 'small head' paradigm denotes the fact that the smallest femoral heads created the least UHMWPE wear [35].

B) Introduction of Larger Diameter Co-Cr Heads

The range of Co-Cr heads used with historical UHMWPE cups has ranged between 22 mm and 32 mm (Fig. 1). The advent of the Co-Cr/UHMWPE hip resurfacing in the 1970's opened the door for larger head diameters (38 to 54 mm: Fig. 1). However the higher wear rates and greater incidence of osteolysis let to this concept being abandoned by the 1980's [4]. In the 1990's, the FDA approval of XLPE cups and the all-metal, Metasul™ THR opened the door once again for larger Co-Cr head sizes (Table 1). While the hip resurfacing has gone to all-metal bearings, contemporary THR concepts promote up to 44 mm diameter

Surgery	Author	Femoral shell	Acetabular cup
1988	Weber MD	28, 32 mm Metasul™	1pc cement PE/MOM
1991	Dorr MD	28 mm Metasul™	1pc cement PE/MOM
FDA 2001	CenterPulse/Zimmer	28 mm Metasul™	1pc cement PE/MOM
FDA 2002	Wright Medical Tech	28, 32 mm Lineage™	MOM to 32 mm
FDA 2002	Wright Medical Tech	35-56 mm BFH™	MOM to 56 mm
FDA 2003	Biomet	38-60 mm Magnum™	MOM to 60 mm

Table 1:
The metal-on-metal (MOM) total hip replacements have been leading the way for THR designs using larger femoral heads to provide more motion and greater stability. This for the first time has resulted in FDA approvals (1999-present) for a coherent range of 32 mm to 60 mm diameters of Co-Cr heads.

Co-Cr heads for use with XLPE cups. This brings into focus the synergistic effects of the diameter of the Co-Cr head, the roughening effect of the Co-Cr surface *in vivo*, and the activity levels of patients be they moderate or high activity.

C) Surface roughness effects of Co-Cr Bearings

Surface roughness of the femoral heads has long been regarded as one of the most significant variables affecting wear. Laboratory studies have predicted that surface scratches (roughness'Ra' 10 to 200 nm damage) could create 6 to 20-fold more wear [13]. In contrast, some authors reported no relationship between UHMWPE wear and a range of surface roughness [14,15]. Thus, the surface roughness consequences of Co-Cr bearings have seldom been clear to the physician.

Overall, various THR and TKR retrieval studies have documented a wide range of roughness values, from 20 nm to 500 nm and higher (Fig. 2). At various centers, measurements of retrieved Co-Cr heads revealed roughness up to 500nm (Ra) from cemented hip implants within 3-years of use, i.e. a 25-fold increase from their pristine condition [16,17]. In terms of effects of fixation, Jasty *et al* [18] described damage as extensive on 80% of retrieved, non-cemented implants (up to 7 years *in vivo*) but only 50% of cemented implants (up to 19 years in vivo). A contrary conclusion on fixation effects has also been expressed [16]. Thus, from an overall clinical perspective it would appear that a 'worst-case' roughness value for Co-Cr bearings may be represented by Ra = 500 nm. Compared to the nominal 20 nm roughness (Ra) of a pristine Co-Cr ball, this represents a 25-fold increase in vivo.

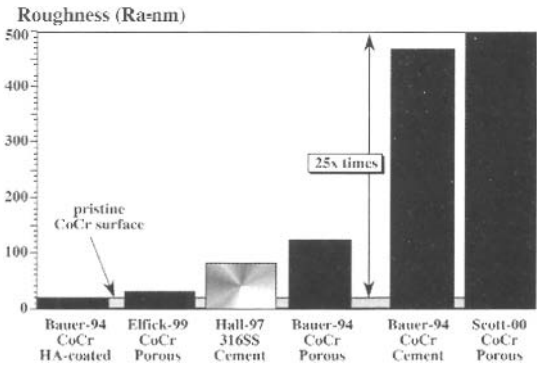

Figure 2:
Assessment of surface roughness (Ra = nm) on retrieved Co-Cr and stainless steel femoral heads (316SS). Against background surface finish of 20 nm for new Co-Cr implants, the retrieved Co-Cr heads were up to 25 times rougher. The THR fixation methods are listed as cement, porous-ingrowth or hydroxyapatite coated (HA) [38].

D) Role of XLPE Cups with CoCr Bearings

A consensus has been established that use of very highly-crosslinked polyethylene (XLPE) will result in 'zero' or 'near-zero' wear conditions [19,20,21]. However, this phenomenon, created under idealized laboratory conditions, may not adequately represent clinical situations. The laboratory's 'zero-wear' paradigm may be a great simplification compared to the rigors of patient use, particularly in the high-demand patients with longer life expectancy. In the 100-Mrad, crosslinked cups studied in Japan, the XLPE wear rates averaged a 5-fold wear reduction but were not zero [22]. Similarly in 13-Mrad cups studied in South Africa, some patients showed wear rates that were not that different from the historical norm [23]. In the USA, one group's studies of XLPE cups described radiographic wear and on retrieval, impingement damage with surface cracking and plaque delaminations [24,25]. Therefore, while XLPE cups may show "zero wear" under idealized laboratory conditions, it is to be anticipated that the high-risk patients will continue to produce XLPE wear debris, either due to 3-body abrasive wear, due to roughening of the Co-Cr surfaces, or other modes of failure [26].

Compared to conventional PE, XLPE is much more sensitive to roughened femoral conditions [15,27-29]. In simulator wear studies, roughening of the Co-Cr head has been shown to significantly increase the number of XLPE wear particles under normal walking [30,31], (Figs. 3a and c). When simulating more 'severe' gait conditions, i.e. fast-jogging, the numbers of XLPE particles dramatically increased with roughened Co-Cr heads [31,35], (Figs. 3b and d). It is also known that XLPE wear particles are generally smaller than conventional UHMWPE particles due to the effects of irradiation and embrittlement [27,32]. The small particles are also the most bioactive [33]. This suggests that there is a synergy involved in which high activity and CoCr surface roughness will interact to produce significant wear of XLPE cups and release millions of minute XLPE particulates.

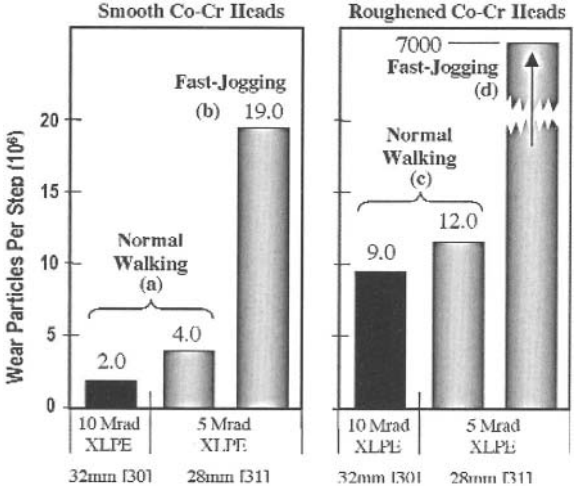

Figure 3:
Number of XLPE wear particles generated per step against Co-Cr heads in a hip simulator under (a) normal walking – smooth head, (b) fast-jogging – smooth head, (c) normal walking – roughened head, and (b) fast-jogging – roughened head. For 10 Mrad XLPE (32mm) - roughened surface: Ra =150 nm, Rp 2500 nm [30]. For 5 Mrad XLPE (28mm) – roughened surface: Ra =400 nm, Rp=3000 nm[31].

E) Effects of clinical range of roughness on accelerated cup wear

At LLUMC we studied the effect of progressively rougher Co-Cr heads over the measured clinical range (Ra = 25 to 600 nm) using an accelerated hip wear model. The roughened 28 mm heads were provided by Biomet Inc. (Warsaw IN) and surface finish analysis was performed by laser interferometer (Zygo Corp., Middlefield, CT). Our custom polyetrafluoroethylene (PTFE) cups were machined from extruded bar stock and not sterilized as per the historical norm [11]. The PTFE wear was very rapid and increased concomitantly with surface roughness in a very linear manner (Fig. 4). In this range of clinical roughness the cup wear increased 30%. This was similar to the wear increase reported for 32 mm versus 28 mm diameter heads used with conventional UHMWPE (Fig. 1) and was the original reason for downsizing femoral balls [11,34].

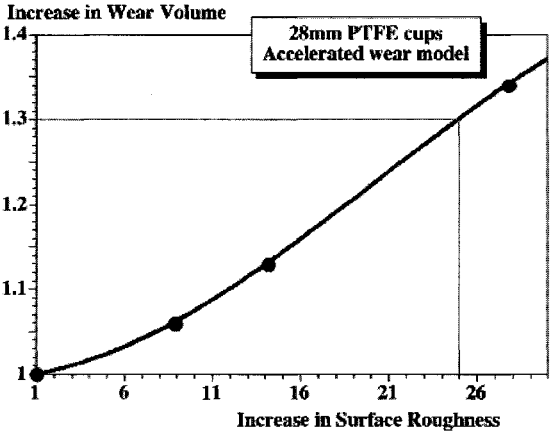

Figure 4:
Hip simulator wear study of Co-Cr heads roughened over the range 1 to 25-fold (Ra=20-500 nm: see clinical range in Fig. 2) [35]. The 28mm polytetrafluoroethylene (PTFE) cups were used as an accelerated wear model of clinical significance and their wear increased linearly up to 1.3 fold as roughness increased [11].

Now our latest microseparation wear studies at LLUMC on UHMWPE and XLPE cups have included roughened Co-Cr surfaces. Using 36 mm pristine Co-Cr heads, the XLPE cups showed the expected dramatic wear advantage over conventional PE cups (smooth heads: Fig. 5a). However, under roughened conditions (Fig. 2: upper value of clinical roughness), the XLPE cups had same wear as the control UHMWPE (Fig. 5b). When viewed against prior work for 28 mm

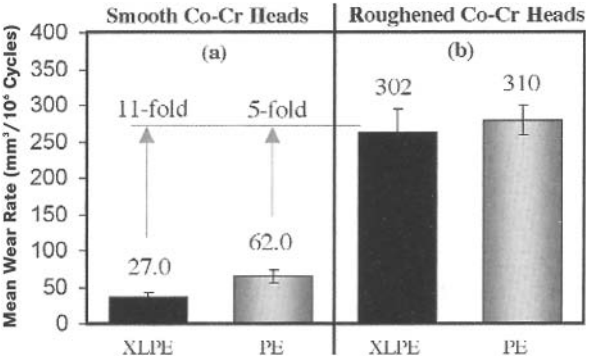

Figure 5:
Mean steady-state volumetric wear rates for 36 mm XLPE and conventional PE acetabular cups under (a) smooth, and (b) roughened Co-Cr heads under micro-separation test mode (roughened surfaces: Ra = 600 nm, Rp 3800 nm).

cups using similar CoCr roughness [36], these results presented a dramatic relationship between XLPE volumetric wear and femoral head diameter (Fig. 6). Even with contemporary XLPE cups, these wear rates can be increased from < 100 $mm^3/10^6$ cycles to > 300 $mm^3/10^6$ cycles by the effects of ball size. This relationship between roughness and head diameter is both intuitive and logical. Therefore, it appears that using larger and larger Co-Cr head diameters in young and more active patients may be at some cost [35]. It is also clear that using alumina heads on XLPE cups would obviate the concerns of surface roughening with Co-Cr bearings. However the role of 3-body abrasive wear mechanisms affecting the XLPE as the more sensitive material is still present. Therefore we believe that these higher activity patients with extended expectations would better benefit from alternative bearing surfaces such as ceramic on ceramic. In addition, there are less obvious modes of particulate generation, i.e. impingement, backside wear, etc [4,37]. However, we still know very little about these mechanisms for XLPE cups, especially understanding changes in debris morphology and concentrations.

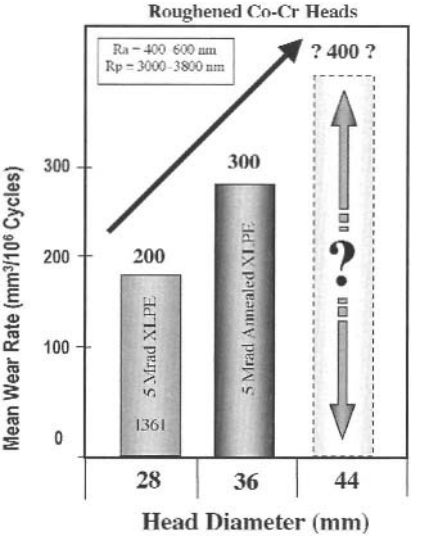

Figure 6:
Hip joint simulator studies of 28 mm [36] and 36 mm 5-Mrad crosslinked polyethylene cups showing volumetric wear under roughened Co-Cr femoral heads, indicating a potential increase in wear with increased femoral head diameter [35].

Conclusions

1) It is clear that an some percentage of Co-Cr femoral heads can be expected to roughen in vivo as represented by our 'high risk' patients. The effects of THR fixation mechanisms, various types of XLPE, nature of 3rd-body wear particles, femoral head diameter, and length of follow-up can all be expected to play a role in release of XLPE particulates.
2) The CoCr roughening effect suggests that we take due consideration when selecting CoCr/XLPE combinations for our younger more active patients, particularly those indicated for larger femoral heads to reduce dislocation risks.
3) It is clear that using alumina heads with XLPE cups will obviate at least the concern of surface roughening of the Co-Cr bearing. However the role of 3-body abrasive wear mechanisms affecting the more sensitive XLPE material will continue. Therefore we believe that these higher activity patients with extended expectations will better benefit from alternative bearing surfaces such as ceramic on ceramic.

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2.4 Polyethylene wear in Total Hip Arthroplasty -matched pair analysis of ceramic and metal heads

C. S. Ranawat, V. J. Rasquinha and J. A. Rodriguez

Purpose

The objective was to study the most important variable i.e. femoral head in the generation of polyethylene wear debris in THA.

Method

52 pairs of patients (minimum follow-up of 4 years) were matched for age, gender, body weight, surgeon, duration of follow-up and implant design and fixation. The only difference was the primary bearing surface, which was either ceramic or metal on polyethylene. The head diameter (28 mm) and head-neck taper was the same in both groups.

The wear measurements were determined by two independent observers utilizing computer-assisted wear analysis on digitized standardized radiographs described by Martell et al (1997) due to the least reported observer variability. The radiographs were also evaluated for osteolysis or aseptic loosening.

Results

The mean linear wear rate in the ceramic group was 0.13mm/yr and in the metal group was 0.17mm/yr, which was significant ($p<0.05$). There was no case of osteolysis or aseptic loosening at a mean follow-up of 5.5 years.

Clinical Relevance

The superior wear characteristics of ceramic on polyethylene hip articulations have the potential to markedly improve the longevity of contemporary THA.

2.5 Two Ceramic Bearing Surfaces with a Self Adjusting cup: A New Application of Delta Ceramics to reduce the Risk of Dislocation and Subluxation

J.-Y. Lazennec, L. M. Jennings, J. Fisher and B. Masson

Introduction

Dislocation remains one of the most common complications after total hip arthroplasty (THA). Its prevalence ranges from 0.6 to 27% in different series. Dislocation is reported as a major cause of failure of ceramic-on-ceramic THA prostheses compared to a classical Metal PE bearing couple (0.51% versus 0.14%). Subluxation also appears as an important factor for hard on hard joint surface lesions.

Precise cup position appears to be a main factor as significant variations occur for frontal and sagittal acetabular tilt and anteversion according to sitting or standing positions. Double-mobility polyethylene hip prosthesis have been extensively used in France. Clinical results confirm the efficiency of such systems to prevent dislocation. However concerns remain with regards to polyethylene wear and osteolysis.

An innovative tripolar ceramic system has been investigated to solve these problems.

It has been suggested as a method to reduce the occurrence of recurrent hip dislocation and wear. The performance of delta ceramics from CeramTec has enabled the 3D▲ tripolar joint to be manufactured (Fig. 1). Using two bearing ceramic surfaces, the intermediate component acts as a "self adjusting cup", dealing with the variations of pelvic orientation and acetabulum anteversion.

Figure 1:
Description of the 3D▲ tripolar device

Biomechanical studies

The use of the 3D▲ tripolar joint seems an interesting alternative to face difficult or unexpected situations for cup adjustment and cases with hip instability.

The position of the center of rotation influences joint stability

Some publications explain that a few millimeters inset of the rotation center increases the peak resisting moment against dislocation. This benefit in terms of stability has a significant disadvantage due to the decrease of range of motion (ROM) with classical ball-insert systems. The 3D▲ tripolar joint allows the movement of the center of rotation much deeper inside the insert without a negative impact on the ROM.

Two biomechanical studies have confirmed the improved resistance to dislocation with the 3D▲ system. Experimental investigations have been performed using in vivo data of Bergmann et al, at definite implant positions replicating close-to-reality conditions for T.H.A. orientation and loading conditions. A further measuring parameter for the dislocation stability was the torque during subluxation (resisting moment) against levering the head out of the cup.

Relevant combined movements related to posterior and anterior dislocation have been tested (i.e. internal and external rotation of the leg with adjusted 90° of flexion and 0° of abduction /adduction as well as with 10° extension and 15° adduction).

The 3D▲ tripolar joint revealed higher torques against subluxation in comparison to the classical Al-Al systems, even with 36mm head diameters, or 41 mm Metal on Metal bearing. More stable situations can be obtained even in poor implant positions, while the classical systems dislocated earlier and spontaneously without previous impingement. This was clearly demonstrated in case of steep cup position or insufficient anteversion.

The "Self adaptation" of the intermediate cup has been demonstrated with computational models and experimental studies

- The additional outer-bearing surface motion creates a second "adjustable acetabulum" due to the eccentration between the rotation center of the ball head and the rotation center of the bipolar head.
- This offset creates a resultant force Fr that rotates the bipolar component. This phenomenon has been evaluated and validated on computational models.

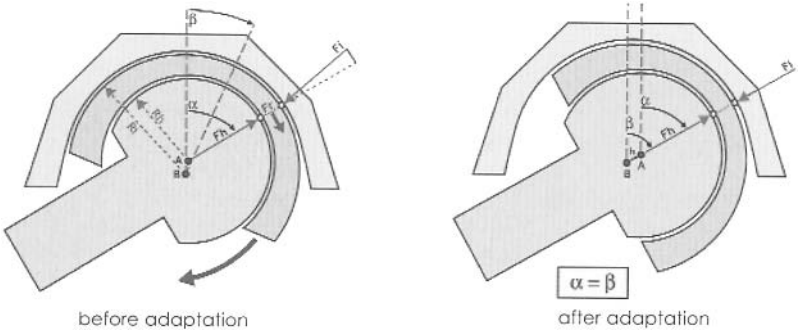

Figure 2:
Illustration of the tripolar prosthesis at a non-equilibrium and equilibrium position

Measuring the motion of the intermediate component is important for understanding the mechanism of the tripolar prosthesis and its efficiency against dislocation and microseparation The system was evaluated using a series of video-based motion analysis tests in two types of loading conditions, shear-out and lever-out situations. Shear-out was defined as the situation that leads to dislocation without impingement. Lever-out was defined as the situation that leads to a dislocation, accompanied with impingement. The study provides evidence that the relative motion of the intermediate component is closely related to the eccentricity between the intermediate component and the femoral head.

Mechanical performances

The mechanical characteristics of Biolox® Delta enable the manufacturing of this special device and especially of the intermediate cup with excellent strength properties. In collaboration with CeramTec AG a qualification program has been established to evaluate the mechanical reliability of this device. Standard qualification programs have been performed on the 22,2 mm Ball Head and the standard XLW fix insert 32/41 mm.

Regarding the bipolar (intermediate piece) component, a new program has been set up, based on a ball head qualification program. Specifications of the bipolar component (diameter, roundness, clearance, etc.) are strictly the same as a 32mm ceramic ball head

The bipolar part shows a particularly high resistance to fracture.

	Load (kN) Average value	Required Value FDA	Load (kN) Minimum value	Min. Required Value FDA
Static Test	129	>46 kN	58	>25 kN
Post Fatigue test	91	>46 kN	82	>20 kN

All 3 components successfully passed the qualification.

A finite element analysis (FEA) has been performed for the complete device in worst case scenario and specially for the bipolar component. This study shows that the stress distribution is optimised by the two bearing surfaces and they have a positive impact on the ceramic strength.

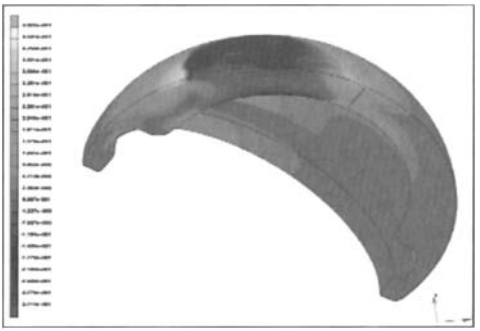

Figure 3:
Finite Element Analysis (FEA) of the Bipolar component

Regarding the PE ring, dislocation tests have been performed to evaluate its resistance to secure the ball head inside of the intermediate component. Results are comparable to similar PE rings that have been used for more than 18 years for classical double-mobility hip joint. The same tests have been performed using the PE ring after 5 millions cycles with micro separation in hip simulator. Results demonstrate that the locking mechanism is still efficient and intact after 5 millions cycles with micro separation, even if this test is very challenging for the components.

Dislocation Test of the PE ring	Average Maximum Load (N)
New PE ring before Hip Simulator Tests	**151**
PE ring after Hip Simulator Tests with Micro separation	**175**

Tribological tests

The aim was to assess the wear characteristics under standard test conditions and tests incorporating swing phase micro-separation between 200 and 500µm. Micro-separation is more appropriate for evaluation of ceramic bearings, as clinical wear rates, wear mechanism and wear debris are reproduced. The simulator was run for a total of 5 million cycles and the lubricant changed every 330,000 cycles. Wear of the ceramic components could not be detected gravimetrically. There was no visual macroscopic evidence of wear.

In a previous study, wear of conventional Biolox Delta components under microseparation conditions in the same simulator was measurable with reported wear rates of 0.32mm^3/million cycles during bedding-in (0-1 million cycles), reducing to a steady state wear rate of 0.12 mm^3/million cycles (1-5 million cycles). Furthermore, a stripe of wear was formed on the standard Biolox Delta heads, which increased the surface roughness Ra from <0.005 µm to between 0.02 µm and 0.13 µm. However, no stripe wear was observed in the testing of the 3D▲ tripolar joint.

The wear of the 3D▲ tripolar all ceramic hip was less than 0.01 mm^3/ million cycles, the detection limit for wear measurement.There was no change in the surface roughness of the inserts. The 3D▲ tripolar joint showed reduced frictional torque due to articulation at the smaller diameter 22mm inner femoral head. The wear volume of the PE rings could not be accurately quantified as it was within the systematic error of the soak control ring.

The design of the 3D▲ tripolar joint with the mobile ceramic head prevented edge loading of the head on the edge of the cup, so significantly reducing wear under these severe, but clinically relevant microseperation conditions.

Conclusion

Dislocation and microseparation are major causes of failure for ceramic-ceramic hip prosthesis. The use of the 3D▲ tripolar joint seems an interesting alternative to optimize T.H.A function, as, in some cases, no ideal solution can be found for acetabular implantation. The "self adaptation" of the intermediate cup can be demonstrated: the additional outer-bearing surface motion creates a second "adjustable acetabulum".

The efficiency against dislocation and microseparation can be explained geometrically and experimentally.

The design and testing carried out on the tripolar bearing with the mobile ceramic head show very high resistance to wear and stripe wear. Reducing the risk of dislocation and reducing wear drastically are two advantages that can place the 3D▲ tripolar joint as the best choice in primary Total Hip Arthroplasty. Obviously this choice applies to recurrent dislocation also.

The use of the 3D▲ device could have a positive impact in terms of cost by significantly reducing the number of revisions.

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2.6 20 Years Experience of Zirconia Total Hip Replacements

I. C. Clarke, D. D. Green, G. Pezzotti and D. Donaldson

Synopsis

Total hip replacements have used zirconia balls with polyethylene (PE) cups from the 1st generation, pioneering era (1985-1995), the 2nd generation HIPed and proof-tested product (1995-2001) and the 3rd generation alumina-doped zirconia (2000-). The yttria-stabilized zirconia (Y-TZP) has shown controversial performance in both laboratory and clinical studies. The zirconia combination alone (Zr/Zr) and combined with alumina ceramic (Zr/Al) has rarely been used due to concerns of degradation with long-term use. In the laboratory the Zr/PE combinations generally showed the least wear compared to CoCr/PE and Al/PE. However the greatly differing thermal conductivity between such ball materials may have had a major effect in-vitro, with serum-lubricated wear studies.

It is likely that the 1st generation, non-HIPed zirconia balls have predominated in Zr/PE results reported to date. Clinical studies with Zr/PE bearings have shown mixed results. Generally speaking the wear rates, osteolysis and revision rates for Zr/PE combinations have been adversely higher compared to conventional CoCr/PE and Al/PE series. Retrieval studies also showed many variations with increased roughness of Zr-balls from 10nm to 250nm and monoclinic transformation detected from 10% to 85%. Revision rates have varied from zero to 70% with long-term follow-up, although there were many confounding differences in implant design and quality of PE cups. There do not appear to be studies detailing the performance with the 2nd generation HIPed zirconia ball, or the 3rd generation, alumina-doped zirconia ball that is reputed to have overcome the risk of metastability challenges.

Introduction

The wear of polyethylene (PE) cups used now with over 400,000 zirconia balls [1] is of importance worldwide. It is therefore interesting that the laboratory and clinical performance of zirconia implants used in total hip replacements (THR) have been somewhat controversial over 2 decades [2]. By 2002, a French study had concluded that good clinical results were rare with zirconia/PE combinations [3]. Note that this is not in reference to the unique fracture problem in one manufacturing process that began January 1998 (Prozyr™ zirconia) [2]. In this report we shall focus solely on the wear performance of the zirconia/PE bearing combination and its efficacy in the patient.

Several companies worldwide have manufactured zirconia balls. In Europe and the USA the most common vendors were Norton Desmarquest Inc. (France) and Morgan Matroc Inc. (UK); in Japan it was Kyocera and Kobelco corporations. The most common form of zirconia was that stabilized by yttria (Y-TZP: ISO 13356), a metastable ceramic that has three polymorphs called cubic, monoclinic and

tetragonal phases. Unlike the stable alumina ceramic (Al: ISO-6474, ASTM F-603), Y-TZP zirconia (Zr) has a transformation-toughening effect due to its ability to transform from tetragonal to monoclinic phase with a slight increase in volume [1,2]. The Y-TZP strengthening effect while very useful is also complex and its metastability is not easily defined in terms of long-term bearing performance in the human body.

Any material that has the possibility to degrade is of concern for long-term implant use. Studies by Norton Desmarquest Inc. (France) predicted that as a benchmark their pioneering Prozyr™ zirconia would experience less than 10% monoclinic transformation over 10 years of patient use [1]. The 2nd generation Prozyr™ zirconia introduced in 1995 incorporated a hot isostatic pressure (HIP) process to further improve density and transformation resistance. The manufacturer indicated that the benchmark 10% transformation would now take up to 30 years of patient use with the HIPed balls [1]. Nevertheless it is now evident that Zr balls have experienced up to 85% monoclinic within 8 years of clinical use (Table 1). The question is do such reports represent isolated clinical problems, were they endemic to 1st generation product manufactured before 1995 or alternatively do they represent a failure path common to Y-TZP implants?

Study	Surgeries began	Series Ended	Max follow-up	Zirconia THRs	Max transformation	Max Roughness (Ra nm)	PE Wear notes
Green 2003	2001[a]	NA	2, 10 Yrs	N = 2 revised	8%	24 nm	NA
Prozyr	1995[a]	2001	---	Began HIPing	---	---	---
Norton 2002	1995[b]	1999	6 Yrs	N = 29,9 revised	NA	NA	Hylamer™ cases
Green 2003	1994[a]	2002	8 Yrs	N = 1 revised	85%	255 nm	150
Haraguchi 2001	1992[c]	1994	6 Yrs	N = 21, 2 revised	30%	120 nm	NA
Walters 2005	1991[a]	1994	6 Yrs	203(28mm) 47(32mm)	85%	NA	Zr=0.19mm/yr CoCr=0.14mm/yr
Hernigou 2003	1988[b]	1990	12 Yrs	N = 40 cases, 3 revised	30%	50 nm	Al=56 Zr=245mm³/yr
Santos 2004	NA [d]	NA	10 Yrs	N = 18 revised	70%	39 nm	NA

Table 1:
Ranking of begin-dates for surgery in retrieval studies of Zr/PE combinations compared to introduction date of 2nd generation 'HIPed' Prozyr™ zirconia balls in 1995. The details of maximum monoclinic transformation and maximum surface roughness are indicated for each study.
Key: a = Norton Desmarquest Inc.
b = manufacturer not identified
c = Kobelco Inc.
d = Astromet, Ceraver and Kyocera Inc.
NA = data not available
*Hylamer™ = cups gamma-sterilized in air (Depuy-J&J Inc, Warsaw IN) with published record of high wear, osteolysis and revision rates [38].

Zirconia evaluation with wear-screening machines

The preferred geometry for wear screening of ceramic-on-ceramic THR combinations has been the ring-on-disc configuration. As described by Willmann [4], the typical 'reciprocating ring-on-disc' procedure (ISO-6474) incorporated a ceramic ring oscillating on a ceramic disc (O.D. 20mm; 50° arc at 1Hz) with some external cooling to counteract the significant frictional heating with ceramics. The applied load was constant (pressure 9.4 MPa) and water was used as the lubricant (typically 360,000 cycles; 100-hour test).

The Zr/Zr and Zr/Al combinations always resulted in catastrophic wear with the ring-on-disc test mode. As early as 1978 an Italian group demonstrated that their Zr wear couple produced several thousand times more wear than the alumina couple [5]. Subsequent wear studies by Japanese and German investigators also came to that same conclusion [4,6]. Willmann et al [4] reported that their Zr/Zr study was terminated at only 50,000 cycles due to massive wear, with the Zr roughness increasing from 10nm Ra to 400nm.

Ceramic on polyethylene (PE) bearing combinations provided a much more forgiving wear couple [7,8]. Laboratory studies have generally reported lower wear rates with Zr/PE than CoCr/PE [9,10]. Thus the Zr/Zr and Zr/Al combination was rejected by ring-on–disc wear studies while the Zr/PE combination was approved by pin-on-disc wear studies (Table 2).

Test Mode	Combination	Lubricant	Comments	Resukt
ring-on-disc	Zr:Zr, Zr:Al	water	catastrophic wear	relevance uncertain
pin-on-disc	Zr/PE	water, serum	wear Zr/PE < CoCr/PE	irrelevant
hip simulator	Zr/PE	water	wear Zr < CoCr/PE	irrelevant
hip simulator	Zr/PE	serum	wear Zr < CoCr/PE	degradation artifact

Table 2:
Reviews of laboratory wear studies of zirconia combinations.

Zirconia/PE evaluation in hip simulator machines

Over 2 decades previously, bovine serum was advocated as lubricant of choice in PE wear studies [11,12]. However, water was frequently used to demonstrate lower wear with ceramic/PE combinations than with CoCr/PE (Table 2) [13-15]. Therefore at LLUMC we ran a series of simulator studies with CoCr/PTFE, CoCr/PE, Al/PTFE, and Al/PE to better define the relevance of water-based, wear studies. We included Plasmion™, a protein-containing alternative solution. Thus it was demonstrated that with water the ceramic/PE wear drops close to zero but with CoCr/PE much less so [16-21]. Thus the fact that wear of Zr/PE < CoCr/PE we would explain simply an artifact of water lubrication (Table 2). Saline and Plasmion behaved just like water in such PE wear studies.

The first Zr/PE study using bovine serum as lubricant compared CoCr/PE, Al/PE and Zr/PE combinations [22]. It was noted that contaminants from the lubricant (90% serum concentration, calcium phosphate precipitates) adhered tenaciously to the femoral balls and hence considerably affected both frictional torque and wear values. Similar problems have been encountered in metal-metal wear studies [23,24]. McKellop [22] et al proposed minimizing these protein-degradation artifacts by adding 20 mMol EDTA to the test solution. Subsequent

tests showed that steady-state PE wear ranked Zr < CoCr < Al (Table 2) with the CoCr/PE and Al/PE being 40% and 64% higher than Zr/PE, respectively. A subsequent simulator study run in 30% serum concentration demonstrated a 3-fold wear reduction compared to CoCr/PE [10]. In the 2nd study included, Zr balls were aged in an autoclave for 15 hours at 134° C to produce 40% monoclinic transformation. Highly transformed Zr balls produced only a modest PE wear increase of 10% [10].

It is worthy of note that the Zr, CoCr and Al wear ranking described by McKellop [22] had the same ranking as the thermal coefficients of conductivity for the ball materials. Thus, the alumina material was 29-times more effective than Zr in conducting frictional heating away from the wear zone. Our interpretation would be that inferior heat elimination with Zr balls would tend to favor more serum degradation with greater precipitation of proteins. Studies have shown that degradation of serum proteins also reduced the PE wear rates [18,25]. Thus we would favor the hypothesis that the apparently lower wear with Zr/PE THR may be an artifact created by the presence of degraded proteins interposed between bearing surfaces [25]. An alternative hypothesis would be that destruction of serum proteins created a 'lubricant' that behaved more like water.

Thus in overview, it is clear that simulator studies run with water lubrication and appearing to show Zr/PE superiority have no clinical relevance (Table 2). What is not so clear is the Zr/PE superiority when run in serum, given the complexity of the protein interactions with a) low thermal conductivity of Zr, b) the thermal capacitance of varied serum chamber sizes and c) the serum type and concentration. Thus it may be adequate to assume that the Zr/PE and Al/PE combinations have comparable wear performance in vitro.

Zr/Zr and Zr/Al evaluation in hip simulators

In 1996 a clinical study combined Zr balls with alumina cups in 5 cases [26]. At 5-year review, there were no revisions or other negative results. In contrast, a milestone laboratory study of Zr/Zr compared to Al/Al THR predicted very negative results [27]. This simulator study had three important attributes compared to ring-on-disc tests; 1) all test specimens were of appropriate THR geometry, 2) implants were made by an experienced biomaterials group of a major ceramic corporation (Bioceram™, Kyocera Inc, Japan) and 3) the hip simulator had been well validated [19,22,28-30]. Saline lubrication was used in this study and ceramic tolerances were given as roughness (Ra) < 10nm, sphericity < 1um and radial tolerances given as 5-10μm range [27]. With the Zr/Zr combination, all THRs "dislocated" before 1 million cycles duration due to high frictional torques and the wear rates were 10-fold higher than with Al/Al combinations. The Zr surfaces showed loss of high polish and SEM revealed cratering at 500,000 cycles duration. The XRD studies showed higher monoclinic transformation on the worn surfaces. In contrast the simulator wear studies by manufacturer Norton Desmarquest used 30% bovine serum as the lubricant of choice. The French study ran to 5 Mc duration and were detected no wear or other negative effects [10], thus apparently contradicting the simulator study with saline lubrication [27].

To investigate this dichotomy of simulator claims, we ran Zr/Zr (Prozyr™) and Zr/Al combinations in both water and serum lubricants. At 5-Mc duration we found ultra-low wear of both Zr balls and cups [30,31]. Under these pristine test

conditions, our run-in wear rates for Zr/Zr and Zr/Al combinations averaged 0.34 and 0.17 mm^3/Mc, respectively, compared to 0.54 mm^3/Mc with Al/Al [30]. We then extended the serum-lubricated study to 21 million cycles duration, looking for long-term negative effects. Even in such a lengthy test, Zr wear was minimal and under SEM study the surfaces looked perfect [16]. In contrast, when we ran the same THRs with water lubrication there was catastrophic breakdown of the surfaces at only 6,000 cycles duration [31]. Since such bearings have survived at least 5 years in the patient [26], our conclusion once again was that water-lubricated and saline-lubricated tests did not represent the bearing conditions in the patient.

A microseparation simulator test was introduced to better represent the more severe type of stripe wear seen on ceramic retrievals [32,33,34] Under 'mild' microseparation, the combination Zr-ball/Al-cup produced less wear than Al/Al, an excellent result with Zr bearings [35]. However, under 'severe' microseparation conditions, the Zr/Zr run-in wear was 10.6 mm^3/Mc. This was more than twice as high as the Al/Al combination but still not catastrophic.

Thus in overview, only the water-lubricated and saline-lubricated simulator studies reproduced the catastrophic Zr/Zr wear predicted by the ring-on-disc tests. In contrast, with serum lubrication, Zr/Zr bearings tended to produce less wear than Al/Al combinations in simulator studies. This was also true under mild microseparation conditions. Only in one 'severe' test did the Zr/Zr wear actually exceed that of Al/Al. However none of these studies answered the question of which tribological model better represented the patient.

Clinical studies with the Zirconia ball/PE Cup

Detailed clinical reviews with Zr-ball/PE-cup combinations are few in number (Table 3). There would appear to be only one series of Zr/PE cases claiming good results [2,40]. In addition the series with Hylamer cups [36-38] may be compromised due to the gamma-air sterilized cups having a history of high wear, osteolysis and revisions [38]. The clinical study with the longest follow-up noted that the 6-fold increase in wear in cases with Zr-balls compared to Al-balls only became evident after 8 years. Their XRD studies of 3 retrievals (> 8 years duration) showed monoclinic transformation increased from < 4% to 19-30% and ball roughness (Ra) increased from 5nm to 50nm. It was not clear if any clinical studies used the 2nd generation, HIPed Zr balls.

Study	Zr THR (N)	Zr-ball	Cup	Retrievals	Duration (Yrs)	Wear	Trans-formation
Hernigou 2003	40	28mm	NS	N=3	11	Zr=4x Al	19-30%
Stewart 2005	2100	22mm	UHMWPE	N=7	8	NS	4-30%
Wroblewski 2003	96	22mm	Hylamer	0	8	Zr=2xCoCr	NA
Walters 2005	250	28/32mm	UHMWPE	N=19 8% revisions	6	Zr=1.3xCoCr	Up to 85%
Norton 2004	29	22mm	Hylamer	68% revisions	6	osteolysis	NA
Kim 2001	70	22/28mm	Hylamer	0	6	Zr > CoCr	NA
Hamadouche 2002	51	22mm	Duration	0	4	osteolysis	NA

Table 3:
Summary of clinical studies of Zr/PE combinations ranked by length of follow-up (NA = not available).

Zirconia ball/PE Cup Retrievals

The retrieval study by Haraguchi et al in 2001 [41] was a milestone, being the first in a 16-year history of Zr/PE THR. Both revision cases were complicated with case-1 at 3 years showing a disassociated PE liner/lock-ring and case-2 at 6 years having recurrent dislocations. However these did reveal a dramatic 30% transformation to monoclinic phase (Table 1). The surface roughness of the Zr balls increased to 37 and 120 nm and revealed extensive surface cratering. Dr. Sugano kindly donated one of these Zr retrievals to our LLUMC Retrieval Lab for further study. We confirmed the surface roughness and cratering by SEM and our XRD and Raman Spectroscopy studies revealed that damaged areas had > 20% transformation while the non-used areas had < 4% monoclinic [2]. With this beginning, our LLUMC retrieval lab now has gathered more than 100 Zr balls with some showing up to 85% monoclinic phase.

A recent Zr study [21] reviewed 18 retrieved balls originally made by Astromet (5), Ceraver (7) and Kyocera (6). Data included follow-up to 10 years for comparison with 5 new balls (Ceraver). Unfortunately there was no stratification by manufacturer or production era in this study. The surface roughness had increased somewhat (Ra < 40 nm) and monoclinic phase was typically < 20% but 3 retrievals showed transformation in the 50-70% range (> 5 years in vivo).

The long-term series of 22mm Zr THRs from England contributed 7 retrievals for analysis [40,42]. While the 22mm Zr ball roughness showed some increase (< 4nm up to 10 nm) the surface finish was still very good and the XRD studies revealed monoclinic transformations < 8%. In our collaborative studies with Leeds University [34] we used the high resolution, confocal Raman Spectroscope (CRS) in the Dept. of Chemical, Materials Science and Engineering (Kyoto Institute of Technology). This CRS data was generally in good agreement, with the unused Zr ball revealing < 5% monoclinic. The data were also in good agreement for the < 2-year retrieval, showing < 10% monoclinic. In the remaining cases, the higher resolution CRS-method detected approximately double the transformation levels indicated by XRD. However such changes with retrieved 22mm balls (< 5 years in vivo) were still slight compared to changes seen in the 28mm balls (Table 1). Thus it may be hypothesized that among other parameters, the manufacture of the small ball may have provided a more stable zirconia than those manufactured in larger diameters.

Zirconia Transformation

One unanswered question is whether the high monoclinic transformations seen in some retrievals (Table 1) were endemic to the 1st generation zirconia balls (< 1995)? The HIPed balls (2nd generation) and zirconia balls doped with higher levels of alumina (3rd generation) have been proposed as incremental and significant improvements [1]. For example it has been predicted [1,43] that the Al-doped Zr would take more than 50 years to get to the 10% monoclinic threshold assumed to occur in 10 years with 1st generation Zr balls.

To investigate such differences between 2nd and 3rd generation zirconia, we studied the effects of artificial aging (autoclave) on two types of 28mm Zr balls (2nd generation Prozyr, Norton Desmarquest; Al-doped Zr; Bioceram, Japan). The balls were studied before and after autoclaving (30 and 60 hours at 121°C).

Surface roughness measured by Zygo interferometry on pristine balls showed no difference in surface roughness with Ra average maximum < 3 nm. SEM studies of the pristine bearing surfaces showed a grain size in the range 0.2-0.3µm. The balls were then scanned by XRD and confocal Raman Spectroscopy (CRS) from the pole (0°) to 90°-orientation. On the 3rd generation Bioceram balls, the CRS scans showed no monoclinic transformation after 60 hours autoclaving. SEM studies of the bearing surfaces showed no grain pop-outs or other disruption to the surface integrity. The surface stresses were predominantly neutral with small foci of low compressive and tensile regions. On the 2nd generation Prozyr balls, the CRS detected major transformation after 30 hours of autoclaving that ranged 5-30% monoclinic and after 60 hours ranged 35 - 65% monoclinic (Fig. 1). These surfaces showed regions with very high compressive stresses and tensile stresses. In these areas there was correspondingly higher surface roughness due to transformation. Thus this simple aging test showed a major transformation resistance between 2nd and 3rd generation zirconia balls.

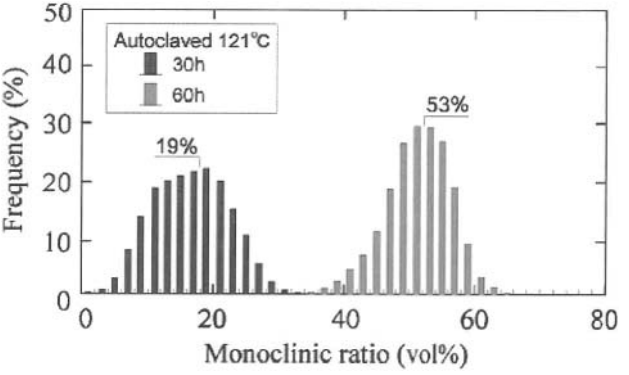

Figure 1:
High-resolution scans by Raman Spectroscopy showing approximately 20% of bearing surface of zirconia ball transformed to monoclinic phase by 30 hours of autoclaving and 53% after 60 hours of autoclaving. This was of the same magnitude as reported previously [2].

Discussion

Contributing to the enigma of zirconia implants has been the gradual evolution of tribological knowledge over the years. While the ring-on-disc method dramatically 'failed' the Zr:Zr and Zr:Al combinations, the pin-on-disc method 'passed' Zr/PE as superior to CoCr/PE. However the credibility of the pin-on-disc studies has also been impacted by invalid predictions of PE performance [19]. It is therefore interesting that serum-lubricated, hip simulator studies also approved the Zr/PE combination as superior [22,44]. However from our tribological perspective, we remain suspicious over the effect that different thermal conductivities (Zr < CoCr <Al) of the femoral balls may have on the degradation of the proteins in the serum [45]. This is a major consideration because the quality and concentration of the biological proteins control the wear-rate of PE cups in vitro [16,46]. Thus we have concerns that the biological proteins interacting with zirconia may have produced non-physiological effects in such laboratory studies. For this reason we have not favored using the Zr/PE combination since this zirconia enigma was first raised [22].

Clinical studies with Zr/PE combinations have also been confusing. Studies with the 22mm Zr/Hylamer combination can reveal either zero revisions or up to 67% revisions (Table 3). Mid to long-term, clinical studies have reported 30% increased

wear to 400% increase in wear rates with Zr/PE compared to Al/PE and CoCr/PE combinations [39,47]. Some Zr ball retrievals may show surface roughness in an acceptable range (10-50nm) or as high as 250nm while the monoclinic transformations may be < 10% or over 80%. Indeed, some Zr ball retrievals may show no roughening or transformation over a 10-year period [48]. Thus there may be many confounding manufacturing differences as well as temporal variations in the quality of both the zirconia balls and the PE cups used over this 20 year history (Table 1). Indeed, was the increased wear reported with Zr/PE THR only a function of increased roughening of the zirconia balls? In some studies the degree of roughening appeared relatively quite minor (Table 1). It would be interesting to speculate that there might be some other interaction of the metastable zirconia with the lubrication and wear mechanisms in vivo.

It was also interesting that 8 years or more may be required for the wear effects with Zr/PE THR to become radiographically significant (Table 3). This could be interpreted as the necessary aging period for 1st generation Zr balls (pre 1995) to undergo enough transformation and surface roughening. Interestingly, the cases studies from Japan with 30% monoclinic transformation featured 2nd generation zirconia balls implanted in the 1991-1994 era [41]. However these represented 2 complex cases. As yet there appears to be no clinical study uniquely identifying the detailed performance of 2nd generation, HIPed Zr balls. While one manufacturer indicated 1995 as the year of introduction for their HIPed zirconia, we have no information as to how quickly the hospital inventories were replaced country by country. One retrieval study included Bioceram balls but these were not identified as to what generation or condition received [21]. Nevertheless our thermal stability study of 3rd generation Bioceram zirconia compared to the 2nd generation Prozyr balls appeared encouraging.

In conclusion, a review of the risks and benefits of zirconia implants comes down to the credibility and rigor of four study areas, namely wear-screening tests, hip wear simulations, clinical reviews and retrieval studies. It seems appropriate therefore that the clinical study by Dambreville et al [49] gave this curious title to their paper, "Zirconia ceramics, or by night all cats are grey". The authors went on to comment that, "In the absence of rigorous scientific clarification, information on biomaterials is frequently a source of confusion and misleading generalizations worrying to orthopedic surgeons". It is unclear today whether it is possible to stratify the published zirconia failures by material, manufacturer, implant types or patient parameters (Table 4).

PARAMETER	DETAILS
zirconia chemistry	Standard versus Al-doped
manufacturer	varied
fabrication steps	HIPed versus non-HIPed
production years	most studies < 1995
ball diameters	22, 28, 32mm
design of cup	all-PE versus metal-backed
cup inserts	PE, Hylamer, XLPE
fixation modes (3rd-body wear mode)	cemented, non-cemented, HA-coated
duration of follow-up	most studies < 8 years
patient activity level	varied
Complex patient issues	liner disassociation, neck impingement, dislocations

Table 4:
Summary of confounding factors involved in interpretation of clinical results with zirconia implants.

Acknowledgements

We acknowledge Bioceram (Kyocera Inc, Japan), Biomet (Warsaw IN) and the Peterson Foundation of LLU for support of our zirconia hip and knee wear studies. We would also like to thank Drs. R. Pitto MD (Auckland), M. Ries MD (San Francisco), L. Sedel MD (Paris) and W. Walters MD (Sydney) for their contributions of zirconia balls to our LLORC Retrieval laboratory. Thanks are also due to G. Willmann PhD and P. Williams MSc for their editorial assistance.

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2.7 Controlled Zirconia Phase Transformation in BIOLOX® delta - a Feature of Safety

M. Kuntz, N. Schneider and R. Heros

Introduction/Background

The introduction of the use of ceramics in the field of orthopedic implants in the early 1970's has brought about the widespread recognition that the proper application of ceramics can resolve many challenges existing in orthopedic surgery. Of these the greatest contribution has been made in the wear reduction area in total joint replacement as it is now universally accepted that the use of an alumina ceramic substantially reduces wear and the often resultant osteolysis.

Beside the successful use of alumina ceramics, the late 1980's and early 1990's marked the entry into orthopedics of the zirconia family of engineered ceramics. The initial focus for this higher strength ceramic material was smaller femoral ball heads and increased reliability as it was felt that the enhanced mechanical properties would allow designers to offer 22 and 26mm ball heads as well as increase reliability when compared to the only other ceramic used in orthopedics, alumina.

It is unfortunate that much controversy exist as a result of very mixed clinical results in the use of this ceramic material. This has been created by two conditions. On the one hand, ceramists have known that the use of zirconia ceramics under certain conditions of temperature and stress and in an aqueous environment could create surface changes that could affect the wear characteristics of the material. This is based on the characteristic fact that after sintering, zirconia exists in the meta-stable tetragonal high-temperature phase. The material seeks to reach the low energy monoclinic low-temperature phase. This phase transformation occurs with a 4% volume expansion due to crystal lattice reorganization which can lead to surface changes of zirconia components.

These surface changes, created by the transformation of grains from one phase of the material to a different phase with an accompanying volume growth have now been documented to occur in actual clinical use of these components [1,2,3]. Secondly, numerous articles exist detailing the fact that the expected increased reliability claims as compared to alumina ceramics did not materialize in actual clinical use [4].

The final chapter in the zirconia family seems to have been written by the exit of the company Norton Desmarquest that introduced its use in orthopedics from the business as a result of a major processing problem in a number of their production batches which resulted in a large number of clinical fractures. While this issue was clearly created by specific problems related to the production of some of their product, it nonetheless highlighted the fact that the zirconia family was not the ultimate ceramic material for the future.

With this background in mind, the CeramTec Medical Products Division set clear goals for the development and introduction of a new family of ceramic material that would complement alumina ceramic where needed. It had to

posses the highest possible toughness, the smallest matrix grain size all leading towards improved mechanical reliability but this had to be accomplished without sacrificing the wear resistance and chemical stability of current day alumina ceramics.

Alumina Matrix Composites were selected as the best new family of ceramics to provide the foundation for an expanded use of ceramics in orthopedics. The microstructure (Fig.1) of this Alumina Matrix Composite, BIOLOX®*delta* reveals its optimized nature: The main characteristics of this Alumina Matrix Composite are its two toughening mechanisms. One is given by in-situ grown platelets (Fig.1, elongated grains) which have a hexagonal structure and are homogeneously dispersed in the microstructure. Their task is to deflect any sub-critical cracks created during the lifetime of the ceramic and to give the entire composite stability.

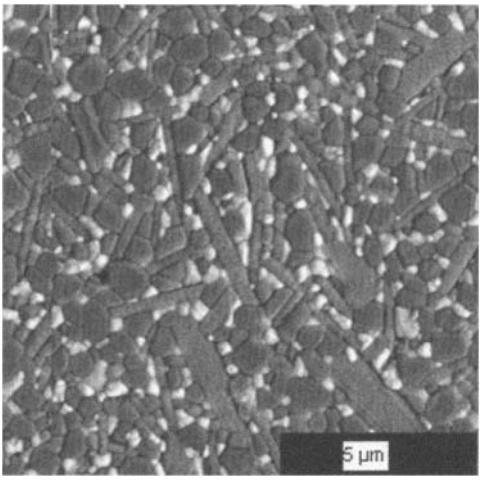

Figure 1:
micrograph of BIOLOX® delta

The other important characteristic is related to the addition of 17 vol.-% zirconia nano-particles (Fig.1, bright grains) that are dispersed homogeneously and individually in the alumina matrix (Fig. 1, dark grains). This increases strength and toughness of the material to levels equal and in some cases above those seen in pure zirconia. Here, the effect of tetragonal to monoclinic phase transformation is used as a toughening mechanism. In the case of micro-crack initiation the local stress triggers phase transformation at an individual zirconia grain which acts then as an obstacle to further crack propagation. It is a desired behavior which uses the volume expansion in an attempt to prevent further crack propagation.

These two well known effects in material science, crack deflection (Fig. 2) and transformation toughening (Fig. 3) give BIOLOX®*delta* a unique strength and toughness unattained by any other ceramic material used in a structural application in the human body.

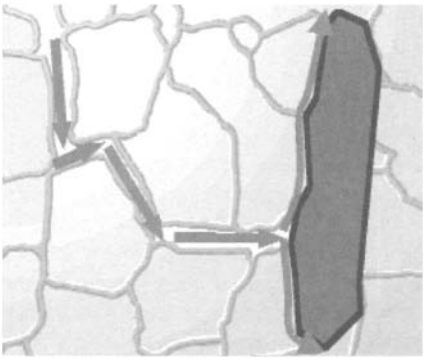

Figure 2:
crack deflection

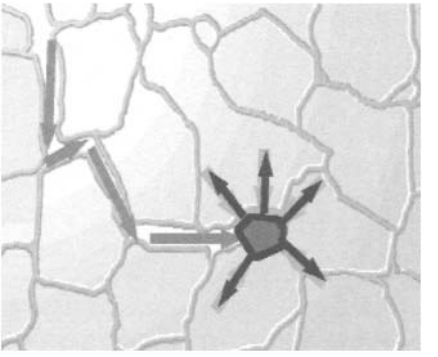

Figure 3:
transformation toughening

Triggering of Monoclinic Phase Transformation

As in monolithic zirconia, in the Alumina Matrix Composite phase transformation is a desired effect that is part of the material system. To gain full advantage of the toughening system, it is useful to keep monoclinic phase content as low as possible prior to use. As mechanical impetuous can trigger transformation it is important to ensure minimum monoclinic content at the end of all manufacturing steps. In accordance with the material data sheets, CeramTec delivers all BIOLOX®*delta* components with a monoclinic content below 10% (of the zirconia fraction, measured on a flat polished surface). During production, especially after hard-machining the level of monoclinic phase content increases due to mechanical treatment. This is reversed by a heat treatment and polishing step which transforms zirconia back to the high-temperature tetragonal phase (Table 1).

When discussing the ratio of zirconia monoclinic content it has to be kept in mind that all of these measurements give the ratio of monoclinic content of the zirconia phase but as zirconia takes up only 17vol.-% of the BIOLOX®*delta* composition the overall values of monoclinic zirconia phase in BIOLOX®*delta* are 6-fold lower than given in the measurements below.

	ratio monoclinic/ (monoclinic+tetragonal)	**ratio monoclinic zirconia/ total matrix**
as-sintered	6%	1%
machined	16%	2,7%
heat treated, polished	7%	1%

Table 1:
phase content during manufacturing (measured on the pole of ball head)

Performance of BIOLOX® *delta*

A study by Clarke et al. [5] shows that with ideal ball head position there is no difference between pure alumina wear couple of BIOLOX® *forte* and BIOLOX® *delta* wear couple. Only under severe conditions such as in microseparation tests the BIOLOX® *delta* wear couple shows considerable lower wear rates than the BIOLOX® *forte* wear couple. Also a combination of BIOLOX® *forte* and BIOLOX® *delta* for ball head and insert (and vice versa) performs favorably. After 1.1 million cycles under these worst case conditions, monoclinic phase content in the affected area increases up to 15-30% levels. However, calculated for the entire matrix it corresponds to a ratio of monoclinic zirconia phase of 2.5 to 5%. It has to be noted that transformation takes place only in the regions of wear.

Pecharromán et al. [6] have analyzed the threshold limit (based on percolation theory) for hydrothermal stability of zirconia in alumina matrix composites by steam sterilization. They calculated a theoretical limit of 16vol.-% although the measured data in their publication revealed that a relevant aging level is given at 18 to 22% volume content of zirconia.

The fact that BIOLOX® *delta* shows such outstanding performance is proof that the toughening mechanism of phase transformation achieves its design goals. It can be concluded that controlled tetragonal-to-monoclinic phase transformation of zirconia is a valid method to reach the target of improved wear resistance.

Conclusions

The introduction of a new family of ceramic material to the orthopedic implant field requires a great deal of evaluation and testing. The Alumina Matrix Composite Material herein discussed has been designed with certain built in mechanisms that ensure the proper stability of the material in actual use. The built in mechanisms actually impart very positive material properties to the Composite. These are:

- BIOLOX® *delta* utilizes the monoclinic phase transformation of the zirconia grains in the microstructure as a desired materials response against severe mechanical overloading.
- Severe wear, such as can occur from multiple dislocation clinically or from the microseparation wear testing protocol carried out by Clare et al [5]. can trigger transformation of zirconia to monoclinic phase. In the case of BIOLOX® *delta* this transformation creates a favorable effect under extreme conditions as it impedes microcracking
- Monoclinic phase transformation in BIOLOX® *delta* is a mechanism that is stable and controlled and an integral part of the material enhanced fracture toughness.

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SESSION 3

Clinical Results of Ceramic on Ceramic Systems

3.1 Alternative Bearing Surfaces: Alumina Ceramic Bearings for Total Hip Arthroplasty

W. N. Capello, J. A. D'Antonio, J. R. Feinberg and M. T. Manley

Abstract

Osteolysis resulting from polyethylene wear debris is one of the most common causes of implant failure in young, active individuals who undergo total hip arthroplasty. Reducing wear may help extend implant life in younger, more active patients. Contemporary alumina ceramic/alumina ceramic bearing articulations are harder, are scratch resistant, and are more hydrophilic than other bearing couples. This results in reduced wear and reduction of particle load to the surrounding tissue. Therefore, bearings made of alumina ceramic may be a preferable bearing choice for younger, more active patients.

To investigate this hypothesis, a total of 495 patients (514 hips), average age of 53 years, were enrolled in a prospective, randomized, multicenter study comparing an alumina-on-alumina ceramic bearing to a cobalt-chrome-on-polyethylene bearing control. At an average of four years post-implantation, no difference in clinical outcome was observed between groups. There were no ceramic head or liner fractures in this group, nor were there any revisions due to the ceramic liner.

Another investigational group was added to the study one year after enrollment in the original study was closed. The same inclusion/exclusion criteria were used. A total of 194 consecutive patients (209 hips) received an alumina liner that included a thin metal backing designed to allow bearing replacement and ease operative assembly. At an average follow-up of 30 months, no liner or head chips or fractures were observed in this group.

Introduction

Advances in implant materials and design have improved the longevity of total hip arthroplasty (THA) with survivorship of 10 to 15 years or more commonplace. As a result of these improvements in both implant and technique, more arthroplasty surgeons have extended the indications for THA to include younger and more active patients. In addition, as life expectancy increases, research in total hip arthroplasty must continue to focus on obtaining greater longevity. Wear of polyethylene (UHMWPE) and biologic reactions to wear debris leading to periprosthetic osteolysis are the leading cause of reoperation of hip implants [1]. Thus, the need for improved bearing surfaces in THA has led to the development and study of alternative bearing materials. These now include cross-linked polyethylene, metal-on-metal, zirconia-on-polyethylene, and alumina ceramic-on-alumina-ceramic bearing surfaces. Of these, the low-wear bearing pair available at the time of the commencement of our study was ceramic/ceramic.

Pierre Boutin first introduced ceramics into orthopaedics in the early 1970's as an alternative to UHMWPE [2]. The hardness, "wetability", and biocompatibility of ceramics make them very desirable as a bearing surface. In addition, ceramics

are chemically inert and highly resistant to corrosion. Early clinical applications were disappointing because of increased component loosening, ceramic component fracture, and isolated examples of accelerated wear of the bearing surface [3]. Fracture rates as high as 13% were seen [4]. One reason for the failure of these first generation ceramics was that they could not be processed to full density because of long sintering times, which resulted in large crystal sizes [5]. A second generation of ceramics developed in the late 1980's and early 1990's found that adding materials such as calcium- or magnesium-oxide to the ceramic resulted in smaller grain sizes [5]. Fracture rates decreased to less than 5% with these second generation improvements in manufacturing [2,6].

The current or third generation of ceramic manufacturing, using hot isostatic pressing, produces a highly pure, fully dense ceramic with small grain size. Grain size in first generation ceramics was 4.2 μm, compared to 3.2 μm in second generation ceramics and 1.8 μm in third generation ceramics [7]. Corresponding to the reduction in grain size, burst strength increased from 46 kN in 1984 to 65 kN in 1995 [8]. Optimum density and a fine microstructure are necessary to provide good mechanical strength. Hot isostatic pressing produces the optimal material strength. During manufacturing, proof testing is done to validate the mechanical properties, and laser etching rather than mechanical engraving is used to prevent stress risers [9]. Fracture rates of ceramic femoral heads made with third generation techniques are approximately 0% to 0.004%, or four per 100,000 [9,10]. Alumina-on-alumina bearings demonstrate wear rates 4000 times less than that of cobalt chrome-on-highly cross-linked polyethylene [11,12]. Alumina-on-alumina bearings produce between 0.2 and 2 billion wear particles per year compared to the 0.6 to 1.2 trillion wear particles per year produced by cobalt chrome-on-polyethylene bearings, and ceramic particles are smaller than polyethylene particles [7]. In addition, alumina bearings are more resistant to scratching from third body particles than metal-on-polyethylene bearings are [13]. After approximately five years of clinical investigation, the use of alumina-on-alumina bearings for total hip arthroplasty in the U.S. was approved by the Food and Drug Administration in February, 2003. The results of our multicenter study of alumina-on-alumina bearings follow.

Materials and Methods

Between October, 1996 and October, 1998, 458 patients (514 hips) were enrolled in a prospective, randomized, multicenter IDE study to compare alumina-on-alumina bearings with cobalt-chrome-on-polyethylene bearings in primary total hip arthroplasty. Patients were randomly assigned to one of three study groups. Each patient had a one-third chance of receiving any one of the three cup designs and a two-thirds chance of receiving an alumina-on-alumina bearing surface. All patients/hips received the same hydroxyapatite (HA) coated femoral stem (Omnifit® HA femoral stem, Stryker Howmedica Osteonics, Mahwah, NJ). Groups I and II both received the alumina-on-alumina bearing couple (ABC). Patients/hips in Group I (Fig. 1 – System I) received a porous-coated titanium shell (MicroStructured™ ABC, Stryker Howmedica Osteonics, Mahwah, NJ), and patients/hips in Group II (Fig. 1 – System II) received an arc-deposited titanium shell with a HA coating (Secur-Fit® HA ABC, Stryker Howmedica Osteonics, Mahwah, NJ). Patients/hips in Group III were the control group, and they received

a microstructured, porous-coated titanium PSL shell with a polyethylene liner and a cobalt-chrome femoral head (Fig. 1 – System III). All cups had a peripheral locking design with a 1mm increased peripheral radius over the dome of the socket. Ninety percent of hips receiving the ABC system had 32-mm femoral heads, whereas 82% of the control group had 28-mm femoral heads.

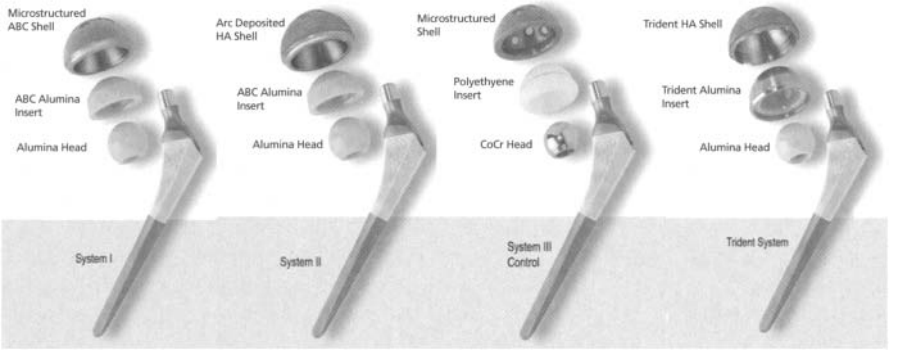

Figure 1:
(A) Porous-coated acetabular shell, alumina ceramic acetabular insert, alumina ceramic femoral head, and hydroxyapatite (HA) -coated titanium femoral stem. (B) Titanium arc deposited HA-coated acetabular shell, alumina ceramic acetabular insert, alumina ceramic femoral head, and HA-coated titanium femoral stem. (C) Titanium porous-coated acetabular shell, polyethylene acetabular insert, cobalt-chrome femoral head (ion bombarded), and HA-coated titanium femoral stem. (D) Trident ® HA-coated acetabular shell, metal-backed alumina liner, alumina head, and HA-coated titanium femoral stem.

In 1999 a new investigative device, a metal-backed alumina liner (Trident®, Stryker Howmedica Osteonics, Mahwah, NJ), was added as the fourth arm of the study (System IV). Between September, 1999 and September, 2000, 194 patients (209 hips) were enrolled in that arm of the study. Because enrollment had closed for the first three arms of the study, there was no random assignment. Consecutive patients meeting the original study criteria were enrolled into this fourth arm of the study. The Trident® acetabular shell has the same external geometry and surface configuration as the one used in System II of the original alumina-on-alumina study, and the same femoral component (that was received by all the other patients in the study (Fig. 1 – Trident System). With the Trident® system, acetabular components with an inner diameter of 36 mm and 36 mm femoral heads were available for implants with an outer diameter of 58 mm or more.

The demographic characteristics of the study population are shown in Table 1. There are no differences in demographic characteristics between the four groups in the study. In this study, the typical study patient was a young male with osteoarthritis of the hip, which is the anticipated patient profile for a wear-resistant prosthesis. No patients with inflammatory arthritides were included in this study. Patient follow-ups ranged from three to five years with a mean of 3.9 years for patients with Systems I, II, or III and an average 2.6 years with a range from two to four years for patients with System IV.

	System I	System II	System III	System IV
Patients/Hips (N)	163/172	171/177	161/165	194/209
Male/Female (%)	65/35	66/34	60/40	66/34
Age (Years)	53	53	53	52
Body Mass Index	28.3	29.0	28.7	28.9
Follow-up (Months)	47.2	47.6	46.6	30.7
OA/AVN/Other (%)	81/14/5	76/18/6	76/16/8	81/11/8

Table 1:
Demographic Characteristics of the Three Study Groups

Data coordinators at each of the 16 participating institutions compiled clinical and radiographic data preoperatively, early postoperatively (six to eight weeks), at six months, one year, and annually thereafter. Clinical parameters included level of pain and function, need for support for ambulation, limp, and participation in various daily activities, including recreational activities. A composite Harris Hip Score [14] (HHS) was calculated at each assessment period. Anteroposterior and lateral radiographs were obtained at each designated assessment period, and the radiographs were assessed by an orthopaedic surgeon outside of the investigative group. Radiographs were evaluated for radiolucent lines, implant stability, implant migration, and cortical bone erosion or osteolysis. Component stability was rated using the criteria of Engh [15].

Results

Clinical Outcome

At most recent clinical follow-up, 91% (System I), 93% (System II), 95% (System III), and 94% (System IV) of hips had no pain or slight pain. No limp or a mild limp only was seen in 99% (System I), 96% (System II), 96% (System III), and 99% (System IV). The average Harris Hip Score across the four groups (Systems I-IV, respectively) was 95.5, 96.7, 97.0, and 97.2, and the percentage of each group with a Harris Hip Score rated as good or excellent was 92%, 96%, 98%, and 97%. The percentage of patients in each group who reported being satisfied with their hip replacement at their latest follow-up was (for Systems I-IV, respectively) 97%, 99%, 96%, and 97%. There were no statistically significant differences in these clinical outcome percentages regardless of group/system assignment.

Complications

Complications are shown in Table 2. Thirteen hips underwent revision of one or both components. There were a total of five isolated cup revisions, one in System II (titanium arc-deposited HA shell) secondary to recurrent dislocation, three in System III (titanium porous-coated shell), one due to sepsis, and two due to aseptic loosening at 3.0 and 3.5 years postoperatively, and one in System IV due to aseptic loosening of a vertically positioned cup. Five femoral components were revised, one in System I secondary to a post-traumatic periprosthetic fracture, one in System II secondary to subsidence and loosening post-trauma, two in System III, one secondary to post-traumatic femoral fracture and one due to painful leg length discrepancy, and one in System IV secondary to a postoperative

Complication	System I	System II	System III	System IV
Revision – Cup	0	1 (0.6%)	3 (1.8%)	1 (0.5%)
Revision – Stem	1 (0.6%)	1 (0.6%)	2 (1.2%)	1 (0.5%)
Revision – Both	1 (0.6%)	2 (1.1%)	0	0
Revision – Liner and/or Head Only	0	0	5 (3.0%)	2 (1.0%)
Intraoperative Femoral Crack/Fracture	6 (3.5%)	7 (4.0%)	7 (4.3%)	4 (1.9%)
Postoperative Femoral Fracture	5 (2.9%)	2 (1.1%)	2 (1.2%)	1 (0.5%)
Deep Joint Infection	1 (0.6%)	1 (0.6%)	2 (1.2%)	0
Dislocation	4 (2.3%)	6 (3.4%)	7 (4.2%)	4 (1.9%)
Ceramic Liner Chip upon Insertion	5 (2.9%)	4 (2.3%)	NA	0

Table 2:
Complications

fracture. Three hips have had both the acetabular and femoral components revised, one in System I and two in System II, all due to suspected or confirmed deep joint infection. An additional seven hips, five with a cobalt chrome-on-polyethylene bearing (System III), underwent liner and/or head exchange, four due to recurrent dislocation and one due to excessive polyethylene wear and osteolysis at 52 months postoperatively. Two hips with alumina-on-alumina bearings (System IV) underwent liner and/or head exchange, one due to recurrent dislocation and one due to subluxation at 22 months post-THA. A peripheral chip occurred upon insertion of the liner in nine hips (2.6%) with an alumina-on-alumina bearing surface; none occurred in the revised liner design group (System IV). In eight of the nine cases the alumina liner, shell, or both were replaced. In one hip the chipped insert was seated and left in place without any secondary complications. None of these nine cases has had any other complications associated with the chipped insert, and none has undergone a reoperation or component revision.

Radiographic Outcome

In unrevised components, one stem in a System III hip was determined to be radiographically unstable at the four-year assessment. A second stem in a System I hip was noted to have subsided into a new stable position at the one-year assessment following a skiing accident. On the acetabular side, three unrevised cups showed three zone radiolucencies. One System I (porous) cup met the criteria for an unstable implant. Two System III (porous) cups were classified as fibrous stable. These patients were asymptomatic at their most recent follow-up. Cortical erosions (erosive scalloping lesions at the femoral resection level) were noted in three hips in System I (1.7%), one hip in System II (0.8%), and 17 hips in System III (13.3%). The difference in numbers of alumina-on-alumina ceramic hips (Systems I or II) with cortical erosions (4/273) versus those with cobalt chrome-on-polyethylene hips (System III) (17/128) was statistically significant ($p < 0.001$) at an average four-year follow-up. Figure 2 shows an anteroposterior radiograph of a typical ceramic-on-ceramic total hip arthroplasty at five years post-implantation.

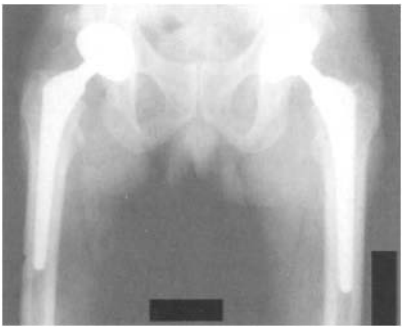

Figure 2:
Anteroposterior radiograph of a right ceramic-on-ceramic (System II) total hip arthroplasty in a 54-year-old male at five years post-implantation.

The mechanical failure rates for each component in the study are shown in Table 3. The overall mechanical failure rate for the HA-coated femoral components in this study was 0.3% (two of 767 stems) at two to five year follow-up compared to 0.8% (six of 767 cups) on the acetabular side (p = ns). Analysis of component failure by bearing surface revealed no difference on the femoral side, with one stem revised in an alumina-on-alumina hip and one revised in a cobalt chrome-on-polyethylene hip. On the acetabular side, hips with alumina-on-alumina bearings had a mechanical failure rate of 0.4% (two of 558 hips) compared to 2.4% (four of 165 hips) in the cobalt chrome-on-polyethylene bearings group (p = 0.037).

	System I	**System II**	**System III**	**System IV**
N (hips)	172	177	165	209
Bearing type	ABC	ABC	CoCr /Poly	ABC
Acetabular Side				
Revisions for AL	0	0	2	1
Radiographically loose	1	0	2	0
MFR	0.6%	0%	1.2%	0.5%
Femoral Side				
Revisions for AL	0	1	0	0
Radiographically loose	0	0	1	0
MFR	0%	0.6%	0.6%	0%

Table 3:
Component Mechanical Failure by System

ABC = alumina-on-alumina
CoCr/Poly = cobalt chrome-on-polyethylene
AL = aseptic loosening
MFR = mechanical failure rate (revisions for aseptic loosening plus radiographically loose)

Discussion

The primary goal of THA is to provide a painless, safe, durable artificial joint. As the longevity of hip implants has increased through improved implant designs and fixation methods, surgeons have expanded the indications for THA to include younger and more active patients. However, debris produced from wear of the bearing surfaces may produce osteolysis, which can potentially lead to premature loosening of a hip implant.

Alumina-on-alumina bearing couples have a number of theoretical advantages. Ceramics are extremely hard, making them wear and scratch resistant. In hip simulator testing, alumina-on-alumina bearings produced linear wear rates of less than one micron per year compared to 200 microns per year for a traditional cobalt chrome-on-polyethylene bearing surface [16]. The current third-generation ceramics are hot isostatic pressed and proof tested to reduce the probability of bearing fracture. In addition, alumina is biocompatible and precludes concerns over metal ion release.

Fracture remains a concern with ceramic bearing couples. Early ceramics had insufficient purity, low density, and a coarsely grained microstructure, which led to poorer mechanical strength of the ceramic [9]. In the 1980's, inadequate implant design contributed to unacceptable fracture rates. Concerns included neck socket impingement, leading to femoral neck wear, cup rim fracture, debris generation, and eventual loosening [17]. In the United States, a fracture rate of 1.9% was reported with use of alumina ceramic femoral heads [18]. However, these fractures were once again attributed to a design issue, that being a mismatch between the alumina ceramic head and the trunnion of the femoral stem. Precise matching of the taper-lock interface between the alumina ceramic and femoral or acetabular components is crucial in order to minimize the risk of stress risers and fracture. No ceramic heads or liners have fractured during the period of this study.

The early results of this randomized, controlled, multicenter study of 723 hips, 558 of which have an alumina-on-alumina bearing surface, are excellent. Clinically, 95% of the ceramic hips have a good or excellent Harris Hip Score. The overall mechanical failure rates for all systems are small, and differences between systems cannot be shown. However, upon analyzing the cases in which we observed small, erosive lesions at the neck resection, we found a statistically significant ($p < .001$) relationship between a lesion occurring with polyethylene bearings as compared to ceramic bearings. We suggested in an earlier publication that erosion lesions are associated with particles released from the bearing [19]. The reduced number of lesions observed with the ceramic bearings appears to support our earlier hypothesis.

In the ceramic hips (System I and System II), nine ceramic liner chips occurred upon insertion. The problem of insert chipping was shown to be caused by the impaction of a liner not seated completely within the rim of the shell. This problem was solved by adoption of the Trident® design (System IV).

The metal-backed Trident® alumina insert is assembled with a shrink-fit titanium sleeve on the outside that mates with a peripheral taper lock within the shell, making it easy to seat. The ceramic insert is recessed in the titanium sleeve, which then acts as a bumper, protecting against ceramic scoring of the femoral neck, which could lead to mechanical failure. The shell features two independent locking mechanisms that can accept either a ceramic or a polyethylene liner. This provides more intraoperative flexability in a revision setting. The Trident® design allows the use of larger diameter heads, which may help improve joint stability and allow for increased range of motion.

One criticism of ceramic bearings is cost. Although the costs of such implants are currently higher than metal-on-polyethylene implants, it may be anticipated that these costs will decrease as demand and manufacturing increase. One must also consider the cost over time. An initially higher cost of a primary THA factored over 20 or 30 years or longer when implanted in a young, active individual, may

well be more cost effective than a less expensive implant requiring reoperation or revision after 10 or 15 years. Only long-term data will confirm or refute the costs and merits of alumina-on-alumina bearing couples in THA. However, the potential for alumina ceramic bearings in THA appears to be great and optimally suited to the young, active individual needing a THA.

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3.2 Ceramic-on-Ceramic Total Hip Arthroplasty: The USA Experience

J. P. Garino

Introduction

With the great success of total hip arthroplasty and its ability to restore high levels of comfort and function more consistently and reliably than any other procedure developed for disabling hip disease, its indications, have been extended logically to encompass both younger and more active patients. Couple this with the ability to obtain high rates of durable cementless fixation with many designs and coatings, the bearing surface remains the most vulnerable aspect of the prosthetic replacement. As such, alternative, more durable bearings have become highly desirable. Ceramic-on-ceramic articulations are such a bearing with some advantages over other types of bearing options.

Alumina ceramics have been in use for over thirty years, and, therefore, is a well known and well understood material. The early years of its usage saw problems related to fixation of the uncoated monoblock acetabulum and a relatively high rate of fracture. However, even in those early times, osteolysis from wear related debris was a very uncommon occurrence [1]. Revisions of loose components were straightforward due to the relative preservation of bone stock. Development of cementless fixation, particularly on the acetabular side resulted in a high rate of osteolysis in the 1980's due to thin polyethylene that had been processed with gamma sterilization in air, leading to oxidation and a significant reduction in its mechanical properties. However, the modular design of these sockets has lead to a resurgence in the use of hard bearing in total hip arthroplasty in an effort to reduce the risk and rate of significant osteolysis.

Materials Properties

Alumina is an ideal bearing material. It is extremely hard. It is much harder than both zirconia and cobalt chrome. This hardness is an important advantage as it imparts both the ability to create very smooth components and high scratch resistance to the articulation. This scratch resistance results in a reduction of abrasive (mode 1) wear as well as a resistance to third body wear (mode 3). The latter characteristic results from the inability of bone and cement, due to their much lower hardness, to scratch the alumina parts. Alumina bearings are also highly wettable. Their hydrophyllic nature allows for high lubricity and reduced adhesive wear (mode 2). The significant reduction of both adhesive and abrasive wear has resulted in a wear reduction of about 200 times less than standard metal-poly articulations [3]. The added benefit to this tremendous wear reduction is that it allows the use of larger ball heads due to the insignificant increase in volumetric wear.

Alumina debris, although capable of inducing an osteolytic response, has seldom done so as the high numbers of particles required are rarely generated from well functioning articulations. In bulk form, the material is inert and, unlike metal-metal debris, the particles remain locally.

Perhaps the only downside to the ceramic-ceramic articulation is that occasionally, the components may fracture. This complication must be placed in proper perspective as the number of fractures of ceramic components is quite small when compared to the numbers of components implanted. As such most instances of ceramic component fractures have reached the scientific literature in the form of a case report. In the United States, alumina ceramics made by CeramTec under the trademark name of Biolox® forte, are the only ceramics used in ceramic-on-ceramic applications. This latest generation material has enjoyed over ten years of world wide success, mostly in Europe, with minimal complications. This material is the result of manufacturing and scientific improvements of the alumina material over the decades. Such important improvements as increased purity in the material, laser etching, hot isostatic pressing and proof testing have resulted in a stronger material with higher reliability. Recent reviews of the CeramTec database put the fracture rate of this material at about 0.01-0.02% [2]. When compared with other complications of total hip replacement, these numbers stack up quite favorably. Indeed, if one were to factor in wear related failures, the failure mode virtually eliminated by the use of a ceramic wear couple, these complications are even more favorable. It is this philosophy and perspective that have made this new bearing articulation quite popular in the United States since full FDA approval in February of 2003. This approval, of course, was the culmination of several successful Investigational Device Exemptions.

Materials and Methods: The IDE's

In 1996, Osteonics (Now part of Stryker Orthopedics) and Wright Medical Technology began FDA (Food and Drug Administration) initiated clinical studies following the Investigational Device rules of the FDA for the Ceramic-Ceramic bearings in total hip replacement. Although ceramic-on-ceramic bearings had been introduced a decade earlier in the form of the Mittelmeier Autophor prosthesis, the ceramic articulation was not proven successful until a new design concept was introduced which captured the ceramic liner within the metal cup by means of a Morse taper locking mechanism. This new design was therefore reviewed and evaluated by the FDA and classified as "investigational" requiring extensive clinical trials to be conducted prior to market introduction. The FDA imposed approval process was contingent upon a minimum 2-years follow up with successful outcomes and high follow-up rates for all patients. The results of several of these IDE's represent the basis of this paper.

Osteonics

The Osteonics IDE was the first to begin in late 1996. In this study, 514 patients were randomized into three groups. The femoral component was the same in each group. The control bearing was metal on standard poly and was used in 171 hips. The experimental groups were both ceramic-ceramic (343 hips total) with one group using an HA coated cup while the other used a porous coated cup. In this first series 65% of patients assigned to one of the ceramic-ceramic group were male, while only 605 in the control group were male. 76 % of patients had a pre-op diagnosis of osteoarthritis. Harris hip scores increased to 96 in both groups and the other demographics were similar including an average age of 53 years.

A second series was then undertaken where another 328 hips were randomly enrolled in an extended study group with 222 enrolled in ceramic-ceramic arms. In this group 64% of the patients randomized to a ceramic-ceramic articulation were male while only 61% in the control group were male. Follow-up for these groups ranged from 3-7 years.

The system underwent a design change where the ceramic liner was placed into a titanium jacket. This was done to eliminate chip fractures which were an occasional occurrence and a concern of the FDA. In this group an unrandomized additional 209 ceramic-ceramic total hips were implanted in 194 patients. 66% were male, 81% had a diagnosis of osteoarthritis, and the mean age was 52 years [4].

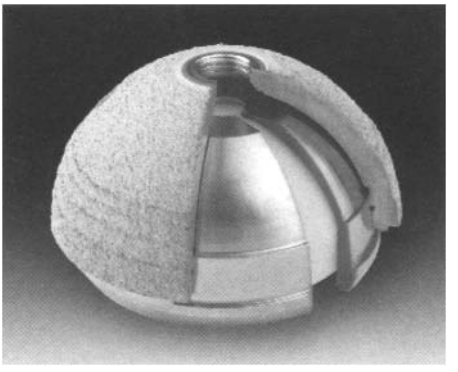

Figure 1:
Trident Ceramic cup
Courtesy of Stryker

Wright Medical Technology

This particular IDE began in April 1997. It was different from the Osteonics approach in so far as the choice was made not to use a control group, but rather use historical controls. This was a bit risky because if a number of complications were to result, without a control group it might not be easy to discount the ceramic articulation as a contributing factor and invalidating the results. But confidence in total hip replacement techniques and success as well as confidence in the new ceramic bearing led to the streamlining of the IDE. From 4/97 to 8/98, 337 hips were enrolled in the study. 61 % were male, the average age was 52, the pre-op HHS score was 45 and OA was the primary diagnosis 71% and AVN 19% [5].

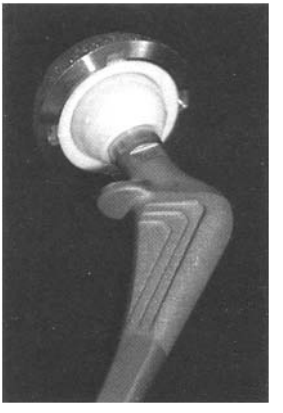

Figure 2:
Transcend™ Ceramic-Ceramic THR
Courtesy of Wright Medical Technology

Smith & Nephew

This randomized and prospective study began in November of 1998. In this series all hips used ceramic ball heads and the control was a poly liner whereas the experimental group was given a ceramic liner. 315 THR's were implanted in 276 patients. 61% of the patients were male. 174 hips were randomized to the ceramic-ceramic group and 141 were randomized to the control group. The average age was 50 in the Ceramic group and 53 in the control. Pre-op HHS scores were 44 in the experimental hips and 41 in the controls [5] (Fig. 3).

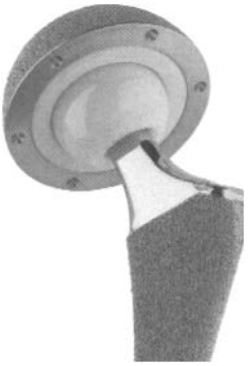

Figure 3:
Reflection Ceramic THR
Courtesy of Smith and Nephew

Others

Other companies have embarked on IDE studies including Depuy, Zimmer and Encore. Encore has completed their study successfully and received full FDA approval for ceramic-ceramic THR in the fall of 2003. Virtually every company in the USA has a ceramic bearing option in their plans for their hip systems in the future and are preparing accordingly.

Results

Stryker

The original ABC study had excellent success at early to mid term. HSS scores increased to 96 on average in both groups and, as such there was no statistically significant difference. There were 10 dislocations in the two experimental groups and 7 in the single control group.

There were no Ceramic component fractures, but 9 insertional chips which were corrected intra-op. There were 15 revisions in the series with 6 in the two experimental groups and 9 in the single control group. In the experimental groups 2 of the revisions were performed for femoral complications (1 fracture due to trauma, 1 subsidence). 3 revisions were for sepsis or suspected sepsis and one for recuurent dislocation. In the experimental group, 4 revisions were for recurrent dislocation, 2 for acetabular loosening, 1 for femoral fracture, 1 for sepsis, and one for leg length discrepancy. In the Trident series, the mean HHS score improved to 97% and there were no insertional chip fractures. 4 revisions were performed, 2 for recurrent dislocation, 1 for acetabular loosening one for femoral loosening [3].

Wright Medical Technology

The HSS score increased in these patients to 95. Revisions in this cohort were performed for the following reasons:

–3 for recurrent dislocations
–1 loose acetabulum
–2 loose femoral components
–1 deep infection
–1 liner malinsertion
–1 cup Malposition with levering
–1 liner head mismatch

There were no ceramic component fractures, but 4 chipped inserts.
Since the completion of the study, there have an additional 1700 hips implanted as part of the continued access program. Over 800 of these had a minimum of 2 years of follow-up. During that time only 2 ceramic related revisions were performed. One for impingement related lysis and one for late instability with a cracked margin of the ceramic liner [5].

Smith & Nephew

This series reported an increase in the HHS score to 95 and 92 in the experimental and control groups respectively. There were 8 dislocations in the ceramic group and 6 in the control. There were 2 revisions in the control group, one for infection and one for recurrent dislocation. In the experimental group, there were two revisions for recurrent dislocation, 1 for infection and one for loosening. There was one ball fracture in a recurrent dislocator and one liner fracture. There were also 2 chipped liners [5].

Discussion

The American experience with ceramic-ceramic THR has been quite favorable with minimal revisions at this early to midterm stage a very low percentage of which is due to ceramic component failure. With the increasing activity demands of patients and the expansion of indications into younger patients, the ceramic-ceramic articulation is a very attractive alternative to other bearing systems with a low complication rate and a very promising future in the USA and globally. The opportunity to also take advantage of larger ball head sizes to reduce dislocations and increase range of motion in this active group is another benefit of the bearing with out the worry of allergic or possible carcinogenic side effects. Complications will likely continue to decrease as new generation of Ceramic bearings with greater strength is on the horizon and surgeon experience and comfort increases.

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3.3 Ceramic-on-Ceramic versus Ceramic-on-Polyethylene Bearings in Total Hip Arthroplasty: Results of a Multicenter Prospective Randomized Study and Update of Modern Ceramic Total Hip Trials in the USA

B. S. Bal, T. J. Aleto, J. P. Garino, A. Toni and K. J. Hendricks

Abstract

One reason why otherwise well functioning total hip replacements have a finite service life is eventual aseptic loosening of the implants because of osteolysis induced by wear particles from the artificial bearing. Pain and osteolysis from wear debris can manifest even in the absence of aseptic loosening. Total hip replacements with ceramic-on-ceramic articulations have shown less wear both in vitro and in vivo. A randomized prospective clinical trial was conducted to compare the outcomes of ceramic-on-ceramic articulations to ceramic-on-polyethylene articulations. Two year data are of interest since premature failures of ceramic femoral heads usually occur by this time interval. Of 500 patients enrolled in this trial, half received total hip replacements with alumina-on-alumina bearings, while the other half had ceramic-on-polyethylene bearings. At the two-year follow-up, 444 patients (217 study group and 227 control group) were available for review. The clinical and radiographic outcomes between the groups were comparable, and reflected the typical results of primary total hip replacements. No complications related to spontaneous failures of the ceramic bearings were observed at this early follow-up period. Further follow-up is needed to confirm these findings over the long-term, but the short-term safety of alumina ceramic bearings in hip replacements reported in other recent reports is further validated by our findings.

Introduction

Total hip arthroplasty is considered among the most successful and cost-effective surgical innovations of the twentieth century [14]. Since the pioneering work of Charnley that led to predictable results from artificial hips, metal-on-polyethylene bearings have been the standard in prosthetic hip bearings in the United States [7]. Until recently, relatively less attention was devoted to investigating alternative bearings in total hip arthroplasty, such as metal-on-metal and ceramic-on-ceramic, at least in the United States [3,27].

In the evolution of hip replacement surgery, fragmentation of the acrylic cement used to secure cemented implants to bone led to the development of cementless implants [22,34]. When cementless fixation of implants ultimately proved durable, aseptic loosening from inflammation and osteolysis induced by microscopic wear particles was recognized as the major problem limiting total hip replacements, particularly in young and active patients [46]. Interest was therefore directed to alternative bearings with improved wear properties, and to further improvements in the wear properties of metal-on-polyethylene itself to reduce the incidence of wear-induced osteolysis.

In the 1980's, sporadic failures of alumina femoral heads that lacked uniform quality control of the raw material and manufacturing parameters, combined with uncontrolled variables related to implant design discouraged widespread adoption of ceramic bearings in the U.S. [8,38]. In the 1990's, improved manufacturing, processing, and design techniques contributed to improved reliability of ceramic bearings [20]. Encouraging clinical results reported by European centers with ceramic-on-ceramic and metal-on-metal bearings further stimulated a renewed interest in alternative bearings [16,43]. Several U.S. orthopaedic implant manufacturers began Food and Drug Administration (FDA)-approved clinical trials to evaluate the efficacy of modern ceramic bearings in total hip replacements. In 1996 and 1997 respectively, Howmedica Osteonics (Rutherford, N.J.) and Wright Medical Technology (Arlington, Tenn.) initiated clinical trials of total hip replacements with ceramic bearings, and these studies have already reported excellent short term results [10,13]. The purpose of this report is to summarize the data from a multicenter clinical trial initiated by Encore Medical, L.P. (Austin, Texas) comparing the outcomes of total hip replacements performed with ceramic-on-ceramic to ceramic-on-polyethylene bearings, with the goal of reviewing the incidence of complications specific to the ceramic devices.

Materials and Methods

In 1998, Encore Medical, L.P. obtained an Investigational Device Investigation Exemption (IDE) from the FDA to conduct a clinical trial investigating ceramic bearings in total hip arthroplasty. A total of 17 investigators at 17 sites subsequently participated in this investigation. The FDA and each investigator's institutional review board approved the study protocol. Patients were enrolled randomly into two groups; one that received total hips with ceramic-on-ceramic bearings, and the other that received ceramic-on-polyethylene bearings instead.

Each ceramic femoral head used in this investigation was 28 mm in diameter; made of alumina (CeramTec AG, Plochingen, Germany); and available in three neck lengths. One of three press-fit femoral components made by Encore could be used at the discretion of the operating surgeon, with a press-fit acetabular component that could be fixed to the pelvis with or without screws. The cementless implants used to support the ceramic bearings in this trial were similar in design to those used in other recent trials, in that these implants already had an established history of success with metal-on-polyethylene bearings.

Patients in the study group received alumina-on-alumina bearings; the alumina liner was made of the same material as the femoral head, and it was attached to the inside of the metal acetabular shell with a taper. Patients in the control group received a total hip with an alumina femoral head, but a polyethylene acetabular liner instead. Randomization was controlled via shipping of the implants; neither the surgeon nor the patient was aware of the implant type prior to surgery.

Demographic data such as the diagnosis of hip disease, and the Harris Hip Scores [17] were recorded for each case. After the procedure, patients were evaluated at six-month and twelve-month intervals, with yearly follow-up thereafter. At each interval, Harris Hip Scores, radiographs, complications, revision surgery, and patient satisfaction were recorded. Only patients with at least two-year follow-up were included in the present report.

All postoperative radiographs, which included AP and lateral views, were digitized and reviewed by a single orthopaedic surgeon who was not otherwise involved with the study. Serial radiographs were examined to determine implant migration, radiolucent lines, and osteolysis. Radiolucent lines around implants were reported according to the acetabular zones described by DeLee and Charnley [11], and the femoral zones described by Gruen [15]. Component loosening was diagnosed if there was a circumferential radiolucent line of greater than 2 mm in width around any component, or subsidence of the femoral component of greater than 5 mm, or a greater than 3 degree change in the angular orientation of the acetabular component.

Statistical comparisons with two-way ANOVA were made on the demographic data as well as the pre- and post-operative Harris Hip Scores, complication rates, and revision rates to identify differences between the control and study groups. Statistical significance was set at a probability value < 0.05.

Results

During January 1998 and January 2001, 500 total hips were implanted, consisting of 250 study devices (238 patients) and 250 control devices (241 patients). Forty-two patients underwent bilateral total hip replacement. Twelve patients received study devices in both hips; nine patients received control devices in both hips; and 21 patients received one of each type. These 21 patients are counted in both groups.

Nine deaths occurred (six patients in the study group, and three patients in the control group) prior to the two-year evaluation. None of the deaths was related to the hip replacement. Seven revision procedures had been performed before the two-year evaluation (one in the study group; and six in the control group). All revision operations in this investigation, with the exception of one control hip, were performed for hip instability. The one control hip was revised for a loose acetabular component. Thirty-nine patients (26 control implants and 14 study implants) did not return for their two-year evaluation. This resulted in 444 implants that were available for review with a minimum two-year follow-up.

Comparison of demographic variables showed that the mean patient age was statistically higher in the control group than in the study group (60.9 years versus 55.0 years).

	Total	Study	Control
Number of Patients	500	250	250
Patient Age			
Mean Age + SD	57.95 ± 14.1	54.97 ± 14.7	60.93 ± 12.81*
Range	17-94	17-91	19-94
Gender Distribution			
Male	255	138	117
Female	245	112	133
Diagnosis			
Osteoarthritis	343	160	183
Post-traumatic	38	19	13
Inflammatory	19	8	11*
Avascular Necrosis	85	51	34
Other	15	12	9

Table 1:
Comparison of Patient Variables (* = $p < 0.05$.)

A comparison of the patient variables between groups is summarized in Table 1. Harris Hip Scores improved significantly in both groups compared to preoperative values, and did not differ significantly between the two groups.

The only complication related to the ceramic bearings in this series of 500 hips occurred when an alumina acetabular liner chipped during insertion into the metal shell. This liner was impacted before it was fully seated in the taper inside the shell, resulting in a chip breaking off at the edge. The bearings were exchanged for new components in this one case at the time of the index procedure. Other complications encountered in this series are summarized in Table 2. Of note, no complications relating to the ceramic bearing occurred after surgery in any patient. The incidence of complications was not statistically different between the study and control groups.

	Study	Control
Alumina liner Fracture	1	0
Dislocation	7	10
Femur Fracture	6	2
Deep Venous Thrombosis	4	4
>2 cm Leg Length Change	0	2
Acute Wound Drainage	5	4
Late Sepsis	0	0

Table 2:
Incidence of Complications

Radiolucent lines of less than 2 mm width were present around the uncemented implants in 119 study cases, and 103 control cases; none of these were complete. An incomplete radiolucent line of greater than 2 mm in width was present around 8 femoral implants in the study group only. None of the femoral components in either group had a complete radiolucent line around it on any view. One acetabular component, mentioned earlier, had been revised for radiographic loosening. With the exception of this component, none of the other acetabular components in either group had a circumferential radiolucent line around the metal shell. No osteolysis was observed in any of the cases in either group in this investigation.

Discussion

A successful outcome and reasonable durability over time can be expected of total hip replacement surgery today, if implants with known long term successful outcomes are used [5]. The previous problems with component fixation and implant design have been addressed by modern cementing techniques, reliable uncemented devices, and implant design improvements [41,42]. The variable that now limits the longevity of artificial hips in the human body is the inflammatory response to wear debris, i.e. polyethylene, and subsequent osteolysis and implant loosening [18]. Decreasing the wear of artificial bearings in total hips is therefore desirable, since it should enhance the longevity of the otherwise very successful results of total hip replacements, particularly in young and high-demand patients [35].

The standard metal-on-polyethylene bearing coupling used in total hip surgery can be improved by using cross-linked polyethylene, that has been reported to have improved wear properties [29,30]. While early data with highly cross-linked polyethylene is encouraging, the long term performance of this material is yet unknown [26]. Concerns have been raised about the adverse effects of cross-linking polyethylene on the ultimate strength and fracture toughness of this material [28].

Hard bearing surfaces are an alternative to metal-on-polyethylene couplings in total hips. These include metal-on-metal [24], and ceramic-on-ceramic bearings [3]. Both of these were associated with failures when first introduced in the U.S., and in most instances, the failures were not a function of the bearing material, but a reflection of other variables such as suboptimal implant design, poor fixation of the implants to bone, and surgical technique [25,40].

While metal-on-metal bearings have reduced wear compared to polyethylene-based bearings [12,21], the long term effects of exposure to systemically elevated metal ion levels remains a theoretical concern., particularly in the young patients with relatively long life expectancies [4]. The concern is that elevated metal levels may be associated with the development of cardiomyopathies, sarcoid-like lesions, dermatologic reactions, and delayed-type hypersensitivity reactions [40,44].

Ceramic bearings are attractive because they are associated with the lowest wear rates of all modern total hip bearings [43]. Ceramic bearings have demonstrated superior wear compared to metal-on-polyethylene *in vitro* [9], and the *in vivo* wear of ceramic articulating against itself is superior to that of metal-on-polyethylene and metal-on-metal bearings [31]. The average alumina-on-alumina wear rate is in the order of 3 microns per year [37].

Ceramics are very hard materials, second only to diamond on the MOHS scale [3]. This allows ceramics to be polished to a much lower surface roughness than metal, resulting in less friction and wear, and increased resistance to scratching and three-body wear. These properties, combined with their hydrophilic nature that contributes to a fluid film surface lead to minimal adhesive wear in ceramic bearings [40].

In addition to superior wear properties, ceramics are biologically inert, thermodynamically stable, and insoluble in aqueous environments. Wear particle related osteolysis in total hips is associated with macrophage activation and a subsequent inflammatory response [32,36,45]. Lower levels of inflammatory mediators of osteolysis such as TNF-alpha and PGE_2 are associated with alumina particles compared to high-density polyethylene particles [19,39]. While alumina particles can elicit a macrophage response in vitro, other studies have shown a predominantly fibrocytic response to ceramic wear particles with minimal macrophage involvement [2,23].

Ceramic bearings have evolved over time, just like any other bearing material used in total hip replacement surgery, since the first application of this technology by Pierre Boutin, in 1970 [3]. In the early 1980's, the Mettelmeier-designed Autophor and Xenophor devices demonstrated many early failures [25] because of suboptimal implant design that led to bearing failure, wear debris, and impingment [40]. While these failures did not reflect an inherent problem in ceramic bearings, they curbed the early enthusiasm for ceramic bearings in hip replacements in the U.S.

Modern third-generation alumina ceramics are produced from a finer grain size with fewer impurities, thus resulting in an improved material with increased durability [1]. Improved manufacturing and quality control processes, including proof-testing and laser-etching have contributed to a reliable and safe product [40]. Catastrophic fractures of ceramic femoral heads occurred in the past because of material quality, taper mismatch between the head and femoral component, impingement, and technical errors [43]. Modern total hip trials in the U.S. are based on the premise that combining proven total hip implants with successful outcomes and the current generation of alumina bearings will result in superior outcomes, with no femoral head fractures or other complications related to the bearing. The early and intermediate term data from these trials confirms the efficacy and safety of modern alumina bearings in total hip replacement surgery [10,13].

The two-year data presented here demonstrating an absence of ceramic femoral head fractures are important because nearly all such fractures occur in the first 24 months following implantion [6]. Review of the historical literature describing catastrophic failures of ceramic femoral heads demonstrates that 80 percent of ceramic femoral head fractures occur within the first two years, and 90 percent occur within the first three years after surgery. The results of recent U.S. trials of total hips with alumina ceramic bearings have demonstrated no alumina head failures *in vivo*, with the only bearing-related complication being the intraoperative chipping of the alumina liner secondary to improper implantation [10,13]. Our study further confirms these findings.

While long-term data with modern ceramic bearings in the U.S. will require further followup, the data from European investigators is encouraging. A minimum 18.5 year followup of 118 patients with alumina ceramic hip bearings demonstrated no instances of catastrophic failures, no osteolysis or wear-related sequelae, and failures associated only with deficient fixation of components [16]. Data from total hip registries in Finland further support the view that the risk of ceramic head fracture can be ignored when implanting contemporary alumina bearings [33]. Based on these reports, the long term performance of alumina bearings should be at least comparable to that of any other coupling in terms of safety and efficacy, with markedly superior wear characteristics that should contribute to longer lasting arthroplasties.

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3.4 European Experience with Ceramic Systems

A. Toni and F. Traina

Introduction

Medical applications of alumina followed its use in mechanical engineering and electronics, which started in the 1950s.

The application of ceramics for joint replacements is going back to early 70s, after that the first successful bio-inert Alumina material (Degusit AL 23) was propose and patented in England for dental implants (Sandhaus, 1965).

In Europe, Boutin (France, 1970) was the first to introduce Alumina (Al_2O_3, Ceraver) for hip arthroplasty bearing surfaces [1], Germans followed: Mittelmeier in 1974 [2], Heimke in 1977 [3], than Salzer in 1976 in Austria [4].

In Italy, the first experience with a ceramic prosthesis followed the first European Society of Biomaterials in 1975 in which, by a cooperation between the Istituti Ortopedici Rizzoli and Prof. Chiari from Austria, a prosthesis with ceramic surfaces was devised [5].

In these early experience, only monolithic ceramic cups were used. They were fixed without cement and presented only large diameters (more than 58mm). Monolithic cups were not successful because of their poor osseointegration potential that lead to early failure [6].

To avoid this problem, in 1985 we proposed and clinically introduced a cup made of dense alumina, coated by 3-D porous alumina beads on the dome, and contoured by a self cutting screw thread made of titanium [7]. The first series of this prosthesis was made of Ostalox, a ceramic that showed poor biomechanical properties, the second series presented a Biolox head and a Ostalox cup, finally the third series was a Biolox-Biolox coupling with a 32mm head. Notwithstanding the evolution of the ceramic material the prosthesis showed a early high failure rate [8], major problems were related to the design of the cup and to the coating of the first series of the stem [9,10].

Since 1994, we started to use a new hemispheric press-fit cup made of titanium alloy with a modular Biolox Forte liner that at the beginning was coupled with a 28mm Biolox head, and then with a 28mm Biolox Forte head.

It is the purpose of thisstudy to present our experience with ceramic bearing surfaces for total hip arthro plasty. In the first part of the study a comparative analysis of our experience with ceramic-ceramic versus metal-polyethylene coupling will be presented. To collect a statistically significant amount of data, a long-term survival analysis comparison of the 2 cohorts was inferred from Rizzoli's Register of Orthopaedic Prosthetic Implants (RIPO) [11]. In the second part of this study our experience with a modern cementless prosthesis with Biolox Forte coupling will be reported.

Materials and Methods

Part 1

At the time of this retrospective study, 8177 primary hip arthroplasties were collected in the RIPO; of these, 3465 metal on polyethylene and 3018 ceramic on ceramic couplings were recorded. Threaded cup prostheses included solely in the ceramic on ceramic cohort were excluded from the comparison, because of a statistically significant low long-term survival [11]. Excluding cases that did not have a proper follow-up, the survival of 3357 metal on polyethylene prostheses was compared with the survival of 1935 ceramic on ceramic prostheses. The cumulative probability of revision was estimated by Cox's proportional hazards regression [12]. Cox's proportional hazards model selects the variables to be included in the regression, and estimates the hazard rate, considering the fact that all of the variables can influence this rate. Definition of failure was revision for any reason for at least one prosthetic component. Log-rank and Wilcoxon tests were used to compare the two cohorts.

Part 2

From August 1995 to August 2003, 1752 primary hip replacement were consecutively performed in our Division.

The prosthesis (An.C.A. Fit, Wright-Cremascoli) presents an anatomic titanium alloy stem (Ti6A14V), proximally coated with 80μ high crystalline plasma sprayed hydroxyapatite.

In all the surgeries a 28 millimetres ceramic head and a ceramic liner (Biolox® Forte, Ceramtec, Stuttgart, Germany) were used.

To evaluate the influence of the learning curve on ceramic coupling, the series was divided in two cohorts. The first 864 consecutive surgeries performed from August 1995 to December 2000 were included in the first cohort, of these patient 16 were lost to follow-up leaving under observation 848 prostheses. The following 888 consecutive surgeries performed between January 2001 and August 2003 were included in the second cohort: in this group 2 patients were lost to follow-up leaving 886 prostheses under control. Summarizing 18 patients (1.02%) out of 1752 were lost to follow-up, the remaining 1734 patients were investigated. The stem survival was estimated by the Kaplan-Meier method [12].

Results

Part 1

A total of 26 ceramic on ceramic and 175 metal on polyethylene prostheses were replaced. A 94.1% survivorship for ceramic on ceramic and 88.3% survivorship for metal on polyethylene were calculated at 11 years follow-up, the difference between the 2 cohorts being statistically significant ($p<0.05$).

Part 2

Dislocation rate of the 1734 prostheses, with a ceramic coupling without a liner lip, was 1.4% (25 patients), 6 of them required a revision surgery (0.3%). Eighteen implants failed, 6 for recurrent dislocation, 5 for late aseptic loosening, 3 for early failure (2 cases for intra-operative cracks leading to femoral fractures, 1 for stem undersizing), and 3 for septic loosening. The survival rate of the prosthesis, without

septic loosening, was 97.5% (C.I. 94.9-100%) at 8 years. None of the revisions was due to ceramic failure. The two cohorts did not differ for long term implant survival.

Discussion

The choice of the best possible prosthetic-bearing coupling for hip arthroplasty is still a topic open to debate [13].

This study shows that ceramic on ceramic coupling presents a lower removal rate than metal on polyethylene coupling. Major criticism against the use of ceramic on ceramic coupling is mainly based on its brittleness [14]. In our experience with 3018 ceramic on ceramic prostheses, 3 alumina head fractures were recorded. Fractures occurred only when a 28mm Biolox®, head was used. Despite this, no fractures occurred when 32mm Biolox®, or 28mm Biolox® Forte, were chosen. These results revealing a low fracture rate are comparable with those reported by Hamadouche et Al. at a minimum of 18.5 years follow-up [15].

Another concern regarding alumina coupling is the higher rate of dislocations due to the lack of an antidislocation lip on the liner. In the first series, ceramic on ceramic prostheses dislocated more than metal on polyethylene prostheses, the difference between the two being statistically significant (p=0.03). But instead of 175 revisions as was the case with metal on polyethylene, the alumina coupling accounts for only 26 replacements; this higher survival rate is probably enough to justify more cases of dislocation. Besides, with the new prosthesis with modular necks, the dislocation rate was considerably low (1.4%), and only in 0.3% of the cases a revision surgery was needed.

Furthermore ceramic is known to need a particularly precise and careful surgical technique, because surgeon errors could lead to catastrophic ceramic failures [16]. During surgery, we usually careful clean the Morse taper joints of the prosthesis before the coupling with the ceramic head and liner, and we also avoid contact between ceramic surfaces and hard metallic surgical instruments. Finally, before reduction, a careful checking of the coupling is performed to avoid malalignment of the components. Following these simple advises from the beginning of our experience, we do not have recorded an influence of the learning curve on ceramic hip survival.

Finally, the over costs of alumina coupling versus metal on polyethylene coupling was compared; if at the time of surgery alumina over costs amount 590 Euro per prosthesis, at 10 years, considering the higher revision rate of metal on polyethylene coupling, the savings drop to 26 Euro and the trend is negative. A balanced budget is thus almost reached after 10 years for metal on polyethylene versus alumina, even without taking into account other unquantifiable costs, such as those related to patients' needs, and to avoidable revision surgery. Furthermore, there is a higher incidence of surgical complications, longer in-staying, a higher risk of death, and longer rehabilitation time in revision surgery.

By this considerations, we are confident to consider our experience with alumina coupling successful, and to consider ceramic a valuable alternative to polyethylene.

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3.5 Australian Experience with Ceramic Systems

W. K. Walter

Introduction

Polyethylene wear and associated osteolysis has been the main reason for failure of hip replacements in recent years. This unacceptably high polyethylene induced failure rate convinced us that modern ceramic on ceramic bearings would be more likely to give superior longterm results. We commenced using Biolox® Forte ceramic on ceramic articulations routinely in hip replacements in July 1997, and continue to use ceramic on ceramic bearings routinely in both primary and revision hip surgery.

From July 1997 to September 2004, we have carried out hip replacements using ceramic on ceramic bearings in 2503 hip replacements. The first 300 of these hips have been reviewed at 5 year follow up.

Our Indications for Ceramic on Ceramic Bearings

We routinely use ceramic on ceramic as a bearing surface in primary hip replacements in a great majority of patients. In recent years we have been performing a moderate number of metal on metal resurfacing procedures especially in younger male patients.

There is a special place for ceramic on ceramic bearings in developmental dysplasia of the hip, as it allows the use of a small acetabular component, with a ceramic insert, as this overcomes the problems associated with thin polyethylene if polyethylene was used as an alternative.

Wherever possible in revision hip arthroplasty, ceramic on ceramic bearings are used. Most of these revisions have been carried out for osteolysis, secondary to polyethylene wear debris, and it seems unwise to insert further polyethylene where it can be avoided by converting the hip to a ceramic on ceramic bearing. This can often be achieved by revision and replacement of the polyethylene acetabular component with a metal backed cup with a ceramic insert. On the femoral side, in many systems a well fixed stem can be left in place and the used chrome-cobalt ceramic head can be replaced with a modern ceramic head protected by a titanium alloy sleeve inside the ceramic head, designed and manufactured to fit the original taper on the femoral stem.

We routinely use a posterior surgical approach to the hip in both primary and revision surgery.

Results

Our experience using ceramic on ceramic bearings over 8 years is encouraging, and we continue to routinely use these bearings.

Patients are followed up at regular intervals and information stored on a database.

Ceramic Breakage

One male patient sustained breakage of a ceramic acetabular insert without significant trauma and required revision. There have been no other incidences of catastrophic ceramic failure to our knowledge.

Osteolysis

None of the patients have required revision for osteolysis, and none of the patient to date has shown evidence of significant acetabular or femoral osteolysis.

Edge Loading Wear

We have analyzed 16 alumina ceramic on ceramic bearings (Biolox® Forte). These bearings were retrieved at the time of reoperation for a number of causes, including psoas tendonitis, infection, periprosthetic femoral fracture, and recurrent dislocation. Of these 16 patients, 11 had evidence of edge loading stripe wear due to micro-subluxation, the position of the wear stripes on the femoral heads and acetabular liners, indicating that the great majority of these were edge loading due to microsubluxation of the hip in the flexed position.

In none of these patients was the wear extensive, the deepest head wear in the series was 30 microns, giving a volumetric wear of the head of 2 cubic millimetres.

In those patients requiring re-operation after a long period, the region of edge loading stripe wear on the femoral head showed signs of repolishing, suggesting that the wear process may be self limiting, or at least may progress more slowly as the area of contact between the microsubluxed head and the rim of the ceramic liner gradually increased with the wear process, decreasing the load per unit area at the area of contact. Initially, with edge loading, the stress generated is very high due to the point contact but with time and wearing, the areas of contact increase with subsequent fall in the load per unit area of the contact area.

Squeaking Hips

Of the 2503 ceramic on ceramic bearings in this series, 10 have reported intermittent squeaking. We are currently analyzing these patients to try to determine the cause of the squeak. At least some are due to impingement of the neck of the implant against the rim of the cup but others appear to be arising directly from the ceramic bearing surfaces. None of these squeaking hips have to date required revision. It is planned to examine two of these squeaking hips arthroscopically in the near future.

Discussion

We have been using ceramic on ceramic bearings (Biolox Forte) now for over 7 years and have a large series of 2503 hips. None of these hips has required revision for osteolysis and this contrasts dramatically with our prior experience using polyethylene as a bearing surface. Ceramic breakage has not been a major problem with only one of these patients requiring revision for ceramic failure, with breakage of a ceramic cup insert.

Our major concern with these bearings is the high incidence of edge loading stripe wear, which occurs mainly with hip flexion. We take great care during surgery to make sure that the hip joint is reasonably "tight" and is not sloppy, which would encourage edge loading wear. We also take particular care at the time of surgery that the hip does not have a tendency to partial subluxation when the hip is flexed and internally rotated. Often it is necessary to surgically excise a portion of the anterosuperior capsule which tends to become enfolded between the anterosuperior aspect of the trochanter and the anterosuperior part of the acetabulum, causing a tendency for the femoral head to lever away from the acetabular component when the hip is flexed and internally rotated.

Overall we have been satisfied with the results, particularly with the virtual absence of any osteolysis in these hips over an 8 year period.

Time will tell whether these ceramic on ceramic bearings are superior to other alternatives over a 15-20 year period, but we remain optimistic that at this point in time and development, ceramic on ceramic bearings offer the best alternative in modern day hip replacement surgery.

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SESSION 4

The Ceramic Option: Indications, Contraindications, Revision and Surgical Challenges

4.1 Evolution of Total Hip Arthroplasty: Computer-Assisted, Minimally Invasive Techniques Combined with Alumina Ceramic-Ceramic Bearings

S. B. Murphy and M. Tannast

Introduction

Total Hip Arthroplasty was initially introduced as a cemented construct with a metal femoral stem and a polyethylene acetabular component, performed through a transtrochanteric exposure. Over the ensuing thirty years, improvements to total hip arthroplasty have included the advent of uncemented acetabular and femoral components components and the popularization of alternative exposures including the posterior and anterolateral exposures. The potential improvements and potential perils of total hip arthroplasty have accelerated greatly in the very recent past with improvements in bearings, surgical exposures, and computer-assisted techniques all occurring simultaneously. These current surgical procedures barely resemble the conventional procedures that are so well established. The current manuscript reviews personal perspectives on and results of less invasive surgical techniques, computer-assisted techniques, and alumina ceramic-ceramic bearings for total hip arthroplasty.

Computer-Assisted Total Hip Arthroplasty

Computer-assisted techniques are very simple in principle. Systems can be categorized by their method of tracking and their method of imaging. Thereafter, all navigation systems will allow for tracking of the pelvis and/or femur and allow for the tracking of any desired rigid surgical instruments. In addition, the change in leg length and impingement-free range of motion of the hip can be calculated, if both the femur and pelvis are tracked during surgery [1].

Tracking Methods

Bones and surgical instruments can be tracked optically or using electromagnetic fields (EM). Infrared stereoscopic optical tracking is currently the standard method used by most navigation systems. Optical tracking has the advantage that it is simple and reliable in most circumstances. The primary limitation is that the optical camera must have a clear view of the surgical field. In contrast, electromagnetic systems have distinct advantage that a clear optical view of the surgical field is not necessary. Unfortunately, many of the instruments that we typically use during hip surgery are incompatible with EM tracking since many of our conventional metal and power instruments distort EM fields, preventing accurate navigation.

Imaging Methods

Image-free navigation

Each surgeon must make a choice about what, if any, images are used as part of computer-assisted total hip arthroplasty techniques. Image-free navigation refers to techniques where all navigation is based on landmarks that are digitized at the time of surgery without confirmation by imaging. For the pelvis for example, a reference frame is attached to the pelvis and the superior spines and pubic symphysis landmarks are digitized while the optical camera tracks the pelvic reference frame and digitizer simultaneously. A coordinate system for the pelvis is then established and the position of the pelvis can be tracked throughout the procedure as long as the pelvic reference frame is visible to the optical camera. Image-free techniques are the simplest and are therefore popular. They are especially useful for surgeons who operate with the patient in the supine position because the necessary landmarks are easily accessible (Fig. 1).

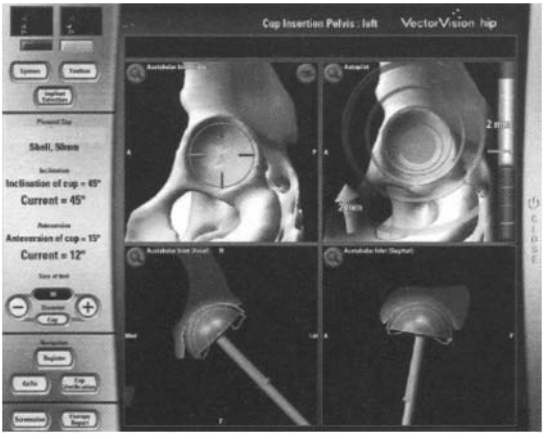

Figure 1:
Image-free hip navigation is based simply on digitized landmarks. The bone models are idealized images and are not based on the patient's actual anatomy.

Image-free navigation is somewhat less useful if the patient is operated upon while in the lateral position since the reference must be applied first with the patient in the supine position. The patient is then re-prepped and draped in the lateral position after the landmarks are digitized. Image-free navigation has another profound limitation: there is not way to assess the accuracy of the navigation in any individual patient. This means that if a critical landmark is incorrectly digitized, the navigation will be inaccurate. This is a particular risk in larger patients where landmarks are more difficult to palpate.

Fluoroscopic Navigation

Fluoroscopic navigation involves applying references frames to the bones to be tracked and to the fluoroscopic intensifier. The system then records the positions of these frames at the time that the given image is taken. Each fluoroscopic image allows for very accurate two-dimensional navigation. Combining information from more than one image taken at different angles then allows for three-dimensional navigation. For example, if two images of each superior spine and the pubic symphysis are taken during surgery, the three-dimensional positions of these critical landmarks can be calculated.

Fluoroscopic navigation has several advantages. First, no preoperative imaging or planning is necessary. Second, if anything changes during the surgery, new images can be acquired. Fluoroscopic navigation is especially useful then in cases of revision THR where metal artifact may degrade preoperative CT images, but where some form of imaging is necessary, particularly in cases where cement is lodged far into the distal femur or where hardware is broken and buried in the bone. In these cases, image-free navigation is useless, and CT-based navigation is unpredictable. Since fluoroscopic navigation is very versatile, it is especially useful in very complex cases, such as conversion of a hip fusion to a total hip arthroplasty (Fig. 2).

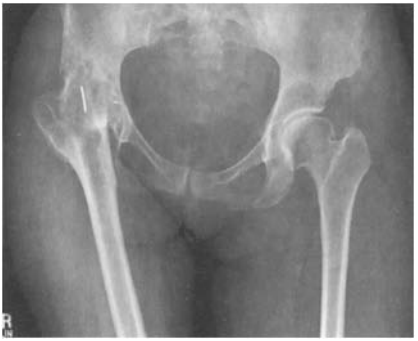

Figure 2a:
A surgically fused hip in a 42 year old woman preoperatively.

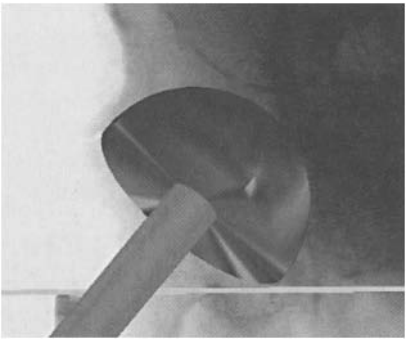

Figure 2b:
Navigation of an acetabular reamer on a fluoroscopic image.

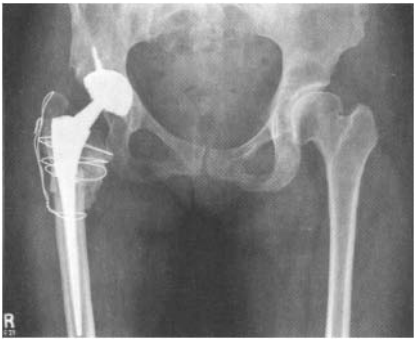

Figure 2c:
Postoperative reconstruction following ceramic-ceramic THA with fluoroscopic navigation.

Fluoroscopic navigation though has the distinct disadvantage that fluoroscopic equipment must be available and that the surgery is disrupted, however briefly, by the acquisition of the fluoroscopic images. Fluoroscopic techniques are also less sophisticated than CT-based techniques in so far as the bony anatomy, implant placement, predicted range of motion, and alteration in leg-length cannot be analyzed and planned pre-operatively.

CT-based Navigation

CT-based navigation is the gold-standard for hip navigation and greatly enhanced cababilities as compared to image-free and fluoroscopic-based navigation. CT-based navigation allows for detailed preoperative planning of components sizes and positioning, leg-length alteration, and calculation of impingement-free range of motion. CT-based methods also allow for the calculation of the effect of any variable such as neck length, neck diameter, head diameter, cup position, and stem position on motion and leg length. The pre-operative computer models are linked to the actual bone models at the time of surgery using a process called registration. Registration involves digitizing points on the bone surface at the time of surgery and then performing a calculation that maps those points onto the computer model of the bone. The accuracy of the matching can be calculated and quantified at the time of surgery by placing a digitizer on the bone surface and calculating the distance between the actual and predicted bone surface at any desired location. CT-based registration has the advantage that it is very rapid. Compared to fluoroscopic navigation, it has the advantage that no intra-operative imaging equipment is required and that no intraoperatively acquired images are necessary (Fig. 3).

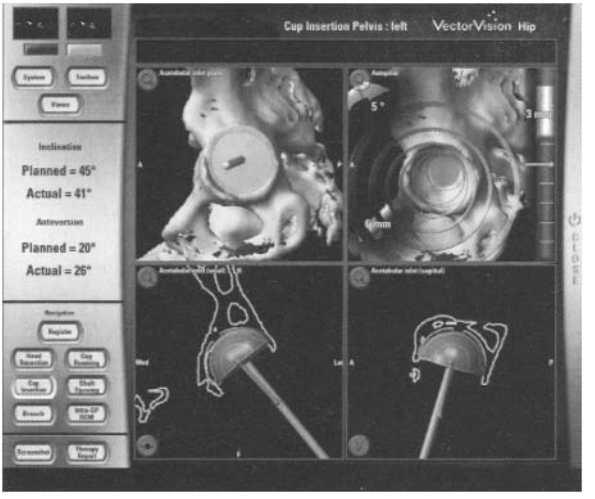

Figure 3:
CT-based navigation showing the patient-specific CT model during placement of the acetabular component.

Compared to image-free methods, CT-based navigation has the advantage that the surgery and registration can both be performed in the lateral position without the need for repositioning during surgery. CT-based navigation also has the advantage that the accuracy of the navigation can be checked. Conversely, CT-based navigation has the disadvantage that preoperative imaging and analysis are necessary.

CT-Fluoro Matching

CT-Fluoro matching involves pre-operative CT analysis followed by the use of fluoroscopic images, rather than surface points digitized on the bone, to achieve registration (Fig. 4).

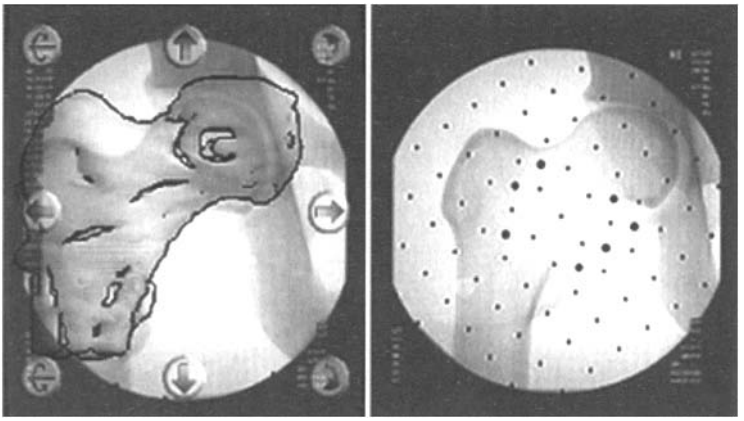

Figure 4:
CT-fluoro registration utilizes intraoperatively acquired fluoroscopic images to register a preoperatively acquired CT dataset to the patient's anatomy.

CT-Fluoro matching has the additional advantage that anatomic information further away from the hip (that is accessible to fluoroscopic imaging, but not to a digitizer) can be acquired. Data that is further from the hip reduces any potential errors in the registration process, potentially improving the accuracy.

Minimally-Invasive Total Hip Arthroplasty

Minimally-invasive total hip arthroplasty is a term that can mean almost anything and is therefore almost meaningless. Less-invasive surgical techniques are better classified by the soft-tissue interval used for the surgery and by the structures that are divided and those that are intended to be preserved during the surgery. While some less-invasive techniques can greatly accelerate recovery, less-invasive techniques have also been associated with increases in perioperative complications. In general, the maximal preservation of normal tissue around the hip joint during total hip arthroplasty requires significant effort whereas injury to normal tissue is virtually effortless. Consequently, the effective performance of less-invasive, tissue-preserving methods is very technically demanding and requires significantly more attention to detail than do more conventional surgical methods. There are a wide variety of techniques available to perform total hip arthroplasty through smaller incisions; some are tissue-preserving, some are traditional operations performed through smaller incisions, and some may produce more tissue damage than conventional procedures. Each technique should be considered for its advantages and disadvantages.

Anterior Exposures

Anterior exposures for arthroplasty have been employed since the time of mold arthroplasties and so these techniques actually pre-date total hip arthroplasty. Refinements in the use of the Smith-Petersen exposure have evolved with better instrumentation and with the use of the fracture table as popularized by Joel Matta, M.D. [3]. The Smith-Petersen exposure is especially effective for acetabular instrumentation, but has significant limitations when attempting to instrument the femur.

Posterior Exposures

Mini-posterior exposures for total hip arthroplasty are basically the same as traditional posterior exposures through a smaller incision. The surgery is facilitated by minor modifications of traditional instruments and the more judicious use and placement of retractors. While the posterior capsule and short rotators are incised during the surgery, they are typically repaired at the conclusion of the procedure. This technique has been proven to be safe and effective in the hands of many surgeons although a recent clinical study demonstrated that there was no difference in recovery between patients having the posterior exposure through a traditional or a shorter incision [13]. The primary limitation of the posterior exposure is that the risk of dislocation his higher than with other exposures so unlimited motion cannot be safely allowed after surgery. Further, a clinical studies have clearly shown that repaired external rotators typically fail early following surgery [11,12].

Direct Lateral Exposure

The direct lateral exposure has many forms, but generally involves developing an anterior flap that includes the anterior third of the gluteus medius, the gluteus minimus, and the anterior of the hip joint capsule. The mini-direct lateral exposure is simply the same technique performed through a smaller incision [7]. Using this technique, excellent exposure of both the acetabulum and femur can be achieved and the posterior hip joint capsule and short rotators are preserved which allows for safe unrestricted motion after surgery. While the primary advantage of this procedure is the maintenance of hip joint stability, the primary disadvantage of this procedure is that the abductions must be protected after surgery to allow them to heal so immediate progression to full weight bearing cannot be safely recommended. Further, even when the abductors are protected during the healing phase after surgery, the abductors fail to heal in a small percentage of patients leading to residual pain, a limp, or both.

Two Incision Minimally Invasive Techniques

There are a number of two incision techniques that have been developed. All basically using one exposure for the femur and another for the acetabulum. Typically, one of the incisions in the primary incision and the other is a subordinate incision. The technique that has gained the greatest notoriety is a method developed by Dana Mears, MD. It involves using the Smith-Petersen exposure as the primary exposure and for acetabular implantation. The femur is then prepared and inserted semi-blindly through an interval that is either behind or through the abductor muscles. This technique is the most anatomically offensive of the available surgical techniques because respect for the abductor muscles is a paramount principle of hip surgery and the abductor muscles are not adequately protected using the technique. Anatomical studies have documented that injury to the abductor tendons and muscle is significantly greater using this technique as compared to a mini-posterior exposure [2]. Several clinical reports have noted higher than acceptable incidences of femur fracture, stem loosening, and lateral femoral cutaneous nerve injury in addition to the high incidence of abductor injury.

Evolution of Tissue-Preserving Total Hip Arthroplasty through a Superior Capsulotomy

The technique of performing a total hip arthroplasty through an incision in the superior capsule began as a two exposure technique. The initial goal was to combine the abductor rehabilitation advantages of the posterior exposure with the hip joint stability advantages of the direct lateral exposure while eliminating the disadvantages of both techniques [4,6,8]. It was clear immediately that the femoral component could easily be inserted through an incision in the superior capsule that was placed posterior to the abductors and anterior to the piriformis tendon. The acetabulum could then be inserted anteriorly through a Watson-Jones exposure. The femur was prepared with the head and neck left intact to minimize motion of the femur, to allow the use of leverage retractors around the femoral neck, and to maintain the strength of the proximal femur during broaching to minimize the risk of femur fracture. The femoral neck.was always transected insitu and the femoral head was excised without hip dislocation, since the act of posterior/superior hip dislocation can cause avulsion of the short rotators and posterior capsule. Using these two intervals, the components could be placed while preserving the abductors, posterior capsule, and short rotators.

As experience with the superior capsulotomy exposure increased, more and more of the procedure was performed through that interval. For example, the acetabular reamers and acetabular components were placed into the acetabulum through the superior capsulotomy and connected to straight reamer and impactor handles that were inserted through the Watson-Jones interval using a small incision. Over time, this anterior incision became shorter and shorter, down to about 15mm eventually. At that point, it became apparent that the anterior incision could be eliminated entirely if angled instruments were for cup reaming and cup impaction were manufactured (Fig. 5).

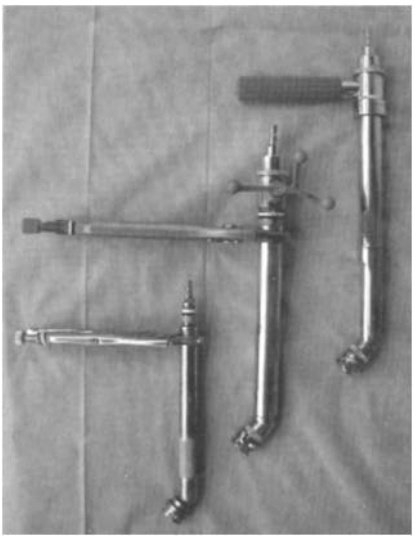

Figure 5:
Evolution of 45 degree angled reamers for tissue-preserving THA through a superior capsulotomy.
Left: July, 2003
Middle: March, 2004
Right: March, 2005

With these new instruments, the technique evolved back into a single incision by July of 2003 and has remained so since.

Detailed Description of Technique

The patient is prepped and draped in the lateral position and the leg is flexed and internally rotated with the foot on a Mayo stand. An incision 7 to 8cm in length is made beginning at the tip of the greater trochanter and extending proximally, in line with the femoral shaft axis. The gluteus maximus fascia is incised and the fibers are spread at the level of the greater trochanter. The posterior border of the gluteus medius is identified and retracted anteriorly to reveal the piriformis tendon. The piriformis tendon is incised at its insertion. This tendon may be repaired at the conclusion of the procedure if desired.

The posterior border of the gluteus minimus muscles is then elevated from posterior to anterior, developing the interval between the minimus and capsule as far anterior and inferior as the minimus tendon insertion. A blunt homan retractor is placed deep to the minimus, outside the capsule, on the anterior femoral neck reflecting the minimus anteriorly. A spiked homan retractor is placed into the anterior ilium, deep to the minimus as well. A second blunt homan retractor is placed posteriorly in the interval between the posterior capsule and short rotators to fully expose the superior capsule.

A vertical capsulotomy is then made in the superior capsule from 6 o'clock in the trochanteric fossa to about 1 hour posterior of 12 o'clock at the acetabular rim. The anterior capsular flap is tagged with a suture at the acetabular rim (Fig. 6).

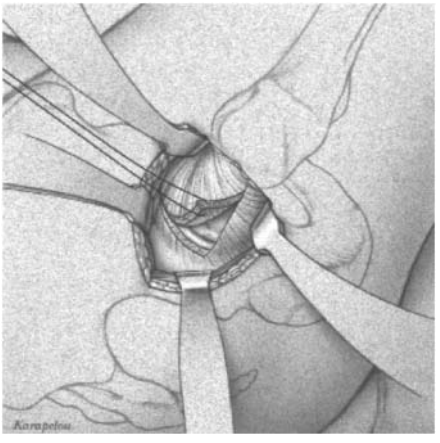

Figure 6:
The superior capsule is exposed by developing the interval posterior to the minimus and anterior to the piriformis tendon. Reprinted with permission from Operative Techniques in Orthopedics.

The anterior capsule is then opened along the acetabular rim for about 15mm and along the femoral neck, deep to the minimus tendon. This creates a U-shaped flap of anterior capsule with its base along the anterior acetabular rim. The posterior capsule is left undisturbed. A second spiked homan is placed into the posterior/superior portion of the femoral head to facilitate the exposure. A spike homan retractor is not placed in the region of the posterior acetabular rim so as not to injure this area. The blunt homans are placed inside of the capsule around the anterior and posterior femoral neck and the femoral diaphysis is entered by passing reamers through the trochanteric fossa. Conical metaphyseal milling instruments are used to open up the proximal femur to ensure that the diaphyseal reamers are properly aligned.

Once the diaphysis is prepared, the superior portion of the femoral neck and head are opened to allow broaches to be fully seated up to the final size (Fig. 7).

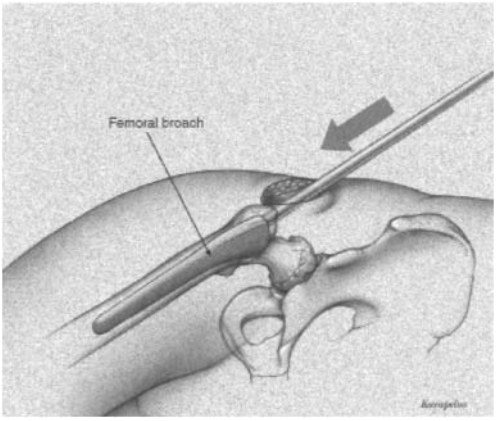

Figure 7:
The femur is fully prepared prior to transection of the femoral neck and removal of the femoral head. Reprinted with permission from Operative Techniques in Orthopedics.

A pelvic reference frame for surgical navigation is percutaneously affixed to the iliac wing and a pre-reconstruction leg-length measurement is made. The femoral neck is then transected using an oscillating saw, using the blunt homan retractors to protect the surrounding soft tissues. A long shanz screw is placed into the femoral head and a T-handle chuck is attached. A slap-hammer attached to the T-handle chuck is used to extract the femoral head.

The blunt homan retractors are then placed inferiorly through the anterior and posterior capsule to complete the acetabular exposure. Data for CT-based navigation or images for fluoroscopic navigation are acquired to establish the pelvic coordinate system.

The acetabulum is reamed using a 45 degree angled reamer and a Z-shaped cup impactor is used to insert the acetabular component (Fig. 8).

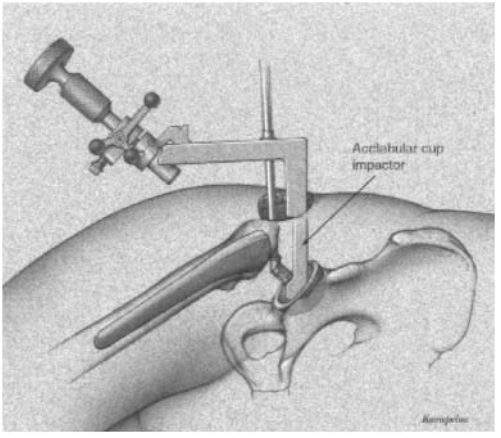

Figure 8:
Insertion of acetabular component using a double-angled impactor that exits the incision vertically. Reprinted with permission from Operative Techniques in Orthopedic Surgery.

Typically, the femoral head is inserted into the acetabulum and the femoral neck is reduced into the head. This maneuver appears to require less displacement of the surrounding soft-tissues than does a traditional reduction maneuver. After the real implants are inserted, the superior capsule is closed as is the fascia over the gluteus maximus. Patients are allowed to progress to unrestricted motion as tolerated and to progress weight bearing so long as there is no limp without support.

Clinical results of alumina ceramic-ceramic, computer-assisted, and tissue-preserving total hip arthroplasty techniques

To date, the we have performed 369 alumina ceramic-ceramic total hip arthroplasties beginning in 1997, 251 total hip arthroplasties using computer-assisted techniques beginning in 2001, and 179 total hip arthroplasties using tissue-preserving techniques. 165 of the 179 tissue-preserving total hip arthroplasties were performed using computer-assistance and 170 of the 179 tissue-preserving total hip arthroplasties received alumina ceramic bearings. Our alumina ceramic bearing experience demonstrates an implant survivorship (from all causes of failure) of 99% at 7 years (Wright Medical Technology, Arlington, TN and Biolox Forte XLW acetablular liners and femoral heads by Ceramtec AG, Plochingen, Germany). There have been no cases of osteolysis or bearing fracture [9]. Experience with computer-assistance has clearly demonstrated that the standard deviation of acetabular cup position is greatly reduced as compared to conventional THA using both fluoroscopic and CT-based navigation [10]. Finally, a prospective study comparing THA using the modified direct lateral exposure versus the tissue-preserving technique demonstrated a statistically significant faster recovery at 6 weeks in the tissue-preserving group [5]. There was no selection bias in the groups based on surgical complexity or body mass index. In fact, contrary to studies that have demonstrated a higher incidence of complications with less invasive surgical techniques, the complications in the tissue-preserving group were actually lower than in the conventional THA group.

Discussion

The advent of alumina ceramic-ceramic bearings, the use of computer-assisted surgical navigation, and the development of new, less-invasive techniques have all contributed dramatically to the practice of total hip replacement surgery. Alumina ceramic bearings clearly result in a very low wear state and a dramatic reduction in the incidence of periprosthetic osteolysis as compared to traditional total hip arthroplasty bearings. Computer-assisted techniques reduce the likelihood of component malposition, even as less-invasive techniques and smaller incisions are used. Tissue-preserving techniques, while technically demanding, offer the potential to produce a stable hip joint with minimal abductor morbidity and rapid rehabilitation.

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4.2 Acetabular Positioning to Maximize Range of Motion

J. A. D'Antonio

Acetabular preparation and component positioning has a direct effect on hip biomechanics, bearing surface wear , functional range of motion and stability, and I believe is the greatest challenge for a successful total hip arthroplasty. Several years ago Dr. Capello and myself with engineers Adam Bastiaan and Mike Cusick developed a computer range of motion model looking at cup position on range of motion of total hip arthroplasty. We found that cup positioning is a three dimensional combination of abduction and version with version being a combination of internal rotation and flexion. Altering the cup position has a direct positive or negative effect on range of motion before impingement in some direction. We standardized the femoral implant with a number eight Omnifit having a 30 head/neck offset with a 28 millimeter head diameter. We then altered the cup position through a multitude of combinations of abduction and version. Using the cup position of 45° of abduction and 15° of version assuming a femoral anteversion of 15° as our baseline we kept the femoral anteversion at 15°. Our computer range of motion model demonstrated that the most desirable acetabular position to maximize range of motion before impingement was a combination of 40°-50° of abduction (45°) and 20°-30° of anteversion or flexion (25°). This combination with 15° of femoral anteversion yields a combined femoral and acetabular anteversion of approximately 40°.

The greatest challenge for the surgeon is to consistently achieve this desirable acetabular position at the time of surgery. The pitfalls include anatomic variations, the presence of hypertrophic bone, orientation of the patient on the table (the use of external alignment guides), and visualization of the acetabulum. To avoid these pitfalls, one must first have an approach permits complete visualization of the acetabulum and includes appropriate soft tissue releases. Having done that, then the use of anatomic landmarks can lead to correct component orientation to maximize functional range of motion and minimize impingement. I would caution against the use of external alignment guides. They assume the desired position of the pelvis and there is no accounting for the pelvic tilt or pelvic flexion. In short, external alignment guides for placement of the acetabular component are notoriously inaccurate and should not be used and relied upon at the time of surgery. In preparing the orientation of the acetabular component, the anatomic landmarks that are most useful include the ishium which is nearly flush with the posterior wall, the sciatic notch, the acetabular fossa and inferior rim, and of course the anterior and posterior walls to a lesser degree. A study of acetabular and femoral morphology published by Maruyama, Capello, D'Antonio and Feinberg in the December issue of Clinical Orthopedics and Related Research validated the accuracy of certain anatomic landmarks. This study specifically defined the acetabular anteversion angle, acetabular ridge configuration, and defined the notch acetabular angle. The study found the acetabular anteversion angle measured 19.9° ± 6.6° and measured on the average of 21.3° for females and 18.5° for males. It defined the notch acetabular

angle as the angle at the intersection of the line from the sciatic notch to the posterior acetabular ridge and the line from the posterior to anterior acetabular ridge.

Therefore an insertion of an acetabular component following appropriate reaming and preparation one can use the ishium which is relatively flush with the posterior wall and the sciatic notch as an excellent indicator of anteversion and to increase the anteversion of the femoral component to 25° or 30° beyond the normal 19°, one would have to orient the insertional tool towards the top of the sciatic notch as opposed to the center of the wing of the ileum. Likewise by placing the socket inside the acetabular fossa or inferior rim, one could be relatively certain of not exceeding 40°-45° of abduction.

In conclusion, acetabular component positioning has a major effect on hip stability and hip biomechanics. We believe that the combined femoral and acetabular anteversion should be in the neighborhood of 40° and given the femoral anteversion most often in the neighborhood of 15°, the most desirable acetabular position for functional range of motion is 45° of abduction and 25°-30° of anteversion. It is important to beware of external alignment guides which are fraught with error. We strongly recommend the use of anatomic landmarks and advise the use of the sciatic notch as an accurate guide for proper visual placement of the socket.

4.3 Acetabular Positioning without Navigation – Anterior Approach

W. J. Hozack

Introduction

Navigated preparation of acetabular bone and placement of acetabular components is a new tool available to the orthopedic surgeon - traditional techniques are still the most commonly used. The goal of this chapter is to highlight those traditional techniques which can ensure reliable component positioning and can minimize complications such as instability and leg length discrepancy which occur when acetabular component position is not ideal. Successful placement of an acetabular component can be divided conveniently into three steps:

1. exposure
2. bone preparation
3. component insertion

Exposure

Regardless of the surgical approach chosen, the quality of the surgical exposure significantly influences the quality of the clinical result. The critical facet of each hip exposure is identification of all key bony landmarks. This requires appropriate removal of both soft tissue and bone tissue.

Soft Tissue Removal

Soft tissue impediments to proper acetabular exposure are the labrum and the foveal contents. The acetabular labrum overhangs the bony margins of the acetabulum (especially in acetabular dysplasia) and must be excised in its entirety prior to reaming of the socket. Failure to do so can lead to over-reaming of either the anterior or posterior column or both. Occasionally the labrum is fully calcified and must be removed with a rongeur. Foveal contents are invariably present even in the most deformed acetabulum (with the exception of protrusio cases), and need to be identified and removed prior to proceeding with any acetabular preparation. These foveal contents allow the surgeon to identify the teardrop, which locates the inferior position of the acetabular component.

Bony Landmarks

Acetabular bony landmarks that need to be identified and are critical to the surgical result are: anterior column, posterior column, ilium, and teardrop. The acetabular teardrop represents the anatomic position of the acetabulum. Cups placed inferior to the teardrop can create leg length discrepancies. Full identification of the anterior and posterior columns prevents improper reaming location and ensures proper cup location. Full identification of the ilium prevents inadvertent lateralization of the hip center of rotation. In both the regular and especially in the most deformed acetabulum, the easiest and safest way to

identify the bony landmarks is to work your way down from the ilium across the anterior and posterior columns to identify the pubis, ischium, and teardrop.

Bone Removal

Bony impediments to acetabular exposure are located in the foveal area and also peripherally about the acetabular rim. Evaluation of the preoperative radiographs can provide some guidance as to the presence of these potential problems. The foveal area can be completely obscured with osteophytes, thus preventing proper identification of the anatomic position of the acetabulum. These overhanging osteophytes must be excised completely. Peripheral rim osteophytes can confuse the surgeon as to the proper acetabular anatomy. Lateral osteophytes develop as a consequence of certain types of arthritis – reliance on these osteophytes for mechanical support of the acetabular component is a recipe for failure. Further, certain osteophytes can direct a reamer in an inappropriate direction with potentially disastrous consequences. Failure to remove large inferior osteophytes can push reaming proximally from the anatomic position.

Bone Preparation

No attempts to prepare the bone of the acetabulum should be undertaken until all anatomic landmarks of the acetabular anatomy have been identified properly.

First Reamer

Acetabular reaming should follow specific guidelines. The first acetabular reamer should be significantly smaller than the true anatomic size – this may require extremely small reamers (36 – 39 mm) in certain situations. The initial reamer is used to medialize subsequent reamers to the anatomic position.

Subsequent Reamers

Subsequent reaming of the acetabulum requires a three dimensional approach. Ultimately the acetabular component must be placed concentrically within the bony confines available. My approach is to visualize the ultimate position of the acetabular component within the acetabular bed, and then the gradually fit the reamers to achieve this goal. Anatomic guides are the teardrop off which the cup hinges, and the anterior and posterior columns that ultimately determine the size of the acetabular component. The wear and tear of osteoarthritis often creates a situation in which reaming achieves an anterior-posterior fit prior to full contact of the reamer with the superior rim. The surgeon should not feel obligated to continue reaming until full contact is obtained circumferentially – to do so would critically compromise the bony integrity of the acetabulum. As long as a pressfit can be achieved between the anterior and posterior columns, partial lack of coverage of the cup laterally will not compromise component fixation.

Component orientation is somewhat dependent upon surgical approach. Abduction angle of the socket is 30 to 45 degrees – this angle should be created during reaming. Anteversion varies somewhat. The anatomic anteversion of the acetabulum (once osteophytes are removed) is 10 – 15 degrees. This is

acceptable for anterior approaches, but posterior approaches may require 20 degrees in order to avoid higher dislocation rates.

Component Insertion

Complicated external jigs or guides for acetabular component insertion are undependable - the surgeon must rely upon anatomic clues. As mentioned previously, proper identification of the bony landmarks is essential. Off these anatomic landmarks are based all decisions.

Specific Issues Related to the Anterior Approach

The experience with total hip replacement using the anterior approach at Rothman Institute Orthopedics has evolved over 30 years. During this period, we have found that performing the surgery with the patient in the supine position has offered us tremendous advantage in terms of hip stability and leg length equality. It is my opinion that the supine patient position allows the surgeon to "navigate" the position of the pelvis at all times during the surgical procedure. Very much like current computer assisted navigation, the surgeon can easily palpate the anterior superior iliac spines and the pubic symphysis – something not easily done when the patient is in the lateral decubitus position. This allows the surgeon to utilize his brain as a computer (infinitely more sophisticated than any computer program) to properly orient himself when reaming the acetabulum and when inserting the acetabular component.

4.4 "Stem first": A simplified method for optimized positioning of components in Total Hip Arthroplasty

K.-H. Widmer

Summary

Background: Clinical experience and mathematical analysis could demonstrate that a maximized range of motion can only be achieved when the relative orientation of total hip components is optimized. Most often positioning of the stem is anatomically predetermined, while the orientation of the cup is much more flexible. So, it is near at hand that the stem is implanted first and the orientation of the cup is derived from the stem position. Doing so requires that the relationship between range of motion (ROM) and the component positions is known.
Material und Methods: A three-dimensional geometric mathematical computer model of a THA was developed and the ROM until impingement between cup and neck was analyzed. ROM was tested for a variety of cup and stem positions. Additionally, more parameters like head/neck ratio and design of the stem and the cup opening were considered.
Results: There is a linear relationship between cup anteversion and stem antetorsion and also between cup antversion and stem neck-shaft angle. After inserting the stem the cup can be positioned relative to the stem using a simple mechanical navigation device.
Conclusion: The stem position predetermines the orientation of the cup for a maximized ROM. Therefore, the trial stem should be inserted first and the cup should be oriented relative to the stem accordingly. This method can be used easily in a manual or computer-assisted implantation but also in a minimal-invasive approach.

Introduction

In total hip arthroplasty there is a high correlation between the position of total hip components, the risk for dislocation, the articular wear and the prosthetic range of motion. Any combination of orientations of cup and stem that is beyond the recommended range increases the risk for neck-to-cup impingement, subluxation and even dislocation [3,8]. In hard-hard articulations like metal-on-metal or ceramic-on-ceramic impingement has a very detrimental effect. In order to reduce the risk for impingement and dislocation there are recommendations that help to position the components relative to each other in order to maximize the range of motion (ROM) [9,13]. The ROM of a specific total hip arthroplasty depends on the orientation of the components but also on the design of the components. Hence, there are parameters that can be controlled by the surgeon during surgery, for example orientation of the components, but there are others that are determined preoperatively as soon as the surgeon has

made his choice for a specific type of implant (Table 1). Choosing an implant, he determines the CCD-angle, the neck/head ratio, the shape and diameter of the neck, the design of the opening plane of the cup and the position of the hip center relative to the opening plane of the cup. All these parameters do have a great impact on the prosthetic range of motion of a specific total hip system.

Parameters	
controlled by the surgeon	**cup inclination** **cup anteversion** **stem antetorsion**
adjustable (modular implants)	**head/neck ratio** **stem CCD-angle**
design dependent	**center of rotation relative to opening plane** **chamfer of opening plane** **elevated lips** **neck cross section**

Table 1:
Parameters of a prosthesis system that determine the prosthetic range of motion. Only the top three parameters are under the control of the surgeon during implantation. In modular prosthesis systems additional parameters can be adjusted, for example head-to-neck ratio and/or CCD-angle.

Numerous recommendations for component positioning are given in the literature, most of them empiric in nature [1,2,5-8,10-12,15]. In addition, there is a strong clinical and theoretical evidence that the combined orientation of the components relative to each other must satisfy certain conditions [3,13] and that there is not a unique ideal position for each component for all patients and all prostheses. The sum of stem antetorsion and cup anteversion for example, which is also called the combined version, should be between 40 to 60° according to Jolles or should satisfy the equation given by Widmer [13]. The same is true for the combined inclination, i.e. the cup inclination and the neck-to-shaft angle and amazingly also for cup anteversion and CCD-angle (Widmer 2005, submitted paper). During the operation the surgeon can only adjust inclination and anteversion of the cup as well as antetorsion of the stem. Some newer systems allow even modification of the CCD-angle in conjunction with the offset of the stem. But in general, there are close restrictions for the rotational position of the stem within the femur, this means its antetorsion. There are exceptions to this rule like the S-ROM prosthesis for example. Depending on the shape of the femur there is always one preferred rotational position where the stem fits best in the medullary canal. This should be the position to implant the stem because it guarantees best its initial stability and hence its osseointegration in particular when non-cemented. Mathematical simulation demonstrates that during implantation the first of the four positioning parameters can be chosen more or less arbitrarily but that the subsequent positioning has to stick to ranges that are restricted more and more for the succeeding components [13]. As the position of the stem is the most restricted one, it is recommended to start with the stem first and to orient the cup in a compliant way. In other words, stem and cup are not referenced to bony landmarks or the axis of the body anymore but they are considered to represent a coupled biomechanical system where the orientation of the cup is adjusted accordingly to the position of the stem. Consequently, the

objective of this paper is the hypothesis that the stem should be implanted first and the cup secondly as it can be adjusted much more easily to the stem than the other way round.

Methods

A three-dimensional computer model of a total hip prosthesis was created using the Mathematics-Software Maple R8 (Waterloo Maple Inc., 57 Erb Street West, Waterloo, Ontario, Canada N2L 6C2) (Fig. 1). This model is modified by varying the design parameters like head-to-neck ratio, CCD angle etc.. Movement of this virtual hip joint was tested with various component orientations until neck-to-cup impingement did appear. This provides nomograms showing the range of motion as a function of the component position and that are valid for the tested prosthesis system. They are slightly different from prosthesis to prosthesis. The model tested here consists of a ball head, diameter 28mm, where the centre of rotation is in the opening plane of the cup. The prosthesis neck is a rotational symmetric conic cylinder with a cone angle of 5.71°. The neck diameter underneath the prosthesis head is 12mm wide resulting in a head/neck ratio of 2.33. The coordinate system for the moving joint was defined according to the recommendations of the International Society of Biomechanics (ISB)[14] (Fig. 1). The rotational axis for abduction/adduction was chosen as the so-called "floating axis".
All combinations of the following cup and stem positions were tested: cup inclination from 20° to 70°, cup version from 20° retroversion to 50° anteversion in increments of 10°, torsion of the stem from 20° retrotorsion to 50° antetorsion in 5° increments, CCD-angle, i.e. the angle between the prosthesis neck and shaft, from 110° to 150° in 2.5° increments.

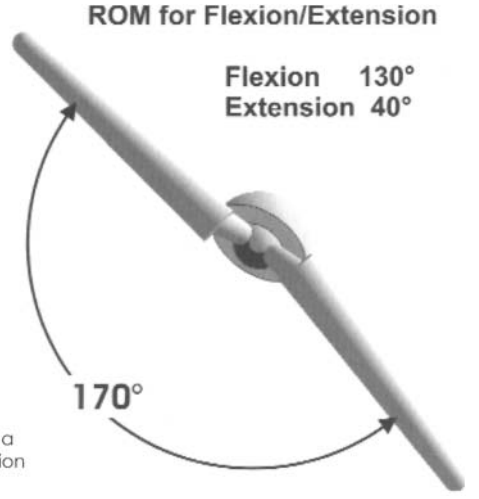

Figure 1:
Antero-lateral view of the computer model of a total hip prosthesis showing the flexion/ extension movement till cup-to-neck impingement.

The concept of the "intended Range of Motion" (iROM) was applied, where a predefined ROM must be reached by the patient without prosthetic impingement and where the computation determines the component orientation that is recommended in order to achieve the predefined iROM.

Results

The physiological ROM according to Kapandji [4] was defined as the iROM: Flexion up to 130°, Extension up to 40°, Abduction up to 50°, Adduction up to 50°, external rotation up to 40° and internal rotation up to 60°.

The computation reveals that there is a well-defined zone where cup inclination and cup anteversion must be located in order to achieve the intended ROM (Fig. 2). The position of this zone however is also dependent on stem antetorsion and the CCD-angle of the stem. Moreover, cup anteversion and stem antetorsion are linearly correlated. The same is true for cup anteversion and CCD-angle at least for CCD-angles between 110° and 130° and to a minor degree for cup inclination and CCD-angle.

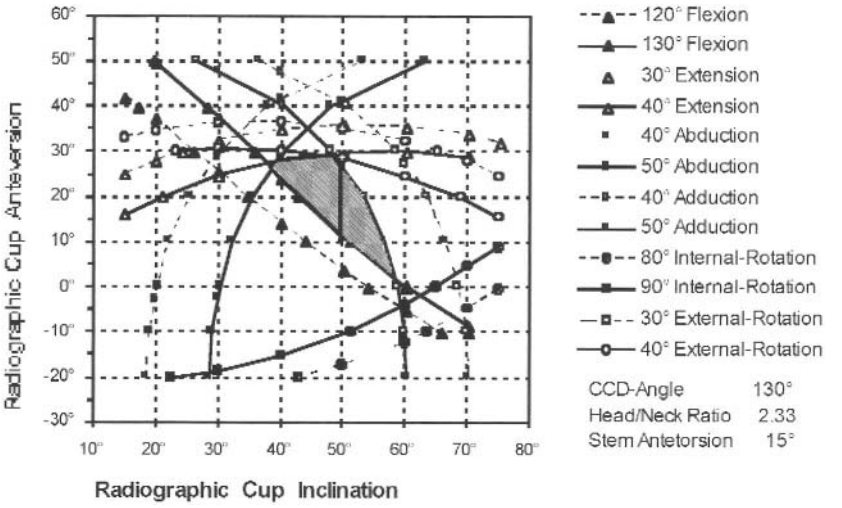

Figure 2:
The hatched safe-zone indicates cup orientations that are compliant with a 15° stem antetorsion and allow the intended range of motion (ROM). The location of this zone is dependent on stem antetorsion and on the CCD-angle.

In other words, there is a close correlation between the orientation of the stem and the compliant position of the cup with respect to the intended ROM. This also means that the optimal orientation of the cup can be derived from the orientation of the stem. And again, as the position of the stem is more or less predetermined by the morphology of the medullary canal the stem also predetermines the optimal orientation of the cup relative to the stem. Of course, the location of the safe-zone is also dependent on the prosthesis system since the design parameters are different from prosthesis to prosthesis.

Discussion

It can be demonstrated that there is a high correlation between cup and stem position in total hip arthroplasty with respect to both optimizing and maximizing range of motion. This correlation is linear for stem antetorsion and cup

anteversion, stem CCD-angle and cup anteversion and for stem CCD-angle and cup inclination. This offers the option to orient the cup mainly relative to the stem thus considering cup and stem as components of a coupled biomechanical system. Of course other factors like containment of the cup, bone-to-bone impingement and implant-to-bone impingement must also be considered.

The question is how the orientation of the cup relative to the stem can be transferred into the operating situs. There are several options to fulfill this task. The simplest one is a trial head that shows the tracks of the neck on its surface (Fig. 3). During implantation the only task for the surgeon is to orient the cup in such a way that none of the tracks is covered by the articulating surface of the cup. The trial head is fixed to the stem and hence rotated together with the stem and therefore it shows the optimal orientation of the cup according to the combined anteversion of stem and cup. This is in accordance with the linear correlation so that the anteversion of the cup is automatically adjusted to the antetorsion of the stem within a certain range, i.e. rotation of the stem translates into anatomic anteversion of the acetabular socket. As this relationship is very close to linear no additional navigation tool is required. Even in malrotated stem the trial head shows the compliant position of the cup. It compensates larger anteversion by a lower anteversion of the cup so that the sum of stem antetorsion and cup anteversion is correct according to the linear equation. From the diagram one may even derive how the orientation of the cup must be modified in order to reach more flexion or extension for example, i.e. for a modified intended ROM.

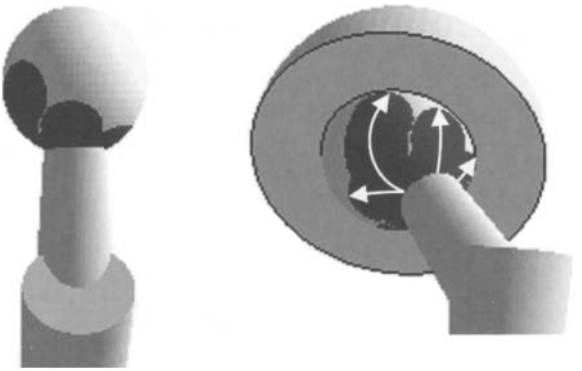

Figure 3:
Trial head with tracks of the neck cross section indicating the surface that must not be covered by the articulating surface of the cup.

Of course the orientation of the cup indicated by the trial head must be balanced against cup containment since secure primary fixation does have the highest priority in implant fixation. Medial positioning of the cup deeply into the acetabular fossa may need a higher stem offset which is often realized by a modified CCD-angle. As the CCD-angle also determines the position of the safe-zone a modified CCD-angle requires another trial head that shows the tracks of that specific prosthesis system.

The ROM and hence the tracks on the trial head are also dependent on the head-to-neck ratio. A higher head-to-neck ratio results in a greater ROM, i.e. the zones for compliant positioning of stem and cup are larger. In other words, a greater head-to-neck ratio will increase the "room for error". This is in accordance with clinical experience. On the other hand, each prosthesis system requires its own trial head that considers all parameters which are relevant for the ROM.

Furthermore, altering the intended ROM will give rise to alter the tracks on the trial head too.

Such a simple guiding tool like the "tracked" trial head will be precise enough to avoid outlayers in manual implantation. Therefore, computer-based navigation techniques can probably be reserved for special cases. But one should be aware of the fact that each prosthesis system requires its specific recommendations for the optimal positioning of its components and hence its own trial head with specific tracks. There is no absolute recommendation for component orientation that is valid universally as the relative orientation of the components to each other is more relevant than their absolute position relative to bony landmarks.

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4.5 Revision Surgery utilizing Ceramic Bearings

J. P. Garino

Introduction

Revision surgery is a highly variable experience depending on the reason for the failure of the currently implanted hip replacement and the bone stock. The current technology in hip replacement revision surgery on the femoral side has evolved into a complex array of highly modular, extensively coated or very long devices that seek to establish durable fixation in whatever remaining bone has been left behind. These devices often take into account or have the versatility to adapt to varied and abnormal anatomy often encountered in revision surgery. On the acetabular side, bone loss has created a development of a wide variety of solutions ranging from the jumbo cups to "double bubble" and cage designs. Ceramic-ceramic bearings are quite new to the primary hip market in the USA, and therefore there is little experience with their use in revisions [1]. This paper will address some practical aspects of revision of or with ceramic bearings.

Revision With Ceramic Bearings

The vast majority of revision surgery usually involves the revision of either the acetabular or femoral component, but usually not both. Frequently one or the other has become loose and painful and replacement of the offending component is necessary to allow the patient to return to a reasonable level of comfort and function. When both components are not changed, then rare will be the circumstance that a ceramic-ceramic bearing can be introduced. If both the acetabular and femoral components are being changed out, then an opportunity for ceramic bearings to be used may well exist. Currently there are three things to keep in mind. First, obviously, one must choose to perform the revision using components from a manufacturer that has approval for ceramic bearings as most companies do not yet have such an approval. Secondly, acetabular bone loss must be at a moderate level and one should be planning to solve the problem with a moderate to large cup as ceramic bearings do not as yet exist in the "Jumbo" sizes. Thirdly, ceramic ball heads require the use of a limited number of taper sizes that might not exist on all revision stems in a manufacturer's armamentarium. Clearly, if these three premises are met, then ceramics can be entertained as a bearing solution for the revision at hand. Ceramics may be a good choice in younger and more active to reduce the risk of another wear related failure in the near future. In addition, ceramic bearings thrive on the use of larger ball heads which should positively impact the risk of dislocation.

Other things to keep in mind when considering ceramic bearings in revision include the limited range of neck lengths (as skirted balls are not allowed) and the single acetabular liner option (as offset or face changing liners are not available). These issues may limit the ability of ceramic bearing to be used effectively in revisions. Nonetheless, in younger and more active patients, serious

consideration should be made for employing ceramic bearings in revision THR with a back-up plan available should the needs of the patient not be met by current component availability.

Revising Ceramic Bearings

There are two "may" category subtypes in this circumstance. The first is revising for a fractured ceramic component and the second is revision for any other reason.

In the case of ceramic ball head fractures, ideally, the use of another ceramic-ceramic THR would be best. This is due to the hardness of the material and its resistance to abrasive wear. In spite of most adequate attempts to removal all of the small broken ceramic particles, complete clearance is difficult. With the retention of ceramic debris, there is an increase risk of developing significant third body wear, and the use of a new ceramic articulation reduces that risk to its lowest level.

There are two ways of accomplishing this, however only one is currently available in the United States. That would be the exchange of the acetabular or the femoral component that had sustained the ceramic failure. When a ceramic component fails it may have done so because there was some damage on the taper through which the ceramic part transferred load. In addition this taper gets exposed to ceramic debris after the failure and usually sustains further damage. For both of these reasons it is not advisable to reuse that taper for another ceramic component. Use of a ceramic component in this situation carries an increased risk of a repeat failure.

Revision of a well fixed total hip replacement often not an easy undertaking. In this circumstance, an acceptable alternative solution would be the placement of a metal ball on the femoral component and insertion of a poly liner into the acetabular component. In the case of the acetabular component, some manufactures may now be introducing a multibearing cup which would allow for easy interchangeability in these difficult situations. In cups that are specifically manufactured for a ceramic bearing, a decision needs to be made by the surgeon if the cup should be excised with an attempt to re-establish a ceramic-ceramic articulation, or if a simple poly line should be cemented into that cup. Both are viable and acceptable solutions.

On the femoral side, alumina composite materials with increased mechanical properties and a significantly increased fracture toughness may offer a reliable solution in situations where a new ceramic ball head is desirable. This material, with a metal sheath which can slip over the current femoral taper is now being used in Europe with encouraging results (Fig.1) [2].

Figure 1:
CeramTec's Revision Ball head System, BIOLOX® option.

Finally, if an acetabular revision is being carried out and the femoral component has a ceramic ball head and the surgeon wishes to remove the ball head either to enhance exposure or to change the diameter or length of the current ball, what can be done?

The manufacturers of ceramic ball heads list very clearly in their label that the tapers of modular parts are never to be re-used. This is done because the quality of the taper and the mechanism of the ball removal is not in their control and can sustain some degradation or damage, particularly if the ball is removed roughly. All manufacturers have a ball head removal tool. This tool, although with differences in design for manufacturer to manufacturer, essentially places a tensile load across the taper, breaking it and separating the parts. This careful and non-destructive manner of removing the ball allows for the potential for re-use of ceramics once again. However, care must again be taken to protect the taper during the revision, often a difficult challenge. A 22 mm ball head trial can often be used for this purpose. It is therefore recommended to perform the revision with the original ball head in place if possible, and replace it at the end of the case. This eliminates the need to protect the taper for that long period of time during the cup revision. With great care, this type of replacement can be considered and, although an "off-label use" of the ceramic components, the surgeon can make a judgement that this an appropriate approach given the difficulty in removing well fixed components and the inferiority of other bearings in young and/or active patients.

Laurent Sedel, has had this approach and in his experience of over 55 cases, no fractures of components exchanged at revision has occurred [3].

Conclusion

Ceramic revisions can be difficult due to the critical nature and therefore imposed limitations in the transfer load mechanisms designed in the stem taper to ball head and shell taper to insert. This coupled with the material limitations from both a mechanical property standpoint as well as an availability standpoint can create a challenge for the operating surgeon. With great thought, care and utilization of the guidelines outlined in this paper, the revision Total hip Replacement being performed can often be optimized for new or continued use of ceramic bearings.

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4.6 Surface Changes to Alumina Femoral Heads after Metal Staining during Implantation, and after Recurrent Dislocations of the Prosthetic Hip

B. S. Bal, M. N. Rahaman, T. Aleto, F. S. Miller, F. Traina and A. Toni

Abstract

Metal staining of alumina ceramic femoral heads can occur during implantation of total hip components and during reduction of a dislocated total hip. To determine whether or not such staining results in surface damage to alumina ceramic femoral heads in vivo, we examined two groups of explanted femoral heads. Group 1 consisted of four femoral heads with surface metal staining from inadvertent contact with the metal acetabular shell during hip implantation. Group 2 consisted of ten femoral heads removed from patients with recurrent dislocations of the prosthetic hip. Femoral heads were coated with carbon and observed in a scanning electron microscope fitted with an energy dispersive X-ray analysis (EDS) attachment for microchemical analysis.

Alumina heads that had touched the metal acetabular shell during surgery demonstrated dark metallic markings with a composition corresponding to a Ti-6Al-4V alloy. Particles with a size range from sub-micron to several tens of microns were deposited on the surface in Group 1 specimens, and these could be removed by a benign chemical etch, leaving no changes on the alumina surface. In contrast, alumina femoral heads removed after recurrent dislocations in Group 2 demonstrated significant surface deterioration, consisting of uneven wear, cracks, embedded particles, deep groves and pits. A subset of the femoral heads in Group 2 that had suffered three or more dislocations demonstrated gross damage to the acetabular bearings.

Our work shows that metal transfer to alumina femoral heads that can occur if the head slides against the acetabular shell while reducing the hip during surgery is a superficial phenomenon that does not damage the alumina surface. In contrast, alumina femoral heads removed after multiple hip dislocations demonstrate significant, non-uniform surface degradation, in addition to metal deposition. Recurrent dislocations associated with alumina femoral heads may warrant early surgical intervention because of the potential for surface damage to the bearing and the potential for increased wear.

Introduction

Alumina ceramic femoral heads are associated with some of the lowest wear rates reported in total hip replacements, whether articulating against ultra-high molecular polyethylene inserts [1,2], or against alumina liners [3,4]. Alumina is a hard biomaterial that can be polished to a smooth surface, resulting in very low friction and wear when used as a bearing [5]. The smooth surface of an alumina femoral head can become stained with metal if the alumina head comes into contact with the rim of the acetabular component during surgery [6], or during

closed reduction of a dislocated total hip [7]. The purpose of this investigation was to examine the surface of alumina femoral heads that had visible metal staining from either of these phenomena, to determine the extent of damage to the alumina surface.

Materials and Methods

During total hip replacement with alumina ceramic femoral heads, the femoral head inadvertently contacted the metal acetabular rim in four patients as the hip was being reduced. This occurred in part because of a prominent circumferential rim at the periphery of the acetabular components, which is a design feature to prevent impingement of the metal neck against the ceramic liner [8]. Metal staining of the femoral heads was noticed in each case, and the alumina heads were removed since we were uncertain about the significance of this finding. The four femoral heads thus retrieved comprised Group 1 of the specimens available for this investigation.

Group 2 consisted of explanted alumina heads and liners from patients who had suffered recurrent dislocations and closed reductions, or recurrent sub-luxations of the prosthetic hip. Group 2 specimens were further divided into Groups 2A and 2B.

Group 2A consisted of four alumina femoral heads that were identical in type to those in Group 1, except that Group 2A specimens were retrieved during revision surgery from patients who had experienced no more than three dislocations or subluxations of the artificial hip. The alumina femoral heads in Groups 1 and 2A were a third-generation material marketed under the trade name of Biolox Forte (CeramTec AG, Plochingen, Germany), which differs from the earlier generation Biolox alumina in that it is treated by hot isostatic pressing and has a smaller grain size with less impurity [9].

Group 2B consisted of six alumina femoral heads that were removed from patients who underwent revision surgery after more than three dislocations or subluxations of the prosthetic femoral head. Table 1 summarizes the pertinent clinical data related to the retrieval specimens in Groups 2A and 2B. All except two femoral heads in this study were 28 millimeters in diameter.

Group	Specimen number	Alumina type (28 mm heads)	Patient age	Number of dislocations or subluxations before retrieval	Damage to metal cup	Damage to alumina liner
2A	1	Biolox Forte	47	3	No	No
	2	Biolox Forte	67	2	No	Light stain
	3	Biolox Forte	51	3	No	No
	4	Biolox Forte	48	3	No	No
2B	1	Biolox (32 mm size)	53	>3 (Numerous)	Yes	Chipped
	2	Biolox (32 mm size)	74	4	Yes	No
	3	Biolox Forte	67	4	Yes	No
	4	Biolox Forte	67	>3 (Numerous)	Yes	No
	5	Biolox Forte	65	>3 (Numerous)	Yes	Fragmented
	6	Biolox	52	5	Yes	Chipped

Table 1:
Clinical Data for Specimens in Groups 2A and 2B

Femoral heads from the above groups were inspected carefully for any gross evidence of surface damage. The acetabular components (alumina liners and titanium metal shells) were examined for any signs of metal fretting, liner chipping, or other damage. Metallic stains on the femoral heads were wiped with a cotton cloth dipped in dilute nitric acid (0.1 N), rinsing twice with ethanol, and drying with a jet of air. This treatment was chosen because it can dissolve the metal stain without affecting the alumina.

The surface of each alumina head was then examined in the metal-stained area, and the adjacent areas, with light microscopy, followed by scanning electron microscopy (SEM; JEOL T330A) with an energy dispersive X-ray analysis (4pi Revolution using KEVEX Quantum detector, Durham, N.C.) attachment for microchemical analysis of the metal stain. Specimens were coated with carbon prior to SEM analysis to prevent electrostatic charging.

Results

Except for the metal staining, none of the alumina femoral heads in this investigation had any gross evidence of surface damage or irregularity. Group 1 alumina heads had isolated streaks of metal staining where the head had contacted the acetabular rim during intraoperative reduction of the total hip (Fig. 1). Each Group 1 alumina heads could be wiped clean with the treatment described above, leaving a smooth surface free of the metal deposits (Fig. 2). Analysis of the metal stain showed that its composition corresponded to that of a Ti-6Al-4V alloy, transferred from the rim of the acetabular component. SEM analysis of the alumina heads in Group A following stain removal revealed a smooth surface, comparable to adjacent areas that did not have metal staining.

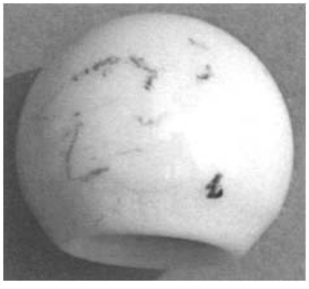

Figure 1:
Metal staining of alumina head following contact with the metal acetabular rim during hip replacement.

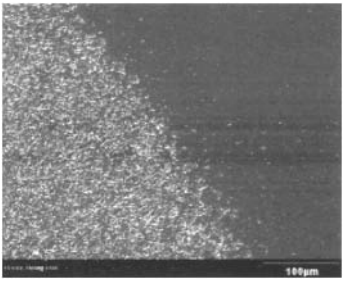

Figure 2:
SEM photomicrograph of an alumina head surface showing superficial metal deposition (left) that is removed with a chemical etch, leaving the undamaged alumina surface (right).

Group 2A alumina heads were identical in material properties to the specimens in Group 1, except that Group 2A specimens had been retrieved during hip revision surgery for three or fewer episodes of hip instability. Each alumina head in Group 2A had a more prominent area of metal staining compared to the specimens in Group 1 (Fig. 3). Metal stains in Group 2A could not be completely removed with the dilute nitric acid treatment described above. SEM analysis revealed significant

surface deterioration of the alumina, with a wide range of features, including uneven wear, cracks, embedded metal particles, deep grooves, and pits on alumina surface (Fig. 4). Adjacent areas on the femoral heads that had not contacted the metal shell remained smooth and undamaged. The alumina acetabular liners in this group contained light, inconsistent metal staining, but no evidence of the scratches or surface damage seen on the femoral heads.

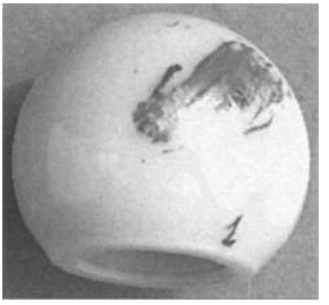

Figure 3:
Heavier metallic staining on the alumina head that had three episodes of dislocation of the prosthetic bearing.

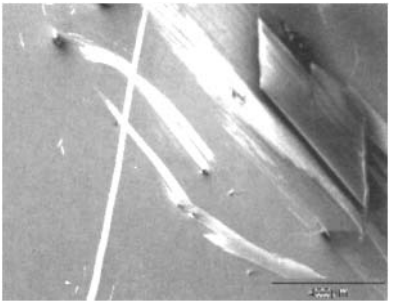

Figure 4:
SEM photomicrographs showing surface irregularities on an alumina head that had three dislocations.

In Group 2B, each of six alumina femoral heads had undergone several, i.e., ≥ 3, dislocations or subluxations of the hip arthroplasty. The gross appearance of these femoral heads was nearly identical to that of Group 2A, i.e., extensive metal staining was present on the alumina surface with no other gross findings (Fig. 5). Unlike Group 2A, visible damage to the acetabular components was also present in each Group 2B retrieval specimen (Fig. 6). This damage consisted of changes either to the alumina liner, or to the metal acetabular shell, or to both. Liner damage consisted of chipped and frayed pieces of alumina ceramic, while acetabular shell damage consisted of metal fretting, fraying, and disintegration at the site where the femoral head had moved in and out during hip instability. Gross metal and ceramic debris were encountered in the prosthetic joint space at the time of revision surgery in each of the Group 2B cases.

Figure 5:
Extensive metal staining, but no obvious damage to an alumina head retrieved from a patient with multiple, i.e., > 3 dislocations of the prosthetic hip.

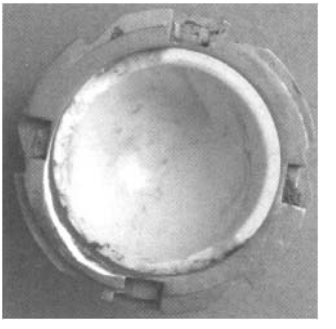

Figure 6:
Acetabular liner and shell retrieved from a patient showing gross damage to the liner and metal.

Discussion

Our results show that metal staining of alumina femoral heads from incidental contact of the head against the acetabulum is a superficial phenomenon that does not damage the alumina surface. In contrast, hip instability with alumina femoral heads can result in microscopic degradation of the alumina surface, in addition to metal deposition. Care should be taken during surgery to protect the femoral head during reduction to avoid contact with metal, and recurrent dislocations associated with alumina femoral heads should be addressed early because of the potential for damage to the bearing components, and the possibility of increased wear.

The titanium staining of Biolox Forte alumina heads from contact with the acetabular shell has been reported following difficult intraoperative reduction of total hip components [6]. The authors of that report speculated that metal transfer into the ceramic articulation might explain the sporadic cases of excessive wear of alumina-on-alumina bearings and alumina-on-polyethylene bearings [10-15]. Thomsen and Breusch observed metal transfer from the acetabular component that occurred during surgery in seven out of 20 alumina heads explanted after three to 13 years; no grooves or scratches were found on SEM analysis of these femoral heads [16]. Luchetti et al. reported two cases of metal transfer to zirconia ceramic femoral heads; one occurred after a single dislocation and the other during a forceful reduction of the hip during surgery [7]. The authors remarked that metal transfer to ceramic heads had not been reported in previous reviews of retrieved ceramic heads [9].

Our data show that metal transfer to alumina heads that can occur if the head contacts the acetabular component during surgery is not associated with surface damage to the alumina, and that the metal deposits can be removed. Metal transfer occurs because of a surface metal oxide layer, which detaches from the underlying titanium surface and becomes deposited on the alumina [17]. The titanium alloy (Ti-6Al-4V) that is widely used in metal acetabular shells is a relatively soft material that is known to result in extensive tissue discoloration and the release of particulate metallic debris when used as a bearing [18,19].

If metal remains on the alumina, three-body wear of the articulation is a theoretical possibility, although alumina-on-alumina bearings are relatively resistant to this mode of wear. Experimentally, three-body abrasion wear tests of zirconia ceramics using Ti-6Al-4V particles as third-body debris have shown no evidence of abrasion, material removal, or subsurface damage [20,21]. Hard alumina bearing surfaces would also be expected to show abrasion resistance comparable to zirconia for titanium particulate debris [20]. Bragdon et al. reported third-body abrasive damage on four retrieved yttria-doped alumina ceramic femoral heads, but the authors acknowledged that the yttria-based material released from the bearing itself could have contributed to the damage in their specimens [22]. As such, their findings may not apply to modern alumina bearings that do not contain yttrium.

While ceramic-on-ceramic bearings may be relatively resistant to wear from interposed metal particles, three-body wear is a concern if ceramic heads articulate against polyethylene. Metal staining with surface scratching and pitting of an alumina head retrieved after multiple dislocations was associated with damage to the highly cross-linked polyethylene liner from the same articulation [23]. Ceramic heads made of zirconia can undergo transformation

from a tetragonal phase to a monoclinic phase, leading to microcracking and release of small zirconia particles, and increased bearing roughness and accelerated wear of zirconia-polyethylene articulations [24].

Transfer of metal debris similar to what we observed in this investigation probably occurs when cobalt-chrome femoral heads are used, but the discoloration is difficult to detect [7]. Experimentally, transfer of titanium debris occurs onto cobalt chrome surfaces, resulting in increased surface roughness and abrasive wear [20]. Retrieved cobalt-chrome femoral heads have shown microscopic surface damage, presumably from third-body wear from metal particles entrapped in the articulation [25]. Since cobalt-chrome heads usually articulate with polyethylene liners, interposed metal debris may be of greater concern with cobalt-chrome heads in terms of increased abrasive wear [20].

Our data show that metal transfer to alumina heads associated with hip instability is associated with damage to the smooth alumina surface. Subluxation and relocation of alumina heads is known to result in scratching of alumina heads [26], which is a distinct phenomenon from the wear associated with the edge loading of ceramic-on-ceramic bearings [26,27]. SEM analysis of alumina femoral heads that eroded through titanium acetabular shells after failure of the polyethylene liners has demonstrated metal deposition with roughening of the alumina surface [28].

Alumina ceramic femoral heads have demonstrated the lowest wear rates both in clinical studies [1,24] and experimental investigations [4,5,29]. Ceramic bearings offer increased hardness, scratch resistance, and decreased surface roughness compared to metals [5]. These benefits of ceramic femoral heads are clinically relevant compared to metal femoral heads [2,30]. Decreasing the surface roughness of a bearing is correlated with less wear; therefore if the roughness of alumina heads is increased following instability of the prosthetic hip, increased wear can reasonably be expected [5,17]. Our data suggest that to realize the full potential of alumina femoral heads, contact between the head and metal should be carefully avoided during surgery. Furthermore, the surgeon should be aware that instability of alumina femoral heads can compromise the smooth ceramic surface, and if instability continues, gross damage to the articulating surfaces and increased wear may follow.

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SESSION 5

Reliability of Alumina Ceramics: Myths and Reality

5.1 Ceramic Component Fracture: Trends and Recommendations with Modern Components based on improved Reporting Methods

J. P. Garino

Abstract

Fractures of ceramic components have been reported in the literature with highly variable rates, many of which include obsolete designs and previous generations of ceramic materials. With improved worldwide reporting since the year 2000, the database of the largest manufacturer of medical grade ceramics was analyzed with respect to the demographics of modern ceramic component fractures. Although the overall fracture rate based on an excess of 1 million components being produced with the latest technology was a safe and low 0.015% and compared favorably with other complications such as infection, stem breakage, dislocation, etc, the analysis revealed many interesting findings. Three of the most significant were: 28 mm ball heads fracture at a substantially higher rate than the 32mm ball heads; 90% of fractures occur within the 36 months of implantation; due to continued quality improvements the rate continues to decrease (actual > expected rates).

Introduction

The objective of this report was to re-examine the safety and fracture record of alumina implants as we enter a new era of ceramic clinical use in the USA. This review will consist of four sections. The first being the summary of the enhancements added to the alumina implant technology over the years. The second will be to provide a partial overview of published fracture cases from 1970 to 1995 [1] as well as a review of some of the latest clinical publications on ceramic THR from the USA and around the world. The third section attempts to introduce perspective to ceramic component failure as compared to other implant related failures. Finally, we will present our review of the largest database available on ceramic component failure and will present recommendations intended to reduce ceramic component complications in the future.

Material, Manufacturing and Quality Improvements

The materials used in the early years were vastly different from those used today. Improvements in manufacturing methods have substantially contributed to the request for more reliable components. The introduction of a controlled environment in the powder processing area has reduced inclusions and improved homogeneity; improved sintering techniques and hot isostatic pressing (HIP) has improved density and reduced grain size; laser etching has reduced surface stress risers and proof testing has added a new dimension to the reliability

of components by functionally testing 100% of the components at the end of the manufacturing process. Today's materials have much reduced level of inclusions, substantially lower grain size and posses a much higher density level than early ceramics [1]. These improvements translate into improved mechanical and physical properties, improved wear characteristics, optimized biocompatibility and excellent reliability. The advances were made by pioneering companies in Germany (CeramTec), in France (Ceraver), in England (Morgan Matroc) and in Japan (Japan Medical Materials, formerly Kyocera). All four have remained committed to the constant improvements and evolution necessary to overcome the reliability problems of the early years. Their commitment to the goal of increased reliability has given us substantial improvements when compared to the early ceramics. These advances have been an essential support to the continued improvements in reliability required today by orthopedic surgeons around the world.

Acting in parallel with the ceramic manufacturers, the implant manufacturing companies have also made great strides in combining the newer ceramic components with proven stem and acetabular designs. They have also greatly improved their ability to produce superior quality mating surfaces for the ceramic to metal connection with optimum designs for the transfer of loads in harmony with the ceramic components. Table 1, illustrates the progress made in material development of the alumina family of ceramics over the last 30 years.

	1970's Alumina	**1980's Alumina**	**1990's Alumina**
Strength (MPa) min.	400	500	580
Hardness HV min.	1,800	1,900	2,000
Bending Strength (MPa)	>450	>500	>550
Wetting Angle (°)	<50	<50	<50
Microstructure [µm]	≤4,5	≤3,2	≤2.0
Density [g/cm^3] min.	3,86	3,94	3,96
Young's Modulus (GPa) min.	380	380	380
Laser Making	No	+	+
HIP	No	-	+
Proof-tested	No	-	+
100% Control	+	++	+++
Suitable for ceramic-ceramic	+	++	+++

Table 1:
Mechanical Properties of Alumina

It is important to understand why these early pioneering companies selected Alumina Ceramics as a solution for younger and more active patients in an effort to reduce wear induced osteolysis. First of all Alumina is extremely hard, with a hardness of more than 2000 HV. Other commonly used orthopedic materials such as cobalt chrome, titanium and other materials have a hardness level of less than 500 HV. Alumina is also quite stable at high temperature in an aqueous environment. It is hydrophilic in an aqueous environment allowing for fluid lubricant to cover larger areas of the bearing surfaces. The last of the critical characteristics is the bio-inertness of alumina ceramic in both bulk and particle

(non-ionizing) form. All of these characteristics clearly point to the advantages of this material as a means of reducing wear in the younger, more active patient who would benefit from a longer term joint replacement implant.

Historical Review of Ceramic Failures

The most complete report on alumina fracture incidence in THR was published by Heros and Willmann (1998) [1]. They reviewed the results from 35 ceramic publications, predominantly from European surgeons and representing the 1970's, 1980's and part of the 1990 era. From their table of clinical data published in the early 1990's (representing the 1980's), the fracture incidence varied from 0% to 0.8%, i.e. 8 fractures per 1,000 cases. The fracture incidence was highly dependent upon the manufacturer and the implant design. The two companies that had the highest fracture incidence abandoned the orthopedic field in the early 1980's.

Additionally, there have been many reports from the Sedel group in Paris on their 26-year THR experience with the alumina wear couple manufactured by Ceraver. Their experience in over 3,500 cases shows a fracture rate of 2% in the 1970's, dropping to 0.1% in the 1980's. Current estimate over the last decade appears to be about 0.05% [2].

These early clinical series produced less than ideal patient results when measured to today's standards, however it is important to understand that the femoral and acetabular components holding the ceramic components were of a dated design, patient selection often was not restricted and initial fixation was seldom reached. These three factors sealed the fate of these early generation systems.

Latest Ceramic THR Reports

The new generation of alumina inserts used in rigid porous coated or treated metal shells is a fairly recent development and therefore not nearly as comprehensively followed in the medical literature when compared to the alumina ball heads. Reviewing the latest ceramic THR series as reported in major journals (Table 2) there were 10 studies representing over 1,200 cases. From the group in Paris, Sedel, Hamadouche and Bizot presented their various developments of ceramic implants, showing zero fractures in their selected series followed to 20 years [3]. From Austria Boehler reported on 243 cases followed 6 years with no fractures [4]. From the FDA multi-center studies recently conducted in the USA, Garino (2000) [5] reported on 333 cases followed up to 3 years with no fractures. Delauney (2001) [6] from France reviewed 133 cases followed 5 to 10 years with no fractures. In the USA, Urban et al (2001) [7] reported on a smaller series of 64 cases followed minimum of 17 years with zero fractures. Also in the USA, Drs. D'Antonio and Bierbaum reported in 2002 on their 514 cases at 3 and 4 years follow-up periods, respectively, also with zero fractures [8,9]. Thus in this recent international set of publications involving >1,200 cases with follow-ups from 3 to over 20 years, there were zero fractures reported.

Year	Journal	Author	Country	F-Up (yrs)	THR (N)	THR	Fxs
2003	ISTA	Sedel	France (1980)	20	118	CoC	0
2002	CORR	Bierbaum	USA (96-98)	4	514	CoC	0
2002	JoA	D'Antonio	USA (96-98)	3	514	CoC	0
2002	JBJS	Hamadouche	France (79-80)	>18	118	CoC	0
2001	CORR	Bizot	France (97-)	<3	96	CoC	0
2001	JoA	Delauney	France	5-10	133	CoC	0
2001	JBJS	Urban	USA	17-21	64	CoC	0
2000	CORR	Garino	USA (97-98)	1-3	333	CoC	0
2000	CORR	Bizot	France	>5	234	CoC	0
2000	CORR	Boehler	Austria (90-)	6	243	CoC	0

Table 2:
Summary of clinical reports following >1200 ceramic cases up to 21 years with zero fractures (published in major journals)

The results of clinical usage in the carefully controlled FDA type of clinical studies present a very positive picture which will be further detailed. However, one issue which was extensively discussed and presented at numerous open forums in the early stages of introduction of the insert to shell taper locking concept to the European and American surgeons was that of intraoperative chipping. This is the occasional rim chipping and fracture of ceramic inserts that can occur intraoperatively [10,11,12] as a result of minor malinsertion by the surgeon. This incidence has been drastically reduced in later day systems as the technique of assembly is better understood by the surgical community and improved designs have made the assembly of the ceramic insert into the metal shell even more forgiving. The statistics for alumina-metal cup systems used in the USA has indicated a 2-3% incidence of chipping during surgery [13,14,15] in the early phases of the the clinical trials as surgeon training was still not fully developed. A review of the ceramic component manufacturer, CeramTec clearly confirms this drastic reduction in the intraoperative chipping issues over the years in cases reported to them from 0.022 % in 2000 to 0.008 % in 2003. (See recommendation section, number 5).

Perhaps the strongest case for the improved reliability experienced by current day ceramic inserts and ball heads is made by the fact that the Food and Drug Administration has now approved three Pre-Market Application and one Product Development Protocol submitted by four companies. Each of these submissions has required the companies to conduct extensive pre submission laboratory testing, followed by a clinical study of several hundred cases with extensive reporting requirements and severe scrutiny of their manufacturing operations. This level of testing and proof of safety and efficacy of a technology is simply unprecedented in the orthopedic implant field until this time.

Corporation	C-M Taper	Cup or shell	Case#	Fractures
Howmedica-Osteonics	yes	Rigid taper lock	2,000	0
Wright Medical	yes	Rigid taper lock	1,250	1
Encore Medical	yes	Rigid taper lock	800	0
Smith and Nephew	yes	Rigid taper lock	300	0

Table 3:
FDA clinical trials and continued access clinical results reported until December 2003.

The fact that the ceramic on ceramic wear couple was classified as a class III device has resulted in tremendous benefit to the orthopedic community. The first one is the fact that the approval of three PMA's and one PDP is a tribute to the robustness of the proof of safety and effectiveness of the ceramic taper locking inserts and ball heads that the supplier, CeramTec and the individual orthopedic companies mentioned in Table 5 have designed and manufactured. The second one is the high degree of confidence in the manufacturing and quality control area of both the ceramic supplier and the orthopedic implant companies that has been gained as a result of the more stringent approval process of a Class III product. The final one is the continually stronger clinical proof of safety and effectiveness that will result from the conditions of approval of each of these systems by the FDA which at minimum include a yearly follow up of all patients of 5 years and a maximum of 10 years (post market surveillance).

Unlike other alternative bearing technologies, such as highly crossed linked polyethylenes, the ceramic on ceramic articulation has undergone one of the most grueling evaluations of clinical safety ever used in the orthopedic implant field.

Survey of Publications on Clinical and Implant-related Complications

Total Hip Replacement is one of the most successful procedures available today, with the most serious side effect and complications dropping dramatically over the past several decades as clearer understanding of the causes and preventive measures that can reduce risks have improved. However, as is the case in a surgical procedure there can be serious risks to the patients.

The first area of risks are related to clinical complications in THR surgery. The actual risks to the patient are: dislocation, bone fracture, pain and stiffness, leg length discrepancies, infection, osteolysis, nerve injuries and even death. While the incidence for these is low, it is important for the reader to keep in mind that they are generally higher much than those related to implant complications. Since ceramic component fractures represent an implant failure requiring a revision, the crucial question is: How does the risk of a ceramic component failure affect the overall risk of revision? In Mahomed et. al. [20] the authors used a large database in order to illustrate the clinical complications and their frequency. Table 4 below presents the actual data from this article.

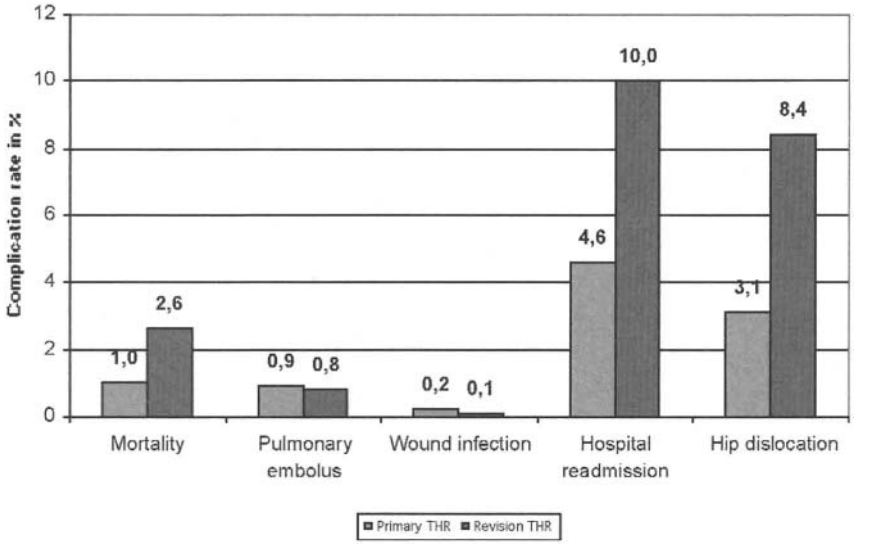

Table 4:
Clinical complication rates in the THR Medicare population

Another perspective would be to compare the incidence of ceramic component fractures with that of other mechanical failures of prosthetic components in THR surgery. Heck et al [18] conducted a survey that polled over 60,000 cases performed in the 1990's in the USA over a 5-year period. These cases included the use of 5,023 ceramic balls containing 11 reports of a ball fracture. However, the survey documented only 10 fracture cases with 3 of these being taken from a set used on femoral stems manufactured at a hospital machine shop. This data should probably be excluded since they represented a unique manufacturing environment by a hospital group [16,17] not properly equipped to produce the high tolerance components required for mating with ceramic ball heads. After adjusting for these, the fracture rate in Heck's review was apparently 7 fractures in 5,023 cases for a ratio of 1.4 per 1,000. To put this in perspective, the same poll documented the combined risk of wear-through and fracture in cemented UHMWPE cups as 24 per 1,000 and fractures of the femoral stem as 2.7 per 1,000. In other words, fracture of ceramic balls was a somewhat rare complication overshadowed by the fracture incidence for femoral stems and gross failures with the cemented UHMWPE cups.

In order to provide a different perspective, we reviewed an article by Castro et.al. [18] that identified the incidence of components failure in Total Hip Replacement as reported in the form of adverse reports to the Food and Drug Administration. In this article the most common device related component related failures were: Polyethylene acetabular insert fracture followed by insert disassociations and closely followed by stem fractures. In all cases the percentages of these component failures was higher than that of ceramic component fracture.

In Depth Review of the Database of the Largest Ceramic Manufacturer

In order to completely answer the issue of reliability and offer some constructive comments to the users in future years, the authors contacted the CeramTec company in Stuttgart, Germany and received their cooperation in analyzing their database as further support for this publication. The analysis was limited to 1995 to the present database in order to identify overall trends, however it was further limited to the 2000 to September 2004 database as the authors felt that it was important to take advantage of the improved reporting methods and corresponding details available resulting from changed reporting requirements imposed by CeramTec for this time period. In addition the large number of components involved in the rigid USA FDA IDE studies, the continued access patients and the post market surveillance required has virtually eliminated any under reporting of component failure by the orthopedic manufacturers for this complication in the USA. The relatively recent Zirconia recall by another ceramic manufacturer due to excessively high fracture rates following a manufacturing change has increased the concerns of potential fracture by regulatory bodies globally increasing the pressure on manufacturers and surgeons to report any failures from most countries promptly.

The validity or applicability of this database as a predictor of clinical results is not proposed. It is fully understood that not all failures in vivo are reported to the manufacturer or even to the regulatory agencies around the world. The degree of underreporting of complications is a major problem and is certainly a major discussion point. Additionally, we would like to point out that the statistics are based on average numbers not on the extremes reported by each individual company or achieved by each system. Our thinking in presenting this publication is that this large database by the sheer magnitude of the numbers involved can be an effective means to identify trends that may help us all in reducing fracture of a ceramic component in one of our patients.

Our analysis leads us to the following observations:

1. Ceramic component fractures are created by specific events.

An analysis of the reported clinical fractures showed that the biggest reported reasons for fracture are related to patient trauma, followed closely by the use of components not designed to work together (mismatched, off label use), poor handling (for example, cooling by quenching into room temperature water after autoclaving) and effects related to dislocation/poor cup position. While this is based on analyzing only 49 reports with sufficiently complete information, we do believe that it serves to illustrate a ranking of events potentially leading to ceramic component failure.

2. Ceramic components tend to break early on in their service life.

There are clear indications from the database that both ball heads and inserts fail in a similar pattern with roughly 60 % of all reported failures occurring in the first 12 months after implantation. At the end of 24 month the number increases to 80 % of all failures and by 36 months nearly 90% of all failures have been reported.

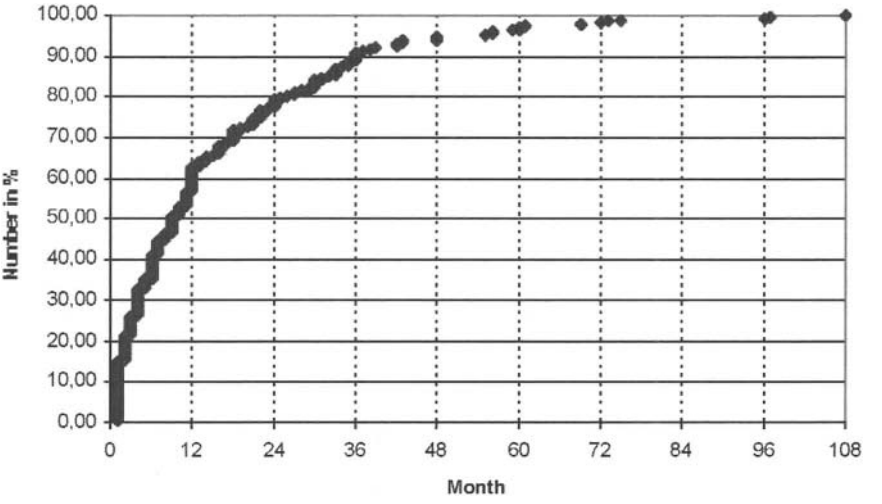

Table 5:
Ceramic component in vivo fractures vs. time (Biolox Forte, based on reported fractures from 1995 - Sep. 2004)

3. The reliability of ceramic components has been steadily improving over the years.

If this "expected" fracture rate is applied to components produced in the last four years, the current rate is actually somewhat lower than expected and outlined in Table 6. We suspect that this is due to improved quality improvement of both ceramic and metal components of THR systems as well as continued education and training of surgeons by orthopedic manufacturers.

In Table 6 we present the reported fracture rate extracted from the data base as well as the expected total fracture rate which is a derived calculation based on applying the survival curve shown in Table 5.

Ball heads and inserts, Biolox Forte, production year 2000-2003, based on fractures reported until 9-2004

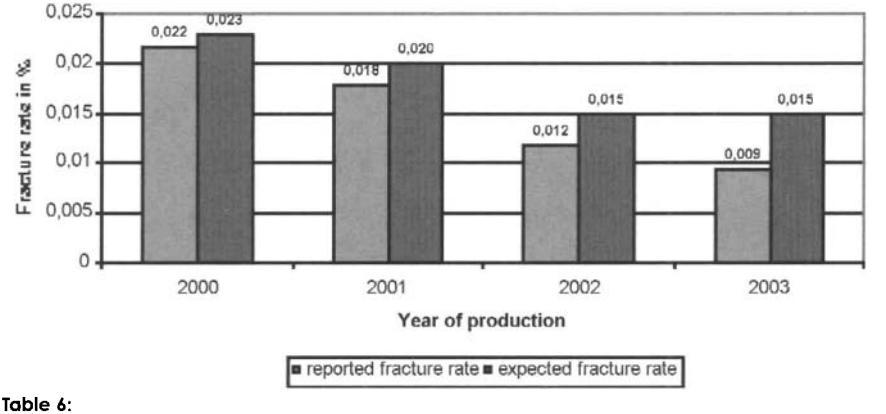

Table 6:
Ceramic components in vivo fracture rate

4. Ceramic on ceramic systems using larger ball head and insert sizes obtain improved reliability.

There is a clear benefit in reliability to be gained by using the 32 or 36 mm wear couple. Specifically, the fracture rate for 32 mm ball heads at 0.004 % is substantially lower than that of smaller sizes. Without a doubt the single biggest action that a surgeon can take in order to improve the reliability of the ceramic system implanted in a patient is to use the largest possible ball head and insert construct possible. The other inherent benefits, i.e. gains in range of motion, improved joint stability and reduced dislocation, are also gained from the use of the larger wear couple.

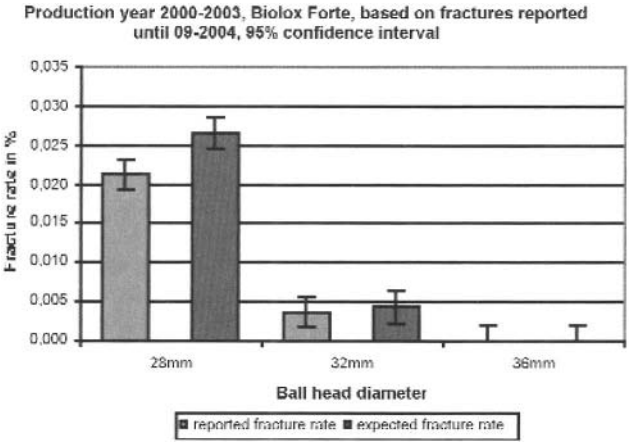

Table 7:
Reliability by ceramic ball head size

5. Every ceramic component design is a compromise between the needs of the system and component reliability.

The dataset also indicated that even within a particular size range, i.e. 28 mm ball heads, there are differences in reported fracture rates. The short and long neck sizes have a significantly higher fracture rate when compared to the medium's neck size. In other words the optimum design parameters for the entire system of components are incorporated into the medium size ball heads in areas like size of the contact area for load transfer, material, length of stem taper engagement and others. The take home message is clear in that the surgeon should do a more extensive pre-operative analysis in order to use the medium neck length version of the ball heads in the majority of the cases.

6. Intra-operative chipping of ceramic inserts is preventable.

Chipping of a ceramic insert has been drastically reduced over the last few years. One company has introduced a slightly modified design which encases the ceramic insert an intermediate titanium sleeve with an elevated rim in order to protect the ceramic component. It can occurs when a surgeon tries to use the same techniques that he has been using with a polyethylene insert. An action such as placing the insert and impacting it to its final place in order to engage the locking mechanism simply will result in a rim sliver or chip of the ceramic insert. Therefore, it is important that when using a taper locking insert, the surgeon manipulates the insert into the shell's final position, confirms that it is properly

seated by visual observation or palpation and only after verification of proper position is the final seating required with a properly designed impactor and a soft mallet tap in order to seat the component properly.

The statistics extracted from the database were very clear in showing a strong decline from 0.022 % in 2000 to 0.008 % in 2003 in the incidence of intraoperative chipping reported. This improvement is likely due to the fact that the chippings were, for the most part unanticipated, and once they occurred, appropriate design changes and surgeon education efforts were put into effect.

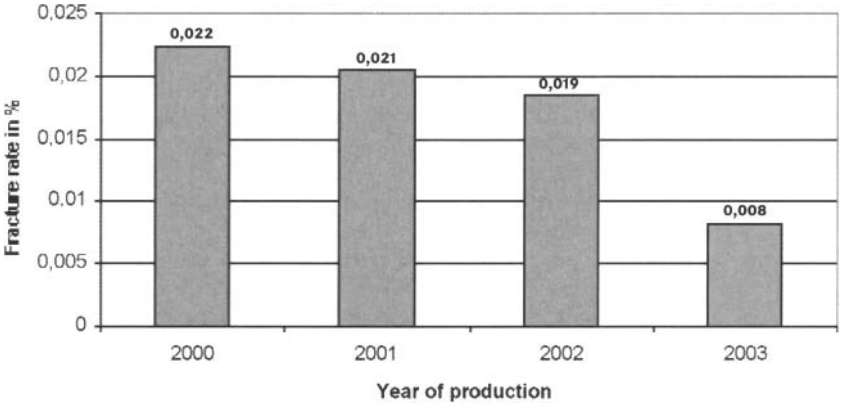

Table 8:
Incidence of reported intraoperative chipping of Biolox Forte inserts

7. Identical ceramic components can have varying degrees of reliability.

The ceramic components discussed are highly dependent on the load transfer capabilities of the stem taper and shell taper that they interacting with. The statistics clearly prove that different manufacturers using the same identical ceramic devices can achieve different clinical reliability (rates that vary up to three times the average) in their systems. This is due to the fact that the load transfer mechanism is dependent on the taper conditions, i.e. material hardness, roughness, type of roughness and many other factors. No two companies produce components with all of these variables being equal.

Conclusion

Current day ceramics are the result of much development and refinement over the last 30 years. Their benefit in reducing wear debris and its accompanying benefits to the young and active patient are established and well accepted by the global orthopedic community. The supporting evidence derived from the FDA type controlled clinical studies that have been completed in the United States provide strong proof of excellent safety and effectiveness by the ceramic on ceramic new generation modular system. These confirm the reality that today's ceramics are different, perform extremely well and have a very low incidence of clinical failure.

It is important for the surgeon using ceramic components to keep in mind that ceramic components are reliable and offer a very low incidence of complications when compared to other THR component related complications. In addition, when one considers overall short term risk of revision (2-5%) to a patient, the risk of a ceramic component failure adds little additional risk to infection, dislocation, early loosening and other types of mechanical failures. In fact, the mortality rate in primary THR is between 1 and 2 orders of magnitude higher than the ceramic component failure rate [20]. In many ways it seems that it is easier to accept many (25%) progressive failures related to polyethylene wear than one acute fracture from time to time [21]. If one takes this comment one step further, the mortality rate for revision surgery is nearly 3 times higher than that of primary surgery. If the use of ceramic on ceramic systems can prevent the need for revision in a large number of patients, then an indirect reduction in the substantial complications resulting from revision THR could be avoided.

Our analysis of the database of the world's largest supplier of these ceramic components offers tremendous insight and reassurance of the current day situation. The lessons learned from this analysis we feel should help the surgeon user in making a contribution towards increased reliability of the system he implants. Continued quality improvement, surgeon education and new developments in ceramic materials should result in an even further decline in ceramic component fractures. As such the benefits of low wear, low osteolytic potential and increased range of motion and stability that these devices can offer will benefit many future patients.

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5.2 Ceramic Manufacturing Overview

M. Dietrich

Introduction

The manufacturing of ceramic components for joint replacement implants is a very complex process consisting of a sequence of more than 60 manufacturing and quality assurance steps. The totality of these process steps produces the exceptional properties of implant ceramics as compared to the properties of ceramics for more usual applications.

High Performance Ceramic

Ceramics are frequently used in domestic or construction industry applications. For decades ceramicists have known that the so-called high performance ceramics have properties which are greatly superior to those of the commonly used ceramics. Among these high performance ceramics can be included:

- Cutting tools for use in the metal-machining industry. In particular, in the machining of cast steel the machining time is reduced many times as compared to the use of hard metal tools.
- Printed circuit boards for high power electronic applications. The ceramic printed circuit boards are so thin that they can be rolled and are to a large extent good thermal conductors, while remaining good electrical insulators.
- Piezo electric elements, which make use of special ceramics which exhibit the piezo electric effect. These are used for example for the control of fuel injection devices for use in diesel engines.
- Ceramic pipes for the chemical industry, in which aggressive liquids can be transported in extremely thin tubes with internal diameter of as little as 100 µm.
- Ceramic components as bearing surfaces for joint replacement implants. In this application use is made of the following outstanding properties of ceramics, namely very low wear, very high biocompatibility and excellent wettability. Furthermore, a very high tensile strength can be obtained, which is equivalent to that obtained with metal parts. The manufacture of these ceramic implants, in particular with regards to very high reliability, is described in the following section.

The Manufacturing Process for Ceramic Components for Joint Replacement Implants

The received raw material is high purity alumina powder produced from aluminum oxide. In addition a number of additives must be included in the raw material, some in very small quantities and some in the case of a our alumina composite material in quantities up to 25%. In the following the manufacture of aluminum oxide ceramic (trade name BIOLOX® forte) is described. The manufacture

of mixed oxide ceramic (specifically CeramTec's BIOLOX®delta) is different however only in a few work steps.

A basic illustration of the main work steps is shown in Figure 1.

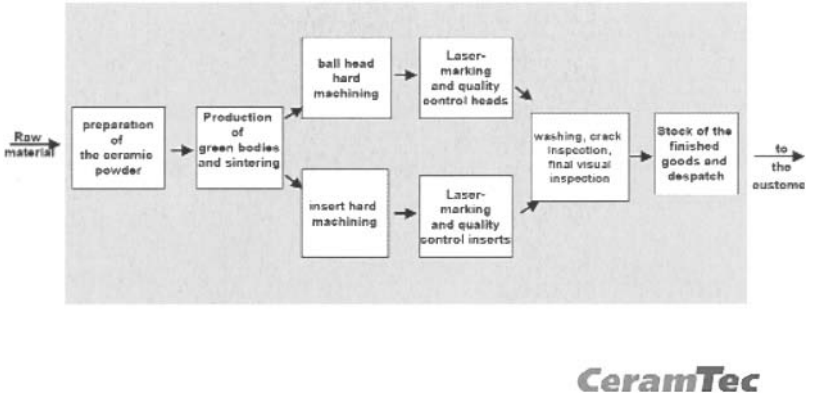

Figure 1:
Medical Product Division
The Manufacturing Process of Ceramic Components for Hip Implantation

After a thorough receiving inspection process the raw material is mixed with a number of additives that must be homogeneously dispersed throughout the material in order to be able to further process the powder. Using milling and stirring processes the raw materials are mixed in an aqueous solution until they reach the needed state of homogeneity. The use of special additives or binders makes it possible to achieve a good compaction prior to sintering. This step is followed by a spray drying process and a subsequent humidification process in order to produce a powder ready to be pressed.

Once the ready to press powder is obtained a variety of control and measurement processes are employed to ensure that the required parameters for the intermediate product are achieved. The parameters include for example the density, the grain size, the flow density and the specific surface to name only a few. In addition, in special laboratory conditions bending test samples are formed by pressing and are then sintered, in order to determine the mechanical strength of the samples after sintering.

The final step in this area is a quality gate review of all testing and documentation prior to release of the powder for subsequent steps.

The next manufacturing step is the manufacture of the compacted powder blanks. This is done by introducing the ready to press powder into high capacity hydraulic presses in order to produce pre forms or cylinders. These pre forms are then machined by computer controlled turning centers to near contour shape. These parts are known as "green parts" and they already possess the shape of finished parts (Fig. 2). However they are more than 20% larger in order to allow for the shrinkage that occurs during the sintering process as well as the required material removed during the hard machining processes.

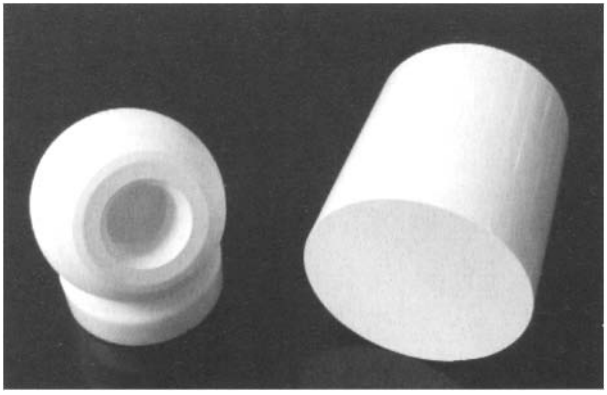

Figure 2:
Photo of a cylinder press and of a blank

In the ceramics industry a distinction is made between machining processes which are predominantly completed before sintering and those which are predominantly completed after sintering. Post-sintering machining is known as hard machining. It is similar to the machining of metals, however, because of the high hardness of ceramics, diamond tools and diamond grinding and polishing materials must be used.

In the case of our ceramic hip joint replacement implants important machining operations are performed both before and after sintering. While before sintering the ball heads and cup inserts acquire their basic shape, after sintering there follows a grinding process which achieves the high level of dimensional accuracy required in this critical application.

The "green parts" receive three sintering processes, pre-sintering, hipping and tempering. In the first, the so-called pre-sintering process, the above mentioned binders are removed by heating the "green blanks" to approximately 1500°C. The sintered blanks from this process do not yet meet the final end product specification.

In the second sintering step the blanks are again heated to a temperature of approximately 1500°C, however this time they are also subjected to an extremely high pressure of approximately 1000 bar (approximately 1000 times atmospheric pressure). It applies the principle of hot isostatic densification, also known as Hot Isostatic Pressing (HIPing). This very important sintering process increases the density, reduces the final grain size and enhances the mechanical properties of the blanks.

Next there is a third sintering step at roughly the same temperature which is necessary to obtain the required final properties of the ceramic. Afterwards the blanks are stored in the designated storage area. A few blanks are immediately processed further for the purpose of creating test parts which are then tested in order to confirm and permanently document compliance of the sintering processes and of the powder batches used with the appropriate specifications. Assuming all quality requirements are met, the batch can be released and the hard machining can begin.

The grinding and polishing processes which follow are in fact essentially the same for ball heads and cup inserts, but they require specific machines which are different in detail. Consequently the subsequent production is separated into lines for the hard machining of ball heads and lines for the hard machining of cup inserts (Fig. 1).

For technical and logistical reasons there are several lines for ball heads and cup inserts, which always consist of a series of grinding and polishing machines. Depending on the geometry, ceramic material, state of the technical development of the machines and of the technology at the time when the capital investment was made, the individual lines for ball heads and cups differ slightly. Taking into account the need for a high level of flexibility it is nevertheless the objective that a significant part of the cup and ball head product range can be produced on all machines and can still achieve the identical product specifications.

During the grinding and polishing processes in-process measurements are made on a regular basis to ensure that the quality requirements are met. Furthermore, after specified process steps the entire surface is checked by means of visual inspections. Furthermore regular washing of the parts is also included in the hard machining processes.

Upon completion of the hard machining every individual part is laser etched in the quality module. In addition to the geometry and manufacturer information each part is given an individual part number so that the individual part can be traced back to it's own manufacturing and quality records (Fig. 3).

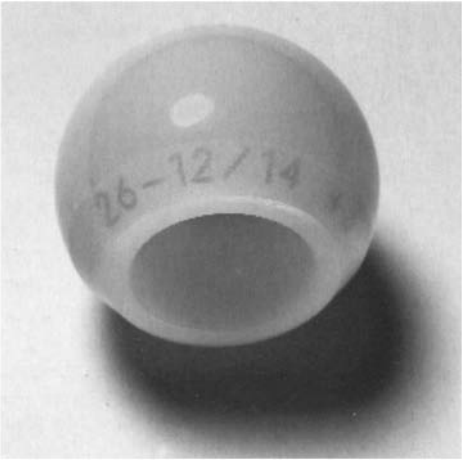

Figure 3:
Laser marking

The next step in the process is the measurement of the key dimensional characteristics of the parts with respect to the agreed dimensional values. For this purpose we utilize state of the art Zeiss coordinate measurement machines whose output measurements for critical dimensions is recorded as an integral part of our quality system.

In a subsequent "Proof test" to which almost every part is subjected, loading conditions, which are quite similar to those encountered in vivo, are simulated, but the load level is significantly higher, so that defects of the ceramic in highly loaded areas are detected. If technically and practically possible, the load will be chosen to be at such a level that a small percentage of the parts fail. If the percentage of failed parts in any given quantity exceeds a specified percentage, then the entire work order will be scrapped.

Once the parts passed laser etching, dimensional verification and proof testing, the hard machining processes are concluded.

The next step is the final processing module in which the parts are inspected, cleaned and packaged. Included in this area is the Zyglo or crack inspection process. In this process the parts are inspected for cracks which are so small that they cannot be detected either by means of the previous visual inspections or by means of a magnifying glass. In this process the parts are immersed in a special liquid which thanks to its creep properties and fluorescence provides extremely good crack detection using magnification and fluorescent light.

After the crack detection test the parts are washed and then subjected to a final visual inspection. In this inspection every part is carefully evaluated under magnification for any sort of surface scratch or damage under a magnifying glass by highly trained inspectors.

Next comes the packaging of the parts in appropriate bulk containers in order to identify the individual parts and protect them during shipping to our customers. Upon customer request CeramTec is able to package under clean room conditions.

Every production lot is accompanied by comprehensive documentation on the production, testing and quality verifications conducted on each product as it went through the entire manufacturing process.

Conclusions

The manufacturing process for ceramic components for implants is a very complex process in order to meet the extremely high quality requirements, both in production and also during the entire lifetime of the implant. CeramTec's manufacturing process has been well tested over the last 32 years that we have been involved in the medical field.

We have now produced over 4,000,000 ceramic components that have been implanted around the world. This high number is excellent proof of the outstanding reliability and performance achieved by our components as a result of our deep commitment to offer the highest reliability possible in our ceramic components.

This extremely high level of product safety has been achieved by means of:

- A systematic and extensive product development process
- Safe and reproducible manufacturing processes
- Comprehensive state of the art quality system
- A precise and conservative change control system

Only the sum of all these crucial points can guarantee the high level of product safety, which at the same time satisfies and even exceeds all regulatory requirements, including in particular those of the FDA.

Also we should mention the very good collaboration which we have with the manufacturers, who integrate our ceramic components into their complete hip joint replacement systems and with the orthopedic surgeons, who collaborate closely with us in the same way that they do with the hip system manufacturers. These successful collaborations are further reasons for the high product reliability achieved by today's ceramic components produced by CeramTec.

5.3 State of the Art in Ceramic Manufacturing

R. Lenk

Introduktion

Ceramics are among the oldest materials in the service of mankind. First of all the ceramic materials which were used were predominately natural, silicates in origin, i.e. mixtures of clay, feldspars and quartz. In the twentieth century the range of available materials was enlarged by the addition of synthetics, as for example oxides, carbides, titanates and nitrides. These materials also known as technical ceramics exhibit a series of exceptional properties such as high hardness, high strength, good thermal and chemical stability and various functional properties. Well known for example is the piezo electric effect which makes possible the conversion of mechanical pressure or sound into electrical signals and vice versa. Today by means of multiple and yet unique combinations of mechanical, electrical, optical and chemical properties modern ceramic materials open up completely new application possibilities. Evidence of this point are many innovative examples taken from energy technology, from mechanical, construction or automotive engineering, as for example high temperature fuel cells, cutting tools and brakes for Formula 1 racing cars.

The chemical composition and structure determine the properties of high perform-ance ceramic materials. The spectrum of structural characteristics extends from open porosity (e.g. for filtration applications or as carriers for catalysts) to porosity-free and 100% dense (e.g. for sealing rings in water pumps or bath mixers). For high performance ceramics not only the particle size of the original powder, but also the grain size of the microstructure of the material are often in the region of one micron in size or finer. If the region is in nanometers, then the properties such as hardness and strength become especially good. If the grains are smaller than the wavelength of light, then aluminum oxide ceramic can even become transparent. In many cases the original powder is dosed with additives in order to modify the material properties or the formation of the material structure during the sintering process.

Ceramics are produced using powder technology. The material is created by means of material transport processes which occur during sintering and which initiate within the powder package at high temperature, provided the particle size is small (and the associated sintering activity is high) and provided the inter-particle separation is small. The resulting material properties are determined by the fineness and homogeneity of the post-sintering microstructure. For this reason very pure and very fine powder is used. This raw material powder is in the form of undefined agglomerates and first of all it must be prepared. To create a material of the desired quality various powders and sintering additives must be mixed without contamination until they are homogeneous. In the powder pressing process defined granules with optimized processing properties are used, so that homogeneous densification can be achieved both in pressing and in sintering. Damage to the material as a result of processing either in the green state or post-sintering must be reduced to a minimum. All production processes must be held within tight tolerances and must be extensively controlled. There are many

possibilities for quality assurance in the characterization of both the process and the material itself.

In this way by means of the design of the structure and the optimization of the tech-nology high performance materials have been developed, whose properties with re-gard to reliability and longevity need fear no comparison. Take, for example, ceramic roller bearings, which have a clearly longer working life than the conventional steel equivalents, which reduce both friction and weight, which have good corrosion resistance and high temperature stability and which are very suitable for lubricated and dry use. So it is not surprising that today nine out of ten Formula 1 racing car teams – including that of the world champion of the past 6 years – rely on ceramic roller bearing technology and that 90% of all microprocessors and D-RAMs memory modules worldwide are produced with the help of high performance ceramic roller bearing technology. A Formula 1 front wheel bearing, which lasts about 2,000 km in a race, lasts about 200,000 km in a production vehicle such as a Porsche 911 and at the same time gives a weight reduction of 85%. In all three main engines of the US Space Shuttle silicon nitride cylindrical rollers were employed in one of the fastest rotating roller bearings in the world. (The speed of rotation was 3.5 million mm x min^{-1}. The bearing was lubricated with liquid hydrogen at a temperature of - 253 °C). These bearings achieved a 60 times higher service life than the equivalent steel bearings and were suitable for use in 12 shuttle missions, rather than in a single one, as was the case for steel bearings [1].

Project Description

Ceramic implants for hip joint replacement belong together with ceramic high per-formance roller bearings and many other products to the group of already established and reliable high technology products made from high performance ceramics. CeramTec AG is known as the leading manufacturer worldwide of ceramic ball heads and cup inserts under the trade name BIOLOX®.

The failure rate of BIOLOX-*forte* ball heads in the last few years was between 0.004 and 0.02% depending on ball head diameter. The failure rate of BIOLOX-*forte* (Cer-alock) cup inserts is even lower [2]. The identified failure rate has continued to fall from the time of the first introduction of alumina as a bioinert ceramic material for use in hip joint replacements (1975). The reason for this reduction was the improvement of the material (the use of high purity powder, the development of finer grain structure) together with the improvement of the technology (hot isostatic pressing, alternative marking processes). With the development of BIOLOX-*delta*, a fine grained mixed oxide ceramic, the strength of implant ceramics has been once again significantly increased.

In order to evaluate more comprehensively possible risks in the manufacturing proc-ess, CeramTec AG initiated a project with the Fraunhofer Institutes IKTS in Dresden and IPT in Aachen. The objective of this collaboration was to determine and specify possible risks in the manufacture of hip joint implants made from BIOLOX-forte and BIOLOX-delta. By means of the perspective of an independent party with applicable technical expertise it is intended that CeramTec's existing internal and external evaluations may be enlarged upon, so that the remaining residual risks can be identified and so that appropriate risk reduction actions can be initiated.

Method

The appraisal of the Fraunhofer Institute was made taking into account the descrip-tion of the manufacturing processes as specified in the in-house manufacturing standards for "Powder Preparation", "Green Part Production", "Material Development / Sintering", "Hard Machining / Measurement of Dimensions" and "Quality Management / Production Logistics". Not only were the risks evaluated with respect to their technical relevance, but also further risks were taken into consideration. The analysis of ceramic implant failure statistics showed that the cause of existing failure cases can in principle lie both within production and elsewhere. Even if the analysis of the existing cases reveals that no material or production defect was the likely cause of failure, it may under certain circumstances be required to verify that the product was manufactured without defect and that complete production and quality assurance records were available. The risks associated with this verification process were also evaluated.

The assessment evaluated the special features which occurred in the manufacture of ball heads and cup inserts. Over the entire manufacturing process, especially with reference to the formation of the material itself, special attention was paid to the manufacturing of BIOLOX-*delta*, because for implants of this quality the long term experience with this material was less than with BIOLOX-*forte*. The assessment of the design and product development processes for individual components and for combinations of components did not however form a part of this assessment.

Results and Discussion

Expert teams were formed consisting of scientists from the Fraunhofer Institute (eleven in all) plus employees of CeramTec AG having the necessary responsibility. The five tasks were performed in parallel and in various phases and were evaluated regularly and in such a way that all the special topic areas were encompassed. First in the "Process Analysis" phase the actual state of the manufacturing processes in the relevant areas of production at CeramTec were inspected and documented. In the second phase, the "Process Description", the sequences of manufacturing steps were investigated for possible deficiencies which would be relevant to the later use of the components in the human body. In the "Risk Analysis" phase possible residual risks from identified sources of defects within the manufacturing processes were defined, and in doing so a special importance was assigned to "Risks which could lead to Implant Failure". The residual risks were compared both within the individual special topic areas and also were compared with identified risks associated with other topic areas. Finally in order to obtain a complete description or portfolio of the risks each residual risk was assigned an individual weighting factor and they were all viewed visually [3].

In this way all determinable risks could be evaluated using a single method with re-spect to their probability of occurrence and to the significance of the resulting defect in a worst case situation, so that a comprehensive, special topic area encompassing evaluation of their potential could be obtained. Next the risks with high and middle potential were evaluated, having assigned to them individual weighting factors which took into account the actual likelihood of the risk causing damage and the likelihood of the resulting defects being detected. Finally in this

way an evaluation of the remaining residual risks was made possible. The risks with middle risk value were evaluated with respect to their impact one upon another. In this way both risks which have a relatively high active influence value and also those which have a strong mutual effect were identified.

All identified risks in the manufacturing process are only residual risks, whose prob-ability of having an effect upon patients in the form of a ceramic implant failure, be-cause of the high quality standard and the 100% testing, can be considered as very small. As a result of the combination of the manufacturing standard, the procedures, the work instructions and the testing which is done the manufacturing processes are in their entirety very well controlled, which is also apparent from the high level of product quality which is achieved. The Fraunhofer Institute scientists, who took part in this project, based on their extensive experience can confirm that in the manufacture of hip joint ball heads and cups made from BIOLOX-*forte* and BIOLOX-*delta* there is a high level of quality awareness.

Potential causes of implant failure in vivo, in addition to the manufacturing processes (material, design and manufacture), are the further use of the implants including their approval for use in combination with other products. The risks associated with this use are higher than all others. While those risks which have been identified in the manufacturing process are considered to have an exceptionally low effect on patient safety, as confirmed statistically by the retrospective data and analysis of the existing ceramic implant failures for BIOLOX-*forte* products, it is however theoretically possible that as a result of sudden, undiscovered manufacturing non-conformities both single defects and also, depending on the actual lot size, in unfavorable circumstances multiple defects could arise. In practice, however, the latter possibility can be eliminated, as the analysis of the measures to assure quality before, during and immediately after product manufacture has confirmed; from the material ageing process the residual risk is unknown but of a low magnitude. The risks, however, associated with the use of the product are in certain circumstances high, but as a rule lead to single failures and are randomly occurring single events, so that the risk of multiple failures can be excluded. The likelihood that the rate of ceramic failures rises significantly above the 1:10,000 level is low. The possibility that multiple failures may occur, which result from defective manufacturing processes, can be practically eliminated.

The procedures and methods which are used in the development, manufacture and testing of ceramic implants precisely define the status of the technology. The costs associated with the control of the manufacturing and quality assurance processes are exceptionally high, but because of the product safety requirements they are necessary. Compared with any other high technology products made from high performance ceramics, ceramic ball heads and cup inserts for use in hip joint replacement demonstrate best of all that competent and responsibility-conscious processing using currently available materials and technologies makes possible the safe application of high performance ceramics.

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SESSION 6

New Applications for Ceramics

6.1 Primary Total Knee Replacement with a Zirconia Ceramic Femoral Component

B. S. Bal, D. D. Greenberg and T. J. Aleto

Abstract

This report presents the minimum two-year clinical results with a zirconia femoral component in a series of primary total knee replacements (TKR) performed by one surgeon. A posterior stabilized TKR was performed for degenerative arthritis in 36 patients (39 knees). All components were cemented; these included a femoral component made of yttrium-stabilized zirconia and a cobalt-chrome alloy tibial baseplate. The ultracongruent bearing insert and patella were made of ultra high molecular weight polyethylene (UHMWPE). Mean WOMAC indices improved from 41 to 86, and mean Knee Society Scores (KSS) improved from 40 to 92. Revision to constrained implants was required in one patient who developed persistent knee instability after trauma. These early results are encouraging, but larger studies with much longer follow-up data are needed to determine whether ceramic bearings will prove to be a suitable alternative to metal, and to define the role of alternative bearings in total knee replacement.

Introduction

The advantages of ceramic bearing surfaces in terms of superior lubrication, friction, and wear properties compared to cobalt-chrome alloy (CoCr) surfaces in total joint arthroplasty are well recognized [1,2]. Laboratory and clinical data have demonstrated that ceramic bearings are associated with fewer wear particles that incite a less intense inflammatory host immune response than the metal-on-polyethylene articulations that are the accepted standard in total hip and knee replacement surgery [1,3,4].

Periprosthetic osteolysis and aseptic loosening are the biologic and clinical manifestations of the body's reaction to particulate wear debris generated from the metal-on-polyethylene articulation [5]. Ceramic bearings are attractive because less wear and inflammation are expected to result in a reduced incidence of periprosthetic osteolysis and aseptic loosening, resulting in artificial joints with a longer service life [1,3,4]. Ceramics have other advantages that relate to their role in orthopaedic bearings. Surface lubrication is improved in ceramics because of their hydrophilic nature, thereby decreasing adhesive wear [6]. The hard surface of ceramic bearings minimizes scratching and abrasive wear [3]. Also, speculation exists that metal particles in the body may be associated with the potential for carcinogenesis and delayed hypersensitivity reactions [7,8]. If these concerns are ever validated in future investigations, ceramic bearings could offer the additional advantage of avoiding metal ion release.

While alumina and zirconia ceramic bearings have been used in artificial hips in the United States, experience with ceramic biomaterials in total knee replacements is limited [9-11]. The purpose of this study was to evaluate the safety

and efficacy of a yttrium stabilized zirconia ceramic (Y_2O_3-ZrO_2) femoral component at a minimum follow-up of two years in a consecutive series of primary total knee replacements performed by a single surgeon.

Materials & Methods

Patient Demographics

Thirty-six patients (39 knees) who met enrollment criteria for a feasibility trial sponsored by Encore Orthopaedics, Inc. (Austin, Texas) were included in this study, following approval by our Institutional Review Board. Exclusion criteria for entering patients into the study included the following: skeletal immaturity, greater than or equal to 70 on preoperative Knee Society Score (KSS), previous knee surgery that had adversely affected bone stock or prior total knee replacement (TKR), post-patellectomy, insufficient collateral ligaments (as judged by the physician), mental conditions that could interfere with the ability to give informed consent or willingness to fulfill the study requirements, active infection, pregnancy, or materials sensitivity. A primary TKR was performed for degenerative joint disease in each patient.

Operative Technique

A standard medial parapatellar approach was used in each case, with sacrifice of the posterior cruciate ligament. Balancing of the collateral ligaments using the flexion and extension gaps was carried out using standard techniques, after the distal femoral and proximal tibial cuts had been made using intramedullary instrumentation. All components were cemented in place using Surgical Simplex P bone cement (Stryker Corp., Limerick, Ireland) the components included a cobalt-chrome alloy tibial base plate, and a three-peg polyethylene patella (Foundation Knee System, Encore Orthopaedics Inc.). The femoral component was made of solid yttrium-stabilized zirconia (Y_2O_3-ZrO_2) manufactured by SGCA Desmarquest, France, and distributed by Encore Orthopaedics Inc. (Fig. 1). In this ceramic material, the zirconia grains are stabilized by yttrium oxide. An ultra-congruent polyethylene insert was used in each knee to substitute for the posterior cruciate ligament. All procedures were performed by the same surgeon, who was experienced in performing the identical procedure with a cobalt-chrome femoral component until this study was initiated.

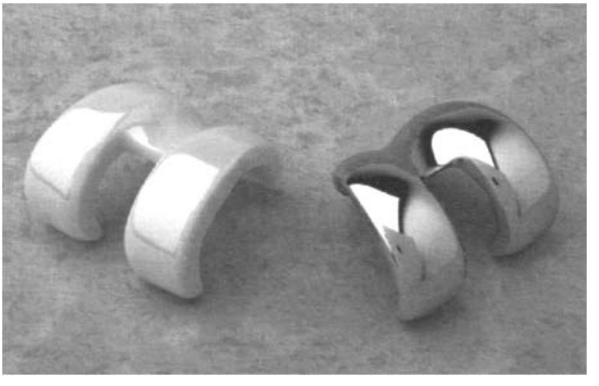

Figure 1:
Zirconia femoral component, left; with the cobalt-chrome counterpart, right (Foundation Knee System, Encore Orthopaedics, Austin, Texas).

Antithromboembolic prophylaxis consisted of dose-adjusted oral warfarin and pneumatic compression pumps. Postoperative rehabilitation consisted of full-weight bearing, and rehabilitative exercises associated with a standard total knee protocol.

Data Collection and Outcome Variables

All patients were evaluated preoperatively, six months after surgery, and annually thereafter. Data collected at these intervals included the KSS, the function score, and the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index. The KSS is made up of pain, stability, and range of motion. Flexion contracture, extension lag, and malalignment are deducted from the total score. The maximum score is 100 points. A score of <60 points indicated a poor result; 60 to 69 points, a fair result; 70 to 84 points, a good result; and 85 to 100 points, an excellent result [12]. The function score includes distance walked, support, and stairs. The maximum score is 100 points and represents a patient who can walk an unlimited distance and go up and down stairs without support. The WOMAC was used as a self-administered questionnaire in accordance with the developers' instructions [13]. The index consists of 24 questions probing clinically important symptoms in the areas of pain, stiffness, and physical function. Individual scores are summed to form a raw score ranging from 0 (worst) to 96 (best). These raw scores are then normalized to produce a reported WOMAC score between 0 (worst) and 100 (best).

The primary endpoint was survivorship, which was defined as none of the devices being revised.

Radiographic Evaluation

Radiographs were made preoperatively, immediately after the operation, at six months, and at one-year intervals thereafter. The radiographs included anteroposterior, lateral, and sunrise patellar views of the knee only; full-length from the hip to ankle were not obtained. Preoperative and postoperative radiographs were assessed for alignment of the limb and the presence and location of any radiolucent lines at the bone-cement interface, according to the recommendation of the Knee Society [14]. Radiographic failure was defined as a complete radiolucent line >2mm wide at the bone-cement interface or >3 degrees or >3mm migration of the component.

Statistical Analysis

The paired *t*-test was used to compare the variables of preoperative and postoperative clinical scores and range of motion scores. In all analyses, p-values less than 0.05 were considered to be significant.

Results

Overall Demographics

Two patients had died of cardiac disease before the minimum two-year follow-up. One patient withdrew from the study, and refused further followup. One patient underwent revision surgery because of a fall from a ladder that led to persistent medial instability of the knee. After conservative treatment failed, this knee was revised with constrained components. No damage to the retrieved knee components was observed during the revision procedure. Excluding these four patients, thirty-two patients (35 knees) were available for follow-up at a mean duration of 31 months (range 24-40 months). In this group, the mean

patient age was 59 years (range 29-80 years); with 23 females and nine males. The mean body mass index (BMI) for all patients was 36 (range 19-55) [5].

Clinical Results

Mean WOMAC indices improved from 41 preoperatively (range 15-78) to 86 postopertively (range 41-100), and this difference was statistically significant ($P < 0.05$). Mean KSS improved from 40 prior to surgery (range 9-66) to 92 (range 87-100) after the procedure; again, the difference was significant ($P < 0.05$). Mean function scores likewise improved significantly from 42 (range 5-80) to 69 (range 30-100) ($P < 0.05$). The low function score of 30 at follow-up was in a patient who had developed additional co-morbidities unrelated to the knee arthroplasty since the index procedure.

The clinical result was excellent for 34 knees; and good for one knee. The improvement in patient scores resulting from the procedure is illustrated in Figure 2. Follow-up radiographs did not show any evidence of change in implant position, nor any radiolucent lines or osteolysis around any of the prosthetic components.

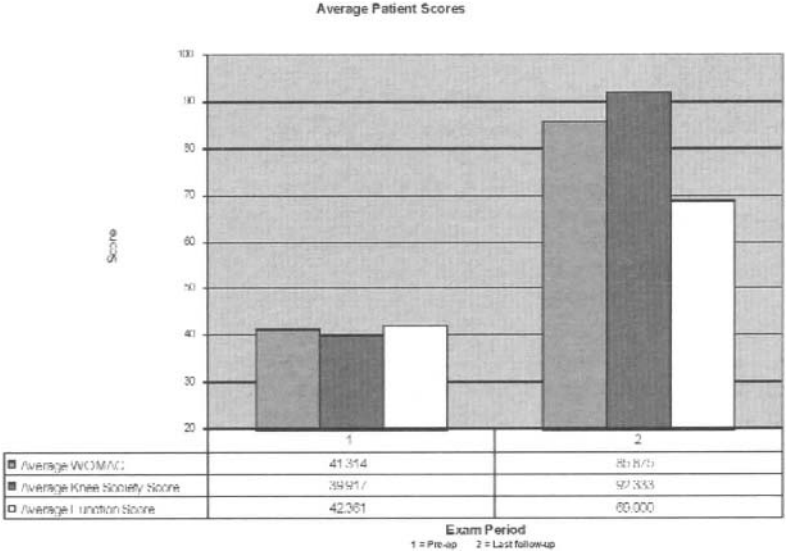

Figure 2:
Average Patient Scores

Complications

None of the femoral components failed catastrophically at this short duration of follow-up. One patient had a deep venous thrombosis following the procedure.

In addition to the revision procedure performed for instability, two additional patients underwent surgery since the index procedure. In one patient, persistent medial pain and mechanical symptoms developed after a twisting injury several months after surgery. When symptoms proved refractory to conservative management, arthroscopy of the knee joint revealed a tense fibrotic band that extended from the infrapatellar area to the medial retinaculum. This pathologic tissue impinged against the prosthetic femoral component during knee flexion. Although the patient obtained relief following arthroscopy, she refused further participation in this study. In one other patient, superficial wound drainage

required irrigation and debridement of the joint with retention of the components before the patient left the hospital following the index procedure. No evidence of deep sepsis was encountered in this patient.

Discussion

Although the long-term results of total knee replacement are very durable in most reported series, aseptic loosening related to polyethylene wear is the ultimate long-term failure mode of TKR. In theory, alternative bearing surfaces, with lower wear rates, could therefore improve the longevity of total knee replacements by decreasing bearing wear and reducing the incidence of periprosthetic osteolysis and aseptic loosening [5].

Laboratory wear data comparing zirconia ceramic and CoCr femoral components with a 10-mm-thick tibial polyethylene component has demonstrated reduction of wear with the polyethylene-ceramic coupling [15]. The femoral component used in this investigation has demonstrated at least a 50 percent reduction in ultra-high molecular weight polyethylene (UHMWPE) wear, compared with a cobalt-chrome-molybdenum (CoCrMo) component of the same design, with deeper and more numerous scratches observed on the metal component after five million cycles in a knee simulator [16]. The wear performance of oxidized zirconium is also superior to metal; with an eighty-five percent reduction in UHMWPE wear compared to CoCrMo [17]. Other studies have also reported reductions in polyethylene wear with ceramic counterfaces articulating against polyethylene experimentally [17,18], and in several knee simulators [17,19,20].

A ceramic femoral component in a total knee replacement is a hard-bearing surface that resists roughening and provides a very low-friction articulation with ultra-high molecular weight polyethylene, reducing abrasive and adhesive wear [16,17]. Early clinical data with such components can provide limited but useful information about their efficacy and safety; long-term studies are necessary to confirm whether the reduction in bearing wear will result in significant improvements in component longevity in vivo. In a randomized prospective study comparing femoral components of the same design but fabricated either of cast CoCrMo or oxidized zirconium, Laskin demonstrated comparable clinical outcomes in the two groups, with no adverse effects related to the ceramic surface at the two-year evaluation [21]. The oxidized zirconium femoral component in that investigation consisted of a ceramic surface on a zirconium-niobium prosthesis [17,21]. In contrast, the component used in the present investigation was a monolithic, all-ceramic component made of yttrium-stabilized zirconia. The early clinical and radiographic results reported here reflect the typical outcomes of total knee replacements in terms of pain relief and improvement of function, comparable to those seen with traditional metal-on-polyethylene total knee replacements. No complications related to the ceramic device were encountered at this early follow-up interval.

The brittle nature of ceramics and the inability of ceramic materials to withstand high-impact tensile forces is of concern in orthopaedic applications [5]. Although breakage of the ceramic femoral components in total knees has yet to be reported, precautions were taken during placement of the zirconia component on the distal femur in this investigation. The precautions consisted of careful preparation of the distal femur so that the ceramic component could be

implanted without forceful impaction with a hammer. The ceramic component was implanted using direct pressure in each case, with final seating on the distal femur achieved by reducing the knee in extension. These precautions were exercised even though previous biomechanical data have demonstrated the ability of ceramic components to withstand forces well in excess of those generated at the knee joint without failure [11].

Of note, clinical reports describing total knee replacements with ceramic components, at follow-up times of up to 18 years after the procedure, have yet to identify catastrophic component breakage as a mode of failure [9,11,22,23]. Most recently, Akagi reported the results of 223 consecutive primary posterior-stabilized knee replacements with an alumina ceramic femoral component, without any instances of ceramic component breakage at four to nine years after surgery [9]. The alumina ceramic femoral component in that study had a surface roughness that was substantially less than that of a cobalt-chrome component (Ra=0.02 micrometer for alumina versus Ra=0.05 micrometer for the metal component).

Zirconia ceramics exist in three phases of crystal structure (monoclinic, tetragonal,and cubic), and the transformation from one phase to another occurs at very high temperatures [24]. The material used to make the femoral component used in this series is referred to as yttrium-stabilized tetragonal zirconia (Y-ZTP), which has the highest mechanical strength of the three phases and is used for surgical applications. Phase transformation of Y-ZTP can be induced at a relatively low temperature in the presence of water and pressure [25]. Transformation from the tetragonal to the monoclinic phase involves a volume expansion of 3-4% which seals cracks within the material and discourages their propagation in the tetragonal phase [24,26]. If extensive transformation of Y-ZTP to the monoclinic phase occurs however, this crack resistance advantage is lost, and the implant may become susceptible to surface damage and increasing surface roughness [27]. It has been postulated that femoral heads made of Y-TZP undergo an aging process *in* vivo from transformation of the surface layers into the monoclinic phase, with increased susceptibility to wear and surface roughness [26-28]. As a result, while Y-TZP ceramics possess superior hardness and compression strength than alumina at the time of implantation, changes related to phase transformation *in* vivo could make this material less desirable for total hip replacements [29]. Whether or not these concerns apply to Y-TZP in total knee replacements is unknown at the present time.

Improved survival and reduced bearing wear are desirable goals as total knee replacement surgery is offered to younger, heavier, and more active patients. This patient population may challenge the excellent long term results of total knee replacements with CoCrMo articulating against UHMWPE [30]. A batch of defectively manufactured zirconia femoral heads was recently associated with premature bearing failures in total hip replacements [31] but there is no evidence that the biomaterials in this study had any relationship to that report. Clinical trials with monolithic yttrium-stabilized zirconia femoral components in total knees are still ongoing in the U.S. [32]. Larger trials and longer follow-up durations will be essential to validate the performance of ceramic components in total knee replacements, and to find out whether or not this technology has a role in total knee replacement. The present trial only demonstrates the short-term feasibility, efficacy, and safety of ceramic–polyethylene articulations in a small series of total knee replacements.

Acknowledgements

The authors wish to thank Luke Buhrmester, BS, and Cary Sanders, BS, for their help in collection of data for this study.

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6.2 Alternative Bearing Surfaces

M. Manley and K. Sutton

Introduction

The articulating joints of hip prostheses generate wear debris, and accumulation of wear particles in the local tissues can result in osteolysis, which may ultimately require replacement of the prosthesis. The purpose of new hip bearing materials is to extend implant life by substantially decreasing the amount of wear debris generated thus greatly reducing, or even eliminating, the incidence of osteolysis.

In past decades, surgeons focused on achieving excellent implant fixation during total Hip Arthroplasty (THA) because good initial fixation generally was considered to be a reliable predictor of the future performance of a device. In the 1990's, it became clear that polyethylene wear debris generated with time by the articulating bearing surface of a hip implant was associated with the occurrence of osteolysis, often leading to reoperation and possibly shortening the useful life of an implant [12,14,17,20]. As average life expectancy continues to increase and younger and more active patients have THAs, limiting the amount of wear debris could help extend the average life expectancy of an implant [4,5,19].

Bearing combinations include polymeric, ceramic, metallic, and carbon fiber PEEK materials. These materials are categorized as hard or soft, with polymers classified as soft and ceramic and metallic materials classified as hard. Advances in the existing class of hard/soft bearings have been made also. Each bearing combination has strengths and potential weaknesses; however, all of these new bearing combinations exhibit wear that is reduced compared to the wear of earlier hip bearings.

Hard/Soft Bearings

Wear Mechanisms

A direct relationship has been reported between the level of bearing wear and the occurrence of periprosthetic osteolysis [10]. Wear greater than a threshold value of 0.1 mm/year appears to increase the incidence of osteolysis, while wear substantially below the threshold value makes osteolysis uncommon. However, the relative contribution to joint wear from the head and cup, the level of total wear, and the wear particle size may be different for different bearing types.

To address the problem of polyethylene wear and subsequent debris mediated osteolysis, polyethylenes with improved wear performance have been developed [11,16,28]. Crosslinking of the polyethylene material has been shown in the laboratory to decrease the polyethylene wear rates up to 90% over conventional polyethylene. Cross-linked polyethylenes with enhanced resistance to wear now are in use clinically, but long-term results still are unknown [9,13,15,18].

Femoral Head Materials

Cast or forged cobalt chromium alloy predominates as the choice of femoral head material for articulation against UHMWPE. The wear of this combination is the standard against which all other bearing combinations are measured.

Alumina and zirconia ceramics have both been used as femoral head materials with polyethylene cups. One reason is that the hardness of ceramic heads reduces the incidence of scratching and surface damage, which is believed to reduce polyethylene wear. However, laboratory and clinical studies provide conflicting reports on whether the wear of polyethylene is indeed reduced. Alumina is used widely. Zirconia has dropped from favor due to reports of phase transformation of the material in vivo, protruding ceramic grains, surface roughening, and increased polyethylene wear rates. Recently, oxidized zirconium femoral heads have been introduced. Laboratory studies indicate lower polyethylene wear and resistance of the femoral head surface to abrasion. The clinical experience is too short to indicate whether this material is superior to those already in use.

Conventional UHMWPE

The majority of UHMWPE components are machined from powder converted into solid form. The final step in the manufacturing process is sterilization. Although ethylene oxide (ETO) was used initially, and gas-plasma more recently, the vast majority of polyethylene components implanted in the period 1975 to 1995 were sterilized by gamma radiation (2.5 to 4 MRads) in air. Sterilization of UHMWPE by gamma radiation introduces crosslinking of the polyethylene molecules from the interaction of the free radicals formed during irradiation.

Laboratory and clinical studies have shown improved wear resistance in the hip compared to UHMWPE sterilized by non-ionizing means (ETO or gas plasma), as the latter methods do not produce crosslinking. Gamma air sterilized UHMWPE components demonstrated excellent clinical outcomes in a variety of settings. However, by the early 1990's, research on the structure and properties of UHMWPE identified the potential for oxidation of polyethylene gamma sterilized in air due to the existence of free radicals that had not crosslinked. Oxidation reduced mechanical properties. Consequently, some manufacturers changed the sterilization process to gamma irradiation in an inert atmosphere, such as nitrogen, argon, or vacuum. The lack of oxygen prevented the oxidation process from commencing. Other manufacturers either switched to non-ionizing sterilization methods or continued with them, despite the potential downside of lower wear resistance.

Research on the link between polyethylene structure and wear continued. Further exploration of the role of crosslinking in reducing wear led to the development of the current highly crosslinked polyethylenes that were introduced in the late 1990's.

Highly Crosslinked UHMWPE

Because crosslinking reduced wear, it was theorized that increased crosslinking would result in an even more wear resistant UHMWPE. In these new processes, crosslinking results from using higher doses of radiation followed by or combined with heat to encourage the crosslinking process. The key variables are radiation dose and the temperature of heating to form the crosslinks. Heating above the polyethylene melting range is known as "remelting" and heating below the melting range as "annealing". Manufacturers have introduced different highly crosslinked polyethylenes by making different choices in these variables, e.g., radiation dose and selection of remelting or annealing.

Because UHMWPE is a semi-crystalline polymer, its mechanical behavior is affected by its crystalline morphology. Heating UHMWPE above its melt temperature eliminates free radicals, but changes material morphology. Heating UHMWPE to a point below melt temperature preserves its morphology and thermal processing history, but can leave some free radicals behind. In general terms, highly crosslinked UHMWPE that is annealed maintains its mechanical properties but contains free radicals, while remelted materials have lower mechanical properties but do not contain detectable free radicals.

Laboratory studies demonstrate that highly crosslinked polyethylenes have significantly lower wear rates than conventional polyethylene. Although highly crosslinked polyethylenes have been in clinical use for only five years, early clinical measurements indicate that in vivo wear rates are greatly reduced with these new materials.

Hard/Hard Bearings

Metal-Metal Bearings

Metal-on-metal bearings have extremely low wear compared with metal-on-polyethylene bearings. Although good clinical results have been reported with metal-on-metal bearings [1,24], the long-term effect of accumulated metal ions in otherwise healthy tissue is unknown [23,26,27]. Negative effects of elevated metal ion levels in people with compromised kidney function have been reported [3,21].

Concerns regarding osteolysis caused by polyethylene wear debris created a renewed interest in metal-on-metal (M/M) bearings for total hip replacement. M/M designs were introduced 40 years ago, but their clinical performance overall was compromised by both poor implant and poor bearing design. However, some of these original M/M hips were found to be well functioning after 20-30 years in vivo. The hypothesis is that the survivors of these original hips represent the potential for contemporary M/M hips if design and bearing deficiencies are addressed. Consequently, manufacturers made improvements to the design of the so-called "first-generation" M/M hips.

Laboratory studies conducted on these second-generation M/M components showed decreased wear compared to that of first-generation M/M components. Measurements on second-generation components retrieved after clinical use indicate comparable levels of wear to first-generation long-term survivors. The volume of wear debris released by M/M bearings is about 100-200 times lower than that of traditional polyethylene gamma sterilized in air. The actual M/M wear rate seems dependent on the type of cobalt chromium alloy used, its surface finish, bearing clearance and bearing sphericity. It appears that the bearing design parameters rather than the alloy play the most important part in determining the level of wear. This is because the bearing size, clearance, sphericity and surface finish determine the degree of fluid film lubrication attained. Alloy characteristics may be of consequence only if contact between the articulating surfaces occurs.

Ceramic/Ceramic Bearings

Alumina ceramic offers several theoretical advantages over other hard bearing materials. Alumina ceramic is extremely hard and scratch resistant; it has a low coefficient of friction and excellent wear resistance; it is more hydrophilic

than either polyethylene or metal and provides improved lubrication; there is no potential for metal ion release; and alumina particulate debris is less bioreactive than either polyethylene or metal debris [6,22,25]. Excellent early clinical results have been reported [2,7,8].

Early designs of alumina-on-alumina hips that were introduced over 30 years ago had unacceptable performance due to wear and fracture. These shortcomings were due to designs that allowed stem impingement on the ceramic together with the relatively poor mechanical properties of early alumina (first generation) materials.

Second generation alumina ceramics were introduced after 1977. The average grain size was reduced and porosity was lowered resulting in improvements in strength. In 1980, the U.S. Food and Drug Administration allowed alumina ceramic bearing components (Autophor/Xenophor, Osteo, Selzach, Switzerland) to be marketed in the U.S. based on European data. Despite improved alumina properties, this design was unsuccessful because of pain, neck-socket impingement, ceramic fracture, and loosening. These data indicated that the improved bearing properties cannot compensate for the design shortcomings of a hip implant.

Over the past two decades, there has been a substantial improvement in prosthesis design, implantation technique, and the quality of the alumina components. Third generation alumina materials were introduced in 1994 (e.g. Biolox Forte, CeramTec, Plochingen, Germany).

Several hip simulator studies conducted in the late 1990s found a steady-state wear rate for alumina-alumina bearings between 1 to 2 μm/million cycles, which is equal to or lower than that of M/M bearings. Wear measurements on retrievals of first- and second-generation alumina components demonstrated a strong direct relationship between wear and grain size.

The wear debris from alumina-alumina bearings is comparable in size to metallic wear debris from M/M bearings. However, in contrast to metallic debris, there is no ion release and the debris appears to be well tolerated. Alumina-alumina total hip prostheses were introduced to the United States via clinical trials in the mid-1990's and were approved by the Food and Drug Administration in 2003. The results have been good at these short to medium follow-up periods.

Future Directions with Bearing Materials

At the present time, highly crosslinked UHMWPE materials represent a compromise in that polymer mechanical/fatigue properties can be largely maintained with the presence of free radicals, or free radicals can be eliminated at the expense of mechanical/fatigue properties. The current direction of research is to determine whether these limitations can be overcome, resulting in a material with no detectable free radicals but with excellent mechanical and fatigue properties. The results to date are highly promising.

Longer development efforts will focus on composite materials such as polyurethane, polybutylphthalate, and carbon fiber PEEK as bearing materials. However, it is most likely that any future advances in bearing technologies will be design driven by design rather than material.

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6.3 Wear of a Novel Ceramic on Metal Bearings for Hip Prosthesis

J. Fisher, P. Firkins, J. L. Tipper, R. Farrar and E. Ingham

Introduction

Concerns about polyethylene wear debris induced osteolysis has led to renewed interest in alternative bearing couples such as ceramic on ceramic and metal on metal. Conventionally, bearing couples in artificial joints, as well in engineering systems, are comprised of different materials. They frequently have a harder surface and a sacrificial softer surface that wears, for example metal on polyethylene in artificial joints. In alternative hard bearing couples, "like on like" material combinations have been used. While harder materials typically wear less, it is not common practice in tribological systems to design "like on like" bearing couples, as adhesive friction and wear can be high, and both bearing surfaces have the potential for wear. To date, hard bearing couples in artificial hip joints have not been studied as dissimilar bearing materials.

Metal on metal bearing couples are attractive from a design perspective, as the material toughness and hardness allows design flexibility, while delivering low wear of the order of one cubic millimetre per year. While the wear volume is low, and at least ten fold lower than cross linked polyethylene, the wear particles are very small, (circa 10 nm), providing a large surface area for metal ion release [1]. Elevated metal ion levels are a clinical concern for patients with metal on metal bearings [2]. Ceramic femoral heads have been extensively used for over thirty years in artificial hip joints and offer a reliable alternative to metallic alloy femoral heads. In this study alumina ceramic femoral heads were paired with metallic acetabular cups producing a novel differential hardness hard bearing couple. We report the wear performance of this novel differential hardness ceramic on metal bearing couple [3] and compare it with conventional metal on metal bearings.

Methods

Size 28 mm diameter bearing couples were selected for this study. Standard metal on metal bearings, comprising of cobalt chrome alloy femoral heads and acetabular cups, were used as controls. Biolox Forte ceramic femoral heads were articulated against cobalt chrome acetabular cups to produce a differential ceramic on metal bearing couple. At least three couples of each type were studied in the Leeds physiological hip joint simulator, under both standard walking cycle conditions and microseperation conditions [4,5]. Wear tests were carried out to five million cycles in 25% (viv) new born calf serum and wear measurements were carried out every million cycles. Wear was determined gravimetrically, metallic ion levels in the lubricant were determined by atomic absorption spectroscopy and wear particles were isolated and characterised by TEM [1]. Wear surfaces were analysed by 2D surface profilometry and SEM.

Results

The overall volumetric wear rates of the metal on metal and ceramic on metal bearings after five million cycles are shown in Table 1.

Bearing	Overall wear rate; mm^3/million cycles	Cobalt ion levels ppm
Ceramic on metal	0.01	0.5
Metal on metal	1.6	18

Table 1:
Volumetric wear rates of metal on metal and ceramic on metal bearings

The metal on metal bearings showed a higher initial bedding in wear rate and then the steady state wear rate reduced to 1.25 mm^3/ million cycles, providing an overall wear rate of 1.6 mm^3/million cycles. In contrast the ceramic on metal wear rate was over 100 fold lower at 0.01 mm^3/million cycles. The reduction in metallic wear was reflected in a similar level of reduction in the metal ion concentration in the lubricant. While the cobalt ion levels for the metal on metal bearing were 18 ppm, the levels of less than one ppm for the ceramic on metal hips were close to the resolution of the measuring system used and similar to the ion levels found with metal on polyethylene and ceramic on ceramic hip prostheses in this hip simulator system. An additional set of simulator studies was carried out with size 36mm Biolox Delta ceramic heads on cobalt chrome acetabular cups. The wear of the ceramic on metal was less than 0.01 mm^3/million cycles, approximately 100 fold less than the wear of the 36mm diameter metal on metal bearing. Under microseperation simulator conditions, the wear of both metal on metal and ceramic on metal increased, but the ceramic on metal bearing had a substantially lower wear rate. Wear particles from both bearing types was similar in size in the 10 to 30 nm size range. No wear or damage was detected on the harder ceramic femoral heads.

Discussion

Differential hardness hard on hard bearings have not been previously studied. Although a reduction in wear was postulated for ceramic on metal, the magnitude of the reduction, 100 fold was surprising. In addition to the benefit of differential hardness and only one wearing surface, ceramic on metal may also have benefited from reduction in the chemical and corrosive wear found in metal on metal. The ceramic on metal bearing has now entered clinical studies and short term studies of metal ion levels in the patients will allow us to determine if the wear reduction found in vitro is reflected in clinical performance.

Acknowledgments

This work was supported by EPSRC and DePuy.

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6.4 Future Ceramic Strategies

M. Kuntz

Introduction

The ongoing success of orthopaedic surgery over several decades reveals evidence that long term reliability of articulating implants demands highly wear resistant friction partners. In particular, for younger patients it is advisable that the surgeon offer to implant systems which offer extremely low wear rates and biocompatibility. As a result the use of a ceramic wear couple in total hip replacement (THR) is becoming more and more popular [1,2,3].

Ceramic, in particular alumina, as a biomaterial is easily distinguished from other materials used in orthopedic implants. High hardness and stiffness provide the physical basis for the highest wear resistance of all current day biomaterials. The extraordinary thermal and chemical stability excludes any ageing or degradation effects under physiological conditions. Furthermore, alumina features excellent compatibility in the body; high surface affinity to the synovia as the natural lubricant of the articulating system and no detrimental physiological reactions. These unique characteristics provide the ceramic implant the reliability that it needs in order to perform well under particular individual circumstances of live style. For example, the ratio of static and dynamic friction is close to unity, which prevents the artificial joint from painful jerky loading which may occur at sudden movement after a resting period. Another aspect of the long term behaviour anticipated from the use of the ceramic wear couple is the fact that, taking into account the very low wear rate, ceramic wear particles do not seem to trigger issues of sensitivity to wear debris normally associated with poly debris.

While discussing the reliability of a ceramic implant, it is inevitable to consider the brittle failure behaviour. In fact, even though the material properties and the test procedure for quality assurance of BIOLOX® has been steadily improved since introduction into the market in the beginning of the 1970's, CeramTec has continuously been committed to the goal of further decreasing the actual clinical failure rate. The recently published scientific exhibit of Dr. Jonathan Garino identifies to a fracture rate of less than 0.02% and places in the category of a rare clinical complication [5,6]. Nevertheless, CeramTec's strategy of developing bioceramics is dedicated to offer products that achieve the highest possible reliability. In order to achieve these goals, 3 milestones are required:

- Design excellence
- Quantitative materials live-time prediction
- Composite solutions for sensitive applications

Design excellence is on the one hand dedicated to the process development necessary in order to surpass present geometrical limitations, namely towards larger, thin walled, irregular or miniaturized components. On the other hand, design optimization is needed in order to increase the robustness of the design against abnormal and excessive loading conditions.

Live time prediction is a task of material science accounting for the unique loading conditions of an implanted system. In-vivo conditions mean for the material a superposition of wear, mechanical cyclic loading, impulsive forces and chemical attack due to the synovial environment. Thus, we will increase our efforts of supplementing the permanent joint-simulator experiments with basic live-time studies simulating worst case scenarios for the material. The combination of these test concepts will provide tools for the derivation of live time parameters, thus enabling us to predict lower bounds of live time in the case of new designs or new material concepts.

BIOLOX® delta is the tradename used by CeramTec in order to identify the highest rendition of our alumina based materials up to this point. Its exceptionally high design strength and fracture toughness opens up the possibility for advanced applications [7,8]. Nevertheless, CeramTec AG will continue to be committed to further material development. We are focusing much attention in the area of ceramic composites as they offer the chance of substantially activating energy absorbing mechanisms in the case of severe overloading. Such development may be a basis for expanding the use of ceramic based components even for extraordinary difficult and sensitive applications. The new composites will still offer a wear resistance and reliability that is substantially improved over the current BIOLOX® products.

In this paper we outline the current activities of CeramTec AG which are dedicated to provide improved solutions for their customers at the present and in future.

Today's and Future Technology

The orthopedic surgeon operating in this day and age is generally well supported and equipped to handle all of the needs presented to him by his patient. He has access to:

- Instrumentation systems that allow him to plan his surgery pre-operatively as well as anticipate the needed implants required by that patient (in most cases) and guide him in order to place his implants correctly.
- Metallic femoral and acetabular components that utilize proven materials and follow clinically proven design concepts.
- Total hip components that when properly implanted integrate well into the surrounding bone structure providing a stable and long lasting platform for the implants and the wear couple to perform satisfactorily.
- A very complete arsenal of wear couple options allowing him to match the wear couple he implants to the expected demands and needs of the patient.

One of the key goals in our future products is to design components which offer an increased range of motion in order to provide more alternatives for the implanting surgeon. In other words, our focus will be to incorporate the maximum range of motion possible into our components so that when the surgeon faces the challenge presented by the actual surgery he will be able to maximize the in vivo range of motion as much as possible in that individual patient. It is of importance to revisit the fact that historically the emphasis on implanting smaller ball heads and acetabular inserts (28mm) has been driven by an effort to reduce wear in metal polyethylene devices not by the intrinsic benefits of this size wear

couple. This same need does not exist when using the ceramic on ceramic wear couple as a result of the extremely low wear generated by this couple and the fact that the differences in wear between the three different wear size couples is almost negligible [1].

CeramTec's product development efforts will be directed to accomplish this by introducing new neck length options to our entire range of ball heads; by adding a new wear couple bearing size (>36 mm) and by optimizing the design and minimizing the thickness of our acetabular inserts. All of these will work in unison to create a more cohesive group of components designed to maximize range of motion. In this context, it is important to point out that the ball head size which is sufficient for avoiding the detrimental effects of limited range of motion is still not clearly defined. There are indications that increasing the ball head size larger than 36mm will only show a negligible benefit. Nevertheless, this certain aspect is a matter of further research.

In the following, we will summarize in detail the introduction of new products over the next few months:

Ball Heads:
We will add a number of new options to our BIOLOX® forte 12/14 standard product line of ball heads over the next 12 to 18 months. These are:

1. 32 mm diameter 12/14 extra long neck providing an extra 3 to 4 mm of neck length.
2. 36 mm diameter 12/14 extra long neck providing an extra 4 mm of neck length.
3. A range of 22 mm ball heads.

Acetabular Inserts:
In the area of acetabular inserts, we will be introducing a variety of new sizes with a newly optimized design which will allow the surgeon to use a larger wear couple in a smaller shell size than previously possible. The specific acetabular inserts sizes in our standard Ceralock® design that we will be introducing are:

1. In the 28 mm wear couple size - a 28/35 insert.
2. In the 32 mm wear couple size – a 32/39 insert will allow our customers to offer a shell with the 32 mm wear couple in a shell with a 2 mm smaller diameter.
3. In the 36 mm wear couple size – a 36/44 and 36/48 will allow our customer to offer a shell of at least 8 mm smaller diameter with the 36 mm wear couple.

All of the additions in the ball head and insert product offering are in the process of undergoing evaluation by our customers and will be introduced into their product systems in the near future.
Further for the wear couple size 40 mm appropriate inserts sizes will to be developed for large diameter bearing couples.

BIOLOX® Option ball heads with titanium sleeves:
In the past wear couple upgrading has been limited by the fact that the use of a ceramic ball head required that previously unused and undamaged femoral stem tapers be used. CeramTec has been able to draw upon the enhanced mechanical properties offered by its high strength Alumina Matrix Composite,

BIOLOX®delta, in order to produce a ball head with a unique taper. These ball heads are designed to be used in conjunction with a titanium adaptor that mates the internal taper of the ball heads on one side with a standard CeramTec 12/14 eurotaper on the internal side. The adaptor is produced using a titanium alloy material (Ti_6Al_4V) so that its unique properties can complement those of the BIOLOX® delta ball heads.

Figure 1:
BIOLOX® Option ball heads with titanium sleeves

The new BIOLOX® Option System (Fig. 1) provides the surgeon with an expanded series of ball head options that complement the current range of 28, 32 and 36 mm ball heads offered by CeramTec. The system incorporates a series of specially designed BIOLOX® delta ball heads (our high strength Alumina Matrix Composite Material) as well as metallic adaptors designed to be intra-operatively assembled in order to provide 4 neck length options (Short, medium, long and extra long for proper reconstruction of the joint. Moreover, the new material allows further extensions in the adjustment of CCD-angle and further off-sets.

In addition to the shorter term projects outlined above, we will be working on longer term projects in the following areas.

Ceramic knee implants:

The long-term survival rate for total knee replacement has been impressive, but may have been limited by tribological considerations related to the use of polyethylene (friction, wear, delamination) as well as by metal sensitivity related issues. In the past the application of ceramics was limited by the need to make thick components with simple shapes, but the introduction of BIOLOX® delta enables total knee replacement components to be manufactured in ceramics.

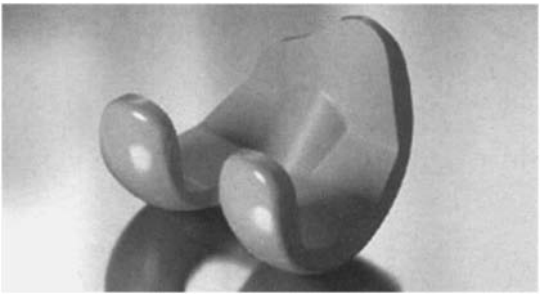

Figure 2:
Femoral component of knee prosthesis from BIOLOX® delta

CeramTec has completed a variety of laboratory tests for femoral components similar to the one shown in figure 2. In recent cyclic fatigue tests the components performed approximately 20% better than cast alloy femoral components having the equivalent size and geometry.

The development of the ceramic based knee prosthesis is anticipated to be implemented on the basis of 3 milestones. First, within the current systems of total knee replacement the femoral component will be substituted, which will, on the one hand, lead to substantially reduced polyethylene abrasion and in addition will provide a new alternative in the case of patients with severe metal sensitivity. The second milestone will be the replacement of the tibial plateau by a ceramic component in order to avoid the use of metal components. Finally, the creation of a ceramic on ceramic wear couple for the knee with or without the need of a meniscular component.

To date no extensive clinical trials have been conducted using our total knee replacement component technology. However, feasibility studies have convinced us that it is now time to enter clinical trials in this area. Full ceramic solutions will significantly improve the tribological system and live time of the mobile bearing. As more and more clinical results will become available and new production methods are being developed, we anticipate excellent acceptance and growth of the ceramic total knee replacement market.

Other ceramic joint replacement implants:

We expect that other ceramic applications, presently under investigation, will be commercialised in the future. These include spinal implants, shoulder replacements, finger joint replacements and other wear applications in the body. In particular, spinal prosthesis applications like intervertebral discs are expected to develop as an important and expanding market segment. The ceramic components offer stability against aging and perform well in case of magnetic resonance or X-ray imaging when compare to metal components.

Osseointegration:

The modification and treatment of ceramic surfaces in order to make possible osseointegration with human tissue is an ongoing research project. Already some methods have given encouraging results in animal experiments and these could provide further new applications for ceramics, thereby avoiding the need for space-consuming metallic interfaces. The "direct to bone" concept is dedicated to possibly be used in a variety of prosthesis components (except of the ball head) where osseointegration is supported by a specific bone affinity surface topography and chemistry.

Conclusion

Ceramic devices produced by CeramTec have been in clinical use for more than 32 years with excellent documented clinical results. The success of ceramic implants is underscored by the fact that up to now more than 4 million CeramTec components - ball heads and acetabular inserts - have been implanted demonstrating an exceptionally low rate of complications. Continuous product improvements and increased reliability during this time period have established CeramTec's high purity alumina, BIOLOX® forte, as the state of the art against which future ceramic materials will need to be compared.

Product extensions are planned in the standard range of ball heads and inserts in order to provide the surgeon with an increased range of options designed to improve clinical results. Additionally, CeramTec has developed a ceramic material, BIOLOX® delta with substantially improved material properties. This innovative material along with CeramTec's osseointegration work will open the door to new and exciting applications of ceramic wear reduction benefits in areas such as the knee, spine and others in the future.

Finally, and more importantly, CeramTec remains completely committed to the goal of providing continued improvements in reliability as required by the orthopedic surgeons and their patients around the world.

References

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KEYNOTE ADDRESS

The Relationship between Acetabular Osteolytic Lesion Volume and Polyethylene Wear in Cementless Total Hip Arthroplasty

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The Relationship between Acetabular Osteolytic Lesion Volume and Polyethylene Wear in Cementless Total Hip Arthroplasty

N. Kitamura, R. H. Hopper, S. B. Leung, C. A. Engh, Jr. and Ch. A. Engh

Abstract

Background: Osteolysis has been attributed to polyethylene debris and higher wear rates have been associated with an increased incidence of osteolysis. While several recent studies have used computed tomography to examine the correlation between acetabular osteolytic volume and polyethylene wear, conflicting results have been reported. In the context of a single cup design, this study used computed tomography to measure the volume of periacetabular osteolysis after total hip arthroplasty and evaluated the relationship between osteolytic volume and polyethylene wear.

Methods: We examined 41 hips (37 patients) that had a Duraloc 100 cup (DePuy) and a computed tomography scan that was taken at least five years postoperatively. Computed tomography scans were analyzed with a computer-aided imaging program to measure periacetabular osteolysis volume. The volumetric lysis rate was calculated for each hip by dividing the osteolytic volume by the time in situ. Total volumetric wear was evaluated based on the most recent anteroposterior pelvic x-ray using a validated, computer-assisted technique. A least-squares linear regression based on at least three serial volumetric wear measurements was used to compute the volumetric wear rate for each total hip arthroplasty.

Results: At a mean follow-up of 8.9 ± 1.9 years, periacetabular osteolysis was found in 38 of 41 hip computed tomography scans. Among the 38 hips with osteolysis, the mean volume was 17 ± 17 cm^3 (range 0.2 to 60 cm^3) and corresponding volumetric lysis rate was 2.0 ± 1.9 cm^3/year (range 0.03 to 6.6 cm^3/year). For all 41 total hip arthroplasties, the mean volumetric wear rate was 103 ± 90 mm^3/yr (range 0.3 to 442 mm^3/yr). Among all hips, there was a moderate correlation between the total volumetric wear and osteolysis volume ($r=0.52$, $p<0.001$). A slightly stronger correlation was found between volumetric wear rate and the volumetric osteolysis rate ($r=0.67$, $p<0.001$).

Conclusions: In this relatively high wear rate population, osteolysis was detected in 93% of hips and higher wear rates correlated with larger osteolytic lesions. While the wear rate accounted for 45% of the variance in the volumetric lysis rate, the remaining variance indicated that osteolysis is a multifactorial process. Contrary to studies using plain radiographs, there was no wear threshold below which osteolysis did not occur.

Introduction

Peri-prosthetic osteolysis adjacent to an acetabular cup is typically asymptomatic. With time it can contribute to cup loosening and acetabular fracture [1-3]. Osteolysis can also increase the complexity and compromise the

effectiveness of revision surgery. Radiographic studies have demonstrated that patients with high polyethylene wear rates are prone to develop osteolysis [4-7]. Unfortunately, plain radiographs tend to underestimate the incidence and extent of osteolysis [8-11]. Lytic lesions in front or behind the acetabular implant relative to the x-ray beam source can be obscured by the prosthesis. The two-dimensional nature of plain radiographs also makes it impossible to accurately assess the volume of an osteolytic lesion. Specialized computed tomography (CT) image post-processing algorithms now exist to facilitate volumetric measurements of osteolytic lesions [8,12,13]. Using these newer CT methods, Looney et al. [12] found that peri-acetabular osteolytic volume correlated directly with polyethylene wear. In contrast, Puri et al. [9] found no correlation between osteolytic volume and linear polyethylene wear. We observed in our own clinical practice that, even with a single cup type, not all patients with high wear developed radiographic evidence of osteolysis and not all patients with low wear are free of this complication. In the context of a single cup design, this study evaluated the correlation between volumetric osteolysis and volumetric polyethylene wear. We hypothesized that there would be moderate correlation ($0.3 \leq r \leq 0.7$) [14] between the volumetric polyethylene wear rate and the volumetric osteolysis rate.

Materials and Methods

Between 1990 and 2000, the Duraloc cup (DePuy, a Johnson & Johnson Company, Warsaw, Indiana) was used for the vast majority of total hip arthroplasties (THAs) performed at our institution. After surgery, our follow-up protocol currently includes preoperative and annual examinations for the first three years. At follow-up visits, we obtain anteroposterior pelvic radiographs in addition to anteroposterior and Lowenstein lateral radiographs of the femur. After three years, these same radiographs are obtained on alternate years in the absence of complications. When patients have unexplained pain or demonstrate radiographic evidence of substantial head eccentricity or osteolysis, we now routinely order a CT scan. In cases where a patient with bilateral hip implants has these findings on only one side, bilateral CT images are routinely obtained.

For this retrospective, Institutional Review Board-approved study, we used our database to identify patients who had a CT scan at least five years after their primary THA. We also limited the study to patients who had a postoperative anteroposterior pelvic x-ray and at least three additional anteroposterior radiographs of adequate quality to assess implant stability, evaluate femoral lysis, and measure femoral head penetration. The mean time interval between surgery and the CT scan for the 41 hips (37 patients) that comprised the study population was 8.9 ± 1.9 years (range 5.4 to 12.1 years). Implant and patient related demographic variables are summarized in Table 1.

The acetabular cup was considered stable if serial x-rays revealed no evidence of change in component position and no new radiolucencies developed at the bone cup interface. Similarly, the femoral component was considered stable if there was no evidence of change in component position and no continuous bone-implant radiolucency. Femoral lysis was defined as a sharply demarcated lucent area adjacent to the femoral component that was not evident on the immediate postoperative radiographs [15,16]. The wear measurements and the

Patients	
Gender	22 male 19 female
Pre-operative diagnosis	34 osteoarthritis 3 osteonecrosis 2 inflammatory arthritis 1 developmental hip dysplasia 1 post-traumatic arthrosis
Age at surgery	56.1 ± 11.2 (35 - 72)
Years between surgery and CT	8.9 ± 1.9 (5.4 - 12.1)
Implant	
Cup design	41 Duraloc 100
Polyethylene liner material	22 Hylamer 19 Enduron
Femoral head material	29 cobalt-chrome 12 ceramic
Femoral head diameter	4 32-mm 36 28-mm 1 26-mm
Stem fixation	41 cementless
Hole eliminator	15 not used 6 plug with positive stop 20 plug without positive stop 10 flush 5 partially advanced 5 disengaged
Terminal sterilization	26 Gamma-air standard dose 9 Gas plasma 4 Gamma-barrier standard dose 1 Gamma-barrier low dose 1 Unknown
Shelf storage duration (months)	12.5 ± 12.5 (0.5 - 41.0)*
Number of measurements used to compute wear rate for each hip	6.3 ± 2.0 (3 - 11)
Cup abduction angle	40.5 ± 7.8 (25 - 55)
* - excludes one liner with an unknown shelf storage duration For continuous variables, the data include mean ± standard deviation (range)	

Table 1: Patient and Implant-related Demographics

determination of the polyethylene wear rate and volume were carried out on the serial anteroposterior pelvic radiographs which had all been taken with the beam centered over the pubic symphysis while the patient was supine with their legs internally rotated 20 degrees. The volumetric wear associated with the two-dimensional head penetration was determined for each follow-up x-ray relative to the immediate postoperative view with a validated [17] computer-assisted technique (Hip Analysis Suite version 5.0, University of Chicago Medical Center, Chicago, Illinois). Using at least three serial anteroposterior pelvic radiographs taken at least 0.75 years postoperatively, a least-squares linear regression was used for each hip to determine the slope of the line that best fit the relationship

between the volumetric wear and the time in situ [18,19]. The slope of the linear regression represented the volumetric wear rate of the polyethylene. Linear wear rates were calculated for each hip in the same fashion using the linear head penetration data derived from Hip Analysis Suite.

Hips were scanned in the axial plane (GE High Speed ADVantage, Waukesha, Wisconsin, and Siemens Somotom 4, Munich, Germany) and coronal and sagittal images were reconstructed from the axial images. The thickness of the scan slices ranged from 1.0 to 3.0 mm. The image data was analyzed slice by slice in the axial, sagittal and coronal planes. Regions of osteolysis were manually traced and segmented by a single experienced observer using a computer-aided imaging program (Muscular-Skeleton Analysis Software, VirtualScopics, Rochester, NY). Osteolytic lesions were defined as sharply demarcated regions devoid of trabecular bone [9,12]. Based on the segmented slice data, the volume of osteolysis was determined using the software program. The volumetric pelvic osteolysis rate was determined by dividing the total volume by the time *in situ*.

The relationship between two continuous variables was assessed using Pearson's Correlation. A p-value of 0.05 was defined as the threshold for statistical significance.

Results

All cups and stems were radiographically stable. A total of 72 discrete lesions were identified in 38 (93%) of 41 hips on CT. Among the 38 hips with pelvic osteolysis, the mean volume for each hip was 17.0 ± 17.0 cm^3 (range 0.2 to 59.7 cm^3) and the volumetric lysis rate was 2.0 ± 1.9 cm^3/year (range 0.03 to 6.6 cm^3/year). Periacetabular osteolysis was found in 27 (66%) of 41 hips on plain radiographs. Large lesions were typically evident on x-rays (Fig. 1) while smaller lesions were less likely to be identified on plain films (Fig. 2). Among all hips, the mean volumetric wear based on the most recent x-ray was 883 ± 559 mm^3 (range 18 to 2,570 mm^3) and mean volumetric wear rate was 103 ± 90 mm^3/year (range 0.3 to 442 mm^3/year). The mean linear head penetration was 1.7 ± 1.0 mm (range 0.1 to 4.3 mm) and the mean linear wear rate was 0.20 ± 0.15 mm/year (range 0.01 to 0.73 mm/year).

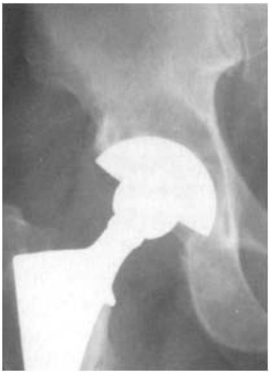

Figure 1a:
Immediate post-operative anteroposterior radiograph.

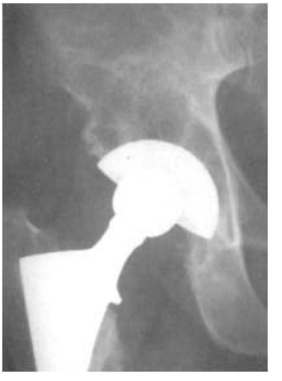

Figure 1b:
Anteroposterior radiograph of the asymptomatic hip at 11.6-year follow-up demonstrating osteolysis.

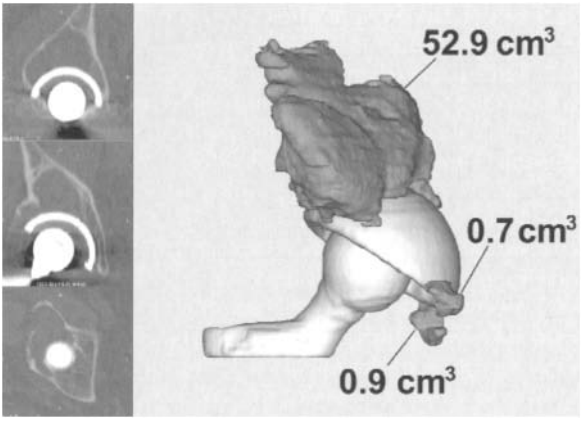

Figure 1c:
Three-dimensional reconstruction of the implant and pelvic osteolysis at 11.3-year follow-up. Three discrete lesions were identified with computed tomography.

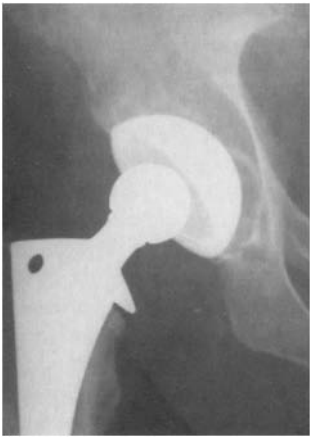

Figure 2a:
Immediate post-operative anteroposterior radiograph.

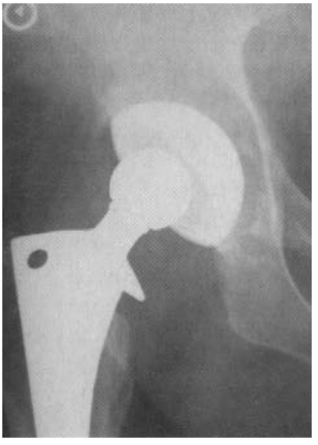

Figure 2b:
Anteroposterior radiograph of the asymptomatic hip at 8.6-year follow-up without evidence of osteolysis.

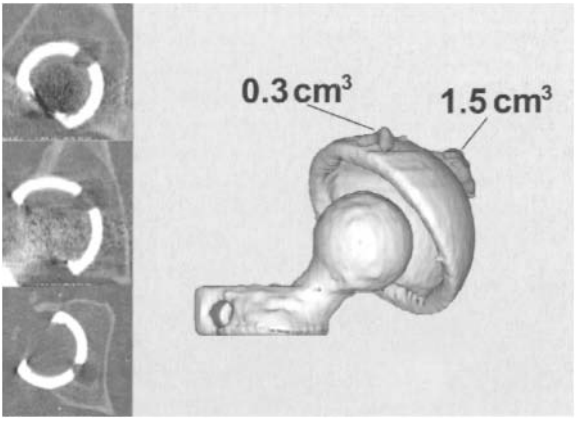

Figure 2c:
Three-dimensional reconstruction of the implant and pelvic osteolysis at 8.6-year follow-up. Two discrete lesions were identified with computed tomography.

For all 41 hips, there was a moderate correlation between the total volumetric wear and osteolysis volume ($r=0.52$, $r^2=0.27$, $p<0.001$). A slightly stronger correlation (Fig. 3) was found between the volumetric wear rate and the volumetric osteolysis rate ($r=0.67$, $r^2=0.45$, $p<0.001$). A moderate correlation was also found between linear head penetration and total pelvic osteolytic volume ($r=0.59$, $r^2=0.35$, $p<0.001$). While these correlations confirm that patients with higher wear rates are more likely to develop larger osteolytic lesions, they account for less than half of the variance ($r^2<0.5$) in the osteolytic volume data and cannot be used to accurately predict the lytic volume for an individual patient based on their polyethylene wear rate.

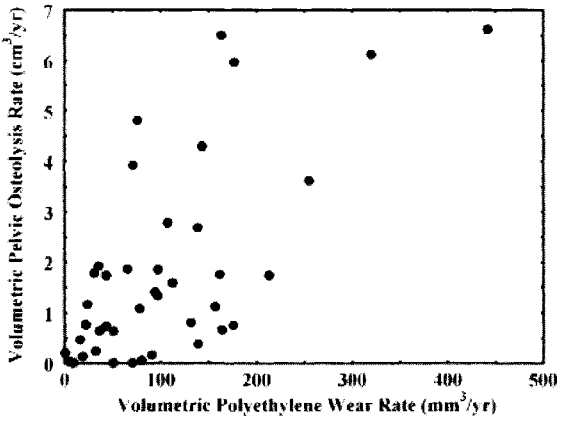

Figure 3:
A moderate correlation was found between the volumetric wear rate and the volumetric osteolytic rate ($r=0.67$, $p<0.001$).

Femoral osteolysis was identified in 28 (68%) of the 41 hips on plain radiographs. Among these 28 hips, the femoral lysis was confined to Gruen Zones 1 and 7 and had a mean size of 1.5 ± 1.5 cm^2 (range 0.1 to 5.1 cm^2). In 14 hips, the femoral lytic area was less than 1 cm^2. Although it was not strong, there was a statistically significant correlation between acetabular osteolytic volume and femoral lytic area ($r=0.36$, $p=0.02$).

Discussion

We are aware of two other reports in the literature that correlate polyethylene wear with periacetabular volumetric osteolysis measured on CT images. Based on 50 hips with uncemented cups of various designs, Puri et al. [9] reported no correlation between volumetric bone loss and linear wear of the polyethylene ($r=0.036$). Using the 41 hips in this study, we found a moderate correlation between volumetric osteolysis and linear head penetration that was statistically significant ($r=0.59$, $p<0.001$). Although our findings appear to contradict the results of Puri et al., closer examination suggests that the data from both studies are similar. In the work by Puri et al., the mean volumetric bone loss among the 26 hips with lysis detected on the CT scans was 4.9 cm^3. For the 16 hips that comprised their highest wear group, the mean linear head penetration was 1.5 mm. In contrast, the mean linear head penetration among the 38 hips in our study with pelvic osteolysis was 1.7 mm and the mean lytic volume was 17 cm^3. If we limit our

analysis to those hips with head penetration values less than 2.0 mm, 13 THAs would be excluded from our analysis. Among the remaining 28 THAs, the mean head penetration was 1.1 mm, the mean linear wear rate was 0.13 mm/year, and the mean acetabular osteolytic volume was 9.2 cm^3. For these 28 hips, the correlation between osteolysis volume and linear head penetration did not attain our threshold for statistical significance ($r=0.35$, $r^2=0.12$, $p=0.07$). This analysis indicates that the significance of our results stems, in part, from the relatively high wear rates among the patients in our study population. While most cases included in our study had CT images ordered after x-ray evidence of osteolysis was observed, Figure 3 reflects that several hips were included that had ow wear rates and very small osteolytic lesions that were not evident on x-rays. For a more typical population of hips with a mean linear head penetration rate of 0.1 mm/year, we would expect the correlation between volumetric wear and pelvic osteolysis to be weaker.

In an analysis of 20 hips with various uncemented acetabular components, Looney et al. [12] found that volumetric periacetabular osteolysis derived from CT scans correlated directly with polyethylene wear rate ($r^2=0.494$, $p=0.027$). The average volume of wear in the Looney study was 1010 mm^3 and was similar to the mean volumetric wear of 883 mm^3 of in our study. Looney et al. noted that if they excluded two patients that had recurrent dislocation and one patient with a Biomet prosthesis, the correlation between wear and osteolysis improved ($r^2=0.685$, $p=0.002$). These observations led them to suggest that "most patients have a fairly tight relationship between wear and osteolysis, but that there are outliers who have a relatively high amount of wear compared to the amount of osteolysis seen." While our results had greater statistical significance, the correlation between volumetric periacetabular osteolysis and volumetric polyethylene wear yielded an r^2 value of 0.27. Based on the distribution of the data points in Figure 3, we cannot exclude a small number of data points and achieve a substantially higher coefficient of determination (r^2). As a consequence, we would characterize the relationship between volumetric wear and lysis as moderate with appreciable variability as opposed to fairly tight.

We believe that there are several factors that may contribute to the variance in the periacetabular osteolysis volume data that is not accounted for by wear rate data. In particular, the central hole plug utilized in some cases may restrict the joint fluid and particulate debris from accessing the periacetabular bone through the central hole. The volume of lysis could also vary depending upon the depth and placement of the acetabular cup. If the acetabular component is placed against the inner pelvic cortex, there is less space in the cancellous bone for osteolysis to develop than if the cup is placed further away from the medial wall wedged on the lateral rim. The access route to the cancellous bone also may play an important role. If the path of osteolysis extends around the rim of the cup, the volume of the osteolytic lesions may be different than if it occurs through a central hole. The volume of the lytic lesion also may depend upon whether the lesion is contained or uncontained. For example, if there has been perforation of the inner cortex, an osteolytic lesion behind the cup would no longer be contained within the cortical walls. Another potentially important and unquantified factor in the development of osteolysis may be the susceptibility of individual patients and the variation in the host response to the particulate polyethylene debris. Although we have described some of the difference among patients and implants in Table 1, a larger number of cases would be required to assess the role of these factors in the osteolytic process.

Periprosthetic osteolysis can appear in either the pelvis or femur. In this study, we were concerned that larger lesions in one bone might be associated with smaller lesions in the other. Unfortunately, the artifact associated with the cobalt-chrome femoral stems that we typical use prevents measurement of femoral osteolysis volume. As a consequence, we measured the two-dimensional area of femoral osteolysis on the most recent anteroposterior x-ray using Martell's Hip Analysis Suite. The correlation between pelvic lysis volume and femoral lytic area was not strong but statistically significant ($r=0.36$, $r^2=0.13$, $p=0.02$). While the relatively low r^2 value indicates considerable variability, the positive r-value reflects a trend for larger pelvic lesions to be associated with larger femoral lesions.

For this analysis, we analyzed a single CT scan and used the definitions of osteolysis employed by other investigators [9,12]. As a consequence, we have assumed that all periacetabular bone defects represent osteolysis. In fact, some of the small bone defects may represent osteoarthritic cysts that existed prior to the THA procedure. Since osteoarthritic cysts are generally small and frequently less than 1 cm^3, they would contribute very little to the variance in the osteolytic volume data. As a consequence, their inclusion or exclusion would not have a substantial impact on our findings. In the future, we would ideally compare bone defects found on follow-up CT images with those occurring on a preoperative CT. In the absence of a preoperative CT, a preoperative or immediate post-operative x-ray would also be useful for identifying pre-existing periacetabular bone cysts.

Summary

Using a single cup design, we found a moderate relationship between volumetric osteolysis rate and volumetric wear rate that was statistically significant. However, since the relationship accounted for only 45% of the variance in the volumetric wear rate data, we also conclude that the wear rate alone is not strongly correlated with osteolytic volume. Our results confirm that patients with higher wear rates are more likely to develop larger lesions but indicate that we cannot expect to accurately predict osteolytic volume based solely on the polyethylene wear rate. Using plain x-rays, several investigators have proposed that osteolysis is unlikely to occur below a critical wear threshold, typically on the order of 0.1 mm/year [20]. In this study, we identified osteolysis among THAs with linear wear rates as low as 0.01 mm/year. Our results indicate that reduced polyethylene wear rates will tend to decrease osteolytic lesion volume but osteolysis can still occur at very low wear rates. Because metal and ceramic bearing surfaces are associated with dramatically reduced volumetric wear rates compared to polyethylene, they represent a promising means of reducing wear-mediated osteolysis.

Acknowledgement

This study was supported, in part, by general research funding provided by Inova Health System.

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