

Selected Technical Papers



STP 1560

Metal-On-Metal Total Hip Replacement Devices

Editors:

Steven M. Kurtz

A. Seth Greenwald

William M. Mihalko

Jack E. Lemons

Selected Technical Papers STP1560 **Metal-On-Metal Total Hip Replacement Devices**

Editors:

Steven M. Kurtz
A. Seth Greenwald
William M. Mihalko
Jack E. Lemons



ASTM International
100 Barr Harbor Drive
PO Box C700
West Conshohocken, PA 19438-2959

Printed in the U.S.A.

ASTM Stock #: STP1560

Library of Congress Cataloging-in-Publication Data

Symposium on Metal-On-Metal Total Hip Replacement Devices (2012: Phoenix, Ariz.), author.
Metal-on-metal total hip replacement devices / editors, Steven M. Kurtz, A. Seth Greenwald,
William M. Mihalko, Jack E. Lemons.

p.; cm. -- (Selected technical papers; STP1560)

Includes bibliographical references and index.

ISBN 978-0-8031-7546-4 (alk. paper)

I. Kurtz, Steven M., 1968- editor of compilation. II. Greenwald, A. Seth., editor of compilation.
III. Mihalko, William M., editor of compilation. IV. Lemons, Jack E., editor of compilation.
V. ASTM International, issuing body. VI. Title. VII. Series: Journal of ASTM International.
Selected technical papers; STP1560.

[DNLM: 1. Arthroplasty, Replacement, Hip--instrumentation--Congresses. 2. Equipment Failure
Analysis--standards--Congresses. 3. Hip Prosthesis--standards--Congresses. 4. Metal-on-Metal
Joint Prostheses--adverse effects--Congresses. 5. Metal-on-Metal Joint Prostheses--standards--
Congresses. WE 860]

RD561

617.5'820592--dc23

2013023318

Copyright © 2013 ASTM INTERNATIONAL, West Conshohocken, PA. All rights reserved.
This material may not be reproduced or copied, in whole or in part, in any printed, mechanical,
electronic, film, or other distribution and storage media, without the written consent of the
publisher.

Photocopy Rights

Authorization to photocopy items for internal, personal, or educational classroom use, or the
internal, personal, or educational classroom use of specific clients, is granted by ASTM
International provided that the appropriate fee is paid to ASTM International, 100 Barr Harbor
Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, Tel: 610-832-9634; online:
<http://www.astm.org/copyright>.

The Society is not responsible, as a body, for the statements and opinions expressed in this
publication. ASTM International does not endorse any products represented in this publication.

Peer Review Policy

Each paper published in this volume was evaluated by two peer reviewers and at least one editor.
The authors addressed all of the reviewers' comments to the satisfaction of both the technical
editor(s) and the ASTM International Committee on Publications.

The quality of the papers in this publication reflects not only the obvious efforts of the authors
and the technical editor(s), but also the work of the peer reviewers. In keeping with long-standing
publication practices, ASTM International maintains the anonymity of the peer reviewers. The
ASTM International Committee on Publications acknowledges with appreciation their dedication
and contribution of time and effort on behalf of ASTM International.

Citation of Papers

When citing papers from this publication, the appropriate citation includes the paper authors,
"paper title", STP title and volume, STP number, Paper doi, ASTM International, West
Conshohocken, PA, Paper, year listed in the footnote of the paper. A citation is provided as a
footnote on page one of each paper.

Foreword

THIS COMPILATION OF *Selected Technical Papers*, STP1560, on *Metal-On-Metal Total Hip Replacement Devices*, contains 20 papers presented at a symposium with the same name held in Phoenix, AZ, USA on May 8, 2012. The symposium was sponsored by ASTM International Committee F04 on Medical and Surgical Materials and Devices and Subcommittee F04.22 on Arthroplasty.

The Symposium Co-Chairs and STP Editors are Steven M. Kurtz, A. Seth Greenwald, William M. Mihalko, and Jack E. Lemons.

Contents

Overview	vii
----------------	-----

Post-Market Surveillance

Prevalence of Metal-on-Metal Bearings in the United States S. M. Kurtz, K. L. Ong, E. Lau, A. S. Greenwald, and K. Bozic	3
Metal-on-Metal and Other Bearing Trends Among Fellows of the AAOS K. L. Urish, M. Amini, and W. M. Mihalko	19
Risk of Complications, Revision, and Cancer for Metal-on-Metal Patients in the Medicare Population K. L. Ong, E. Lau, and S. M. Kurtz	32

Diagnostic Assessment

Serum Metal Ion Concentrations Decline (But Do Not Rapidly Normalize) Following Revision of Metal-on-Metal Total Hip Bearings J. A. Browne, Z. Wan, W. M. Novicoff, Q. Cui, and T. E. Brown	51
Low Cobalt and Chromium Levels from a Single Metal-on-Metal Total Hip Arthroplasty Implant A. F. Chen, M. T. Pigott, E. J. McClain, and B. A. Klatt	61
A Prospective Case Series Examining the Use of a Large-Head Metal-on-Metal Total Hip System V. Chatrath, I. Catelas, and P. E. Beaulé	73
A Method to Isolate and Characterize Wear Debris from Synovial Fluid and Tissues A. E. Kavanaugh, P. Benya, and F. Billi	86
Lymphocyte Reactivity to Nickel Correlates with Reported High-Pain Levels in Patients with Total Joint Arthroplasties: Implications for Pain-Related Hypersensitivity Responses M. S. Caicedo, L. Samelko, and N. J. Hallab	99

Retrieval Analysis

Approach, Rationale, and Examples of Metal-on-Metal Device Retrieval and Analysis for Evidence-Based Education J. Lemons, D. Sarver, P. Beck, D. Petersen, and A. Eberhardt	115
The Development of a Standard Method for Assessing Wear of Explanted Metal-on-Metal Hip Joints R. J. Underwood, M. Fowell, R. Sayles, S. M. Kurtz, and P. Cann	130
Method of Characterizing Fretting and Corrosion at the Various Taper Connections of Retrieved Modular Components from Metal-on-Metal Total Hip Arthroplasty G. B. Higgs, J. A. Hanzlik, D. W. MacDonald, W. M. Kane, J. S. Day, G. R. Klein, J. Parvizi, M. A. Mont, M. J. Kraay, J. M. Martell, J. L. Gilbert, C. M. Rimnac, and S. M. Kurtz	146

Normal and Adverse Wear Patterns Created In-Vivo on Metal-on-Metal Surfaces— A Retrieval Study Representing Four Vendors	
I. C. Clarke, T. K. Donaldson, M. D. Burgett, E. J. Smith, J. Bowsher, C. Savisaar, A. John, J. Y. Lazennec, E. McPherson, and C. L. Peters	157
Analysis of Comprehensive Measurements from Retrieved Implants to Determine Factors Contributing to Failure Modes and Wear	
P. Campbell, E. Ebrahimzadeh, S. Azad, F. Billi, Z. Lu, and H. McKellop	193
A Protocol to Assess the Wear of Head/Neck Taper Junctions in Large Head Metal-on-Metal (LHMoM) Hips	
R. J. Underwood, S. B. Kocagoz, R. Smith, R. S. Sayles, R. Siskey, S. M. Kurtz, and P. M. Cann.	209
Plastic Deformation from Edge Loading is Common on Retrieved Metal-on-Metal Hips and Can Be Predicted With Finite Element Analysis	
D. McHugh, J. Currier, F. Kennedy, J. Collier, and D. Van Citters.	235
Microstructure of Retrievals Made from Standard Cast HC-CoCrMo Alloys	
P. Stemmer, R. Pourzal, Y. Liao, L. Marks, M. Morlock, J. J. Jacobs, M. A. Wimmer, and A. Fischer	251

Pre-Clinical Testing

Development of a Stop-Dwell-Start (SDS) Protocol for In Vitro Wear Testing of Metal-on-Metal Total Hip Replacements	
M. Hadley, C. Hardaker, S. Williams, Z. Jin, G. Isaac, and J. Fisher.	271
Tribochemical Reactions in Metal-on-Metal Hip Joints Influence Wear and Corrosion	
M. A. Wimmer, M. T. Mathew, M. P. Laurent, C. Nagelli, Y. Liao, L. D. Marks, R. Pourzal, A. Fischer, and J. J. Jacobs	292
Denatured Protein Deposits Identified on Simulator and Explant Hip Bearings	
M. Burgett, T. Donaldson, I. C. Clarke, C. Savisaar, and J. Bowsher	310
Study on Tribological and Electrochemical Performance of Metal Artificial Hip Joint Materials in Simulated Synovial Fluids	
Z. K. Hua, G. Mcknight, and J. McCloy	323
Author Index	333
Subject Index	335

Overview

One step forward, two steps back is a concerning assessment of the currency of contemporary metal-on-metal (MOM) total and surface replacement hip systems employed as a remedy in the treatment of degenerative arthritis. First introduced almost four decades ago, MOM bearings have represented as much as 40% of the primary total hip systems utilized in the United States as of 2008. Since then, they have received growing attention in the peer reviewed literature, by orthopedic registries, and in international press coverage, much of it with a negative slant, describing adverse local tissue reactions (*ALTR*) and the risk of revisions associated with certain designs of MOM bearings.

The combination of mounting scientific evidence and growing public scrutiny has triggered recent United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) warnings on the use of MOM articulations and a series of regulatory actions by the United States Food and Drug Administration (US FDA). On May 6, 2011, the FDA issued a 522 ruling ordering the submission of post-market surveillance studies, and on January 17, 2013, the FDA issued a proposed order requiring the submission of PMA applications for MOM total hip replacement designs in the US Market. It seems the world of MOM articulations is at a watershed as a bearing couple for total hip and surface replacement designs.

This ASTM special technical publication (STP) is an outgrowth of an ASTM Symposium held on May 8, 2012, in Phoenix, Arizona. The purpose of this Symposium was to provide a forum for consensus development and scientific exchange on the needs for characterization and standardized testing related to MOM hip replacement devices. The main focus of this Symposium was to address unmet standardization needs and to help establish best testing practices in the following four areas:

- Characterization of Adverse Local Tissue Reactions
- Wear/Corrosion: Metallic Product Measurement in Fluid and Tissue Samples
- Analyses of Retrieved MOM Implants
- In Vitro Testing of MOM Implants under Adverse Conditions

This STP contains 20 papers from clinicians and scientists whose goal was to provide contemporary insight into the evolving knowledge base of MOM hip implants.

www.astm.org

ISBN: 978-0-8031-7546-4

Stock #: STP1560