



ASTM INTERNATIONAL
Selected Technical Papers

Beyond the Implant

Retrieval Analysis Methods for Implant Surveillance

STP 1606

Editors:

William M. Mihalko
Jack E. Lemons

A. Seth Greenwald
Steven M. Kurtz



SELECTED TECHNICAL PAPERS
STP1606

Editors: William M. Mihalko, Jack E. Lemons, A. Seth Greenwald,
and Steven M. Kurtz

Beyond the Implant: Retrieval Analysis Methods for Implant Surveillance

ASTM STOCK #STP1606
DOI: 10.1520/STP1606-EB

Library of Congress Cataloging-in-Publication Data

Names: Mihalko, William M., editor. | Lemons, Jack E., editor. | Greenwald, A. Seth, editor. | Kurtz, Steven M., 1968- editor. | ASTM International, issuing body.

Title: Beyond the implant : retrieval analysis methods for implant surveillance / editors, William M. Mihalko, Jack E. Lemons, A. Seth Greenwald, Steven M. Kurtz.

Description: West Conshohocken, PA : ASTM International, [2018] | Series: Selected technical papers ; STP1606 | Includes bibliographical references. | Description based on print version record and CIP data provided by publisher; resource not viewed.

Identifiers: LCCN 2018001781 (print) | LCCN 2018002782 (ebook) | ISBN 9780803176584 (ebook) | ISBN 9780803176577 (pbk.)

Subjects: | MESH: Joint Prosthesis | Arthroplasty, Replacement | Product Surveillance, Postmarketing | Congresses

Classification: LCC RD686 (ebook) | LCC RD686 (print) | NLM WE 312 | DDC 617.5/80592--dc23

LC record available at <https://lcn.loc.gov/2018001781>

ISBN: 978-0-8031-7657-7

Copyright © 2018 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 the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, Tel: (978) 646-2600; <http://www.copyright.com/>

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, STP number, book editor(s), ASTM International, West Conshohocken, PA, year, page range, paper doi, listed in the footnote of the paper. A citation is provided on page one of each paper.

Printed in Brainerd, MN
June, 2018

Foreword

THIS COMPILATION OF Selected Technical Papers, STP1606, *Beyond the Implant: Retrieval Analysis Methods for Implant Surveillance*, contains peer-reviewed papers that were presented at a symposium held May 9, 2017, in Toronto, Ontario, Canada. The symposium was sponsored by ASTM International Committee F04 on Medical and Surgical Materials and Devices, and Subcommittee F04.22 on Arthroplasty.

Symposium Chairs and STP Editors:

William M. Mihalko
Campbell Clinic–University of Tennessee
Memphis, TN, USA

Jack E. Lemons
University of Alabama at Birmingham
Birmingham, AL, USA

A. Seth Greenwald
Orthopaedic Research Laboratories
Cleveland, OH, USA

Steven M. Kurtz
Exponent, Inc.
Philadelphia, PA, USA

Contents

Overview	ix
<hr/>	
Defining Issues Pertaining to Retrieval Analysis of Orthopaedic Devices	
<hr/>	
Current Status of Standards and Unmet Needs in Retrieval Analysis Christine S. Heim and A. Seth Greenwald	1
<hr/>	
Retrieval Analysis Experience at a Single Center since 1970 and Recommendations for Future Directions Jack E. Lemons and Alan Eberhardt	10
<hr/>	
Medical Device Regulation and Retrieval Analysis Jorge A. Ochoa, Ryan L. Siskey, Carrie M. Kuehn, and Lauren Ciccarelli	23
<hr/>	
The Need for Standardization, Terminology, and Interfacing Retrieval Analysis with Registries Kevin L. Ong and Ellen T. Chang	39
<hr/>	
Topics Pertaining to TKR Implants	
<hr/>	
Analysis Techniques for Polyethylene Implants in Total Knee Arthroplasty Christina M. Arnholt, Julie Lowell, Meredith Perkins, Steven M. Kurtz, and William M. Mihalko	49
<hr/>	
Long-Term Wear Analysis of Retrieved Medially Pivoting TKA Inserts Satya Nambu and Irina Timmerman	65
<hr/>	
Linear Penetration as a Surrogate Measure for Volumetric Wear in TKR Tibial Inserts Elmira M. Rad, Michel P. Laurent, Christopher B. Knowlton, Hannah J. Lundberg, Robin R. Pourzal, and Markus A. Wimmer	75
<hr/>	
Topics Pertaining to THR Implants	
<hr/>	
Novel Heterodyne Fringe Projection Technique for Measuring Volumetric Wear in Acetabular UHMWPE Retrievals: A Pilot Study Francisco J. Medel, María Povar, and Jorge Santolaria	93

Fretting Corrosion and Polyethylene Damage Mechanisms in Modular Dual Mobility Total Hip Arthroplasty	106
Hannah Spece, Daniel W. MacDonald, Michael A. Mont, Gwo-Chin Lee, and Steven M. Kurtz	
Using Coordinate Measuring Machine Validated with White Light Interferometry to Identify Contributors to Material Loss Due to Corrosion of Total Hip Replacement Modular Junctions	118
Audrey J. Martin, Brian J. McGrory, Avram A. Edidin, and Douglas W. Van Citters	
Imprinting and Column Damage on CoCrMo Head Taper Surfaces in Total Hip Replacements	131
Deborah J. Hall, Stephanie M. McCarthy, Jonas Ehrich, Robert M. Urban, Alfons Fischer, Joshua J. Jacobs, Hannah J. Lundberg, and Robin Pourzal	
Methods for Characterization of Edge Wear in Ceramic-on-Ceramic Acetabular Cups	156
Darshil Kapadia, Radu Racasan, Luca Pagani, Mazen Al-Hajjar, and Paul Bills	
Characterization of Material Loss from Femoral Stem Taper Surfaces through Development of a Responsive Morphological Filtering Technique	173
Karl Dransfield, Radu Racasan, Liam Blunt, and Paul Bills	
Beyond the Implant	
Inflammatory Cytokines as Potential Biomarkers for Damage in Total Knee Arthroplasty	191
Meredith Perkins, Julie Lowell, Anita Kerkhof, and William M. Mihalko	
The Use of Semiquantitative Histology for Reporting Periprosthetic Tissue Features: A Review	203
Patricia A. Campbell, Michelle Nguyen, and Nathaniel Yuan	
Opportunities and Challenges of Retrieval Analysis: The Role of Standardized Periprosthetic Tissue and Fluid Analysis for Assessing an Aggravated Host Response	215
Yelizaveta Torosyan, John G. Bowsher, Steven M. Kurtz, William M. Mihalko, and Danica Marinac-Dabic	
Metals Measurements in Body Tissues and Fluids: Toxicological and Clinical Importance of Standardizing Quality Analytical Methods for Differentiating Cobalt Partitioning on a Molecular Level	229
Brent D. Kerger, Russell Gerads, Hakan Gurleyuk, and Joyce A. Tsuji	
MRI as a Biomarker for Clinical Problems in Total Joint Arthroplasty: The Role of Retrieval Analysis	245
Timothy M. Wright, Matthew F. Koff, Christina I. Esposito, Douglas E. Padgett, Thomas W. Bauer, and Hollis G. Potter	

Genetic Links to Total Joint Arthroplasty Outcomes: A Systematic Review	261
Meredith Perkins, Reed Butler, Lucas Tidwell, Weikuan Gu, and William M. Mihalko	
Other Implant Retrieval Analysis and Considerations	
The Biomechanics and Retrieval Analysis of Orthopaedic Trauma Devices	277
Meredith Perkins, Julie Lowell, Dema Assaf, John Weinlein, and William M. Mihalko	
Lessons Learned from Retrieved Total Elbow Implants	292
Timothy M. Wright, Darrick Lo, Joseph Lipman, Mark Figgie, and Robert Hotchkiss	

Overview

This ASTM Selected Technical Papers (STP1606), *Beyond the Implant: Retrieval Analysis Methods for Implant Surveillance*, completes a coordinated trilogy that initiated in 2011 with the publication of STP1560, *Metal-on-Metal Total Hip Replacement Devices* (2013), and subsequently STP1591, *Modularity and Tapers in Total Joint Replacement Devices* (2015). The four co-chairmen envisioned a logical sequence of a scientific discourse which would ultimately address unmet standardization needs and help establish best testing practices in the following four areas:

- Characterization of fretting, corrosion, and associated adverse tissue reactions
- What retrievals tell us in total joint arthroplasty
- Contemporary and evolving test methodologies
- Design parameters for taper connections in total joint arthroplasty

This STP particularly focuses on retrieval analysis of medical implants including established and evolving techniques as well as host issues that may contribute to clinical outcomes where revision is the endpoint. The STP is organized into five sections. The first section, “Defining Issues Pertaining to Retrieval Analysis of Orthopaedic Devices,” focuses on historical perspectives and unmet needs in the field including terminology, regulatory issues and future standards. The second section focuses on polyethylene wear assessments in specific types of total knee replacement designs including mobile bearing and medial pivot implants. In the third section, topics pertaining to total hip replacement devices are addressed. These topics include polyethylene wear, metal head bearing analyses, ceramic bearings and modular taper analyses. The next section is one of the most exciting sections, which addresses future needs related to host considerations that go beyond the implanted device. These topics include inflammatory cytokine and biomarker analyses, the need for histological staging and standard terminology, genetic related issues, imaging modality analysis of surrounding anatomy and the need for tissue and fluid analysis that may include a repository for retrieval databases. Finally, in the last section, topics about other types of devices including trauma and total elbow implants are provided.

The topics covered in this STP provide an expanded basis for continued studies and related consensus standards activity in the field of retrieval analysis. As we move forward, many of these STPs will serve as components of discussions on modified and new standards that will give better insight into the reasons for revision and thus contribute to their avoidance.

ASTM INTERNATIONAL
Helping our world work better

ISBN: 978-0-8031-7657-7
Stock #: STP1606

www.astm.org