

Alternative  
Bearing  
Surfaces in

# TOTAL JOINT REPLACEMENT

Joshua J. Jacobs  
and Thomas L. Craig  
editors

100 YEARS



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# *Alternative Bearing Surfaces in Total Joint Replacement*

*Joshua J. Jacobs and Thomas L. Craig, Editors*

ASTM Stock #: STP1346



ASTM  
100 Barr Harbor Drive  
West Conshohocken, PA 19428-2959  
Printed in the U.S.A.

ISBN: 0-8031-2494-5

ISSN: 1050-8104

**Library of Congress Cataloging-in-Publication Data**

Alternative bearing surfaces in total joint replacement / Joshua J.

Jacobs and Thomas L. Craig, editors.

p. cm. — (STP : 1346)

“ASTM stock number : STP 1346.”

Proceedings of the Symposium on Alternative Bearing Surfaces in  
Total Joint Replacement, held in San Diego, Calif., on Nov. 11-12, 1997.

Includes bibliographical references and index.

ISBN 0-8031-2490-2. — ISBN 0-8031-2490-2

1. Artificial joints—Bearings—Materials—Congresses.

2. Tribology—Congresses. I. Jacobs. Joshua J., 1956-

II. Craig, Thomas L., 1947- . III. Symposium on Alternative  
Bearing Surfaces in Total Joint Replacement (1997 : San Diego,  
Calif.) IV. Series: ASTM special technical publication ; 1346.

[DNLM: 1. Hip Prosthesis congresses. 2. Biocompatible Materials  
congresses. 3. Friction congresses. 4. Materials Testing  
congresses. WE 860 A466 1998]

RD686.A44 1998

617.4'720592—dc21

DNLM/DLC

for Library of Congress

98-47496

CIP

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To make technical information available as quickly as possible, the peer-reviewed papers in this publication were prepared “camera-ready” as submitted by the authors.

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. The ASTM Committee on Publications acknowledges with appreciation their dedication and contribution of time and effort on behalf of ASTM.

Printed in Fredericksburg, VA

December 1998

# Foreword

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This publication, *Alternative Bearing Surfaces in Total Joint Replacement*, contains 18 papers presented at the Symposium on Alternative Bearing Surfaces in Total Joint Replacement held in San Diego, California on November 11 and 12, 1997. The symposium was sponsored by the ASTM Committee F04 on Medical and Surgical Materials and Devices. Joshua J. Jacobs of Rush Medical College in Chicago, Illinois and Thomas L. Craig from Smith & Nephew Richards, Inc. of Memphis, Tennessee presided as symposium chairmen and are editors of the resulting publication. The editors would like to express their thanks to the ASTM staff members who assisted in the organization of the symposium and to those who assisted in the editorial process. The editors also wish to thank the many members of the F04 Committee who served as peer reviewers for the manuscripts contained herein.

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# Overview

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Over the last decade, there has been a resurgence of interest in wear of the bearing surfaces in total joint replacement components. The most commonly used wear couple, cobalt-based alloy articulating with ultrahigh molecular-weight polyethylene, has had an excellent track record. However, there is an increasing recognition that long-term clinical failures of total joint replacement devices are attributable to the release of a relatively high volume of particulate wear debris generated from these bearings.

Numerous studies have documented that polyethylene is the most abundant wear particle within the tissues surrounding the implanted device. Thus, there has been an intense interest in the development and utilization of alternative bearing surfaces to mitigate the effects of particulate polyethylene debris. These effects include aseptic loosening and osteolysis, the most common long-term complications of total joint replacement. Although in widespread use in certain centers abroad, alternative bearing surfaces are currently in the developmental or early clinical trial stage in the United States. There are numerous manufacturing, regulatory, scientific, and clinical issues that need to be carefully examined prior to the widespread introduction of these devices. The goal of this symposium was to provide a forum for the discussion of these issues in the context of relevant standards development. There was broad participation in this symposium with speakers and attendees from Europe and North America representative of industry, academia, clinical practice, and the regulatory and standards communities.

This volume is presented in four sections. The first section has two papers on wear testing. The paper by Sauer, et al. is an exhaustive historical review of the clinical and laboratory wear performance of orthopedic bearing materials. This is a valuable contribution in that it provides a context with which to interpret many of the subsequent papers. The paper by Wimmer, et al. describes the development of a novel screening method for wear analysis that may prove helpful in the pre-clinical evaluation of alternative bearing surfaces.

The second section presents nine papers on metal-on-metal bearings. The first three papers concern general developmental issues. The paper by Poggie, et al. presents an overview of the effects of design, contact stress, and materials on the tribological performance of metal-on-metal bearings. Varano, et al. examine the metallurgy of the cobalt-base alloys used for modern generation metal-on-metal bearings, while Tesk, et al. discuss the potential applicability of glassy alloy surfaces for this application. The second three papers, by Ciperia, et al.; Medley, et al.; and Chan, et al., discuss issues related to the characterization and tribological performance of these bearings based on *in-vitro* tests, including hip simulator studies. The latter paper also presents a numerical analysis, using elastohydrodynamic lubrication theory, describing the lubrication regime in metal-on-metal bearings. The nature and thickness of the lubricant may be key factors that govern the clinical performance of these devices. The final three papers in this section, by Park, et al.; Reiker, et al.; and Scott, et al. present analyses of clinical retrievals of both first and second generation metal-on-metal components. Critical information can be gleaned from such retrievals including the wear rate, wear mode, and patterns of surface damage and the relation of these parameters with design, metallurgy, geometry, and clinical performance. The paper by Scott, et al. deserves special mention as it was the recipient of the annual student award paper awarded by ASTM Committee F04.

The third section is comprised of four papers on ceramic bearings. Three of these papers originate from Europe, attesting to the longstanding clinical experience with these devices overseas. Papers by Richter, et al. and Cales, et al. address the tribological and mechanical behavior of ceramic-on-ceramic bearings. The paper by Armini, et al. examines the feasibility of using ceramic coatings on conventional metal balls to improve wear performance. Finally, Meunier, et al. present long-term clinical results of ceramic-on-ceramic bearings. This clinical information is quite valuable and provides key information to assess the applicability of these technologies to orthopedic practice.

The final section contains three papers on alternative polymeric bearings. The first two papers, by Megremis, et al. and Mosleh, examine the feasibility of using composite bearing materials where both the fiber and matrix are fabricated from ultrahigh molecular-weight polyethylene. Polineni, et al. examine the feasibility of using a composite polymeric material fabricated from carbon fibers and polyetheretherketone.

Following the symposium, concurrent breakout sessions, followed by a plenary session, were held to develop a consensus statement on the state-of-the-art of alternative bearings for total joint replacement vis-a-vis standards development. The following were felt to be the most urgent issues facing the standards community:

- 1) Development of meaningful screening tests which will accurately rank the wear performance of candidate bearings. The kinematics of such screen test should be carefully characterized;
- 2) The development of standard joint simulators which should be validated by the wear testing of known clinical failures. Such simulator testing will include a standard lubricant which produces wear rates and wear patterns consistent with clinical retrievals. In addition, simulation studies should be able to test "worst case" scenarios including the presence of third bodies;
- 3) The development of standardized tests to determine the effects of sterilization and aging on bearing surface performance, for both polymeric and ceramic bearing surfaces; and
- 4) Development of standard methods for i) characterization of the biocompatibility and toxicity of wear debris, ii) the recovery of wear debris from hip simulator fluids and periprosthetic tissue, and iii) the characterization of the morphology of wear debris.

ISBN 0-8031-2490-2