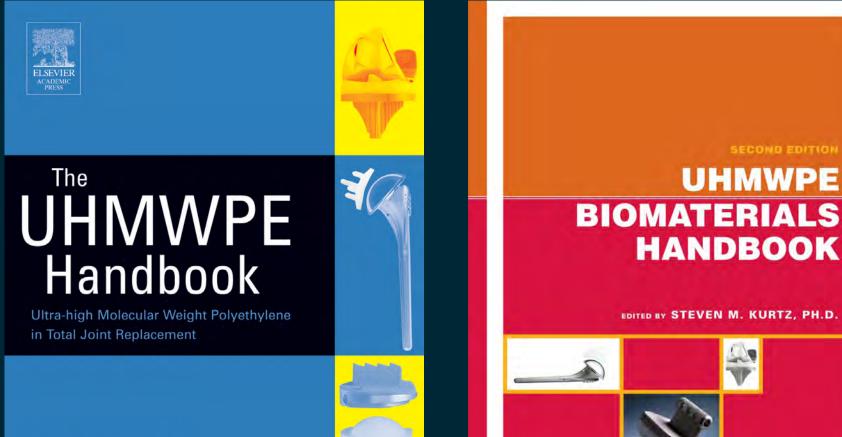
UHMWPE Implant Technology in 2009: Current State of the Art and Future Directions

Steven Kurtz, Ph.D. Exponent, Inc., and Drexel University

Changes in UHMWPE Technology



Steven M. Kurtz, Ph.D.

2004



Mechanisms for Change: 1st UHMWPE Meeting in 2003



3rd UHMWPE Meeting: Madrid 2007

Website: www.uhmwpe.org

UHMWPE

The Lexicon Reference

Table of Contents Foreword

- 1. A Primer
- 2. Processing UHMWPE
- 3. Sterilization and Packaging
- 4. Origins in Orthopedics
- 5. Clinical Performance
- Alternative Bearings for Joint Replacement

(NEW) UHMWPE Forum

A bulletin board for online discussions about medical grade UHMWPE.

Publications & Reports

Standards Development

Conferences

Atlas of UHMWPE Microscopy

-

Select a Chapter

Basic Resources

HEED Background Reading HEED Related Web Sites HEED Standardization Guide HEED NIST Reference Material The UHMWPE Lexicon is the online reference for ultra-high molecular weight polyethylene used in total joint replacements. The additional goals for this website are to provide an overview of stateof-the-art research in several key polyethylene related problems of clinical significance and to encourage hypothesis driven polyethylene research.

About Contact Site Map in Spanish (en Español)

(+) Read more about us.

Publications & Reports

Oxidation of Electron-Beam Irradiated UHMWPE Stabilized With Vitamin E

In the present work, medical grade UHMWPE was blended with 1.1, 2.3 and 11 mmol/l of vitamin E and consolidated by compression moulding. Small blocks of reference and of vitamin E-blended UHMWPE were then electron-beam irradiated at 30, 60 and 90 kGy, both in vacuum and in air. The reaction between vitamin E and macro-alkyl radicals or unlikely with peroxy radicals has been demonstrated and a correlation between the decrease of macroradicals and the stabilization effect of vitamin E has been shown.

Alternative Bearing Surface Usage in Total Hip Arthroplasty in the United States

The specific indications for the use of alternative bearings remains controversial. The purpose of this study was to characterize the epidemiology of bearing surface utilization in total hip arthroplasty in the United States with respect to patient, hospital, geographic, and payer characteristics. The most commonly reported bearing was metal-on-polyethylene (51%) followed by metal-on-metal (35%) and ceramic-on-ceramic (14%). The usage of total hip arthroplasty bearings varies considerably by patient characteristics, hospital type, and geographic location throughout the United States. Despite uncertain advantages in older patients, hard-on-hard bearings are commonly used in patients over the age of sixty-five years.

Features

(NEW) The 2nd Edition of the UHMWPE Biomaterials Handbook.

The 2nd Edition of the UHMWPE Biomaterials Handbook, edited by Steven M. Kurtz, Ph.D., is published by Elsevier Academic Press. The new edition includes 35 chapters and over 15 contributors, expanding upon the history, properties, and clinical performance of biomaterials used for joint replacement. The new edition contains dedicated chapters to remelted and annealed highly crosslinked



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UHMWPE, Vitamin E stabilization, composite biomaterials, high pressure crystallization, as well as chapters covering advances in characterization, such as hip and knee simulator testing, radiographic wear measurement, biological response of wear debris, and fatigue and fracture behavior. The book can be ordered via the <u>Amazon website</u> or downloaded as an <u>ebook</u>. A <u>preview</u> of the ebook is also available.

NEW Spine Technology Handbook

A new frontier for surgical grade UHMWPE is in the field of spine implants. The Spine Technology Handbook, edited by Steven M. Kurtz, Ph.D., and Avram A. Edidin, Ph.D., is published by Elsevier Academic Press. The 16 chapters of the Spine Technology Handbook (S60 pp.) describe the bioengineering principles, biomaterials, and designs of implants used in the treatment of spine disorders. Major technologies reviewed



include devices used for fusion (screws, plates, rods, and cages),



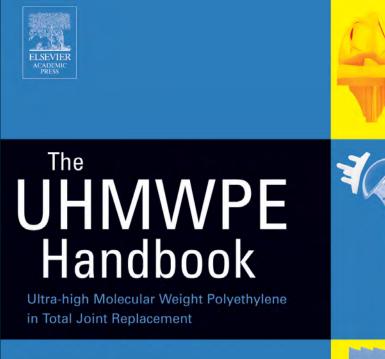
4th UHMWPE Meeting Details

- Abstracts, posters, and presentations (with permission) available on www.uhmwpe.org after the meeting
- Selected presenters will be invited to submit full-length papers for a CORR symposium (special issue)
- Manuscript deadline: December 31, 2009

CLINICAL · ORTHOPAEDICS

AND · RELATED · RESEARCH ·

UHMWPE State-of-the-Art in 2004





Steven M. Kurtz, Ph.D.

 Crosslinking was "topic du jour"

 International scientific debate

 Stabilization by post-irradiation heat treatment

- Annealers
- Remelters

2004

Clinical Performance of Annealing and Remelting: Wear Reduction

Remelted Liners

- Durasul: 5 studies, 20-94% reduction
- Longevity: 4 studies, 31-90% reduction
- Marathon: 4 studies, 56-95% reduction

• Annealed Liners

Crossfire: 5 studies, 42-86% reduction

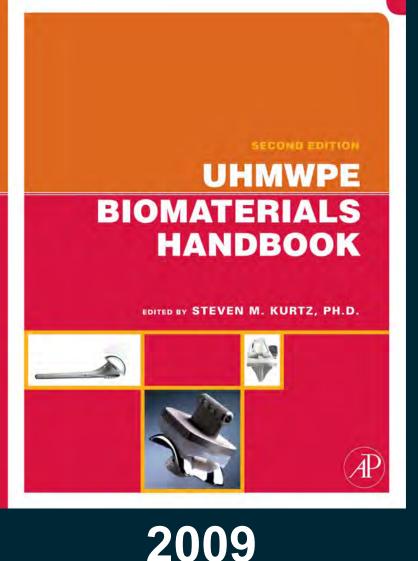
Source: Ch. 20 in UHMWPE Handbook (2nd Ed.)

Concerns with 1st Generation Annealed and Remelted Materials

Rim fracture

- Tower et al. JBJS 2007
- Furmanski et al. AAOS 2008
- Moore et al. JBJS 2008
- Duffy et. al. JOA 2009
- In vivo oxidation
 - Currier et al. JBJS 2007
 - Kurtz et al. CORR 2006

UHMWPE State-of-the-Art in 2009

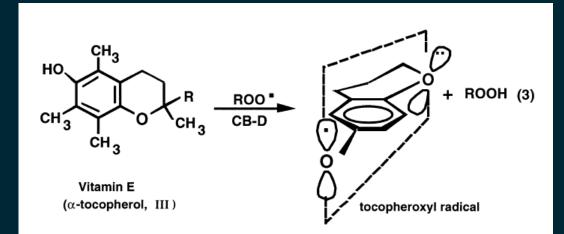


- Vitamin E is "topic du jour"
- International scientific debate
- Stabilization by chemical additives
 - Dopers
 - Blenders

Vitamin E and Medical Grade UHMWPE (500-16,000 ppm)

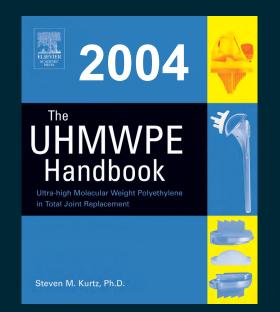
Tomita, Shibata, Mori (1999+)

- Kyoto, Japan
- Wolf, Lederer (2002+)
 - Leoben, Austria
- Costa, Bracco
 - Torino, Italy
- Oral, Muratoglu
 - Boston, USA

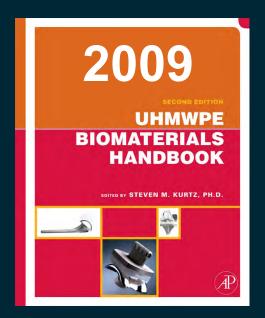


Crosslinked UHMWPE THA: Bearing Design Creep

- Largest Head Size: 36-44 mm
- Thinnest Bearing:
 5-6 mm

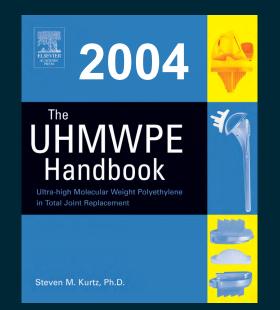


- Largest Head Size: 36-48 mm
- Thinnest Bearing: 3.8-6 mm

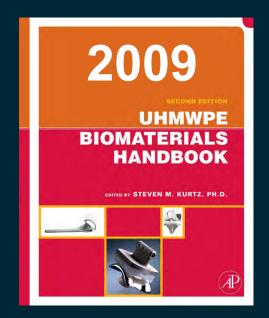


Crosslinked UHMWPE TKA: Increased Bearing Acceptance

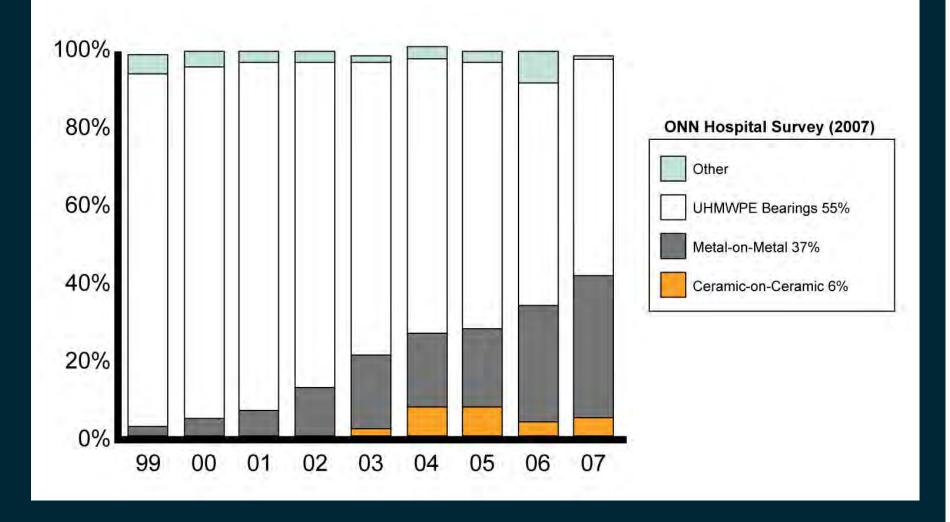
- Two Manufacturers: Sulzer, Zimmer
- Thinnest Bearing:
 5-6 mm



- All Major Manufacturers
- Thinnest Bearing: 5-10 mm



Hip Bearing Usage USA (1999-2007)



Bearings in America

• Four principal bearing couples -Tracked by new ICD9 codes -Widely used in Medicare population -Indications not yet established Clinical effectiveness -Bearing materials -Design (i.e., head size) Administrative data -NIS, Medicare -Total joint registries

International Survey of Primary and Revision Total Hip Replacement

+¹Kurtz, SM; ²Röder, C; ¹Lau, E; ¹Ong, K; ³Widmer, M; ⁴Maravic, M; ⁵Gomez-Barrena, E; ⁶Pina, MF; ⁷Manno, V; ⁸Geesink, R.

 Exponent, Inc., Philadelphia PA, USA; 2. University of Bern, Switzerland; 3. Swiss Health Observatory, Neuchâtel, Switzerland 4. Höpital Léopold Bellan, Département d'Information Médicale, France; 5. Universidad Autonoma de Madrid, Spain; 6. Universidade do Porto, Faculdade de Medicina and Instituto de Engenharia Biomédica - INEB, Portugal; 7. Istituto Superiore di Sanita, Rome, Italy; 8. University of Maasricht, Maastricht, Netherlands skurtz@exponent.com

Introduction: Total hip arthroplasty (THA) is currently the international standard of care for degenerative hip joint disease. Although national registries have been established in selected European countries. Australia, and New Zealand, few international studies have been performed comparing the historical utilization of primary and revision joint arthroplasty [1]. Previous surveys of medical technology utilization have reported wide variations in per capita medical technology expenditures among European countries and compared with the U.S. (http://www.eucomed.be/). Furthermore, in the U.S., the utilization of total hip arthroplasty has increased substantially in the past decade [2]. It is not known whether the trend of increased THA utilization over time can generalized to countries other than the U.S. The goal of this study was to compare the epidemiology and historical trends of utilization for THA around the world. The leaders of the Scandinavian registry movement introduced the concept of a national revision burden [3]. We sought to answer the following research questions: (1) What is the international variance in THA rates and revision burden around the world? (2) How have the rates of THA utilization increased over time?

Methods: Collaborators with access to national inpatient data in Western Europe were invited to participate in this research. The nine national inpatient databases queried for this study included the Nationwide Inpatient Sample (U.S.), Registro de Altas – CMBD (Spain), National Hospital Discharge Register (Portugal, Netherlands), Hospital Morbidity Database (Canada), National Hospital Database (France), Hospital Discharge Records Database (Italy), Hospitals Statistics, FSO (Switzerland), German Federal Statistical Office database (Destatis). Inpatient data were also compared with published registry data for six countries with operating arthroplasty registers (Romania, Denmark, We observed that the procedure rate significantly increased over time for the countries in which historical data were available, with the exception of France (p = 0.068, Figure 1). The compound annual growth of the THA utilization rate (proc/100K population) was 3.2%, on average, and ranged from 0.6% (France) to 10.3% (Romania).

Discussion: We observed nearly a ten-fold range of THA utilization rates between the 15 different countries included in the survey. These international variations do not appear to be simply explained by patient demographics (e.g., age or gender). It is also apparent from the results of this study that the demand for THA has risen substantially over the past decade in countries besides the United States. Our research is limited to a relatively small number of countries, but we look forward to expanding the survey over time to include representation from our orthopedic colleagues around the world. In addition, it is not yet clear whether observed differences might be explained by national factors, such as the type of health care system (i.e., public vs. private), access to care, number and distribution of orthopedic surgeons, and the prevalence of joint disease, which could not be included in our study at this time. Despite these limitations, the data reported in this study may be useful in their current form for policy and planning purposes in Australia, Europe, and the U.S., and will serve as a quantitative basis for statistical projections of future international demand in THA surgery.

Acknowledgements: Special thanks to the Ministerio de Sanidad in Spain, Superior Institute of Health in Italy, Central Administration of the Portuguese Health System, and to the Canadian Institute for Health Information.

References: 1. Scheerlinck, Acta Orthop Belgica, Vol. 70, 2004; 2. Kurtz, JBJS-A, Vol. 89, 2007; 3. Malchau, JBJS-A, Vol. 84, 2002.

International Survey of Total Hip Replacement

- Utilization of THA increased in the U.S. during the 1990s
- Did this trend occur in other countries?
- Research questions:
 - -What is the international variance in THA rates and revision burden around the world?
 - -How have the rates of THA increased over time?

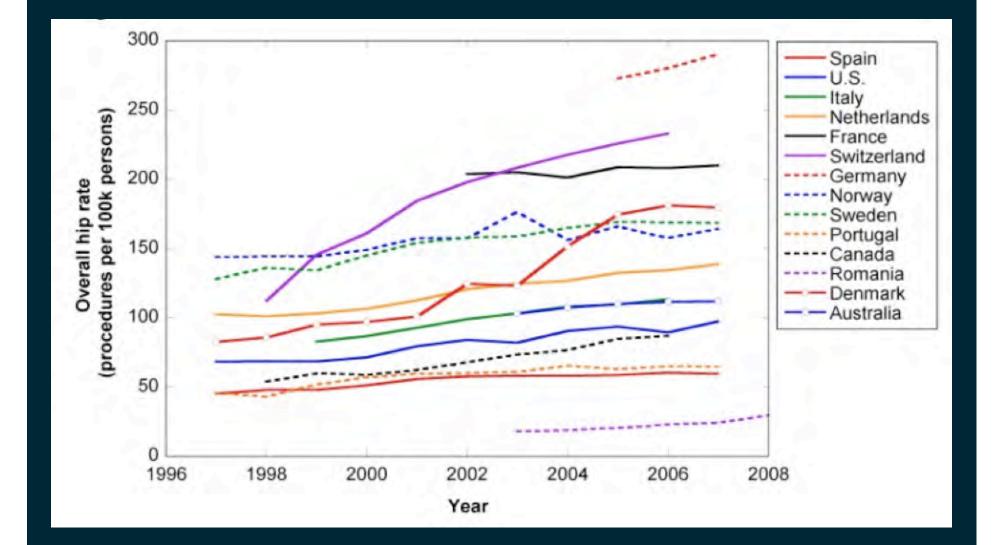
Sources of Inpatient Data

- Nationwide Inpatient Sample (USA)
- Registro de Altas CMBD (Spain)
- National Hospital Discharge Register (Portugal, Netherlands)
- Hospital Morbidity Database (Canada)
- National Hospital Database (France)
- Hospital Discharge Records Database (Italy)
- Hospitals Statistics, FSO (Switzerland)
- German Federal Statistical Office database (Destatis)

International Rates of THA

Country (Year)	Primary & Revision THAs (×1000)	THA Rates (Proc/100K pop.)	National Revision Burden (%)
Romania (2008)	6.4	29.6	7.3
Spain (2007)	26.5	59.6	16.6
Portugal (2007)	6.9	64.8	15.2
Canada (2006)	28.3	87.0	10.3
U.S. (2007)	293	97.5	13.3
Australia (2007)	23.6	112	14.6
Italy (2006)	66.7	113	11.1
England & Wales (2007)	62.8	116	10.1
Netherlands (2007)	22.7	139	
Norway (2007)	7.7	164	13.6
Sweden (2007)	15.4	169	10.1
Denmark (2007)	9.8	180	14.4
France (2007)	133	210	11.2
Switzerland (2006)	17.4	233	13.2
Germany (2007)	239	290	14.6
Overall/Total	959	131	12.9

International Trends of THA



International Utilization of THA

 Survey includes 15 countries in North America, Europe, and Pacific Rim -959,000 primary and revision THAs per year -131 procedures/100,000 population -32.9% <65y (Range: 24.8-44.3%) -12.9% revision burden Study submitted to ORS 2010

International Utilization of TKA

Survey includes 17 countries in North America, Europe, and Pacific Rim
-1,183,000 primary and revision TKAs per year
-159 procedures/100,000 population
-29.4% <65y (Range: 18.5–42.4%)
-8.3% revision burden

Study submitted to ORS 2010

The Future Landscape

Anti-oxidants and additives
Structural composites
New polymerization techniques

5th International UHMWPE Meeting

Drexel University Philadelphia, USA September 2011 skurtz@drexel.edu

Thank