



# The UHMMYPE Handbook

Ultra-High Molecular Weight Polyethylene in Total Joint Replacement





Steven M. Kurtz, Ph.D.

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## The UHMWPE Handbook

To Karen, for listening to all my stories.

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### **Preface**

This book has its origins in a review article, "Advances in the Sterilization, Processing, and Crosslinking of Ultra-High Molecular Weight Polyethylene for Total Joint Arthroplasty" (*Biomaterials* 1999; 20: 1659–1688), which I coauthored with Orhun Muratoglu, Mark Evans, and Av Edidin. Our review was written between 1997 and 1998, at a time when highly crosslinked and thermally treated UHMWPE materials were about to be clinically introduced for total hip replacement. Several other important milestones in the clinical use of UHMWPE had occurred, including the abandonment of gamma sterilization in air (at least in the United States) and the trend to reduce calcium stearate (a processing additive) in the UHMWPE powder.

Since 1998, a major shift in the orthopedic application of UHMWPE has occurred. Currently six different highly crosslinked UHMWPE formulations are in clinical use for both hip and knee replacements. Although intermediate-term clinical follow-up data are not yet available, the adoption by surgeons of highly crosslinked UHMWPE for total hip replacements has been pervasive. A similar, but somewhat slower, trend has been initiated with the use of these new materials in total knee replacement starting in 2001.

If we include the alternative bearing solutions (e.g., metal on metal and ceramic on ceramic) for total joint arthroplasty, the number of choices available to the orthopedic surgeon is far greater today than in 1998. Yet, with all these advanced technologies available, we should still be mindful that for very elderly patients, artificial joints incorporating conventional UHMWPE will continue to afford long-term clinical benefits that could potentially last the rest of these patients' natural lives. On the other hand, the more recently introduced alternative bearing technologies, including crosslinked UHMWPE, should provide the greatest benefit to young patients (younger than 60 years) who lead an active lifestyle and who need a total hip replacement. For patients in need of knee arthroplasty, shoulder arthroplasty, or total disc replacement, conventional UHMWPE continues to prevail as the polymeric bearing material of choice.

The latest generation of new processing technology has contributed to some confusion, among surgeons and researchers alike, regarding the technical details associated with highly crosslinked UHMWPE. My goal in writing the UHMWPE Handbook is to explain the common concepts underlying all UHMWPE materials, as well as the technical differences in specific formulations for an audience of surgeons, researchers, and students who may be starting

work in this field. Some of the early chapters in this book may also be of interest to current or prospective patients who are motivated to learn more about current treatment options. Because all of the alternative bearing solutions (both highly crosslinked UHMWPE as well as hard-on-hard bearings) have their origins in the 1950s, 1960s, and 1970s, it is important to understand the historical context in which the first generation of highly crosslinked UHMWPEs were originally developed. With this in mind, I have also taken some care to review the historical development of UHMWPE bearings for joint replacement.

The story of UHMWPE in orthopedics, seemingly immutable and static, still continues to evolve. Early in 2002, I undertook the task of expanding my website, the UHMWPE Lexicon (www.uhmwpe.org), with an online monograph of six introductory chapters covering the basic scientific principles and clinical performance of UHMWPE in hip replacement. The response to these online chapters was overwhelmingly positive and encouraged me to revise the first six chapters for hardcopy publication and to develop the additional nine chapters for the *UHMWPE Handbook*.

Despite my diligent efforts to summarize the state of the art in this field, I appreciate that current trends related to UHMWPE in orthopedics will give way to new ideas as further clinical data becomes available in the future. For this reason, I hope that the UHMWPE Lexicon website will continue to disseminate new research findings to the orthopedic and polymer research communities. The Lexicon website and this current *Handbook* play complementary roles. When the accumulation of new ideas and findings has diffused sufficiently into the orthopedic clinical and research practice, it will be time to update this written work. I look forward to your comments and suggestions for future expansion of the UHMWPE Lexicon website and the *UHMWPE Handbook*.

This monograph would not have been possible without the suggestions and advice of many supportive colleagues. I am especially grateful to my coauthors, experts in the fields of joint arthroplasty, spine, as well as in the testing and evaluation of UHMWPE, who have cheerfully contributed chapters to this book on relatively short notice. I have also included acknowledgements at the end of chapters to thank my many friends and associates for their contributions.

—Steven Kurtz, Ph.D. Philadelphia, PA October 3, 2003



www.UHMWPE.org

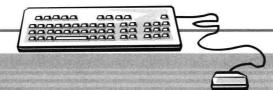


to learn about:

THE LATEST SCIENTIFIC & CLINICAL RESEARCH NEW STANDARDS FOR MEDICAL GRADE UHMWPE

### The UHMWPE Lexicon website provides:

- Online Reference for Ultra-High Molecular Weight Polyethylene used in Total Joint Replacements
- Overview of State-of-the-Art Research in Several Key Polyethylene Related Problems of Clinical Significance
- Ideas for Hypothesis Driven Polyethylene Research



### **Contents**

-	Contributors	xi
	Preface	xiii
1.	A Primer on UHMWPE	1
	Introduction	1
	What Is a Polymer?	2
	What Is Polyethylene?	4
	Crystallinity	6
	Thermal Transitions	7
	Overview of the Handbook	9
2.	From Ethylene Gas to UHMWPE Component: The Process	
	of Producing Orthopedic Implants	13
	Introduction	13
	Polymerization: From Ethylene Gas to UHMWPE Powder	14
	Conversion: From UHMWPE Powder to Consolidated Form	22
	Machining: From Consolidated Form to Implant	31
	Conclusion	32
3.	Packaging and Sterilization of UHMWPE	37
	Introduction	37
	Gamma Sterilization in Air	38
	Gamma Sterilization in Barrier Packaging	41
	Ethylene Oxide Gas Sterilization	44
	Gas Plasma Sterilization	45
	Shelf Life of UHMWPE Components for Total Joint Replacement	47
	Overview of Current Trends	48
4.	The Origins of UHMWPE in Total Hip Arthroplasty	53
	Introduction and Timeline	53
	The Origins of a Gold Standard (1958–1982)	55
	Charnley's First Hip Arthroplasty Design with PTFE (1958)	56
	Implant Fixation with Pink Dental Acrylic Cement (1958–1966)	56
	Interim Hip Arthroplasty Designs with PTFE (1958–1960)	58

The First Wear Tester Searching to Replace PTFE UHMWPE Arrives at Wrightington Implant Sterilization Procedures at Wrightington Overview 68  5. The Clinical Performance of UHMWPE in Hip Replacements Introduction Joint Replacements Do Not Last Forever Range of Clinical Wear Performance in Cemented Acetabular Components Wear Versus Wear Rate of Hip Replacements Comparing Wear Rates Between Different Clinical Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Components Components Conclusion 6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Total Knee Arthroplasty Polycentric Knee Arthroplasty Polycentric Knee Arthroplasty Polycentric Knee Arthroplasty Patello-Femoral Arthroplasty Patello-Femoral Arthroplasty Unicondylar Polycentric Knee Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty UHMWPE Is the Only Alternative for Knee Arthroplasty	Final Hip Arthroplasty Design with PTFE (1960–1962) Implant Fabrication at Wrightington	58 61
UHMWPE Arrives at Wrightington Implant Sterilization Procedures at Wrightington Overview  5. The Clinical Performance of UHMWPE in Hip Replacements Introduction Joint Replacements Do Not Last Forever Range of Clinical Wear Performance in Cemented Acetabular Components Wear Versus Wear Rate of Hip Replacements Comparing Wear Rates Between Different Clinical Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Patello-Femoral Arthroplasty Unicondylar Total Knee Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Introduction Biomechanics of Total Knee Arthroplasty Islandary Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty		
UHMWPE Arrives at Wrightington Implant Sterilization Procedures at Wrightington Overview  5. The Clinical Performance of UHMWPE in Hip Replacements Introduction Joint Replacements Do Not Last Forever Range of Clinical Wear Performance in Cemented Acetabular Components Wear Versus Wear Rate of Hip Replacements Comparing Wear Rates Between Different Clinical Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Patello-Femoral Arthroplasty Unicondylar Total Knee Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Introduction Biomechanics of Total Knee Arthroplasty Islandary Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty	Searching to Replace PTFE	64
Overview 68  5. The Clinical Performance of UHMWPE in Hip Replacements Introduction 71 Joint Replacements Do Not Last Forever 73 Range of Clinical Wear Performance in Cemented Acetabular Components 75 Wear Versus Wear Rate of Hip Replacements 77 Comparing Wear Rates Between Different Clinical Studies 79 Comparison of Wear Rates in Clinical and Retrieval Studies 82 Current Methods for Measuring Clinical Wear in 70 Total Hip Arthroplasty 88 Range of Clinical Wear Performance in Modular Acetabular 70 Components 88 Conclusion 86  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty 88 Introduction 93 Metal-on-Metal Alternative Hip Bearings 94 Ceramics in Hip Arthroplasty 101 Highly Crosslinked and Thermally Stabilized UHMWPE 109 Summary 114  7. The Origins and Adaptations of UHMWPE for Knee 88 Replacements 123 Introduction 123 Frank Gunston and the Wrightington Connection to 70 Total Knee Arthroplasty 129 Unicondylar Polycentric Knee Arthroplasty 129 Unicondylar Polycentric Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello-Femoral Arthroplasty 134 Patello-Femoral Arthroplasty 141 UHMWPE with Metal Backing 142 Conclusion 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Replacements 151 Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 153		66
5. The Clinical Performance of UHMWPE in Hip Replacements Introduction Joint Replacements Do Not Last Forever Range of Clinical Wear Performance in Cemented Acetabular Components Wear Versus Wear Rate of Hip Replacements Comparing Wear Rates Between Different Clinical Studies Comparison of Wear Rates in Clinical and Retrieval Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty	Implant Sterilization Procedures at Wrightington	66
Introduction 71 Joint Replacements Do Not Last Forever 73 Range of Clinical Wear Performance in Cemented Acetabular Components 75 Wear Versus Wear Rate of Hip Replacements 77 Comparing Wear Rates Between Different Clinical Studies 79 Comparison of Wear Rates in Clinical and Retrieval Studies 82 Current Methods for Measuring Clinical Wear in 70tal Hip Arthroplasty 83 Range of Clinical Wear Performance in Modular Acetabular 7 Components 85 Conclusion 86  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty 93 Introduction 93 Metal-on-Metal Alternative Hip Bearings 94 Ceramics in Hip Arthroplasty 101 Highly Crosslinked and Thermally Stabilized UHMWPE 109 Summary 114  7. The Origins and Adaptations of UHMWPE for Knee 8 Replacements 123 Introduction 123 Frank Gunston and the Wrightington Connection to 7 Total Knee Arthroplasty 126 Polycentric Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello-Femoral Arthroplasty 134 Patello-Femoral Arthroplasty 141 UHMWPE with Metal Backing 142 Conclusion 151 Introduction 151 Biomechanics of Total Knee Arthroplasty 151 Clinical Performance of UHMWPE in Knee Arthroplasty 151 Biomechanics of Total Knee Arthroplasty 151 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172	Overview	68
Joint Replacements Do Not Last Forever Range of Clinical Wear Performance in Cemented Acetabular Components 75   Wear Versus Wear Rate of Hip Replacements 77   Comparing Wear Rates Between Different Clinical Studies 79   Comparison of Wear Rates in Clinical and Retrieval Studies 82   Current Methods for Measuring Clinical Wear in 70tal Hip Arthroplasty 83   Range of Clinical Wear Performance in Modular Acetabular 70   Components 85   Conclusion 86   Conclusion 86   Conclusion 86   Conclusion 86   Conclusion 93   Introduction 93   Introduction 93   Introduction 94   Ceramics in Hip Arthroplasty 101   Highly Crosslinked and Thermally Stabilized UHMWPE 109   Summary 114   Conclusion 123   Introduction 124   Polycentric Knee Arthroplasty 126   Unicondylar Polycentric Knee Arthroplasty 129   Unicondylar Polycentric Knee Arthroplasty 132   Bicondylar Total Knee Arthroplasty 134   Patello-Femoral Arthroplasty 134   Patello-Femoral Arthroplasty 134   Conclusion 146   Conclusion 151   Biomechanics of Total Knee Arthroplasty 153   Clinical Performance of UHMWPE in Knee Replacements 151   Introduction 151   Biomechanics of Total Knee Arthroplasty 153   Clinical Performance of UHMWPE in Knee Arthroplasty 160   Osteolysis and Wear in Total Knee Arthroplasty 172		
Range of Clinical Wear Performance in Cemented Acetabular Components Wear Versus Wear Rate of Hip Replacements Comparing Wear Rates Between Different Clinical Studies Comparison of Wear Rates in Clinical and Retrieval Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty Patello-Femoral Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty		
Wear Versus Wear Rates of Hip Replacements Comparing Wear Rates Between Different Clinical Studies Comparison of Wear Rates in Clinical and Retrieval Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty Patello–Femoral Arthroplasty 134 Patello–Femoral Arthroplasty 145 Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty	Range of Clinical Wear Performance in Cemented	
Comparing Wear Rates Between Different Clinical Studies Comparison of Wear Rates in Clinical and Retrieval Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  109 Summary  114  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Patello–Femoral Arthroplasty Patello–Femoral Arthroplasty 134 Patello–Femoral Arthroplasty 145 Conclusion  151 Introduction Biomechanics of Total Knee Arthroplasty Conclusion  151 Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Clinical Perfo		
Comparison of Wear Rates in Clinical and Retrieval Studies Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion 86  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion 151 Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty		
Current Methods for Measuring Clinical Wear in Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Clinical Performan		
Total Hip Arthroplasty Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Total Knee Arthroplasty Patello-Femoral Arthroplasty UHMWPE with Metal Backing Conclusion  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		02
Range of Clinical Wear Performance in Modular Acetabular Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction 93 Metal-on-Metal Alternative Hip Bearings 94 Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE 109 Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements 123 Introduction 123 Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty 134 Patello-Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		83
Components Conclusion  6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction 93 Metal-on-Metal Alternative Hip Bearings 94 Ceramics in Hip Arthroplasty 101 Highly Crosslinked and Thermally Stabilized UHMWPE 109 Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements 123 Introduction 123 Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty 126 Polycentric Knee Arthroplasty 127 Unicondylar Polycentric Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello-Femoral Arthroplasty 134 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		
6. Alternatives to Conventional UHMWPE for Hip Arthroplasty Introduction 93 Metal-on-Metal Alternative Hip Bearings 94 Ceramics in Hip Arthroplasty 101 Highly Crosslinked and Thermally Stabilized UHMWPE Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements 123 Introduction 124 Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty 129 Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty 134 Patello-Femoral Arthroplasty 134 Patello-Femoral Arthroplasty 134 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		85
Introduction 93 Metal-on-Metal Alternative Hip Bearings 94 Ceramics in Hip Arthroplasty 101 Highly Crosslinked and Thermally Stabilized UHMWPE 109 Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements 123 Introduction 123 Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty 126 Polycentric Knee Arthroplasty 129 Unicondylar Polycentric Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing 142 Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements 151 Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172	Conclusion	86
Metal-on-Metal Alternative Hip Bearings Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Inicondylar Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Total Knee Arthroplasty		
Ceramics in Hip Arthroplasty Highly Crosslinked and Thermally Stabilized UHMWPE Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty 129 Unicondylar Total Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		
Highly Crosslinked and Thermally Stabilized UHMWPE Summary  7. The Origins and Adaptations of UHMWPE for Knee Replacements Introduction Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty Patello–Femoral Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		
Summary 114  7. The Origins and Adaptations of UHMWPE for Knee Replacements 123 Introduction 123 Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty 126 Polycentric Knee Arthroplasty 129 Unicondylar Polycentric Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing 142 Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements 151 Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		
7. The Origins and Adaptations of UHMWPE for Knee  Replacements 123  Introduction 123  Frank Gunston and the Wrightington Connection to  Total Knee Arthroplasty 126  Polycentric Knee Arthroplasty 129  Unicondylar Polycentric Knee Arthroplasty 132  Bicondylar Total Knee Arthroplasty 134  Patello–Femoral Arthroplasty 141  UHMWPE with Metal Backing 142  Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements 151  Introduction 151  Biomechanics of Total Knee Arthroplasty 153  Clinical Performance of UHMWPE in Knee Arthroplasty 160  Osteolysis and Wear in Total Knee Arthroplasty 172		
Replacements123Introduction123Frank Gunston and the Wrightington Connection to126Total Knee Arthroplasty129Unicondylar Polycentric Knee Arthroplasty132Bicondylar Total Knee Arthroplasty134Patello-Femoral Arthroplasty141UHMWPE with Metal Backing142Conclusion1468. The Clinical Performance of UHMWPE in Knee Replacements151Introduction153Biomechanics of Total Knee Arthroplasty153Clinical Performance of UHMWPE in Knee Arthroplasty160Osteolysis and Wear in Total Knee Arthroplasty172	Summary	114
Introduction 123 Frank Gunston and the Wrightington Connection to Total Knee Arthroplasty 126 Polycentric Knee Arthroplasty 129 Unicondylar Polycentric Knee Arthroplasty 132 Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing 142 Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements 151 Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		102
Frank Gunston and the Wrightington Connection to  Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction 151 Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172	•	
Total Knee Arthroplasty Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty Patello–Femoral Arthroplasty 134 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		125
Polycentric Knee Arthroplasty Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction 151 Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		126
Unicondylar Polycentric Knee Arthroplasty Bicondylar Total Knee Arthroplasty 134 Patello–Femoral Arthroplasty 141 UHMWPE with Metal Backing Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction 151 Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		
Patello–Femoral Arthroplasty  UHMWPE with Metal Backing Conclusion  142  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		132
UHMWPE with Metal Backing Conclusion  142  Conclusion  146  8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		134
Conclusion 146  8. The Clinical Performance of UHMWPE in Knee Replacements 151 Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172	* · ·	
8. The Clinical Performance of UHMWPE in Knee Replacements Introduction Biomechanics of Total Knee Arthroplasty Clinical Performance of UHMWPE in Knee Arthroplasty Osteolysis and Wear in Total Knee Arthroplasty 172		
Introduction 151 Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172	Conclusion	146
Biomechanics of Total Knee Arthroplasty 153 Clinical Performance of UHMWPE in Knee Arthroplasty 160 Osteolysis and Wear in Total Knee Arthroplasty 172		
Clinical Performance of UHMWPE in Knee Arthroplasty  Osteolysis and Wear in Total Knee Arthroplasty  160		
Osteolysis and Wear in Total Knee Arthroplasty 172		

9.	The Clinical Performance of UHMWPE in Shoulder	
	Replacements	189
	Stefan Gabriel	
	Introduction	189
	The Shoulder Joint	190
	Shoulder Replacement	191
	Biomechanics of Total Shoulder Replacement	195
	Contemporary Total Shoulder Replacements	197
	Clinical Performance of Total Shoulder Arthroplasty	203
	Controversies in Shoulder Replacement	207
	Future Directions in Total Shoulder Arthroplasty	211
	Conclusion	213
10.	The Clinical Performance of UHMWPE in the Spine	219
	Marta L. Villarraga and Peter A. Cripton	
	Introduction	219
	Biomechanical Considerations for UHMWPE in the Spine	222
	Total Disc Replacement Designs Using UHMWPE	226
	Clinical Performance of UHMWPE in the Spine	237
	Alternatives to UHMWPE for Total Disc Arthroplasty in the Spine	239
	Conclusion	240
11.	Mechanisms of Crosslinking and Oxidative Degradation	
	of UHMWPE	245
	Luigi Costa and Pierangiola Bracco	
	Introduction	245
	Mechanisms of Crosslinking	245
	UHMWPE Oxidation	250
	Oxidative Degradation after Implant Manufacture	256
	In Vivo Absorption of Lipids	257
12.	Characterization of Physical, Chemical, and Mechanical	
	Properties of UHMWPE	263
	Stephen Spiegelberg	
	Introduction	263
	What Does the Food and Drug Administration Require?	264
	Physical Property Characterization	265
	Intrinsic Viscosity	269
	Chemical Property Characterization	274
	Mechanical Property Characterization	280
	Other Testing	284
	Conclusion	284
13.	Development and Application of the Small Punch Test to	
	UHMWPE	287
	Avram Allan Edidin	•
	Introduction	287

	Overview and Metrics of the Small Punch Test	288
	Accelerated and Natural Aging of UHMWPE	291
	In Vivo Changes in Mechanical Behavior of UHMWPE	294
	Effect of Crosslinking on Mechanical Behavior and Wear	295
	Shear Punch Testing of UHMWPE	298
	Fatigue Punch Testing of UHMWPE	301
	Conclusion	305
14.	Computer Modeling and Simulation of UHMWPE	309
	Jörgen Bergström	
	Introduction •	309
	Overview of Available Modeling and Simulation Techniques	310
	Characteristic Material Behavior of UHMWPE	311
	Material Models for UHMWPE	317
	Discussion	334
15.	Compendium of Highly Crosslinked and Thermally Treated	
	UHMWPEs	337
	Introduction	337
	Honorable Mention	338
	Crossfire	339
	DURASUL	342
	Longevity	345
	Marathon	348
	Prolong	351
	XLPE	352
	Current Trends and Prevalence in Total Hip and	
	Total Knee Arthroplasty	353
	The Future for Highly Crosslinked UHMWPE	357
	Appendix	365
	Index	369

### Chapter 1

### **A Primer on UHMWPE**

### Introduction

Ultra-high molecular weight polyethylene (UHMWPE) is a unique polymer with outstanding physical and mechanical properties. Most notable are its chemical inertness, lubricity, impact resistance, and abrasion resistance. These characteristics of UHMWPE have been exploited since the 1950s in a wide range of industrial applications (Figure 1.1), including pickers for textile machinery, lining for coal chutes and dump trucks, runners for bottling production lines, as well as bumpers and siding for ships and harbors. More than 90% of the UHMWPE produced in the world is used by industry.

Since 1962, UHMWPE also has been used in orthopedics as a bearing material in artificial joints. Each year, about 1.4 million joint replacement procedures are performed around the world. Despite the success of these restorative procedures, UHMWPE implants have only a finite lifetime. Wear and damage of the UHMWPE components is one of the factors limiting implant longevity.

UHMWPE comes from a family of polymers with a deceptively simple chemical composition, consisting of only hydrogen and carbon. However, the simplicity inherent in its chemical composition belies a more complex hierarchy of organizational structures at the molecular and supermolecular length scales. At a molecular level, the carbon backbone of polyethylene can twist, rotate, and fold into ordered crystalline regions. At a supermolecular level, the UHMWPE consists of powder (also known as resin or flake) that must be consolidated at elevated temperatures and pressures to form a bulk material. Further layers of complexity are introduced by chemical changes that arise in UHMWPE due to radiation sterilization and processing.

The purpose of this *Handbook* is to explore the complexities inherent in UHMWPE and to provide the reader with a background in the terminology, history, and recent advances related to its use in orthopedics. A monograph such as this is helpful in several respects. First, it is important that members of the surgical community have access to up-to-date knowledge about the properties of UHMWPE so that this information can be more accurately communicated to



**Figure 1.1**Dump truck liner of UHMWPE, an example of an industrial application for the polymer.

their patients. Second, members of the orthopedic research community need access to timely synthesis of the existing literature so that future studies are more effectively planned to fill in existing gaps in our current understanding. Finally, this handbook may also serve as a resource for university students at both the undergraduate and graduate levels.

This introductory chapter starts with the basics, assuming the reader is not familiar with polymers, let alone polyethylene. This chapter provides basic information about polymers in general, describes the structure and composition of polyethylene, and explains how UHMWPE differs from other polymers (including high-density polyethylene [HDPE]) and from other materials (e.g., metals and ceramics). The concepts of crystallinity and thermal transitions are introduced at a basic level. Readers familiar with these basic polymer concepts may want to consider skipping ahead to the next chapter.

### What Is a Polymer?

The ultra-high molecular weight polyethylene used in orthopedic applications is a type of polymer generally classified as a linear homopolymer. Our first task is to explain what is meant by all of these terms. Before proceeding to a definition of UHMWPE, one needs to first understand what constitutes a linear homopolymer.

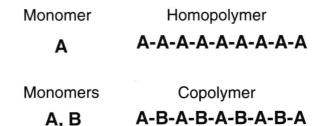
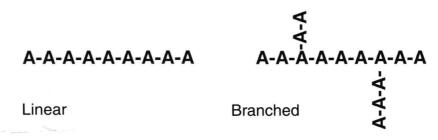


Figure 1.2
Schematics of homopolymer and copolymer structure.

A *polymer* is a molecule consisting of many (*poly-*) parts (*-mer*) linked together by chemical covalent bonds. The individual parts, or monomer segments, of a polymer can all be the same. In such a case, we have a homopolymer as illustrated in Figure 1.2. If the parts of a polymer are different, it is termed a *copolymer*. These differences in chemical structure are also illustrated in Figure 1.2, with generic symbols (A, B) for the monomers.

Polymers can be either linear or branched as illustrated in Figure 1.3. The tendency for a polymer to exhibit branching is governed by its synthesis conditions. Keep in mind that the conceptual models of polymer structure illustrated in Figures 1.2 and 1.3 have been highly simplified. For example, it is possible for a copolymer to have a wide range of substructural elements giving rise to an impressive range of possibilities. In industrial practice, polyethylenes, including UHMWPE, are often copolymerized with other monomers (e.g., polypropylene) to achieve improved processing characteristics or to alter the physical and mechanical properties of the polymer. For example, according to ISO 11542, which is the industrial standard for UHMWPE, the polymer can contain a large concentration of copolymer (up to 50%) and still be referred to as UHMWPE. However, most of the UHMWPEs used to fabricate orthopedic implants are homopolymers, and so we will restrict our further discussion to polymers with only a single type of monomer.

The principal feature of a polymer that distinguishes it from other materials, such as metals and ceramics, is its molecular size. In a metallic alloy or ceramic,



**Figure 1.3** Schematics of linear and branched polymer structures.

the elemental building blocks are individual metal atoms (e.g., Co, Cr, Mo) or relatively small molecules (e.g., metal carbides or oxides). However, in a polymer, the molecular size can comprise more than a 100,000 monomer units, with molecular weights of up to millions of g/mol.

The molecular chain architecture of a polymer also imparts many unique attributes, including temperature dependence and rate dependence. Some of these unique properties are further illustrated in the specific case of UHMWPE in subsequent sections of this chapter. For further background on general polymer concepts, the reader is referred to textbooks by Rodriguez (1989) and Young (1983).

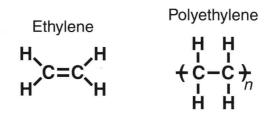
### What Is Polyethylene?

Polyethylene is a polymer formed from ethylene ( $C_2H_4$ ), which is a gas having a molecular weight of 28. The generic chemical formula for polyethylene is  $-(C_2H_4)_n$ -, where n is the degree of polymerization. A schematic of the chemical structures for ethylene and polyethylene is shown in Figure 1.4.

For UHMWPE, the molecular chain can consist of as many as 200,000 ethylene repeat units. Put another way, the molecular chain of UHMWPE contains up to 400,000 carbon atoms.

There are several kinds of polyethylene (LDPE, LLDPE, HDPE, UHMWPE), which are synthesized with different molecular weights and chain architectures. LDPE and LLDPE refer to low-density polyethylene and linear low-density polyethylene, respectively. These polyethylenes generally have branched and linear chain architectures, respectively, each with a molecular weight of typically less than 50,000 g/mol.

HDPE is a linear polymer with a molecular weight of up to 200,000 g/mol. UHMWPE, in comparison, has a viscosity average molecular weight of up to 6 million g/mol. In fact, the molecular weight is so ultra-high that it cannot be measured directly by conventional means and must instead be inferred by its intrinsic viscosity (IV).



**Figure 1.4**Schematic of the chemical structures of ethylene and polyethylene.