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Ultra-High Molecular Weight Polyethylene in Total Joint Replacement

Steven M. Kurtz, Ph.D.

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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

Contents

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

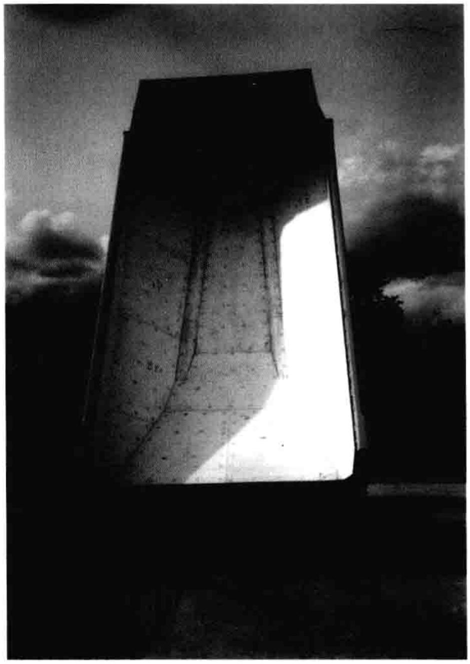

Figure 1.1
Dump truck liner of UHMWPE, an example of an industrial application for the polymer.

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.

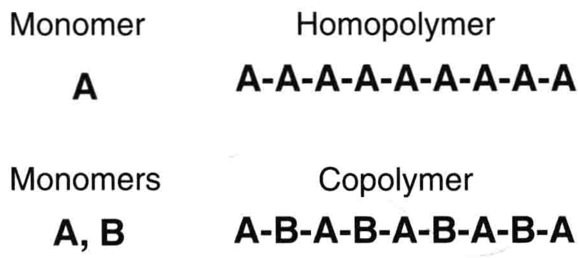

Figure 1.2
Schematics of homopolymer and copolymer structure.

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,

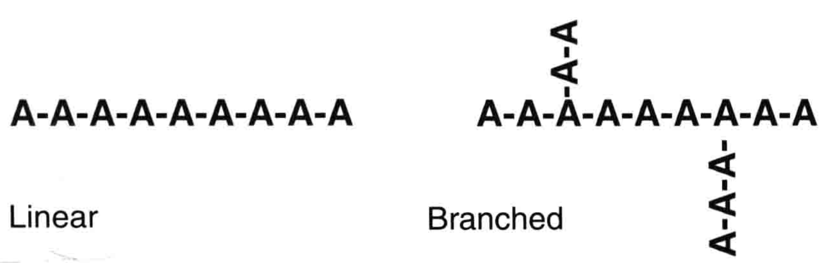

Figure 1.3
Schematics of linear and branched polymer structures.

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).

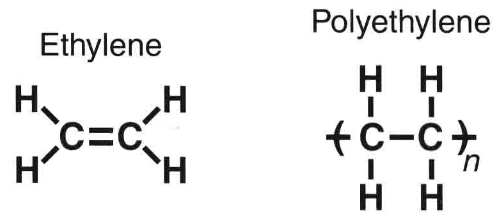

Figure 1.4

Schematic of the chemical structures of ethylene and polyethylene.