SPINE
Technology Handbook

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“To myself I am only a child playing on the beach, while vast oceans of truth lie undiscovered before me.”

Sir Isaac Newton

Editors’ Dedications:

To Katie, Peter, Michael, Sophia, and Andrew Kurtz for their patience during the time I worked on this little project.

To my wife, Cathleen, and my daughter, Alex, for their love and support as this challenge moved from conceptual kernel to finished work. And, to my parents, Profs. Michael and Ruth Edidin, for instilling in me a love of inquiry and science from an early age.

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Preface

This book is geared toward bioengineers inclined to the historical and contemporary study of spine implant technology. Of great value to the practicing clinician, the book is authored by spine implant experts and allied professionals, and is also of interest to the general bioengineering audience. To focus on current spine technologies we have intentionally restricted the scope of the book to topics that have some track record in the peer-reviewed literature. Newer technologies in this rapidly evolving field, such as facet replacement and dynamic posterior instrumentation, are still under development and thus outside the scope of our review. Nonetheless, we have strived to make the book a valuable reference for bioengineers working on the newest technologies.

Our strategy when developing the scope for this book was first to cover bioengineering fundamentals, followed by detailed review of current spine implant technologies, including key activities required to bring new devices to market. To achieve both the desired breadth and necessary depth in each of the selected topics, we have recruited leading experts in the field. We thus wish to profoundly thank the authors who took time away from their research, teaching, and professional duties to contribute to this book.

—*Steven Michael Kurtz, Ph.D.*
Avram Allan Edidin, Ph.D.
January 2006

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Chapter 1

The Basic Tools and Terminology of Spine Treatment

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1.1 Introduction

Technology-based therapies form the foundation of modern spinal disorder treatments. Such therapies may be pharmaceutical, biological, or mechanical, but they are all primarily focused on relieving chronic, intractable back pain. While specific modalities are effective to a degree, the aggregate spine disease treatment remains problematic in that there are few clear technological solutions that can completely alleviate chronic back pain, especially when due to advanced disc degeneration. In the late stages of spine degenerative disease, implant technology has shown potential to relieve some, but not all, back pain.

Early intervention with new spine implant technologies has the potential to mitigate and possibly forestall the painful cascade of degenerative changes that occur with age. One must therefore approach spine implants today with the understanding that the new implant technologies have not reached full maturity. As such, the field of spine implant technology geared toward earlier intervention in the degenerative disc cascade is effectively a new field that is evolving rapidly around the world.

The primary standard treatment for intractable back pain unresponsive to nonsurgical treatment is decompression and fusion, which consists of immobilizing the spine using bone graft, metal plates or rods, and screws. Because fusion is irreversible and stops all motion at the implanted level, it can be perceived as an end-stage procedure, naturally opening the door to many earlier-stage motion-preserving technologies for treating the diseased spine. Motion-preservation technologies cover a wide range of techniques, including nucleus repair, total disc replacement, and vertebral fracture repair. Novel motion-preserving technologies, many of which are still under design, will require innovative implants and instruments for deployment in the body.

Although treating chronic, intractable back pain is the underlying motivation for creating and developing new spine implants, the origins and causes of such pain are complex, involving organic disease, as well as psychological and societal factors. Because of the psychosocial aspect of back pain, simply treating the organic disease does not necessarily imply that a patient's pain symptoms will be totally alleviated. The magnitude of the psychosocial aspect of back pain distinguishes spine surgical intervention markedly from other elective procedures, such as hip or knee replacement.

The typical candidate for total joint replacement is elderly, greater than 65 years in age, and has retired from his or her professional activities [NIH 1994; NIH 2003]. Therefore, at least in North America, the hip or knee replacement patient typically has a remaining life expectancy of one or two decades. Joint replacements are, by and large, successful and durable procedures [NIH 1994; NIH 2003]. In the elderly patient population, for example, hip and knee replacement survival rates typically exceed 90% after 10 years [NIH 1994; NIH 2003].

Candidates for spine surgery are typically middle aged (i.e., less than 65 years) and still working. The national demographics for patients in the United States receiving a fusion at any level of the spine are summarized in Figure 1.1. These patients have many remaining decades of life expectancy, placing extraordinary design requirements on a load-bearing implant design, as it must remain *in vivo* for a long period of time. Chronic back pain can be severe and debilitating, and patients may be effectively incapacitated by the time they are ready to consider spine surgery as a viable option. During a recent clinical trial for total disc replacement, for example, 29 out of 39 (74%) surgical candidates were already taking narcotic medication for pain management [Zigler 2004].

Treatment of patients is the provenance of physicians, whereas the creation of tools and instruments is the traditional purview of engineers. When the tools and instruments are intended to modify or enhance parts of the human body, they are designed by bioengineers. The fields of medicine and bioengineering are intertwined and mutually interdependent. For this reason, bioengineering should not be considered subordinate to medicine, or vice versa. The fields mutually enhance and reinforce. Even the most perfectly conceived implant solution could have disastrous results if it is implanted for the wrong reason, in the wrong patient, or in the wrong location.

Spine implant technology provides a unique and important motivation for studying bioengineering. Beginning in the 1970s and 1980s, bioengineering played a fundamental role in the development of orthopedic hip and knee implants, to great clinical and commercial success. By the late 1990s, orthopedic bioengineering reached a period of stable, predictable growth (Figure 1.2).

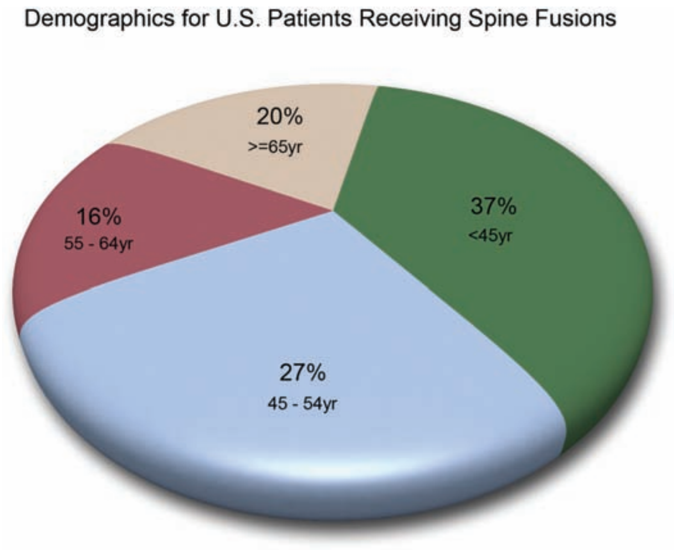

Fig. 1.1.
Patient demographics (gender, age) for fusion procedures in the United States (2003). *(Data source: National Hospital Discharge Survey. Courtesy of Kevin Ong, Exponent, Inc.)*

On the other hand, the expansion of spine implant technologies has been comparatively explosive, with the global market for spine implants growing at an expected rate exceeding 20% per year at the start of the twenty-first century (Figure 1.2). Between 1990 and 2003, the total number of primary cervical and lumbar fusion procedures in the United States alone grew from 121,400 to 281,300, representing an increase of 170% (Figure 1.3). For motion-preserving alternatives to fusion, researchers have predicted the creation of a new $2 billion market by 2010 [Singh 2004]. There is, and will continue to be, a strong demand for bioengineering talent among the producers of spine implant technology.

The thrust of this book is to provide a foundation of concepts, principles, and data crucial to bioengineers for the design, development, and clinical deployment of new spine implant technologies. The bioengineer is responsible for materials selection, component design, and testing of promising new implants. Once a promising device is developed, its release is subject to the stipulations of multiple regulatory agencies. In addition, an important consideration is the payer. In the United States this is usually private insurance or a federal program, such as Medicare or Medicaid. As a result, the successful introduction of a new spine implant technology in the clinic depends on the complex interplay among engineering, design, materials science, regulation, and health care economics. This book reviews these topics to provide a broad perspective to the engineer considering a career in spine implant development. In this chapter, we review the basic terminology and anatomy underlying the structure and function of the spine.

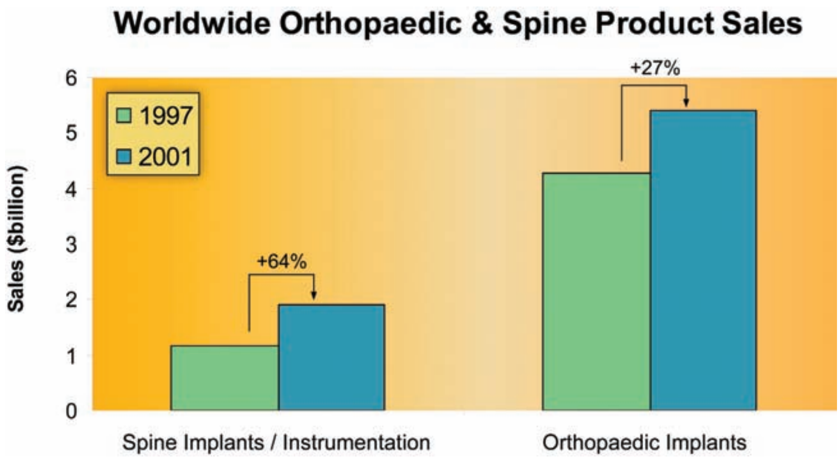

Fig. 1.2.
Growth of the global market for spine implant technology relative to other segments of the orthopedic market. *(Data source:* 1999–2000 Medical & Healthcare Marketplace Guide, *edited by R. C. Smith, M. A. Geier, J. Reno, and J. Sarasohn-Kahn. New York: IDD Enterprises, L.P., 1998. Courtesy of Christopher Espinosa, Exponent, Inc.)*

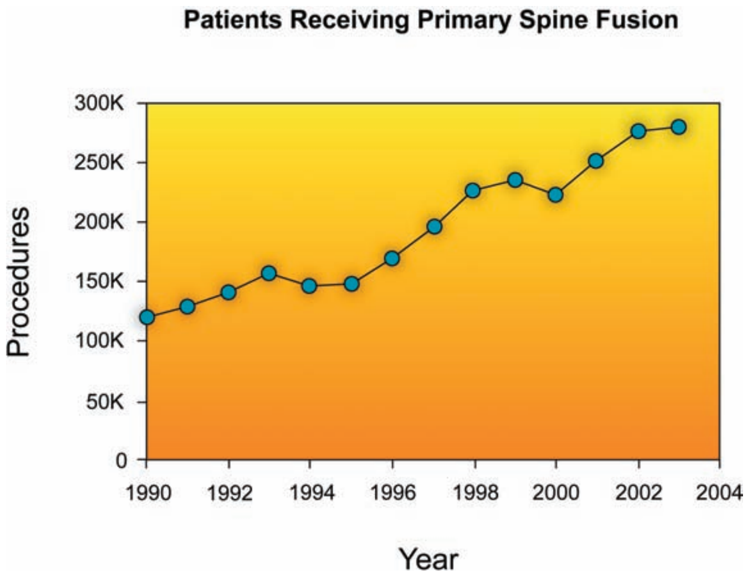

Fig. 1.3.
Primary cervical and lumbar fusion procedures in the United States (1990 to 2003). *(Data source: National Hospital Discharge Survey. Courtesy of Kevin Ong, Exponent, Inc.)*

1.2 Which Way Is Up?

Physicians visualize and operate in terms of both global and anatomical reference frames. To design implants and communicate with surgeons, it is most efficient to adopt a clinical vocabulary not only for anatomical locations but also for anatomic directions. Anatomic reference directions are illustrated in Figure 1.4.

Consider a right-handed coordinate frame, which is centered in a standing person's center of gravity (located near the center of the pelvis). In anatomic coordinates, the vertical direction is *superior*; the downward direction is *inferior*. *Anterior* refers to the front of the human body, whereas *posterior* points toward the back. The person's left and right should be self-explanatory, but both are considered *lateral* to the body. In anatomic terms, the *medial* direction is toward the middle of the body.

People do not spend all of the their time standing, so a more specific vocabulary in local anatomic coordinates is needed. With respect to limbs, for

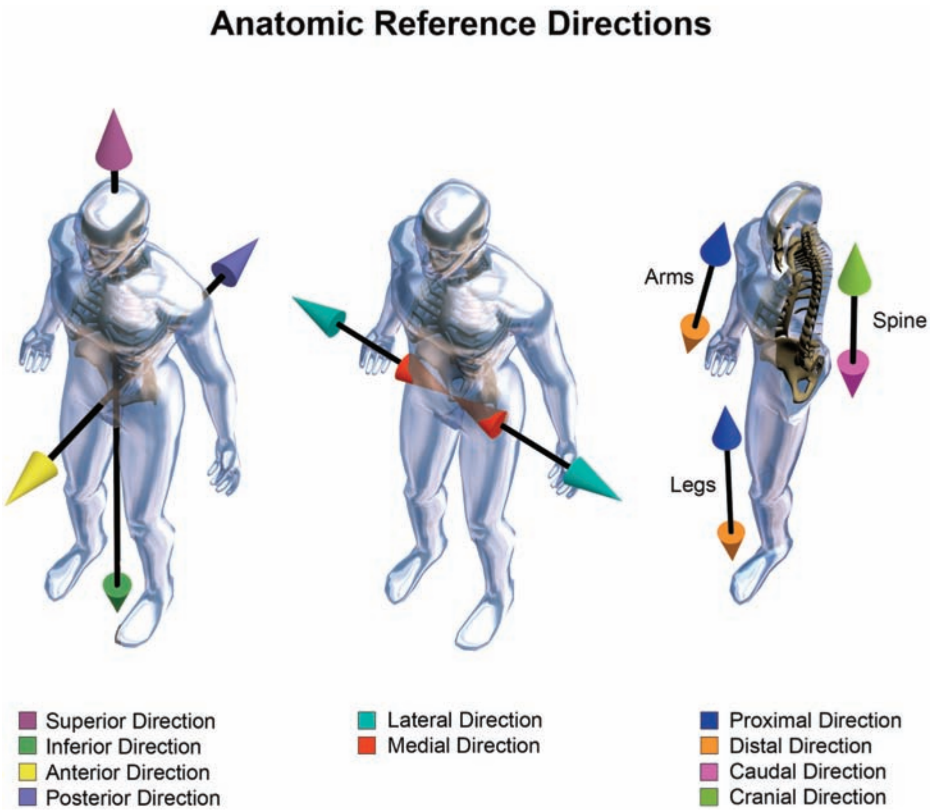

Fig. 1.4.
Anatomic reference directions. *(Courtesy of Christopher Espinosa, Exponent, Inc.)*

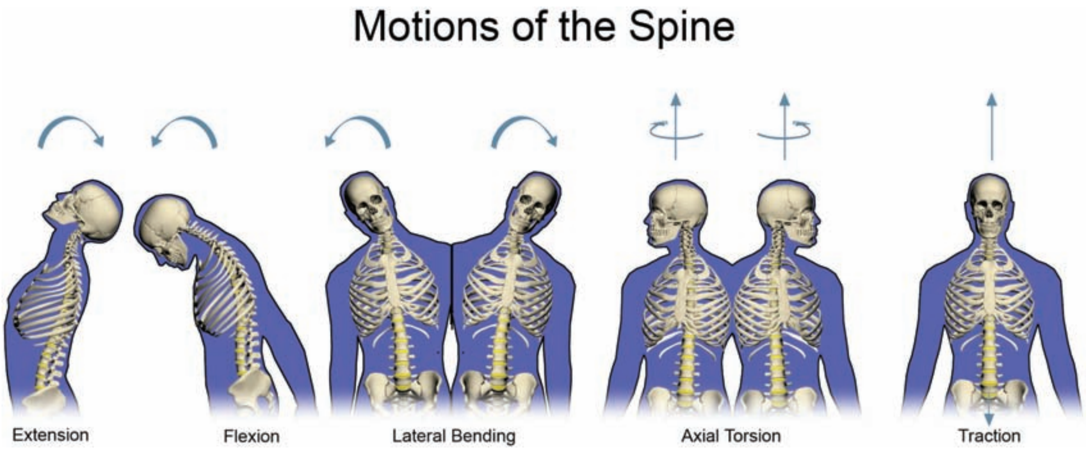

Fig. 1.5.
Anatomic terms used to describe the motions of the spine. *(Courtesy of Christopher Espinosa, Exponent, Inc.)*

instance, *proximal* refers to the region closest to the body, whereas *distal* is the furthest away. In the spine, *caudal* means in the direction "toward the tail," and *cranial*, or cephalad, means "toward the cranium, or head."

Finally, additional anatomic terms are used to describe the kinematic motions of the spine. These include *flexion* (bending anteriorly), *extension* (bending posteriorly), *lateral bending*, and *axial torsion* (Figure 1.5). Application of axial displacement to the spine is termed *distraction* instead of tension.

1.3 The Spine

The spine is a complex structure with hard and soft tissue constituents. The bones of the spine, the *vertebrae*, are the hard elements of the structure. They also protect the vulnerable spinal cord and emanating nerves. The structure and function of the vertebrae vary somewhat along the length of the spine. In general, however, each vertebral body consists of an anterior portion that is optimized for sustaining compressive loads and posterior elements that are optimized for protection of the spinal cord while facilitating motion by providing anchorage for muscle attachments.

Between the vertebral bodies, the *intervertebral discs* form a viscoelastic cushion to distribute and attenuate forces with concomitant flexibility. The aggregate spinal column is tied together by ligaments and actuated by muscles. These soft tissues are the subject of Chapter 3, whereas the vertebrae are detailed in Chapter 4.

The spine is divided into *cervical*, *thoracic*, *lumbar*, and *sacral* regions. The seven *cervical vertebrae* of the neck provide maximum flexibility and range of

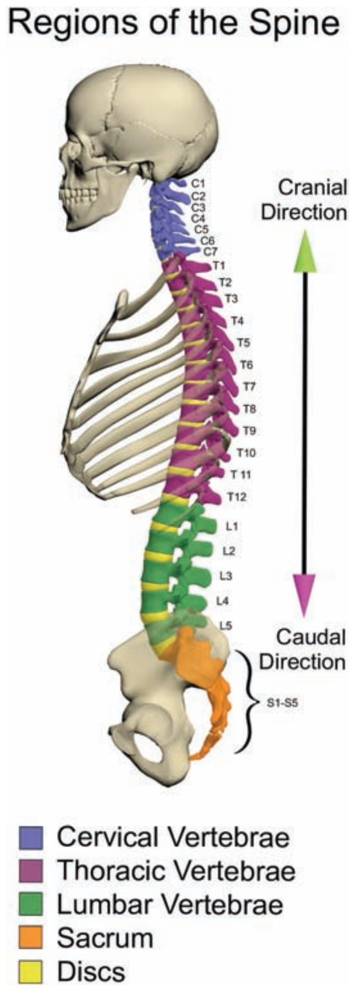

Fig. 1.6.
Cervical, thoracic, lumbar, and sacral regions of the spine. *(Courtesy of Christopher Espinosa, Exponent, Inc.)*

motion for the head. These vertebrae are designated C1 through C7 in the cranial-to-caudal direction (Figure 1.6). The underside of the cranium, where it attaches to the spine, is designated C0. The discs are identified based on their adjacent vertebral bodies (e.g., C1-C2 for the disc between C1 and C2).

The 12 *thoracic vertebrae* (T1 through T12) support the ribs and the organs that hang from them (Figure 1.6). In the thoracic region, the vertebral bodies are optimized for a combination of structural support and flexibility.

Caudal to the thoracic region, the five *lumbar vertebrae* (L1 through L5) are subjected to the highest forces and moments of the spine (Figure 1.6).

Consequently, they are largest and strongest of the vertebral bodies. These bones are optimized for structural support as opposed to flexibility.

The *sacrum* attaches the spine (at L5-S1) to the illiac bones of the pelvis (at the sacroilliac joint) (Figure 1.6). The coccyx is located inferior to the sacrum, at the most caudal region of the spine. The bones of the coccyx are thought to be the vestiges of a tail, and hence its reference as the "tail bone."

1.4 Overview of the Handbook

This book is intended to serve as a primary text for an undergraduate bioengineering course focused on the spine. The book is divided into three principal sections: Part I covers the fundamentals of spine bioengineering, Part II reviews the historical and current applications of spine technology, and Part III outlines the principal steps of developing a new spine implant technology. Part II is sufficiently detailed so as to serve as the basis for a graduate course in spine implants. Parts II and III, in particular, are also intended as references for engineers and scientists working with spine implants.

The fundamentals section of the text, Part I, presupposes two years of engineering fundamentals. The first six chapters cover, from an introductory perspective: synthetic biomaterials (Chapter 2), the soft and hard tissues of the spine (Chapters 3 and 4), and spine biomechanics (Chapter 5). The properties and geometry of these structures vary considerably from person to person and are further altered by trauma and disease (Chapter 6).

Part II of the text covers spine implant technologies that are well established or currently in the advanced stages of clinical trials. The historical development of spine fusion technology, and current implant concepts, are reviewed in Chapters 7 and 8, respectively. Chapter 9 is devoted to biologic technologies for spine repair. Chapters 10 and 11 describe two different modalities of current motion-preserving technologies intended to treat early and late intervertebral disc degeneration, respectively: disc repair and total disc replacement. Chapter 12 summarizes percutaneous vertebral fracture repair technologies, including vertebroplasty and kyphoplasty.

Part III of the text provides guidance on the process of assessment and commercialization of new spine implant technologies. Some of the unique aspects of spine implant testing are summarized in Chapter 13. Chapter 14 describes the application of finite element methods to spine implants. Chapter 15 reviews the regulatory process for obtaining approval of spine implants in the United States, and Chapter 16 provides an introduction to economic (cost/benefit) assessment of spine implants.

Understanding the properties and limitations of synthetic as well as natural biomaterials is crucial for bioengineers who intend to design future generations of spine implants. Therefore, the second chapter reviews the properties of polymers, metals, and ceramics from which today's spine implants are currently fabricated.

1.5 Acknowledgments

The authors are grateful to Christopher Espinosa and Dr. Kevin Ong of Exponent, Inc., for providing the illustrations for this chapter.

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