

PREFACE

When I first entered orthopedic surgical practice in 1978, the typical spine surgeon was trained principally in deformity correction. Simple discectomies were performed by orthopedic surgeons and neurosurgeons. Orthopedic surgeons performed the few fusion operations that were done, and there was a wide variation in the use of fusion in different communities. The typical uninstrumented posterolateral fusion was an unhappy affair for patients who frequently experienced severe pain and required large amounts of narcotic medications, which then resulted in high rates of atelectasis, pneumonia, ilius, and urinary retention. Nurses had difficulty even in log-rolling the patients in bed because of pain. The surgeon typically got two or three night-time phone calls about each fusion patient because of management difficulties. The average hospital stay was about 21 days. An often-quoted aphorism was that “Young surgeons fuse patients’ backs; middle-age surgeons re-fuse their patients’ backs; mature surgeons refuse to fuse patients’ backs.”

In the mid-1980s Dr. Art Steffee and others developed pedicle screw fixation systems to facilitate treatment of degenerative lumbar conditions. These systems were initially approved by the U.S. Food and Drug Administration as generic bone screws and plates and entered widespread use before safety and efficacy data were established. When used correctly, pedicle screw systems allowed patients a much easier postoperative course and quicker rehabilitation. The average hospital stay was reduced to about 11 days. Unfortunately, when these systems were used incorrectly, severe complications occurred. A crisis of pedicle screw litigation roiled the community of spine surgeons for much of the 1990s.

In the mid-1980s I was consumed with the need to provide reliable anterior column support to ensure dependable fusion success for treating degenerative spinal conditions. With this goal in mind, I began the development of carbon fiber reinforced polymer (CFRP) implants, which Steffee described as “cages.” Working with AcroMed Corporation, which later became DePuy-AcroMed, and now DePuy Spine, we spent 10 years completing a 2-year clinical study and finally, after many delays, achieved FDA approval of these devices. The average hospital stay was reduced to 5 days in the study. More recently, patients typically remain in the hospital 2 or 3 nights and often declare their preoperative pain gone when they first ambulate after surgery. Today, with an increasing number of collaborators, we have developed a family of CFRP devices to provide anterior column support and interbody fusion in other areas of the spine including devices for anterior cervical fusion, anterior lumbar interbody fusion, and corpectomy for reconstruction of fractures and tumors.

In recent years, the Food and Drug Administration has approved a large number of derivative devices labeled as “cement restrictors” or “vertebral body replacements,” and the companies have promoted them as interbody fusion devices with little or no supporting clinical data. Significant variations in techniques are promoted by surgeons without outcome data to support their recommendations.

Because I receive financial benefit from the sales of the DePuy CFRP interbody fusion devices, I have accepted the moral and ethical challenge of documenting the safety and efficacy of the CFRP devices in this textbook. A critical objective for this text was to achieve academic validity. This validity is based on four elements. First, I have accepted no financial support from DePuy Spine or from any other source. No company has had any editorial input in the contents of this book. Second, I have worked closely with Dr. Carl Laurysen as coeditor. Dr. Laurysen brings the perspective of a neurologic spine surgeon who has critically reviewed every aspect of this book. Third, together we have received chapters from prominent spine surgeons from around the world who have reported their independent results. And fourth, we had an international meeting in Costa Rica in February 2005, during which many of the principal authors presented their chapters and provided peer review.

Among the prominent chapters, Dr. Wolfgang Rauschnig has presented his extraordinary work detailing the applied surgical anatomy of the cervical and lumbar spine. Dr. Christopher Stowell, director of the Blood Transfusion Service at Massachusetts General Hospital, has written guidelines for transfusion management for surgery of the spine. Dr. Thomas Bauer and Daisuke Togawa of The Cleveland Clinic Foundation have presented their histologic studies of bone inside retrieved and biopsied interbody fusions. Professor Cody Büniger and associates from Denmark have described their multiple studies of biologic performance of CFRP implants in experimental studies in pigs. Dr. Büniger has worked with Professor Robert Fraser of Australia to detail the evidence base of anterior lumbar interbody fusion using CFRP implants.

Dr. Tomio Yamamoto—who was an initial investigator for the CFRP implants in clinical studies in Japan—has teamed with coworkers Tetsuo Ohwada and Akira Miyauchi to describe the long-term results of CFRP cage PLIF in 528 patients in Osaka. This study includes a 95% follow-up at an average of 54 months after surgery. Although their methods of outcome assessment—the Japanese Orthopaedic Association Low Back Score and the Hirabayashi’s Recovery Ratio score—were different from some other studies, the Osaka group reported clinical success in 93% of patients and fusion success in all but 13 segments (2.4%).

Professor Kiyoshi Kaneda of Sapporo has presented a study of interbody fusion using CFRP implants to treat degenerative lumbar scoliosis, and compared results using CFRP cages versus results using titanium mesh implants. Dr. Stefano Boriani and associates from Bologna, Italy, have described classification and treatment of spine tumors using the CFRP Stackable Cage System. Dr. Boriani and Dr. Chris Spreuwers from Belgium have described the use of the Stackable Cage System for treatment of thoracolumbar fractures.

The contributors have presented what we believe are the optimal surgical techniques for use of these devices. We have provided case reports not only of successful cases but also of those that are unsuccessful so that we can emphasize the need for the surgeon to do everything possible to achieve success in every case. We have described the unexpectedly low rate of fusion success at L1-2 through a posterior approach, along with Dr. Tomoyuki Hashimoto's recommendation that these thoracolumbar fusions should be performed through an anterior approach. We have described a statistical study that demonstrates that the narrower 9 mm cages have a slightly lower fusion success rate compared with the system as a whole (91.1% versus 96%), and we have described the design parameters causing this difference.

Spine surgery has been a developing frontier. Some have described a frontier as an area of isolation, distant from central government, characterized by conflict, and producing self-reliance and an ability to cope. Spine surgery is finally leaving this frontier stage and evolving to a new more advanced state. Currently many fellowships emphasize the treatment of degenerative spine conditions. Instead of coping with the unknown, surgeons can now select implants and techniques based on proven safety and efficacy. Casual changes in implant design and technique should not be made. Those who propose improvements should conduct careful clinical studies before recommending widespread use. Surgeons should insist on reviewing valid data before making treatment decisions.

In this text we present the data supporting the use of CFRP implants for interbody fusion collected by expert surgeons from around the world. This text is intended for all orthopedic and neurosurgery spine surgeons who treat degenerative conditions, fractures, and tumors. It also provides important information for nonsurgical spine professionals who refer patients for surgical treatment or who participate in their rehabilitation. We hope that this information will lead to improved care for our patients and will inspire others to build on the progress that has been made to date. I would like to thank Michelle Berger, Karen Berger, and their associates at Quality Medical Publishing for their assistance and support in helping to bring this work to fruition.

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