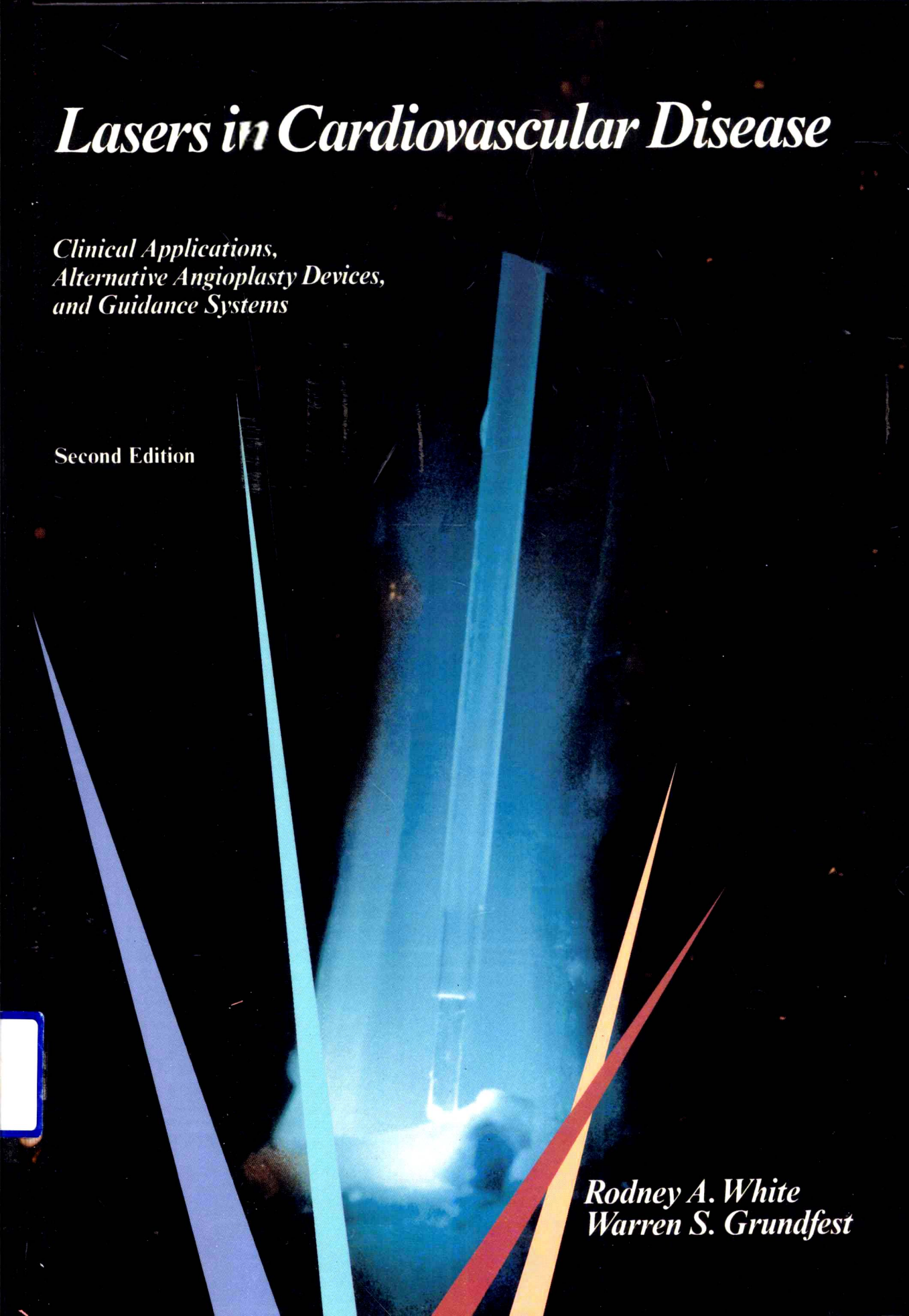
Lasers in Cardiovascular Disease

Clinical Applications, Alternative Angioplasty Devices, and Guidance Systems

Second Edition



Rodney A. White
Warren S. Grundfest

Lasers in Cardiovascular Disease: Clinical Applications, Alternative Angioplasty Devices, and Guidance Systems

Second Edition

RODNEY A. WHITE, M.D.
Associate Professor of Surgery
UCLA School of Medicine
Los Angeles, California
Chief, Vascular Surgery
Harbor-UCLA Medical Center
Torrance, California

WARREN S. GRUNDFEST, M.D.
Assistant Clinical Professor of Surgery
UCLA School of Medicine
Assistant Director of Surgery
Cedars-Sinai Medical Center
Los Angeles, California

YEAR BOOK MEDICAL PUBLISHERS, INC.
Chicago • London • Boca Raton

1 2 3 4 5 6 7 8 9 0 PR 93 92 91 90 89

Library of Congress Cataloging-in-Publication Data

Lasers in cardiovascular diseases : lasers, alternative angioplasty devices, and guidance systems / [edited by] Rodney A. White, Warren S. Grundfest. — 2nd ed.
p. cm.
Includes bibliographies and index.
ISBN 0-8151-9259-2
1. Cardiovascular system—Laser surgery. 2. Laser angioplasty. 3. Cardiovascular system—Laser surgery—Instruments. 4. Laser angioplasty—Instruments. I. White, Rodney A. II. Grundfest, Warren S.
[DNLM: 1. Cardiovascular Diseases—therapy. 2. Lasers—-therapeutic use. WG 166 L343]
RD597.L37 1989
617.4'1059—dc20
DNLM/DLC
for Library of Congress

89-5721
CIP

Sponsoring Editor: Nancy E. Chorpenning
Associate Managing Editor, Manuscript Services: Deborah Thorp
Production Project Coordinator: Carol Reynolds
Proofroom Supervisor: Barbara M. Kelly

This book is dedicated to the hope of improving the quality of patient care through an interdisciplinary approach, without doing any harm.

CONTRIBUTORS

GEORGE S. ABELA, M.D.
Associate Professor of Medicine
Division of Cardiology
University of Florida College of Medicine
Gainesville, Florida

LOUIS ADLER, M.D.
Director Vascular Radiology
Attending Radiologist
Cedars-Sinai Medical Center
Los Angeles, California

WILLIAM B. ANDERSON, B.S.
Physicist, Optics and Delivery Systems
Advanced Interventional Systems
Irvine, California

YVON BARIBEAU, M.D.
Research Fellow
Cardiovascular Laser Surgery
Beckman Laser Institute and Medical Clinic
University of California at Irvine
Irvine, California

MICHAEL W. BERNS, PH.D.
Professor of Surgery and Cell Biology
Beckman Laser Institute and Medical Clinic
University of California at Irvine
Irvine, California

ALBERT K. CHIN, M.S., M.D.
Cardiovascular Research Staff
Sequoia Hospital
Redwood City, California

PHILIP D. COLMAN, M.B., B.S., F.R.A.C.S.
Fellow in Vascular Surgery
Harbor-UCLA Medical Center
Torrance, California

EDWARD B. DIETHRICH, M.D.
Medical Director
Arizona Heart Institute
Chief of Cardiovascular Surgery
Chairman, Department of Cardiovascular Services
Humana Hospital
Phoenix, Arizona

D. LYNN DOYLE, M.D., F.R.C.S. (C)
Clinical Assistant Professor
Department of Surgery
University of British Columbia
Health Sciences Center Hospital
Vancouver, British Columbia

JOHN EUGENE, M.D.
Assistant Professor of Surgery
Beckman Laser Institute and Medical Clinic
University of California at Irvine
Irvine, California

THOMAS J. FOGARTY, M.D.
Director of Cardiovascular Surgery
Sequoia Hospital
Redwood City, California

JAMES S. FORRESTER, M.D.
Professor of Medicine
UCLA School of Medicine
Director, Cardiovascular Research
Cedars-Sinai Medical Center
Los Angeles, California

ROY M. FUJITANI, M.D.
Research Associate
Senior Surgical Resident
Harbor-UCLA Medical Center
Torrance, California

TSVI GOLDENBERG, PH.D.
Vice President
Optics and Delivery Systems
Advanced Interventional Systems
Irvine, California

WARREN S. GRUNDFEST, M.D.
Assistant Clinical Professor of Surgery
UCLA School of Medicine
Assistant Director of Surgery
Cedars-Sinai Medical Center
Los Angeles, California

CAROL GUTHRIE, M.D.
Research Associate
Surgical Resident
Harbor-UCLA Medical Center
Torrance, California

LISA HESTRIN, M.P.H.
Patient Coordinator
Laser Angioplasty Program
Cedars-Sinai Medical Center
Los Angeles, California

ANN HICKEY, M.D.
Associate Cardiologist
Division of Cardiology
Cedars-Sinai Medical Center
Los Angeles, California

YORK N. HSIANG, M.B., CH.B., M.HS., F.R.C.S.(C)
Clinical Instructor
Department of Surgery
Division of Vascular Surgery
Health Sciences Center Hospital
University of British Columbia
Vancouver, British Columbia

GEORGE E. KOPCHOK, B.S.
Biomedical Engineer
Director Experimental Laser Laboratory
Harbor-UCLA Medical Center
Torrance, California

SHARON KUPFER, B.S.
Optical Engineer
Optics and Delivery Systems
Advanced Interventional Systems
Irvine, California

JAMES B. LAUDENSLAGER, PH.D.
Vice President, Laser Development
Advanced Interventional Systems
Irvine, California

FRANK LITVACK, M.D.
Assistant Professor of Medicine
UCLA School of Medicine
Associate Director
Cardiac Catheterization Laboratory
Cedars-Sinai Medical Center
Los Angeles, California

LOUANN W. MURRAY, PH.D.
Adjunct Assistant Professor of Pediatrics
Department of Pediatrics
Harbor-UCLA Medical Center
Torrance, California

SHI-KAUNG PENG, M.D., PH.D.
Professor of Pathology
Department of Pathology
Harbor-UCLA Medical Center
Torrance, California

THOMAS L. ROBERTSON, M.D.
Chief, Cardiac Diseases Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland

DAVID ROSENBAUM, M.D.
Research Associate
Harbor-UCLA Medical Center
Torrance, California

TIMOTHY A. SANBORN, M.D.
Associate Professor of Medicine
Director, Interventional Cardiology
Research and Laser Angioplasty Program
Department of Medicine
Division of Cardiology
Mount Sinai Medical Center
New York City, New York

MICHELE SARTORI, M.D.
Methodist Hospital Cardiology Section
Houston, Texas

JAMES M. SEEGER, M.D.
Associate Professor of Surgery
Department of Surgery
University of Florida College of Medicine
Chief, Vascular Surgery
Veteran's Medical Center
Gainesville, Florida

JACOB SEGALOWITZ, M.D.
Fellow, Department of Surgery
Cedars-Sinai Medical Center
Los Angeles, California

TAKANOBU TOMARU, M.D.
Research Fellow
Division of Cardiology
University of Florida College of Medicine
Gainesville, Florida

JERRY W. VLASAK, M.D.
Research Associate
Surgical Resident
Harbor-UCLA Medical Center
Torrance, California

GEOFFREY H. WHITE, M.D.
Assistant Professor of Surgery
UCLA School of Medicine
Los Angeles, California
Vascular Surgeon
Harbor-UCLA Medical Center
Torrance, California
Chief, Vascular Surgery
Veterans Administration
Wadsworth Medical Center
Los Angeles, California

RODNEY A. WHITE, M.D.
Associate Professor of Surgery
UCLA School of Medicine
Los Angeles, California
Chief, Vascular Surgery
Harbor-UCLA Medical Center
Torrance, California

PREFACE TO THE SECOND EDITION

The second edition of this book follows the first edition by 2 years. Half of the chapters are new and, all have been updated; only three remain without substantial revision or lengthy addition of new material. These changes reflect the rapid accumulation of clinical data and an attempt to define the role of lasers in cardiovascular diseases, as well as the development and use of ancillary devices.

At the time of the first edition, lasers were solely a research tool; their role in clinical vascular interventions was only speculative. Since then, there has been an explosion in the use of laser for angioplasty, with two manufacturers having FDA-approval for their devices, and approval rapidly approaching for many more manufacturer's devices. The number of cases has been estimated at nearly 20,000 in more than 600 centers that have devices. Although the technique remains experimental, evidence is accumulating that substantiates benefit from therapy in at least a segment of the patients, and if improvement in devices and guidance methods continues, the laser techniques may dramatically change the treatment of vascular disease in a significant segment of the population.

Accompanying these rapid developments is an unrealistic depiction, particularly in the media, of the new devices as panaceas for cure of hopeless cases. Consumer awareness, patient demand, and a mystical appeal of the laser methods have created substantial economic pressures for physicians to at least know the methods, and to have the technique available if patient volumes are to be maintained. Controversies regarding indications for use and involvement of surgeons, cardiologists, and radiologists in applying the technology have led to unfortuante in-fighting in institutions where collaboration is not initiated early. It is our strong conviction that collaborative efforts yield better patient care and case selection. For these devices, defining the indications for use requires careful follow-up evaluation of several hundred cases. The rush to prove that one device is better than another must give way to the understanding that time, experience, and knowledge regarding case selection are required to appropriately assess the role of each device.

This book addresses the state of the art in applications of lasers in cardiovascular disease by reviewing the current theory of laser-tissue interactions, providing a review of all available experimental and clinical data, and detailing the limitations and future research needs. Considering the interest and controversy surrounding this topic, we have attempted to provide a detailed review of all pertinent issues from several perspectives so that the readers can draw their own conclusions based on the spectrum of available information and opinions.

Rodney A. White, M.D.
Warren S. Grundfest, M.D.

PREFACE TO THE FIRST EDITION

The use of lasers in medicine and surgery has generated significant interest. The initial enthusiasm was based mainly on the fascination for a "star-wars" concept, which ascribes mystical powers to this unique form of energy. The idea that a laser can be used as a surgical instrument to cut tissue, destroy tumors, and open obliterated atherosclerotic arteries triggered a degree of speculation and enthusiasm that preceded the reality that scientists and physicians have been trying to determine. This effort has required the development of a unique collaboration among physicists, engineers, biologists, and clinicians. To the pleasant surprise of all, many of the speculations regarding the potential uses of lasers in medicine are rapidly developing into applications.

The adaptation of lasers as therapy for cardiovascular diseases is in its infancy, but the use of lasers to treat difficult clinical problems and improve overall care of patients is coming close to reality. The ability to selectively ablate abnormal tissues and atherosclerotic lesions and enhance the technical accuracy and healing of vascular repairs is now more than an appealing concept.

The objective of this book is to convey a basic understanding of laser physics, safety, and laser-tissue interactions, and to describe the current state-of-the-art and eminent developments to physicians, allied health professionals, and those interested in the frontiers of medicine. It will become evident that the current laser applications are not the cure-all that the extensive publicity may lead one to believe; in a curious way the field is developing in a manner that adds credence to some of the early speculations regarding the use of laser surgery.

Rodney A. White, M.D.
Warren S. Grundfest, M.D.

ACKNOWLEDGMENTS

We wish to thank the contributors for their timely assistance in the preparation of this book. Special thanks are given to Gloria Stevens who provided expert assistance in manuscript preparation and word processing. Special recognition is also given to our colleagues, research associates, and support personnel at Harbor-UCLA and Cedars-Sinai Medical Centers who consistently provided help and encouragement. We also thank Carol Reynolds, Deborah Thorp, Nancy Chorpenning, and Beth Caldwell of Year Book Medical Publishers for their help and support.

Rodney A. White, M.D.
Warren S. Grundfest, M.D.

CONTENTS

PART I

Introduction

Chapter 1

Overview of Administrative and Safety Considerations

George Kopchok, B.S.

Rodney A. White, M.D.

The recent development of lasers for use in medicine and surgery has created a new frontier with numerous potential cardiovascular applications. Among the questions to consider while exploring this new technology are (1) Why use lasers to treat cardiovascular disease? and (2) What are the special considerations required for choosing appropriate instrumentation, assuring facility safety, and conducting personnel training?

Lasers are expensive equipment that have unique space and facility requirements. Unless they fulfill a need in our armamentarium that is not available by current, less expensive technologies, the use of lasers in cardiovascular medicine is not appropriate. As outlined in the remainder of this text, there are several advantages that lasers offer to the cardiovascular surgeon, cardiologist, and radiologist. Specific ablation of intracardiac and intravascular lesions, disobliteration of totally occluded small internal diameter arteries, augmentation of current clinical techniques such as percutaneous balloon dilatation, and laser welding of vascular tissue are current applications that may soon find significant clinical utility. The initial studies using percutaneous transluminal balloon angioplasty were performed less than a decade ago, but this technique is now used widely for rapidly expanding indications. Laser vascular surgery appears to have the same potential for broad applicability and development.

CHOICE OF MEDICAL LASER SYSTEMS

In most cases the lasers that are currently available in hospitals are improperly designed or have inadequate power ranges to make them easily adaptable to cardiovascular applications. Because of the expense of purchase, installation and maintenance of lasers, hospitals are obviously concerned with maximizing the use and cost-effectiveness. A new laser system that is to be used primarily for cardiovascular applications should, if possible, have the broadest applicability to multiple specialties. The desirability of any particular instrument directly increases with its versatility.

Conceptually, the ideal laser should be an instrument that can be dialed over a wide power range (watts), is tunable over the entire spectrum of wavelengths, permits fiberoptic transmission and is designed to accommodate any future demands that would be placed on the instrument. Unfortunately, at the present state of technology, lasers that meet these specifications are not available. Dye lasers use various organic dyes as lasing media to produce a tunable characteristic over the range of approximately 300 to 1,000 nm, although they are currently far from ideal. Each dye provides wavelengths over a narrow range. The dyes are cumbersome to use, and some dyes are unstable. The free electron laser is a theoretical solution to this problem as it may be tunable over all wavelengths and produce a wide range of power, but it requires a very large and expensive particle separator for operation.[1] Currently, carbon dioxide (CO_2) (10,600 nm), neodymium:yttrium-aluminum-garnet (Nd:YAG) (1,060 nm), and argon (488 to 515 nm) are the clinical lasers available at most hospitals. The CO_2 lasers have power outputs of a few hundred milliwatts to 100 W and are used for cutting or ablation of soft tissue. The Nd:YAG lasers are most reliable between 1 and 60 W and are used by general surgeons and gastroenterologists for tissue coagulation. Argon lasers provide a steady output from the milliwatt to 15-W level and are used primarily in ophthalmology and dermatology to coagulate pigmented lesions. The argon and Nd:YAG lasers are transmitted through flexible quartz optic fibers, while CO_2 can only be transmitted via mirrors and articulating arms or potentially by a hollow tubular waveguide. Although other promising laser prototypes are at various stages of experimental development, none of them at present are commercially available for cardiovascular applications. Throughout this interval of rapid development, one must keep in mind the current availability of lasers and separate that from what may be state-of-the-art in the future.

ORGANIZATION/PERSONNEL

In order to make rational decisions regarding lasers, establishment of laser safety protocols and laser acquisition should be scrutinized and controlled by a hospital laser technology committee. Key individuals who should be involved in the laser committee activities are administrative personnel, the hospital safety officer, a representative from the hospital mechanical services and nursing, and a representative from each of the medical and surgical subspecialties that have interest in laser applications. Frequent meetings of this group are necessary to assess the current state of laser applications within the hospital, to evaluate the priorities in laser program development, and to assess the utility and cost-effectiveness of proposed new purchases.

An administrative representative to the laser committee is obviously essential to evaluate the cost-effective use of instrumentation and to represent the fiscal responsibilities and priorities in hospital program development. It is also administrative responsibility to address billing for laser procedures. Most of the cardiovascular laser applications are still considered experimental, and third-party payers may decline payment on this basis. Some of these procedures are done as adjuncts to other standard procedures, such as laser-assisted balloon angioplasty. The technology is also being used in combination with, or as a substitute for, standard procedures in the operating room. In this instance, the laser procedures may significantly reduce the cost of therapies that currently pay a substantial diagnosis-related group (DRG) fee.

At present, several billing mechanisms exist, primarily because the methods of reimbursement vary among states. A few institutions that do large volumes of cardiovascular

TABLE 1–1.
Credentialing Standards

A. Laser safety standards and practices should be developed by a hospital laser technology committee. The primary responsibility for laser safety should be organized by an individual designated by the institution and approved by the committee as the laser safety officer.
B. Department chairmen or their selected representative within the department or divisions hold the basic responsibility to ensure that the use of lasers on their service is performed by competent personnel. Staff members shall petition for permission to use laser through their department chairman or department/divisional representative.
C. Staff members desiring to utilize the laser must be trained in the use, care, and physics of the laser and have fulfilled the following criteria:
    1. The candidate has demonstrated proficiency, knowledge, and safety in the use of lasers through previous use, which is common knowledge of the department chairmen or his representative and the laser safety committee.
    2. The candidate may present certification of approved training sessions indicating that the staff member has completed a laser course of at least 4 hrs of didactic and 2 hrs of "hands-on" experience. The applicant should also demonstrate proficiency specific to that physician's specialty by observation of a departmental preceptor for two or more procedures, if necessary, based on the preceptor's decision. Documentation of the preceptor's approval should be kept on file.
D. The department chairman will forward all approved laser use requests to the chairman of the laser technology committee for proficiency verification and activation to user status.
E. "Active laser use status" staff members will receive a copy of the laser safety guidelines and will acknowledge their reading and understanding of these guidelines by signing a copy that will be kept on file in the office of the department chairman and/or the laser technology committee chairman, and in the facility where the laser is being used (i.e., operating room, etc.).
F. Each department chairman by generating a list of laser treatments within his specialty, will document which procedures the petitioning physician will have permission to perform. When appropriate, privileges that are limited to the use of particular type(s) of laser(s) should be noted. The laser technology committee has the final responsibility for ensuring appropriate and safe use of laser devices.

laser procedures have negotiated payment schedules from appropriate carriers but, in general, a uniform payment schedule has not been developed. It is likely that codes will be assigned by the insurance industry in the near future.

The laser safety officer or his designee fulfills an important role on the laser committee by establishing laser safety protocols for the institution and by ensuring that instrumentation, new programs, and new facilities fulfill these requirements and are accompanied by the necessary approvals.[2–5] A representative from mechanical services is needed to evaluate the power and plumbing requirements for new instrumentation and to expedite facility construction. Nursing plays a key role in space planning, training programs, equipment maintenance, and oversight of the safe use of the lasers.

CREDENTIALING

The final responsibility for laser safety and for determining appropriate requirements for credentials to use the lasers rests with the institutional laser technology committee. Physicians can demonstrate proficiency by either previous experience or by certification by an approved training program. Each department chairman should generate a list of approved laser treatments and decide in conjunction with the laser technology committee which procedures a particular physician can perform. Table 1–1 displays a sample format for credentialing standards.

Considerable concern exists regarding credentialing criteria for cardiovascular applications of lasers, in particular, laser angioplasty. The appropriate use and monitoring of these new, rapidly developing devices and techniques generate interest in most institutions because many of the new cardiovascular laser procedures are being used by multiple

subspecialties, i.e., surgeons, radiologists, and cardiologists. For this reason, the primary factor in establishing appropriate guidelines in any institution is a cooperative effort among the interested specialties to deal with all appropriate concerns and to prevent "in-fighting" over the technology. We encourage collaboration and find that each group learns from the expertise of the other, i.e., surgeons benefit from the percutaneous and catheter techniques of the radiologists and cardiologists, and the success of the radiologists and cardiologists is enhanced by the vascular surgeons' understanding of arterial pathology derived from direct observation and intraoperative skills.

For individuals applying for privileges on the basis of a course certificate, the course should consist of 4 to 6 hours of lecture that outlines all pertinent safety information, clinical data, etc. and also includes 2 to 4 hours of hands-on experience. The didactic material is quite well standardized. Controversy exists regarding what constitutes adequate hands-on training. In most instances, hands-on training is limited to use of the instruments in animal models on an in vitro and occasionally in vivo basis. Animal models of arterial diseases have limited availability and are not useful except for preliminary training. For this reason, the best approach is to combine the course requirement with a specified number of proctored minimal-risk cases.

It is likely that most specialties will develop their own guidelines for laser use. When this document exists, it should be used for the specialty that develops the document but not be used to exclude other subspecialties requesting similar privileges. Ultimately, we must rely on the Board of each specialty and the training programs to provide trainees with knowledge of the new procedures so that credentialing can be based on the Board Certificate. As an example, 90% of the vascular surgery training programs now include balloon angioplasty experience, and the majority are adding laser angioplasty and angioscopy. In general, we recommend that patients undergoing percutaneous procedures should be evaluated before the procedure by a physician with "bed privileges" so that hospitalization and care for complications can be accomplished readily.

In most cases, laser surgery, including laser angioplasty, is credentialed by an institutional committee primarily because it is a major safety issue not only for patients, but also for hospital personnel. Aside from requirements for course training and proctoring, the new technologies can be introduced into clinical practice with minimal risk.

LASER SAFETY

Establishment of a laser safety protocol, facility specifications, approvals, in-service training, and continuing education for personnel are essential to maintain a safe environment. Personnel training regarding operating procedures and precautions to prevent personal injury and property damage must be given to all laser users. Only certified personnel should be permitted to set up, use, and discontinue use of laser equipment. Although laser radiation can cause eye damage, skin burns, and combustion of flammable materials, these hazards can easily be averted by a carefully planned program.

The physician and all key operating room personnel should be fully versed with an understanding of laser physics, appropriate nomenclature regarding laser energy, and laser tissue interactions.[2, 6] The physician user is ultimately responsible for selecting the wattage and appropriate lens or fiber for each procedure. However, a laser safety officer or his designee should be present at all cases (American National Standard for the Safe Use of Lasers in Health Care Facilities, ANSI Z136.3, 1988).

Laser procedure and operating rooms must have all windows covered with nontransparent barriers to prevent inadvertent passage of laser light (Fig 1–1). All doors must be

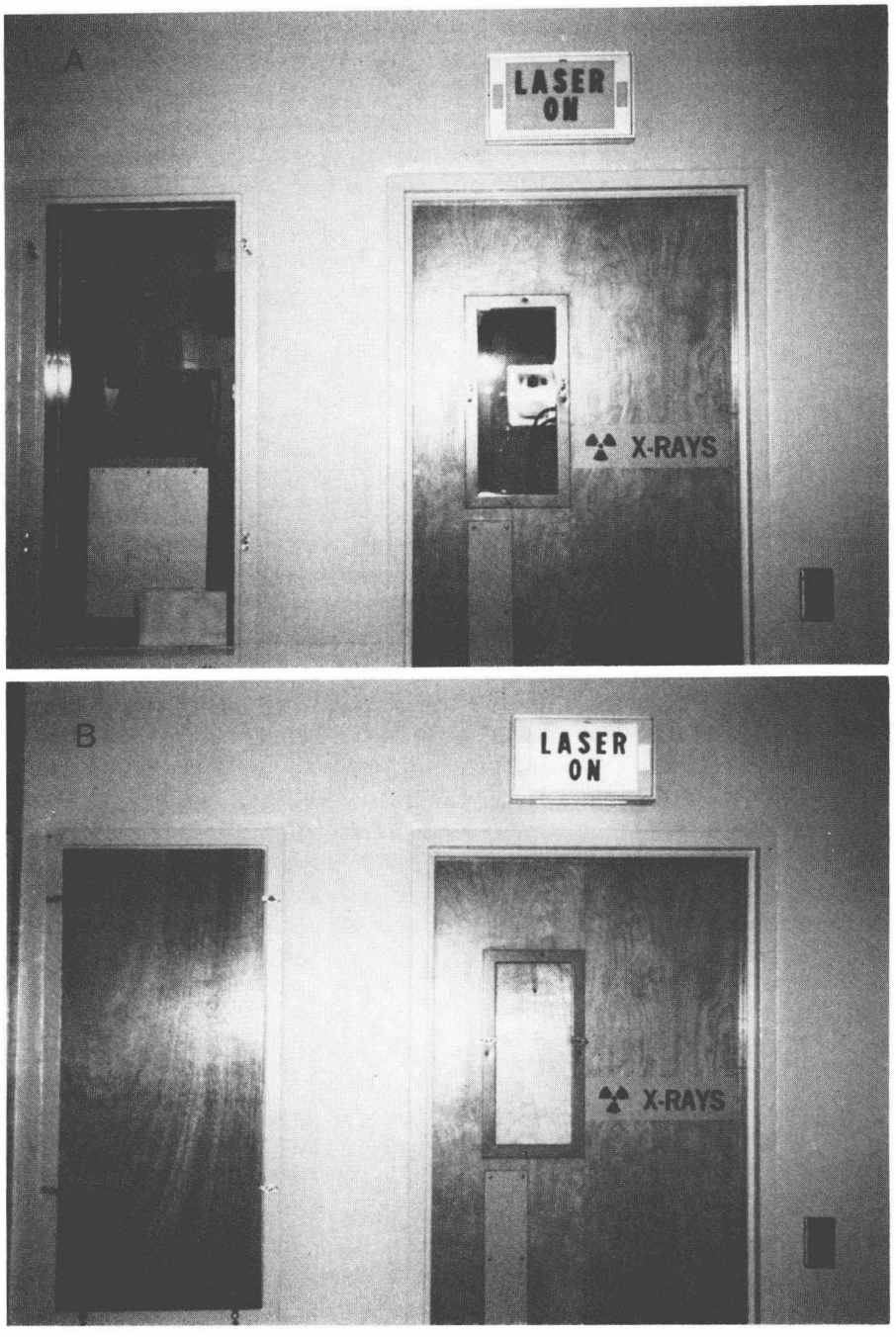


FIG 1–1.
Windows of the operating rooms **(A)** are covered by nontransparent barriers to prevent passage of laser light **(B)**. Clearly visible flashing lights are also activated during procedures to help control access to the room.