Optical and Laser Technology in Medicine

Robert J. Landry, David Sliney, Robert Scott
Chairmen/Editors

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Session 1—Medical Lasers: Applications, Tissue Effects, and Delivery Systems
Robert J. Landry, Center for Devices and Radiological Health, FDA

Session 2—Optical Radiation: Materials Characteristics, Propagation in Tissue, and Diagnostic Techniques
Robert Scott, Pacific Institute for Laser Optics and Technology

INTRODUCTION

In the last few years there has been a dramatic growth in the use of optics and lasers in medicine. This includes the development of new laser surgical applications in the treatment of gastrointestinal, gynecologic, ocular, otolaryngeal and respiratory diseases, among others. New lasers such as the excimer and free electron (FEL) are being explored for medical applications. Finally, new medical devices are being developed for phototherapy applications and for moitoring biological functions, while new optical techniques are being explored for noninvasive diagnosis of ocular and oncological diseases. Some of these new developments were discussed at this conference.

The conference was divided into two sessions and a panel discussion.

SESSION 1, MEDICAL LASERS:	Applications, Tissue Effects, and Delivery Systems.
SESSION 2, OPTICAL RADIATION:	Materials Characteristics, Propagation in Tissue, and Diagnostic Techniques.
PANEL DISCUSSION:	Need for the Clinician in the Device Design Process.

The first session provided papers on new technological developments in the application of lasers in medicine. This included the discussion of new laser devices such as applications with a hand-held surgical CO_2 laser, and the possible application of a new instrument in angioplasty, as well as new laser surgery delivery systems. The remaining papers were concerned with laser beam/tissue interactions and experimental applications of lasers in medicine.

The second session provided papers on the characterization of the optical properties of tissues and photosensitizing drugs, diagnostic evaluation of human lenses, and image analysis of ocular lesions.

The panel discussion at the conclusion of the meeting addressed the need for the clinician in the device-design process, medical device regulatory issues, and the role of governments in the development of medical devices. An excellent exchange of information and ideas was carried out between clinicians, physicists, design engineers, manufacturers, regulators, and basic scientists. Many interesting issues were reviewed.

Significant new advances, devices, and information were described at this conference. It is anticipated that the growth in new applications of optics, devices, and laser technology in medicine will continue to accelerate as more attention is focused on this area. Much remains to be learned about the optical properties of tissue and laser beam/tissue interactions. We expect to follow this growth in knowledge and new applications in future conferences.

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The papers appearing in this book comprise the proceedings of the meeting mentioned on the cover and title page. They reflect the authors' opinions and are published as presented and without change, in the interests of timely dissemination. Their inclusion in this publication does not necessarily constitute endorsement by the editors or by SPIE.

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An Overview

Optics and Lasers in Medicine

Speech, Thursday, January 23, 1986 at
the INTERNATIONAL SPIE CONFERENCE
Los Angeles, California

Ladies and Gentlemen,

The year 1986 marks the twentieth anniversary of the use of the laser in clinical medicine.

This light ray, since Flash Gordon, has been the favorite subject of science fiction. It was hailed as the magic weapon, but also as the magic cure for many diseases. This is no longer a fantasy. We have the SDI program and we also see multi-disciplinary laser clinics. The non-contact laser beam performs surgery with significantly reduced trauma and bleeding and has actually changed treatment requiring hospitalization to ambulatory surgery. LASER MEDICINE today stands for BETTER HEALTH CARE at LOWER COST.

Today, I am going to offer a broad overview of medical laser technology...principal applications, market opportunities, and where the industry has been...and where I believe it's headed. I have wrestled with the future of this industry for more than a decade and I will quickly take you through a capsule history of medical laser development.

Research on the effect of laser beams on living organisms began in the early sixties with ruby lasers. Documented success in surgical applications, however, did not come until the late sixties when argon and CO_2 surgical systems became commercially available. My mentor and friend, Dr. Thomas Polanyi, then at American Optical, developed the first CO_2 surgical system, and Dr. Geza Jako at Boston University used it for the first time. And what a system it was! His famous AO 100, like the early computers, was large and unwieldy, to say the least. It was appropriately nicknamed "The Telephone Booth." It was a monster--but it worked.

Since those early days of the Telephone Booth, the pace of research, trial, and clinical success accelerated through the nineteen seventies and now, by 1986, lasers have established a permanent position in medicine and surgery. The laser is the modality of choice in many specific procedures. And, with professional respectability, has come widespread use and an emerging support industry. Today, the medical laser market is approaching the critical mass necessary for rapid and sustained growth.

A brief discussion of the current array of laser types helps in formulating a perspective on the industry.

First, the Argon laser. This laser produces a low-power blue-green beam which passes through clear tissue (such as the cornea of the eye), but which coagulates red tissue (such as vessels in the back of the eye).

Argon's most important applications are in ophthalmology, its early acceptance and widespread use making it the most prevalent type of surgical laser system today--a case of good medicine and good economics achieving rapid recognition by practitioners and patients alike.

There are roughly three times as many lasers in use today for ophthalmic applications as for all other uses in medicine combined. Sales of Argon lasers, however, could slow down if the more efficient and powerful frequency doubled Nd:YAG laser takes its place. In frequency-doubled form, the Nd:YAG has a wavelength of 530 nm in the green portion of the visible spectrum. This is close to the Argon laser's wavelength, with the capability of delivering much higher power.

The Carbon Dioxide laser is the laser of choice where ultra-precise control of the depth and lateral extent of tissue destruction is necessary, such as in neuro-surgery. The CO_2 laser's infrared beam is readily absorbed by water and most other liquids, making it ideal for cutting or vaporization of tissues throughout the body. A noted laser specialist has said, "For precise tissue destruction, the CO_2 laser has no equal in any other surgical device ever invented. The CO_2 laser is the ultimate bloodless, precision, non-steel scalpel."

Between now and 1990, it is predicted that the CO_2 laser will be the fastest growing laser type. This is due to its numerous applications in microscopic and endoscopic--KEYHOLE--surgery, and its ramifications in terms of non-traumatic, ambulatory medicine and the resulting impact on medical economics.

The development of a suitable optical fiber which will transmit the CO_2 laser's infrared beam will widen the scope of applications tremendously. However, a non-toxic, really flexible fiber has not been developed as of today.

The pulsed Nd:YAG laser will be the third most important type by the end of this decade. For the moment, however, it is still used under IDE from the FDA. At this time, 28 companies have entered the market, several have received final FDA approval for their ophthalmic laser, and others will surely follow.

There is also a fast growing market in CW Nd:YAG lasers for surgical applications, and several companies have received IDE approval from the FDA. The important uses of the Nd:YAG are in coagulatory applications. At its near-infrared wavelength of 1.06 microns, it penetrates deep into sóft tissues and, because it can be transmitted through quartz optical fibers, delivery of the beàm to the operating site is very easy.

A newly developed beam delivery device for the CW-YAG laser is a contact ceramic probe. This heat-resistant quartz scalpel comes in contact with a selected volume of tissue, for example a tumor, and will vaporize it. Adjacent tissue will not be effected. The non-contact technique can be applied next and will form a thick sealed-off scar. The combination of these two methods are very promising and have also brought down the requirement of applied laser energy.

Other laser types include the Dye laser which is capable of continuous wave output at different wavelengths, but presently very expensive (pumped by an Argon-ion laser). Potential in the market is high, because of applications in Photo-Radiation Therapy, which I will discuss in more detail later.

Excimer lasers are high power lasers which are considered by many to "usher in the next wave of medical laser applications in ophthalmology." Its great potential is in the performance of Radial-Keratotomy. This procedure could obsolete most contact lenses and glasses.

An Excimer laser is produced by combining argon, krypton, or xenon, with a halogen gas such as fluoride or chloride. The resulting beam has a very short wavelength in the ultraviolet spectral region. It can be focused to very small spot sizes (40 microns is routine). Its other principal surgical advantage is that it has no effect on tissue surrounding the point of contact with the beam. There is <u>no</u> adjacent tissue damaged by thermal effect. Experimentation is in the initial stages only. These lasers are bulky, complex, and expensive--they are also very powerful and need taming before they are suitable for routine medical work.

In sum, medical lasers, regardless of type, are less invasive, non-traumatic, provide for quick healing, ambulatory, and cost-effective medicine.

When all is said and done, the fact remains that basic laser technology has been well-established for some time and is not really a new story. Ergonomically designed, smaller systems--such as those being developed around sealed-off CO_2 technology--will probably parallel the evolution of the microprocessor in terms of steady reductions in size and scale. In lasers, the excitement is in the development of delivery systems that can bring the beam to the tissue site in the neatest, fastest, safest, and most efficient manner. Delivery is everything in keyhole surgery for abdominal, thoracic, rectocolon, cardiovascular, and a host of other procedures. Bleeding ulcers, especially prevalent in high-anxiety environments such as the trading floor pictured here, can be easily accessed in this keyhole procedure. The traditionally complex and costly heart bypass operation may be replaced by precisely-aimed lasers blasting through blocked arteries.

The United States is the land of physical fitness. Jogging, aerobics, and squat jumps, not to mention old football injuries sustained in high school, are often the cause of knee injuries. Just seven weeks before winning the Gold Medal, this woman had a knee operation: Mary Lou Retton, one of an astounding 280,000 victims of knee injuries each year. Arthroscopic procedures will soon be made infinitely simpler and far less traumatic by a laser directed through an arthroscopic attachment. The range of surgical laser applications is, to say the least, wide-open.

To put the laser market in perspective, a few key points should be underscored. I have said that the medical laser market is approaching critical mass necessary for rapid growth. But reaching that point has been arduous. For years, laser technology was a case of solutions chasing problems. As in the early days of industrial laser applications, medical lasers have been unprofitable. To be profitable, it had to be shown that the laser was a cost-effective replacement for cold steel--the scalpel--which, after all, has been the preferred surgical tool since the Middle Ages. One has to be very convincing to get a doctor to replace a ten dollar scalpel with a $20,000 piece of equipment! To accomplish this, a massive professional education effort is taking place. Only the companies with sufficient muscle could do this. Johnson & Johnson, Cooper LaserSonics, and Coherent have spent millions of dollars over the past few years in educating medical professionals on the viability of lasers as a cost-effective surgical tool. The industry has had to prove that acceptance of the new technology, in addition to fostering better economics, also meant better medicine--better post-operative recovery, fewer problems, and reduced risks.

As always, the economic imperative dictates whether the chips will fall in favor of one technology or another. With the soaring health care costs over the last twenty years, the Federal government recognized the need to take action that would force health care providers to reconsider and reorder priorities in determining appropriate treatment. This Federal government mandate called for deregulation, reduced cost of Medicare, payment on a per case basis, efficient treatment, and shorter hospital stay. Prospective payment is tied to 467 specific diagnosis-related groups--DRG's--into which all medical procedures have to fit. For each DRG, there is a fixed rate of payment. To maintain profitability, hospitals are now forced to seek cost-saving technologies. DRG's create demand for the appropriate technology rather than any technology at any cost. Medical lasers fit the nationally mandated prospective payment model perfectly. According to Forbes magazine, "No more of this buying a piece of equipment just because it's the newest thing. Hospitals are going to have to buy equipment to process a lot of patients quickly and easily. Medical equipment makers whose products have clear cost-effectiveness will do best: automated laboratory testing equipment and surgical lasers, for example." The laser's burgeoning role in fostering better medicine and better economics is propelling the industry to the fore.

Data on market share and market size is notoriously inconsistent from source to source. The potential of the industry has drawn a considerable number of market research firms to publish data based on a somewhat thin understanding.

I am now going to provide you with figures I have generated which owe as much to hands-on market experience and proximity to the action as they do to arms-length demographic surveys.

As you see from this chart, the U.S. market will triple in the five-year period 1984-88. Ophthalmic and non-ophthalmic surgical sales are approximately equal in the U.S. by 1985. After that, the non-ophthalmic sales will increase at a considerably faster rate. By 1990, the ratio will be 3:1 in favor of non-ophthalmic.

Today, the United States represents more than 50% of the world market now, a share that is predicted to rise through the remainder of this decade. As an international manager for various laser companies, I grew to understand the complexities of serving the world market, a market that is fragmented by definition. Although the world market will remain strong and grow steadily, there are complicating factors which make quantification difficult. Many countries have nationalized health services where politics intrude into the purchasing decision. Each country is, in effect, a separate small market and, therefore,