Transmyocardial laser revascularization

Background

Transmyocardial laser revascularization (TMLR) is a surgical procedure designed to treat patients suffering from end-stage coronary artery disease who no longer respond to medication or conventional treatments such as bypass surgery, angioplasty, or stents. During TMLR, surgeons use a high-powered CO\textsubscript{2} laser to drill pinholes into the left ventricle of the heart. Channels form from these holes, encouraging fresh blood to flow to the portion of the heart that has been deprived of oxygen due to narrow or blocked arteries. Restored bloodflow to the myocardium then reduces chest pain or angina in the patient.

In clinical studies of the Heart Laser System manufactured by PLC Medical Systems, 650 angina patients, most of whom had already had undergone at least one bypass surgery, were treated with the laser. Ninety-one of the patients were treated in a randomized, controlled trial conducted at 12 medical centers in the United States. Study results showed that 72\% of patients treated with TMLR experienced a significant reduction in angina pain, an effect that remained when patients were followed up one year later, according to the Food and Drug Administration (FDA). Yet, only 13\% of patients treated with medication alone reported the same relief.

TMLR also has its risks. Major cardiac arrhythmias were reported in 10\% of patients and early death within a month of the operation were reported in 3\% of patients. Additionally, the overall mortality after one year was similar for patients who received the laser treatment and for those who did not, reports the FDA.

The Heart Laser System, currently the only laser approved by the FDA for TMLR, sells for about $400,000, according to PLC. The laser is also offered under a pay-per-use plan for $25,000 down and $3,500 per procedure. Not far behind is Eclipse Surgical Technologies of Sunnyvale, CA, which has a similar device in the works and has received investigation device exemptions from the FDA to conduct clinical trials, one of which includes TMLR using an open-chest approach.

Involved specialists
Cardiac surgeons and cardiovascular surgeons.

Position of societies and academies
ACC, ACP/ASIM, SCAI, and STS

The American College of Cardiology, the American College of Physicians/American Society of Internal Medicine, the Society for Cardiac Angiography and Interventions, and the Society of
Thoracic Surgeons have no position on the granting of privileges for TMLR.

ACS The American College of Surgeons (ACS) has no position on the granting of privileges for TMLR. However, in its Guidelines for Standards in Cardiac Surgery, which were revised in 1996, the ACS states that “specification of the qualifications for cardiac surgeons in an established practice is beyond the scope of these guidelines. Surgeons practicing cardiac surgery should be certified or awaiting certification by the American Board of Thoracic Surgery or its Canadian equivalent within five years after the completion of an approved residency program in cardiac surgery. It is recommended that hospital committees for staff accreditation exercise their judgment for privileges based on the nature of the cardiothoracic residency or postresidency experiences of the applicant.”

Furthermore, the ACS states that “a team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room. It is recognized that, depending on the particular setting and situation, the assistant on a particular case may vary in experience and qualification.”

With regard to hospital operative volume as related to adult cardiac surgery, the ACS states that “the 1975 report of the Inter-Society Commission on Heart Disease Resources recommended that cardiac surgical programs in a hospital should perform at least 200 procedures annually. This recommendation was based on the premise of a hospital dedicating one operating room to cardiac surgery and functioning at 80% capacity (four cases per week x 52 weeks = 200 per year).

While there are no presently available data linking an individual surgeon’s patient volume and hospital mortality rate, there are data to suggest that an annual volume of at least 100 to 125 open-heart procedures (including coronary artery bypass procedures, valve replacements, and other operations requiring the use of cardiopulmonary bypass) per hospital is necessary from a quality standpoint and that there is a greater variation in adjusted mortality rates for teams performing lower volumes of procedures as compared to those doing a higher volume. While 100 to 125 cases per year per hospital appears sufficient from a quality standpoint, it is likely that considerably more, and at least 200 procedures per year as previously recommended, are necessary in order for a program to function efficiently.”
In its 1995 *Statement on Laser Surgery*, the ACS states that it believes “surgery using lasers is a standard form of surgical intervention, and, as such, is subject to the same regulations that govern the performance of all surgical procedures. The College therefore believes that patients should be assured that individuals who perform laser surgery are licensed physicians who meet appropriate professional standards as evidenced by comprehensive surgical training and experience, including the management of complications, and who have credentials in both the appropriate surgical specialties and the use of lasers.”

Additionally, “individuals who perform laser surgery should meet the principles of the College in all respects, including avoidance of misrepresentation to the public regarding specific advantages of the laser as compared with traditional operative techniques.”

**ACOS and AOA**
The American College of Osteopathic Surgeons and the American Osteopathic Association have no position on the granting of privileges for TMLR.

**Positions of other interested parties**

**FDA**

As of August 1998, the FDA has approved the Heart Laser System for TMLR under a PMA or pre-market approval status. The approval is for commercial use of the laser, which is manufactured by PLC Medical Systems Inc. of Franklin, MA.

The FDA has asked PLC to conduct a post-approval study to gather further information on mortality and the long-term benefits to patients. Use of the PLC laser is restricted to surgeons trained in its use and to patients with severe angina who cannot be helped by other means who give informed consent, according to the FDA.

**Audubon Heart Institute at Columbia Audubon Hospital**

Physicians wishing to perform TMLR should first have a background in cardiovascular surgery, according to Allan Lansing, MD, PhD, director of the Audubon Heart Institute at Columbia Audubon Hospital in Louisville, KY. In addition, he or she should attend a training program on the use of the Heart Laser System at one of PLC’s designated “centers of excellence,” of which Audubon is one.

These one-and-a-half-day training programs cover patient selection, preoperative management, operative management, postoperative management, anesthetic considerations, nursing considerations, as well as introduction to the CO₂ laser system and laser safety.
PLC then sends a team to each newly trained surgeon’s institution to proctor him or her in the first few TMLR cases. The team consists of a cardiovascular surgeon, who is also a director at one of the centers of excellence; a nurse clinical coordinator who deals with patients both on the floor and in the recovery room or intensive care unit; a technical individual from the laser company to supervise the setup of the laser system; and often a regional manager from PLC who is available for follow-up questions from the newly trained laser group, says Lansing, who is also one of the principal investigators for the Heart Laser System.

As far as the TMLR operation itself, Lansing sees it as a relatively simple procedure. “You just need to see it, have instruction, and have someone standing beside you supervising,” he explains. “Any good cardiovascular surgeon can do the operation. The problem is in the selection of patients ahead of time and their management during and after the operation.”

Since patients who undergo TMLR have failed all other medical therapy and have no other options for relief of angina, surgeons must be very careful in who they select for the procedure. The key is to select patients who are most likely to benefit and least likely to be harmed, Lansing advises.

Robert J. March, MD, assistant professor of cardiovascular surgery at Rush Presbyterian-St. Luke’s Medical Center in Chicago, IL, agrees that the danger with TMLR lies not so much in the actual operation but in the selection of patients. “If a patient doesn’t do well, you’d rather have been within a certain set of guidelines for patient selection and done everything you could in offering the procedure appropriately to that particular patient than to have just picked the wrong patient.”

March, who is also a principal investigator for the Heart Laser System, says one of his goals in teaching the procedure is to get his students to perform it as safely as he does.

On the other hand, he notes, there’s no guarantee that course participants are going to be safe users. “We’re just simply giving them a series of lectures and hands-on experience with the device to go over some of the safety aspects as outlined in the manual . . . How to say someone will be laser-safe? It’s going to be up to the principal investigators at the current sites and then up to the principal investigators at future sites.
Myocardial revascularization had its beginnings in the early 1950s when surgeons used needles to poke holes into the heart, says Kamuran A. Kadipasaoglu, PhD, director of laser research at the Texas Heart Institute in Houston, TX. However, such mechanical means did not prove successful because of the trauma and scarring caused to the heart.

TMLR emerged in the 1970s when a Milwaukee surgeon proposed, for the first time, to use a laser during the procedure. Now, after two decades of experimentation, PLC has created a high-energy laser that not only cuts a channel into the heart in a single pulse but is also synchronized with the beating of the heart to prevent arrhythmias.

“In order to avoid arrhythmias, you have to have the heart maximally filled with blood, so that you have a nice zone of blood to act as a buffer,” explains Kadipasaoglu. “This laser can actually go through steel but it won’t go through water. It’s an infrared laser and the property of infrared light is to be absorbed maximally by water. So blood acts as a nice break.”

Patients who benefit most from the TMLR treatment are those with end-stage refractory angina secondary to distal and diffused coronary artery disease. “Distal and diffused lesions are not isolated, so they are really hard to treat with the bypass and are almost impossible to treat with the balloon or stent,” Kadipasaoglu notes. “Cardiologists can adjust medication in these patients and have them reduce their level of activity. But there comes a point where the disease advances and the patient starts getting pain even at rest. Before TMLR, these patients were usually left to their sort—nothing much to do.”

The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has no formal position concerning the delineation of privileges for TMLR. However, its 1998 Comprehensive Accreditation Manual for Hospitals (CAMH) states (MS.1.1.1), “Each medical staff . . . includes fully licensed physicians and
may include other licensed individuals permitted by law and by 
the hospital to provide patient care services independently in 
the hospital [both physicians and these other individuals are 
referred to as ‘licensed independent practitioners’].”

Furthermore, the 1998 CAMH states (MS.5.4), “Professional 
criteria . . . constitute the basis for granting initial or continu-
ing medical staff membership and for granting initial, 
renewed, or revised clinical privileges.” The JCAHO further 
requires (MS.5.4.3) that “the criteria at least pertain to evi-
dence of current licensure, relevant training or experience, 
current competence, and the ability to perform the privileges 
requested.”

While the JCAHO does not require hospitals to use any specif-
ic method in delineating clinical privileges, it does require 
such privileges to be hospital-specific and based on an individ-
ual’s demonstrated current competence (MS.5.15). It further 
requires (MS.5.15.1–MS.5.15.1.3) “privileges to be related to 
an individual’s documented experience in categories of treat-
ment areas or procedures, the results of treatment, and the 
conclusions drawn from organization performance improve-
ment activities when available.”

**CRC draft criteria**

**Basic education:** MD or DO  
**Minimal formal training:** The applicant must be able to 
demonstrate successful completion of an approved 
residency/fellowship training program in cardiac or 
cardiovascular surgery.  
**Required previous experience:** The applicant must demon-
strate completion of an FDA-approved instruction course in 
the use of the CO\textsubscript{2} laser for TMLR.  

*Note: A letter of reference must come from the individual responsible for formal TMLR training or a physician who is familiar with the surgeon’s experience with TMLR.*

**Additional considerations**  
Due to variations in the ability to acquire the required skills 
(i.e., the learning curve), it is recommended that each organi-
ization, in defining privileges, identifies the appropriate num-
bers of procedures required based on the volume of patients, 
number, and skills of credentialed physicians.

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Privilege request form
Transmyocardial laser revascularization

To be eligible to request clinical privileges for transmyocardial laser revascularization, a physician must meet the following minimum threshold criteria:

- **Education:** MD or DO
- **Minimal formal training:** The applicant must be able to demonstrate successful completion of an approved residency/fellowship training program in cardiac or cardiovascular surgery.
- **Required previous experience:** The applicant must demonstrate completion of an FDA-approved instruction course in the use of the CO$_2$ laser for TMLR.
- **References:** A letter of reference must come from the individual responsible for formal TMLR training or a physician who is familiar with the surgeon’s experience with TMLR.

Additional considerations
Due to variations in the ability to acquire the required skills (i.e., the learning curve), it is recommended that each organization, in defining privileges, identifies the appropriate numbers of procedures required based on the volume of patients, number, and skills of credentialed physicians.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ____________________________________________________

Typed or printed name: ___________________________________________________

Date: ___________________________________________________________________
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