Laser Assisted Angioplasty in Peripheral Arterial Disease

*BHAGWAN SATIANI**

Since the popularity of percutaneous transluminal balloon dilatation (BD) for peripheral arterial lesions, physicians have concentrated on helping develop newer generation of catheter related devices that would extend our ability to reopen or recanalize stenosed or obstructed arteries. Laser recanalization (LAR) has now evolved from an experimental modality to clinical reality with second generation lasers being developed to overcome the limitations of the current technology. This paper will attempt to briefly introduce basic laser principles, types of lasers in clinical use, current role of lasers in atherosclerotic arterial lesions with their limitations and future applications of lasers in peripheral vascular disease.

The word laser is an acronym for Light Amplification by Stimulated Emission of Radiation. Light generated by conventional sources such as fluorescent lights has a wide distribution of frequencies or colors with scattering in all directions. Consequently, by the time light reaches a distant point the energy drops off inversely as the square of the distance between the light source and the target. In lasers, an atom, molecule or ion in its resting state is excited to a higher energy state by the absorption of thermal, electric or optical energy. After energy absorption, this returns to its resting state and generates absorbed energy as a photon. The energy generated emerges as light which has the three important characteristics of laser energy: the light is coherent, of a single wavelength and is in temporal and spatial phase. This enables the beam to be focused, made divergent or collimated. When the light comes in contact with tissue it may be absorbed, reflected, scattered or transmitted, the quantity absorbed being dependent on the presence of chromophores (hemoglobin and water) in the tissues.

* Program Director, Peripheral Vascular Surgery, Grant Medical Centre & Clinical Assistant Professor of Surgery, The Ohio State University.

TYPES OF LASERS AND APPLICATION (1)

Lasers in common usage are listed in Table 1. The CO2 laser is used in surgery for cutting and

TABLE 1

TYPES OF LASERS

TYPE	WAVELENGTH (nanometers)	POWER	APPLICATION
CO2	10,600	10-100W	Surgery-cuts by vaporization, cauterizes seals, coagulate
Nd: YAG	1060	< 100W	Photocoagulation, GI bleeding, Bronchial
		¾ 100mJ	Ophthalmology, photo ablation.
Ruby	694	< 5J	Photoablation, plastic and dermatology
Argon	488,514	1-10W	Photocoagulation, ophthalmology, plastic and dermatology.
Tunable dye	400-900	0.1-2W	Photodynamic therapy
Excimer	193-248		Research, dermatology, plastic and ophthalmology, cuts with no visible necrosis.
'Smart"	480		Plaque specific, for arteries.

vaporization as it is greatly absorbed by water. Since CO2 energy transmission requires a series of mirrors etc. it is not practical to transmit laser energy through fibers. Argon laser light is heavily absorbed by hemoglobin but can be transmitted through water, urine, gastric fluid etc. and is used for nonbleeding vascular lesions where minimal penetration is required. The Neodymium-yttrium aluminumgarnet (Nd:YAG) has much absorption by water or hemoglobin and is used for palliation of esophageal carcinomas where it causes a depth of injury of about 3mm in the tissues. Dye lasers are able to emit throughout the visible spectrum (380-700 nm) depending on the dye selected as the medium. Photodynamic therapy using tunable dye lasers is now used in the treatment of many cancers.

Laser Recanalization (LAR)

Background:

The potential for the use of laser energy on cardiovascular tissues has been demonstrated by many animal and human studies(1). These applications include angioplasty, endarterectomy, repair of aneurysms and arterial dissections, excision of venous valves, sealing of arterial and venous anastomoses, transmyocardial neovascularization, valvuloplasty, ablation of abnormal conduction pathways and myectomy or endocardiectomy. The common lasers used for vascular lesions include Nd:YAG, argon, excimer, tunable dye, CO2 and the new free electron laser. Investigation has focused on the development of new optical fibers, thermal probes, contact probes, pulsed laser catheter systems, etc. Commercially available optical fibers have been used intravascularly with the Nd:YAG and argon lasers in animal and clinical experiments. However, with bare fibers the risk of perforation of the arterial wall from mechanical (stiffness of the fiber) and thermal causes has been a problem. Also, thrombus and thermal debris accumulates on the fiber during use, leading to "burnback" with damage to the fiber tip and adherence of the tip to the arterial wall. This results in faulty transmission of energy and detachment of the arterial intima.

Metal tipped laser catheter systems have been the most commonly used for human arterial LAR. Metal caps are attached to the ends of the laser fibers, heated by laser energy to 200-400C in order to vaporize atheromatous plaque in stenotic or occluded peripheral arteries. The resulting small channel is then BD by conventional balloon catheters over a guidewire. Fourrier in France developed a catheter system using a Nd:YAG laser with the fiber tip coupled to a sapphire tip(2).

CLINICAL USE IN PERIPHERAL ARTERIES:

The natural history of peripheral arterial vascular disease has been well documented in the past. Most patients with stable claudication do not require any form of intervention and the limb loss rate at ten years remains between 7 - 12%. It is important to remember this when recommending any form of intervention be it surgery, BD or LAR. When claudication symptoms progress and become disabling or tissue ischemia occurs, options for revascularization must be explored. BD alone is only applicable to $< 10\%$ of all patients with symptomatic arterial disease. The 20-40% restenosis rate in smaller arteries within one year and larger arteries within five years has prompted investigation of the laser. The hypothesis is that by vaporizing part of the plaque, a larger channel may be created with less restenosis and myointimal hyperplasia. Ginsberg was the first to report successful LAR with argon laser at the end of a. balloon catheter to open a 95% profunda femoris stenosis(3). He later reported success in eight of 17 (47%) peripheral vessels with perforation in three. Abela reported using a angioscope to guide a bare argon fiber with perforation in six of 13 arteries (4). The fiberoptic laser delivery system with the most clinical use has been the LASERPROBE (R) (Trimedyne Inc, Santa Ana, California). In this system argon laser energy is converted to heat which is then transmitted to the plaque by a rounded metallic cap. The thermal effect is apparently associated with minimal charring and a smaller, thinner thrombus. Sanborn and Cumberland reported a combined experience acquired at Boston University and Sheffield (England) with the use of a 12 W argon laser system (Trimedyne) and a 2mm Laserprobe tip(5). Sanborn et al have reported initial angiographic and clinical success in 77% of 129 femoropopliteal lesions treated by laser thermal angioplasty(6). The overall patency at one year was 77% in the 99 lesions initially recanalized. The patency for short (1-3 cms) occlusions and stenoses was 93% at one year but only 58% for lesions > 7 cms. A hybrid version of the metal tip called the Spectraprobe (R) consists of an opening at the tip of the metal cap which allows about 20% of the laser energy to directly interact with the plaque in addition to the 'hot tip'.

Laser vascular welding consists of using a low energy beam to fuse vascular tissue at the coapting edges of the repair. Initial stay sutures are placed at several locations around the desired anastomosis and laser energy is passed over and over the edges till fusion occurs. Tissue vaporization or coagulation/charring may occur if excessive energy is used and nonunion occurs if inadequate laser energy is utilized. Laser energy has been successfully used in humans in repairing medium sized arteries, veins and artery-vein anastomoses(1). The purported advantages include: healing without much foreign body reaction secondary to the sutures normally used, decreased intimal hyperplasia and possibly unrestricted expansion and growth of the growing host vessel.

GRANT MEDICAL CENTER EXPERIENCE:

Patients selected for inclusion in this United States Food and Drug Administration approved protocol included those with progressive, disabling claudication, ischemic rest pain or ulceration and gangrene. Non - invasive vascular laboratory examination was required in all patients preoperatively. Angigraphic criteria in the iliac, superficial femoral, profunda, popliteal or tibial arteries included > 85% stenosis, total occlusion not to exceed 25 cms in length and patent distal vessels with reasonable runoff. Excluded were patients with contraindications to laser therapy, > 25 cm long occlusions, poor distal runoff, aneurysmal disease, proximal embolic source, extensive tissue necrosis making limb salvage unlikely, bifurcation lesions and tortuous arteries. Informed consent (approved by our Institutional Review Board) was obtained in all patients. Local, regional or general anesthesia was administered taking into account the pateint's preference as well medical necessity. A size 7 or 8 french Cordis introducer sheath was placed percutaneously or through a small cutdown via the seldinger technique. Heparinization was accomplished with 5000 units of heparin given through the sheath. A three way stopcock was attached and continuous heparin flushing was started. Baseline contrast angiography was performed with identification of the lesion and # 18 gauge needles were placed in the skin over the lesion to mark the proximal and distal extent of the obstruction. Protective eye glasses were worn and all other laser safety precautions taken. A Nd:YAG (Surgical Laser Technology, Malvern, Pennsylvania) was used in conjunction with a 600um flexible quartz fiber and a synthetically hardened sapphire crystal connected to a metal connector was screwed on to the end of the fiber. This tip has 1.8-3.0 mm diameter range and is cooled by a continuous infusion of isotonic saline at 4-8 cc/mt. The fiber is directed to the proximal end of the lesion and serial laser energy pulses using 8-20 watts of power for 0.5 to 1.5 sec pulses at 5 second intervals are utilized with quick to and fro movements. Following recanalization, contrast angiography is performed and if a satisfactory channel is visualized, an appropriate sized balloon catheter (3-8 mm) is passed over a guidewire through the sheath and the lesion dilated. Repeat contrast study is performed with a permanent hard copy (Fig. 1 and 2). Pulses are palpated and doppler pressures are recorded. The sheath is then removed, direct manual pressure is applied or in the case of a cutdown the opening is sutured. The patient is heparinized at 500 units/hr, started on oral aspirin and followed closely by the nursing staff on a specialized vascular unit.

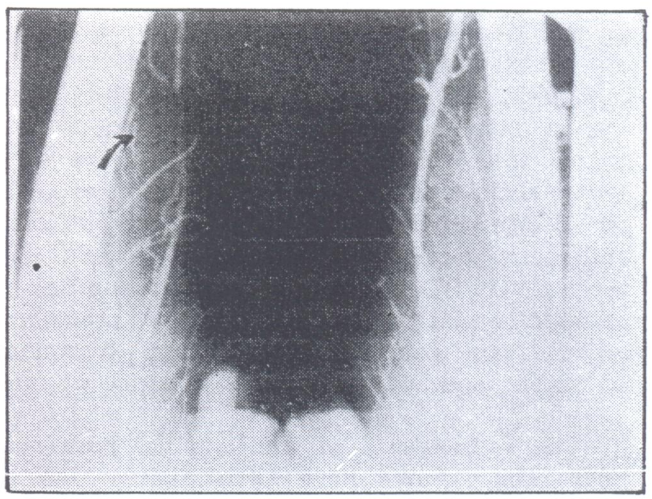

Figure 1. Preoperative arteriogram showing segmental occlusion of the left superficial femoral artery (arrow).

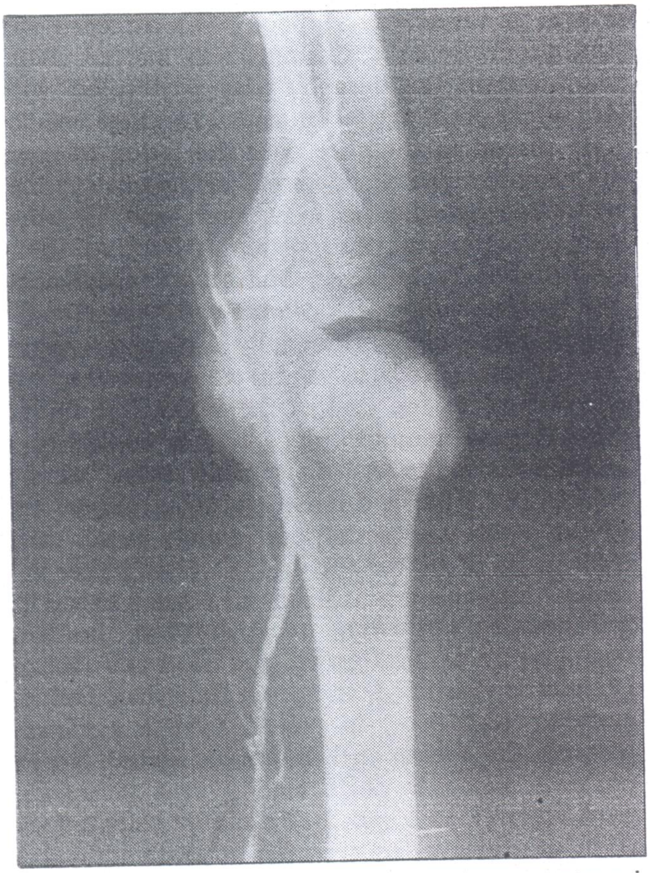

Figure 2. Completion post laser and balloon angioplasty on table arteriogram showing patency of previously occluded segment of superficial femoral artery (arrow).

All patients are examined in the office every three months, and have doppler studies at three, six and twelve months. Outpatient arteriography is performed at six and twelve months after LAR. Our LAR program began in September 1987 and to date we have used it in 24 patients. To put it into proper perspective, we have seen approximately 2500 patients referred for peripheral arterial disease, of whom about 500 have undergone reconstructive arterial surgery and another 40 BD alone. The limited number of patients subjected to any invasive procedure reflects our generally conservative treatment of stable and non-progressive arterial disease.

The success rate of the laser has been over 80%. The failures have been mainly due to dissection of the wall or thrombus/embolus following use of the balloon catheter. One perforation occurred with the laser with no bleeding or harm to the patient. Two patients have restenosed within six months and both were relasered with a good result thus far. Two other patients have a mild residual/recurrent stenosis and are being followed. All our LAR attempts have been in arteries below the groin. Our first patient is now 22 months post-LAR and has no restenosis or symptoms. A review of the literature showed that by mid 1987, 219 patients were reported to have had LAR with the 'hot tip' Trimedyne system with a 65% clinical success rate in 75 patients followed for one year.

TABLE 2
ADVANTAGES
1. PERCUTANEOUS OR SMALL CUTDOWN INCISION
2. USUALLY LOCAL / REGIONAL ANESTHESIA
3. CAN BE SAFER IN HIGH RISK PATIENTS
4. DECREASED HOSPITALIZATION (1-2 DAYS)
5. MINIMAL MORBIDITY, PAIN & EARLY RETURN TO WORK
6. REDUCTION IN COST
7. IF RESTENOSIS, LESION CAN BE RELASERED OR OPERATED ON.

The immediate risks of LAR include perforation, hemorrhage, dissection, distal arterial embolization, thrombosis and hazards associated with the laser (Tables 2 & 3). The lack of long term clinical data does not allow comparison

TABLE 3
DISADVANTAGES
1. ALL LASERS CAUSE SOME THERMAL DAMAGE, UNKNOWN CONSEQUENCES
2. INABILITY TO ABLATE HEAVILY CALCIFIED PLAQUES
3. NOT SUITABLE FOR LONG LESIONS OR OBSTRUCTIONS.
4. RISKS OF PERFORATION, HEMORRHAGE, DISSECTION, DISTAL EMBOLI
5. LONG TERM PATENCY NOT KNOWN.

with established and effective methods of palliating atherosclerotic plaques such as BD or surgical endarterectomy/bypass.

Future place of lasers:

There will probably continue to be further advances in wire design and balloon catheter technology but several inherent limitations of the BD technique remain. It is not well suited for diffuse, long lesions. Totally occluded segments do not have good long term results and restenosis because of intimal damage and an insufficient residual lumen are drawbacks.

Limitations of current laser technology include: poor results in long segments, calcified arteries, tortuous or smaller vessels (i.e. tibials), the present limitations of the size of laser tip and therefore the need for completion BD, risk of perforation, non steerable catheters for tortuous small vessels such as the coronaries and finally restenosis which may become more evident as long term follow-up becomes available. Goals for the future include: further improvement in guidewire and catheter engineering enabling a higher success rate at crossing stenotic or occluded arteries, removing more of the plaque so less residual stenosis is present, the percutaneous or surgical cutdown ability to use larger laser probes so as not require balloon catheters, develop the ability to selectively ablate atherosclerotic plaque with tunable dye lasers, and finally to develop systems allowing coronary applications with safety.

Exciting new developments in LAR include radiofrequency lasers, the excimer laser and the concept of a 'smart' laser. The 'smart' laser is a computer based system with the ability to discriminate plaque from healthy tissue. To address the risk of thrombosis following BD or LAR, intraluminal stents are being placed to expand the arterial lumen.

The inability to vaporize significant amounts of plaque with LAR has led to the invention of "atherectomy" catheters designed to cut or remove plaque (7). There are at least six different devices either in clinical trials or being introduced. The Simpson catheter has a bullet shaped tip with one side of the casing being open. A balloon is inflated to engage or push the plaque into this casing chamber. A sharp edged cup is then advanced down to shave the plaque. The Kensey catheter consists of a rotating tip from which tiny jets of water are released with enough energy to pulverize the plaque. The Auth/Richie Rotablater uses a tip studded with diamond chips which shave the protruding plaque. The Simpson catheter has been used in 190 peripheral arteries and 130 coronary arteries. Apparently the acute complication rate is only 1% and the restenosis rate is 16% at six months. These devices cannot currently penetrate totally occluded vessels and the long term results are not available.

The new developments in balloon and laser technology are indeed exciting and offer alternative forms of therapy to patients with peripheral and coronary artery occlusive disease. However, one must remember the natural history of the disease being treated before recommending any new form of treatment. There are definite risks to BD and LAR and caution is advised mainly because the long term results with LAR are not available and early reports suggest a $>$ 20 - 25% incidence of restenosis at one to two years with the available lasers.

REFERENCES:

1. White RA, Grundfest WS: Lasers in cardiovascular disease. Year Book Medical Publishers Inc, Chicago, 1987.
2. Fourrier JL, Brunetaud JM, Prat A, Marache P, LaBlanche JM, Bertrand ME: Percutaneous laser angioplasty with sapphire tip. Lancet : 105, 1987.
3. Ginsberg R, Kim DS, Guthaner D, Toth J, Mitchell RS: Salvage of an ischemic limb by laser angioplasty: description of a new technique. Clin Cardiol 7: 54-58, 1984.
4. Abela GS, Normann SJ, Cohen DM et al: Laser canalization of occluded atherosclerotic arteries in vivo and in vitro. Circulation 71: 403 - 411, 1985.
5. Cumberland DC, Tayler DI, Welsh CL et al: Percutaneous laser thermal angioplasty: Initial clinical results with a laser probe in total peripheral artery occlusions. Lancet 1: 1457-1459, 1986.
6. Sanborn TA, Cumberland DC, Greenfield AJ, Welsh CL, Guben JK: Percutaneous laser thermal angioplasty: Initial results and 1-year follow-up in 129 femoropopliteal lesions. Radiology 168: 121-125, 1988.
7. Medical News and Perspectives: Atheroma Curettage: An idea whose time may come as several devices begin trial. J.A.M.A 261: 498-499, 1989.