Title
LASER-ASSISTED VERSUS MECHANICAL RECANALIZATION OF PERIPHERAL OCCLUSIONS - A RANDOMIZED TRIAL

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Authors
TOBIS, JM
CONROY, R
DEUTSCH, LS
et al.

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Laser-Assisted Versus Mechanical Recanalization of Femoral Arterial Occlusions

Jonathan M. Tobis, MD, Robert Conroy, MD, Larry-Stuart Deutsch, MD, Ian Gordon, MD, PhD, Junko Honye, MD, PhD, Jeff Andrews, BA, Glen Profeta, BS, Sherrie Chatzkel, MD, and Michael Berns, PhD

A randomized clinical trial was performed to test the hypothesis that a laser-heated probe is superior to standard techniques to reopen occluded femoral arteries. Twenty patients were treated with a standard guidewire and balloon dilation method. In a second group of 20 patients, the laser probe was initially used as a nonheated mechanical device. If the probe was unsuccessful in mechanically reopening the artery, an Argon laser was activated to heat the probe. The mean length of occlusion was 15.9 ± 10.3 cm. The success rate for the laser probe was 15 of 20 (75%), which was not significantly different from the standard method, 19 of 20 (95%). Most of the success in the laser-probe group was due to the probe's mechanical properties. The laser probe was successful as a cold, mechanical device in 13 of 15 (87%) arteries. It was necessary to heat the probe in 5 patients. When heated, the laser probe assisted recanalization in 2 but perforated the artery in 3 cases.

The results of this randomized trial do not support the hypotheses behind the use of the thermal laser probe. The laser probe functions primarily as a mechanical device. The thermal activation does not significantly improve the success rate without increasing the risk of perforation. This small additional benefit does not justify the large cost of current thermal laser devices. This controlled study also demonstrates a higher success rate in long occlusions than previous reports of mechanical balloon recanalization. This is due to a combination approach of retrograde and anterograde probing of the occluded segment.

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The use of laser energy to ablate atherosclerosis and assist peripheral or coronary angioplasty has caught the imagination of the medical profession and the patient population. As of June 1990, it was reported that 30,000 cases of laser-assisted thermal angioplasty had been performed.[1] In response to early reports of a high perforation rate with bare fiber catheters,[2,3] most of the procedures have been performed with a fiberoptic conduit with a metal cap at the distal end.[4,5] This device uses laser energy to heat the metal tip which produces a thermal-tissue interaction to perform the arterial recanalization. The theoretical assumptions of the mechanism of action of the laser-assisted thermal probe are: (1) that it reopens occluded arteries by tracking the original lumen; and (2) the thermal energy ablates atherosclerotic tissue, thereby reducing the mass of atheroma which helps to recanalize the artery and also improve the long-term patency rate.[6] Despite these theories and the high rate of use of these Food and Drug Administration approved devices, there has been no randomized clinical trial to demonstrate any benefit of the thermal probes over standard techniques for arterial recanalization. The purpose of the present study was to conduct a randomized clinical trial to test the hypothesis that (1) the laser-assisted probe, either as a mechanical or thermal device, is superior to standard guidewire and catheter techniques currently in use; and (2) there is an additional benefit to using thermal energy to recanalize peripheral arteries compared with the mechanical effect of the probe.

METHODS

Patient selection: Patients were recruited to participate in this study if they had symptoms of claudication and angiographic evidence of an occluded superficial femoral artery. Only patients with complete occlusions on angiography were included in this protocol; stenotic lesions were not treated by the laser probe and were excluded from this study. In addition, the length of the occlusion or the degree of calcification was not used to exclude patients. At least 1 patent tibial vessel for runoff was a criterion for inclusion. The primary end point for a successful result was recanalization of the occluded segment of artery with angiographic evidence of direct flow between the proximal and distal lumens.
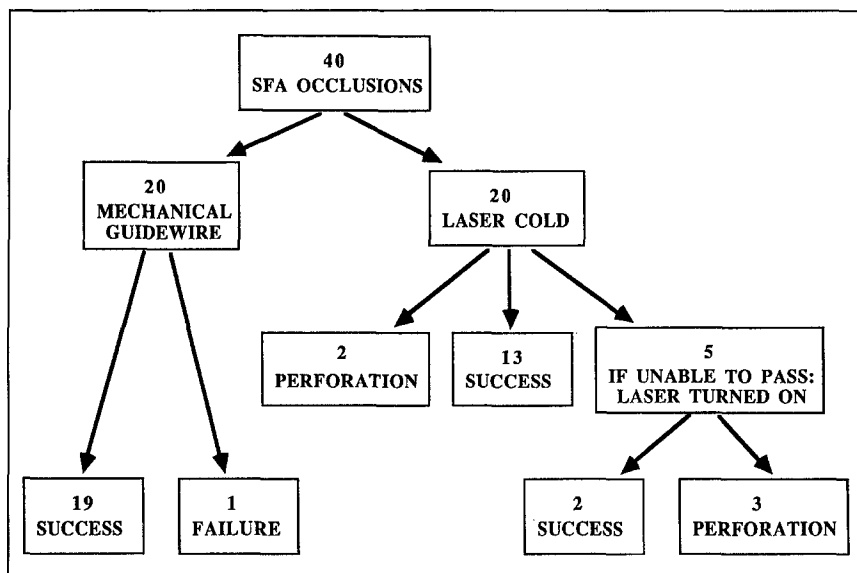
FIGURE 1. Representation of randomized trial treatment protocol. SFA = superficial femoral artery.

There were 40 patients (36 men and 4 women, mean age 65 years (range 42 to 83) who participated in this study. All patients had been cigarette smokers (1 to 4 packs per day). Ten had diabetes mellitus, but only 1 required insulin. All patients had symptoms of claudication for a period of 3 months to 17 years before entering the study. Five of the patients had pain at rest, but no patient had gangrene or an active skin ulcer due to vascular insufficiency. Baseline clinical evaluation, including Doppler-measured systolic occlusion pressure in the leg and arm, was performed in all patients. The patients signed the institutional consent form approved by the Human Subjects Review Committee.

Study protocol: Patients were randomly assigned by a computer-generated rotation to 1 of 2 treatment protocols: a standard guidewire method or the laser probe method. In the patients assigned to the standard mechanical guidewire group, a variety of 0.035 inch guidewires (Cook, Rosen, straight) were inserted
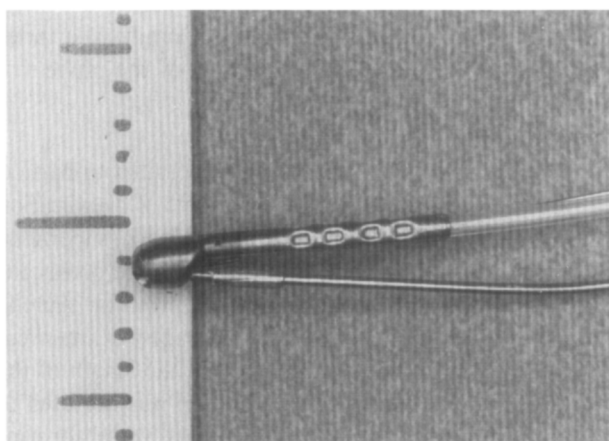

FIGURE 2. Magnified view of the metal capped fiberoptic catheter used in this study. The 1.5 mm diameter tip has a blunted shape to facilitate penetration of occluded arterial segments.

through a 6Fr or 7Fr plastic catheter (Van Andel, multipurpose, or Torcon pull-down catheter). The area of obstruction was probed with the guidewire under fluoroscopic control and the catheter was advanced over the guidewire as it progressed distally through the arterial occlusion. If the operator felt that the attempt at mechanical recanalization was no longer feasible, then the patient could cross over to the laser-assisted method.

In the patients assigned to the laser protocol, the laser probe was initially used as a cold, mechanical device without turning on the laser. The outline of the randomization protocol is seen in Figure 1. The laser probe used in this study was a 1.5 mm diameter Laserprobe model PLR-plus (Trimedyne, Inc., Santa Ana, California) (Figure 2). Two different laser generating systems were used: An Argon laser, Optilase model 900 (Trimedyne Inc, Santa Ana, California) or a KTP-YAG laser model 532 (Laserscope, San Jose, California). The laser probe was inserted through a Tuohy-Borst adaptor Y connector (to prevent backbleeding and permit contrast injections) and was passed alone through the introducer sheath or through a 7Fr Judkins right coronary angioplasty guiding catheter to provide support for the laser probe. The guiding catheter tip was steam-heated to straighten the distal curve. Under fluoroscopic guidance, the laser probe, without activating the laser, was pushed into the occlusion with increasing force which was subjectively determined by the operator. The same operator manipulated the laser probe in all patients while mechanical guidewire manipulation was performed primarily by the interventional radiologists. After the laser probe advanced 3 to 5 cm, contrast was injected to determine if there was a perforation or if the catheter pathway was still within the boundary of the artery. The laser probe was advanced in this manner until the obstruction was reca-

nalized, the artery was perforated, or the operator subjectively felt that further mechanical force was unlikely to be successful. If successful recanalization occurred, the laser probe was withdrawn and an 0.035 inch guidewire was advanced through the new channel. Balloon dilation angioplasty was then performed in all cases with an appropriately sized balloon (4 to 7 mm diameter).

If recanalization was unsuccessful with the laser probe as a cold, mechanical device (and if a perforation had not occurred), then the laser was turned on at 10 to 12 W to heat the metal-tipped catheter to approximately 200°C. Gentle pressure was maintained on the heated-tipped catheter at the level of occlusion for 5 to 10 seconds. If no forward progress was achieved, the laser was turned off and the catheter was moved back and forth rapidly for 3 seconds to permit the heat to dissipate without tissue agglutination around the metal tip. The heated tip catheter was advanced intermittently in this manner until recanalization was achieved or the artery was perforated.

There were 14 arteries where the procedure was performed in a retrograde direction from the popliteal artery.[7] In these 14 arteries, the residual patent lumen of the proximal superficial femoral artery was <1 cm long or was completely occluded at its origin at the bifurcation with the common femoral artery, which precluded initial penetration into the superficial femoral artery with any device (Figure 3). Percutaneous entrance into the popliteal artery was performed with the patient in a prone position. There was no special guidance for percutaneous entry into the popliteal artery in the first 2 arteries but ultrasound color/Doppler imaging was used in the other 12 patients to help direct the needle puncture.

In 5 patients, the retrograde approach from the popliteal artery permitted the guidewire or laser probe to pass into a dissection plane within the artery up to the level of the common femoral artery. Despite multiple attempts, the wire or probe was parallel to the lumen, but could not be manipulated into the lumen of the common femoral artery. In these cases, the catheter was left in the superficial femoral artery extending from the popliteal insertion and the patient was turned onto his back. A second percutaneous puncture was performed on the ipsilateral side from an anterograde direction into the common femoral artery. A 0.035 inch guidewire was directed toward the catheter that remained in the recanalized dissection plane of the superficial femoral artery. The anterograde guidewire was used to forcefully break into the recanalized dissection plane and thus complete the connection from the lumen of the common femoral artery to the lumen of the popliteal artery (Figure 4). The recanalized channel was

then enlarged by balloon dilation. Patients were followed by clinical evaluation and Doppler measurement of ankle/arm systolic occlusion pressure index.

RESULTS

There were 20 patients assigned to the mechanical guidewire method and 20 patients assigned to the laser probe method. The length of the occlusions ranged between 1 and 45 cm (mean of 15.9 ± 10.3). Randomization was adequate because the mean length of occlusion was 15.3 ± 10.0 cm in the mechanical guidewire group and 16.6 ± 10.5 cm in the laser probe group (p = not significant). In the patients who had successful recanalization, the mean length of occlusion was 16 ± 11 cm, and in the unsuccessful group, the mean length was 15 ± 5 cm, which was not statistically different. The combined success rate in both treatment groups for
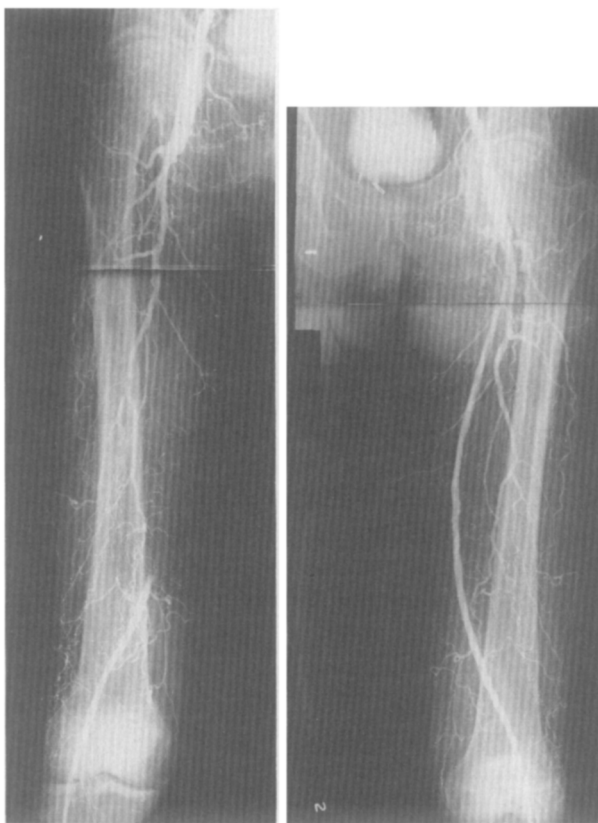

FIGURE 3. Left, angiogram of the right iliac and femoral artery recorded in the supine position. There is complete occlusion of the proximal superficial femoral artery at its bifurcation with the right common femoral artery. There is collateral blood flow through the profundis artery to the distal superficial femoral artery which reconstitutes at the adductor canal. The length of occlusion was 37 cm. Right, angiogram of the right superficial femoral artery in the prone position after successful recanalization, and balloon angioplasty from a retrograde direction from the right popliteal artery with reconstitution of blood flow from the common femoral artery through the superficial femoral artery. The artery was opened with the laser probe initially as a cold device; further penetration was achieved with the laser activated as a thermal device; final re-entry into the common femoral artery was successful by standard guidewire manipulation.

recanalizing occlusions 1 to 7 cm long was 100%, for occlusions 8 to 14 cm long the success rate was 77%, and for occlusions 15 to 45 cm long the success rate was 83%. The Doppler-measured ankle/arm index was 0.62 ± 0.14 before and 0.90 ± 0.06 after treatment in the patients who had a successful recanalization.

In the mechanical guidewire group there were 19 (95%) successful cases of recanalization and subsequent balloon angioplasty. The 1 failure resulted in a mechan-

ical perforation of the artery with the guidewire. No patient from the mechanical treatment group required crossover to the laser treatment group.

In the laser probe group, the overall success rate was 15 of 20 (75%), which was not significantly different from the standard mechanical method. The laser probe was initially used as a cold mechanical device and was successful in 13 (65%) patients. There were 2 arterial perforations when the catheter was used as a mechanical probe. The laser was activated in the other 5 patients after no further progress could be achieved with the catheter as a cold device. After the laser probe was heated, it resulted in successful progression of the device in 2 additional patients; however, the thermally active catheter created a perforation in the other 3 patients.

Even when the laser probe was successful in recanalizing the length of the occluded arterial segment, it often required insertion of a guidewire to make the final reentry into the distal lumen segment. This was necessary because laser probes or guidewires usually enter a dissection plane between the intimal plaque and the media during the process of recanalization.[8] Once the device traversed the length of the occluded segment, it required directional control to repenetrate the plaque and enter the distal lumen. This process is illustrated by the case shown in Figure 3.
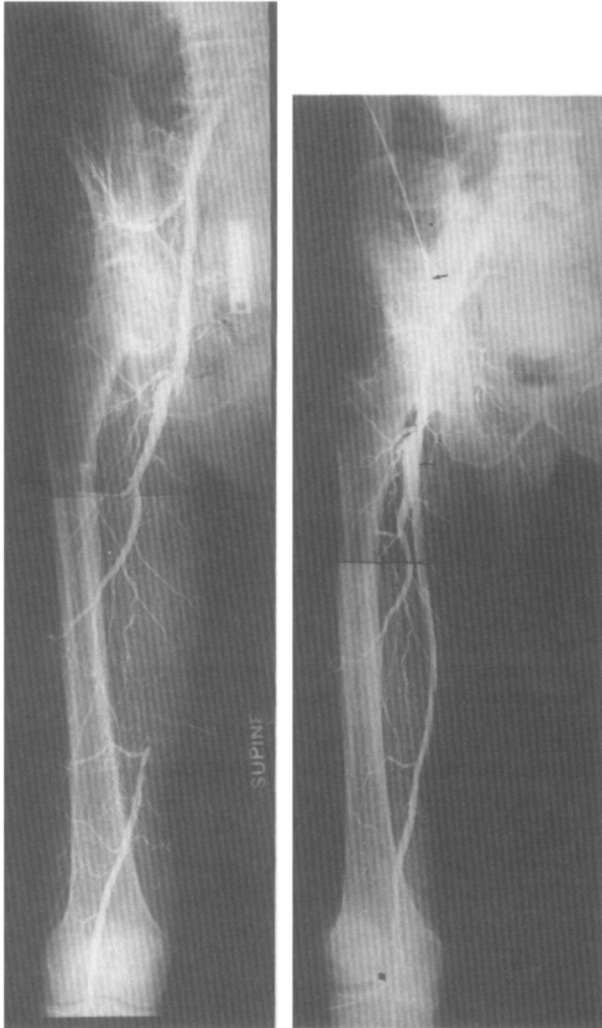

FIGURE 4. *Left,* angiogram of a right superficial femoral artery that is occluded 1 cm after its origin and reconstitutes 27 cm distally. *Right,* the superficial femoral artery was reopened from the popliteal approach using 0.035 inch Coon's guidewire and a Torcon 7 to 5Fr pull-down catheter. The guidewire passed along parallel to the lumen of the common femoral artery but did not reenter the nubbin of the proximal superficial femoral artery. The patient was turned on his back and an anterograde puncture of the right common femoral artery was performed. A guidewire was passed through the residual nubbin of the superficial femoral artery and forcefully pushed into the recanalized dissection plane to complete the connection from the lumen of the common femoral artery to the lumen of the popliteal artery. *Longer arrow* designates the anterograde catheter in the femoral artery and *short arrow* indicates the second catheter entering the popliteal artery. This angiogram was obtained after balloon dilation throughout the 30 cm segment.

FIGURE 5. Scout film radiograph of a patient with extensive calcification of the superficial femoral artery. This vessel could not be recanalized with either an 0.035 inch guidewire and supporting catheter or the laser probe as a mechanical device or thermally activated.

There were 32 patients who had radiographic evidence of calcium on the baseline scout film. Radiographic calcium was present in 26 (76%) of the 34 successful cases and was present in 6 (100%) of the 6 unsuccessful cases (p = not significant). Although the presence of calcium at the proximal superficial femoral artery or at the adductor canal often acted as the point at which the guidewire or laser probe would deflect and enter the dissection plane parallel to the plaque, the presence of calcium was the obvious cause of an inability to recanalize the artery in only 1 patient (Figure 5).

Complications: Three types of complications occurred during this study. The first complication was perforation of the arterial wall, which occurred in 1 patient due to a mechanical guidewire and in 3 due to the heated laser probe. The perforation resulted in some extravasation of blood and contrast into the soft tissues, but each case was treated conservatively and no patient required surgical repair. In these 4 patients, there was no attempt to recanalize from the opposite direction (i.e., a retrograde popliteal puncture if the initial perforation occurred from the anterograde approach) because these results occurred early in our series. The combined anterograde and retrograde approach was only used, if necessary, after the twenty-sixth patient.

In the first patient who had angioplasty performed from a retrograde entry into both popliteal arteries, an arteriovenous fistula developed at both percutaneous entry sites. Both of these popliteal arteries were punctured without ultrasound guidance. Because of this event, the subsequent patients in which the retrograde approach was chosen had color/Doppler ultrasound imaging of the popliteal artery and vein performed to identify the percutaneous route into the popliteal artery. In the subsequent 12 cases, 2 arteriovenous fistulas developed despite the use of ultrasound guidance. These cases were managed conservatively and did not undergo surgery.

The third complication was a hematoma at the suprainguinal insertion site. One patient developed hypotension after the procedure was completed and the sheath had been removed. He responded to fluid replacement and did not receive a blood transfusion. A second patient had a retroperitoneal hematoma which was seen with symptoms 3 days after the procedure. The inguinal puncture site into the common femoral artery was closed surgically.

Follow-up studies: Initial successful recanalization of the occluded superficial femoral artery was obtained in 34 (85%) of the original 40 patients. Patency, as documented by relief of symptoms and improvement in the ankle/arm systolic occlusion pressure index, persisted for the first month of follow-up in 29 of the 31 successfully recanalized patients who returned for follow-

up. However, by 6 months the patency rate decreased to 60% (Figure 6). In 12 patients who have been followed for 1 year, arterial patency documented by lack of symptoms, a palpable pulse, and a sustained improvement in the Doppler ankle/arm index was 50%. There was no difference in the follow-up patency for patients treated with mechanical recanalization with guidewires versus patients treated with mechanical recanalization with the laser probe. The number of successfully treated patients who had laser-activated thermal angioplasty is too small to comment on the long-term patency compared with the mechanical approach. The mean length of initial occlusion in the 15 patients who had patent arteries at 6 months was 13.8 ± 8.7 cm compared with the 10 patients with clinical symptoms of reocclusion whose initial mean length of occlusion was 18.9 ± 11.3 (p = not significant).

DISCUSSION

The use of laser-assisted thermal angioplasty raises many questions as to its potential mechanism of action and the possible beneficial effects of heat or direct laser energy on atherosclerotic plaque. The primary purpose of the present study was to determine whether the laser probe is more effective than standard mechanical techniques to reopen an occluded peripheral artery. Therefore, this study carefully included only patients who had complete occlusions of the superficial or popliteal artery and did not include any patient who had a stenosis with a residual patent lumen. The results of this randomized trial do not support the hypotheses behind the use of the thermal laser probe. In the present study, the success rate of the laser probe was not superior to standard mechanical methods to reopen occluded superficial femoral arteries. This result was independent of the length of the occlusion or the presence of calcium
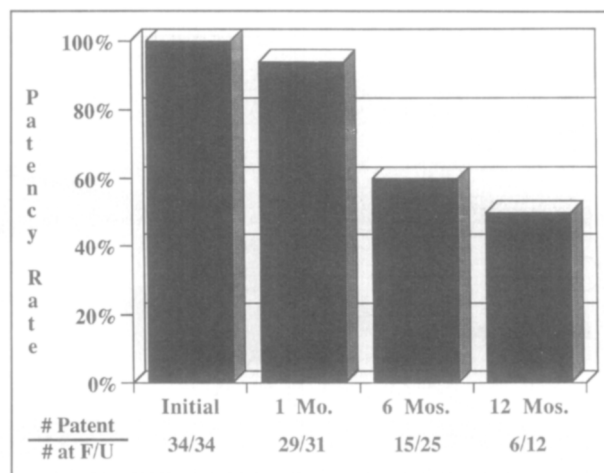

FIGURE 6. Graph of follow-up (F/U) patency results of recanalization of superficial femoral artery documented by relief of symptoms and sustained improvement of systolic occlusion pressure index.

on the radiograph. The mean length of the occluded segment was similar in the mechanical (15.3 ± 10.0 cm) and in the laser probe (16.6 ± 10.5 cm) groups. The overall success rate was higher in the mechanical guidewire group, with 19 of 20 (95%) successful recanalizations, compared with 15 of 20 (75%) successful recanalizations with the laser probe, but this did not reach statistical significance.

In previous clinical studies of laser-assisted thermal angioplasty performed without randomization, the laser-heated probe was successful in 66 to 90% of occlusions depending on the length of the artery, the tortuosity of the vessel and the presence of calcium.[1,6,8,9] One of the primary claims for a beneficial effect of the laser probe was that it seeks the previous lumen of the occluded segment and stays well within the boundary of the media. However, an in vitro study revealed that in 95% of the cases with either guidewires or the laser probe, the devices were deflected from dense atherosclerotic plaque and found the path of least resistance in a dissection plane between the plaque and the wall of the artery along the internal elastic membrane.[8] The guidewire or laser probe, once it enters this plane, could continue within this dissection plane until the atheroma becomes thinner permitting the device to reenter the true lumen distally, or it could perforate the wall laterally (Figure 7). This mechanism of recanalization was corroborated in a human study where an intravascular ultrasound imaging catheter was used to follow the pathway of recanalization by the laser probe in an occluded superficial femoral artery that was successfully reopened without turning the laser on.[10] The intravascular ultrasound images demonstrated in vivo that the laser probe had entered a plane between the internal elastic membrane and the atheroma, i.e., the laser probe did not recanalize the artery by burning a tunnel

through the plaque, but it successfully reopened the long occlusion by mechanically burrowing around the plaque. The present randomized clinical study was performed to test the hypotheses that evolved from these preliminary observations.

The purpose of the present study was first to address the issue of whether the thermal probe functions better than the existing method of using guidewires and diagnostic catheters, and second to determine if the success of the laser-assisted probe is due to its mechanical properties or the thermal effect. Our interpretation of the data is that the laser probe functions primarily as a mechanical catheter, which is moderately successful in recanalizing completely occluded peripheral arteries. It is difficult to direct the laser probe, and therefore the success rate with the laser probe is not as high as with standard guidewires. In addition, for the purpose of this protocol, when the laser probe could not adequately penetrate the plaque as a cold device, the laser was activated to heat the probe to 200°C. However, this additional thermal energy was more likely to result in a perforation of the artery than to act in a beneficial manner. There were only 2 cases (10%) in which thermal energy improved the mechanical function of the laser probe, but in 3 of the 5 cases (60%) in which thermal energy was used, perforation resulted.

This protocol was chosen to determine whether thermal energy is necessary in addition to mechanical action of the catheter. Our success rate is similar to results in previous nonrandomized trials in which the laser probe was always thermally activated. In 486 patients with occluded proximal or midsuperficial femoral arteries from 1 clinical trial, the success rate was 80% (lesion length not reported).[1] The success rate in the present study without the thermal effect was 100% for occlusions 1 to 7 cm, 77% for occlusions 8 to 14 cm and
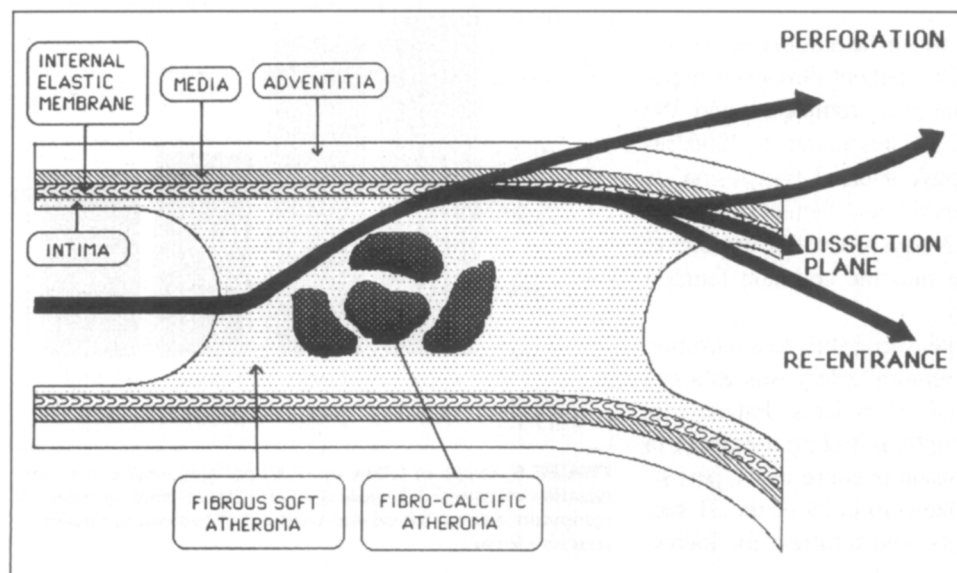
FIGURE 7. Diagram of laser probe and standard catheter pathways. When there is a densely calcified or fibrotic atheroma, the laser probe is deflected around the atheroma and advances into a less resistant dissection plane between the internal elastic membrane and the atheroma plaque. Eventually these devices may reenter the native lumen when the atheroma becomes thinner; they may remain within the dissection plane for an extended distance (>30 cm), or they may perforate externally. (Reprinted with permission from Cardiovascular Reviews and Reports, Inc.)

TABLE I Comparison of Clinical Trials to Recanalize Occluded Superficial Femoropopliteal Arteries

Author	Technique	No. of Arteries	Occluded Length (cm)	Percent Primary Success	1 Year Patency of Pts. with 1° Success (%)
Zeitler	Mechanical	304	<10	82	NA
1980		133	>10	53	NA
Martin	Balloon	46	NA	76	57
1981			(mean 4 cm in 1° success group)		
Krepel	Balloon	18	<3	89	93
1985		19	>3	26	50
Hewes	Balloon	18	1–3		81
1986		10	4–7		100
		13	>7		91
	Total	59	NA	83	82
Morganstern	Balloon	46	1–20	74	NA
1977–80	Balloon				
1981–88		70	1–10	91	NA
Thermal Angioplasty Studies					
Levy	Balloon or	14	NA	86	NA
1989	laser probe	13	NA	69	NA
Sanborn	Laser probe	17	<3	100	93
1988	Heated	37	4–7	70	76
		53	>7	66	58
	Total	107	9.6	73	72
Tobis	Laser probe	17	10.9 ± 7.2	67	40
1989	Heated				
McGowan	Laser probe	15	5.6 ± 3.1	93	NA
1988	Heated				
Leachman	Laser probe	Total 117	<10	80	NA
1989	Heated		>10	50	NA
Tobis	Balloon	20	14.2 ± 6.9	95	60
Present series					
1991					
	Laser probe Cold (15) Hot (5)	20	16.6 ± 9.7	75	50

NA = not available.

83% for occlusions 15 to 45 cm long, with an overall primary success rate of 85%. It is difficult to compare different clinical studies because some reports combine patients who have stenoses with those who have complete occlusions. In addition, the length of occlusion or how the lengths are subdivided varies between the reports. Some of the frequently cited clinical trials for recanalization of occluded superficial femoral arteries are presented for comparison in Table I for both mechanical and thermal angioplasty.

Earlier nonrandomized laser studies used historical control groups to claim that mechanical balloon angioplasty has a limited primary success rate in occlusions >3 cm and certainly >7 cm. However, a recent report[11] and the current study demonstrate a higher rate of primary success using mechanical guidewires and supportive catheters. The high rate of success in the present series of recanalizing long occluded segments of the superficial femoral artery is attributed to the alternative approaches used: either retrograde from the popliteal artery or the combined anterograde and retrograde punctures. In addition, the observation that the mechanism of recanalization proceeds along the perimeter of the plaque, was used advantageously. Instead of terminating the procedure once the dissection plane was observed, it was used to burrow around the plaque until the distal lumen could be reentered by tearing into it from the perimeter. It is ironic that in the attempt to find a better method than mechanical recanalization, our experience with laser-assisted thermal angioplasty lead to refinements in technique that improved the results with standard mechanical balloon angioplasty. This experience reemphasizes how the use of historical control groups may be misleading.

This randomized trial demonstrates that the laser-assisted probe is not superior to the results with standard guidewire manipulation to reopen occluded superficial femoral arteries. In addition, this study indicates that the predominant effect of the laser probe appears to be due to the mechanical component of the probe and not laser-induced heat. The blunted bullet-shaped contour of the laser probe was well designed to penetrate atheroma. This penetration occurs around the obstruction between the internal elastic membrane and

the plaque. Once in this dissection plane, it is more likely that the thermally active 200°C metal tip will perforate laterally through the thin media and adventitia. Thermal activation of the probe added successfully to the mechanical effect of the device in only 2 of 20 (10%) patients assigned to the laser group. This meager additional benefit does not appear to justify the large cost of current laser devices. The fact that 30,000 cases of laser-assisted thermal angioplasty have been performed without a randomized trial raises serious concerns about the scientific foundation on which decisions of treatment are made in interventional procedures with new devices.[12-14]

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