Nd:YAG Laser With Sapphire Tip Combined With Balloon Angioplasty in Peripheral Arterial Occlusions

Long-term Results
E. Pilger, MD; J. Lammer, MD; H. Bertuch, MD; G. Stark, MD; M. Decrinis, MD; K.P. Pfeiffer, PhD; and G.J. Krejs, MD

In 167 patients with complete occlusion (>3 cm) of the femoropopliteal artery, percutaneous transluminal laser angioplasty (PTLA) was performed after an unsuccessful attempt at crossing with a guide wire and was immediately followed by balloon dilatation. An Nd-YAG laser and an optical fiber delivery system with a sapphire tip serving as a contact probe were used for PTLA. In 132 of 167 (79%) patients, the occluded segment was successfully reopened. Clinical symptoms improved in 126 of 167 (75%) patients. PTLA was unsuccessful in 35 patients, and in 15 of these, injury of the vessel wall occurred. In one patient, surgical drainage of a large hematoma became necessary. All patients in whom recanalization had been achieved were randomized to receive long-term treatment with either phenprocumarol or acetylsalicylic acid (ASA) plus dipyridamole to prevent rethrombosis. At 36 months of follow-up, the cumulative patency rate (CPR) was 63%. A complete reobstruction in 32 patients (24%) and a partial reobstruction in 15 patients (11%) were found angiographically. The CPR after 36 months was significantly lower (p<0.05) in patients younger than 60 years of age (54%) than in patients older than 60 (68%); it was also significantly lower (p<0.05) in patients with reduced peripheral runoff (55%) due to obstructed arteries of the lower leg than in patients with unaffected runoff (73%). The CPR was 65% in recanalized segments shorter than 7 cm and was 62% in recanalized segments longer than 7 cm. In patients treated with ASA plus dipyridamole, the CPR was 60%, and in patients who underwent anticoagulation therapy, the CPR was 65% (NS). The CPR was also significantly lower (p<0.05) in patients who were still smoking during follow-up (62%) than in patients who never smoked or quit smoking (77%). These results suggest that PTLA combined with balloon dilatation is beneficial for the management of patients with chronic peripheral arterial occlusion and provides good long-term patency rates. (Circulation 1991;83:141-147)

Balloon angioplasty is a well-established method for recanalizing chronic arterial obstruction. However, the primary success rate and long-term patency rate after balloon angioplasty are disappointing for complete occlusions longer than 3 cm (26% primary success rate and a 50% 1-year patency reported by Krepel et al.2 and a 23% 6-month patency reported by Murray et al.3). The feasibility of percutaneous transluminal laser angioplasty (PTLA) combined with percutaneous transluminal angioplasty in reopening complete arterial occlusion has been demonstrated. However, long-term patency rates, factors predisposing for reocclusion, and the most effective medical maintenance therapy remain to be established in assessing the therapeutic benefit of this procedure. We present long-term results of 132 patients who had complete occlusion of peripheral arteries who successfully underwent PTLA with a sapphire-tipped optical fiber delivery system followed by conventional percutaneous transluminal angioplasty. To evaluate the influence of medical treatment on reocclusion rates, we compared phenprocumarol with acetylsalicylic acid (ASA) plus dipyridamole therapy in a controlled and randomized manner.

See p 350
Methods

Patients

Patients selected for participation in this study had been consecutively referred to the Division of Angi-ology by general practitioners, vascular surgeons, and other physicians.

A total of 167 patients (mean age, 66 years; range, 30–87 years), who had complete chronic occlusion of the femoropopliteal artery, were studied according to a protocol approved by the ethics committee of Karl Franzens University. Patients recruited for the study had to have a history of claudication or pain at rest for more than 4 months (mean, 14 months; range, 4–36 months); on angiography, the occluded segment had to be longer than 3 cm (mean length, 9 cm; range, 3–24 cm) and would not allow a Teflon-coated guide wire (0.035 in., TM 35150, J3, Medrad, Pittsburgh, Pa.) to pass through. According to the suggested standards for reports dealing with lower-extremity ischemia,6 of 167 patients (125 men, 42 women), 116 patients (70%) were classified as being in clinical category 3 (severe claudication), 34 (20%) in clinical category 4 (resting pain), and 17 (10%) in clinical category 5 (tissue damage at the heel [10x], at the first toe [3x] or at the fifth toe [4x]). Moderate arteriosclerotic lesions of the aortoiliac vessels without obstruction were detected in 79 of 167 patients. All of the patients included in the study had adequate inflow documented by angiography. In 132 patients, bypass surgery was planned in the event that PTLA failed. Of 167 patients, 121 (72%) were smokers, and 52 (31%) had a history of diabetes mellitus. All patients gave written, informed consent.

Angioplasty Procedure and Follow-up

An Nd-YAG laser (CL 60, Surgical Laser Technologies, Malvern, Pa.) was used as described previously.5 After puncture of the common femoral artery distal to the inguinal ligament, a 7F catheter sheath was placed in the superficial femoral artery. The flexible quartz fiber with a 2.2-mm sapphire tip serving as a contact probe was introduced through the introducer sheath and was advanced under fluoroscopic control to the occlusion. The percutaneous access was not precluded by common femoral artery disease in any of the patients. To prevent acute rethrombosis, all patients received 330 mg ASA plus 75 mg dipyridamole three times daily, starting at least 1 day before PTLA. After channel reopening by laser, balloon dilatation of the new channel was performed in all patients (Olbert-Catheter-System, Surgimed A/S, Olstykke, Denmark). Heparin (5,000 IU) was administered intra-arterially immediately after successful PTLA followed by heparin 1,000 IU/hr i.v. given for 48 hours. Patients were subsequently randomized7 to receive either an oral anticoagulant (phenprocumarol) or ASA (330 mg) plus dipyridamole (75 mg) three times daily as long-term treatment, which was maintained during the entire follow-up. The design of this follow-up study was in accordance with the ethical guidelines of the Declaration of Helsinki. All patients gave informed, written consent for this follow-up study. Patients were mobilized 24 hours after the procedure.

Peripheral circulation was evaluated before PTLA; on the day of discharge (third to fifth day after PTLA); and 1, 3, 6, 12, 18, 24, 30, and 36 months after recanalization by clinical examination and assessment of the arterial ankle/arm pressure ratio. The morphology of the recanalized arterial segment was assessed by intravenous digital subtraction angiography 6 and 24 months after treatment or when reocclusion was suspected by either clinical symptoms (claudication, resting pain) or a decrease (>0.2) of the arterial ankle/arm pressure ratio.

Patency

Patency was defined by angiographic criteria. The arterial segment was classified as patent when antegrade flow of the contrast medium was fluoroscopically detected.

Partial Reocclusion

A partial reocclusion was considered when an antegrade flow of the contrast medium was still detected on follow-up angiography, but the diameter of the recanalized segment was restricted by more than 50%.

Clinical Improvement

Clinical improvement was considered to be present when the ankle/arm pressure ratio increased by more than 0.1 and when the clinical condition improved by at least one or two steps in the classifications (from category 3 to 2, category 4 to 3, and category 5 to 3).6

Runoff Circulation

Runoff circulation was defined as reduced when obstruction was detected in the popliteal artery or in more than one calf artery. The runoff circulation was classified as unaffected when no obstruction of the arteries below the recanalized segment could be detected or when obstructions were detectable in one of the three calf arteries.

Statistical Analysis

The $\chi^2$ test8 was used for analyzing primary success rates and reocclusion rates of different subgroups. The Cox-Mantel test9,10 was used for analysis of cumulative patency rates.

Results

Primary Vascular Reopening Rates

In 26 (14%) of 193 patients, balloon angioplasty alone was performed because a Teflon-coated guide wire could be passed through the occluded segment. These patients were excluded from the study.

The present series includes 167 patients with a femoropopliteal occlusion in whom a primary recanalization rate of 79% ($n=132$) was achieved. Ankle/
Reopening by PTLA was prevented either by calcification of the occluded segment (20 patients) or by vessel wall injury by the laser (15 patients). The clinical symptoms in these 35 patients did not worsen during the days after the unsuccessful effort of PTLA. In 19 of 35 patients in whom PTLA failed, the occluded segment was bypassed surgically as planned; in another patient, the leg had to be amputated because PTLA, as the last possible recanalizing treatment, had failed. The remaining 15 patients were treated intravenously with vasodilating agents.

**Side Effects and Complications**

Of 167 patients, 103 (62%) reported a sensation of warmth in the treated area. Fifteen of these patients complained of burning pain. These symptoms ceased promptly in all patients when the laser was not activated. In 15 patients (9%), laser treatment caused dissection (n=9) or perforation (n=6) of the vessel wall, which was detected by arterial dye injection. Vessel injury prevented recanalization in all 15 patients but did not increase the peripheral ischemia and did not necessitate emergency surgery. A curved arterial segment, through which the laser fiber could not follow (n=6), or a calcified plaque, which deflected the laser fiber (n=9), was thought to have caused the vessel wall injury. In one patient, a local hematoma developed at the perforation site compressing the popliteal vein, thus causing peripheral venous stasis. Surgical drainage was performed electively. Twenty-four patients (14%) bled from the arterial puncture site; in 21 patients (13%), only a small hematoma developed; in three (2%), bleeding caused a decrease in the hematocrit level by more than 5%. Heparin had to be discontinued, and recanalization before randomization. These three patients underwent bypass surgery. Peripheral embolism was precipitated in two patients; subsequent intra-arterial thrombolysis reestablished the patency of the lower-leg arteries in both patients.

**Long-term Results**

Initially 132 patients with a reopened arterial segment were included in the follow-up study. The mean follow-up period was 14 months (range, 1–36 months). Three patients died from myocardial infarction, and nine patients (7%) dropped out because of side effects. Of these nine, eight received ASA plus dipyridamole and had severe gastrointestinal side effects (3x gastrointestinal bleeding). One patient receiving oral anticoagulation therapy experienced a subural hematoma and fully recovered after surgical drainage. Overall, gastrointestinal symptoms were reported by 19 patients (30%) of the ASA plus dipyridamole group and by four patients (6%) of the phenprocumarol group (p<0.01). Administration of H$_2$-blockers abolished gastrointestinal symptoms in all four patients receiving anticoagulation therapy and in 11 of 19 patients receiving ASA plus dipyridamole. Forty-seven (36%) patients had a complete (n=32, 24%) or partial (n=15, 11%) recanalization.
Tables 2. Partial Reocclusions and Complete Reocclusions After Percutaneous Transluminal Laser Angioplasty Combined With Percutaneous Transluminal Angioplasty for the Treatment of Chronic Occluded Arterial Segments

<table>
<thead>
<tr>
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<th>PR</th>
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<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>SFA</td>
<td>106</td>
<td>85</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>SFA+PA</td>
<td>12</td>
<td>52</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>PA</td>
<td>14</td>
<td>70</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>132</td>
<td>79</td>
<td>15</td>
<td>11</td>
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PR, primary recanalization; P-RO, partial recanalization; C-RO, complete recanalization; SFA, superficial femoral artery; PA, popliteal artery.

The length of the completely reoccluded segment was of the same length as the originally occluded segment in 25 patients; it was longer (range, 1–12 cm longer than the originally occluded segments) in 13 patients, and it was shorter (range, 1–6 cm shorter than the originally occluded segment) in nine patients. The reocclusion rate did not differ among the three treated segments (Table 2).

One patient with a reduced runoff after recanalization lost all arteries below the knee joint upon reocclusion and required a below-the-knee amputation. Except for this one patient, reocclusion neither caused worsening of clinical symptoms nor prevented bypass surgery that had originally been planned. The cumulative patency rate after 36 months of follow-up was 63%. The rate of reocclusion did not correlate with the length of the recanalized segment (Figure 2) and with the type of medical treatment (Figure 3), but it correlated with reduced peripheral runoff (Figure 4) and age of the patient (Figure 5). Reocclusion occurred significantly more often in patients younger than 60 years.

All 15 patients with a partial reocclusion underwent a second balloon dilatation. In eight patients, a completely reoccluded segment was reopened by a second PTLA. Twelve patients underwent femoropopliteal bypass surgery, one patient had a below-the-knee amputation. Despite morphological reocclusion, 11 patients remained clinically improved, thus obviating the need for further recanalizing treatment.

Discussion

Surgical treatment of chronic peripheral arterial occlusions has major limitations. Therefore, percutaneous techniques have been developed to open peripheral arterial occlusions. These include balloon angioplasty, intra-arterial thrombolysis through an indwelling catheter, and PTLA. We demonstrated a 79% initial reopening rate in 167 patients with complete peripheral arterial occlusions that were not crossed with a guide wire by using PTLA with a sapphire contact probe. As reported, this approach is safe; in our series, only one of 167 patients required elective surgical drainage of a hematoma due to a perforated femoral artery.

Primary Results

In all patients, we attempted to pass the Teflon-coated guide wire through the occluded segment

![Cumulative Patency Rate (%)](image)

**Figure 2.** Plot of cumulative patency rate (CPR) after percutaneous transluminal laser angioplasty (PTLA) for patients in whom reopened segments were 3–7 cm and longer than 7 cm. The difference in CPR observed was not significant. Numbers below the figure indicate the number of patients (upper row, 3–7 cm; lower row, >7 cm) evaluated at each point of follow-up.

![Cumulative Patency Rate (%)](image)

**Figure 3.** Plot of cumulative patency rate (CPR) after percutaneous transluminal laser angioplasty (PTLA) for patients receiving acetylsalicylic acid (ASA) and dipyridamole and patients receiving anticoagulation therapy. Difference in CPR observed was not significant. Numbers below the figure indicate the number of patients (upper row, ASA+dipyridamole; lower row, phenprocumarol) evaluated at each point of follow-up. Three patients in whom the reopened segment reoccluded before randomization were not included in this figure.
were excluded from the study. The primary success rate for balloon angioplasty alone was much lower than those reported in previous studies.\textsuperscript{1,2,3,14,15} This difference might be explained by the older age and by the soft guide wire used in our study. In addition, to minimize the risk of vessel wall perforation and not to preclude PTLA, we may have less aggressively attempted to pass the guide wire through the occlusion in this study than in the previous studies.

The successful reopening of the remaining 132 occlusions by mechanical means before the laser was activated can be excluded because the laser fiber was pushed forward only when there was no resistance to minimize the risk of peripheral embolism. Therefore, reopening by laser-induced vaporization must be assumed in all of the successfully recanalized arteries. How an Nd-YAG laser with a contact probe works in recanalizing occluded peripheral arteries has been discussed previously.\textsuperscript{5} Recanalization by means of the Nd-YAG laser was limited by two factors. First, extremely calcified plaques could not be vaporized; second, the limited maneuverability of the laser fiber restricted its use to straight vessel segments (in our series, the vessel wall was perforated in six patients because of a curved segment).

Successful recanalization did not always result in clinical improvement. Despite morphological recanalization, six patients were clinically not improved, probably because of extensive intensive mediadysclerosis and obstructed calf arteries.

Recanalization rate and clinical improvement were significantly higher in patients suffering from peripheral vascular disease in clinical category 3 than in patients who were in clinical category 4 or 5. This may be explained by a much longer course of the disease resulting in a higher calcification of the occluded segment in these patients. The length, however, did not significantly influence the primary reopening rate.

PTLA can also be performed by using a laser-heated metal-capped fiber (hot tip).\textsuperscript{12} In recanalizing complete occlusions and stenoses, a primary success rate of 77\% has been reported.\textsuperscript{13} Thus, those results are not comparable with our findings that pertained to complete obstruction only.

**Long-term Results**

In this study, we further report the results on long-term patency of the vessels successfully reopened by PTLA in 132 patients. The cumulative patency rate of primarily reopened vessels was found to be 63\% after a follow-up period of 36 months. This high overall patency rate was obtained by subsequent drug treatment with either ASA plus dipyridamole or phenprocoumarol. At this point of follow-up, the reclosure rate was not significantly different between these two treatment regimens. The side effects, however, were significantly higher in the ASA plus dipyridamole group than in the anticoagulation group.
Similar results using the hot tip were reported by Sanborn et al.\(^{13}\) The 1-year cumulative clinical patency rate for 99 lesions was 77%; when the reopened occlusion was longer than 7 cm, the cumulative patency rate decreased to 58%.

Analysis of subgroups of patients revealed that the patency rate was high in older patients (older than 60 years of age) and in patients who had open runoff arteries in the lower leg. The unexpected lower patency rate in the younger patients remains unexplained. It may be due to a higher rate of continued smoking in this group (Table 3). We also speculate that vascular occlusive disease that manifests itself at a younger age runs a more severe and progressive course and is, thus, more difficult to influence by therapeutic manipulations. Reocclusions occurred also more often in patients who had diabetes mellitus (Table 4). Hyperlipidemia, an important risk factor for peripheral vascular disease, was not considered in further analysis because of its high prevalence (89%) in patients treated by PTLA. Reduced runoff in patients with obstruction of the arteries in the lower leg caused impaired flow after recanalization resulting in a lower patency rate in this group. It is important to note that the long-term patency rate was not influenced by the length of the reopened arterial segment.

It must be pointed out that during the period of follow-up, "progression" of the vascular disease only occurred at the site of treatment and beyond. Therefore, a potential effect of the thermal and mechanical damage on recurrent disease must be assumed.

Patients who received balloon dilatation alone in our study were also followed up (n=26). Ten (38%) reocclusions occurred during a mean follow-up period of 12 months.

However, statistical comparison of long-term results after balloon dilatation alone with PTLA combined with balloon dilatation could not be conducted in this study because the occlusions in the two groups were not comparable. A guide wire could be passed through the occlusion in the balloon dilatation group but not in the PTLA plus balloon dilatation group. Therefore, the occlusions in the two groups may have different physical and chemical properties.

In addition to the primary recanalization by the laser, we think that there might be another advantage for performing PTLA combined with balloon dilatation in completely occluded peripheral arteries. By use of the laser before balloon dilatation, the organized thrombus and the occluding atherosclerotic plaque are partially vaporized by the laser; thus, a smaller amount of occluding material has to be pressed against the vessel wall by the subsequent balloon dilatation than when balloon dilatation alone is performed. This might reduce the incidence of recurrences. Certainly, we are aware that this hypothesis has to be proved in a controlled study.

In conclusion, PTLA combined with balloon dilatation is a promising technique for reopening complete peripheral arterial occlusions, which cannot be passed through by a guide wire. We have demonstrated that patients suffering from vascular occlusive disease in an early stage with lifestyle-limiting claudication may benefit the most from this technique. We further observed that neither a failed PTLA nor a recanalization of a primarily recanalized vessel prevented or influenced the outcome of subsequent vascular bypass surgery. Although our results were obtained in an open study, we think that they provide important information on the treatment of patients with complete occlusion of the femoropopliteal artery. Nevertheless, further improvement of the laser technique and the delivery system are necessary to minimize its failure rate.

### References


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### Table 3. Risk Factors for Reocclusion After Percutaneous Transluminal Laser Angioplasty Combined With Percutaneous Transluminal Angioplasty

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>NS/ND</th>
<th>S</th>
<th>D</th>
<th>S+D</th>
<th>RR-O</th>
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<tbody>
<tr>
<td>&lt;60</td>
<td>39</td>
<td>11</td>
<td>28</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>&gt;60</td>
<td>93</td>
<td>33</td>
<td>35</td>
<td>36</td>
<td>15</td>
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<tr>
<td>Total</td>
<td>132</td>
<td>44</td>
<td>33</td>
<td>56</td>
<td>18</td>
</tr>
</tbody>
</table>

NS, nonsmoker; ND, nondiabetic; S, smoker; D, diabetes mellitus, RR-O, reduced runoff.

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### Table 4. Reocclusions After Percutaneous Transluminal Laser Angioplasty and Percutaneous Transluminal Angioplasty in Patients With Different Vascular Risk Factors

<table>
<thead>
<tr>
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<th>Primary recanalization</th>
<th>Reocclusion</th>
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<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Nonsmoker/nondiabetic</td>
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<td>10</td>
</tr>
<tr>
<td>Smoker (without diabetes)</td>
<td>56</td>
<td>21</td>
</tr>
<tr>
<td>Diabetic (without smoking)</td>
<td>18</td>
<td>8</td>
</tr>
<tr>
<td>Diabetic and smoker</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>132</td>
<td>47</td>
</tr>
</tbody>
</table>

Follow-up ranged from 1 to 36 months (mean, 14 months).

Nonsmoker, patient who never smoked or stopped smoking after PTLA; smoker, patient who still smoked during follow-up. *p<0.005; †p<0.02; ‡p<0.01.

KEY WORDS • vascular occlusive disease • phenprocumarol • acetylsalicylic acid • laser
Nd:YAG laser with sapphire tip combined with balloon angioplasty in peripheral arterial occlusions. Long-term results.
E Pilger, J Lammer, H Bertuch, G Stark, M Decrinis, K P Pfeiffer and G J Krejs

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