JACC Vol. 30, No. 3
September 1997:649–56

Recanalization of Chronic Total Coronary Occlusions Using a Laser Guide Wire: A Pilot Study

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Objectives. **This study sought to prospectively evaluate the performance of a laser guide wire in crossing chronic total coronary occlusions in patients with a failed previous mechanical guide wire attempt.**

Background. **Despite continued refinement of mechanical hardware available for coronary angioplasty, restoration and maintenance of blood flow through a chronically occluded coronary artery remains a true challenge.**

Methods. **Fifty patients with a chronic total coronary occlusion and a previous failed attempt at recanalization using mechanical guide wires were included. A mechanical attempt to cross the occlusion was repeated. In case of failure, an additional attempt was made with the laser guide wire.**

Results. **The median age of occlusion was 22 weeks (range 5 to 200), and the occlusion length was 23 ± 11 mm (mean ± SD). A repeat mechanical attempt was successful in six cases (12%). Dissection occurred in five other cases, and device crossover was not attempted. Thus, in 39 patients an attempt was made with the laser guide wire, with successful recanalization in 23 (59%). Thereby the overall success rate increased from 12% to 58% (29 of 50 patients). The amount of contrast medium used was 515 ± 154 ml, fluoroscopy time was 99 ± 43 min, and total procedure time was 2 h 48 min (±55 min). Procedural success was achieved in 26 cases and clinical success (procedural success without in hospital events) in 24. In-hospital events were two non–Q wave myocardial infarctions related to subacute reocclusion. In one patient, a balloon dilation after laser guide wire perforation resulted in tamponade requiring pericardiocentesis. After a successful procedure, the angina class decreased from 2.9 ± 0.2 to 1.4 ± 0.7 at 3 months of clinical follow-up. Six-month angiographic follow-up was completed in all 24 eligible patients and showed vessel patency in 20 (80%).**

Conclusions. **The use of the laser guide wire for recanalization of chronic total coronary occlusions refractory to treatment with mechanical guide wires is feasible and relatively safe and was successful in 59% of cases. This device must thus be considered a valuable addition to the interventional armamentarium and accordingly will be evaluated in a randomized clinical trial.**

(J Am Coll Cardiol 1997;30:649–56)

Total coronary artery occlusion is estimated to be present in approximately one-third of the patient population undergoing diagnostic angiography for symptomatic coronary artery disease (1). Despite a steady improvement in angioplasty tools to recanalize totally occluded vessels over the past decade, success rates have not dramatically increased (2–7). A recently developed laser guide wire that combines the mechanical properties of a typical coronary guide wire with the ablative energy of a XeCl excimer laser may facilitate the recanalization of chronically occluded coronary arteries. Therefore, the primary goal of this study was to evaluate the performance of this new device in patients with symptomatic coronary artery disease due to a chronic total coronary occlusion.

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Manuscript received February 12, 1996; revised manuscript received May 5, 1997, accepted May 22, 1997.

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Methods

Patient selection. From August 1993 to January 1995, a prospective observational pilot study was conducted at the Thoraxcenter of the University Hospital of Rotterdam to evaluate the performance of the Spectranetics Prima Total Occlusion System in crossing chronic total coronary occlusions. Inclusion criteria were a Thrombolysis in Myocardial Infarction (TIMI) flow grade 0 coronary occlusion (8) and a failed previous attempt at recanalization using conventional guide wires. In all cases, a mechanical attempt to cross the total occlusion was repeated before (in case of failure) an ensuing attempt was made with the laser guide wire.

To evaluate the true potential of this new device, there were no exclusion criteria, with the exception of acute myocardial infarction within 2 weeks of the intervention. Thus, lesions that are typically considered unfavorable for a mechanical attempt at recanalization, including bridging collateral vessels, a major side branch originating from the stump of the occlusion, eccentric lesions or a nonvisible entry point, were intentionally not excluded (Fig. 1). The age of occlusion was assessed in

Published by Elsevier Science Inc.

0735-1097/97/$17.00
PII S0735-1097(97)00209-X

Abbreviations and Acronyms

CK = creatine kinase
ELCA = excimer laser coronary angioplasty
PTCA = percutaneous transluminal coronary angioplasty
QCA = quantitative coronary angiography
TIMI = Thrombolysis in Myocardial Infarction

combination by angiographic data and from clinical history. The stump morphology was evaluated from the preprocedural angiogram. The distal vessel lumen was routinely visualized by a contrast medium injection in the contralateral coronary artery so that both femoral arteries were punctured in all cases. The length of occlusion was measured by quantitative coronary angiography (QCA) after visualization of both the occluded stump and the distal lumen by means of a simultaneous bilateral coronary injection at the commencement of the procedure. Fluoroscopic time, total procedure time and the amount of contrast medium used were recorded. Blood samples for creatine kinase (CK) analysis were taken 12 h after the procedure.

Because the first-generation laser guide wire was less steerable than most conventional guide wires, *wire success* was defined as angiographic evidence of reaching the true lumen of any branch distal to the occlusion. *Procedural success* was defined as an average diameter stenosis <50% in two orthogonal views by on-line QCA. *Clinical success* was defined as procedural success without death, myocardial infarction, coronary artery bypass graft surgery or repeat angioplasty during the index hospital stay.

Laser guide wire. The laser guide wire (The Prima Total Occlusion System, model 018-003, Spectranetics) consists of an 0.018-in. guide wire containing 12 silica fibers with a 45-μm diameter. The supplied support catheter has a 2.5F tapered tip, providing additional coaxial backup support. The model 018-001 (Generation 1) had a nonshapable and subsequently nonsteerable tip that could only be advanced in straight coronary sections. The model 018-003 (Generation 2A) with a shapable steerable tip was introduced in December 1993. It was originally designed to function as an exchange guide wire. Because the floppy proximal part of the guide wire did not allow for an easy exchange, the Generation 2B with a stiffened proximal exchange section was introduced in April 1994.

The laser was the Spectranetics CVX 300 XeCl excimer laser. The fluence typically used during a laser guide wire procedure was 60 mJ/mm^2, with a pulse repetition rate of 25 Hz. On encountering resistance with the guide wire, the laser was activated in pulse trains for a maximum of 5 s. During laser activation, the laser guide wire was advanced at a rate of ~1 mm/s, usually during a simultaneous injection of contrast medium in the contralateral coronary artery. Biplane fluoroscopy was used to guide the alignment of the guide wire with the target segment (Fig. 2). Whenever the laser guide wire encountered intraluminal resistance during laser activation (e.g., in more calcified lesions), the pulse repetition rate was increased to 40 Hz, thus increasing the ablation rate.

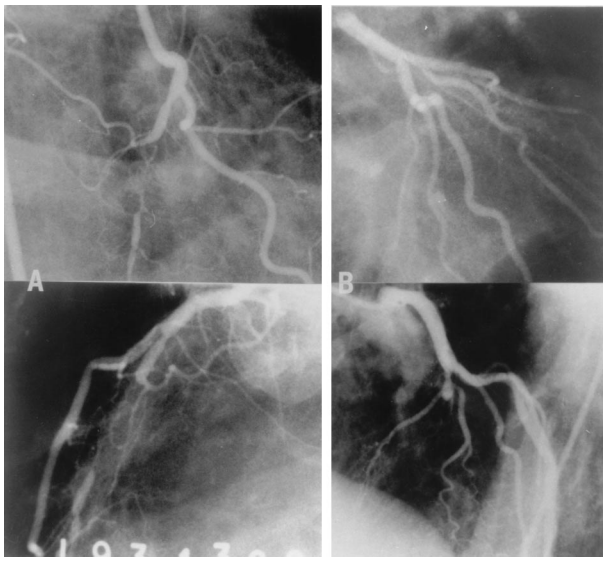

Figure 1. A, Total occlusion of the right coronary artery with a blunt stump, a major side branch originating in the stump and bridging collateral channels (**top row,** frontal view; **bottom row,** lateral view). **B,** Total occlusion of the proximal left main coronary artery with a septal branch and a diagonal branch originating in the stump. There is a lesion in the ostium of the diagonal branch (**top row,** right inferior oblique view; **bottom row,** left superior oblique view).

Procedural data. An initial attempt was made to cross the occlusion using conventional guide wires, typically using a balloon catheter (Medtronic 18 K) for additional backup support. If unsuccessful, a second attempt was made with the laser guide wire. Table 1 shows the various types of guide wires that were used. The conventional guide wire used most was the Schneider 0.014-in. guide wire (n = 32), whereas the currently used Generation 2B laser guide wire was available only in the last 18 cases. Because all these procedures were repeat percutaneous transluminal coronary angioplasty (PTCA) procedures, we avoided excessive use of very stiff guide wires, so as not to risk dissections that would preclude use of the laser guide wire. Moreover, because the distal end of the first-generation laser guide wire was extremely floppy, its potential to cross an occlusion mechanically was somewhat limited. After successful guide wire crossing, angioplasty was usually performed using excimer laser coronary angioplasty (ELCA), using the Spectranetics 1.4- or 1.7-mm Vitesse-C rapid-exchange coronary catheter, and adjunctive balloon angioplasty. ELCA procedures were performed using a saline flush to facilitate removal of contrast medium and blood before and during laser activation to diminish vascular wall damage resulting from shock wave formation (9). Occasionally, placement of one or more stents was required to obtain an optimal procedural result (n = 6). After successful angioplasty, patients received a heparin infusion for 24 h that maintained the activated partial thromboplastin time between 60 and 90 s.

Patient follow-up. Patients were recalled after 3 months for a clinical assessment and after 4 to 6 months for a follow-up

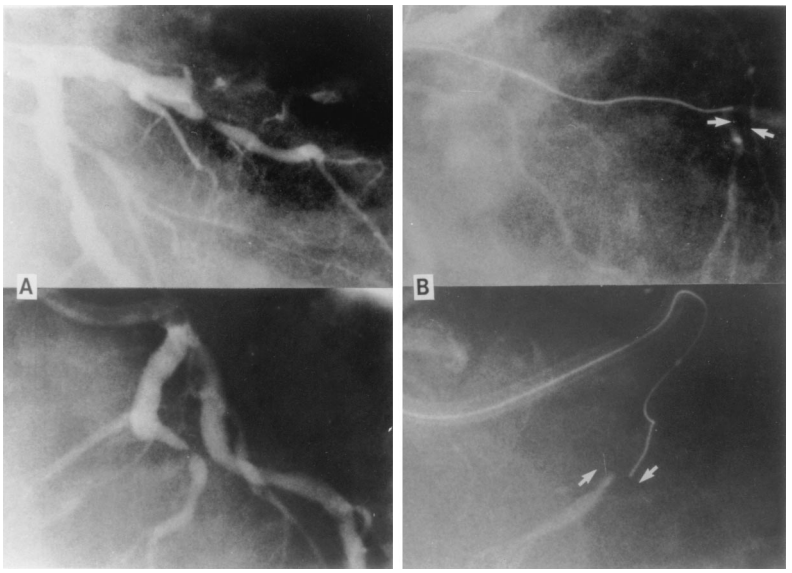

Figure 2. A, Total occlusion of the left anterior descending coronary artery. **Top panel,** right inferior oblique view; **bottom panel,** left superior oblique view. **B,** Alignment of the guide wire tip with the distal lumen is suggested in the **top panel (arrows).** Due to a simultaneous bilateral injection of contrast medium and biplane angiography, the malalignment of the guide wire with the distal lumen is clearly visible in the **bottom panel (arrows).**

coronary angiogram. In case of a failed procedure, patients were referred for elective coronary artery bypass graft surgery.

Statistical analysis. Results are expressed as mean value ± SD, unless otherwise indicated. Univariate logistic regression analysis was performed to determine whether clinical, angiographic or procedural factors were predictive of success. The predictive value was expressed as an odds ratio with corresponding 95% confidence interval.

Informed consent. The study protocol had the approval of the University Hospital of Rotterdam Medical Ethics Committee. Written informed consent was obtained from all patients.

Results

Procedural data. Data for 61 consecutive patients with a TIMI flow grade 0 total coronary occlusion in at least one coronary artery on diagnostic angiography and who were referred for a laser guide wire attempt at recanalization were prospectively collected. Of these, nine patients appeared to have TIMI flow grade 1, two TIMI flow grade 2 at the time of the procedure. These patients were consequently excluded from analysis. In the remaining group there were 51 occlusions in 50 patients. This patient cohort represented <20% of the total number of patients undergoing PTCA for a TIMI flow grade 0 total occlusion in our department during this period (10). The baseline clinical characteristics are given in Table 2 and confirm that the patient group is representative of current clinical practice with percutaneous angioplasty. The baseline angiographic data are given in Table 3.

The duration (procedural time) of the initial attempt to cross the occlusion using a conventional guide wire was 33 ± 34 min. The duration of a subsequent attempt using the laser guide wire was 36 ± 28 min. The total fluoroscopic time was 99 ± 43 min, with a total procedural duration of 2 h 48 ± 55 min. The amount of contrast medium used was 515 ± 159 ml.

Wire success. Despite a previously failed mechanical attempt at recanalization, a repeat attempt to cross the occlusion with a mechanical guide wire was successful in six patients (12%). In five patients the procedure was terminated due to the presence of a mechanically induced dissection, considered to preclude the further use of a laser guide wire. With increasing experience it became evident that the occurrence of a dissection did not necessarily increase the risk or diminish the chance of success. In a number of cases with dissection, a new entry point could be created by steering the tip of the laser guide wire away from the site of the entry point of the dissection (Fig. 3). Careful biplane angiography in several

Table 1. Guide Wires Used in the Present Study

Conventional guide wires	
Schneider 0.014-in. J-tip	32
ACS HTF 0.014 in.	5
ACS standard 0.018 in.	4
Schneider 0.012 in.	2
Scimed Roadrunner	1
Magnum wire	1
Not recorded	5
Laser wires	
Generation 1	7
Generation 2A	15
Generation 2B	17

Table 2. Baseline Clinical Characteristics of 50 Study Patients With 51 Occlusions

Age (yr)	58 ± 10
Male	43 (86%)
Previous MI	32 (64%)
CCS angina class	
II	4
III	46

Data presented are mean value ± SD or number (%) of patients. CCS = Canadian Cardiovascular Society; MI = myocardial infarction.

Table 3. Baseline Lesion Characteristics

LAD	21 (41)
LCx	3 (6)
RCA	27 (53)
Age of occlusion (wk)	
Angiographic age	
Median	10
Range	2–200
Clinical age (n = 42)	
Median	22
Range	5–200
Length of occlusion (mm)	23 ± 11
Stump morphology	
Central funnel	24 (47)
Eccentric funnel	11 (22)
Blunt stump	15 (29)
MSB	19 (37)
Microcapillary refill	5 (8)
Nonvisible entry point	2 (4)

Data presented are mean value ± SD or number (%) of lesions, unless otherwise indicated. LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; MSB = major side branch originating from the stump; RCA = right coronary artery.

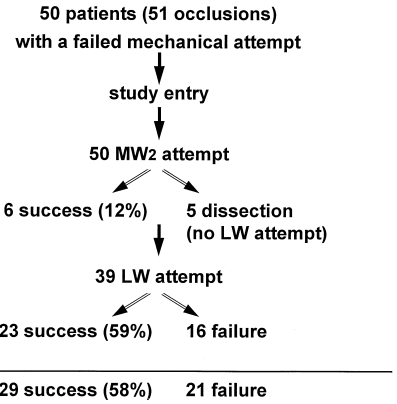

Figure 4. Breakdown of the results. All patients who entered the study had a previous failed attempt at recanalization using mechanical guide wires. LW = laser guide wire attempt; MW2 = a repeat attempt using mechanical guide wires.

orthogonal projection combinations is accordingly an invaluable aspect of the procedure to facilitate reliable, precise and safe maneuvering of the laser guide wire.

Thus, in 39 patients (40 occlusions) an attempt was made with the laser guide wire, resulting in an additional 23 patients (24 occlusions) with a successfully crossed occlusion (59% laser guide wire success). As a result, the overall guide wire success rate increased from 12% to 58% (29 of 50 patients) (Fig. 4).

Although longer and more tortuous occluded segments could be treated with the second-generation steerable wire than the first-generation wire (25 ± 12 mm [n = 32] vs. 19 ± 6 mm [n = 7], p = 0.2), the difference in wire success did not reach statistical significance (53% vs. 86%, p = 0.11). As shown in Table 4, none of the variables normally associated with procedural outcome were predictive of failure or success.

Procedure-related complications. Misalignment of the laser guide wire with the vessel wall boundaries was interpreted as laser guide wire perforation and occurred in seven patients. In one case, the guide wire position was mistakenly thought to be intraluminal. Without previous angiographic proof of the intraluminal localization of the laser guide wire, a 1.5-mm diameter balloon catheter was advanced and inflated. Extravasation of contrast medium occurred, leading to tamponade that was successfully managed by pericardiocentesis. In the remaining six cases, the laser guide wire perforation was the reason for terminating the procedure. Systemic anticoagulation was reversed, and the patients were monitored by transthoracic echocardiography and continuous hemodynamic assessment. There were no clinical sequelae in these patients.

Adjunctive angioplasty failed to restore TIMI flow grade 3

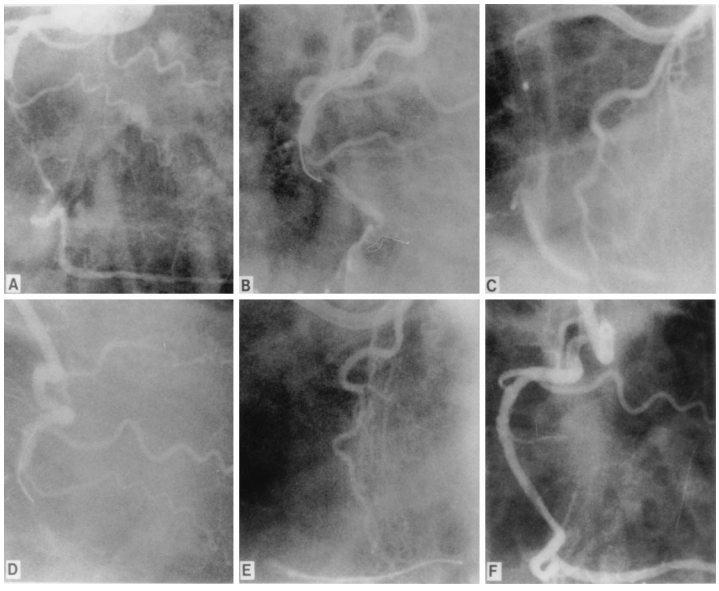

Figure 3. Laser guide wire attempt despite a mechanically induced dissection. **A,** Total occlusion of the right coronary artery with a blunt stump and an ipsilateral collateral channel filling the distal lumen. **B,** Attempt with an 0.014-in. conventional guide wire to cross the occlusion. **C,** Spiral dissection of the right coronary artery. **D,** Introduction of the laser guide wire, creating a new entry point. **E,** Tip of the laser guide wire in the distal lumen of the right coronary artery. **F,** Final result after balloon angioplasty.

Table 4. Angiographic Predictors of Success

	OR (95% CI)	p Value*
Age of occlusion		
Angiographic	1.03 (0.97–1.1)	0.3
Clinical	0.99 (0.98–1.02)	0.7
Location (LAD vs. non-LAD)	0.7 (0.2–2.5)	0.6
Morphology		
RD	0.5 (0.1–2.1)	0.4
Central funnel	0.9 (0.2–3.1)	0.8
Blunt funnel	1.9 (0.4–8.8)	0.4
Eccentric funnel	0.6 (0.1–3.01)	0.6
MSB	0.96 (0.2–3.8)	0.96
Bridging collateral channels	1.1 (0.6–7.1)	0.96
Length of occlusion	0.95 (0.9–1.01)	0.11

*Not significant for all comparisons. CI = confidence interval; OR = odds ratio; RD = proximal reference diameter; other abbreviations as in Table 3.

in three patients with distal dissection. As a result, procedural success was obtained in 26 patients.

Clinical events. Angina recurred within 48 h after an initially successful procedure in two patients (4%), leading to a non–Q wave myocardial infarction in both (CK 270 and 799 U/liter, respectively). A diagnosis of subacute reocclusion was confirmed angiographically, leading to successful repeat angioplasty in one patient and elective bypass surgery in the other. As a result, the overall clinical success rate was 48% (24 of 50 patients).

Clinical and angiographic follow-up. At 3-month clinical follow-up after a successful procedure, the mean angina class (Canadian Cardiovascular Society class) was reduced to 1.4 ± 0.7 versus 2.9 ± 0.3 before the procedure.

In 24 patients the occluded artery was successfully recanalized without occurrence of clinical events. Follow-up angiography was performed in all 24 patients, and 20 had a patent vessel (80%). Seven of these 20 patients (35%) had stenosis >50% by QCA (reference diameter 2.43 ± 0.52 mm, minimal lumen diameter 0.98 ± 0.21 mm, percent diameter stenosis 59 ± 8). As a result, late angiographic success (vessel patency in the absence of reocclusion or restenosis [defined as diameter stenosis >50% by QCA on the 6-month follow-up coronary angiogram]) was achieved in 54% of cases. Six patients (five with restenosis, one with reocclusion) underwent repeat intervention (25% reintervention rate) that was successful in all.

Discussion

Success rates. The past decade has not witnessed a substantial improvement in the success rate of recanalization of chronic totally occluded coronary arteries despite the advent of various new mechanical devices, such as the Magnum guide wire and the Rotacs system (11). Using a meta-analysis of previously published reports, Meier (12) described an average success rate of 65% in recanalizing totally occluded vessels. The low success rate of 12% in our mechanical guide wire group is a reflection of the inclusion of only those patients with a TIMI grade 0 flow occlusion and at least one failed attempt using mechanical guide wires. Furthermore, angiographically unfavorable lesions were deliberately not excluded. Accordingly, a laser guide wire success rate of 59% in such a difficult lesion subset must be regarded as encouraging. Because the laser guide wire was used after a failed mechanical attempt at recanalization in this patient cohort, the question of whether primary use of the laser guide wire will lead to higher success rates still needs to be answered. The Total Occlusion Trial With Angioplasty by Laser Guide Wire (TOTAL) trial, a randomized clinical trial evaluating the safety and efficacy of the laser guide wire, will address this question.

Complications. Laser guide wire perforation occurred in seven patients, without clinical sequelae. However, in one case balloon dilation after a laser guide wire perforation caused a tamponade that was managed by pericardiocentesis. Therefore, we strongly recommend not to advance any device over the laser guide wire before the intraluminal position of the guide wire tip has been angiographically confirmed. Furthermore, although we have not yet encountered such a situation, the possibility of reentry into the true distal lumen after laser guide wire perforation (especially in tortuous segments) must be kept in mind. However, the absence of clinical sequelae in all other cases of laser guide wire perforation suggests that guide wire perforation itself might be a benign phenomenon, allowing continuation of the procedure after withdrawal of the guide wire into the proximal part of the coronary artery (Fig. 5). Although the issue of guide wire perforation should not be downplayed, and is a maneuver that must be avoided as much as possible, the term *perforation* with its ominous connotation could perhaps be replaced by a more benign term such as "guide wire exit." A change in terminology may be too early although, within this context, it seems relevant that the European Multicenter Surveillance Study (13) with the laser guide wire has largely confirmed the benign character of these so-called laser guide wire perforations. Furthermore, the reporting of tamponade as a complication when using mechanical guide wires (14) suggests that this complication is not exclusively associated with the use of a laser guide wire.

In addition to these procedural complications, possible long-term complications due to prolonged fluoroscopy and the relatively large volume of contrast medium should also be considered (15,16).

Long-term follow-up. In accordance with previous reports (7,17,18), we found marked clinical improvement at follow-up in patients with successful recanalization. At 6-month angiographic follow-up, the reocclusion (20%) and restenosis rates (35%) in the remainder of our patient cohort are also in keeping with previously reported results (19). As recently indicated (20–22), more liberal use of intracoronary stents will most likely lead to a significant reduction in the incidence of early and late reocclusion (Fig. 6).

By undergoing recanalization of a total occlusion, a patient at no risk for restenosis is converted to a potential candidate for restenosis or reocclusion. However, the benefit of increasing the number of patent vessels should not be underestimated

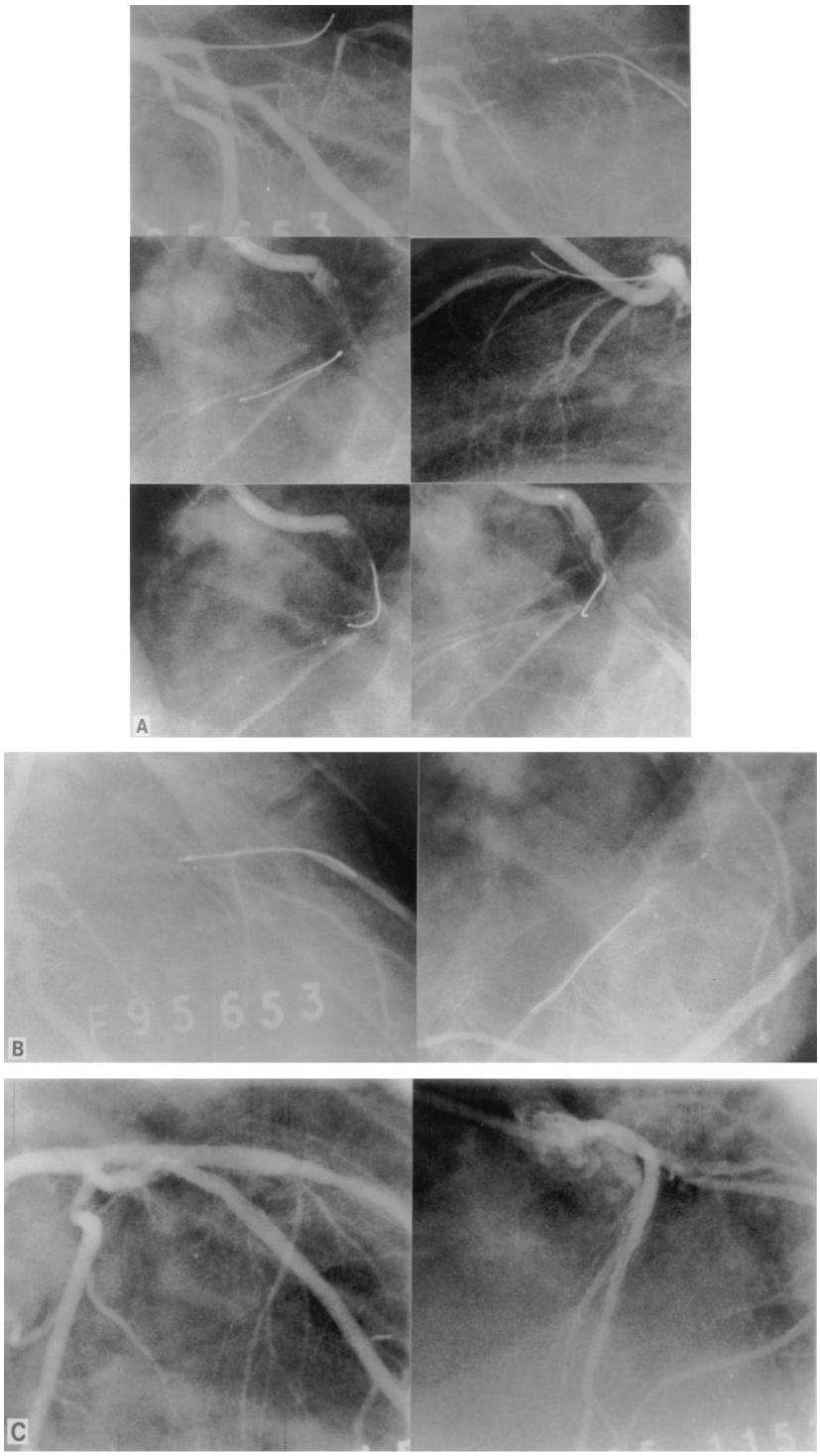

Figure 5. Laser guide wire "exit." **A,** Total occlusion of the proximal left anterior descending artery: numerous laser guide wire exits in different views. **B,** Laser guide wire positioned in the distal lumen. **C,** Final result after ELCA and stenting.

because the number of patent vessels has a strong bearing on the long-term prognosis of patients with coronary artery disease. However, the aim of the present pilot study was the primary evaluation of a laser guide wire. Whether use of a guide wire could affect 6-month restenosis rates is unlikely and beyond the scope of our study.

As the technology of the laser guide wire continues to evolve, it is conceivable that additional refinements, such as remote tip control or simultaneous intravascular ultrasound to guide the procedure, will lead to a further increase in success rates and to a reduction of overall procedure time.

Study limitations. This report describes our initial experience with a technology that was continually improving as our experience increased. We started with a new device that we deliberately tried to "push to the limit." However, soon it became apparent that to be successful, both a visible entry

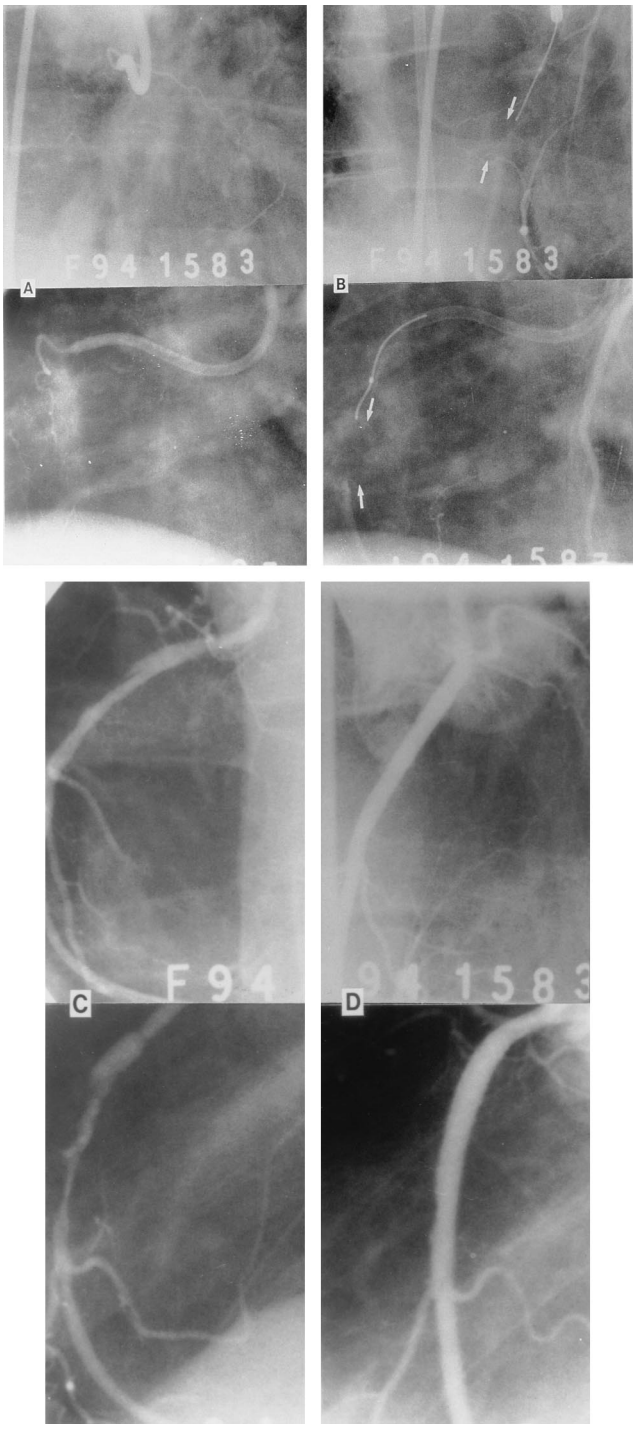

Figure 6. Proximal occlusion of the right coronary artery. **A,** Frontal view. **B,** Lateral view. **C,** Result after a single pass with a 1.7-mm laser catheter. **D,** Final result after placement of multiple stents.

point and visualization of the distal lumen through collateral circulation were mandatory. In addition, the technical changes in the guide wire during this pilot phase possibly interfered with uniform analysis of the results because two-thirds of procedures were performed with the less ideal earlier versions of the laser guide wire. Furthermore, only a relatively small number of patients were included in this pilot study.

Finally, the large difference in success rates with the laser guide wire compared with mechanical guide wires (with additional backup support from a balloon catheter) cannot be ascribed solely to potentially superior mechanical qualities of the laser guide wire. This pilot study was not conducted in double-blind fashion; thus, a potential bias cannot be fully excluded. In this context it has been suggested that a "double-deaf" study—where the laser makes the usual sound during activation with or without producing the actual laser light beam—might resolve this issue.

Clinical implications. With the successful development of new technologies for percutaneous interventions, total coronary occlusion is no longer the exclusive domain of the cardiac surgeon. In the light of a recent report (14) on the high success rate of treating total occlusion with mechanical guide wires, the potential of the laser guide wire should be investigated in a randomized trial. The ongoing randomized TOTAL trial, with serial clinical and angiographic documentation, is expected to evaluate the place of percutaneous recanalization in general and the true value of the laser guide wire compared with the best available mechanical guide wires in particular.

Conclusions. Despite the aforementioned limitations, we conclude that use of the laser guide wire for recanalization of chronic total coronary occlusions refractory to treatment with mechanical guide wires is feasible, relatively safe and successful in 59% of attempted cases.

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