New technologies in interventional cardiology

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The limitations of balloon angioplasty have led to the introduction of new devices designed to improve the short- and long-term efficacy of percutaneous revascularization techniques. Preliminary single-operator experience and registry data have suggested that these devices may be useful in particular anatomical situations. Last year saw the beginning of the next phase of device assessment, the randomized study, directly comparing the new devices with coronary angioplasty either in the total angioplasty patient population or in selected subgroups. Two major randomized studies, the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT) and the Canadian Coronary Atherectomy Trial (CCAT), directly compared directional coronary atherectomy with balloon angioplasty and suggested that coronary atherectomy offers no particular advantage over balloon angioplasty. This year will see the publication of the Belgium Netherlands Stent (BENESTENT) and Stent Restenosis Study (STRESS) randomized trials, which compared coronary stents with balloon angioplasty; further studies comparing balloon angioplasty with other devices are currently under way. We are now entering a new era where randomized studies will directly assess the safety and efficacy of the new devices compared with balloon angioplasty and demonstrate, in a scientific manner, the validity (or otherwise) of their superiority over balloon angioplasty.

Percutaneous transluminal coronary angioplasty (PTCA) is now accepted as effective therapy for selected patients with obstructive coronary artery disease. There are, however, a number of limitations to the even more widespread application of this technique. These include technical factors relating to the coronary anatomy; acute occlusion, which results in increased morbidity and mortality; and restenosis, which limits the long-term efficacy of the procedure. Because of the limitations inherent in balloon angioplasty, a plethora of new devices have been introduced to improve the short- and long-term results of catheter-based revascularization. These can be broadly grouped into three categories: mechanical systems to debulk atheroma, intravascular stents to prevent elastic recoil, and lasers to ablate tissue.

Mechanical atherectomy

A number of mechanical systems have been developed, based on the rationale that plaque removal, rather than just remodelling, may lower restenosis rates. Atherectomy devices such as the Simpson Atherocath (Devices for Vascular Intervention, Inc., Redwood City, CA) cut and remove obstructing atheromatous material, whereas atheroablation devices such as the transluminal extraction catheter, or TEC (Interventional Technologies, San Diego, CA), the Rotablator (Heart Technology, Inc., Bellevue, WA), and the rotational angioplasty catheter system, or ROTACS (Oscor Medical Corp., Palm Harbor, FL), grind the atheroma into small particles, which are subsequently aspirated or allowed to embolize distally.

Simpson Atherocath

The directional coronary atherectomy (DCA) catheter developed by John Simpson was the first of its kind [1•] and preliminary experience from a number of centers suggested that it may improve acute results and reduce restenosis. Our group, however, studied a prospectively collected consecutive series of 87 native coronary artery lesions successfully treated with DCA matched

with 87 coronary artery lesions successfully dilated by balloon angioplasty. Our results suggested that although atherectomy results in a more pronounced increase in minimal lumen diameter, it is subject to a greater late loss, so that the minimal lumen diameter at follow-up and the net gain index were similar in the two groups [2•]. Analogous results were reported by the Coronary Angioplasty Versus Atherectomy (CAVA) group, which studied 126 consecutive atherectomies and 127 angioplasties performed on similar lesions [3].
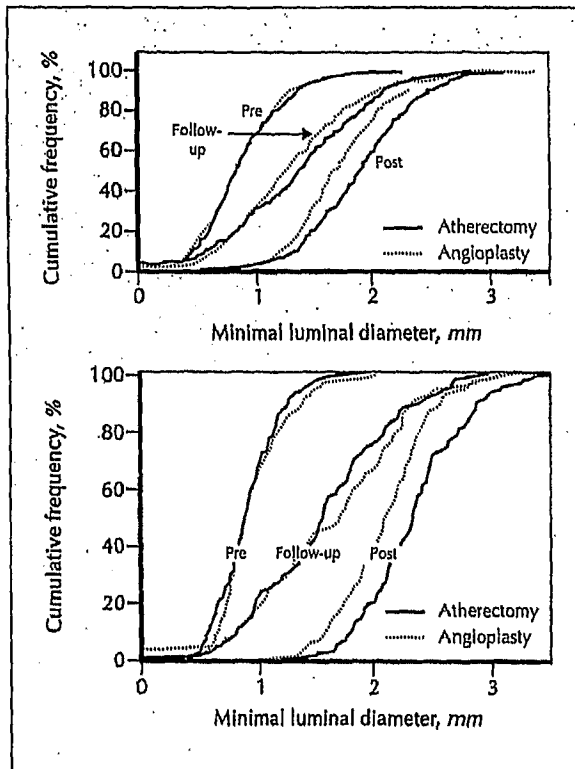

Fig. 1. Cumulative frequency distribution of the minimal luminal diameter of the target lesion in the two study groups in the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT; top panel), and the Canadian Coronary Atherectomy Trial (CCAT; bottom panel). Note that there was no difference in the baseline distribution (pre) but at the end of the procedure (post) more improvement was seen with atherectomy. By the time of the 6-month follow-up, however, there is little significant difference between the two groups. (From the CAVEAT study group [4••] and Adelman et al. [5••]; with permission)

CAVEAT and CCAT

These two studies were the harbingers of the results of two randomized studies, the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT) and the Canadian Coronary Atherectomy Trial (CCAT) (Fig. 1). The CAVEAT study directly compared DCA with balloon angioplasty in 1012 patients [4••]. Removing coronary artery plaque with atherectomy led to a larger luminal diameter and a small nonsignificant reduction in angiographic restenosis compared with PTCA (50% vs 57%), confined mainly to the proximal left anterior de-

scending coronary artery. However, atherectomy led to a higher rate of early complications compared with PTCA (11% vs 5%), increased cost, and showed no apparent clinical benefit after 6 months of follow-up. A similar pattern was seen with the multicenter CCAT study, in which 274 patients with proximal left anterior descending coronary artery lesions were randomly assigned to DCA or PTCA [5••]. The restenosis rate was similar in the two groups, and despite a larger initial gain in the minimal luminal diameter with atherectomy there was a larger late loss, resulting in a similar minimal luminal diameter and clinical outcome in the two groups at 6-month follow-up.

Both papers were the product result of carefully conducted trials. Despite this, however, the results have been seen in some quarters as deceptive and disappointing. Although there was a small trend towards decreased restenosis in the atherectomy group of the CAVEAT study, there was no short- or long-term clinical benefit. As is usual with a large, randomized study, the results have been scrutinized and a sometimes biased polemic discussion has occurred. Arguments have ensued, such as that lesion selection could have been different, use of balloon angioplasty after atherectomy should have been authorized, and better results could have been achieved by the operators based on quantitative coronary angiographic data. Thus, the argument goes, because the optimal DCA result was not achieved, the hypothesis was not adequately tested. These criticisms have primarily been applied to CAVEAT. They have also been applied to the CCAT study, although to a lesser extent, as in that study the ideal target lesion (proximal left anterior descending artery) was the focus of attention and a better quantitative coronary angiographic result was obtained with DCA. Even this study, however, was unable to demonstrate any superiority of DCA over PTCA. These supposed criticisms of CAVEAT and CCAT will be addressed in the forthcoming Balloon versus Optimal Atherectomy Trial (BOAT) in which the optimal DCA is defined as less than 20% residual stenosis (Table 1). If even this attempt to prove the superiority of DCA fails, serious questions regarding the technique will be raised in medical circles, as the procedure is not only more expensive but also more demanding and time consuming than standard balloon angioplasty.

Intravascular ultrasound

The need for optimal results after atherectomy [6,7•] together with previous studies suggesting that lesion characteristics may influence both acute occlusion and restenosis has highlighted the limitations of coronary angiography in guiding therapy, particularly as initial studies had shown that even after angiographically successful DCA a large residual plaque burden still remains. Thus intravascular ultrasound (IVUS), a technique used to visualize the vessel wall directly, is beginning to emerge as an almost mandatory step towards obtaining optimal results after atherectomy. Fur-

Table 1. Completed and ongoing clinical trials assessing new interventional devices or procedures

Study	Device or procedure	Study design	Current status
CAVEAT [4••]	Atherectomy	Randomized	Published
Adelman et al. [5••] (CCAT)	Atherectomy	Randomized	Published
BOAT	Atherectomy	Randomized	Planning
BENESTENT	Stent	Randomized	In press
STRESS	Stent	Randomized	In press
GRACE	Stent	Randomized	Recruiting
REST	Stent	Randomized	Recruiting
MUST	Stent	Nonrandomized	Planning
RESTORE	Stent	Randomized	Planning
AMRO	Laser	Randomized	Completed
TOTAL	Laser	Randomized	Planning
EXACT	Laser	Randomized	Planning
COBRA	Rotablator	Randomized	Recruiting
BAROCCO	ROTACS	Randomized	Completed

AMRO—Amsterdam-Rotterdam Excimer Laser trial; BAROCCO—Balloon Angioplasty versus ROTACS for Chronic Total Occlusion; BENESTENT—Belgium-Netherlands Stent trial; BOAT—Balloon versus Optimal Atherectomy trial; CAVEAT—Coronary Angioplasty Versus Excisional Atherectomy Trial; CCAT—Canadian Coronary Atherectomy Trial; COBRA—Coronary Balloon Rotational Atherectomy trial; EXACT—Excimer Angioplasty Coronary Trial; GRACE—Gianturco-Roubin Acute Closure Evaluation; MUST—Multicentre Stent Ticlodipine study; REST—Restenosis Stent trial; ROTACS—rotational angioplasty catheter system; STRESS—Stent Restenosis Study; TOTAL—Total Occlusion Trial with Angioplasty using Laserwire.

thermore, preliminary evidence also suggests that IVUS plaque characteristics may also be important for both acute success and long-term restenosis; echolucent plaques are easier to resect than echogenic plaques, but are more likely to develop restenosis [8••]. If this single-center experience is confirmed in the larger forthcoming Optimal Atherectomy Restenosis Study (OARS) multicenter trial, which uses ultrasound guidance to optimize the DCA result (Table 2), it may herald a new era in directional atherectomy, particularly as the development of the combined DCA-IVUS catheter currently undergoing clinical trials will reduce costs, obviate the need for repeated catheter exchanges, and allow guidance and immediate assessment of the results of intervention.

Coronary tissue obtained by atherectomy

As an incidental by-product of directional atherectomy coronary tissue is obtained percutaneously from both primary and restenotic lesions. Histopathological and

cell culture analysis of this tissue may provide clues to atherosclerosis in general and restenosis in particular [9•]. Histopathological studies have suggested that intimal hyperplasia is not specific for restenosis, because histologically identical hyperplasia can be found in nearly half of primary coronary artery stenoses, particularly in younger patients and in the left anterior descending artery [10•]. Furthermore, controversy still exists regarding rates of cell proliferation: one study suggested that cellular proliferation is more prominent in restenotic than in primary lesions [11] whilst another found that cell proliferation occurs infrequently and at low levels in both primary and restenotic tissue [12]. A study using in situ hybridization to assess expression of the β isoform of nonmuscle myosin heavy chain in coronary tissue obtained by atherectomy came up with some provocative results, suggesting that increased expression of this protein identifies a group of lesions at high risk for subsequent restenosis after atherectomy [13••]. Subsequently, groups whose results have as yet only been published in the form of abstracts

Table 2. Completed and ongoing clinical trials using new technologies for assessment of coronary interventional techniques

Study	Guidance	Device	Study design	Current Status
PICTURE 1	Ultrasound	PTCA	Nonrandomized	Completed
GUIDE-1	Ultrasound	PTCA	Nonrandomized	Completed
GUIDE-2	Ultrasound	DCA	Nonrandomized	Recruiting
OARS	Ultrasound	DCA	Nonrandomized	Planning
DEBATE	Doppler	PTCA	Nonrandomized	Recruiting

DCA—directional coronary atherectomy; DEBATE—Doppler Endpoints Balloon Angioplasty Trial Europe; GUIDE—Guidance Ultrasound Imaging for Decision Endpoints; OARS—Optimal Atherectomy Restenosis Study; PICTURE—Post Intra-Coronary Treatment Ultrasonic Result Evaluation; PTCA—percutaneous transluminal coronary angioplasty.

have been unable to confirm these promising preliminary results. Cell culture studies using tissue obtained by atherectomy have suggested that the presence of organizing thrombus significantly increases smooth-muscle cell outgrowth [14]. Furthermore, the outgrowth of smooth-muscle cells can be prevented by a recombinant cytotoxin specific for the epidermal growth factor receptor, thus pointing to new directions in the fight against restenosis using the aptly called "chemical atherectomy" techniques [15•].

Transluminal extraction catheter

The transluminal extraction catheter is a flexible torque tube with a terminal cutting cage. The entire torque tube is rotated at 750 rpm, and as it is advanced across the lesion the terminal cutting windows fragment the plaque which is then aspirated by suction through the central lumen of the device. Overall results are not impressive and use of the device is currently restricted to degenerated saphenous vein grafts. Even here, however, the application is limited by the frequent need for adjunctive balloon angioplasty and a high incidence of restenosis and late vessel occlusion [16].

Rotablator

The Rotablator is a high-speed, diamond-tipped atheroablation catheter that grinds atheroma into small particles and allows them to embolize distally. The device has received US Food and Drug Administration approval although it was recalled last year because of a manufacturing problem (now solved). Data from the multicenter registry suggest acute complication and 6-month restenosis rates comparable to standard balloon angioplasty. This was confirmed in the largest single-center experience to date [17•], which suggests that coronary rotational ablation can be performed on lesions unfavorable for PTCA, particularly ostial lesions [18] and diffuse disease, with a high initial success rate and an overall restenosis rate similar to that of balloon angioplasty. Angiographic complications appear to be more common after rotablator therapy, and salvage balloon angioplasty is often required to manage these device-induced complications [19•]. Furthermore, for the treatment of most coronary stenoses, adjunctive balloon angioplasty is required after rotablator therapy to achieve either satisfactory lumen enlargement or to salvage complications [20]. Conversely, rotational coronary atherectomy may be used in selected patients when standard balloon angioplasty is unsuccessful. Its mechanism of benefit in this situation appears related, in part, to changes in plaque compliance resulting from partial atheroma ablation [21•]. The ongoing Coronary Balloon Rotational Atherectomy (COBRA) study is currently comparing rotablator therapy directly with balloon angioplasty in a randomized trial (Table 1).

Low-speed rotational angioplasty catheter system

The rotational angioplasty catheter system, or ROTACS, consists of a steel catheter with an olivelike rounded tip

which is rotated at speeds of up to 200 rpm within a polyethylene tube, to protect the proximal vessel wall. Although useful in patients with peripheral total occlusions, its utility in coronary occlusions is more debatable. A recent study suggests that in selected patients low-speed rotational angioplasty is a safe technique applicable to chronic total coronary occlusions even if the duration of occlusion exceeds 6 months and if the device is used after conventional techniques have failed [22••]. Provisional data, published as an abstract, from a randomized study comparing rotational angioplasty with the classic mechanical approach, however, found no difference between the two techniques in either acute results or long-term restenosis.

Stents

Although intravascular stenting was originally pioneered by Charles Dotter in the 1960s, it was not until the development of adequate catheter delivery system in the mid-1980s .that intracoronary stenting became feasible. The Wallstent (Schneider [USA] Inc., Minneapolis, MN) was the first such device to be used, but was withdrawn from clinical practice in 1991 because of a high incidence of thrombotic occlusions shortly after implantation. It was reintroduced in a modified form in 1992 and is currently used in the bypass patient population in a carefully controlled registry under an international safety committee. The new generation LS (less shortening) stent should be introduced for native coronary arteries in 1994. It is hoped that this version will make positioning and implantation easier. Furthermore, it is hoped that this stent will exert less radial force on the vessel wall, reducing restenosis and, as less metal will be exposed to the flowing blood, lessening thrombogenicity. In addition to the self expanding Wallstent there are currently five other balloon expandable stents in clinical practice. These include the Palmaz-Schatz (Johnson & Johnson Interventional Systems, Warren, NJ), Gianturco-Roubin (Cook Inc., Bloomington, IN), Wiktor (Medtronic, Inc., Minneapolis, MN), Bronco (Applied Cardiac Systems, Inc., Laguna Hills, CA), and Strecker (Boston Scientific Corp., Watertown, MA).

Restenosis remains a major limitation even with stents. The predominant mechanism involved, as in balloon angioplasty, appears to be lumen encroachment by intimal hyperplasia within the stent, with minimal contribution of stent compression by tissue ingrowth from outside [23•]. The time course also appears to be similar to that seen after balloon angioplasty, with a peak incidence sometime between 3 and 6 months [24•, 25•]. It is difficult to predict which lesions are likely to undergo restenosis, although inadequate stent deployment [26•] and the absolute or relative gain [27•] may be independent predictors. Deciding on therapy for treatment of

restenosis within a stent is always difficult, but the results from the multicenter registry [28] suggest that balloon angioplasty is a worthwhile option.

Although the myoproliferative response appears to be greater after stent implantation than balloon angioplasty, observational studies suggest that because of a greater luminal gain at implant time, stenting may be effective at reducing restenosis [25*, 29*]. This was confirmed in a study from our group in which we matched 93 patients undergoing Wallstent implantation with a similar group undergoing balloon angioplasty for baseline stenosis characteristics, lesion site, vessel size, and minimal luminal diameter [30*]. The Wallstent provided a significantly greater increase in minimal luminal diameter compared with balloon angioplasty, and despite a greater decrease in minimal luminal diameter, the minimal luminal diameter at follow-up remained significantly greater in the stent group (Fig. 2). In many ways, these studies laid the foundations the forthcoming Belgium-Netherlands Stent (BENESTENT) and Stent Restenosis Study (STRESS) randomized trials. Those trials suggest that stent implantation results in a signif-

icantly lower rate of restenosis than balloon angioplasty.

Because of its unique properties, intracoronary stenting offers new approaches to the treatment of acute occlusion and has opened up new paths of patient therapy. Although initially viewed as a bridge to surgical bailout, stenting is now heralded by many as the means to avoid surgery. The multicenter registry of "bailout stenting" [31**] demonstrated outcomes comparable to previously reported single-center series with experienced operators. A matched case-control study from the Cleveland Clinic suggested that although early treatment of established vessel closure by intracoronary stenting was associated with a low incidence of both myocardial infarction and emergency bypass surgery, the likelihood or severity of infarction was not reduced among those in whom stents were implanted later and patients with threatened vessel closure could not be shown to benefit from stent treatment [32**]. An observational study by Hearn *et al.* [33] from Emory, however, raised further questions over the risk-to-benefit ratio of bailout stenting. Differences are likely to relate to terminology used, in particular the terms *acute*
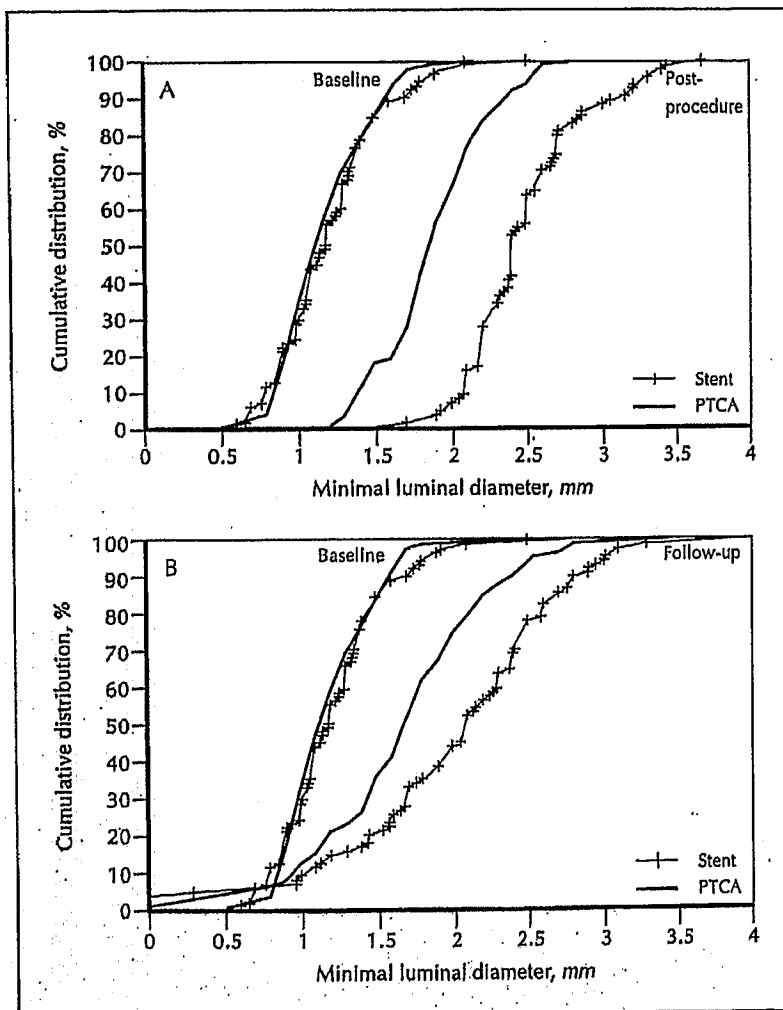

Fig. 2. Cumulative distribution of minimal luminal diameter of patients undergoing stenting and percutaneous transluminal coronary angioplasty (PTCA). The *top panel* compares baseline and immediate postprocedure values, whereas the *bottom panel* compares baseline and follow-up data. Note that there was no difference in the baseline distribution, but at the end of the procedure more improvement was seen with stent implantation. This improvement was maintained by the stent group at the 6-month angiographic follow-up. (*From* de Jaegere *et al.* [30*]; with permission.)

and *threatened acute* closure, as well as the quality of data acquisition and operator experience [34]. These reports need to be validated in larger randomized studies that examine results achieved by experienced operators past their learning curve. The ongoing Gianturco-Roubin Acute Closure Evaluation (GRACE) trial (Table 1) will address the immediate and long-term efficacy and safety of urgent stent implantation by experienced operators, in the setting of failed balloon angioplasty or other coronary intervention.

The postprocedural hazard of acute thrombosis continues to curb enthusiasm for coronary stenting. A study from Nath *et al.* [35••] suggests that early thrombosis after coronary stenting is relatively common (>10%), occurring predominantly in eccentric lesions and in patients with unstable angina pectoris. This complication was associated with significant adverse clinical outcomes and was usually the result of subtherapeutic anticoagulation. In a small proportion of cases it was a direct result of bleeding complications requiring decreased anticoagulation. A similar rate of subacute occlusion was also documented by Haude *et al.* [36], who also identified several variables—including bailout implantation, unstable angina, long and complex (type C) lesions, symptomatic postangioplasty dissections, incomplete wrapping of the dissection after stenting, and vessel irregularities distal to the stented segment—as risk factors for the development of subacute stent thrombosis.

In recent years, the outlook for intracoronary stenting has improved due to advances in the pre-, peri-, and postprocedural management of patients. Current concepts for stent deployment revolve around optimal stent deployment as well as overcoming stent thrombogenicity and the subsequent need for anticoagulation. Optimal stent deployment implies slight "oversizing" (1.1 to 1.3 times vessel diameter), using a noncompliant balloon as long as, but no longer than, the stent. Whether intracoronary imaging such as intravascular ultrasound or angioscopy are required for optimal performance is still unclear [37].

Bleeding complications remain a substantial problem. The femoral plug, a collagen-based device designed to close the femoral puncture site while maintaining full anticoagulation, has not been unequivocally proven to be of benefit [38], and it is not totally foolproof. More recently, the use of anticoagulants has been questioned and the emphasis placed on antiplatelet agents, in particular ticlodipine.

A new generation of stents are currently being developed to solve some of the problems inherent in the current generation and to expand their capabilities. These include coating and cell seeding of stent struts to promote healing and thereby reduce acute occlusion as well as late restenosis. Developments also include temporary and removable stents to treat acute occlusions directly. This year has seen

the first of these advances reaching clinical practice, with the pilot phase of the BENESTENT 2 study. This study uses heparin-coated stents, which experimental work suggests are far less susceptible to thrombosis and may therefore not require such intensive anticoagulation, thus avoiding many of the inherent complications of antithrombotic therapy.

Laser angioplasty

Although a laser was first used to ablate atherosclerotic plaque in the 1960s, it was not until the mid-1980s and the refinement of fiber optics (used to transmit energy) that intracoronary laser therapy became possible. Despite initial enthusiasm, the technique has a number of major limitations, such as an unacceptable rate of arterial perforation and dissection [39•] as well as increased vessel wall spasm and thrombogenicity problems [40]. These problems have proved difficult to overcome.

These limitations are in part due to our limited understanding of the mechanism of action of the technique. More basic understanding of the interactions between the laser and the vessel wall—in particular the concept of fast-expanding and -imploding vapor bubbles that induce extensive wall damage far beyond the excimer light penetration depth [41••, 42••]—suggests that current clinical application is incorrect and partly to blame for the above complications. Blood and contrast media should be removed completely from the field of action and the laser should be used sequentially (multiplexed) to limit damage to the vessel wall. Furthermore, homogenizing the beam by optical or other means may improve the efficiency of the ablation process, reducing the power required and further minimizing vessel damage. The perforation rate may also be reduced by ensuring that the largest laser catheter used is more than 1 mm smaller than the target vessel [39•]. However, the need for adjunctive balloon angioplasty in the majority of cases, and the substantial cost of purchasing and maintaining complex laser hardware systems remain, and make the technique less appealing.

Despite these limitations a large number of patients have been entered into the registry and the device has obtained US Food and Drug Administration approval. The perception by both observers and practitioners of the technique is one of disappointment: lasers presently have no clearly defined niche, and direct clinical benefit is suggested but as yet unproven. Furthermore, the impact of the device on restenosis has not yet been tested in a randomized manner; although the results of a prospective, randomized trial of excimer laser therapy versus conventional balloon angioplasty (the AMRO, or Amsterdam Rotterdam Excimer Laser trial) should be published towards the end of the year.

New developments include the introduction of the holmium laser, which preliminary results indicate to be

comparable to the excimer laser [43]. This solid state device is, however, considerably cheaper, takes up far less space, and requires less maintenance, thus overcoming some of the logistic limitations seen with earlier lasers. Further developments also include the use of a laser wire for recanalization of total occlusions, the initial results of which are encouraging. A final development is the use of lasers for thrombolysis in patients unsuitable for intravenous or intracoronary thrombolysis. Although initial results are encouraging, larger trials are required to assess the role of laser thrombolysis.

Emerging technologies

As our ability to treat more complex cases has increased with the new devices, the limitations inherent in the use of contrast angiography for guiding therapy and assessing the results of interventional procedures have become increasingly obvious. This has been accentuated by evidence suggesting that plaque morphology, the degree of injury to the vessel wall, and the adequacy of the revascularization procedure may all influence the subsequent restenosis rates. IVUS allows direct visualization of the vessel wall and characterization of the atherosclerotic plaque, whereas intravascular Doppler allows the physiological assessment of any residual stenosis. Both techniques, individually and in combination with percutaneous revascularization devices, promise much for the future of interventional cardiology and for guiding therapy and assessing the results of percutaneous revascularization procedures (Table 2).

As well as being useful for directly imaging vessels, ultrasound can also be used therapeutically for the recanalization of total occlusions (Fig. 3). Preliminary experience with peripheral vessels suggests that percutaneous peripheral ultrasound angioplasty may be useful for recanalization of fibrous, calcific, and thrombotic arterial occlusions, reducing arterial stenoses with a restenosis rate of 20% [44••]. Adaptations of the technique, and in particular the introduction of more flexible and steerable probes, have extended the use of the technique to the coronary vessels with promising preliminary results.

Local drug delivery for reducing restenosis after coronary intervention is also another potential area of rapid progress. This technique allows the delivery of high concentrations of active drug to the intervention site, but the first generation of catheters were limited by substantial local vessel trauma. Catheters that are currently undergoing preclinical work promise much in terms of delivering a high local concentration of active drug into the vessel media with minimal additional injury to the vessel wall.
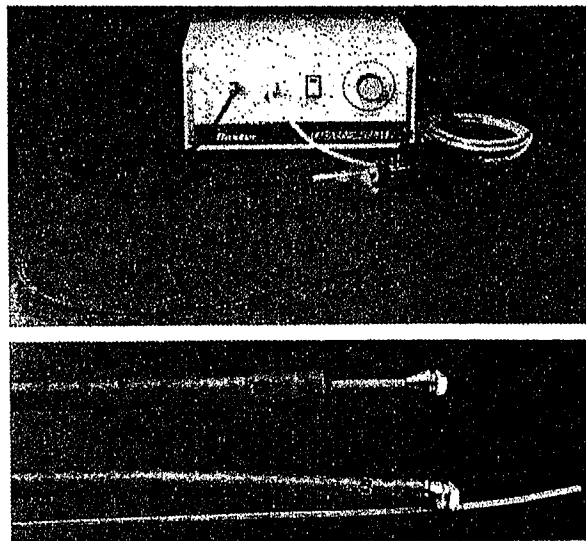

Fig. 3. Top, Ultrasound power generator, (center), foot pedal (left), ultrasound transducer (right) and the over-the-wire probe (waveguide). Bottom, The two ultrasound probe tip configurations used in the clinical trials: the 3-mm ball-tipped (top) and 3-mm ball-tipped monorail over-the-wire (bottom) designs. (From Siegal et al. [44••]; with permission.)

Conclusions

The limitations of balloon angioplasty have led to a plethora of new devices designed to improve the short- and long-term efficacy of coronary revascularization techniques. Preliminary, single-operator experience and registry data suggested that certain of these devices may be useful in particular anatomical situations such as total occlusions or ostial stenoses. More recent data from trials comparing these devices directly with balloon angioplasty have been disappointing, but not disheartening. There are two reasons. The first reason is technological: great technical improvements have taken place, with major advances in the devices themselves, our understanding of how they work, and new modes of intravascular guidance. The second reason is operator-dependent: the more appropriate use of devices in the appropriate place, either individually or in concert with other devices, for an optimal result. The appropriate place for interaction may now be in the larger vessels. Ultrasound imaging of these vessels may indicate microscopic subintimal calcification requiring Rotablator therapy for decalcification. This may then be followed by debulking with atherectomy and then balloon angioplasty to optimize the result. This approach, however, raises two major issues. The first is one of cost. The skyrocketing cost of the new devices will really only be accepted by the medical community if the cost-benefits prove superior to traditional techniques. The second issue relates to the mechanism by which new devices are expected to reduce restenosis. Here we have two antagonistic viewpoints, although

they are at this stage mixed. If the device is able to produce better long-term results, is this because the device is able to increase gain without modifying the response to gain and loss, or does each device have a specific, modifying gain-loss relationship? For example, with stent implantation, are better results due to the resulting greater luminal increase created by this device, or is the gain-loss relationship specific to stenting? Furthermore, is there a certain point at which this gain-loss relationship becomes curvilinear? This would imply that at a certain residual stenosis the Glagov phenomenon can be reset, avoiding thrombogenicity, local platelet accumulation, and subsequent restenosis. Theoretical and experimental work suggests that this may occur with a residual stenosis of less than 40%. Clinical studies, however, suggest that it is very difficult to obtain residual stenoses of less than 40%; even angiographically perfect atherectomies having residual stenoses of over 55%. Whether future guidance with ultrasound may improve these initial results and allow us to optimize the outcomes of intervention remains to be seen.

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The authors examined the incidence of intimal hyperplasia in specimens obtained by directional coronary atherectomy. Although intimal hyperplasia was identified in 93% of patients with restenosis after a prior intervention it was also seen in 44% of primary lesions, demonstrating that even though intimal hyperplasia is an almost universal finding in restenotic lesions, it is not specific for restenosis.

11.   Pickering JG, Weir L, Jekanowski J, Kearney MA, Isner JM: Proliferative Activity in Peripheral and Coronary Atherosclerotic Plaque Among Patients Undergoing Percutaneous Revascularization. *J Clin Invest* 1993, 91:1469–1480.

12.   O'Brien ER, Alpers CE, Stewart DK, Ferguson M, Tran N, Gordon D, Benditt EP, Hinohara T, Simpson JB, Schwartz SM: Proliferation in Primary and Restenotic Coronary Atherectomy Tissue: Implications for Antiproliferative Therapy. *Circ Res* 1993, 73:223–231.

13.   Simons M, Leclerc G, Safian RD, Isner JM, Weir L, Baim
**   DS: Relation Between Activated Smooth-Muscle Cells in Coronary-Artery Lesions and Restenosis After Atherectomy. *N Engl J Med* 1993, 328:608–613.
Plaque material obtained by coronary atherectomy was hybridized with a probe for the β isoform of human nonmuscle myosin heavy chain, a major isoform in activated, but not quiescent, smooth-muscle cells. Atherectomy specimens from 10 of 20 patients showed hybridization with the probe, and at follow-up, restenosis had developed in 8 of 10 patients with positive hybridization results, but was absent in 9 of 10 patients with negative results. The degree of late loss in luminal diameter was also significantly higher in patients with positive hybridization results, suggesting that this increase in expres-

angiographic follow-up). The procedural success rate was higher in patients who underwent atherectomy than in those who had angioplasty (94% vs 88%), with no significant difference in the frequency of major in-hospital complications. At follow-up, clinical outcome was similar, as were the restenosis rates (46% for DCA vs 43% for PTCA).

sion may identify a group of lesions at high risk for restenosis after atherectomy.

14.   Escaned J, de Jong M, Violaris AG, Mcleod DC, Umans V, van Suylen RJ, de Feyter PJ, Verdouw PD, Serruys PW: Clinical and Histological Determinants of Smooth Muscle Cell Outgrowth in Cultured Atherectomy Specimens: Importance of Thrombus Organisation. *Coronary Artery Dis* 1993, 4: 883–890.

15.   Pickering JG, Bacha PA, Weir L, Jekanowski J, Nichols JC, Is-
•   ner JM: Prevention of Smooth Muscle Cell Outgrowth From Human Atherosclerotic Plaque by a Recombinant Cytotoxin Specific for the Epidermal Growth Factor Receptor. *J Clin Invest* 1993, 91:724–729.
Study evaluating the effect of DAB389 EGF (a genetically engineered fusion protein in which the receptor-binding domain of diphtheria toxin has been replaced by human epidermal growth factor) on human vascular smooth muscle cells in culture. DAB389 EGF was found to be highly cytotoxic to human smooth-muscle cells proliferating in culture and to prevent smooth-muscle cell outgrowth from "growth-stimulated" human atherosclerotic plaque.

16.   Safian RD, Grines CL, May MA, *et al.*: Clinical and Angiographic Results of Transluminal Extraction Coronary Atherectomy in Saphenous Vein Bypass Grafts. *Circulation* 1994, 89:302–312.

17.   Stertzer SH, Rosenblum J, Shaw RE, Sugeng I, Hidalgo B,
•   Ryan C, Hansell HN, Murphy MC, Myler RK: Coronary Rotational Ablation: Initial Experience in 302 Procedures. *J Am Coll Cardiol* 1993, 21:287–295.
Single-center experience of Rotablator (Heart Technology, Inc., Bellevue, WA) therapy in 346 lesions. The data suggest that coronary rotational ablation can be performed on lesions with a variety of morphologic features with high initial success rates, but that the overall rate of restenosis (37.4%) is similar to that of balloon angioplasty.

18.   Popma JJ, Brogan WC, Pichard AD, Satler LF, Kent KM, Mintz GS, Leon MB: Rotational Coronary Atherectomy of Ostial Stenoses. *Am J Cardiol* 1993, 71:436–438.

19.   Safian RD, Niazi KA, Strzelecki M, Lichtenberg A, May MA,
•   Juran N, Freed M, Ramos R, Gangadharan V, Grines CL, *et al.*: Detailed Angiographic Analysis of High-Speed Mechanical Rotational Atherectomy in Human Coronary Arteries. *Circulation* 1993, 88:961–968.
Preliminary experience with Rotablator therapy on 116 lesions. The data suggest that for the treatment of most coronary stenoses, PTCA is required after Rotablator therapy to achieve satisfactory lumen enlargement or to salvage complications. The combination of Rotablator therapy and PTCA did not prevent restenosis.

20.   Aguirre FV, Bach R, Donohue TJ, Caracciolo E, Kern MJ: Rotational Coronary Ablation: More Grist for the Interventional Mill? *J Am Coll Cardiol* 1993, 21:296–297.

21.   Brogan WC, Popma JJ, Pichard AD, Satler LF, Kent KM,
•   Mintz GS, Leon MB: Rotational Coronary Atherectomy After Unsuccessful Coronary Balloon Angioplasty. *Am J Cardiol* 1993, 71:794–798.
Initial experience with 50 lesions, referred for rotational atherectomy after standard balloon angioplasty was unsuccessful. Although rotational atherectomy reduced the percent diameter stenosis from 72±14% to 41±16%, adjunct balloon angioplasty was required for optimal results in 44 lesions (88%), thus suggesting that the mechanism of benefit after rotablator therapy may be related, in part, to changes in plaque compliance resulting from partial atheroma ablation.

22.   Kaltenbach M, Hartmann A, Vallbracht C: Procedural Results
••   and Patient Selection in Recanalization of Chronic Coronary Occlusions by Low Speed Rotational Angioplasty. *Eur Heart J* 1993, 14:826–830.
Three-year experience using low-speed rotational angioplasty (RO-TACS) in 200 patients with chronic (mean duration, 12±26 months) coronary occlusions resistant to recanalization by conventional techniques. The overall success rate was 58%, falling from 91% in occlusions less than 3 months old to 8% in those older than 12 months, suggesting that in selected patients low-speed rotational angioplasty may be a safe technique applicable to chronic total coronary occlusions even after conventional techniques have failed.

23   Gordon PC, Gibson CM, Cohen DJ, Carrozza JP, Kuntz RE,
•   Baim DS: Mechanisms of Restenosis and Redilation Within Coronary Stents: Quantitative Angiographic Assessment. *J Am Coll Cardiol* 1993, 21:1166–1174.
Quantitative angiographic evaluation after stent implantation and at follow-up suggests that restenosis after placement of a Palmaz-Schatz stent (Johnson & Johnson Interventional Systems, Warren, NJ) appears to be due predominantly to lumen encroachment by intimal hyperplasia within the stent, with minimal contribution of stent compression.

24.   Kastrati A, Schomig A, Dietz R, Newmann FJ, Richardt G:
•   Time Course of Restenosis During the First Year After Emergency Coronary Stenting. *Circulation* 1993, 87:1498–1505.
Serial coronary angiographic study at 3, 6, and 12 months after Palmaz-Schatz stent implantation for acute or threatened vessel closure. The incidence and time course of restenosis was similar to that reported for conventional PTCA, with coronary luminal dimensions demonstrating a peak change at 3 months and remaining mostly stable after the first 6 months.

25.   Kimura T, Nosaka H, Yokoi H, Iwabuchi M, Nobuyoshi M:
•   Serial Angiographic Follow-up After Palmaz-Schatz Stent Implantation: Comparison With Conventional Balloon Angioplasty. *J Am Coll Cardiol* 1993, 21:1557–1563.
Serial coronary angiographic study the day after Palmaz-Schatz stent implantation, and at 1, 3 and 6 months after the procedure, with the results compared with a cohort of patients undergoing balloon angioplasty. A significantly larger lumen diameter was obtained immediately after stent implantation and this was maintained at 6-month follow-up, leading to a significantly lower restenosis rate in the stent group (13% vs 39%).

26.   Lau KW, Gunnes P, Williams M, Rickards A, Sigwart U: An-
•   giographic Restenosis After Successful Wallstent Stent Implantation: An Analysis of Risk Predictors. *Am Heart J* 1992, 124:1473–14771.
Follow-up angiographic study on 86 patients after initially successful Wallstent (Schneider [USA] Inc., Minneapolis, MN) implantation between April 1986 and October 1990. The stent angiographic restenosis rate was 16% a mean of 8 months after stenting. Of the variables analyzed, only suboptimal stent placement was found to be a significant predictor of restenosis.

27.   de Jaegere P, Serruys PW, Bertrand M, Wiegand V, Marquis
•   JF, Vrolicx M, Piessens J, Valeix B, Kober G, Bonnier H, *et al.*: Angiographic Predictors of Recurrence of Restenosis After Wiktor Stent Implantation in Native Coronary Arteries. *Am J Cardiol* 1993, 72:165–170.
The angiograms of the first 91 patients with successful Wiktor stent (Medtronic, Inc., Minneapolis, MN) implantation were analyzed to identify angiographic variables predicting restenosis. The only statistically significant predictor of restenosis was the relative gain (increase in minimal luminal diameter normalized for vessel size). There was an increased risk of restenosis when this exceeded 0.48.

28.   Baim DS, Levine MJ, Leon MB, Levine S, Ellis SG, Schatz RA: Management of Restenosis Within the Palmaz-Schatz Coronary Stent (the U.S. Multicenter Experience): The U.S. Palmaz-Schatz Stent Investigators. *Am J Cardiol* 1993, 71:364–366.

29.   Ellis SG, Savage M, Fischman D, Baim DS, Leon M, Gold-
••   berg S, Hirshfeld JW, Cleman MW, Teirstein PS, Walker C, *et al.*: Restenosis After Placement of Palmaz-Schatz Stents in Native Coronary Arteries: Initial Results of a Multicenter Experience. *Circulation* 1992, 86: 1836–1844.
Multicenter experience of Palmaz-Schatz stent insertion in 221 stenoses, with a 91% long-term angiographic follow-up. Although the overall incidence of restenosis was 36% the risk of this was dependent upon a prior history of restenosis, on whether multiple overlapping stents were placed, and on whether or not a residual stenosis of 0% was achieved after stenting. If a poststent residual stenosis of 0% was achieved the restenosis rate was as low as 6%, suggesting that placement of single stents in de novo lesions may offer a benefit compared with standard coronary angioplasty.

30.   de Jaegere PP, Hermans WR, Rensing BJ, Strauss BH, de
•   Feyter PJ, Serruys PW: Matching Based on Quantitative Coronary Angiography As a Surrogate for Randomized Studies: Comparison Between Stent Implantation and Balloon Angio-

plasty of Native Coronary Artery Lesions. *Am Heart J* 1993, 125:310–319.
Study comparing differences in the immediate and long-term changes in stenosis geometry between Wallstent implantation and balloon angioplasty in native coronary artery lesions using matched patient populations. Wallstent implantation resulted in a significantly greater increase in minimal luminal diameter compared with balloon angioplasty, and despite a greater subsequent loss, the minimal luminal diameter at follow-up was significantly greater, suggesting that this technique may result in a superior long-term increase in minimal luminal diameter compared with balloon angioplasty.

31. George BS, Voorhees WD, Roubin GS, Fearnot NE, Pinker-
••   ton CA, Raizner AE, King SB, Holmes DR, Topol EJ, Kereiakes DJ, *et al.*: Multicenter Investigation of Coronary Stenting to Treat Acute or Threatened Closure After Percutaneous Transluminal Coronary Angioplasty: Clinical and Angiographic Outcomes. *J Am Coll Cardiol* 1993, 22:135–143.
Multicenter study reporting the initial experience with the Gianturco-Roubin stent (Cook Inc., Bloomington, IN) for acute or threatened vessel closure after coronary angioplasty in 494 patients. Although not randomized, the study demonstrated a high technical success rate (95%) and encouraging results with respect to a low incidence of emergency coronary artery bypass graft surgery and myocardial infarction.

32. Lincoff AM, Topol EJ, Chapekis At, George BS, Candela RJ,
••   Muller DW, Zimmerman CA, Ellis SG: Intracoronary Stenting Compared With Conventional Therapy for Abrupt Vessel Closure Complicating Coronary Angioplasty: A Matched Case-Control Study. *J Am Coll Cardiol* 1993, 21:866–875.
A case-control analysis comparing clinical outcome after intracoronary stenting with results after conventional therapy for abrupt vessel closure in matched patient populations. Although early treatment of established vessel closure by intracoronary stenting was associated with a low incidence of both myocardial infarction and emergency bypass surgery, the likelihood or severity of infarction was not reduced among those in whom stents were implanted later and patients with threatened vessel closure could not be shown to benefit from stent treatment. Additionally, there was no significant difference in the incidence of in-hospital death or event-free survival at 6 months between the two groups.

33. Hearn JA, King SB III, Douglas JS Jr., Carlin SF, Lembo NJ, Ghazzal ZM: Clinical and Angiographic Outcomes After Coronary Artery Stenting for Acute or Threatened Closure After Percutaneous Transluminal Coronary Angioplasty: Initial Results With a Balloon-Expandable, Stainless Steel Design. *Circulation* 1993, 88:2086–2096.

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35. Nath FC, Muller DW, Ellis SG, Rosenschein U, Chapekis A,
••   Quain L, Zimmerman C, Topol EJ: Thrombosis of a Flexible Coil Coronary Stent: Frequency, Predictors and Clinical Outcome. *J Am Coll Cardiol* 1993, 21:622–627.
The authors studied 145 patients who underwent coronary artery stenting with the Gianturco-Roubin stent for abrupt vessel closure or to prevent restenosis to evaluate the predictors and clinical sequelae of stent thrombosis. Early thrombosis was relatively common (>10%), occurring predominantly in eccentric lesions and in patients with unstable angina pectoris. This complication was associated with significant adverse clinical outcomes and may be reduced by more intensive and consistent anticoagulation.

36. Haude M, Erbel R, Issa H, Straub U, Rupprecht JH, Treese N, Meyer J: Subacute Thrombotic Complications After Intracoronary Implantation of Palmaz-Schatz Stents. *Am Heart J* 1993, 126:15–22.

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38. Ernst SM, Tjonjoegin RM, Schrader R, Kaltenbach M, Sigwart U, Sanborn TA, Plokker HW: Immediate Sealing of Arterial Puncture Sites After Cardiac Catheterization and Coronary Angioplasty Using a Biodegradable Collagen Plug: Results of an International Registry. *J Am Coll Cardiol* 1993, 21:851–855.

39. Bittl JA, Ryan TJJ, Keaney JFJ, Tcheng JE, Ellis SG, Isner
•   JM, Sanborn TA: Coronary Artery Perforation During Excimer Laser Coronary Angioplasty. The Percutaneous Excimer Laser Coronary Angioplasty Registry. *J Am Coll Cardiol* 1993, 21:1158–1165.
Analysis of the risk of vessel perforation during excimer laser angioplasty in the Excimer Laser Coronary Angioplasty Registry. A total of 764 patients had 858 stenoses treated with excimer laser angioplasty. Vessel perforation occurred in 23 patients (3%). Multivariate analysis showed that bifurcation lesions, diabetes mellitus, and female gender were associated with an increased risk of vessel perforation. Vessel perforation was seen in 8.3% of lesions in which the laser catheter was equivalent in diameter to the target vessel but in only 1.5% of lesions in which the laser catheter was more than 1 mm smaller than the target vessel, suggesting that complications may be avoided by improved patient and laser catheter size selection.

40. Estella P, Ryan TJ, Landzberg JS, Bittl JA: Excimer Laser-Assisted Coronary Angioplasty for Lesions Containing Thrombus. *J Am Coll Cardiol* 1993, 21:1550–1556.

41. van Leeuwen TG, Meertens JH, Velema E, Post MJ, Borst C:
••   Intraluminal Vapor Bubble Induced by Excimer Laser Pulse Causes Microsecond Arterial Dilation and Invagination Leading to Extensive Wall Damage in the Rabbit. *Circulation* 1993, 87:1258–1263.•
Excimer laser pulses were delivered coaxially in the femoral and iliac arteries of nine normal rabbits. Time-resolved flash photography of dissected arteries in situ and subsequent light microscopy suggests that, in blood, each excimer laser pulse generates a fast-expanding and -imploding vapor bubble. The intraluminal vapor bubble produced microsecond dilation and invagination of the adjacent arterial segment, which induced dissections and extensive wall damage far beyond the penetration depth of laser light.

42. Haase KK, Hanke H, Baumbach A, Hassenstein S,
••   Wehrmann M, Duda S, Rose C, von Munch W, Karsch KR: Occurrence, Extent, and Implications of Pressure Waves During Excimer Laser Ablation of Normal Arterial Wall and Atherosclerotic Plaque. *Lasers Surg Med* 1993, 13:263–270.
Ablation of atherosclerotic plaque and normal arterial wall was performed using a xenon-chloride excimer laser and the acoustic signals generated were measured. There was a significantly shorter rise time and higher pressure increase for calcified tissue in comparison to normal arterial wall, whereas maximum pressures alone did not allow a differentiation of tissue characteristics.

43. Geschwind JH, Nakamura F, Kvasnicka J, Dubois-Rande JL: Excimer and Holmium Yttrium Aluminum Garnet Laser Coronary Angioplasty. *Am Heart J* 1993, 125:510–522.

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••   of Percutaneous Peripheral Ultrasound Angioplasty. *J Am Coll Cardiol* 1993, 22:480–488.
Percutaneous ultrasound angioplasty was performed on 50 peripheral arterial lesions in 45 patients using a fixed-wire probe with 2- or 3-mm ball tips and a 3-mm over-the-wire probe. The data indicates that percutaneous peripheral ultrasound angioplasty may be useful for recanalization of fibrous, calcific, and thrombotic arterial occlusions, may reduce arterial stenoses, and has clinical and ankle-brachial index data indicative of a restenosis rate of 20% at 6 to 12 months.

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