Balloon angioplasty, arguably cardiology’s most important advance of the decade past, now suffers from what we will call the 5-45-50 problem: 5% acute closure,1 45% restenosis,2,3 and 50% unsuitable coronary anatomy. We are now beginning to see the first publications describing multicenter experiences with three types of devices—atherectomy, lasers, and stents—originally designed to reduce the 45% restenosis rate. None have thus far clearly demonstrated an effect on either this problem or the acute complication rate, but the wonderful irony is that they apparently will have an important impact on the 50% problem. Thus, while none of the devices may replace balloon angioplasty, it now seems likely that several will occupy specific niches in interventional cardiology. As reported in this issue of Circulation, Ellis et al relate procedural success with directional atherectomy to stenosis location and morphology,4 thus establishing the first clear niche for one of the devices.

Only in the last year has the concept of niches emerged. In retrospect, the landmark article for this idea may well become the report of the Multivessel Angioplasty Prognosis Study Group, which established that stenosis morphology has a major impact on both short- and long-term outcomes after balloon angioplasty.5 Using the American College of Cardiology/American Heart Association Task Force classification criteria,6 they reported a 92% success rate and a 2% complication rate for type A (noncomplex, short) stenoses. In contrast, type C (complex, long) lesions had only a 61% success rate and 21% of patients had major complications. Some of these more difficult lesions, which clearly present a potential contraindication to balloon angioplasty, seem particularly well suited for therapy with the new devices.

The size of the niche for the new devices currently seems to be between 5 and 20% of the angioplasty population. On first consideration, this seems to be an excessively modest achievement, given the amount of verbiage and text devoted to the topic of new devices in the past 5 years. Viewed from the national health perspective, however, 20% of the angioplasty population is 60,000 patients per year exclusive of those patients currently sent to bypass surgery who might become candidates for therapy. Furthermore, within the niche that each new device occupies, there seems to be an emerging consensus among users that the new devices could become superior to balloon angioplasty for these particular applications.

What are these niches? Because none of the devices is widely available and published data are limited, we can only make speculations based on conversations with users, many of whom have experience with several of the new devices. One can hardly imagine a less scientific (or perhaps more accurate) way of assessing the future. More than a thousand patients have had coronary directional atherectomy. The reported overall 91% acute success rate and 6.2% acute complication rate (death, bypass surgery, or infarction) in one series7 are comparable with balloon angioplasty. As reported by Ellis et al,4 directional atherectomy may be superior to the balloon when used for treatment of eccentric lesions in large arteries. The mass of atheroma removed from the vessel is substantial, and the angiographic appearance is often superior to that obtained with the balloon. The technique also seems to have advantages for treatment of complex (ulcered or thrombotic) lesions in large arteries because removal of this tissue by atherectomy may reduce the incidence of both acute and late complications. However, the diameter and tubular construction of the device suggest its use will be limited to nontortuous vessels of relatively large diameter.4

The rotational atherectomy device,8 which drills through both coronary obstructions and occlusions, has undergone preliminary trial in 315 patients.8 It has entirely different advantages and limitations. Preliminary reports indicate a 95% overall acute success rate, also comparable with balloon angioplasty. An inherent limitation may be the volume of atheromatous material embolized downstream. The niche for rotational atherectomy, therefore, may be

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discrete obstructions in smaller vessels and rigid chronic occlusions that cannot be traversed or dilated by balloon angioplasty.

The transluminal extraction atherectomy device circumvents the limitation of downstream embolization by aspirating atheromatous debris back through the atherectomy catheter. In a preliminary report on 201 patients, the acute success rate is 94% and the acute complication rate is 4.5%. Potential limitations of the transluminal extraction atherectomy device are that a variable volume of blood is aspirated with the atheromatous debris and that its housing has significant size. It may be particularly well suited for treatment of obstructed saphenous vein grafts that are large in diameter, have a large volume of atheromatous material, and for which downstream embolization is a potential problem with balloon angioplasty.

Among the lasers, the excimer energy source currently dominates clinical trials. As with directional atherectomy, over a thousand patients have been treated. Preliminary reports indicate a 94% acute success rate and a 5.2% acute complication rate. The fiberoptic catheter used to deliver laser energy is now quite flexible. The limitation of the excimer laser is that the orifice it creates is the size of the outer diameter of the catheter, the largest of which is 2.4 mm. Thus, it is more likely to be used in small and medium-sized arteries. Because the particulate matter produced by the excimer laser is relatively small in diameter and a substantial component of the atheroma is vaporized, downstream embolization has not been a problem. One niche for the excimer laser is therefore likely to include long segment disease in medium-sized vessels. The success rate for excimer laser treatment of type C lesions (dominantly long lesions) is 88% and the complication rate is only 3%. The excimer laser, like some of the atherectomy devices, also may become preferable to the balloon for treatment of obstructed vein grafts and ostial lesions.

Finally, there are the coronary stents. It seems very likely that these devices will have an important role in treating acute vessel closure. Furthermore, because the size of the residual lumen is large after stent placement, it is not unlikely that stents could reduce the rate of restenosis in some vessels. In vessels with a residual lumen greater than 3.25 mm, there is a preliminary report of a 16% restenosis rate. Nonetheless, the routine use of stents is currently limited by the need for several days of hospitalization to initiate anticoagulation, which must be continued for several months. Until this problem can be resolved, one would imagine that both the dollar cost and the risk/benefit ratio may substantially reduce the routine use of stents during angioplasty.

There are, therefore, some reasonable speculations that we can make about the role of new interventional devices in the 90s. First, the number of patients treatable by angioplasty will increase. Second, several devices will probably be superior to the balloon for specific applications and will find appropriate niches. Third, none of the current devices alone will solve the problem of restenosis. By the end of the decade, the 5-45-50 problem will represent numbers of distant memory.

References


**KEY WORDS**  
atherectomy • angioplasty • coronary morphology • stenoses • lesions • Editorial Comments