Has Excimer Coronary Laser Angioplasty Finally Found a Niche?

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Since the first reported success of percutaneous transluminal coronary balloon angioplasty (PTCA), investigators have forged ahead persistently with new equipment designs and technique modifications to increase procedural success and enhance the long-term result of the intervention.

The enthusiastic response to PTCA by cardiologists has catapulted the procedure to numerical heights far beyond the originator’s vision. Treatment of multiple lesions in multiple vessels on multiple occasions has now become commonplace in many large centers and individual cardiology practices.

Although the majority of these advancements have occurred without feedback from well-controlled comparative studies with the predecessor of PTCA, coronary artery bypass grafting (CABG), results from several such clinical trials now under way should provide an unbiased perspective for patients and physicians on less invasive therapies for coronary artery occlusive disease.

In the interim, however, there appears to be no intent to retard the progression of new technology. To a great extent, this technological explosion was spawned by a serious sequela to balloon angioplasty: restenosis. While this Achilles’ heel of PTCA has been identified, its magnitude remains ambiguous despite mounting registry data.

Realizing that the solution to this problem, or lack of resolution, may well determine the fate of PTCA, investigators have been creating an impressive interventional armamentarium to combat restenosis: metallic stents, atherectomy devices, novel pharmacological delivery systems, and lasers, to list a few.

Among these, the results of early laser research were heralded enthusiastically, but it was not long before we began to realize that current laser systems appear to make no positive contribution toward reducing the incidence of restenosis. Did this portend the end of present-day laser technology as a viable treatment for coronary atherosclerosis?

The excellent report by Cook and colleagues in this issue of Circulation for the first time may have established a niche for coronary laser angioplasty. The classification of coronary morphology developed by the American College of Cardiology/American Heart Association (ACC/AHA) Cardiovascular Procedures Task Force, which identified certain types of lesions that are particularly resistant to current PTCA techniques, theoretically provides a basis for comparing the results of various interventions under relatively similar pathological conditions.

In the series of 100 patients undergoing excimer laser coronary angioplasty (ELCA) reported by Cook et al, nonideal PTCA morphology of types B and C, including ostial lesions, tubular and diffuse disease, and chronic occlusions, was encountered in 65% of the lesions treated. Comparing the excimer experience with the anticipated initial success rates for standard balloon angioplasty in these nonfavorable conditions, Cook et al show us the potential for excimer laser to improve recanalization results in these pathological settings.

In Cook’s study, ELCA yielded favorable results in type A lesions (83% versus 85% or greater for PTCA) and slightly better outcomes in the type B category (88% versus an expected 60–85%). The 85% ELCA success in the nonfavorable type C lesions, however, was highly impressive in light of the anticipated less than 60% success for PTCA.

A recent report by the Multivessel Angioplasty Study Group (MAPS) places even greater significance on the ELCA results in nonfavorable PTCA lesions. The MAPS study, which subdivided the type B category, found certain characteristics of types B2 and C lesions highly predictive of an adverse procedural outcome, concluding that these lesion characteristics should seriously be considered for surgical revascularization rather than PTCA. Certainly, laser and procedural success rates of 85% and 100%, respectively, in type B2 lesions and 85% and 88% in the type C category, as reported by Cook et al, mandates reappraisal of that recommendation, if the results are reproducible on a larger scale.

Equally significant was the outcome in the subcategory of ostial lesions, which are known to be resis-
tant to standard PTCA. Here, 100% of the laser procedures were successful. Considering the nature of this pathology and its high rate of failure with dilation alone, the capability of excimer laser energy to ablate plaque in this setting appears to be an important contribution.

Complications have plagued the development of laser angioplasty since its inception. From the early open-beam fiber with its excessive perforation rate, through the ill-conceived “hot-tip” technology with its thermally induced consequences of spasm, abrupt closure, and poor plaque ablation, the evolution of this technique is testimony to the potentially detrimental components of laser energy. It is both refreshing and reassuring to see now that even the most difficult lesions can be treated successfully using excimer laser energy with an exceedingly low complication rate. Cook et al.\textsuperscript{17} excimer study reported only a 2% complication rate for types B and C lesions, whereas the MAPS results showed 7% and 20% complication rates, respectively, for these pathologies.

Although the plaudits for the work of Cook and colleagues\textsuperscript{17} are substantial, an overzealous response should be tempered. Several factors must be considered before the widespread use of ELCA can be endorsed.

First, only three excimer laser systems currently under clinical investigation have been tested sufficiently to provide usable data. The Technolas 308-nm system, as reported by Karsch et al.,\textsuperscript{12} fell short of the results obtained by Cook et al\textsuperscript{17} with the AIS excimer system, probably because of insufficient energy delivery rather than lesion selection.

Data are available on the Spectranetics CVX-300 excimer laser system used to treat 534 patients in an ongoing multicenter trial (personal communication with investigators). Of these, 238 were classified as types B2 and C lesions, in which laser success was 76.9% and procedural success was 86.1%. Again, these results are somewhat less favorable than those in the series by Cook et al.\textsuperscript{17}

Several reasons for these discrepancies may be suggested, some related to the problems inherent in comparative studies that use different or evolving devices and techniques. Just as the National Heart, Lung, and Blood Institute investigators recognize with the PTCA registries, even standard balloon coronary angioplasty is not being performed in a technologically stable environment.\textsuperscript{4} Balloons, wires, catheters, and the like are changing almost monthly. Even during the course of the Cook et al\textsuperscript{17} investigation, the need for adjunctive balloon angioplasty dropped from 47% to 36% when the 2.0-mm catheter became available. The catheter design itself changed, with the fiber bundle increasing from 12×100 μm to 50×200 μm. When the need for greater fluence (the energy being applied by the laser) to combat calcium was recognized (and the quantification of calcium must be considered subjective at the very least), early fluence ranges of 35–42 mJ/mm² were increased to 40–50 mJ/mm². In the study of Cook et al.\textsuperscript{17} multiple passes (up to five) of the laser catheter across the lesions were used, whereas other investigators using the same equipment within his multicenter trial limited the laser to a single pass across the coronary lesion. Such variables, even within a single study, preclude exact scientific analysis. Comparisons with other interventions or standard PTCA are fraught with spurious findings.

Second, despite significant improvements in the ability to deliver excimer laser energy through a catheter, many limitations and deficiencies persist. Paramount among these is the catheter dead space that contributes to a Dottering effect (dilatation) rather than plaque ablation.\textsuperscript{16} This undesirable consequence obviously influences restenosis. Unless larger catheters with significantly more active area become available, adjunctive balloon angioplasty will continue to be a component of many ELCA procedures, perhaps negatively affecting long-term outcome.

Finally, analysis of ELCA protocols are subject to the same pitfalls that plague PTCA studies. Even the most sophisticated quantitative coronary angiographic studies misrepresent the true condition of the vessel after angioplasty.\textsuperscript{20} For an intervention that possesses the potential for both mechanical and laser energy effect, such an evaluation of the procedural results may be confounding. Unless more accurate assessment modalities become routine, such as angiography and on-line, three-dimensional intravascular ultrasound, the potential for gross misconceptions will persist.

Regardless of these and other unidentified limitations, a niche for coronary laser angioplasty has been established. Clearly, the technique warrants further developmental studies.

References
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