Is rotational atherectomy here to stay?

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Rotational atherectomy was developed to ablate selectively inelastic atherosclerotic plaque, while deflecting normal arterial wall away from the rotating burr. Intravascular ultrasound (IVUS) studies have confirmed that rotablation differentially removes even hard, calcified plaque without damaging normal arterial wall. Early in clinical experience, the ability to ablate previously undilatable lesions established rotational atherectomy as an essential tool in coronary intervention.¹ More recently, rotational atherectomy was also confirmed to ablate differentially non-calcified lesions.² Because of this unique ability to remove plaque without damaging normal structures, the indications for rotational atherectomy have been extended beyond undilatable, calcified lesions in many centres.³⁻⁵

Refinement of technique has established the Rotablator as a predictable device in both straightforward and complex lesions. Analysis of 6647 consecutive patients with elective percutaneous intervention at the Cleveland Clinic between January 1993 and July 1996 revealed that 1243 (19%) rotational atherectomy procedures were performed on 1787 lesions. Sixty six per cent of Rotablator procedures included at least one B2 or C lesion. Major complications occurred in 3% of non-Rotablator and 2.4% of Rotablator procedures. Despite a more complex lesion classification, rotational atherectomy had a reduced incidence of major complications by multivariable analysis, odds ratio (OR) 0.49 ($P = 0.013$). Restenotic lesion type was the only other variable associated with reduced risk (OR 0.55, $P = 0.011$), verifying the predictability of rotational atherectomy in experienced centres.⁴

However, the acceptance and widespread use of rotational atherectomy has been hampered by several factors. The unpredictable occurrence of slow arterial flow and the rare but devastating complication of perforation made some laboratories reluctant to use rotational atherectomy extensively. Many operators still reserve rotational atherectomy for the most difficult, calcified lesions, which cannot be treated successfully by any other method. This extreme selection bias may have perpetuated a high incidence of complications in these laboratories, while preventing operators from getting the experience to use the device effectively. Cost, the paucity of data from randomised trials, and concerns regarding creatine kinase release have also slowed acceptance of rotational atherectomy.

Evolution of Rotablator technique to limit complications

Several modifications appear to have improved the reliability of rotational atherectomy.

Haudenschild confirmed that plaque may actually be heated and burned by rotational atherectomy.⁶ In an in vitro model, Reisman *et al* demonstrated that heat can be generated by pushing the burr to drop > 5000 rpm from baseline, and that the more sustained the rpm drop, the greater the temperature change.⁷ Likewise, the higher the platform speed of the rotating burr, the greater the heat produced per incremental drop from baseline.⁷ Arterial wall heating may provoke epicardial and/or microvascular spasm, which could contribute to slow flow occasionally seen after rotablation. Burning the arterial wall would also conceivably accentuate restenosis. Because of these concerns, the baseline rpm speed in many laboratories has been reduced to 145 000–160 000 rpm, and care is taken to minimise significant rpm drops that result from forcing the burr against resistance.

Analysis of results from the Study To determine Rotablator And Transluminal Angioplasty Strategy (STRATAS) has established that technique is directly related to major complications. Strip chart recorders were used to record rpms versus time during rotational atherectomy, and analysis showed that rpm drops > 5000 for a cumulative time > 10 seconds were highly associated with major adverse events ($P = 0.03$) and with creatine kinase increase ($P = 0.005$).^{8,9} Therefore, operator attention to limit significant rpm drops should improve results.

Even though slow flow was seen in 10% of lesions post-rotational atherectomy in early experience,¹⁰ Stertz and colleagues at Stanford University have evolved their technique to eliminate completely slow flow in their laboratory.⁵ They use a stepped approach with two to three burrs to minimise the amount of atherosclerotic debris per burr used, finishing the procedure with $\geq 70\%$ burr:artery ratio. They add vasodilators to the Rotablator flush solution to diminish epicardial and microvascular spasm. Stertz *et al* also use short runs of 15 to 20 seconds, and typically wait for ST changes and chest pain to resolve completely before another Rotablator pass. Flow is monitored with frequent contrast injections, and rotational atherectomy is terminated if contrast clearance is even transiently sluggish.

Evolution of rotablator equipment

Even though rotablation tends to ablate selectively inelastic plaque, differential cutting can be overridden by pressure from the guidewire and/or drive shaft pushing (biasing) the burr into the arterial wall in significantly angulated segments. To minimise biased cutting, the

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manufacturer has produced tapered, more flexible guidewires that straighten arterial contours less and push the burr into the edge of a curve less forcefully. The distal 9 cm of the drive shaft tubing was removed, also making the shaft more flexible. With evolution of the shaft-guidewire system biased cutting is reduced. However, in severely angulated segments such as the takeoff of a left circumflex from the left main coronary artery with an angle > 120°, a more substantial wire (type C or Extra Support) can be preshaped to match the anatomy. This lesion specific prebending provides more complete abrasion of the plaque with decreased deeply biased cutting.

Remaining concerns

Unfortunately, rotational atherectomy is a demanding technique that requires training and experience to perform with few complications. Praeceptorships and training courses should improve results and acceptance in the future.

Cost effectiveness of rotational atherectomy for other than undilatable lesions is yet to be proven, and cost justification will be required before widespread use of rotational atherectomy can be expected. The RotaLink system, which provides a detachable turbine and drive shaft with the ability to add extra burrs at a reduced cost, is currently being tested. This system will make the cost of rotational atherectomy more competitive.

Debulking is often used in ostial lesions, in diffuse disease, and in calcified segments before stent implantation. Ideally, a debulking device should remove the most calcified and unyielding elements of the plaque, leaving only a soft tissue rim to dilate or stent. The Rotablator should be uniquely suited for these indications, but the lack of confirmatory data from randomised trials, concerns regarding creatine kinase concentrations, and cost issues have hindered widespread use of rotational atherectomy even in these potentially favorable situations.

These concerns are valid and can only be answered by carefully conducted clinical trials. Preliminary data suggest that abciximab may reduce post-rotational atherectomy creatine kinase increase,¹¹ and a randomised trial to address the adjunctive use of abciximab is planned. A trial of rotational atherectomy ver-

sus dilatation before stent implantation is beginning, and a trial comparing angioplasty versus rotational atherectomy is underway (Dilation *v* Ablation Revascularization Trial).

Angioplasty has failed to provide longlasting results with diffuse within-stent restenosis, while preliminary data suggest that rotational atherectomy is effective. A randomised trial to establish the appropriate role of rotational atherectomy in this increasingly common clinical situation is planned.

Rotational atherectomy is still evolving and is now established only as a niche device in coronary intervention. If increasing numbers of operators are able to obtain predictable results from improved technique, if data are favourable from core laboratory monitored trials, and if cost becomes more competitive, then rotational atherectomy is, indeed, here to stay as a major tool in percutaneous treatment of coronary disease.

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If Rotablator is useful, why don't we use it?

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Percutaneous transluminal coronary rotational atherectomy with the Rotablator can improve acute success in difficult lesion subsets—bulky, balloon resistant calcified lesions, lesions on bends, ostial bifurcation and long lesions, lesions in small vessels, and diffuse disease. Debulking before stenting and within-stent

restenosis may be other indications. Despite such a wide range of applications, why is it that only a few cardiologists in the UK have any experience with the device?

Perhaps the first reason is a reluctance to get involved with what appears to be a complex difficult technique using unfamiliar and relatively

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