

# medical device technology

## Improving the Deliverability of PCI Catheters

Information supplied by Cambridge Consultants Ltd, Cambridge, UK

A recent study<sup>1</sup> assessing views of interventional cardiologists on the performance of catheters used in angioplasty, also known as percutaneous coronary interventions (PCI), indicates that there is a need for improvement in the catheter. The particular areas of improvement are reviewed here with some hypotube shaft solutions that promise to improve catheter deliverability.

Image: JuiceDrops

### An expanding challenge

More than five million diagnostic and therapeutic interventional cardiology procedures were performed in the United States in 2004, generating more than US\$4.9 billion in corresponding product sales. An ageing population and lifestyle challenges are leading to growth in the number of cardiovascular disease sufferers and by 2009 sales of interventional cardiology products are expected to reach US\$6.4 billion.<sup>2</sup>

Since the release onto the market of the first stent for percutaneous coronary interventional (PCI) procedures in 1993, the industry has focussed its resources on developing stent technology. Drug-eluting stents continue to advance and increase in market share. However, it should not be forgotten that good delivery systems are the first step to successful stent treatment.

It is in the navigation of tortuous anatomy and the treatment of extremely calcified lesions where well-designed catheters are most differentiated from inferior designs. In these complex procedures, the delivery system becomes the critical part of the PCI catheter. Developments in delivery systems have quietly and effectively evolved to assist delivery of the new devices. If delivery systems in their current form are serving cardiologists'

needs, it could be assumed that they have developed as far as is possible. However, as techniques and devices continue to develop and put more demands on the delivery system, catheter shafts must continue to evolve to address and meet those demands.

There are three general categories of catheter shaft: metal, polymer and composite materials. For PCI catheters of rapid exchange design, a metal catheter shaft, the hypotube, is the standard shaft option and the critical component in effective delivery of the balloon and stent. If the evolution of the next generation of PCI catheters is to provide real clinical benefit, there must be a synergy between balloon and stent technology and performance optimisation of the hypotube shaft. Further development of delivery technologies such as the hypotube may also facilitate development of new and innovative treatment devices.

### Cardiologists' assessment

To facilitate evolution of the PCI procedure, interventional cardiologists were asked what they really want from the hypotube component of the delivery system. There are several things.

■ They highly value the ability of the hypotube to enable the distal portion of the catheter to push and track effectively through tortuous anatomy

and thereby deliver the stent as efficiently as possible.

■ They want to feel confident that the hypotube will not kink or impede balloon deflation.

■ Although satisfied with current delivery systems, they would welcome improvements to kink performance providing these improvements would not compromise any other performance features of the hypotube shaft such as push, track, torque or flexibility.

### Importance of kink resistance

It is important for industry to recognise the potential procedure issues associated with hypotube kinking. If negotiating access to a severe or heavily calcified lesion, there is often a point of significant resistance to catheter advancement. Some procedures require an immense amount of force to be exerted on the proximal end of the catheter, in the hope that the stent or balloon will successfully cross the lesion. However, if the lesion is too severe or calcified, instead of the catheter successfully crossing it, some component of the delivery system may fail. Either the guide catheter will back out of the artery or, if the guide catheter is well seated, the hypotube or distal shaft may give by kinking at some point along its length.

Although extremely rare, a severely

kinked hypotube can lead to breakage, which may require surgical intervention or a complex nonsurgical extraction procedure. Severe kinking may also compromise the cross section of the tube and affect balloon deflation. This makes removal of the balloon extremely difficult, increases the risk of damage from lack of blood supply downstream of the balloon, and can result in a lengthy and difficult procedure to deflate the balloon. These severe kinking-related issues are of high risk to the patient and may cause the cardiologist to lose confidence in the device or even result in a product recall and the possible loss of market share and serious financial or legal implications. Although these are rare events, it is incumbent on catheter manufacturers to reduce the risks associated with kinking events. The move towards zero risk must be a clear objective in the optimisation of the catheter delivery system and in the next generation of PCI catheters.

### The hypotube evolution

Hypotubes provide the highest column strength and push characteristics compared with polymer and composite material counterparts. The most common material used in metal hypotubes is medical-grade stainless steel. Its high elastic modulus provides good push, but this can be at the expense of the flexibility that is achievable with polymer shafts.

Designing the optimum catheter shaft involves taking into account all the individual performance features of the hypotube and improving each of those features as much as possible without negatively affecting any of the other features. The aim of hypotube designers is to produce a hypotube that will display maximum kink resistance at the same time as maximum push, while optimising flexibility, particularly in the section

that transitions to the distal end of the catheter.

The characteristics of current metal hypotubes have meant that to achieve quicker balloon deflation times by thinning the tube wall (increasing the inner diameter (i.d.)), a trade-off with kink performance has had to be made. There no longer need be a trade-off because the decision can be taken to maintain current kink resistance levels while increasing the hypotube i.d..

In the context of the overall catheter, the hypotube is one of many components that affects balloon-deflation time. Although only one design element, any decrease in balloon-deflation time that can be gained from hypotube optimisation is extremely valuable and should be pursued. Rapid and reliable balloon deflation is critical to resume blood flow downstream and avert any long-term damage from lack of blood supply. Hypotube optimisation in terms of increasing the i.d. will have a positive impact on improving balloon-deflation time. This is particularly pertinent in procedures requiring large or longer balloons. Larger balloons contain more fluid and take significantly longer to deflate as a result. Any decrease in inflation time will convey huge improvements in those cases.

Although aiming for zero risk from kinking will provide several benefits (see Table I), the study revealed that push is the element that interventional cardiologists would most like improved. Push and kink resistance are closely related. A hypotube with greater kink resistance will allow the catheter to be pushed with greater force before an adverse event occurs. Future hypotube designs must strive towards greater push capability, but without becoming so stiff that track and kink performance are reduced.

Potential procedure issues associ-

**Table I:** Clinical benefits associated with improved kink performance.

It will allow the cardiologist to push harder and ensure more certainty of balloon inflation/deflation.
Improved catheter control enables the cardiologist to access the lesion more efficiently, the catheter becomes easier to use and procedure times may be shorter.
Increased kink resistance without compromising trackability or push will allow a subset of interventional cardiologists to attempt ever more complex lesions.
Patients are exposed to a more predictable device, which reduces the risk of procedure failure; fewer kinking events lowers the risk of damage to vessels.
A shorter procedure results in a reduction in the patient's exposure to radiation, the total contrast agent that is used and risks associated with postoperative recovery.
New opportunities for reduced and more reliable balloon-deflation times become possible.

ated with performance problems of many aspects of the PCI catheter still exist. Although new advances to stents will continue to come to the market, it is equally important that advances in the easy, safe and efficient delivery of those stents be made at the same time. The challenge to improve delivery systems is far from over.

### References

1. Study into the views of a number of interventional cardiologists in the UK, USA and Germany, conducted in October 2005 by Cambridge Consultants Ltd.
2. US Markets for Interventional Cardiology Products 4Q 2005, MedTech Insight, October 2005, [www.medtechinsight.com](http://www.medtechinsight.com) [mdt](#)

This article is an abridged version of the study, "How To Improve the Deliverability of PCI Catheters" authored by Dr Clare Beddoes, Cambridge Consultants Ltd, and Maura Leahy, Creganna Medical Devices ([www.creganna.com](http://www.creganna.com)), published by Cambridge Consultants Ltd, Science Park, Milton Road, Cambridge CB4 0DW, UK, tel. +44 1223 420 024, e-mail: [info@cambridgeconsultants.com](mailto:info@cambridgeconsultants.com) [www.cambridgeconsultants.com](http://www.cambridgeconsultants.com)