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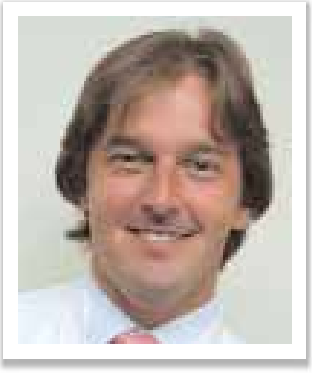
A leading interventional radiologist discusses vascular closure, differences between CE Mark and FDA approval, and highlights of his current research.

With all the various available technologies for vascular closure, is manual compression still the gold standard?

I think manual compression should still be considered the gold standard, mainly because this technique has been used from the very beginning and has been demonstrated effective, although time-consuming. In Europe, there is a trend toward peripheral interventional procedures using 4F and 5F compatible systems, and therefore I do think that manual compression should remain the gold standard when looking at complications, as well as cost-effectiveness.



What are some of the complications associated with the use of closure devices, and how might you overcome these obstacles?

There are two groups of problems that can occur with the use of closure devices. The first set of problems are those related to the arterial puncture itself, and these complications still do occur, although in general less frequently than with manual compression. There is still the risk of hematoma, false aneurysm, or arteriovenous fistula. Closure devices do not address any inadvertent puncture of the posterior wall. Because of this, patients can still have complications that might also be life threatening, such as large retroperitoneal hematomas. On the other hand, you have the problems that are specifically related to closure devices, and these problems depend on the type of device you are using. The devices have improved significantly over the years, and many of the pitfalls have been resolved by the manufacturers. We also have to keep in mind that many of the complications seen are not caused by the closure device itself but result from improper use in diseased or too small caliber arteries. I estimate that this accounts for more than half of the complications that are referred to me, and patients often present with ischemic symptoms. This once more emphasizes the importance of training and following the instructions for use of the manufacturer. Finally, the need to perform ultrasound- or fluoroscopy-guided puncture and femoral angiography or ultrasound to assess the puncture site cannot be stressed enough. Keeping all this in mind, I think that the ideal closure device does not exist yet.

> "The optimal closure device should not leave anything behind in the body in the long term . . ."

How would you describe the optimal closure system?

The optimal closure device should not leave anything behind in the body in the long term, should be easy to handle, should not have a learning curve, and should have a low cost. It is also important that the device can be used in patients with small and/or diseased femoral arteries. This is currently a frequently encountered contraindication and source of potential error, and it therefore should be a key feature to consider in the development of new devices.

You have researched thrombolysis for the treatment of acute blindness. How can this therapy be used effectively in this setting?

This is a technique that is relatively unknown and an offspring of intra-arterial thrombolysis for acute stroke treatment. There have been a lot of advancements in the field of acute stroke treatment over the past several years, including the development of retrieval devices. Acute one-sided blindness may occur due to thrombosis in the ophthalmic artery and central retinal artery. This artery can be reached with microcatheters, and local intra-arterial thrombolysis can be instituted. The success rate of up to 40% to 50% is relatively low, but I think that when you have to choose between this kind of therapy or blindness without attempting the therapy,

(Continued on page 80)

(Continued from page 82)
then you should take the risk of the intervention, specifically when the interventionist who performs the procedure can reduce the complication rate to a minimum.

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What are some of the new endovascular technologies that have reached Europe that we are not yet seeing in the US?

One of the things that I am involved with in my daily practice is not really new technology but improvement of existing technology. Although a lot of the superficial femoral artery interventions are still done with 6F devices in the US, in Europe, there is a relatively large availability of various 4F compatible devices that are used for this purpose. This allows the interventionist to perform the treatment on an outpatient basis easily and without the use of closure devices. Furthermore, in Europe, we have some stents for below-the-knee interventions that are used I believe in the US only in compassionate cases or off-label use. I think we have an advantage here with respect to the US and device approvals.

What do you see as the biggest obstacles for getting CE Mark approval in Europe?

We have less regulatory issues in Europe than in the US. It is relatively easy to for new products to receive CE Mark approval. The authorization of medical devices is guaranteed by a Declaration of Conformity. This declaration is issued by the manufacturer itself, but for products in class IIb (implantable devices such as stents), it should be backed by a Certificate of Conformity provided by a so-called Notified Body, which is a third party that can certify products on a "for-profit" basis. As a general rule, under the normal conditions of use of the device, the evaluation of the side effects and the acceptability of the risk/benefit ratio must be based on clinical data. The evaluation of these data can either be a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics etc., or a clinical evaluation in a limited number of patients (usually fewer than 50) that mainly involves the demonstration of safety, followed by a postmarket surveillance. When you make modifications to existing systems, you need to document the changes made and demonstrate that your manufacturing process is in order and thus continue your CE Mark on the modified device.

The major obstacle from a practical point of view is that you have to demonstrate safety in a limited number of patients, and once the device is approved, you can market it. It is not a big step to make—you just have to find the patients. For some devices, it is possible to obtain CE Mark completely on paper when you can demonstrate good manufacturer practice. In addition, at exhibitions, there are no obstacles to the showing of devices that do not conform to the CE Mark, provided that it is clearly indicated that the device cannot be marketed or put into service. There is a huge difference between the two continents in this respect, although I think both systems have their advantages and disadvantages. In Europe, there is the risk that devices are approved too quickly; on the other hand, in the US, patients are withheld from receiving therapies that are well established. An example of the latter is angioplasty and stenting for iliac disease, in which only few devices using old technology are approved.

What is the current focus of your research?

We recently completed the modernization of our angiosuite, and we now have access to flat-panel technology, including three-dimensional rotational angiography and XperCT (Philips Medical Systems, Best, The Netherlands). Current interest is focused on some very basic aspects of working with flat-panel detectors. Given the higher sensitivity of the new detectors, it is likely that the amount of contrast that we use during procedures can be reduced either by diluting the contrast or just by giving a smaller volume of contrast. This is especially important in patients who are at the edge of renal insufficiency, a problem we are facing more and more with the increasing age of our patient population. We are working on trying to find out how to optimize this on a scientific basis. Furthermore, I still have my interests in three-dimensional rotational angiography and its application in peripheral vascular interventions, endoleak detection, and treatment of the superficial femoral artery and the below-the-knee area. I am involved in several studies in this area. ■