

# Giancarlo Biamino, MD

The world's foremost expert in endovascular laser applications tells of his experiences with the technology and device regulation and adoption in the US and Europe.



**How and when did you come to begin working with laser applications?** We started working with the different types of lasers in 1988. The first application of excimer lasers in femoropopliteal-tract interventions was in January 1989, when we performed recanalization of the popliteal artery in a patient with critical limb ischemia (CLI). We have now performed more than 8,000 cases using the laser. We started to be more aggressive in patients with CLI about 5 or 6 years ago. At the time, the prevailing attitude of the majority of the interventionists concerning CLI was very conservative: refer the patient to the vascular surgeon or accept amputation. Our results showed that it was possible to treat CLI in a more aggressive manner.

A very important step was the fact that we could use the same materials below the knee that are used in the coronary arteries because the vessels are the same size. This dramatically improved the acute result in comparison to old studies. First, we performed the LACI 1 study, which related to only 30 patients, and then we performed the LACI 2 study, which involved more than 150 legs with CLI. In our opinion, the results were very dramatic; the primary success rate was about 90% to 92%. This confirmed that it was possible to save the legs of these patients and that it was not necessary to send the patient to the vascular surgeon. The recent LACI study performed by vascular surgeons achieved the same limb-salvage rate of 93%. What is important to stress with regard to CLI is that, in many cases, it is not necessary to look at long-term patency rates, but rather to look at the short-term. This type of patient needs blood flow for 6 to 8 weeks to either heal, or so that the amputation can be limited to the lower part of the limb. In this way, limb salvage can be achieved; in many cases, we can avoid the larger amputation. Using stents below the knee, the patency rate is maybe 60% to 65% after 1 year; however, the "clinical

patency" rate was over 80%. In fact, the improvement of the clinical symptoms was maintained in a larger part of the cases independently from the patency of the vessel.

**In what additional ways do you see laser applications impacting the endovascular community in the future?**

First, we have to improve the education required to use the laser. The experience is not the same as for using a guidewire or a balloon. The operator must be very familiar with this technique. One extremely important advancement will be the use of lasers in acute thrombotic situations, not only in the leg but in the coronary too, in patients with unstable angina and acute myocardial infarction. The results being achieved in these fields are extremely promising.

At the moment, there are ongoing studies in the US and Europe on acute myocardial infarction using the excimer laser. What we have observed in the periphery has been confirmed in the coronary: by using the laser for debulking thrombus, the amount of peripheral embolic complications is minimal at below 0.5%. This is a big difference in comparing the laser with other debulking systems or primary stenting. However, I must emphasize that it is absolutely necessary to learn to use the laser appropriately because laser energy is completely absorbed by contrast medium and, particularly in the coronary, the tendency to continuously inject contrast medium is very common. However, doing so can create an explosion in the artery, which will cause distal dissections of the vessel, which must be avoided by continuous flushing of saline through the catheter. Finally, it cannot be repeated enough that the penetration of the laser is only 15  $\mu\text{m}$  per shot, so that if you move the laser catheter faster than 1 mm per second, you are dotting and not lasing.

**What new treatments for CLI do you think we'll see in the near future?**

In the very near future, we will learn to use stents below the knee. If you look at the results of the LACI study, we had use of stents in approximately 50% of the cases. What we learned during the last 2 years is that we can use coronary stents below the knee with great success. We do not currently have dedicated stents for below the knee, but it is mandatory that we get them. The dimensions are the same as the coronary, but the mechanical behavior of the vessel is different. When we treat the more distal parts of the vessel, we will need self-expandable stents, not balloon-premounted stents. The next big step could be bioabsorbable stents. This could be a huge market, but we currently do not have any data. There is one study in Europe

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using a new magnesium bioabsorbable stent. We are performing a study in the SFA with a bioabsorbable stent. There are some technical problems to solve related to the size of the stent and the size of the delivery system. The development of more aggressive technologies will be extremely important. I think that the main direction will be laser in combination with stenting and perhaps cryoplasty or atherectomy devices, although we do not have any data at the moment.

**How has carotid artery stenting (CAS) impacted practices in Europe?**

In Europe, there are currently more than seven approved protection devices and at least four dedicated stents. However, there is a completely different attitude in the different countries based on the completely different types of reimbursement. This will always be a big limitation, as will the philosophy of practice changes from country to country. For example, in France, CAS is not a recognized procedure, and it can only be performed in conjunction with studies. In Italy, it is recognized, with more cardiologists and vascular surgeons performing this type of intervention every day. In Germany, although we don't have any official data confirming this, I believe nearly 70% of CAS procedures are performed by cardiologists and only a limited amount are performed by radiologists or neuroradiologists. There is a completely different tendency in England, where the amount of CAS is very limited; they are extremely conservative, and the field is completely dominated by the vascular surgeon. What will happen in the countries that are newly becoming members of the European community is very difficult to estimate. Poland is very modern, very aggressive, and more cardiologists will perform CAS. I suppose that within the next 3 years, we will have more CAS than endarterectomies in Germany and Italy. I think that overall, the number of patients referred to a vascular surgeon for CAS will diminish dramatically in the next 3 years.

**With the FDA approval of CAS possibly coming soon, how do you think it will be adopted by US physicians?**

We know that FDA approval will probably come in the second or third quarter of 2004, at least for high-risk patients. The biggest problem will be how you will define "high risk." The definition changes between different surgeons and among specialties, and consequently, we don't have a very clear definition. Considering the high-risk patients in the SAPHIRE, ARChER, and SECURITY studies, I would say the definition is relatively soft. Nevertheless, if the FDA will accept CAS as a procedure for high-risk patients, there will be a dramatic increase in CAS in the US to the point that there will very soon be more CAS performed than CEA.

**In your estimation, do interventional cardiologists in Europe perform as many peripheral procedures as their counterparts in the US?**

To my knowledge, cardiologists in the US are performing approximately 32% to 36% of peripheral interventions, without consideration of carotid intervention. The numbers in Europe are not uniform. It depends on the reimbursement and the tradition in the different countries. In Germany, we are nearly in the area of approximately 30%. This is also true in Italy and Belgium, but not in the Netherlands. A general consideration in this field is determined by the fact that in many European countries, the necessity to achieve a standard level in coronary procedures is different than in the US. In the US, there is a steady or even slightly decreasing number of patients, so that it is a logical consequence that the cardiologists will try to move into the peripheral field. In some countries, particularly in the eastern part of Europe, the necessity to treat coronary patients is so high that there is not a simultaneous educational process for treating peripheral disease. I suppose that in the next 5 years, more than 70% of the peripheral procedures in the US will be done by cardiologists and the rest will be split between vascular surgeons and radiologists.

**How does the CE Mark approval process differ from that of FDA approval?**

I have concerns with regard to CE Mark approval, but I also have significant concerns about the FDA processes. Sometimes, the FDA is extremely restrictive in proposing to perform very complex studies before they give final approval. In other cases, however, they are very similar to the European authorities. Two examples are cryoplasty and the FoxHollow device. They were both approved without any real scientific data. This is closer to how it is in Europe, where there are companies getting a CE Mark for a system that has never been used in humans. For me, the current state in Europe is not acceptable. There are companies with a CE Mark for carotid stenting technology that have never performed one animal or human study.

The validity for the CE Mark at the moment is very difficult to estimate. I am absolutely convinced that the way of the FDA is the better way of the two, because it requires the demonstration of not only the safety, but also the efficacy and consistency of a new product. Because of the differences between the European countries, it is not very easy to have a uniform attitude. We often hear about "the Weekend CE Mark," because in some countries, you can have a CE Mark approval for a new product over the weekend. This may ultimately make the CE Mark a failure in all European countries. I think that in Europe, we will move more in the direction of the FDA. On the other hand, I hope this trend does not block the development of new technology for years. ■