

# A Clear View of Innovative Stents



At a leading cardiology clinic in Brazil, the Artis zee system from Siemens helps physicians in the clinical trials of bioresorbable polymeric scaffolds.

By Reinaldo José Lopes





Alexandre Abizaid, M.D., and his colleagues at Dante Pazzanese Cardiology Institute, a major medical and research facility in São Paulo, Brazil, are taking part in an international clinical trial of bioresorbable polymeric scaffolds that could have potential advantages over current pharmacological stents. Most of these polylactic acid scaffolds, however, are challenging to image: They are not opaque to X-rays, except for two millimeter-wide platinum “dots” at their tips. To surmount that problem, Dr. Abizaid and his fellow researchers are using the Artis zee system by Siemens.

“The take-home message for me as an interventional physician is that you need high-quality equipment and outstanding image resolution in order to optimize the performance of your implant, and that goes not only for polymeric scaffolds but for metallic stents as well, either bare-metal or drug-eluting ones,” says Dr. Abizaid.

He explains that, although drug-eluting stents have been shown to be an improvement over bare-metal stents – reducing the rate of restenosis from 30% to 5% because they minimize the

rate of intimal hyperplasia – there are still important trade-offs concerning their use. One of them is the need for long-term dual antiplatelet therapy to protect the patient against stent-derived thrombosis. According to Dr. Abizaid, bioabsorbable scaffolds help to address this shortcoming, as they are completely absorbed after 18 months. The polymeric scaffolds would still require dual antiplatelet therapy, however only for the first six to twelve months post-implantation.

There is also the hope that polymeric

scaffolds might avoid the so called “late catch-up” of conventional drug-eluting stents – in such cases, restenosis may be kept at bay at first, only to surface after two years. Besides, some kinds of patients – the ones with more serious coronary disease at younger ages, for example – may have more to gain from bioresorbable stents if repeated implantations are required.

“If several vessels receive a metallic stent, you’re going to have a major problem on your hands if the patient happens to need surgery in the future,”

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Alexandre Abizaid, M.D.,  
Dante Pazzanese Cardiology Institute, São Paulo, Brazil



explains Dr. Abizaid. “Where do you think a surgeon will be able to insert the saphenous vein during coronary bypass surgery if the whole arterial network already has a metal framework?”

This kind of permanent network would not be in place once polymeric scaffolds were absorbed. Finally, polymeric stents, unlike their metallic counterparts, do not create artifacts during tomography, says Dr. Abizaid. “Therefore, the follow-up of patients that receive them could be less invasive.”

### Precision is Paramount

The team at Dante Pazzanese relies on the precise measurements done by Artis zee, starting with quantitative coronary angiography, as a means to avoid problems that could specifically affect polymeric scaffolds.

“Precision regarding size is crucial for bioresorbable stents because they are far less tolerant to post-dilation than metallic stents, which simply go along with it when you use a bigger balloon,” explains Dr. Abizaid. “If you do the same with a polymeric stent, odds are you are going to fracture it, and nobody wants

that. We need to know exactly where the stent boundaries are. That is why viewing those little millimeter-wide dots is so important.”

According to Dr. Abizaid, Artis zee may also be used during late follow-up. “It is going to depend on the symptoms and on the previous exams,” he says. “If the patient shows up, after six or nine months, with angina pectoris and pain, and if a nuclear medicine exam shows ischemia, we will have to do a catheterization.” By viewing the stent’s landmarks inside the vessel, the team should be able to decide whether to use a new stent or to do a surgical intervention.

The Brazilian clinical trials of three different models of bioresorbable stents started in September 2011 at Dante Pazzanese itself. The first patient, a 66-year-old woman, had 93 percent of her right coronary artery obstructed. Two other major medical facilities in Brazil, the Albert Einstein Israelite Hospital (also in São Paulo) and the Instituto do Coração do Triângulo Mineiro (in Minas Gerais State) are also taking part in the trial.

The three hospitals have already treated about 40 patients – the aim is to reach a number of about 100 patients by the end of this year. And, according to Dr. Abizaid, early data looks promising.

“I had the privilege of presenting the results from the six-month follow-up, including 300 patients – ours and from other sites around the world – earlier this year. The revascularization rate is pretty similar to what we see in metallic stents and there is a low rate of thrombosis – both things are consistent with what we thought before the trial,” he says. “Of course, there could be a price to pay for the absorption. It might not be such an innocent thing after all, but so far we don’t see any signs of trouble.”

*Reinaldo José Lopes is the science and health editor at Folha de S.Paulo, Brazil’s leading daily newspaper.*

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