

A Powerful Combination for Coronary Interventions

Common causes of coronary stent thrombosis and restenosis include the incomplete expansion of a stent and poor apposition to the vessel wall. In a standard angiography procedure, the thin stent struts can be difficult to see, and intravascular imaging – such as ultrasound and optical coherence tomography – is not routinely used for coronary interventions.

We spoke with Professor Stephan Achenbach, MD, Chairman of Cardiology at Erlangen University Hospital, about the benefits of using CLEARstent and CLEARstent Live for stent enhancement during percutaneous coronary interventions.

By Hildegard Kaulen, PhD

Before sharing his experience using stent enhancement, Stephan Achenbach explains the challenges that he faces on a day-to-day basis: “We are performing increasingly complex procedures that we would previously not have considered routine or even possible,” he says. “And these require perfect visualization not only of the vessel lumen, but also of the implanted coronary stents. At the same time, stent struts are becoming thinner and thinner and less radiopaque. Strut thickness used to be 140 µm; now it is usually 80–100 µm.” This is not all: Achenbach goes on to explain the new bioresorbable scaffolds: “These most modern versions of coronary stents can only be recognized by extremely small platinum markers at either end. Their

framework is no longer visible in angiography. In addition, patients are getting older, sicker, and more overweight,” Achenbach says. “It is much harder to see the stents in obese patients than it is in slim patients. Also, we often have to insert multiple stents in order to cover longer stenoses, chronic occlusions, or because the procedure involves bifurcations. We are treating more and more patients who already have one or multiple stent implants from previous coronary interventions.”

Improved Decision-Making Process

Achenbach uses a clinical example to illustrate the importance of good stent visibility. A few weeks ago, he was treat-



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Professor Stephan Achenbach, MD,
Chairman of Cardiology at
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ing a patient who presented stent restenosis for the third time. With CLEARstent, he could see that the stent had been incorrectly deployed the first time and was never fully expanded (Fig. 1), and that more aggressive post-dilation should have been performed during the previous interventions. Without CLEARstent, this would not have been visible.

He gives a second example to demonstrate a potential benefit of stent enhancement. An overweight patient with a history of bypass surgery was admitted with acute chest pain. “Angiographically, we found a high-grade stenosis at the insertion of a bypass graft,” says Achenbach. “It was not until we used CLEARstent that we

saw a stent had been implanted in that anastomosis, and what we considered to be de-novo lesion was, in fact, an in-stent stenosis based on a stent fracture (Fig. 2A and 2B). This, of course, influenced our treatment strategy.”

Achenbach has been using both applications for just over a year now and employs them in nearly every interventional procedure he performs. “When I show colleagues the images, they are really enthusiastic,” he says. CLEARstent and CLEARstent Live enable him to answer important questions with confidence: Is the stent expanded completely? Is it severe calcium that prevents full stent expansion? Has the deployment

of one stent led to the deformation of another, for example in a bifurcation? Post-dilation with carefully selected balloon size may be necessary. “This is where the modeling work begins,” Achenbach says. And he knows very well that good visibility is mandatory when handling the complex meshwork of the stents.

The Principles of Stent Enhancement

CLEARstent is a post-processing tool. CLEARstent Live displays the stent enhancement in real time. Both tools are based on the same principles. Balloon markers are identified by the algorithms and the images are enhanced by aligning consecutive

frames according to balloon markers, decrease noise, and improve contrast and resolution, which improves stent visibility. CLEARstent acquires images over multiple cardiac cycles, and projects a high-quality still image. The algorithm requires a few seconds to complete and generates this single high-quality still image. The CLEARstent image is automatically saved as a regular DICOM image; it is enlarged and can be exported to a PACS system for documentation purposes. CLEARstent Live, on the other hand, uses the same principle, but it operates in real time and generates stabilized, enhanced live images even as the balloon or stent is manipulated and moved within the coronary arteries. CLEARstent and CLEARstent Live are fast and easy to use – without requiring any extra effort.

Perfect Partners

Are both tools really necessary? Achenbach answers with a resolute “yes” and names four applications that show how the tools complement each other, and how they are typically used during a percutaneous coronary intervention:

1. Achenbach uses CLEARstent to check that the stent has been fully expanded (Fig. 3). He believes that incomplete stent expansion is probably the reason for in-stent restenosis in a relevant number of cases (as with the patient in the first clinical example he gave).
2. Achenbach uses the stent enhancement tool in real time when he wants to position the balloon for post-dilation using maximum precision (Fig. 4). “We use CLEARstent Live to check that the edge of the balloon is properly aligned with the end of the stent,” he says. “Then we can be relatively confident that we will avoid damaging the coronary artery outside the implanted stent.”
3. He subsequently uses CLEARstent to check that multiple stents have been correctly implanted next to one another, and to ensure the optimal distance between an old and a new stent (Fig. 5). Gaps between stents may also contribute to restenosis.

Too much overlap, on the other hand, may cause a predisposition to stent thrombosis or fractures. The precise positioning of multiple stents is particularly important in bifurcations, when ostia or side branches have to be covered. CLEARstent Live is able to aid in positioning a second stent in real time with optimal precision.

A fourth application is the evaluation of stents that are already in place. “CLEARstent allows us to see stents that are poorly expanded, stent fractures (Fig. 6), and other situations that we might not even be able to identify without stent enhancement, but which are important for making clinical decisions.” To Achenbach, it seems obvious that if the procedure of stent implantation can be optimized through better visualization, long-term clinical results may be improved. He points out, however, that no clinical studies to this effect are available so far.

The Challenge of Bioabsorbable Scaffolds

Achenbach turns his attention to the new bioabsorbable scaffolds. These devices are no longer made of metallic material, but typically from derivatives of poly-L-lactic acid. They are usually not radiopaque and, hence, invisible in X-ray angiography. To support the implantation procedure, most scaffolds carry small radiodense markers at either end (Fig. 7). Their use in coronary interventions is promising to many cardiologists because they completely dissolve within a few years. Achenbach sees two advantages in their use: First, if the scaffolds disappear over time, no foreign objects are left in the vessel. If a second coronary intervention or even bypass surgery become necessary at a later date, there is no metal mesh preventing a free choice of treatment options in any particular area. Second, the ability of the coronary vessel to expand in situations of increased blood flow is likely to be better without a foreign object inside it, which some researchers link to the observation that patients may have less chest pain after treatment with

bioresorbable scaffolds as opposed to conventional stents made of metal. “I personally think that bioresorbable scaffolds will be the primary form of intracoronary devices used for interventions in the future,” says Achenbach. “However, we have to be aware that clinical studies are still ongoing. Initial results are proving positive and bioresorbable scaffolds appear to be as effective and safe as drug-eluting stents. Still, we need to wait for longer-term results of larger studies in a wider range of patients before making a final assessment.” In fact, stent enhancement may be particularly important for interventions using bioresorbable scaffolds, given their requirement for very accurate positioning and post-dilatation, combined with the often very poor visibility of their miniaturized metal markers.

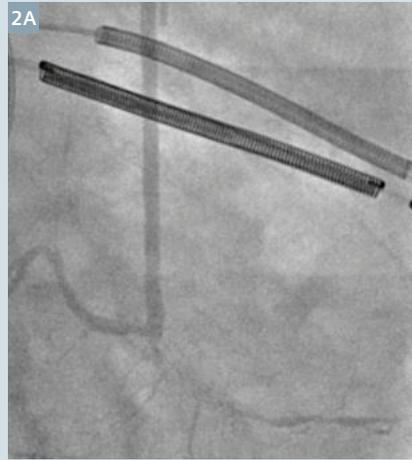
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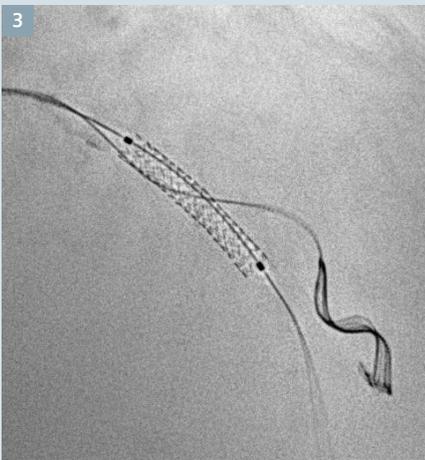
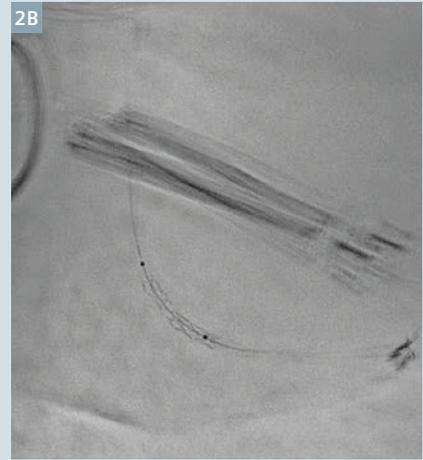
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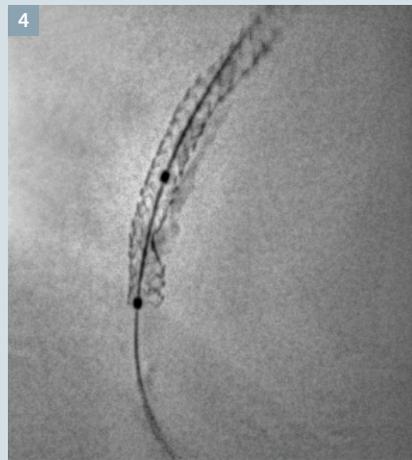
1 CLEARstent shows an incompletely expanded stent.



2 High-grade stenosis at the insertion of a bypass graft showing an implanted stent, which was not seen until the use of CLEARstent.



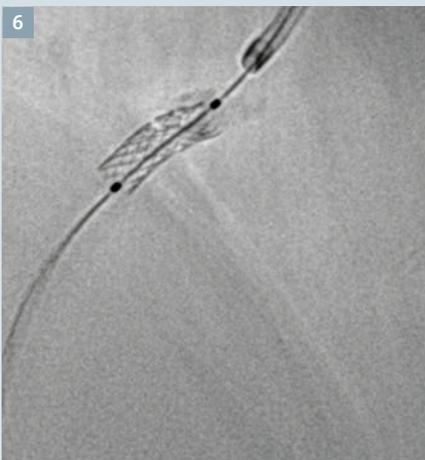
3 CLEARstent of a fully expanded stent.



4 CLEARstent Live frame shows the positioning of a precisely aligned balloon for post-dilatation.



5 CLEARstent used for multiple stent implantations to check the positioning between the old and the new stent – in this case with a gap.



6 CLEARstent allows to see stent fractures, which might not be visible without stent enhancement.



7 Bioabsorbable scaffolds are equipped with small radiodense markers, which can easily be seen with CLEARstent.