How would you describe the clinical presentations you see on a daily basis?

Dr. Goverde: The clinical presentations we routinely see are becoming worse and worse. Five years ago, we treated mostly patients with 5- to 10-cm lesions endovascularly. Now, we see many chronic total occlusions (CTOs). In Belgium, there is a large elderly population with comorbidities, and many of those patients have diabetes. That often makes treatment very difficult, so choosing either endovascular treatment under local anesthesia or general surgery with a risk of infection is an easy choice. At the moment, we do the majority of our procedures endovascularly, and only if it is not feasible or attempts were not successful, we elect for surgical procedures.

Ten years ago, we treated mostly TASC A and B lesions, but now we’re seeing a majority of TASC D lesions. Patients with TASC A and B lesions treated 10 years ago are coming back with a TASC C or D lesion. It’s a progressive disease, so we can treat a patient now, but we know that he will come back. This is why we do very thorough follow-up to pick up recurring problems. If identified during an earlier phase of follow-up, the treatment is less invasive than if the disease in the treated vessel develops to an acute occlusion and thrombolysis is needed.

What are the greatest challenges you encounter when treating complex disease?

Dr. Goverde: We now see more CTOs with occlusion to the superficial femoral artery (SFA) and very calcified lesions, so it is becoming more of a challenge to treat them endovascularly. Ten years ago, we would decide to do a femoral bypass above or below the knee, but now we’re first trying to treat them endovascularly, even the more difficult lesions.

What are the most vital components of your armamentarium for treating SFA disease?

Dr. Goverde: In Belgium, reimbursement is quite restricted, so most revascularizations are performed with simply wires, catheters, balloons, and, if necessary, stents. In our practice, we always have a reentry device on the shelf, but we only use it about twice a year.

If antegrade revascularization fails, we decide quickly to go for retrograde revascularization through pedal or distal access to try to restore the flow from below. In 90% of cases, this is successful, and when the wire is in place, you can try to start with a balloon angioplasty.

Because we now see more long and calcified lesions, the need for a scaffold is becoming greater. With lesions < 10 to 15 cm, the need for stenting is quite low. However, for CTOs and especially with long lesions, it’s difficult to keep them open for a long time without scaffolding in the proximal or distal portion, and sometimes we need a full-length stent.

When selecting a self-expanding stent to implant in the SFA, what features do you look for?

Dr. Goverde: We need to find the right balance between flexibility and compression resistance, although I think the biggest concern is compression resistance so that the stent can withstand both the motion of the artery itself and external forces.

When the second generation of stents was being developed, everyone was focusing on straight vessels. No one took into account that the SFA is a very mobile artery in the proximal portion, and especially in the distal portion, the P1 and P2 segments are very immobile. During mobilization of that artery, a lot of forces are created, so we need to have a scaffold or a stent that can withstand that sort of force.

What is your usual follow-up protocol with your patients?

Dr. Goverde: After the procedure, the patient returns after 30 days for the first follow-up, and depending on the results, will normally return at 3 months and then every 6 months. Most patients are put on dual antiplatelet therapy unless there is a contraindication. Usually, patients are prescribed lifetime aspirin and 3 months of clopidogrel.
What do you believe are the biggest unmet needs in treating SFA disease?

Dr. Goverde: I think one of the biggest goals is to find a way to lower inflammatory response and subsequent intimal hyperplasia. We have already succeeded in some ways, especially with balloon studies, by realizing once again that we need to use our balloons with a proper technique—slow inflation, longer inflation times, and avoiding pressures that are too high.

With that reinvention of balloon use, we could reduce the amount of stenting again, but we still need stents, and we don’t have a real answer for in-stent restenosis (ISR). We are trying to give an answer with atherectomy devices, drug-coated balloons, and covered stents, but at the moment, I don’t think there is a real answer for ISR. That is a big issue we need to overcome by finding a solution to prevent ISR, and then, of course, for treating the patients who have ISR.

Tell us about your involvement with the REALISTIC trial and what this is studying.

Dr. Goverde: When the S.M.A.R.T.® Flex self-expanding stent (Cordis Corporation) came on the market, we wanted to see how well it actually performed, so we started the REALISTIC trial. It is a prospective follow-up study for consecutive patients who underwent intervention of the SFA at the P1 and P2 segments. This is—especially in the distal SFA and proximal popliteal segments—the area where most of the biomechanical forces will act upon the stent because of calcification.

Every patient who had a S.M.A.R.T.® Flex stent implanted was included until we had a patient population of 100. Now, we have almost 18 months of follow-up with very good results and a > 80% primary patency rate.

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CASE REPORT

A 63-year-old man presented to our institution with a chronic wound on his left lower limb that had existed for more than 6 months. He had been a smoker for 45 years and had a history of arterial hypertension, cardiomyopathy, type 1 diabetes, percutaneous transluminal coronary angioplasty, coronary artery bypass grafting, and a covered endovascular reconstruction of the aortic bifurcation for extensive aortoiliac disease in 2012, and he was taking aspirin. His left ankle-brachial index was 0.43. CTA showed a total occlusion of the mid and distal SFA and the popliteal artery to the tibioperoneal trunk (A).

Standard open surgery below the knee was considered, but there were no veins available, and the lower leg wound was infected. Endovascular recanalization and revascularization was chosen instead. Antegrade access of the left common femoral artery was achieved.

Subintimal recanalization with an angiocatheter was performed, and successful reentry in the tibioperoneal trunk was achieved. The wire was exchanged to a 0.014-inch and balloon dilatation was performed with 4- X 200-mm and 5- X 80-mm SABER™ balloons (Cordis Corporation) (B). There was a flow-limiting dissection in the mid to distal SFA (C), so a 5- X 100-mm S.M.A.R.T.® Flex stent was placed (D). There was good flow under both straight (E) and flexed conditions (F and G) due to the S.M.A.R.T.® Flex stent’s ability to mimic the natural movements of the artery. The first postoperative control 3 weeks after the intervention showed healing of the wound, and the patient was put on dual antiplatelet therapy.