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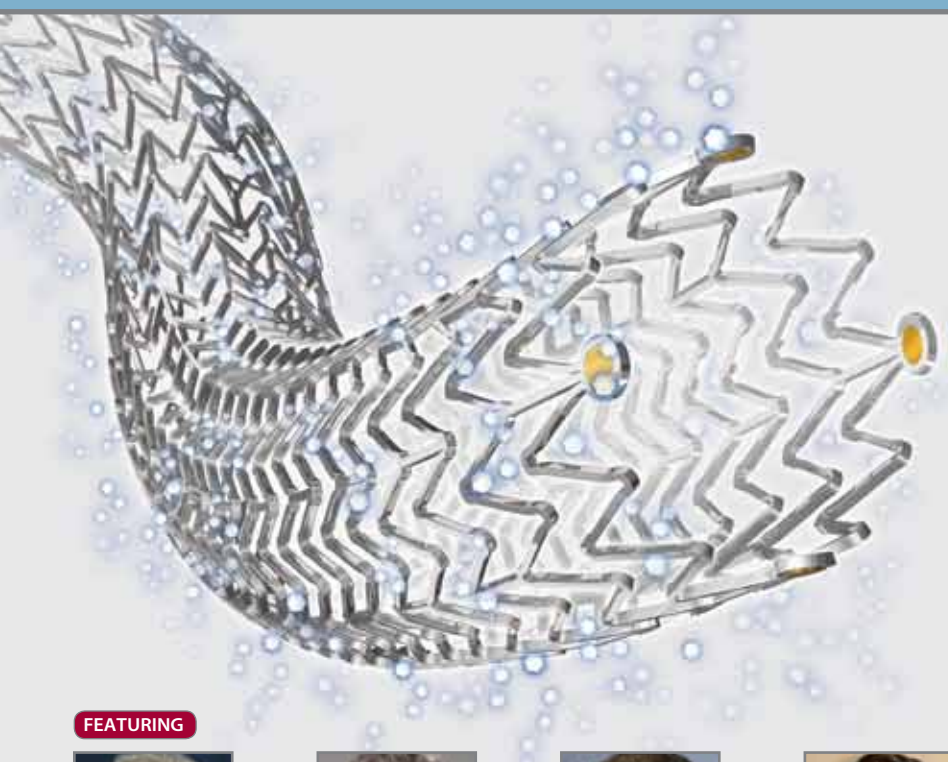
THE NEW ERA OF DRUG ELUTION HAS ARRIVED



Experts share how the drug effect of Zilver PTX is changing SFA treatment.

FEATURING

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THE NEW ERA OF DRUG ELUTION HAS ARRIVED

INTRODUCTION

In November 2012, the Zilver PTX paclitaxel-eluting stent (Cook Medical, Bloomington, IN) became the first drug-eluting platform of any kind to receive US Food and Drug Administration approval for a peripheral vascular indication. Now available in more than 50 markets worldwide, Zilver PTX brings with it a vast amount of data from a multinational randomized, controlled trial, a large single-arm study enrolling nearly all-comers, and the growing experiences of many operators.

This supplement discusses lessons learned from those experiences, and also takes a practical look at how Zilver PTX fits into today's vascular practices and how products with a drug effect will change vascular medicine.

CONTENTS

INDICATIONS: Intended for use in the treatment of symptomatic vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 mm to 8 mm. To avoid involvement of the common femoral artery, the proximal end of the stent should be placed at least 1 cm below the origin of the superficial femoral artery. To avoid involvement of the below-the-knee popliteal artery, the distal end of the stent should be placed above the plane of the femoral epicondyles.

Treating Femoropopliteal Occlusive Disease

What will be the workhorse therapy to address this disease over the next 3 to 5 years?

WITH GARY M. ANSEL, MD; WILLIAM A. GRAY, MD; AND DIERK SCHEINERT, MD

The treatment of superficial femoral and proximal popliteal artery (femoropopliteal) occlusive disease has recently started to mature. For years, we have seen various treatment modalities recommended based primarily on limited registry data. In the last few years, however, we have seen the development of comparative objective performance criteria.[1] More recently, large, higher-quality, core laboratory–controlled, multicenter, randomized trials, such as the Zilver PTX trial (Cook Medical, Bloomington, IN), have been completed. In the United States, there are multiple technologies currently being used in the femoropopliteal region, including balloon angioplasty, atherectomy, bare-metal stents (BMS), and stent grafts. The use of drug-eluting stents (DES) in this anatomy has only recently been approved in the United States. The first two drug-eluting balloon (DEB) trials, LEVANT 2 (Bard Peripheral Vascular, Inc., Tempe, AZ) and IN.PACT (Medtronic, Inc., Minneapolis, MN), have recently completed enrollment, and, if efficacy and safety are again demonstrated, we anticipate the technology to be available in the United States in the next 3 to 5 years.

Thus, physicians are being faced with an ever-changing decision process for treating the femoropopliteal region. Vessel characteristics that may influence the choice of technology include vessel size, disease length, extent of calcification, location in respect to the vessel ostium, the patient's ability to tolerate antiplatelet therapy, blockage relationship to important collaterals, renal function, vascular runoff status, etiology of the obstructive process, available vascular access sites, and the patency duration requirement. Other variables that may influence physician treatment strategies include ease of use, outcomes data, physician reimbursement, and procedural cost.

In this discussion, we will classify the various therapeutic options into three categories—yesterday's technology, niche use, or workhorse.

—Gary M. Ansel, MD

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Dr. Ansel is System Medical Chief: Vascular Services at Ohio Health/ Riverside Methodist Hospital in Columbus, Ohio. He has disclosed that he is a paid consultant for Cook Medical as well as a Co-Principal Investigator for the Zilver PTX trial, and serves on the advisory board for Gore & Associates, Boston Scientific Corporation, Cordis Endovascular, Abbott Vascular, Covidien, Bard Peripheral Vascular, and Idev. He has also disclosed stock ownership in Flexible Stenting Solutions.

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EXERCISE THERAPY AND CILOSTAZOL

Niche Use

Dr. Ansel: Certainly, with access to supervised vascular rehabilitation, this avenue has shown promise for the motivated claudicant patient and should be considered as a first-line treatment strategy.[2] However, due to the lack of reimbursement, the logistics of travel, and the time commitment involved, this treatment strategy has a limited application. Likewise, cilostazol and, to a lesser degree, statins have demonstrated efficacy in up to 50% of the patients who are able to tolerate these medications.[3-5] Medication and exercise efficacy is typically limited to a doubling of the walking distance.

Niche Use

Dr. Gray: There is little question that superficial femoral artery (SFA) patients don't die from their SFA disease—they die from cardiovascular complications of myocardial infarction, stroke, and other related illnesses. Therefore, secondary prevention strategies are critical for these patients. The severity of the clinical presentation with peripheral arterial disease predicts patients' ultimate outcomes, and those outcomes may be modified by medical therapy.

Exercise is a component to any therapeutic plan for a peripheral arterial disease patient. But to be fair, even if you get a good effect from exercise, you may only double walking distance. For somebody who is already experiencing claudication after one block in New York City, that's not going to get you very far. For many people, that is significantly limiting.

If you're less limited in your initial presentation, you may be able to get adequate ambulation. I think the bottom line is that exercise and medical therapy are important components, but they may not replace a need for revascularization because of continued lifestyle limitation.

Niche Use

Dr. Scheinert: There's no question that, particularly for patients with claudication, exercise therapy is a first-line option. It is an option for patients in a good general medical condition. We certainly attempt treatment with structured exercise plans and/or the addition of cilostazol. For medical therapy, many patients actually suffer from unwanted side effects, which reduces compliance to take this medication. There are of course patients who benefit from taking these drugs. The problem with exercise is that many of these patients are not suitable candidates due to comorbidities. In real practice, in our patient cohort, exercise is only applicable to a small number of patients.

BALLOON ANGIOPLASTY

Yesterday's Technology

Dr. Ansel: Although balloon angioplasty has been the cornerstone of endovascular therapy for the femoropopliteal region, we are seeing it slowly vanish as newer technology demonstrates superior efficacy. Since the VIVA group's objective performance criteria were published utilizing both line-item data and literature comparisons showing a combined patency rate of 33% at 1 year for somewhat simple disease, this treatment modality has been increasingly replaced by more effective approaches.[1] Currently, only patients with very focal lesions would appear to routinely be potential candidates for standalone angioplasty, and even this appears to be in question with the results of the Zilver PTX trial.

Workhorse

Dr. Gray: I think for selected, short lesions, POBA is quite effective. Especially for traditional no-stent zones (popliteal artery, common femoral junctions, etc.), angioplasty may be adequate for short-segment occluded stenoses. After atherectomy, POBA is helpful and can provide a stent-like result, reducing the need for stent placement after atherectomy, as has recently been demonstrated with several atherectomy devices. As drug coating comes down the road, I think you are going to see angioplasty replaced by those antiproliferative balloon and stent therapies, possibly as adjuncts to other revascularization therapies.

Yesterday's Technology

Dr. Scheinert: Balloon angioplasty is no question the basic interventional treatment modality after wire crossing to open up a vessel. However, as a standalone therapy, it has only value for short focal lesions (shorter than 4 or 5 cm). For longer lesions, the restenosis rate is just too high to offer this as a standalone solution.

ATHERECTOMY

Niche Use

Dr. Ansel: The recently presented DEFINITIVE LE trial findings were certainly a step forward for data on the atherectomy front.[6] Although we still need a randomized data set to help us compare patency with angioplasty, the ultrasound core lab patency rate of 78% for directional atherectomy gives us some insight as to what to expect for patency of the lesion types enrolled in this study. However, we will also need to continue to be selective, because there was a reported combined perforation and distal embolization rate of 9.1%. Also, recently presented data on orbital atherectomy (CONFIRM trial) have demonstrated high procedural

success with minimal dissection, leading to low bailout stenting.[7] Until there are data on the combined use of DEB and atherectomy (trials have started in Europe), these devices appear to still be niche devices for certain challenging lesions or as debulking devices before stent placement in lesions that are expected to be resistant to balloon dilation.

Niche Use

Dr. Gray: Atherectomy can be useful for long diffuse disease and heavily calcified disease. Because there is a lot of that kind of disease in the patient populations that we see in a tertiary referral center, we tend to use a fair bit of atherectomy. However, it may be more of a niche product for many physicians who want to use it just for short focal calcification or for no-stent zones.

Niche Use

Dr. Scheinert: The utilization of atherectomy in Europe and generally outside of the United States is lower than it is in the United States. This is in part related to the early availability of other devices in Europe, which became available at a much later stage in the US. Conceptually, atherectomy is a good way to remove the plaque rather than just pushing it away with a balloon; however, the clinical evidence around this technology is still very limited. Personally, I think atherectomy procedures have certain disadvantages because they prolong the procedure, they can potentially add complications, and they certainly add procedural cost. At the moment, this makes it a niche technology for very select lesion subsets.

BARE-METAL STENTS

Niche Use

Dr. Ansel: Since the first BMS, such as the balloon-expandable Palmaz stent (Cordis Corporation, Bridgewater, NJ), the self-expanding Wallstent (Boston Scientific Corporation, Natick, MA), and IntraCoil stent (no longer available), technology has continued to evolve. Self-expanding tubular nitinol stents demonstrated an improved ability to be placed accurately and demonstrated improved patency for all but simple lesions compared to balloon angioplasty.[8-10] The next generation of femoropopliteal BMS are focusing on increased radial strength while at the same time adapting to the various external forces exerted on this vascular bed.

The recently released core lab–controlled registry results for the Supera stent (Idev Technologies, Inc., Webster, TX), with a 1-year patency of 80% and no stent fractures, appear very promising.[11] Even with the approval of DES, this flexible stent may continue to find utilization, especially in very resistive calcified lesions because it resists compression better than all the other currently approved stents. Its shortcoming is primarily centered on the lack of precise placement at the proximal end. Typically, this stent has been utilized in the popliteal and adductor canal areas, where significant calcification and compression are more common.

Workhorse

Dr. Gray: I think BMS technology is clearly still a workhorse for subintimal recanalizations and heavily calcified lesions that require some additional scaffolding. Different types of stents will satisfy a lot of the requirements we have for our interventions today. The question will be, how much better can Zilver PTX improve overall long-term durability? In the Zilver PTX trial, the outcomes were much better than the bare Zilver. But how does that fit in the larger pantheon of BMS that are not Zilver comparators? Clearly a biologic effect is going to displace a lot of BMS use.

Yesterday's Technology

Dr. Scheinert: BMS are certainly still a primary therapy option for the femoropopliteal space. I think the wider use of BMS has certainly contributed to better results in the femoral arteries. More patients are being considered for interventional techniques based on the availability of BMS. However, for longer stented segments, the restenosis rate is still considerably high. It seems to me that we have reached a point where BMS on their own cannot perform well in terms of results.

COVERED STENTS

Workhorse

Dr. Ansel: Stent grafts have undergone a significant change in engineering design and outcomes in the last few years. The randomized VIBRANT trial (Gore & Associates, Flagstaff, AZ) demonstrated focal edge restenosis in the stent graft group, but no improvement was demonstrated in primary or secondary patency compared to bare-metal nitinol stents for long, complex femoropopliteal disease.[12] Since the completion of VIBRANT, stent grafts have undergone design changes and now have a contoured proximal edge (where 60% of restenosis occurs) and added heparin bonding. The VIPER registry trial (Gore & Associates), with similar patient and lesion criteria as the VIBRANT trial, demonstrated an improved primary patency rate of 79% at 1 year. In a retrospective angiographic core lab review, a patency rate of 90% was found when the device was sized appropriately.[13] Although no difference in acute limb ischemia due to thrombosis was found in the

VIBRANT trial, this concern still appears to hold back universal uptake.

Niche Use

Dr. Gray: A unique aspect of covered stents is that they do not lose patency by length. The patency of a covered stent is not determined the way it is for most other stenting—by the length of the lesion that it is covering; it is determined by vessel preparation and the proximal edge patency. We've used it as a niche tool for aggressive restenotic patients, but there are other people who use it as a workhorse. It depends a little bit on your patient population. In some patient populations, it's difficult to get routine follow-up. I believe that when one of the outcomes of a restenotic stent could be acute thrombosis, that patients should be monitored closely using noninvasive testing. In certain segments of any patient population, patients travel a fair distance for treatment and follow-up, which is one of the reasons that some may hesitate to use covered stents. But it is a good device and has patency effects, especially for the long lesion. In the most recent VIPER trial, the average lesion length was up to 20 cm; in most BMS trials, they're between 5 and 10 cm. For lesions longer than 10 cm, data are largely lacking for BMS, but we have good data on covered stents.

Niche Use

Dr. Scheinert: Covered stents are probably less frequently used in Europe than the United States. One of the main reasons is the associated cost for the devices and limited reimbursement. I think they have great promise for long lesions because the restenosis rate does not seem to be directly related to the lesion length, as it is with other stent devices. I see it more as a niche indication; specifically for long lesions, it is appealing.

DRUG-ELUTING STENTS

Workhorse

Dr. Ansel: With the recent results of the Zilver PTX trial, in which the device demonstrated improved patency compared to both balloon angioplasty and bare-metal stenting, the treatment paradigm is set to change, just as coronary stent treatment did when drug elution became available. Both short- and long-term patency and freedom from target lesion revascularization have been significantly improved at up to 3 years with a > 45% reduction in repeat revascularization.[14] When restenosis does occur, it appears to be more focal and less diffuse, which may lead to simpler repeat procedures.

The effect of lesion length is even more interesting with DES technology. Even though the FAST trial did not demonstrate improved patency for BMS compared to balloon angioplasty for focal stenoses, the randomized Zilver PTX technology has demonstrated a significant improvement in both patency and target lesion revascularization. Generalization of these results to more complex disease has been looked at in a large multinational study, and the patency and target lesion revascularization curves appear to be very similar to the randomized trial.[15] Subgroup analysis has demonstrated efficacy in patients with diabetes as well as challenging lesions. It is certainly expected that future DES development will follow a pathway similar to that seen in the coronaries, with more flexible stent platforms, newer drugs, and new release mechanisms to be tested.

Workhorse

Dr. Gray: In Europe, they haven't had great penetration, but I'm not sure how much of that is related to the reimbursement landscape. There are good data now from Zilver PTX and the Zilver registry that suggest its utilization should be higher than it is today. While SFA drug-eluting stents have been given a special ICD-9 code for monitoring, there is currently no additional reimbursement over and above other therapies. I think use will pick up if CMS grants additional reimbursement. Where the price ultimately settles will also affect the uptake in the United States.

Workhorse

Dr. Scheinert: I think DES have shown very good results throughout different lesion subsets within randomized trials for short lesions as well as in the world wide registry setting for challenging, real-world lesions. I think they are certainly a first-line treatment option for a wide range of lesions.

DRUG-ELUTING BALLOONS

Workhorse

Dr. Ansel: Multiple DEB platforms have been introduced outside of the United States. Not all of these technologies have been successful, although the majority have demonstrated improved patency in randomized trials compared to balloon angioplasty.[16,17] This treatment option appears to reduce restenosis by decreasing vascular recoil, vessel atresia, and intimal hyperplasia associated with balloon angioplasty. Unlike DES, there is no scaffold to help with the treatment of dissection, and the exact vessel characteristics that may effectively be treated with this approach have yet to be fully defined.

The available technology in Europe may not always be applicable in the United States, as standards for particulate embolization, coating uniformity, etc., seem

to be more stringent. The first two drug-eluting balloon trials LEVANT 2 trial (Bard Peripheral Vascular, Inc., Tempe, AZ) and IN.PACT (Medtronic, Inc., Minneapolis, MN) have recently completed enrollment, and we await patency results. We will look to our European colleagues to give us early insight as to the potential efficacy of bailout stenting and concomitant atherectomy use with DEB.

Niche Use

Dr. Gray: I think as people gain experience with Zilver PTX and other antiproliferative therapies in the next 3 to 5 years, there will be a shift. The nonantiproliferative, nonbiologic solution for most of what we do today in the SFA and popliteal will become a basic, biologic, antiproliferative solution.

Unfortunately in Europe, physician use of DEB has been limited by the reimbursement environment, which limits our "preview" of these therapies. This is shifting a little, so we'll hope to have increasing output from them in terms of what they think of the device. Having said that, the European physicians say that they like DEB for a variety of applications typically not requiring stents, such as diffuse disease, shorter length lesions, nonheavily calcified lesions where dissection may not be as big an issue, and dissection is being managed conservatively when it occurs.

There are other technologies that may help potentiate the use of DEB. For example, there is a new device currently in testing in Europe called the Tack-It (Intact Vascular, Wayne, PA), which allows for a very short segment (approximately 6 mm) of stent length. That may be very useful in a segment of DEB where placing a long stent is not preferable, but where it is necessary to secure a short segment of the vessel with dissection.

Workhorse

Dr. Scheinert: DEB are clearly getting more and more traction in the field of peripheral endovascular procedures, particularly in Europe because a variety of devices is commercially available. I think the current evidence mainly refers to shorter lesions where DEBs have been shown to be clearly more effective than plain balloons. However, I think the greatest promise is for longer complex lesions where they might be an important way to improve results and eliminate the need for long, full-metal jacket stenting. Clearly, there is still a lot of need for scientific data specifically looking at those lesion subsets. ■

1. Rocha-Singh KJ, Jaff MR, Crabtree TR, et al; Viva Physicians, Inc. Performance goals and endpoint assessments for clinical trials of femoropopliteal bare nitinol stents in patients with symptomatic peripheral arterial disease. Catheter Cardiovasc Interv. 2007;69:910-919.
2. Leng GC, Fowler B, Ernst E. Exercise for intermittent claudication. Cochrane Database Syst Rev. 2000;(2):CD000990.
3. Dawson DL, Cutler BS, Meissner MH, Strandness DE Jr. Cilostazol has beneficial effects in treatment of intermittent claudication. Circulation. 1998;98:678-686.
4. Money JR, Herd JA, Isaacsohn JL, et al. Effect of cilostazol on walking distances in patients with intermittent claudication caused by peripheral vascular disease. J Vasc Surg. 1998;27:267-274.
5. Carlon R, Zanchetta M. Statin therapy enhance benefit of exercise training in patients with claudication intermittens. Vasc Endovascular Surg. 2008;42:296-297.
6. Garcia L. Definitive LE trial results. Presented at: VIVA; October 2012; Las Vegas, NV.
7. Das T. Confirm trial results. Presented at: VIVA; October 2012; Las Vegas, NV.
8. Krankenberg H, Schlüter M, Steinkamp HJ, et al. Nitinol stent implantation versus percutaneous transluminal angioplasty in superficial femoral artery lesions up to 10 cm in length: the femoral artery stenting trial (FAST). Circulation. 2007;116:285-292.
9. Laird JR, Katzen BT, Scheinert D, et al; RESILIENT Investigators. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc Interv. 2010;3:267-276.
10. Schillinger M, Sabeti S, Loewe C, et al. Balloon angioplasty versus implantation of nitinol stents in the superficial femoral artery. N Engl J Med. 2006;354:1879-1888.
11. Rosenfield K. Superb trial 1 year results. Presented at: VIVA; October 2012; Las Vegas, NV.
12. Ansel G. VIBRANT trial 3 year results. Presented at: VIVA; October 2012; Las Vegas, NV.
13. Saxson R. VIPER trial 1-year results. Presented at: VIVA; October 2012; Las Vegas, NV.
14. Dake MD, Ansel GM, Jaff MR, et al; Zilver PTX Investigators. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4:495-504.
15. Dake MD, Scheinert D, Tepe G, et al; Zilver PTX Single-Arm Study Investigators. Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. J Endovasc Ther. 2011;18:613-623.
16. Werk M, Langner S, Reinkensmeier B, et al. Inhibition of restenosis in femoropopliteal arteries: paclitaxel-coated versus uncoated balloon: femoral paclitaxel randomized pilot trial. Circulation. 2008;118:1358-1365.
17. Cassese S, Byrne RA, Ott I, et al. Paclitaxel-coated versus uncoated balloon angioplasty reduces target lesion revascularization in patients with femoropopliteal arterial disease: a meta-analysis of randomized trials. Circ Cardiovasc Interv. 2012;5:582-589.

Why Drug-Eluting Stents Are Cost Effective in the Superficial Femoral Artery

The importance of cost effectiveness in health care is accelerating. Implanting drug-eluting stents in the superficial femoral artery may offer a safe, effective, and economically valuable solution.

BY MARK W. BURKET, MD

Consideration of cost and value has entered the field of medicine in an unprecedented fashion in recent years. As never before, concern over health care affordability pervades political rhetoric, corporate analysis, and family budgets. In the United States and elsewhere, the availability of more varied and expensive treatment options has fostered a situation in which health care costs consume a greater and greater proportion of the gross domestic product. This process has occurred simultaneously with economic slowdown in the United States and other countries, compounding the pain. It has become clear to any serious analyst that this is an unsustainable formula. It is therefore not surprising that treatment options are held to a higher standard than in years past. No longer is "safe and efficacious" sufficient; therapy must now provide value in measurable economic terms.

Although these principles apply in all fields of medicine, intense interest has recently been focused on the application of drug-delivering balloons and stents in the lower extremity vasculature. With US Food and Drug Administration (FDA) approval of the Zilver PTX stent (Cook Medical, Bloomington, IN) on November 14, 2012, it is hard to imagine a more relevant time for these discussions. Regulatory agencies in certain countries outside the United States had already approved this paclitaxel-eluting stent, as well as paclitaxel-coated balloons. Thus, health care providers have been grappling with the issues of cost and value of paclitaxel delivery for several years.

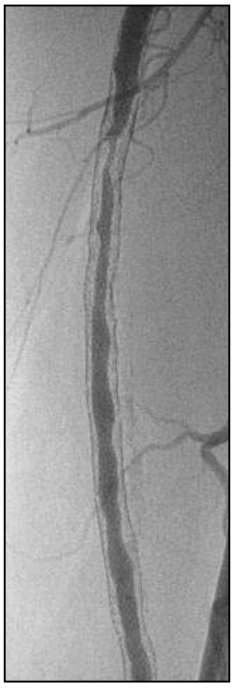

Figure 1. Bare-metal nitinol in-stent restenosis.

WINNERS AND LOSERS?

The efficiency of paclitaxel-coated stents in reducing restenosis is no longer a subject of debate.[1] By 24 months, the reduction in reintervention rates was 54% compared to bare-nitinol stents.[2] At first glance, a reduction in restenosis (and target lesion revascularization [TLR]) may seem to be a good thing for all involved parties. But this may not be the case. Without question, patients are the beneficiaries of coated stents. When this therapy is used, there is a lower chance of restenosis. This means that the patients may avoid recurrent painful symptoms, restriction of activity, and the inconvenience of returning for testing and treatment. If additional procedures are avoided, patients also completely sidestep any additional expenses and the potential for procedural risk. Winners indeed.

The next big winner is whoever foots the bill for TLR. This may be any or all of the following: Medicare, private insurance companies, or the patient. Each case of revascularization that doesn't occur represents 100% savings to those who would have paid.

For the physician, the effects of this new technology are mixed. On the one hand is the satisfaction that comes from knowing that optimal care has been delivered, providing the best chance of a favorable outcome. In economic terms, however, the physician may become a loser. Physician payment is the same for drug-eluting stent placement as for bare-metal stent placement. By passing up on a possible repeat

"Hospitals that offer treatment with coated stents will clearly have an edge in marketing their services to savvy customers who appreciate the definite benefit offered in terms of less restenosis. This provides the potential of growth in patient volume."

intervention, the interventionist also passes up on any potential fee for service. Even in systems where doctors are salaried, their income may be tied to procedural volume. For physicians in training, a reduction in cases of restenosis translates into less hands-on experience, especially in those techniques closely associated with TLR, such as atherectomy, laser, embolic protection, and covered stent placement.

At first glance, paclitaxel-coated stents may represent an economic hardship for hospitals. The price premium for these stents is approximately 33% when compared to bare-metal stents of comparable size. Fortunately for hospitals, this premium is quite modest compared to what was seen with coronary drug-eluting stents when they were first introduced. At that time, the associated price premium was approximately 170%.[3] In striking contrast to what happened in 2003 with the advent of drug-eluting stents for the coronary arteries, Medicare is tracking peripheral DES usage with a special code to consider supplemental reimbursement in the future, and has not yet made provision to reimburse hospitals at a higher level for the use of drug-eluting stents in the femoral artery. Thus, the price premium, although more modest than that seen a decade ago, falls on the shoulders of the hospital budget.

Hospitals take a second hit financially in that the loss of TLR cases represents a loss of revenue. In essence, the more effective an antiproliferative therapy is, the more potential revenue the hospital loses.

The financial impact on hospitals for adopting drug-eluting stents may not be all negative. Hospitals that offer treatment with coated stents will clearly have an edge in marketing their services to savvy customers who appreciate the definite benefit offered in terms of less restenosis. This provides the potential of growth in patient volume. Encouraged by the possibility of better outcomes, physicians may also be willing to perform interventions on patients who would have been managed medically in the past. Reimbursement models are in rapid flux, with a clear emphasis on tying outcomes to reimbursement, such as is seen in heart failure, myocardial infarction, and pneumonia. Drug-eluting technologies fit well into these efforts to align incentives among payers, caregivers, and patients. This strategy is perfectly consistent with the accountable care organization (ACO) model.

COST ESCALATION TO TREAT RESTENOSIS

One of the most underappreciated aspects of femoropopliteal intervention is the degree to which treatment cost increases on second and subsequent procedures. Nearly everyone who treats peripheral vascular disease has an appreciation for the diffuse nature of atherosclerosis affecting the femoral artery. Similarly, it is common knowledge that mechanical stresses on this vessel can lead to stent disruption and loss of patency. These characteristics result in some of the highest restenosis and reocclusion rates of any commonly treated vessel (Figure 1). What is surprising is the void of knowledge that exists about the cost of treatment.

Few interventionists can cite the cost of initial or subsequent treatment of femoropopliteal disease with confidence. We have evaluated representative costs in our institution (University of Toledo Medical Center) and have found that for a typical, straightforward angioplasty and stent placement, the cost is approximately $7,000 to $8,000. These figures are based on actual hospital cost (not charges), plus calculated overhead for such things as nursing care, housekeeping, utilities, etc. Physician reimbursement at Medicare rates is included. Costs change extensively based on patient, physician, and hospital variables. Transatlantic Intersociety Consensus (TASC) type D disease treatment consumes much more interventional equipment than a simple type A stenosis. Physicians may prefer angioplasty, stent placement, or atherectomy as a primary treatment strategy, with progressively increasing costs.

Until recently, the dramatic escalation of cost to treat in-stent restenosis has been unappreciated. Increases come at nearly every phase of reintervention. There is wide variation among operators with

"For a relatively modest increase in purchase price, extremely expensive follow-up care may potentially be avoided."

regard to treatment strategies, but most United States operators will choose a method other than balloon angioplasty as the initial treatment. In every case, anything other than balloon angioplasty is much more expensive. In the current era, balloons have become commodities, with prices now typically around $150, a fraction of what they were in the past. In contrast, devices used to debulk in-stent lesions have price tags that are approximately 20 times as high. Prices vary with individual hospital contracts, but approximate costs for debulking tools range from $2,400 for a simple laser catheter (with an extra $500 for the "Turbo Booster" option) to about $3,200 for directional atherectomy or Jetstream atherectomy catheters (Bayer, Warrendale, PA). With any of these options, it has now become commonplace to use embolic protection devices, which cost roughly $1,650.[4] Cutting or scoring balloons may also be used to disrupt the integrity of neointimal hyperplasia, rendering it more amenable to final treatment.

Debulking is viewed by many operators as necessary but not sufficient to fully treat in-stent restenosis. After debulking, some operators choose to reline the vessel with bare-nitinol stents, although there are significant concerns about the durability of this approach. Rarely is it possible to limit stent length to what was originally used. Often, more or longer stents are used, bringing a higher stent cost on repeat procedures as well as worse outcomes that have been associated with adding more stented length.[5] Another popular approach has been to debulk the restenosis, then reline the vessel with a polytetrafluoroethylene (PTFE)-covered stent. This was the basis of the SALVAGE trial (A Prospective, Multicenter Trial to Evaluate the Safety and Performance of Spectranetics Laser With Adjunct PTA and Gore Viabahn Endoprosthesis for the Treatment of SFA In-Stent Restenosis), initiated by VIVA Physicians, Inc. In this study, laser treatment was followed by placement of Viabahn PTFE-covered stent grafts (Gore & Associates, Flagstaff, AZ). Viewed from a financial perspective, this treatment carries a huge cost, as stent grafts cost in excess of $3,000 apiece. In SALVAGE, 27 patients were enrolled, compared to an original target of 100.[6] One-year primary patency (based on a peak systolic velocity ratio of 2) was 48%.

These examples highlight how rapidly cost escalates with repeat femoropopliteal intervention. Not only is the price of each piece of equipment a multiple of the simpler initial tool, but these more expensive devices are typically used in combination, exponentially driving up cost. For the most part, these aggressive strategies lack clinical trial results proving efficacy. Although they seem logical, they are unproven.

WORST CASE SCENARIOS

Most physicians familiar with treating femoral disease has had the experience of treating patients with repeated episodes of treatment failure. Initial intervention is followed by restenosis or occlusion, prompting a second, more complex procedure. This may then fail in a shorter time interval, initiating what amounts to a cascade of events, with repeated interventions of increasing difficulty separated by shorter and shorter times. Robinson has shown that early failure is predictive of additional failure.[7]

The outcomes of these cascades are uniformly unfavorable. Some patients will be left with continued symptoms from chronic occlusion. Others will require bypass surgery, with hospital costs far in excess of percutaneous procedures. We recently reviewed the cost of repeat interventions in our hospital, for example, and found that a representative case in which bypass surgery was required carried an actual hospital cost (not charge) of $11,035. When coupled with unavoidable overhead costs (eg, nursing services, housekeeping, utilities, etc.) of $6,747 and physician Medicare reimbursement of $1,540, the total came to $19,322. Because this price is added to all previous percutaneous treatment, it clearly highlights an onerous cumulative cost. Furthermore, this assumes an uncomplicated hospital course. When wound infection or other untoward events occur, this burden is increased in multiples.

Even worse than all of the previously described scenarios are those that end in amputation. Although on first glance this may appear to represent a solution to intractable vessel occlusion, it comes at a horrific cost. Dillingham found that of patients who underwent

amputation, 26% required an additional amputation, and 36% had died by 1 year.[8] Major amputation is associated with first-year costs of $40,000 to $45,000, with structured rehabilitation doubling the cost.[9] It is clear that whereas the operative procedure may appear simple, the financial and functional fallout is awful and should be minimized if at all possible.

AN OUNCE OF PREVENTION

If the ancient adage "an ounce of prevention is worth a pound of cure" applies in any medical context, it certainly does in the treatment of the superficial femoral artery. What the previous discussion has shown is that the cost of retreatment of this vessel dwarfs the cost of the first procedure. Any mechanism by which a second procedure can be avoided multiplies financial savings. The Zilver PTX stent has been shown to reduce TLR by more than 50%, at a cost premium of approximately 33%. Therefore, for a relatively modest increase in purchase price, extremely expensive follow-up care may potentially be avoided.

It may be helpful to put this topic in the context of coronary artery disease. When drug-eluting stents first became available, the associated price premium was approximately 170%. Despite this cost increase, studies have supported their cost-effectiveness.[10] At the same time, treating coronary in-stent restenosis is typically relatively straightforward. Unlike femoral in-stent restenosis treatment, there is almost never use of laser atherectomy, embolic protection, or stent grafts. Thus, coronary drug-eluting stents came at a strikingly higher price premium than their femoral counterpart, preventing a problem that is much easier and cheaper to treat and yet still had favorable economics. How much more favorable is a stent that comes at a lower incremental cost and effectively prevents the need for exceptionally expensive treatment?

SUMMARY

With FDA approval of the Zilver PTX stent, physicians have received an effective tool to help minimize one of peripheral intervention's most vexing and costly problems. This can bring substantial economic and quality-of-life value to patients and has the potential to reduce overall expenditures in the management of peripheral arterial disease. ■

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1. Dake MD, Ansel GM, Jaff MR, et al. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropoliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4:495-504.
2. Burket MW. What is the potential economic impact of antiproliferative technologies in the SFA? Presented at: TransCatheter Therapeutics; October 22-26, 2012; Miami, FL.
3. Venkitachalam L, Lei Y, Stolker JM, et al; EVENT Registry Investigators. Clinical and economic outcomes of liberal versus selective drug-eluting stent use: insights from temporal analysis of the multicenter Evaluation of Drug Eluting Stents and Ischemic Events (EVENT) registry. Circulation. 2011;124:1028-1037.
4. Shammas NW, Coiner D, Shammas GA, et al. Distal embolic event protection using excimer laser ablation in peripheral vascular interventions: results of the DEEP EMBOLI registry. J Endovasc Ther. 2009;16:197-202.
5. Scheinert D, Scheinert S, Sax J, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005;45:312-315.
6. Laird JR, Yeo KK, Rocha-Singh K, et al. Excimer laser with adjunctive balloon angioplasty and heparin-coated self-expanding stent grafts for the treatment of femoropopliteal artery in-stent restenosis: twelve-month results from the SALVAGE study. Catheter Cardiovasc Interv. 2012;80:852-859.
7. Robinson WP 3rd, Nguyen LL, Bafford R, Belkin M. Results of second-time angioplasty and stenting for femoropopliteal occlusive disease and factors affecting outcomes. J Vasc Surg. 2011;53:651-657.
8. Dillingham TR, Pezzin LE, Shore AD. Reamputation, mortality, and health care costs among persons with dysvascular lower-limb amputations. Arch Phys Med Rehabil. 2005;86:480-486.
9. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg. 2007;45:S5-S67.
10. Cohen DJ, Bakhai A, Shi C, et al. Cost-effectiveness of sirolimus-eluting stents for treatment of complex coronary stenoses: results from the Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions (SIRIUS) trial. Circulation. 2004;110:508-514.

The Challenges of Bringing Drug Elution to the US Market

Cook Medical Vice President Rob Lyles provides insight on the approval and launch process of Zilver PTX in the United States, as well as next steps in the evolution of drug-eluting therapies.

Now that the device is approved, what's next for Zilver PTX (Cook Medical, Bloomington, IN)?

A lot—we are really excited. The fundamental shift that occurs when drug-eluting technology enters the market is so profound that it can forever change the paradigm going forward. Peripheral drug elution will likely follow a very similar path to that of coronary drug elution. As for Zilver PTX specifically, we anticipate the size range will expand. In the United States, we're working with the FDA to make longer-length Zilver PTX stents a reality.

We will also continue clinical work with the device. Dr. Scheinert just started a trial in Europe that will directly compare Zilver PTX with drug-eluting balloons in a head-to-head fashion. That's an area of great interest for interventionists.

What is the plan for rolling out Zilver PTX?

The rollout will happen in three stages. There is a postapproval study requirement in the United States, so we've decided to move ahead with that first (similar to what we did in Japan), which could involve about 16 to 20 sites. The sites that participated in the clinical trial in the United States will be next because they have the most experience with the product. This will include approximately 30 more sites. Next, we'll continue to the remaining US customers.

Most of the customers in the United States should have availability around the end of this year.

Why will it take a full year to supply the majority of the market?

This is partially because of a commitment to the postapproval study requirement. The other part, which might not be appreciated, is the time it takes to ramp up a revolutionary product such as Zilver PTX. Because we're in such a regulated industry, device manufacturers don't know exactly what the manufacturing requirements are until they receive approval. Once the final requirements are received, the process of ramping up and building out can begin.

We want to be methodical and careful about the way we roll out the device. Even though this technology focuses on ease of use for the operator, we want to make sure that it is used properly. As Zilver PTX is rolled out, training is provided to physician users. This is a technology that will be around for the long-term, and that takes time to implement. Cook has learned over our 50 years of doing business that you must take the time to launch these devices the right way.

Why did the FDA mandate the postapproval study?

Actually, this is pretty common. Most regulators around the world are starting to require some sort of postapproval study. With this type of implantable device, one must go through the proper steps to achieve approval. But once it's released to the market, most regulators want some level of surveillance to monitor longer-term effects or to get an idea of how it is performing in the real world.

In Japan, we performed a fairly large postapproval study (approximately 900 patients), and we were able to enroll that study in just 92 days. Because there was so much enthusiasm for the product, this process went very quickly.

We've heard about market concerns over the cost of drug-eluting stents before the launch. How did Cook address these concerns?

One of Cook's main considerations was to make this technology affordable and cost effective. With the pressures on the health care industry today to deliver bet-

ter outcomes for less cost, part of the innovation of this technology was enabling physicians and hospitals to utilize it at a cost that ensured wide access for patients. Clearly Zilver PTX delivers better outcomes. In terms of price, it's basically in the range of about a 30% premium compared to bare-metal stents, but significantly less than covered stents.

Also, what we're learning from physician experts who are researching the costs associated with reintervention is that Zilver PTX helps offset cost to health care providers, payers, and patients by reducing the need for costly SFA reinterventions. This makes the technology even more attractive from a cost standpoint.

In general, it is a fairly affordable entry into the market. For example, when drug elution was introduced with coronary stenting, those devices cost many times what bare-metal stents did at the time. Zilver PTX is coming in at a much lower entry point, which many believe will drive a lot of market uptake.

What is the next step in the evolution of drug-eluting therapies?

First, Cook is excited about the use of drug elution as the peripheral space absorbs its impact and as physicians start to take full advantage of the technology. We are currently the only company that offers both drug-eluting stents and drug-eluting balloons in the European peripheral market. The next phase is going to be a significant one. Everyone will begin to recognize the importance of the drug effect: if you have the opportunity to use a stent, a drug-eluting stent is likely going to work better than a bare-metal stent; if you have the opportunity to use a drug-eluting balloon, it's likely going to work better than a bare balloon.

But we've got some important questions to answer. To date, there doesn't appear to be good data to support the notion that a drug-eluting balloon performs better than a drug-eluting stent, or even a bare-metal stent. There are two paths to choose from. There's the balloon path and the stent path. Both are critical. There's a time to use balloons, and there's a time to use stents; however, it has not been demonstrated that drug-eluting balloons are powerful enough to cross over and work as well as a stent does. Currently, a long-term drug effect from a scaffold is the best option in the SFA.[1]

Once drug elution is really ingrained in the market, we're going to see a progression similar to what we've seen on the coronary side. Adoption curves for drug-elution technology may go as high as being involved in 80% to 90% of peripheral procedures. The sustained improvement from drug-eluting devices is profound, especially with the growing PAD patient population who need more durable results.[2]

Once drug elution takes hold, it's going to be adopted and penetrate the market. There are many interesting technologies evolving on both the stent side and the drug side. To give a time frame, it will still be at least 3 or 4 years until we see drug-eluting balloons become available due to the regulatory pathway involved in the United States. Bioresorbable technology is even further out—probably 5 to 8 years until it will become available on the US market.

In terms of the practical reality for a physician practicing today, Zilver PTX represents that first move into the drug-eluting world for US peripheral interventionists.

How do you see yourself competing with future technologies such as drug-eluting balloons and bioresorbable devices?

From a timing perspective, the bioresorbable devices are still a long way off. There is also the lingering question of whether it's really going to work or not. The SFA is one of the most hostile pieces of real estate in the arterial system due to the mechanics. There is still a question of whether a bioresorbable scaffold can hold up in that environment.

We're not to the place yet where the implantable device is going away anytime soon, but there's a lot of promise in this field. There's a lot to be done, and there are some technologies even beyond the bioresorbable, which are very promising. ■

Rob Lyles is Vice President and Global Leader of Cook Medical's Peripheral Intervention division.

1. Dake MD, Ansel GM, Jaff MR, et al. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare-metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4:495-504.

2. White CJ, Gray WA. Endovascular therapies for peripheral arterial disease: an evidence-based review. Circulation. 2007;116:2203-2215.

Why Drug-Eluting Stents Are My Gold Standard

Experience with patients treated with Zilver PTX.

WITH HIROYOSHI YOKOI, MD, AND FABRIZIO FANELLI, MD

Atherosclerosis is the leading cause of occlusive arterial disease, and the most frequently affected artery is the superficial femoral artery (SFA). Many authors have reported poor medium- to long-term patency in SFA angioplasty and stenting, although the immediate outcomes were generally satisfactory. Major progress has been made with endovascular therapy for the SFA, and improvements in devices and technology have resulted in an increase in the early-stage success rate, even with complex lesions. However, with bare-metal stents (BMS), there are high rates of restenosis in patients who have Transatlantic InterSociety Consensus (TASC) grade C or D lesions at least 15-cm long, suffer from microangiopathy or diabetes, are women, or are undergoing hemodialysis. In addition, if in-stent restenosis, whether occlusive or diffuse, develops, it tends to recur even if balloon dilatation is carried out, which presents major clinical problems.

Results of a randomized trial comparing the Zilver PTX drug-eluting peripheral stent (Cook Medical, Bloomington, IN) to bare-metal stents showed a patency rate of 83.4% (Zilver PTX) versus 64.1% (bare-metal stent).[1]

Zilver PTX, which was approved for clinical use in Japan in July 2012 and in the United States in November 2012, is the first drug-eluting stent (DES) for treatment of the SFA, and high expectations have been placed on its use for prevention of restenosis. DES present a novel treatment modality because of the inhibition of neointimal proliferation. The enthusiastic results of DES have led to widespread application of these devices.

SAFETY AND EFFICACY IN USING THIS DEVICE TO PREVENT RESTENOSIS

By Hiroyoshi Yokoi, MD

CASE 1: BILATERAL SFA OCCLUSION

An 80-year-old man visited the hospital with bilateral intermittent claudication and was found to have bilateral complete SFA occlusion of TASC grade D. At that time (2011), the only types of Zilver PTX that could be used at Kokura Memorial Hospital in Japan were a pair of 6-F, 60-mm stents and a 6-F, 40-mm stent, which were not adequate for this case. Three 6-F, 100-mm SMART BMS stents (Cordis Corporation, Bridgewater, NJ) were inserted for the right complete SFA occlusion. For the left complete SFA occlusion, two 6-F, 60-mm Zilver PTX stents at a proximal position, a 6-F, 100-mm SMART stent at a central position, and a 6-F, 40-mm Zilver PTX stent at a distal position were used. The patient was then discharged.

After 8 months, the patient visited the hospital again due to recurrence of bilateral intermittent claudication, and angiographic assessment was repeated. The patient's estimated glomerular filtration rate was depressed (26 mL/minute), and angiography was carried out using carbon dioxide. There was diffuse in-stent restenosis with the BMS in the right and left SFA; with the DES, no restenosis was found at the distal position in the left SFA, and only localized restenosis was found at the proximal position (Figure 1). The pattern of in-stent restenosis in the SFA is closely connected to the prognosis,[2] and these findings showed not only lower rates of restenosis with DES than with BMS, but more favorable patterns of restenosis. ■

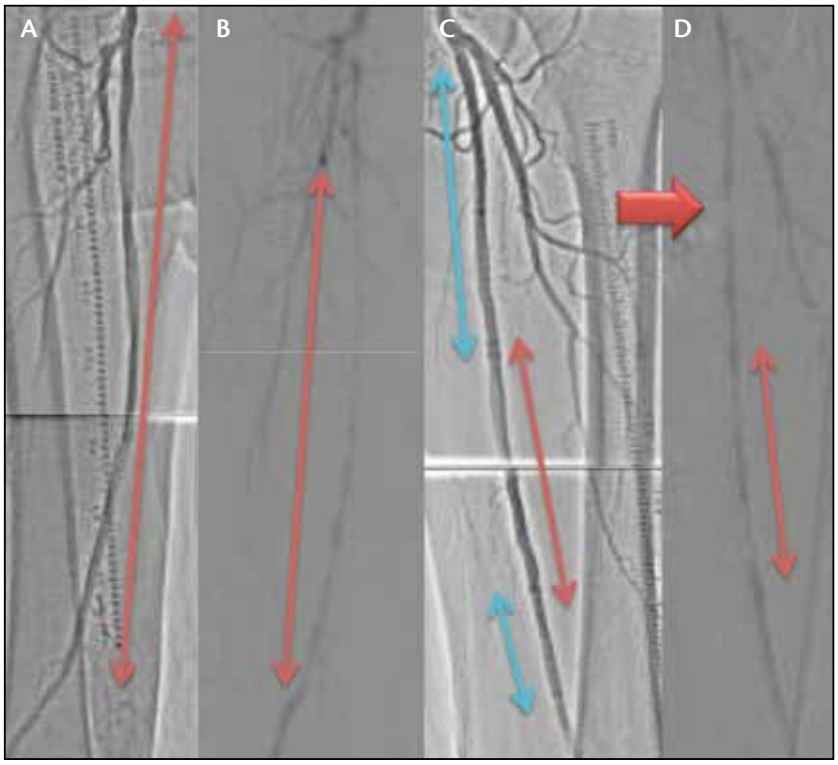

Figure 1. BMS (red arrows) after placement in the right SFA (A), showing diffuse in-stent restenosis after 8 months (B). Zilver PTX stents (blue arrows) and BMS after placement in the left SFA (C); at 8 months, findings show no restenosis in the Zilver PTX at the distal position and only focal restenosis (thick red arrow) at the proximal position, while diffuse restenosis (thin red arrow) was found in the BMS, which was placed centrally (D).

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1. Dake MD, Ansel GM, Jaff MR, et al. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare-metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4:495-504.
2. Tosaka A, Soga Y, Iida O, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol. 2012;59:16-23.

RESTORING PATENCY IN THE SFA

By Fabrizio Fanelli, MD

CASE 1: SHORT SFA OCCLUSION

A 54-year-old man with life-limiting right claudication (< 50 m) presented with several risk factors: diabetes, heavy smoking (> 30 cigarettes/day), and hypertension. In the previous 6 months, a progressive worsening of symptoms was observed. The patient was under medical therapy with statins, aspirin, and an oral hypoglycemic drug.

Clinical examination confirmed the pathological condition with an ankle-brachial index (ABI) of 0.4 on the right side and 0.9 on the left. An ultrasound color Doppler (USCD) showed an occlusion of the middle portion of the right SFA. This was confirmed with selective digital subtraction angiography (DSA), which was performed via a contralateral retrograde common femoral approach (Figure 1A).

The occlusion was managed endoluminally with a standard 0.035-inch hydrophilic Glidewire (Terumo Interventional Systems, Somerset, NJ) in combination with a straight 4-F Beacon catheter (Cook Medical).

Due to the characteristics of the lesion (short occlu-

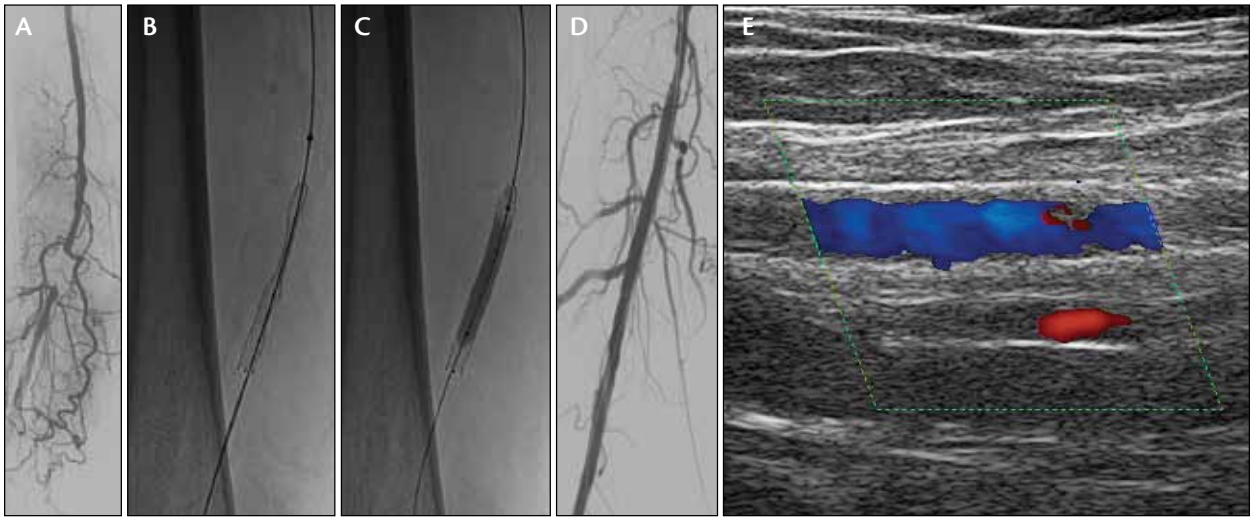

Figure 1. Occlusion of the middle portion of the right SFA (A). Insertion of 6-F, 60-mm Zilver PTX using a 7-F, 45-cm Flexor introducer (B). Postdilatation of Zilver PTX using a 5-F, 60-mm low-profile balloon (C). Final angiogram, showing good flow within the stent (D). USCD showing complete patency of the stent with no restenosis (E).

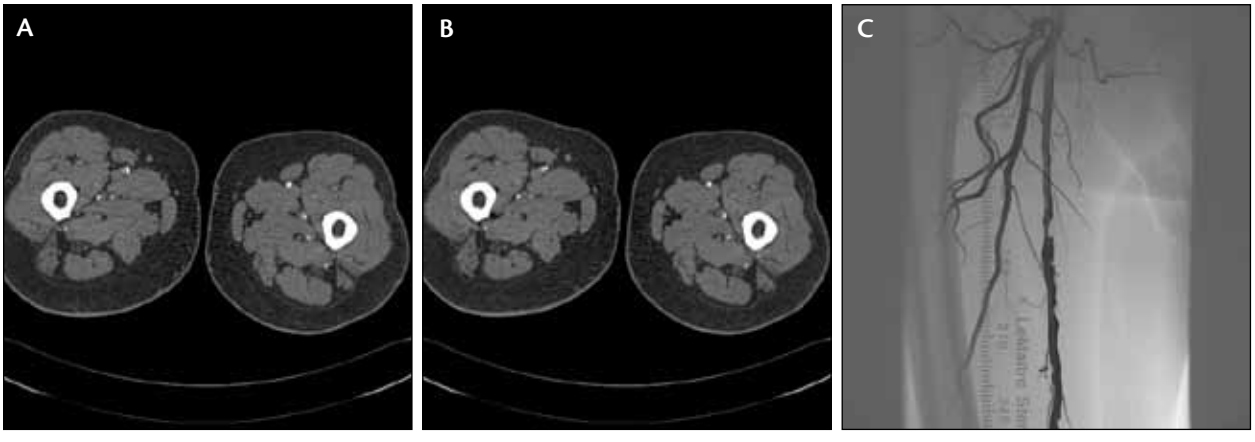

Figure 2. A preocclusive stenosis of the SFA was demonstrated on CT angiography on the axial plane (A, B) and DSA (C).

sion) and of the patient (young, with several risk factors), we decided to perform primary stent treatment. A 6-F, 60-mm Zilver PTX device was inserted through a 7-F, 45-cm Flexor introducer (Cook Medical) (Figure 1B). The stent was postdilatated with a 5-F, 60-mm low-profile Admiral balloon (Medtronic, Inc.) (Figure 1C).

The final angiogram showed a good flow within the stent and in the distal portion of the leg (Figure 1D). Clinical conditions improved immediately, with an ABI of 0.9.

After 6 years of follow-up, the patient is still asymptomatic. USCD confirmed complete patency of the stent without any sign of restenosis (Figure 1E).

CASE 2: MULTIPLE STENOSES IN THE SFA

A 57-year-old male smoker with diabetes on medical therapy with aspirin, statins, and an oral hypoglycemic drug presented with severe right claudication (< 50 m) and multiple stenoses of the SFA.

Clinical examination showed an ABI of 0.4 on the right leg and 0.9 on the contralateral side. USCD showed multiple stenosis along the right SFA. CT angiography confirmed the presence of a severe preocclusive stenosis in the right SFA. On the axial images, the lesion appeared very calcified (Figure 2A and 2B).

DSA was performed with a retrograde contralateral femoral approach using a braided 6-F Ansel Introducer (Cook Medical). Selective angiography confirmed the preocclusive stenosis of the SFA (Figure 2C). The lesion was crossed with a hydrophilic angled 0.035-inch Glidewire (Terumo Interventional Systems) in combination with a 4-F straight Beacon catheter (Cook Medical).

Due to the high quantity of calcium at the level of the lesion, we decided to avoid angioplasty to reduce the risk of dissection. Primary stenting using a Zilver PTX (6 mm X 6 cm) was performed. The selection of Zilver PTX was based on the excellent long-term results reported in the literature, especially in cases of such young patients.

Predilatation was not necessary because the stent presents a very low profile in combination with good pushability. However, a balloon postdilation (Cook Medical) was subsequently performed (Figure 3A and 3B). Final DSA confirmed complete patency of the stent, with an improve-

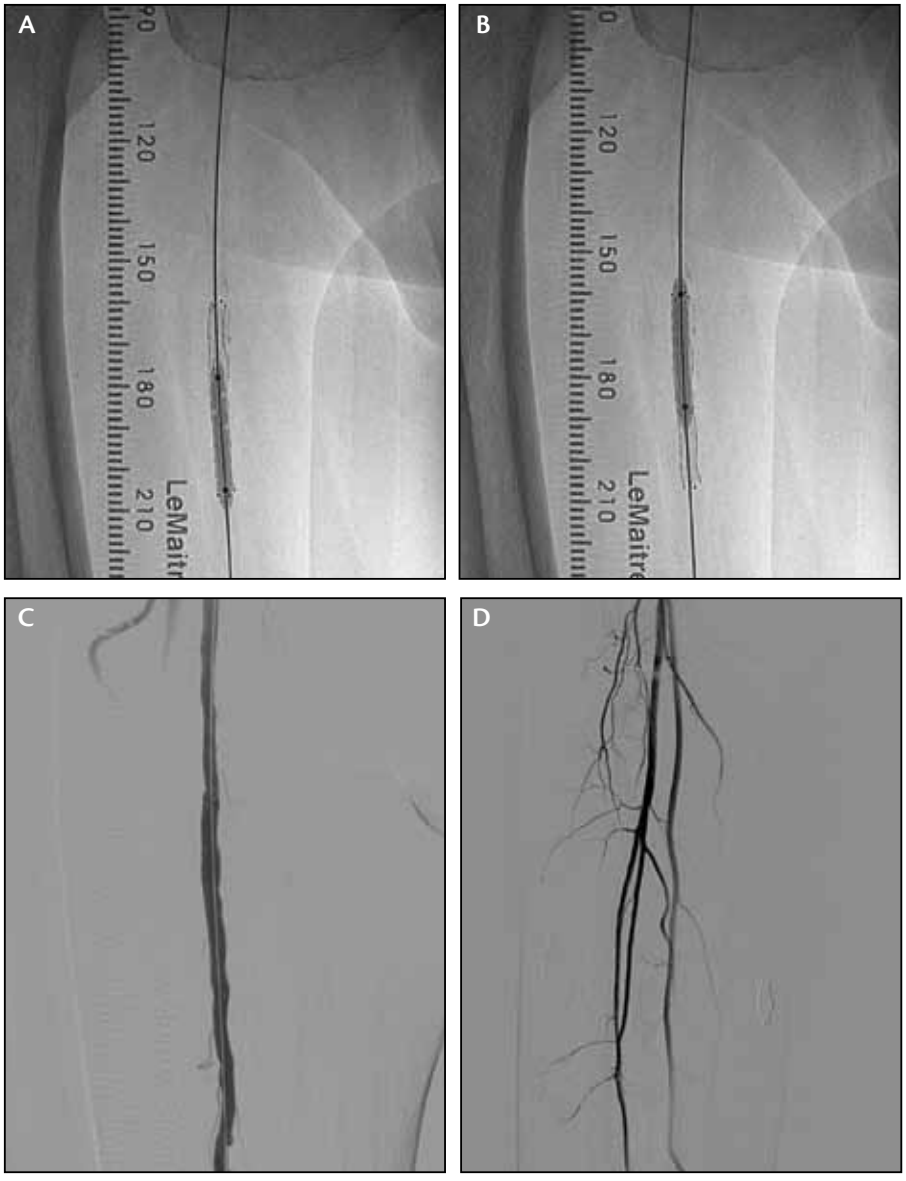

Figure 3. Postdilation of Zilver PTX performed with a low-profile balloon (A, B). The final angiogram showed a good flow within the stent (C) and an improved runoff (D).

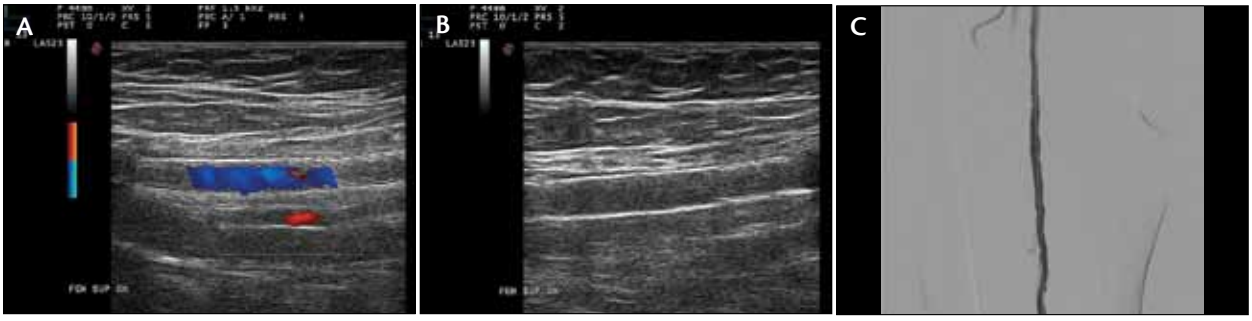

Figure 4. USCD at 3-year follow-up (A, B) and DSA at 5-year follow-up (C) showed complete patency of the Zilver PTX stent.

ment of the distal runoff (Figure 3C and 3D); ABI index improved up to 0.9. After the procedure, the patient was managed with clopidogrel for 2 months, followed by aspirin. USCD at 3-year follow-up showed complete patency of the stent. (Figure 4A and 4B).

Angiography performed at 5-year follow-up showed complete patency of the stent without any sign of intimal hyperplasia (Figure 4C). The patient's clinical conditions were good with an ABI index of 0.85 on the right side. ■

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Suggested reading:

1. Kasapis C, Henke PK, Chetcuti SJ, et al. Routine stent implantation vs. percutaneous angioplasty in femoropopliteal artery disease: a meta-analysis of randomized controlled trials. Eur Heart J. 2009;30:44-55.
2. Tepe G, Zeller T, Albrecht T, et al. Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. New Engl J Med. 2008;358:689-699.
3. Duda HS, Bosiers M, Lammer J, et al. Sirolimus-eluting versus bare nitinol stent for obstructive superficial femoral artery disease: the SIROCCO II trial. J Vasc Interv Radiol. 2005;16:331-338.
4. Dake MD, Scheinert D, Tepe G, et al. Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. J Endovasc Ther. 2011;18:613-623.
5. Dake MD, Ansel GM, Jaff MR, et al; Zilver PTX investigators. Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. Circ Cardiovasc Interv. 2011;4:495-504.
6. Lammer J, Bosiers M, Zeller T, et al. First clinical trial of nitinol self-expanding everolimus-eluting stent implantation for peripheral arterial occlusive disease. J Vasc Surg. 2011;54:394-401.

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