SIGNIFICANT UPGRADE IN THE .035” PLATFORM ARMAMENTARIUM FOR SFA INTERVENTION: THE NOVEL SABER™ .035” ANGIOPLASTY BALLOON.

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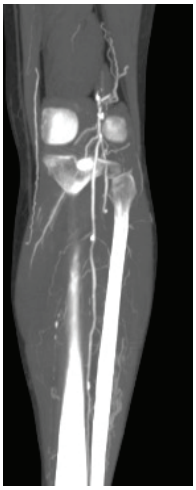
PATIENT PRESENTATION

A 79-year-old woman presented at the emergency department experiencing rest pain of the left foot and superficial peri-malleolar wounds for the past 3 months. Her risk factors were hypertension and diabetes, and she was maintained on 150mg AAS, 20mg atorvastatin, 1000mg metformin and 16mg candesartan. A CT-Angio was performed and showed an aorto-iliac sector without significant disease; significant stenosis of the proximal profunda femoral artery; CTO of the SFA (Superficial Femoral Artery) from its origin extending to the mid-popliteal artery; diffuse tibio-peroneal disease with CTO of the anterior and posterior tibial arteries and peroneal artery patent to the ankle (figure 1). A revascularization procedure was warranted, and an endovascular procedure was preferred to a femoro-peroneal bypass.

FIGURE 1: Pre-operative CT-Angio.

A. CFA (Common Femoral Artery) free of significant disease, focal significant stenosis of the proximal PFA (Profunda Femoris Artery); CTO of the SFA without a stump.



B. Restitution of SFA CTO at the level of mid-popliteal artery. Note the abnormal high origin of the anterior tibial artery (chronically occluded), total occlusion of the posterior tibial artery and calcified plaque at the tibio-peroneal trunk with peroneal artery as the unique vessel patent to the ankle.

INTERVENTION

Under local anesthesia a right femoral artery access was obtained, a crossover access to the Left External Iliac Artery was obtained and a 6-F 55cm guiding sheath was advanced over the guidewire. A diagnostic angiography was performed, confirming a CTO of the SFA without a visible stump and a focal stenosis of the proximal PFA (figure 2).

The lesion was crossed in a subintimal fashion with Roadrunner® PC Hydrophilic Guidewire (Cook Medical) and CXI® support catheter (Cook Medical), progressing to the mid-popliteal artery and regaining true lumen access distal to the anterior tibial artery origin, at the level of the knee joint. A selective contrast injection on the support catheter confirmed true lumen position and showed a pre-occlusive stenosis at the origin of the tibio-peroneal trunk that was crossed with a Glidewire Advantage® Guidewire (Terumo).

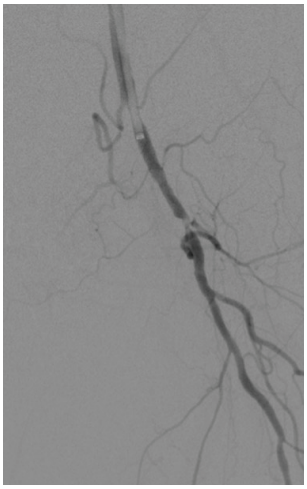
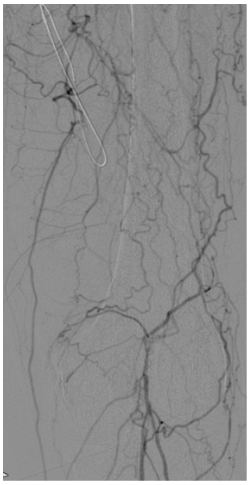
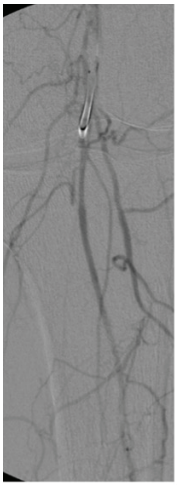


FIGURE 2: Angiographic diagnosis during the intervention, showing a pre-occlusive stenosis of the PFA and a CTO of SFA without visible stump.

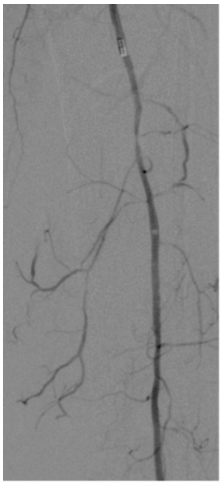
FIGURE 3: Recanalization of the lesion.



A. Sub-intimal recanalization of the SFA with angiography showing re-entry into the target vessel



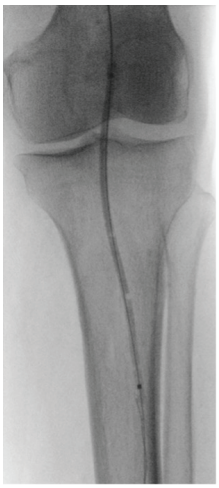
B. Re-entry site at the popliteal artery.



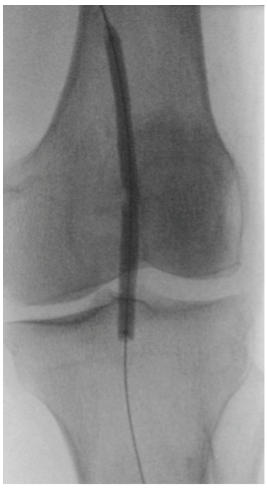
C. Selective angiography showing true lumen access and stenosis of the tibio-peroneal trunk.

Standard balloon angioplasty was performed with a 4.0 mm .035'' SABER™ PTA Balloon (Cordis) of the tibio-peroneal trunk and distal popliteal artery. The SABER™ PTA Catheter easily tracked through the SFA CTO and allowed repeated balloon inflations to open the path for further treatment options.

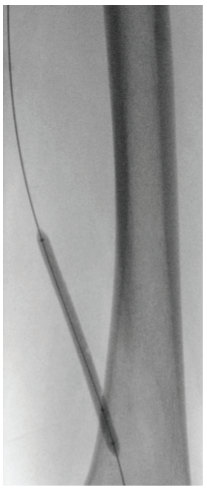
FIGURE 4: Balloon angioplasty of the lesion.



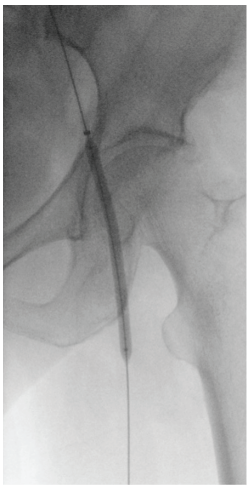
A. Angioplasty of the tibio-peroneal trunk and distal popliteal artery (4mm balloon).



B. Angioplasty of the distal popliteal artery (5mm balloon).



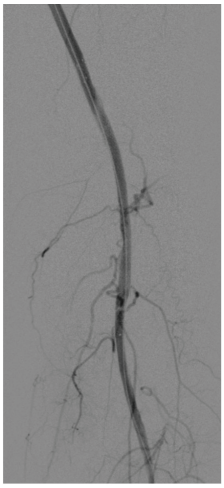
C. Angioplasty of the distal popliteal artery (5mm balloon).



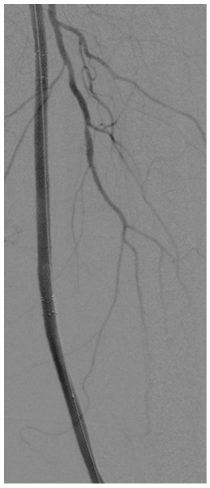
D. Angioplasty of the CFA (5mm balloon).

A control angiogram was performed and showed optimal patency of the distal popliteal artery, tibio-peroneal trunk and proximal peroneal artery although persistent stenosis of the popliteal artery at the reentry site and across the SFA lesion was noticeable, despite repeated angioplasties with 4mm and 5mm balloons. Provisional stenting was performed with drug eluting stents from the popliteal artery 2cm below the knee joint extending proximally to the CFA (5 mm diameter stent at the popliteal artery progressing to 7mm diameter stent at the CFA; 460mm total stent length) A final angiogram showed patency of the SFA, popliteal artery and tibio-peroneal trunk. A stenosis at the origin of the PFA and focal proximal stenosis of the PFA were also noticed.

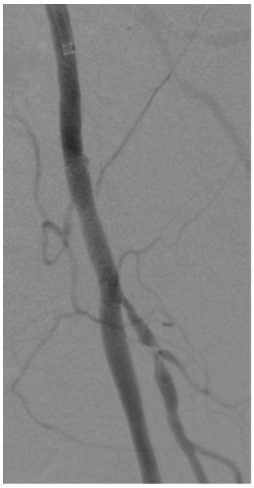
FIGURE 5: Final angiogram.



A. Control angiography of the popliteal artery.

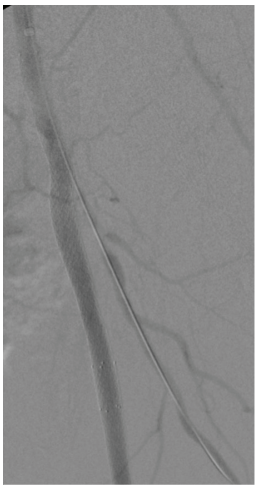


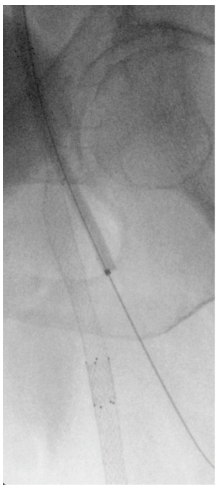
B. Control angiography of the SFA.

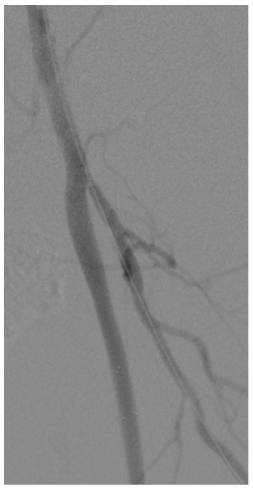


C. Control angiography of the femoral arteries, showing a stenosis of the proximal PFA.

FIGURE 6: Angioplasty of the PFA.







After the procedure significant improvement of rest pain was noted. The patient was discharged on the day after the procedure and follow-up at the outpatient clinic showed a sustained reversal of the rest pain and healing of the peri-malleolar wounds.

DISCUSSION

The SABER™ .035” PTA Catheter (Cordis) demonstrated an optimal performance in this case that compared favorably to the previous “workhorses” PTA catheter balloons available in our Department. We were able to perform the procedure on a .035’’ platform and the SABER™ .035” Balloon showed excellent trackability and ability to perform in repeated dilatations without losing ability to deflate, progress over the lesion and without balloon ruptures.