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Dual layer Supera for Popliteal Artery Aneurysms exclusion: Immediate and Long-Term Results and proof of concept

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Abstract

Objective

Popliteal aneurysms are often associated with chronic distal embolization, while rupture is rare.

Surgical bypass, interposition or covered stents are the treatments of choice. An alternative endovascular strategy is represented by using two Supera™ stents according to the principle of flow diverters, which is long since known from intracranial aneurysm treatment.

Methods

All patients presenting with an popliteal artery aneurysm showing a landing zone of <7.5mm were treated using the dual layer Supera™. Adjunctive thrombolysis was used in the emergency cases, only. Follow up included baseline duplex ultrasound with ABI measurements and at each follow-up visit. Native X-ray of the stents was made if ultrasound findings were inconclusive concerning stent integrity.

Results

Operating time was 44-76 minutes with 88% and 100% aneurysm thrombosis after 48 hours and during 6-month follow-up, respectively. The 30-day mortality was 0%, the overall mortality during follow-up was 5.8%. The 12-month primary patency (PP) was 85.3% and the secondary patency (SP) was 100%. The overall

PP was 68.9% after an average follow-up of 45.6 months. The TLR and conversion rate was 12.7%. Stent fracture or component separation was not seen, but aneurysm shrinkage in 37.4% and no growth. One below the knee amputation was performed due to diabetic foot syndrome.

Conclusion

Meanwhile several publications have proven the flow diverter concept for endovascular popliteal aneurysm repair with patency rates comparable to covered stents at significant lower costs. Zero material fatigue or fractures allowed endovascular re-do procedures and the preservation of collaterals reduced the severity of acute symptoms in case of occlusion.

Keywords: double layer Superastent, popliteal artery aneurysm, flow modulation, material fatigue, thrombus fixation

Introduction

With an incidence of 0.1%-2.8% popliteal artery aneurysm (PAA) represents the most often diagnosed peripheral aneurysm, which in 50% of cases can be found bilaterally.[1] The diagnosis of a PAA demands further diagnostic steps for existing peripheral artery occlusive disease and other aneurysmatic lesions. In 30% of patients, coincident aneurysms can be detected.[2,3] Acute thrombosis of a PAA with preexisting thrombotic lesions in the outflow vessels as a "worst case scenario" shows an amputation rate of up to 70%.[4] Contrary to aortic aneurysms, PAA rupture seems to be a rare occurence (1-5%).[5]

Surgical or endovascular treatment options as described in literature aim to exclude the aneurysm and the thrombotic material from arterial flow and thereby prevent thrombosis and to preserve the outflow vessels. In a single center pilot study in 2015,[6] and a retrospective analysis of 34 patients with long term follow-up, the feasibility of the Supera™ Nitinol woven stent (Abbott global Inc.; Ill., USA) could be demonstrated. Laboratory tests with a single layer and double layer Supera stent in aneurysm models built according to original CT scans could prove the underlying concept of flow diversion in a PAA.[7]

Technical description of the method and underlying technical concept

Flow modulating bare metal stent devices are routinely used in intracranial vasculature based on a proven concept,[8,9] with clinical effectiveness and durability to prevent fatal rupture. For peripheral aneurysms this concept has been hardly realized. Meanwhile, lab tests from the University of Twente have proven the effectiveness of the dual woven Nitinol stent for this purpose in the laboratory, and there are promising clinical results from a single center series with mid- to long-term follow up.[7,10]

The Supera™ woven Nitinol Stent (ABBOTT Medical, Abbott Park, Ill., USA) was used for PAA treatment as a double layer stent system. In elective cases, a minimum of two stents are implanted using a telescope technique (Figure 1, right) to achieve stent overlap over the complete length of the aneurysm. Due to its three-dimensional flexibility, the stent can accommodate varying vessel diameters from 4-7.5mm, expanding to full diameter inside the aneurysm space. The first stent was anchored in the distal landing zone followed by longitudinal compression while being deployed. Ranging from the distal to the proximal landing zone as the optimal configuration was achievable with the longer stents, only (Figure 1). The second stent was deployed starting at the distal edge of the aneurysmatic segment in the same manner to guarantee full coverage of the ectatic segment with a double layer. Due to the design of the Supera™, the stent oversizing resulted in elongation, reducing the crush resistance in distal landing segments, but different from peripheral artery disease indications, without clinical relevance over the follow-up period of up to nine years. The dual layer mesh changes the flow patterns in straight as well as curved stent areas into a laminar forward flow inside the tubular structure. Outside the mesh the flow was significantly reduced with an increased residence time of particles in this thrombogenic environment. Furthermore, the interaction of blood flow and stent mesh results in a platelet activation with further stimulation of thrombus formation in the low flow areas (Figure 1).

Since 2011, thirty-four (33 male) out of 154 PAA were treated electively under local anesthesia using the double layer Supera stent technique presenting with an aneurysm size of 1.9-5.4cm (ø 2.4cm). Patient age ranged from 48 to 75 years (ø54.6 years). Seven lesions extended to the superficial femoral artery, demanding a third stent. 29 PAA were treated from a contralateral access using a 6F 45 cm sheath (Terumo Inc., Tokyo, Japan). 5 patients had ipsilateral femoral access due to previous aortic endograft implantations using a standard

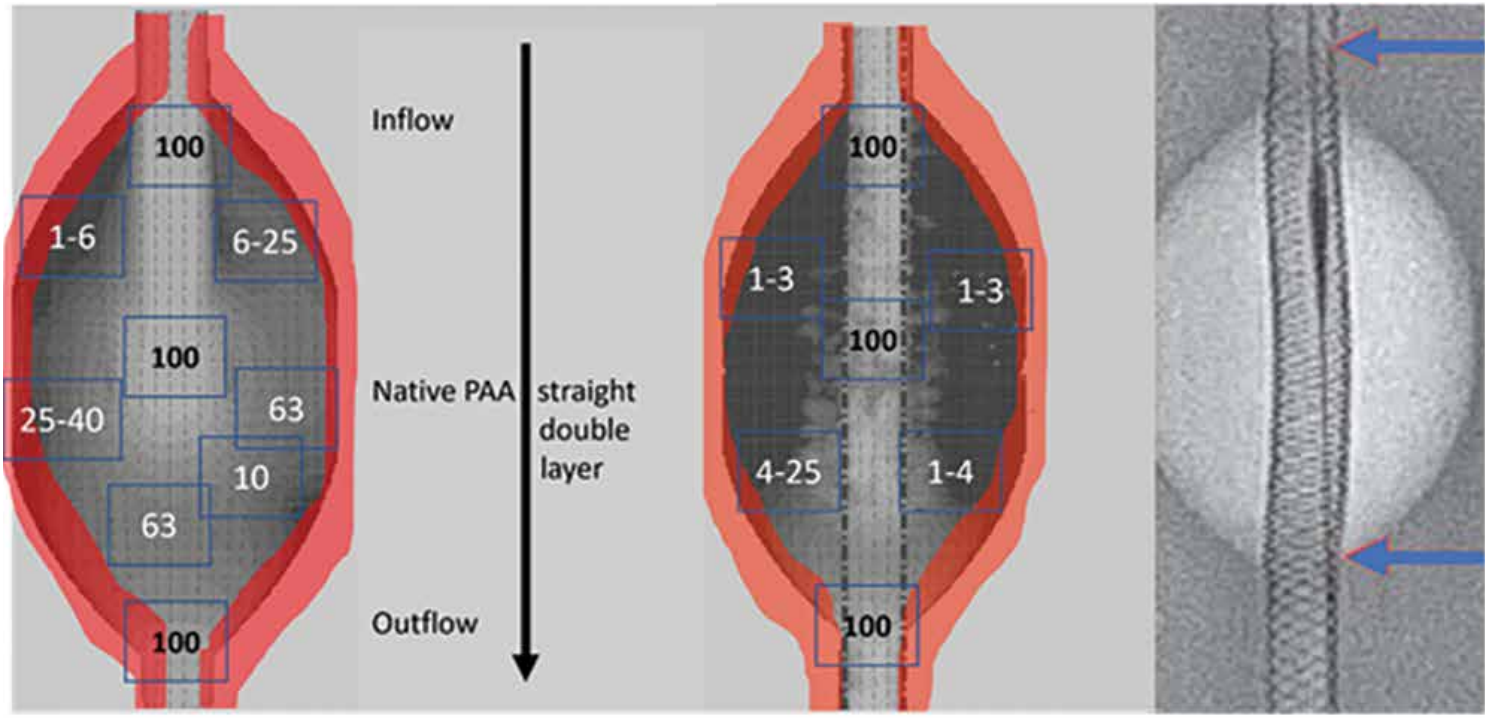


Figure 1: The figure shows from left to right the different flow patterns in the native aneurysm model (left) and after double layer stent deployment using the same pulsatile inflow velocity (middle). The right image shows a PAA model with implanted stents. The arrows indicate the overlap zone of the two Supera stents. After stenting, the flow patterns change to low flow outside the stent [11] (images J. Tessarek, Bonifatius Hospital Lingen).

6F 11cm sheath with duplex ultrasound guided puncture.

Since 2013, due to the restriction of Supera™ diameters to 7.5mm, the 8.5mm Supera was no longer available, so the procedure was limited to patients with a maximum landing zone vessel diameter of 7.5mm thereafter. The stents used were 7.5-8.5 x 100mm, and in the majority of cases 6.5x150-200mm. The distal landing zones were up to 1.5cm long and could reach down to the tibioperoneal bifurcation with a diameter of 4-7mm. Proximal diameters were 5.5-7.5mm. The majority of implanted stents showed a deviation from the longitudinal axis either following the given anatomy (max. vessel axis deviation 78°) or due to compression while being deployed.

All patients received an intraoperative heparin bolus injection of 70 IU/Kg bodyweight followed by dual antiplatelet therapy for 6 months and continuous monotherapy thereafter. Patients with anticoagulation prior to intervention or other platelet inhibiting medication were kept on this medication with additional anti- platelet therapy with 100mg acetylsalicylic acid for six months. The postprocedural standard heparin dose was 10,000 IU/24hours until discharge but this was accommodated to the effective individual patient medication (up to 20.000IE/24h with PTT (partial thromboplastin time) in therapeutic ranges).

Patients had predischarge ABI measurement and duplex ultrasound examination. According to our standard FU protocol for PAD examinations with ABI and DUS imaging were scheduled for 90 days, 270 days and then every twelve months. Native X-ray images were not routinely made, but a are available for all treated patients during follow up. CT scans were made in case of conspicuous DUS findings.

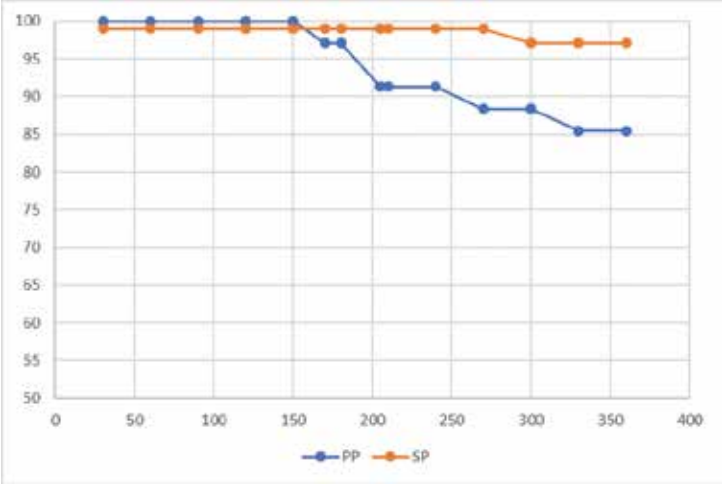
Results

All procedures were performed under local anesthesia with discharge after 1.9days (1-3 days). Technical success, defined as uneventful implantation of the stents, was 100% with complete thrombosis of the aneurysm in all but two patients at discharge (88.2%). 30-day mortality was 0% and there were no adverse or major adverse events, such as embolization, systemic complications with contrast induced renal failure or access site complications. One patient on anticoagulation and dual antiplatelet therapy due to aortic valve replacement and coronary heart disease was referred to the

hospital for acute calf pain 28 days after the procedure, which turned out to be an acute compartment due to intramuscular hematoma, which required surgical evacuation with an INR of 4.5.

During a mean follow up of 44.3 months (6-91 months) all PAA showed complete thrombosis. Two patients died (5.8%) from non-aneurysm related reasons, and two patients were lost to follow up due to relocation.

The primary patency rate at 12 month was 85.3% and 67.66% in the long term. Four reinterventions were performed due to stent occlusion and four patients received bypass surgery. One patient showed a clinically asymptomatic stent occlusion. A 82 year old diabetic patient with unilateral PAA but bilateral distal diabetic vasculopathy was amputated below the knee for progressive gangrene after denial of retrograde arterialization as bail-out surgery. Secondary patency was 97.1% (Table 1).



Tab. 1: The table shows percentage of primary (blue) and secondary patency (yellow) of the double layer Supera stent over 12 mo FU.

PAA shrinkage was noted in 37.4%. None of the PAA showed further growth after treatment. Native X-ray follow-up of the stents did show a single stent fracture 7 years after implantation without clinical relevance. Changes in vessel axis did not influence the material fatigue or component stability (Figure 2).

Discussion

PAA treatment for asymptomatic lesions is preventive and indicated for lesions with a diameter of 20mm or if a 1.5fold diameter increase compared to the healthy reference vessel can be diagnosed. Thrombus thickness

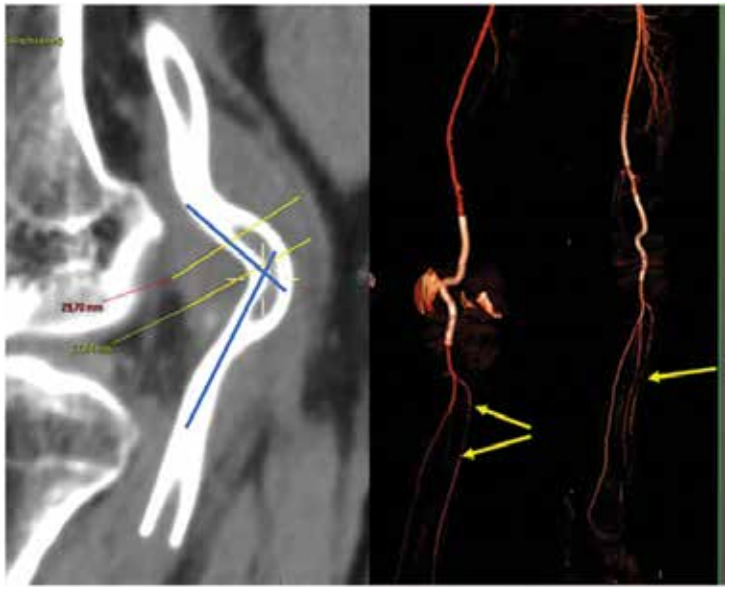


Figure 2: The images show the angulation of the stent following the implantation (left, 78°) and after 3-year follow-up. Due to reconfiguration and tortuosity the angulation seems to be even more severe. The yellow arrows indicate artefacts in the 3D reconstruction (images J. Tessarek, Bonifatius Hospital Lingen).

and circumferential thrombus represent further treatment indications. Symptomatic aneurysms demand treatment independent from their diameter or longitudinal extent.

Beside endovascular options with covered stents or flow modulation, treatment planning has to consider the options for open surgical repair with either prosthetic or venous interposition or bypass. This strongly depends on the available vein material and the ASA status of the patient.

Preventive treatment is crucial, bearing in mind the publication of Linton et al. from 1949 with a perioperative mortality of 22%[12] in case of thrombosis and amputation; by contrast, the rate of vascular complications for untreated PAA is 18-77%, with an amputation rate of 36% in more recent literature.[13-18] The endovascular treatment option for PAA can be regarded as established.

The publication of Mohan et al. from 2015[19] showed a statistically non-significant improved outcome of endovascular PAA treatment in terms of the endpoints occlusion, amputation and death, with 1.8% for endo vs. 4.1% for surgery (p=0.031). Emergency operations made up 8% of this series.

Beside the factors mentioned above, i.e. the emergency situation, the immediate occlusion and the quality of the bypass material turned out to be negative predictive in this study with 1316 patients.[19] Overall, the stent

treatment showed an occlusion rate of 1.3% vs. 4.0% for the bypass (p=0,009). In another retrospective study by Pulli et al.,[20] the major amputation rate was also lower for the stent group (0.72% vs.1.68%), but with inhomogeneity between PAA parameters.

Limb salvage rates after 4 years are identical for stenting and surgery (100%), as shown in the Cochrane Analysis by Joshi et al..[21] A worldwide multicentric PAA registry showed that the treatment numbers and the time of treatment differ significantly with 3.4/million population in Hungary vs. 17.8/million in Sweden. The rate of endovascular procedures was 34.8% in Australia and 0% in Switzerland.[22]

The size of the PAA and the amount of intraluminal thrombotic deposits determine the main risk, which is embolization, and thereby also the treatment aim, which is the prevention of embolization.

Flow modulating implants are widely accepted and have been used in intracranial vasculature for aneurysm treatment for some years.[23] For the peripheral vasculature and popliteal aneurysms, this was a new treatment option. Findings from a pilot study were published in 2015, as well as promising from a small series with thrombosed PAA and emergency use of stent-supported aspiration thrombectomy which were also published in 2016.[13]

In 2018, a variety of lab tests were performed at the University of Twente, the Netherlands, using different aneurysm models with straight and bended anatomy. These tests could prove the underlying concept of flow modulation for the compressed monolayer and the double layer Supera stent in straight, but even more in bended anatomies of the PAA model.[11] Both stent configurations result in separating laminar flow inside the stent with up to 100cm/s from low flow areas of 0.8-2.0cm/s (mean flow rate 1.1cm/s) inside the aneurysm sac.[11] These changes of flow patterns can explain the complete thrombosis of treated PAAs within 48 hours, correlating with earlier findings from intracranial studies.[24]

30-day primary patency was 100%, while covered stents showed an early thrombosis rate of 4-10% within 72hours after the index procedure.[25,26] Patency rates after 12 months (PP at 12 mo = 85,3%, SP 97,1%) are comparable to those of the Viabahn™ (Viabahn™, Gore Inc., Flagstaff, AZ, USA) as published by Karg et al. (91,2% PP and SP). However, this study selected patients with a minimum of two BTK vessels only.[27]

The flexibility, the crush and fracture resistance of the Supera™ stent was already shown in various trials, which demonstrated the reliability and durability of the Nitinol interwoven stent.[28,29] The Viabahn™ also showed also a clinically relevant rate of stent fractures and dislocations out of the landing zones, but also component separation.[30,31] thus making an endovascular bail-out impossible. The procedure related costs are significantly lower for the dual layer Supera™ but the Viabahn™ is available with bigger diameters up to 12mm .

The interwoven Nitinol design enables the Supera™ to adapt to variable diameters by stretching thus making infolding impossible but nonetheless maintaining the full diameter even in sharp bends (Figure 3).

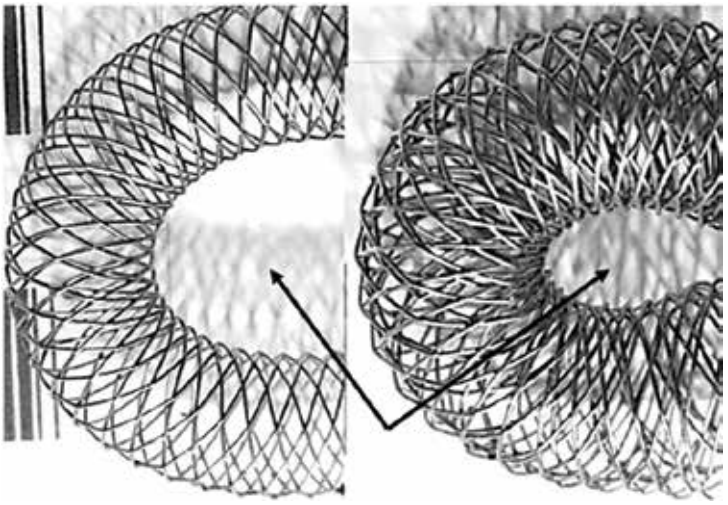


Figure 3: The images show the crush resistance and constant inner diameter of the single layer (180°) and dual layer 6.5mm Supera™ in a 210° bend (right). The higher mesh density becomes visible by the stent itself but also by the shadows (arrows) (images J. Tessarek, Bonifatius Hospital Lingen).

The Viabahn™ allows an oversizing of 1mm maximum. Otherwise, the ePTFE fabric shows crimping and infolding resulting in higher thrombogenicity and edge stenosis.[32]

A diameter mismatch between landing zones of more than 1 mm demands the telescoping of two or more stents with a decrease of stability but immense increase in cost. Early failures might be due to inappropriate expansion in variable diameters, which is crucial.[25,26] Stable Viabahn™ fixation demands a landing zone of 1 cm as minimum in the native vessel, and an overlap of 2 cm resulting in collateral loss and altered stent characteristics in the overlap zone, which might be the reason for stent fractures.

The adaptability of the Supera also allows to use a longer landing zone without sealing side branches and

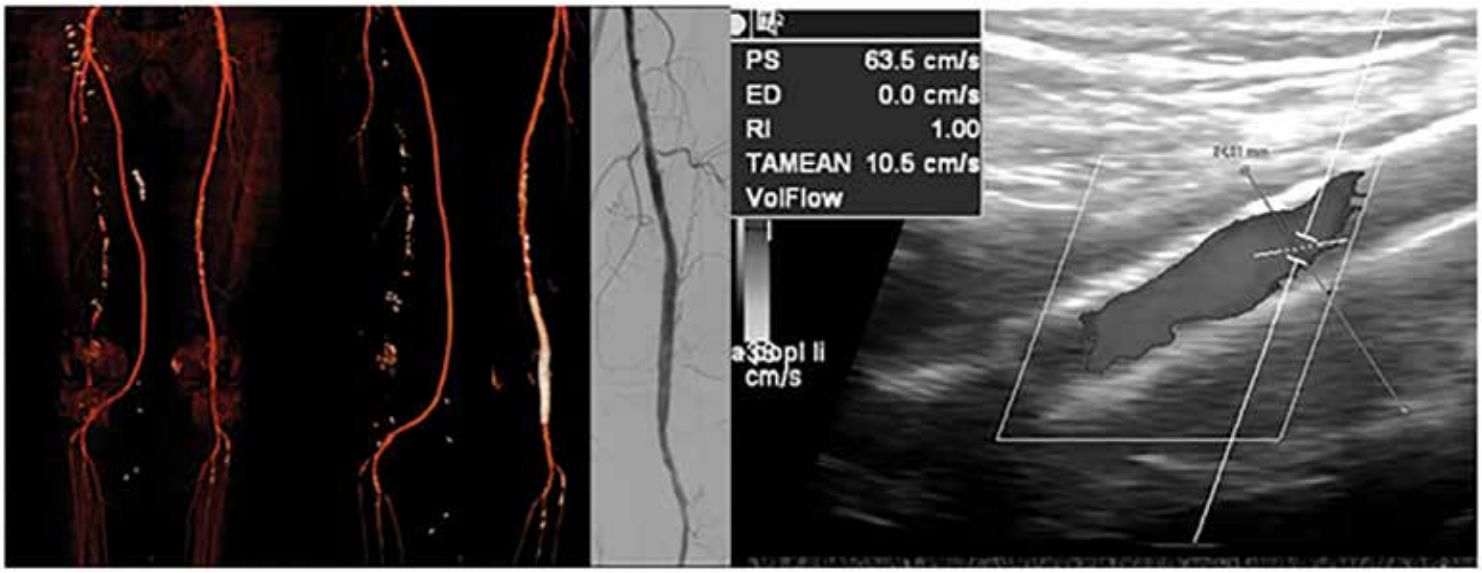


Figure 4: The images show the first patient treated with a double layer bare metal stent in 2011. Angiography in 2015 for BTK POBA (below the knee balloon angioplasty) showed complete patency of the stented segment. The PAA was completely thrombosed and had shrunk from 34mm to 24mm. Indication for bypass in 2009 on the right limb was the long femoropopliteal occlusion (images J. Tessarek, Bonifatius Hospital Lingen).

giving a higher fixation stability. In contrast, the Viabahn™ showed a fracture rate of 17% in the long term (5y)[31] and stent migration or component separation in 7-12%.[33]

The thrombus outside the stent showed resistance to thrombolysis and rotational thrombectomy with 6 and 8F Rotarex® (BD Germany, Heidelberg, Germany, former Straub Medical, Wangs, Schweiz) without angiographically visible reperfusion in those cases with stent occlusion. Aneurysm shrinkage was visible by duplex ultrasound in 37.4% of PAA with constant diameter for the remaining lesions.

The dual layer Supera stent prevents aneurysm growth and increase of thrombus load inside the PAA. The mesh accounts for an effective retention of thrombotic material thereby avoiding distal embolization with preservation of run-off vessel patency and the option for surgical conversion with good run-off.

12 months and long-term patency are in the same range as covered stents at lower costs and without the associated complications such as migration out of landing zones, component separations or fractures making further endovascular bail-out options impossible.[25,26,30,31] Preservation of side branches at the level of landing zones reduces the potential thrombus length in case of re-occlusion resulting in milder symptoms than occlusions in stent grafts.[34] The maximum stent diameter of 7.5 mm represents the technically determined limitation for recruiting patients. Postoperative medication should consist in dual antiplatelet therapy or (if preexisting) anticoagulation and mono antiplatelet therapy for 6 months minimum.

Conclusion

The technique as described here and the additional treatment strategies are concordant with the treatment aims of current guidelines for PAA treatment.[35,36] Further single center series[37] have also shown promising results using the Supera™ for PAA treatment.

A comparative trial for bypass, covered stent and flow modulating dual layer Supera would be necessary for a direct comparison takin into account the different limitations of the three options (Figure 4), while complex aneurysms including multiple femoropopliteal segments still require surgery.

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