

SCAI Guidelines on Device Selection in Aorto-Iliac Arterial Interventions

SUPPLEMENT 2. EVIDENCE TABLES

Abbreviations:

SES = Self-expanding stent

BES = Balloon-expanding stent

ISR = In-stent restenosis

PTA – Percutaneous transluminal angioplasty

Color coding:

Randomized controlled trials

Randomized single arm trials

Prospective multicenter study

Prospective single center study

Multicenter retrospective study on prospective database

Single center retrospective study on prospective database

Multicenter retrospective study

Single center retrospective study

Suppl Table 1. RCTs, Nonrandomized Trials, Observational Studies, and/or Registries of PTA in Aorto-Iliac Arterial interventions

Study Acronym; Author; Year Published	Aim of Study; Study Type; Design; Study Size (N)	Patient Population	Study Intervention (# pts)/Study Comparator (# pts)	Primary Endpoint; Endpoint Results; (include P value; OR or RR; & 95% CI)	Relevant 2° Endpoint (if any); Study Limitations; Adverse Events	Summary/ Conclusion Comment(s)
MIMIC trial; Greenhalgh et al. 2008 (Eur J Vasc Endovasc Surg (2008) 36, 680-688)	<p>Aim:</p> <ul style="list-style-type: none"> To test the effect of adjuvant PTA over supervised exercise, smoking cessation advice and best medical therapy in patients with stable, mild to moderate symptoms of intermittent claudication caused by aortoiliac lesions suitable for PTA <p>• Study type: RCT, multicenter</p> <p>• Size: N=34 pts</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> ABPI <0.9 or >0.9 with a positive stress test Aortoiliac target lesion amenable to PTA <p>Exclusion criteria:</p> <ul style="list-style-type: none"> symptoms too mild or too severe Patients with CLI 	<p>Intervention: PTA (n=19 pts)</p> <p>Comparator: no PTA (n=15 pts)</p>	<p>1° endpoint: AWD in metres at 24 months.</p> <p>Results: At 24 months, the adjusted AWD was 78% greater in the PTA group (95%; CI 0-216) (p=0.05).</p>	<p>2° endpoint: Further benefits were demonstrated for ABPI but not for quality of life.</p> <p>Limitations: Small size</p> <p>Adverse events: 2 strokes</p>	PTA confers adjuvant benefit over supervised exercise and best medical therapy in terms of walking distances and ABPI 24 months after PTA in patients with stable mild to moderate intermittent claudication

<p>Johnston et al 1987 (Ann Surg. 1987 Oct; 206(4): 403–413.)</p>	<p>Prospective single center, n=902</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Stenosis or occlusion of CIA, EIA or aortic stenosis • Claudication, ischemic night pain or rest pain, ulceration or gangrene • Length not analyzed 	<p>PTA</p>	<p>Results:</p> <p>Average pre-PTA pressure gradient fell from 41.8 ± 27.3 to 7.0 ± 10.9 mmHg after the PTA. Average pre-PTA ankle/brachial systolic blood pressure ratio was 0.58 ± 0.19 and increased to an average 0.71 ± 0.23 ($p = 0.001$).</p>	<p>Adverse events:</p> <p>three died of myocardial infarction and one died of bleeding after rupture of the artery. Emergency surgery was necessary in 1 .1% because of bleeding at the puncture site (1 case), severe extremity ischemia (8 cases), false aneurysm (1 case), or an arteriovenous fistula (1 case).</p>	<p>The following combination of variables were found to be predictive of success ($p < 0.05$): (1) indication (claudication vs. salvage), (2) site (common iliac vs. other), (3) severity of lesion (stenosis vs. occlusion), and (4) runoff (good vs. poor).</p>
<p>Khodja et al 2001 (J Cardiovasc Surg (Torino). 2001 Jun;42(3):369-74.)</p>	<p>Single center retrospective study, n=250</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI 	<p>PTA - Group I - iliac PTA without stent placement, n=75; Group II - iliac PTA with BES selective stenting, n=175</p>	<p>Results:</p> <p>The cumulative primary patency rate at 4 years was 62% (58% in Group I, 64% in Group II). The cumulative secondary patency rate at 4 years (including patients who subsequently underwent repeat angioplasty procedures) was 72% (68% in Group I, 74% in Group II).</p>	<p>Adverse events:</p> <p>2 extensive hematoma, 1 distal emboli, 24 late deaths</p>	<p>Stents were an effective means for treatment of initial failures of PTA in patients with iliac artery occlusive disease. However, there were no significant differences in the long term results between PTA alone and PTA with selective stent placement.</p>

<p>Charlebois et al 1986 (AJR 146:369-371, February 1986)</p>	<p>Single center retrospective study; N=14</p>	<ul style="list-style-type: none"> • significant lower abdominal aortic stenosis • bilateral intermittent claudication • Mean length 8mm (5-13) 	<p>PTA by femoral route</p>	<p>Results: Initial success was achieved in all but one patient who thrombosed at the puncture site. At a mean follow-up period of 16 months a persistent beneficial effect was maintained in all patients.</p>	<p>Limitations: Small size</p> <p>Adverse events: 1 right iliofemoral thrombosis, 1 rupture of the PTA balloon</p>	<p>Acceptable safety and effectiveness</p>
<p>Colapinto et al 1981 (Arch Surg 1981;116:277-281)</p>	<p>Single center retrospective study; N=10</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication • Focal 	<p>PTA</p>	<p>Results: The procedure was successful in eight of the ten occlusions, including all seven in which only one of the common or external iliac arteries was obstructed. Follow-up for periods of three to 13 months (average, eight months) showed continued patency in all cases.</p>	<p>none</p>	<p>transluminal recanalization of complete obstruction of the iliac arteries is an alternative to surgery</p>

<p>Insall et al 1993 (Eur J Vasc Surg 7, 31-36 (1993))</p>	<p>Single center retrospective study; N=79</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Distal aorta, CIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>Double Balloon PTA</p>	<p>Results:</p> <p>Fourteen of 17 occlusions up to 6cm long and 67 of 69 stenoses were successfully dilated. After an average follow-up of 49 months (median 51 months, range 7-93), only six patients (7%) developed late recurrence of symptoms requiring further treatment</p>	<p>6 died during follow up, occlusion recurrence, 2 resistant stenosis</p>	<p>Double-balloon percutaneous transluminal angioplasty was seen to be an effective procedure which produced lasting improvement and is recommended as the first choice treatment for localised stenotic and occlusive disease at the aortic bifurcation.</p>
<p>Joosten et al 1996 (Eur J Vase Endovasc Surg 12, 201-206 (1996))</p>	<p>Single center retrospective study; N=38</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta • Claudication, CLI 	<p>PTA</p>	<p>Results:</p> <p>Initial clinical and angiographic success was achieved in 36 patients (94%). Mean follow-up was 34 months (range 1-92). Recurrent stenosis was seen in seven patients (19%) at follow-up.</p>	<p>recurrent stenosis, 2 iliac dissection</p>	<p>PTA is a safe, minimally-invasive and effective alternative to surgery in case of symptomatic stenosis of the infrarenal abdominal aorta</p>

<p>Lankeren et al 1996 (AJR 1996;166:1355-1360)</p>	<p>Single center retrospective study; N=21</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>PTA</p>	<p>Results:</p> <p>Success was scored in 12 patients (group 1) and failure in nine patients (group 2). On the basis of angiographic and pressure measurements, five patients failed at the time of the intervention.</p>	<p>Vascular damage, 9 failed in a month</p>	<p>The qualitative and quantitative effects of PTA in CIA and EIA were similar. The size of the free lumen area and the degree of stenosis seen with intravascular sonography after PTA at the most stenotic site may be predictive of a patient outcome.</p>
<p>Motarjeme et al 1980 (AJR 135:937-944, November 1980)</p>	<p>Single center retrospective study; N=45</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO lesions • Claudication, CLI 	<p>PTA</p>	<p>Results:</p> <p>An overall primary success rate of 84% in dilatation of the stenotic lesions, and 33% in recanalization of totally occluded iliac arteries was achieved. In less than 2 years, there has been a patency rate of 100%</p>	<p>1 total occluded iliac artery patient recanalization complicated by CFA embolus, 1 subintimal dissection, 1 AV fistula</p>	<p>Transluminal angioplasty is the treatment of choice for single stenotic lesions of the iliac arteries. Lack of calcification is not an absolute guarantee of success, but a favorable factor.</p>

Ravimandala m et al 1991 (AJR 156:1257- 1260, June 1991)	Single center retrospective study; N=27	Indications: <ul style="list-style-type: none">• Lower abdominal aorta, CIA• Claudication, CLI	PTA	Results: Dilatation was successful in all patients. Of the other 25 patients, nine of the 10 followed up for 13-48 months and all seven followed up for 3-8 months were free of symptoms.	2 emboli out of which 1 died	balloon angioplasty is an effective treatment of stenoses of the infrarenal portion of the abdominal aorta.
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Suppl Table 2. RCTs, Nonrandomized Trials, Observational Studies, and/or Registries of Specialty balloons in Aorto-Iliac Arterial Interventions

Study Acronym; Author; Year Published	Aim of Study; Study Type; Design; Study Size (N)	Patient Population	Study Intervention (# pts)/Study Comparator (# pts)	Primary Endpoint; Endpoint Results; (include P value; OR or RR; & 95% CI)	Relevant 2° Endpoint (if any); Study Limitations; Adverse Events	Summary/ Conclusion Comment(s)
Kokkinidis et al 2018 (Journal of Endovascular Therapy 2018, Vol. 25(2) 183–191)	2 center retrospective study, n=331	Indications: <ul style="list-style-type: none"> • EIA • Included CTO, calcified, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	Cutting balloon, Atherectomy, SES, BES, Covered stent, Drug coated balloons, atherectomy	Results: 1-year primary patency was 78% and secondary patency was 92%. One-year and 5-year TLR rates were 8.2% and 15.4%, respectively.	Adverse events: 63 deaths, 10 MI, 9 stroke, Dissections, vessel perforation, distal embolization	Intervention to EIA CTOs is associated with increased intraprocedural complexity but with similar midterm outcomes, including high patency and low rates of TLR to 5 years.
Javed et al 2013 (Catheter Cardiovasc Interv. 2013 Dec 1;82(7):1176-84.)	Single center retrospective study; N=24	Indications: <ul style="list-style-type: none"> • CIA, EIA • Included CTO, ISR, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	BMA, Covered stent	Results: The 6-and 12-month primary patency rates were 96% and 82%, respectively. The 12-month primary-assisted patency rate was 90% with clinically driven TLR in three patients.	Adverse events: distal embolization, ISR, 2nd deaths - 1 of sepsis and other from sudden cardiac death	Endovascular treatment of IA-ISR using an approach of balloon angioplasty followed by selective stenting is associated with high-patency rates and low rates of TLR at 1 year.

Suppl Table 3. RCTs, Nonrandomized Trials, Observational Studies, and/or Registries of Drug Coated Balloons in Aorto-Iliac Arterial Interventions

Study Acronym; Author; Year Published	Aim of Study; Study Type; Design; Study Size (N)	Patient Population	Study Intervention (# pts)/Study Comparator (# pts)	Primary Endpoint; Endpoint Results; (include P value; OR or RR; & 95% CI)	Relevant 2° Endpoint (if any); Study Limitations; Adverse Events	Summary/ Conclusion Comment(s)
Kokkinidis et al 2018 (Journal of Endovascular Therapy 2018, Vol. 25(2) 183–191)	2 center retrospective study, n=331	Indications: <ul style="list-style-type: none"> • EIA • Included CTO, calcified, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	Cutting balloon, Atherectomy, SES, BES, Covered stent, Drug coated balloons, atherectomy	Results: 1-year primary patency was 78% and secondary patency was 92%. One-year and 5-year TLR rates were 8.2% and 15.4%, respectively.	Adverse events: 63 deaths, 10 MI, 9 stroke, Dissections, vessel perforation, distal embolization	Intervention to EIA CTOs is associated with increased intraprocedural complexity but with similar midterm outcomes, including high patency and low rates of TLR to 5 years.

Suppl Table 4. RCTs, Nonrandomized Trials, Observational Studies, and/or Registries of Bare Metal Stents in Aorto-Iliac Arterial Interventions

Study Acronym; Author; Year Published	Aim of Study; Study Type; Design; Study Size (N)	Patient Population	Study Intervention (# pts)/Study Comparator (# pts)	Primary Endpoint; Endpoint Results; (include P value; OR or RR; & 95% CI)	Relevant 2° Endpoint (if any); Study Limitations; Adverse Events	Summary/ Conclusion Comment(s)
ICE Trial; Krankenberg et al. 2017 (J Am Coll Cardiol Intv 2017;10:1694–704)	<p>Aim: Compare SE Vs BE stents for patients with moderate to severe claudication from common or external iliac artery occlusive disease</p> <p>Study type: RCT, multicenter</p> <p>Size: N=660 pts</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • CIA or EIA not extending into the aorta or the CFA. RF 1-4 • ≥70% stenosis or occlusion • 10 to 200 mm in length <p>Exclusion criteria: dialysis dependent end-stage renal disease and treatment with oral anticoagulants other than antiplatelet agents.</p>	<p>Intervention: SE (n=340)</p> <p>Comparator: BE (n=320)</p>	<p>1° endpoint: Cumulative incidence of binary restenosis at 12 months.</p> <p>Results: Twelve-month incidence of restenosis was 6.1% after SE implantation and 14.9% after BE implantation</p>	<p>•2° endpoint: Kaplan-Meier estimate of freedom from TLR was 97.2% and 93.6%, respectively (p ¼ 0.042)¶</p> <p>Limitations: DUS completion for primary outcome analysis was lower than anticipated, Not blinded</p> <p>Adverse events: Most of these complications were minor bleeding events at the access site or occurred due to perforation or dissection. In 4 SE patients, a distal embolization occurred and could be resolved during the index procedure</p>	<ul style="list-style-type: none"> • The treatment of iliac artery occlusive disease with SE as compared with BE resulted in a lower 12-month restenosis rate and a significantly reduced TLR rate. No safety concerns arose in both groups.

<p>DUTCH ILIAC trial; Tetteroo et al 1998 (Lancet 1998; 351: 1153–59)</p>	<p>Aim:</p> <ul style="list-style-type: none"> • Comparison of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac-artery occlusive disease <p>• Study type: Prospective randomized multicenter trial</p> <p>• Size: N=279</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Intermittent claudication • reduced ABI • reduction in arterial diameter > 50% • CIA or EIA stenosis ≤ 10 cm in length • occlusion ≤ 5 cm <p>Exclusion criteria: stenosis > 10 cm in length; arterial occlusion > 5 cm in length, or of 5 cm or less not allowing the passage of a guide wire; stenosis involving the distal aorta; severe comorbidity</p>	<p>Intervention: primary stent placement with BES (n=143)</p> <p>Comparator: primary PTA with selective stent placement with BES(n=136)</p>	<p>1° endpoint: No improvement or a worsening of the clinical category compared with the preprocedural clinical assessment</p> <p>Results: Clinical success rates at 2 years were 29 (78%) of 37 patients and 26 (77%) of 34 patients in groups I and II, respectively (p=0.6);</p>	<p>2° endpoint: Quality of life improved significantly after intervention (p<0.05) but no difference during follow-up. 2-year cumulative patency rates were similar at 71% versus 70% (p=0.2), respectively, as were reintervention rates</p> <p>Limitations: Short 2 year follow up</p> <p>Adverse events: Complications included haematoma at the puncture site, arterial-wall perforation, acute occlusion of the treated arterial segment, embolism, and vasovagal collapse.</p>	<p>There were no substantial differences in technical results and clinical outcomes of the two treatment strategies both at short-term and long-term follow-up. Since angioplasty followed by selective stent placement is less expensive than direct placement of a stent, the former seems to be the treatment of choice for lifestyle-limiting intermittent claudication caused by iliac artery occlusive disease.</p>
<p>ACTIVE trial, Molnar et al 2013 (J Endovasc Ther. 2013;20:94–103)</p>	<p>Aim:</p> <ul style="list-style-type: none"> • To determine the safety and effectiveness of the next-generation Assurant cobalt chromium balloon-expandable stent in symptomatic patients with iliac occlusive disease. <p>• Study type: Prospective, multicenter, single arm</p> <p>• Size: N=123</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • symptomatic PAD in the CIA or EIA • de novo stenoses or native artery restenoses between 50% and 100% • ≤100 mm long <p>Exclusion criteria: excessive PAD; fresh thrombus, excessive tortuosity, or calcification, aneurysm</p>	<p>Intervention: Assurant Cobalt Iliac Balloon-Expandable Stent System</p>	<p>1° endpoint: MAE at 9 months was defined as device- and procedure-related death, target limb loss, or clinically-driven TLR/TVR.</p> <p>Results: At 9 months, the rate of MAE was 0.8% with 1 TLR and 99.2% primary patency.</p>	<p>2° endpoint: ABI increased by 0.2-±0.2 at 1 and 9 months</p> <p>Limitations: No control arm</p> <p>Adverse events: No device- or procedure-related deaths or target limb amputations</p>	<p>The balloon-expandable Assurant cobalt chromium iliac stent demonstrated an excellent safety profile and sustained patency associated with marked improvements in objective and functional measures of patency.</p>

<p>Burket et al 2016 (J VascIntervRadiol2016;27:1650–1656)</p>	<p>Aim: To evaluate the safety and efficacy of a self-expanding bare-metal nitinol stent (Astron) for the treatment of atherosclerotic lesions in the CIA and EIA</p> <p>Study type: Prospective multicenter study</p> <p>Size: n=161</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Claudication or rest pain • De novo, re-stenotic or occluded lesions • Length ≤ 140 mm if de-novo or re-stenotic, ≤ 50 mm if occluded • Diameter 6 to 9 mm • Stenosis or occlusion ≥ 70% <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • Life expectancy less than one year • Perforation or aneurysm following pre-dilation • Excessively calcified or tortuous • Major or minor tissue loss in the target limb 	<p>Bare metal Nitinol Astron stent</p>	<p>1° endpoint: Composite of procedure- and stent-related (MAE) rates at 12months post-index procedure.</p> <p>Results: The MAE rate at 12months was 2.1% (3/146; [95% CI: 0.4% to 5.9%]; p < 0.001).</p>	<p>2° endpoint: The primary patency rate at 12 months was 89.8% (115/128). The comparison of baseline and 12-month ABI measurements showed a mean increase of 0.23 0.19 (p < 0.001)</p> <p>Limitations: Not randomized controlled trial</p> <p>Adverse events: One patient died on the day of the index procedure, 1 stent misplacement</p>	<p>The Astron stent system was shown to be safe and effective in the treatment of patients with atherosclerotic disease. The observed MAE rate met the pre-specified performance goal of 15%. The stent demonstrated a high 12-month primary patency rate and showed improvement in quality of life measures.</p>
<p>Donato et al 2015 (Ann Vasc Surg 2015; 29: 738–750)</p>	<p>Aim: to evaluate, in a controlled setting, the 24-month outcome of iliac stenting in TASC A & B and TASC C & D lesions</p> <p>Study type: prospective multicenter registry</p> <p>Size: n=325</p>	<p>Inclusion criteria: RF 2-5 Stenotic or occlusive iliac arteries</p> <p>Exclusion criteria: Type B short (<3 cm) stenosis of infrarenal aorta, type D infrarenal aortic occlusion, aneurysm, life expectancy < 12 months</p>	<p>Abbott vascular iliac stents - self-expanding stent or a balloon expandable stent</p>	<p>1° endpoint: primary patency at 24 months</p> <p>Results: The 24-month primary patency rate after 24 months for the total population was 87.9% (88.0% for TASC A, 88.5% for TASC B, 91.9% for TASC C, and 84.8% for TASC D).</p>	<p>2° endpoint: The 24-month primary patency rates were 92.1% for SES, 85.2% for BES and 75.3% for combination of both stents (P ¼ 0.06).</p> <p>Limitations: Not randomized control study</p> <p>Adverse events: 2 deaths for cardiac arrest, 2 femoral pseudoaneurysm, 1 retroperitoneal bleeding, 1 common iliac artery rupture, 1 wound infection, and 1 SFA thrombosis</p>	<p>The 24-month data from this large, prospective, multicenter study confirm that endovascular therapy may be considered the preferred first-line treatment option of iliac lesions, irrespectively of TASC lesion category.</p>

<p>Faries et al 2018 (Ann Vasc Surg 2018; 51: 37–47)</p>	<p>Aim: to confirm the safety and effectiveness of these stents in treating atherosclerotic disease in the common iliac and/or external iliac arteries</p> <p>Study type: prospective multicenter registry</p> <p>Size: n=75</p>	<p>Inclusion criteria: Atherosclerotic CIA and EIA Upto 10cm in length >50% stenosis RF 2-4</p> <p>Exclusion criteria: use of cutting balloon, scoring balloon, thrombectomy, atherectomy, brachytherapy, cryotherapy, or laser devices during index procedure Aneurysm</p>	<p>Nickel titanium alloy (nitinol) and come premounted on the delivery system.</p>	<p>1° endpoint: MAE rate at 9 months, defined as a composite of periprocedural death, in-hospital MI, clinically driven TLR, and amputation of the treated limb through 9 months after procedure.</p> <p>Results: The MAE rate at 9 months was 1.3% (1/75), with 1 subject experiencing a CD-TLR.</p>	<p>2° endpoint: Primacy patency at 9 months was 95.8%. Freedom from CD-TVR was 98.6% at 9 months.</p> <p>Limitations: Small size, lack of randomization, stent fractures not assessed</p> <p>Adverse events: 8 MAEs, all adjudicated by the core laboratory as CD-TLRs</p>	<p>The 9-month results of the DURABILITY Iliac study demonstrate the safety and effectiveness of 2 nitinol self-expanding stents for the treatment of atherosclerotic lesions of the common and external iliac arteries.</p>
<p>Benetis et al 2016 (Arch Med Sci 2016; 12, 2: 353–359)</p>	<p>Prospective single center, n=54</p>	<p>Indications: Stenotic or occlusive lesion of iliac arteries CLI Length \geq3cm</p> <p>Excluded TASC II type A lesions, abdominal aorta or iliac artery aneurysms and extra-anatomic bypasses.</p>	<p>BES were used preferentially for more focal lesions and severely calcified lesions. SES were usually placed for a diseased long segment or when the contralateral approach was used.</p>	<p>Results: The primary patency rates at 1 and 2 years were 83% and 79.9%</p>	<p>Adverse events: 4 died with MI, 3 ISR, 4 distal embolisations</p>	<p>Iliac artery stenting is associated with decreased primary patency compared with the surgery group. Iliac artery stenting should be considered with priority in elderly patients or in patients with severe comorbidities</p>

<p>Ghoneim et al 2017 (Int J Angiol 2017;26:20–26.)</p>	<p>Aim: to assess the difficulties met with possible recommendations in management of flush common iliac artery occlusive disease (FCIAOD).</p> <p>Study type: Prospective single center</p> <p>Size: n=51</p>	<p>Indications: flush common iliac artery occlusive disease presented by claudication, rest pain, or tissue loss</p> <p>Excluded embolic disease, acute thrombotic ischemia, trauma, autoimmune disorders or arteritis, or connective tissue disorder</p>	<p>Primary stenting was done in all cases, 50-80% SES</p>	<p>Results: Follow-up (12 months) revealed primary patency of 82.5% and secondary patency was 98% with no amputation done</p>	<p>Adverse events: Mortality rate was 4%</p>	<p>Endovascular treatment provides a successful option for the management of FCIAOD with a technical success rate of 92%. Technical consideration includes the use of two accesses as a rule and the option of selective use of pre-stent dilatation. FCIAOD does not preclude the use of unilateral stent in CIA, which can be converted to kissing stents when needed.</p>
<p>Kavaliauskienė et al 2014 (Medicina (Kaunas). 2014;50(5):287-94.)</p>	<p>Aim: to evaluate 1- and 2-year results and the influence of risk factors on the outcome in the patients undergoing iliac artery stenting for TASC II type B, C, and D iliac lesions.</p> <p>Study type: Prospective single center</p> <p>Size: n=316</p>	<p>Indications: Iliac stenotic or occlusive lesion Disabling claudication, rest pain, gangrene (RF 2-5) Length ≥ 3cm</p>	<p>BES were used preferentially for more focal lesions and severely calcified lesions. SES were usually placed for a long segment diseased or when the contralateral approach was used.</p>	<p>Results: The cumulative primary stent patency at 1 and 2 years was 83.0%\pm5.2% and 79.9%\pm5.8%, respectively</p>	<p>Adverse events: Early stent thrombosis in ≤ 30 days was detected in two patients (3.7%)</p>	<p>The localization of a stent in both iliac (CIA and EIA) arteries and poor runoff significantly reduce the primary stent patency. Patients with stents > 61 mm have a higher risk of stent thrombosis or in-stent restenosis development</p>

<p>Kim et al 1999 (Cardiovasc Intervent Radiol (1999) 22:278-281)</p>	<p>Aim: To report the clinical results for recanalizations of an occluded iliac artery by a self-expanding spiral stent.</p> <p>Study type: Prospective single center</p> <p>Size: n=34</p>	<p>Indications: Iliac artery occlusions Intermittent claudication and resting pain Average lesion length was 6.92 cm (range 1-14 cm)</p>	<p>self-expanding spiral metallic stent</p>	<p>Results: Good technical (100%) and clinical (94%) results were obtained.</p>	<p>Adverse events: Reocclusions were noted in two lesions (5%) at 1 week and 15 months, respectively</p>	<p>A self-expanding spiral stent is a safe and effective device for recanalization of an iliac artery occlusion as the primary stent without any previous intervention</p>
<p>Klonaris et al 2008 (J Vasc Surg 2008;47:310-7.)</p>	<p>Aim: evaluate the feasibility, safety, and efficacy of primary stenting in atherosclerotic stenoses and occlusions of the infrarenal aorta</p> <p>Study type: Prospective single center</p> <p>Size: n=12</p>	<p>Indications: infrarenal aortic occlusive disease – 8 aortic stenosis, 4 chronic total aortobiiliac occlusion severe claudication, ischemic rest pain, minor tissue loss</p>	<p>self expanding Sinus-XL, Palmaz P 4014 and Palmaz P5014 balloon-expandable aortic stents with the latter being preferred in heavily calcified lesions.</p>	<p>Results: At the end of the mean follow-up of 18.3 months, the primary clinical and hemodynamic patency was $91.7\% \pm 7.98\%$, and the mean resting ABI values were 0.96 ± 0.04 for the right and 0.92 ± 0.1 for the left side ($P < .01$ compared with preinterventional values)</p>	<p>Adverse events: One patient died 8 months after the procedure of chronic renal failure complications</p>	<p>Primary stenting is feasible, safe, and effective for the whole spectrum of aortic occlusive disease. Especially for patients with infrarenal aortic stenoses, it is recommended as the first-line treatment and should be considered as a viable alternative to surgery for total aortoiliac occlusions</p>

<p>Kordecki et al 2012 (Pol J Radiol, 2012; 77(4): 22-29)</p>	<p>Aim: to assess the effectiveness of endovascular treatment of common and external iliac artery stenosis/occlusion classified according to TASC using a self-expanding stent Jaguar SM</p> <p>Study type: Prospective single center</p> <p>Size: n=95</p>	<p>Indications:</p> <ul style="list-style-type: none"> • common and external iliac artery stenosis/occlusion classified according to TASC II (A, B, C, D) • Intermittent claudication, Limb pain at rest, ulcerations or tissue necrosis 10-90 mm length 	<p>self-expanding Jaguar SM stents</p>	<p>Results: Success rate of the performed procedures as well as in a 30-day observation period was 100% in case of stenosis and 80% in case of vessel occlusion. A follow-up after 12 and 24 months showed patency of treated vessels in 84% and 76% of patients, respectively.</p>	<p>Adverse events: perforation during predilatation, and had a stentgraft implanted</p>	<p>1. Endovascular treatment should be the first-choice therapy in case of focal stenoses or short-segment occlusions. 2. Application of self-expanding Jaguar SM stents is an effective and safe method characterized by high success rate and associated with low complication risk.</p>
<p>Krankenberget al2009 (Clin Res Cardiol (2009) 98:657–664)</p>	<p>Aim: assess the feasibility and safety of a systematic endovascular therapeutic approach in a consecutive series of patients with advanced Leriche syndrome</p> <p>Study type: Prospective single center</p> <p>Size: n=11</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Leriche syndrome, i.e., patients with diffuse occlusions of the distal abdominal aorta and both common iliac arteries • Median occlusion lengths were 3.4 cm in the aorta, 8.6 cm in the left iliac artery, and 13 cm in the right iliac artery RF 2-4 	<p>aortic occlusion - balloon-expandable Palmaz stent</p> <p>iliac occlusion - self-expanding nitinol stent</p>	<p>Results: At a median of 14 months, significant hemodynamic improvement was observed in successfully revascularized legs (ankle-brachial index, 0.79 ± 0.20 vs. 0.48 ± 0.08 at baseline; $P = 0.0004$); walking capacity as well as Rutherford category of peripheral arterial disease had improved in all patients</p>	<p>Adverse events: acute thrombotic aortoiliac occlusion managed by thrombolysis</p>	<p>In this small series of patients with Leriche syndrome, the reconstruction of the totally occluded aortoiliac bifurcation by endoluminal means was shown to be feasible and safe and associated with excellent mid-term clinical outcomes</p>

<p>Mohamed et al 2002 (Cardiovasc Intervent Radiol (2002) 25:472–475)</p>	<p>Aim: To assess outcomes following “kissing stents” for aortoiliac atherosclerotic disease, particularly in the nondiseased/non-symptomatic limb.</p> <p>Study type: Prospective single center</p> <p>Size: n=24</p>	<p>Indications:</p> <ul style="list-style-type: none"> • occlusions, complex stenoses or for failed angioplasty • Fontaine IIa to IV • 25% were non-symptomatic with normal iliac arteries on angiography 	<p>Memotherm, Wall, ST Come, Smart, AVE Bridge stent</p>	<p>Results: Primary patency at 6, 12 and 24 months was 94%, 81% and 58%, respectively. Primary assisted and secondary patency rates were 96%, 84% and 84% respectively for diseased limbs, and 92% and 100% for non-symptomatic/non-diseased limbs.</p>	<p>Adverse events: two thrombolyses, seven angioplasties, two re-stents, one atherectomy, two femoro-femoral crossover grafts and one aorto-bifemoral graft</p>	<p>Kissing stents offer an invaluable alternative to surgery. There were no long-term occlusions following kissing stents in a previously non-symptomatic/non-diseased limb</p>
<p>Schaefer et al 2008 (J Vasc Interv Radiol 2008; 19:182–188)</p>	<p>Aim: To analyze the immediate and midterm success of low-profile stent placement in calcified ulcerated lesions of the infrarenal aorta in patients with arterial occlusive disease</p> <p>Study type: Prospective single center</p> <p>Size: n=13</p>	<p>Indications:</p> <ul style="list-style-type: none"> • 13 symptomatic patients with focal calcified ulcerated stenoses of the infrarenal aorta • Fontaine IIb to IV <p>Excluded calcifications covering more than 75% of the aortic circumference, occlusion, concentric stenosis with a smooth surface</p>	<p>self-expanding stent (Dynalink, Boston Scientific, Natick, Mass [n=5]; Luminexx, Bard, Murray Hill, NJ [n=8])</p>	<p>Results: Primary patency and primary clinical success rates were 85% and 69%, respectively. According to Kaplan-Meier tables, the freedom-from-symptom rates were 92%, 84%, 73%, and 63% at 0, 7, 12, and 21 months, respectively</p>	<p>Adverse events: Two restenosis A stenosis of 50%–60% remained after stent placement because of extended calcification in the infrarenal aorta</p>	<p>Low-profile stent placement in calcified, ulcerated lesions of the infrarenal aorta is an effective and safe treatment for symptomatic stenoses in patients with arterial occlusive disease after a mean follow-up of 26 months.</p>

<p>Tornqvist et al 2016 (Eur J Vasc Endovasc Surg (2016) 51, 358e363)</p>	<p>Aim: To evaluate the role of intra-operative cone beam computed tomography (CBCT) to optimize the primary operation results.</p> <p>Study type: Prospective single center</p> <p>Size: n=53</p>	<p>Indications: mild claudication (2%), moderate claudication (21%), severe claudication (62%), rest pain (13%), and minor tissue loss (2%).</p>	<p>Generally, SES are predominantly used in tortuous and angulated vessels. BES are routinely used in straight vessels with heavy calcification including the aortic bifurcation or when insufficient results are achieved by SES</p>	<p>Results: In 24.5% (13/53) cases, adjunctive procedures were indicated solely by the CBCT findings, as both standard CA and PG were normal. Right sided mean ABI was 0.60 preoperatively; and 0.85 (p < .001) post-operatively. Left sided mean ABI was 0.57 pre-operatively; and 0.90 (p < .001) post-operatively.</p>	<p>Limitations: It is not known whether the adjunctive procedures add any clinical value in the long-term, and the cohort is too small to distinguish any improved short-term patency results.</p> <p>Adverse events: One peripheral embolization intra-operatively, 1 groin hematoma, Four patients had adjunctive surgery because of peripheral atherosclerotic disease</p>	<p>The use of CBCT revealed a significant number of stent compressions that were not found with CA and PG. When performing endovascular procedures at the aortic bifurcation, CBCT is an excellent intra-operative evaluation method to assess the configuration of deployed stents. In this study, CBCT improved the technical results intra-operatively, which might influence the long-term patency positively</p>
<p>Uberoi et al 2002 (Eur J Vasc Endovasc Surg 23, 331–335 (2002))</p>	<p>Aim: to assess the feasibility of duplex follow up of aorto-iliac stents.</p> <p>Study type: Prospective single center</p> <p>Size: n=75</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Claudication, rest pain, ulcer/gangrene • Aorta, CIA, EIA • Length range 1-15cm 	<p>Memotherm, Wall, Sax, Symphoney, AVE, Smart, ST Come, Palmaz, Passenger, Optimed, Jostent</p>	<p>Results: Duplex detected 30 lesions in 23 patients. Twenty-seven lesions were confirmed at angiography. Assisted primary limb patency was 96 and 90% at 12 and 24 months respectively</p>	<p>Adverse events: Three patients died - no stent related deaths</p>	<p>duplex ultrasound follow up is feasible in the majority of patients</p>

<p>Yoon et al 2001 (Korean J Radiol 2001;2:145-150)</p>	<p>Aim: To investigate the effectiveness of the newly designed Niti-S stent in the management of iliac arterial stenoses and occlusions.</p> <p>Study type: Prospective single center</p> <p>Size: n=25</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • highly eccentric lesion, occlusive or failed angioplasty. • mild claudication, severe claudication, rest pain, tissue loss or gangrene • Length 2.0 to 10.0 (mean, 4.1) cm 	<p>Niti-S stent (Taewoong, Seoul, Korea)</p>	<p>Results: ABI improved from 0.63±0.30 to 0.99±0.21 Follow-up over a 27 (mean, 19.8 8)-month period showed that cumulative patency rates were 95.8% at 1 year and 86.2% at 2 and 3 years.</p>	<p>Adverse events: One death due to MI, not procedure-related, occurred within 30 days, 2 died of diabetic nephropathy, 1 died with rupture of an abdominal aortic aneurysm</p>	<p>The Niti-S stent appears to be a safe and effective device for the treatment of iliac stenoses and occlusions. These preliminary results require confirmation with a larger series.</p>
<p>Inui et al 2018 (Ann Vasc Surg 2018; 53: 184–189)</p>	<p>2 center retrospective study on prospective registry, n=21</p>	<p>Indications:</p> <ul style="list-style-type: none"> • RF 3-5 TASC D • Average stent length range=50-250 mm 	<p>Atrium iCAST in the aorta and common iliac segments and/or Viabahn stents in the external iliac arteries</p>	<p>1° endpoint: survival</p> <p>Results: AI patency was 100%, AI bifurcation advancements primary patency 100%, EIA occlusion primary patency 88%, secondary patency 100%</p>	<p>2° endpoint: Secondary end points included primary patency, secondary patency</p> <p>Limitations: Small size, retrospective</p> <p>Adverse events: Two patients (15.4%) died of cardiovascular events.</p>	<p>Although uncovered stents are a common therapy for revascularization of this vascular bed, balloon expanding and self-expanding covered stents may be used to good effect with minimal complications in the intermediate term.</p>

<p>Sixt et al 2008 (J ENDOVASC THER 2008; 15:408-415)</p>	<p>Aim: To compare acute and long-term outcomes of endovascular therapy for TASC A and B lesions Vs TASC C and D lesions.</p> <p>Study type: Single center retrospective study on prospective data</p> <p>Size: n=375</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Stenosis, occlusion • RF 2-4 • Length range 14-128 mm 	<p>SES – SMART, Synfonie, Dynalink, Easy Wallstent, Memotherm</p> <p>BES = Palmaz, AVE Bridge, Inflow Gold, Strecker, Antares</p>	<p>1° endpoint: 1 year primary patency</p> <p>Results: The primary 1-year patency rate was 86% for the entire study cohort, 89%, 86%, 86%, 85% for TASC A to D lesions, respectively. In the TASC A/B cohort, the 5-year event-free survival (70%) was not significantly better than in the C/D cohort (57%, p=0.124)</p>	<p>Limitations: Retrospective</p> <p>Adverse events: 1 stroke, 2 distal thromboembolic events and a distal cholesterol embolism</p>	<p>In experienced hands, endovascular therapy of aortoiliac lesions can be successfully performed with sustained long-term outcome independent of the TASC II classification, even in class D lesions.</p>
<p>Sixt et al 2013 (J ENDOVASC THER 2013;20:64–73)</p>	<p>Aim: To determine the clinical and technical outcomes following endovascular therapy for aortoiliac occlusive disease, including complex reconstruction of the aortic bifurcation</p> <p>Study type: Single center retrospective study on prospective data</p> <p>Size: n=1184</p>	<p>Indications:</p> <ul style="list-style-type: none"> • occlusions, heavily calcified lesions, residual stenosis >30% by visual estimation, or flow-limiting dissection. • Distal aorta, aortic bifurcation, CIA, EIA • RF 2-4 • Length range 0.5-20 cm 	<p>SE or BE stents</p>	<p>1° endpoint: 1-year primary patency</p> <p>Results: The 12- and 24-month restenosis, TLR, and primary/secondary patency rates did not differ among TASC II A–D subgroups. The symptom-driven TLR in the entire cohort was 8% and 9% at the 12- and 24-month follow-up, leading to secondary patency rates of 96% and 91% in the entire cohort.</p>	<p>Limitations: Retrospective</p> <p>Adverse events: Overall, 308 (18%) patients died, 54 cardiac, 10 tumor, 5 stroke, 11 cardiovascular, 13 other and 215 of unknown etiology.</p>	<p>The indication for percutaneous intervention in aortoiliac occlusive disease can be extended to complex TASC C and D lesions in experienced endovascular centers, even if complex reconstruction of the distal aorta or the aortic bifurcation is indicated</p>

<p>Buckley et al 2002 (J Vasc Surg 2002;35:316-23.)</p>	<p>Single center retrospective review of prospective vascular registry; N=52</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • disabling claudication, cases, ischemic rest pain and tissue loss • Lesion length not mentioned 	<p>balloon angioplasty and primary stenting by using Palmaz balloon expandable stent</p>	<p>Results: Kaplan-Meier 3- and 6-year primary patency estimates were 100% and 100% in the IVUS group and 82% and 69%, respectively, in limbs treated without IVUS</p>	<p>2° endpoint: Kaplan-Meier survival estimates at 3 and 6 years for all patients were 84% and 67%, respectively</p> <p>Limitations: Retrospective, all procedures were done with an open femoral artery exposure technique</p> <p>Adverse events: 1 severe MI resulted in death, 1 vessel perforation - the complication could not be related to the use of either the stent or IVUS.</p>	<p>Balloon angioplasty and primary stenting of symptomatic aortoiliac occlusive lesions is a durable treatment option. Long-term follow-up of treated patients shows outcomes that are comparable with direct surgical intervention.</p>
<p>Pulli et al 2011 (J Vasc Surg 2011;53:92-8.)</p>	<p>Single center retrospective study on prospective data, n=212</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Occlusion or stenosis of CIA or EIA • TASC II A-D, RF 3-6 • Mean length 126.7±71 mm for iliac occlusion and 52.1±35.1mm for iliac stenosis 	<p>Nitinol steel, covered</p>	<p>Results: primary patency in iliac occlusion vs iliac stenosis was 97.3% Vs 98.7%, respectively at 30 days and, 82.4% vs 77.7% (P=.9) at 60 months</p>	<p>Adverse events: Four intraoperative iliac ruptures, 14 significant restenosis, 7 thrombosis</p>	<p>Endovascular treatment of iliac occlusions provides excellent early and long-term results, similar to those obtained in the treatment of stenotic lesions</p>

<p>Sullivan et al 1997 (J Vase Surg 1997;25:829-39.)</p>	<p>Single center retrospective study on prospective registry, n=288</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, rest pain, necrosis 	<p>PTA and primary stent placement with either balloon-expandable Palmaz stents or self-expanding Wallstents</p>	<p>Results:</p> <p>The Kaplan-Meier estimates of angiographic patency were 96%, 81%, and 73% at 6, 12, and 24 months. Cumulative patency rates were 84%, 76%, and 57% on the basis of TBI, ABI, and clinical limb status at 24 months.</p>	<p>Adverse events:</p> <p>1 death, 1 stroke, 1 MI, 7 thrombosis, 5 arterial dissection, 1 distal embolization</p>	<p>PTA and stenting of the iliac arteries is associated with reasonable angiographic, hemodynamic, and clinical success</p>
<p>Dohi et al 2013 (Cardiovasc Interv and Ther (2013) 28:327–332)</p>	<p>Single center retrospective study on prospective data, n=27</p>	<p>Indications:</p> <ul style="list-style-type: none"> • intermittent claudication, rest pain or tissue loss • Mean length 145mm 	<p>Primary stenting was predominantly performed with self-expanding stents using a kissing stent technique. In isolated, short or heavily calcified lesions, balloon-expandable stents were preferentially used</p>	<p>Results:</p> <p>At 36 months, primary and secondary patency rates were 76 and 94 %, respectively</p>	<p>Adverse events:</p> <p>Restenosis was observed in 5 patients</p>	<p>Endovascular therapy can be safely done in patients with chronic aortic occlusion. Procedural morbidity and mid-term durability were comparable to those of bypass surgery up to 3 years.</p>

<p>Miki et al 2016 (Heart Vessels (2016) 31:519–527)</p>	<p>Single center retrospective study on prospective data, n=122</p>	<p>Indications:</p> <ul style="list-style-type: none"> • de novo isolated aorto-iliac artery lesions • CTO • Stent length range 50-140mm 	<p>self-expanding stent</p>	<p>Results:</p> <p>TLRs were performed in 13 lesions. Post-procedural minimum stent area was significantly smaller in the TLR group compared to the no-TLR group (16.0 ± 5.8 vs. 25.6 ± 8.5 mm², p < 0.001).</p>	<p>Adverse events:</p> <p>stent edge dissections</p>	<p>Adequate stent enlargement without edge dissection might be important to reduce TLR in the iliac artery lesion.</p>
<p>Piazza et al 2015 (J Vasc Surg 2015;62:1210-8.)</p>	<p>Single center retrospective study on prospective data, n=128</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortic bifurcation, CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>covered stents, Self-expanding nitinol stents were used predominantly, except when the CIA orifice was occluded, in which case BES were used.</p>	<p>Results:</p> <p>At 24 months primary patency of CS vs BMS was similar (93% vs 80%; P= .14), and this finding was maintained after stratification by TASC II C (97% vs 93%; P =.59) and D (88% vs 61%; P =.07); secondary patency was 98% vs 92% (P=.22), and limb salvage was 99% and 95% (P =.35) respectively.</p>	<p>Adverse events:</p> <p>1 major cardiac event, 4 acute thrombosis and 7ISR in BMS group; 1 death, 1 stent thrombosis in CS group.</p>	<p>The use of CSs for severe iliac lesions has similar early and midterm outcomes compared with BMS. In a subcategory of TASC II D lesions with long-segment severe stenosis of both the common and external iliac arteries, CS should be considered as the primary line of treatment</p>

<p>Pulli et al 2015 (Ann Vasc Surg 2015; 29: 543–550)</p>	<p>Single center retrospective study on prospective data, n=229</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortic bifurcation, CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES, BES or covered stent - kissing stent technique (group 1) and other techniques (group 2).</p>	<p>Results:</p> <p>Primary patency rates at 4 years were 70.5% (standard error [SE], 0.09) in group 1 and 75.5% (SE, 0.06) in group 2 (P = 0.7). Reintervention rates were 15.5% in group 1 (SE, 0.1) and 19.5% in group 2</p>	<p>Adverse events:</p> <p>9 deaths, 13 Restenosis, 12 thromboses</p>	<p>The kissing stent technique provided satisfactory results in patients with obstructive aortoiliac diseases, without an increase in immediate and midterm complications, representing an effective solution in complex anatomies.</p>
<p>Schwindt et al 2011 (J Vasc Surg 2011;53:1550 -6.)</p>	<p>Single center retrospective study on prospective data, n=52</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal, Aortic bifurcation, iliac • Included CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES were preferred for long lesions, BES were used in lesions involving the aortic bifurcation, or when more radial force was needed</p>	<p>Results:</p> <p>All patients had an improvement of ABI>0.10. The estimated assisted primary patency at 9 years was 96% and the mean survival time was 86.6 months.</p>	<p>Adverse events:</p> <p>1 death, 1 aortic rupture</p>	<p>Primary stenting offers safe and durable results and should be considered as the first line of treatment for focal aortic lesions.</p>

<p>Derom et al 2001 (Eur J Vasc Endovasc Surg 22, 130–133 (2001))</p>	<p>2 center retrospective study, n=19</p>	<p>Indications:</p> <ul style="list-style-type: none"> • recurrent disease • Infrarenal, CIA, EIA • Claudication, CLI • Aorta focal, iliac both 	<p>Wall stent and Palmaz stent for aortic lesions, Wall stents for iliac lesions</p>	<p>Results:</p> <p>Angiographic cumulative primary patency for aortoiliac lesions was 96% at 1 year and 76% at 3 years</p>	<p>Adverse events:</p> <p>1 amputation, q death, 1 re-thrombosis</p>	<p>Angioplasty with selective stenting of recurrent aortoiliac disease after previous aortoiliac endarterectomy is feasible and safe. Long-term clinical and angiographic patency rates are in accordance with results of aortoiliac angioplasty in general.</p>
<p>Kokkinidis et al 2017 (Catheter Cardiovasc Interv. 2018 Sep 1;92(3):526-532)</p>	<p>2 center retrospective study, n=115</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included CTO, calcified lesions • Claudication, CLI, ALI • Both focal and diffuse 	<p>Covered stents and SES</p>	<p>Results:</p> <p>The 1- and 5-year TLR rates for lesions treated with re-entry device vs. standard approaches were 11% vs. 9%; P=0.8 and 29% vs. 29%; P=0.9 respectively. The 1 and 5-year major adverse limb event rates for lesions treated with re-entry device were 5% vs. 6%; P=0.8 and 11% vs. 11%; P=0.9 respectively.</p>	<p>Adverse events:</p> <p>3 perforations, 2 dissections</p>	<p>Recanalization of CIA occlusions using a RED is safe and is associated with long-term clinical outcomes similar to that of standard crossing techniques.</p>

<p>Danczyk et al 2012 (J Vasc Surg 2012;55:1637-46.)</p>	<p>2 center retrospective study, n=588</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI, ALI 	<p>SES and BES</p>	<p>Results:</p> <p>Survival, reintervention-free survival, late open conversion-free survival, and amputation-free survival were all similar between CIA stents, EIA stents, CIA and EIA stents (all P > .05).</p>	<p>Adverse events:</p> <p>1 death, 1 MI, 1 stroke, 9 arterial dissection. During follow-up, 183 patients died, 95 underwent an endovascular reintervention, and 48 required late open conversion</p>	<p>Outcomes are similar for patients with CIA or EIA stents and for those with combined ipsilateral CIA and EIA stents. Late open conversions for iliac artery stent failure are uncommon and not influenced by the location or extent of prior iliac artery stent placement.</p>
<p>Dorigo et al 2017 (J Vasc Surg 2017;65:99-107.)</p>	<p>3 center retrospective study on prospective registry, n=128</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal, Aortic bifurcation, CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES for lesions between 2 and 10 cm in length. BES were used preferentially for focal, ostial, and severely calcified lesions</p>	<p>Results:</p> <p>primary, assisted primary, and secondary patency rates were similar between aortobifemoral bypass and endovascular recanalization with the kissing stent technique; Univariate and multivariate analysis showed that only the presence of critical limb ischemia was independently associated with poorer primary patency during follow-up (hazard ratio, 2.4; 95% confidence interval, 0.9-6.4; P = .05).</p>	<p>Adverse events:</p> <p>13 deaths, 2 restenosis, 10 thrombosis</p>	<p>endovascular repair of aortoiliac complex lesions with the kissing stent technique provided similar satisfactory early and late results to those obtained with open surgery</p>

<p>Kokkinidis et al 2018 (Journal of Endovascular Therapy 2018, Vol. 25(2) 183–191)</p>	<p>2 center retrospective study, n=331</p>	<p>Indications:</p> <ul style="list-style-type: none"> • EIA • Included CTO, calcified, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	<p>Cutting balloon, Atherectomy, SES, BES, Covered stent, Drug coated balloons, atherectomy</p>	<p>Results:</p> <p>1-year primary patency was 78% and secondary patency was 92%. One-year and 5-year TLR rates were 8.2% and 15.4%, respectively.</p>	<p>Adverse events:</p> <p>63 deaths, 10 MI, 9 stroke, Dissections, vessel perforation, distal embolization</p>	<p>Intervention to EIA CTOs is associated with increased intraprocedural complexity but with similar midterm outcomes, including high patency and low rates of TLR to 5 years.</p>
<p>Lida et al 2013 (J ENDOVASC THER 2013;20:431–439)</p>	<p>Multicenter retrospective study, n=2036</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • Included CTO, calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>S.M.A.R.T. stent group Vs the “other” stent group – SES or BES</p>	<p>Results:</p> <p>4-year primary patency (86% vs. 76%, $p<0.001$) and freedom from adverse limb events (93% vs. 90%, $p=0.04$) were greater in the S.M.A.R.T. Control stent group, while event-free survival rates (75% vs. 77%, $p=0.50$) were similar between S.M.A.R.T. group and other stent groups</p>	<p>Adverse events:</p> <p>0.8% of limbs required major amputation. TLR and surgical conversion were observed in 5.6% and 1.1% of cases</p>	<p>After propensity matching analysis, the durability of the S.M.A.R.T. stent was superior to that of other stents, which might reflect differing design characteristics.</p>

<p>Lida et al 2014 (Eur J Vasc Endovasc Surg. 2014 Feb;47(2):131-8.)</p>	<p>Multicenter retrospective study, n=2012</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • Included CTO, calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>BES, SES, 2 atherectomy</p>	<p>Results: Perioperative complication (POC) was positively and independently associated with follow-up major adverse cardiac events (adjusted hazard ratio [HR]: 1.9; 95% CI: 1.3-2.8; p = .002), but not with major adverse limb events and TLR (adjusted HR: 1.4; 95% CI: 0.7-2.7; p = .25; and adjusted HR: 1.2; 95% CI 0.6-2.6; p = .568), respectively.</p>	<p>Adverse events: 224 all cause death, 44 MI, 66 stroke, 17 amputation</p>	<p>Age >80 years, CLI, and TASC C/D lesion were positively associated with POC after AI stenting. Occurrence of POC appears to adversely affect follow-up cardiovascular, but not limb and vessel prognosis</p>
<p>Sachwani et al 2013 (J Vasc Surg 2013;57:1030-7.)</p>	<p>2 center retrospective study, n=229</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, lesions • Claudication, CLI • Both focal and diffuse 	<p>aortobifemoral (ABF) grafting Vs percutaneous iliac artery stenting (PCIS) with angioplasty performed before and after stenting. Most stents placed in the EIA were SES nitinol, and most stents placed in the CIA were BES</p>	<p>Results: At 72 months, the primary patency for ABF bypass was greater than for PCIS (91% vs 73%; P = .010). Secondary patency rates were equivalent in both groups (98% ABF vs 85% PCIS). Survival in the ABF bypass group was significantly greater than in the PCIS group (76% vs 68%; P = .013)</p>	<p>Adverse events: 1 iliac artery rupture, dissection, distal emboli, 1 amputation</p>	<p>PCIS has lower morbidity, shorter hospital length of stay, and equivalent secondary patency but inferior primary patency compared with ABF.</p>

<p>Shintani et al 2015 (Angiology 2015, Vol. 66(9) 875-881)</p>	<p>Registry Multicenter retrospective study, n=1229</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortic bifurcation, CIA, EIA • Included CTO, lesions • CLI • Both focal and diffuse 	<p>After balloon inflation, nitinol stents – either SMART or Luminexx stents were used were implanted</p>	<p>Results:</p> <p>The assisted primary patency and secondary patency rates were also not significantly different (91.7% vs 93.2%, P = .340, 99.2% vs 98.8%, P = .922).</p>	<p>Adverse events:</p> <p>2 death, 1 stroke, 3 MI, vascular rupture, distal emboli</p>	<p>use of nitinol stents for the AI artery provided good long-term patency and freedom from major adverse limb events for 3 years of follow-up, regardless of whether</p>
<p>Soga et al (Circ J 2012; 76: 2697 – 2704)</p>	<p>Multicenter retrospective study, n=2147</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, Aortic bifurcation, CIA, EIA • Included CTO, calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Primary patency was 92.5%, 82.6% and 77.5% at 1, 3 and 5 years, assisted primary patency was 97.0%, 92.7% and 91.9% at 1, 3 and 5 years and secondary patency was 99.0%, 98.7% and 98.5% at 1, 3 and 5 years. The overall survival rate was 95.0%, 87.6%, and 79.3% at 1, 3 and 5 years.</p>	<p>Adverse events:</p> <p>Among 238 patients who died, the cause of death was cardiac in 80 patients, vascular in 25 patients and non-cardiovascular in 104 patients 3 aortic dissection, 5 stent thrombosis, 7 systemic embolism</p>	<p>The safety and efficacy after AI stenting are feasible compared to surgical reconstruction</p>

<p>Tsujimura et al 2018 (J Atheroscler Thromb, 2018; 25: 344-349.)</p>	<p>2 center retrospective study, n=217</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, ISR lesions • CLI • Both focal and diffuse 	<p>EpicTM self-expanding nitinol stent</p>	<p>Results: Primary patency was 87.3% at 2 years. Freedom from TLR rate was 94.1% at 2 years</p>	<p>Adverse events: More restenosis in diabetics</p>	<p>The EpicTM self-expanding nitinol stent was demonstrated to be safe and effective for AIOD when tested for two years in patients with PAD.</p>
<p>Koizumi et al 2009 (Circ J 2009; 73: 860 – 866)</p>	<p>Single center retrospective study, n=436</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>If there was insufficient dilatation with plain-old balloon angioplasty (POBA), stent implantation was performed concomitantly with Palmaz, Wallstent RP, Luminexx and SMART stents</p>	<p>Results: The 3-, 5- and 10-year patency rates were 67%, 54% and 50%, respectively, with POBA, and 88%, 82% and 75%, respectively, for stenting after suboptimal POBA, showing a significantly higher patency after treatment with a stent (P<0.001).</p>	<p>Adverse events: 127 deaths – 41 from heart disease, 23 from cerebrovascular disease; 2 wire perforation, 1 major dissection</p>	<p>Stent use and a low residual stenosis rate are significantly associated with patency, and favorable long-term patency can be obtained with stent placement for selected TASC-II Type-C/D lesions</p>

Davies et al 2011 (J Endovasc Ther. 2011;18:169–180)	Single center retrospective study, n=937	<u>Indications:</u> <ul style="list-style-type: none"> • CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	SES, BES	<u>Results:</u> Patency rates at 10 years for primary versus recurrent treatment were 73%±2% versus 66±8% for primary patency (p=0.004); 88%±2% versus 74%±7% for assisted primary patency (p=0.005); and 90%±2% versus 78%±10% for secondary patency (p=0.002).	<u>Adverse events:</u> 36% of patients died during follow-up, restenosis	Percutaneous reintervention for recurrent iliac artery disease has a higher procedure-related morbidity compared to primary intervention. Longer-term outcomes are also poorer than for primary lesions
Higashiura et al 2009 (J Vasc Surg 2009;49:645-52.)	Single center retrospective study, n=353	<u>Indications:</u> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, calcified lesions • Claudication, CLI • Both focal and diffuse 	self-expanding stents – Wallstent, Luminexx, SMART, SelfX, Memotherm, 13 Zilver, 6ZA	<u>Results:</u> Cumulative primary patency rates in iliac arteries with and without fractured stents were 90% and 91% at 8 years (P = .80), respectively.	<u>Adverse events:</u> Stent fracture	Fracture of self-expanding stents is rare in iliac arteries, but stenting for chronic occlusion represents a risk factor for fracture. Fractures of stents placed in iliac arteries rarely affect patency

<p>Ichihashi et al 2011 (J Vasc Surg 2011;53:992-9.)</p>	<p>Single center retrospective study, n=413</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>IVUS. Self-expanding stents were mainly used at diffuse lesions, particularly in the EIA. Conversely, balloon-expandable stents were placed at heavily calcified lesions and/or short segments, particularly in the CIA</p>	<p>Results:</p> <p>Cumulative primary patency rates at 1, 3, 5, and 10 years were 90%, 88%, 83%, and 71% in TASC-II C/D and 95%, 91%, 88%, and 83% in TASC-II A/B, respectively</p>	<p>Adverse events:</p> <p>4 amputations, 14 ISR, 1 cholesterol embolism, 1 dissection, 7 distal embolism</p>	<p>Primary stent placement for complex iliac artery occlusive disease provides acceptable long-term outcomes, although the procedure takes relatively longer and is associated with a higher frequency of complications than for simple disease.</p>
<p>Katsanos et al 2017 (Cardiovasc Intervent Radiol (2017) 40:351–359)</p>	<p>Single center retrospective study, n=256</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac • Included CTO, calcified, thrombotic lesions • Claudication, CLI • Diffuse 	<p>bare nitinol stent (BNS) or covered nitinol stent (CNS)</p>	<p>Results:</p> <p>Annualized stent thrombosis rates (per 100 person-years) were 12.5% in case of CNS and 1.4% in case of BNS (HR 6.3, 95% CI 2.4–17.9; p = 0.0002). Corresponding major amputations rates were 8.7 and 2.5%, respectively</p>	<p>Adverse events:</p> <p>Stent thrombosis</p>	<p>acute stent thrombosis and ensuing major amputation risks are significantly lower in the aortoiliac vessels and with use of bare nitinol stents compared to long femoropopliteal covered nitinol stents</p>

<p>Khodja et al 2001 (J Cardiovasc Surg (Torino). 2001 Jun;42(3):369-74.)</p>	<p>Single center retrospective study, n=250</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI 	<p>PTA - Group I - iliac PTA without stent placement, n=75; Group II - iliac PTA with BES selective stenting, n=175</p>	<p>Results:</p> <p>The cumulative primary patency rate at 4 years was 62% (58% in Group I, 64% in Group II). The cumulative secondary patency rate at 4 years (including patients who subsequently underwent repeat angioplasty procedures) was 72% (68% in Group I, 74% in Group II).</p>	<p>Adverse events:</p> <p>2 extensive hematoma, 1 distal emboli, 24 late deaths</p>	<p>Stents were an effective means for treatment of initial failures of PTA in patients with iliac artery occlusive disease. However, there were no significant differences in the long term results between PTA alone and PTA with selective stent placement.</p>
<p>Muller et al 2018 (Angiology 2018, Vol. 69(4) 308-315)</p>	<p>Single center retrospective study, n=443</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, lesions • Claudication, CLI • Both focal and diffuse 	<p>4% PTA, 96% included stent implantation with SES – Smart, Absolute, Everflex and other; or BES – primarily Omnilink</p>	<p>Results:</p> <p>After 1 and 3 years, the primary patency rates were 94% and 86% and the secondary patency rate was 100%, respectively</p>	<p>Adverse events:</p> <p>47 restenosis, 6 restenosis</p>	<p>endovascular therapy for steno-occlusive iliac artery disease was associated with high technical and clinical success rates as well as an excellent long-term patency rate irrespective of lesion complexity.</p>

<p>Roach et al 2015 (J Vasc Surg 2015;62:645-53.)</p>	<p>Single center retrospective study, n=213</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, covered stent</p>	<p>Results: At 1 and 3 years PP was 86% and 53%, assisted PP 98% and 89%, and secondary patency 99% of 98%. PP at 1 year was 91% Caucasian vs 77% non-Caucasian (P = .001), 75% in patients aged <60 years, 86% in patients aged 60-70 years, and 96% in patients aged >70 years, (P <.001); 71% and 88% in patient with and without EIA occlusion respectively occlusion (P =.002),</p>	<p>Adverse events: Vessel perforation, dissection, distal emboli,</p>	<p>younger age, non-Caucasian race, and EIA occlusion were strong predictors for loss of PP.</p>
<p>Baker et al 2015 (Ann Vasc Surg 2015; 29: 55–62)</p>	<p>Single center retrospective study; N=20</p>	<ul style="list-style-type: none"> • lower extremity CTOs • CLI, claudication 	<p>4 bare metal BE and 6 covered BE stents were used in CIA, 7 uncovered SE stents were used in EIAs and SFA. A single DES was used in EIA.</p>	<p>Results: ABIs significantly increased (0.5-0.9; P < 0.01) in the 13 patients with follow-up. Primary patency for the entire cohort was 62% at 12 months</p>	<p>Limitations: retrospective report, small sample size, relatively short follow-up</p> <p>Adverse events: 2 patients died unrelated to the procedure, 1 amputation, and 1 open revascularization.</p>	<p>Recanalization of CTO using IVUS-RED is safe and effective Acceptable safety and effectiveness</p>

<p>Liang et al 2017 (Journal of the Chinese Medical Association 80 (2017) 371e375)</p>	<p>Single center retrospective study; N=10</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>Self-expanding nitinol stents were used</p>	<p>Results:</p> <p>Successful re-entry was achieved in all patients without procedure-related complications. ABI increased from 0.38e0.79 to 0.75e1.28 after the procedure. Imaging follow-up (> 6 months) was available in six patients with patency of all stented iliac artery.</p>	<p>1 dies of malignant lymphoma</p>	<p>The use of Colapinto TIPS needle, especially under cone-beam CT image guidance, appears to be safe and effective to re-enter the true lumen in a subintimal angioplasty for a difficult chronic total iliac occlusion.</p> <p>A Colapinto TIPS Needle was used to aid the true lumen re-entry</p>
<p>Williams et al 1994 (Am J Surg. 1994 Aug;168(2):202-4)</p>	<p>Single center retrospective study; N=83</p>	<p>Indications:</p> <ul style="list-style-type: none"> • aortoiliac • Included CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>BES</p>	<p>Results:</p> <p>Ninety percent of procedures were immediately successful. The ABI improved in all groups.</p>	<p>7 amputations, 1 thrombosis</p>	<p>The procedure is widely applicable, with an apparent initial advantage in mortality, morbidity, charges, and length of stay.</p>

<p>Araki et al 2014 (Cardiovasc Interv and Ther (2014) 29:40–46)</p>	<p>Single center retrospective study; N=82</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES</p>	<p>Results:</p> <p>ABI increased significantly from 0.55 ± 0.19 to 0.88 ± 0.17 ($P < 0.001$). The primary patency rate was 96.5 % at 2 years.</p>	<p>1 reocclusion, 2 restenosis</p>	<p>The 2-year outcome of endovascular therapy with self-expandable stents for CTO of the iliac artery had an acceptable result</p>
<p>Ballard et al 1996 (J Vase Surg 1996;24:545-55.)</p>	<p>Single center retrospective study; N=72</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Stented iliac artery cumulative primary patency rates were 87.6%, 61.9%, 55.3%, and foot salvage rates were 97.7%, 85.1%, 76.1%, at 12, 18, and 24 months, respectively.</p>	<p>7 iliac dissections, 1 stent embolization, 1 cholesterol emboli, 1 stent infection, 1 intimal fracture and emboli</p>	<p>Limb-threatening and life-threatening complications can be associated with iliac artery stent deployment. Stented iliac artery primary patency rates are affected by distal atherosclerotic occlusive disease and the position of the deployed stent within the iliac system. Stent reconstruction of severe iliac artery occlusive disease is feasible but should be thoughtfully selected.</p>

<p>Balzer et al 2006 (Eur Radiol (2006) 16: 124–131)</p>	<p>Single center retrospective study; N=89</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, covered stent</p>	<p>Results:</p> <p>Eighty of 89 patients (89.9%) remained patent at 3-year follow-up. The secondary patency rate was 95.5%.</p>	<p>Restenosis, 1 perforation, 1 stroke</p>	<p>The patency rates were similar in selected TASC C and D patients to those so far published for TASC A and B, with low complication rates. Therefore, percutaneous intervention can be recommended for these patient</p>
<p>Bjorses et al 2008 (Eur J Vasc Endovasc Surg (2008) 36, 424-431)</p>	<p>Single center retrospective study; N=173</p>	<p>Indications:</p> <ul style="list-style-type: none"> • aortic bifurcation, distal aorta, CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, Jostentgraft</p>	<p>Results:</p> <p>Primary, assisted primary and secondary patency was: 97%, 99% and 100%, and 83%, 90% and 95% at twelve and 36 months respectively. There was no significant difference in patency between the TASC groups. Patency was significantly worse for patients in Fontaine class III.</p>	<p>1 % 30 day mortality – most of them died of cardiovascular disease; restenosis, stent occlusion</p>	<p>Aortoiliac kissing stents is a valid alternative to open repair for TASC A-D lesions. The procedure has low mortality and morbidity and good patency at 3 years</p>

<p>Burke et al 2010 (Ann Vasc Surg 2010; 24: 4-13)</p>	<p>Single center retrospective study; N=174</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, aortic bifurcation • Claudication, CLI, ALI 	<p>aortofemoral bypass (AFB) group Vs aortoiliac angioplasty and stenting group with SES, BES, covered stent</p>	<p>Results: The difference between preprocedural and postprocedural ABI was greater for AFB than AS (R, 0.39 and 0.18, $p < 0.001$; L, 0.41 and 0.15, $p < 0.001$). This difference was maintained when patients were stratified by TASC category.</p>	<p>2 death, 2 MI, 2 stroke; revision or amputation</p>	<p>There were no differences between the AFB and AS groups with respect to longterm rates of mortality, amputation, or revision procedures. AFB continues to be performed safely, despite the case numbers in this series correlating with a lower-volume hospital. Morbidities associated with major open surgery in this series were counterbalanced by greater improvements in ABI.</p>
<p>Gandini et al 2008 (Cardiovasc Intervent Radiol (2008) 31:1069–1076)</p>	<p>Single center retrospective study; N=138</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results: Primary patency rates were 90% (SE .024), 85% (SE .029), 80% (SE .034), and 68% (SE .052) at 3, 5, 7, and 10 years, respectively</p>	<p>Reocclusion, 8 stenosis</p>	<p>A primary endovascular approach appears to be justified in the majority of patients as a less invasive alternative treatment to surgery. In any case, a first-line interventional approach should be considered in elderly patients or in patients with severe comorbidities.</p>

<p>Greiner et al 2003 (Eur J Vasc Endovasc Surg 26, 161±165 (2003))</p>	<p>Single center retrospective study; N=25</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>The primary assisted patency rate was 94, 91 and 65% at 6, 12, and 24 months, respectively</p>	<p>Restenosis, 7 patients died and two patients required major amputation</p>	<p>despite acceptable short-term technical and clinical success, as the medium term patency rates are clearly inferior to those of bypass surgery, the kissing stent technique should be reserved for high risk patients with a limited life expectancy.</p>
<p>Haren et al 2017 (J Vasc Surg 2017;65:398-405.)</p>	<p>Single center retrospective study; N=10</p>	<p>Indications:</p> <ul style="list-style-type: none"> • TASC D aortoiliac occlusive disease • Distal aorta, aortic bifurcation, CIA, EIA • Included calcified, CTO lesions • CLI 	<p>Endologix Powerlink unibody bifurcated endograft (Endologix, Irvine, Calif), SES, self-expanding covered stent</p>	<p>Results:</p> <p>The primary and secondary patency rates were 80% and 100%, respectively</p>	<p>1 death from unrelated cardiac cause, iliac artery thrombosis</p>	<p>endovascular repair using a unibody bifurcated endograft for TASC D aortoiliac occlusive disease is feasible, effective, and has excellent midterm patency. It should be considered an effective treatment option when the disease process involves the aorta, in particular if the patient is surgically unfit for a traditional aortobifemoral bypass.</p>

<p>Humphries et al 2014 (J Vasc Surg 2014;60:337-44.)</p>	<p>Single center retrospective study; N=162</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Claudication, CLI, ALI • Both focal and diffuse 	<p>BES, balloon-expanding covered stent</p>	<p>Results: Primary patency, assisted patency, and secondary patency were significantly better in the BMS group. CIAs treated with covered stents were more likely at 1 year or longer to require repeated intervention (hazard ratio, 2.5; 95% confidence interval, 1.2-5.3; P = .009).</p>	<p>Thrombosis, amputation</p>	<p>BMSs had significantly better patency compared with covered balloon-expandable stents for treatment of aortoiliac occlusive disease.</p>
<p>Ichihashi et al 2014 (Ann Vasc Surg 2014; 28: 1449–1455)</p>	<p>Single center retrospective study; N=56</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included calcified, CTO lesions • Claudication, CLI 	<p>BES</p>	<p>Results: The BES achieved $81 \pm 10\%$ of the predicted minimal stent diameter (MSD) in noncalcified CIA lesions and $78 \pm 12\%$ of the predicted MSD in heavy calcified CIA lesions (P = 0.346). In the 9 limbs with insufficient expansion of an SES, deployment of the BES resulted in an improvement in MSD from $39 \pm 16\%$ to $77 \pm 8\%$ of the predicted MSD (P < 0.001).</p>	<p>1 death from sudden cardiac arrest, 3 dissection, 2 distal embolisms, ISR</p>	<p>Sufficient acute expansion of the BES was demonstrated in heavy calcified lesions or in lesions with insufficient expansion of an SES.</p>

<p>Kasemi et al 2016 (Ann Vasc Surg 2016; 30: 277–285)</p>	<p>Single center retrospective study; N=22</p>	<p>Indications:</p> <ul style="list-style-type: none"> • aorta, aortic bifurcation, CIA, EIA • Included calcified, thrombotic, lesions • Claudication, CLI • Diffuse 	<p>SES to EIA, Viabahn covered stent to aorta and CIA</p>	<p>Results:</p> <p>The primary patency rate was 95.2% at 1 year and 90.5% at 3 years, and the secondary patency rate was 95.2% at 1 year and 100% at 3 years.</p>	<p>Perioperative mortality rate was 4.5%, stent thrombosis</p>	<p>The Y-guidewire configuration technique for the aortic bifurcation reconstruction may render the procedure more feasible</p>
<p>Kashyap et al 2008 (J Vasc Surg 2008;48:1451-57.)</p>	<p>Single center retrospective study; N=83</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • Included CTO, thrombotic, lesions • Claudication, CLI, ALI 	<p>recanalization, PTA, and stenting (R/PTAS) with Self-expanding nitinol stent, BES to CIA orifice vs Aortobifemoral bypass (ABF)</p>	<p>Results:</p> <p>Limb-based primary patency at 3 years was significantly higher for ABF than for R/PTAS (93% vs 74%, P .002). Secondary patency rates (97% vs 95%), limb salvage (98% vs. 98%), and long-term survival (80% vs 80%) were similar. Diabetes mellitus and the requirement of distal bypass were associated with decreased patency (P < .001)</p>	<p>4% peri-op mortality, 1 MI, stent occlusion</p>	<p>R/PTAS is a suitable, less invasive alternative to ABF for the treatment of severe AIOD. Infringuinal disease negatively affects the durability of the procedure and patient survival</p>

<p>Klonaris et al 2008 (J Vasc Surg 2008;47:310-7.)</p>	<p>Single center retrospective study; N=12</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>The preprocedural mean resting ABI values of 0.56 ± 0.13 at the right side and 0.59 ± 0.15 at the left were increased to 0.97 ± 0.04 and 0.95 ± 0.06, respectively, after treatment ($P < .01$). At the end of the mean follow-up of 18.3 months (range, 6-37 months), the primary clinical and hemodynamic patency was $91.7\% \pm 7.98\%$,</p>	<p>1 death, a hematoma, 1 reocclusion</p>	<p>Primary stenting is feasible, safe, and effective for the whole spectrum of aortic occlusive disease. Especially for patients with infrarenal aortic stenoses, it is recommended as the first-line treatment and should be considered as a viable alternative to surgery for total aortoiliac occlusions.</p>
<p>Krishnamurthy et al 2011 (Ann Vasc Surg 2010; 24: 487-497)</p>	<p>Single center retrospective study; N=11</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>At follow-up, all patients had palpable femoral pulses. The ankle-brachial index normalized (>0.9) in six patients and improved significantly in the remaining five patients. The amputation-free survival was 100%.</p>	<p>None</p>	<p>Conclusion: True lumen reentry devices greatly improve the technical success and safety of percutaneous recanalization procedures in CTO of the iliac arteries.</p> <p>Comments: Pioneer device was used to achieve reentry</p>

<p>Lacroix et al 1997 (Eur J Vasc Endovasc Surg 14, 204-207 (1997))</p>	<p>Single center retrospective study; N=16</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI 	<p>BES, PTFE graft</p>	<p>Results:</p> <p>The primary patency of the 19 reconstructions was 100% at 1 month and 70% (CL 44-95%) at 1 year. The secondary patency was, respectively, 100% and 93% (CL 81-106%).</p>	<p>Two patients died, one of small bowel ischaemia and the other of a myocardial infarction; graft thrombosis/occlusion</p>	<p>Our experience shows that the reported technique is feasible. Whether the procedure is truly "less invasive" and the long-term results acceptable remains to be shown.</p>
<p>Lastovickova et al 2008 (Cardiovasc Intervent Radiol (2008) 31:43–48)</p>	<p>Single center retrospective study; N=18</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal, iliac • Included calcified lesions • Claudication, CLI • Both focal and diffuse length 2-5 cm 	<p>SES</p>	<p>Results:</p> <p>During the 49.4 months of mean follow up (range 3–96, 4 months) all treated aortic segments remained patent.</p>	<p>No major or minor periprocedural or postprocedural complications occurred. Two patients died during follow-up (one from cardiac disease and one from pulmonary carcinoma)</p>	<p>Endovascular treatment (primary self-expandable nitinol stent placement) of focal atherosclerotic lesions of distal abdominal aorta is a safe method with excellent primary technical and clinical success rates and favourable long term results.</p>

<p>Lee et al 2000 (J Vasc Surg 2000;31:889-94.)</p>	<p>Single center retrospective study; N=69</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>The following differences were noted on primary patency rates (EIA group vs CIA group): 1 year (93% vs 88%), 2 years (91% vs 85%), and 3 years (90% vs 78%) (Cox proportional hazards; P = .13)</p>	<p>some failed patency</p>	<p>Conclusions:</p> <p>Anatomic patency rates for EIA and CIA stents appear to be similar despite the fact that patients with EIA stents were older and had more ischemic limbs compared with the patients who had CIA stents.</p>
<p>Leville et al 2006 (J Vasc Surg 2006;43:32-9.)</p>	<p>Single center retrospective study; N=89</p>	<p>Indications:</p> <ul style="list-style-type: none"> • iliac • Included CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Three-year primary patency, secondary patency, and limb salvage rates were 76%, 90%, and 97%, respectively. Critical ischemia at presentation was associated with decreased patency rates (P = .002), but TASC classification did not significantly alter patency rates.</p>	<p>Distal embolization led to major amputation and eventual death in one patient. Two other deaths occurred in the perioperative period secondary to cardiorespiratory causes</p>	<p>Complex long-segment and bilateral iliac occlusions can be safely treated via endovascular means with high rates of symptom resolution.</p>

<p>Lun et al 2015 (J VascIntervRadiol2015;26:196–204)</p>	<p>Single center retrospective study; N=35</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Juxta and infrarenal aorta, aortic bifurcation, iliac • Included thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES</p>	<p>Results:</p> <p>Mean ABI increased significantly in both groups (P < .001). Primary 1, 3 and 5 year patency rates were 91.4%, 81.8% and 64.2%, respectively (P=.054)</p>	<p>Distal microembolization, iliac artery dissections</p>	<p>Although midterm primary patency rate was lower than for traditional open surgery, aortoiliacstent appears to be a safe, Minimally invasive, and reliable procedure for patients with chronic infrarenal aortoiliac occlusion</p>
<p>Lupattelli et al 1998 (European Journal of Radiology 28 (1998) 80–85)</p>	<p>Single center retrospective study; N=39</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>PTA and subsequent Strecker stent implantation</p>	<p>Results:</p> <p>At a 6-month follow-up, a 89.7% of patency was observed</p>	<p>stent occlusion, one groin hematoma and one distal embolization</p>	<p>Strecker stent can be successfully employed in addition to PTA to treat occlusions of the iliac arteries</p>

<p>Maekawa et al 2017 (Surg Today (2017) 47:293–300)</p>	<p>Single center retrospective study; N=73</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • Included calcified lesions • Claudication • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>The primary patency rates at 1, 3, 5, and 6 years were 96, 96, 96 and 89 %, respectively. The secondary patency rate at 6 years was 100 %.</p>	<p>restenosis or occlusion</p>	<p>Aortoiliac endovascular revascularization is effective treating claudicants with both aortoiliac and femoropopliteal lesions.</p>
<p>Marin et al 1994 (Am J Surg. 1994 Aug;168(2):156-62.)</p>	<p>Single center retrospective study; N=3</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • CLI 	<p>BES, EPTFE graft with BES sutured to each side</p>	<p>Results:</p> <p>Patency and limb salvage has been achieved to 1 year</p>	<p>1 repeat dilation, iliofemoral deep vein thrombosis</p>	<p>Endovascular stented grafts can be inserted to treat limb-threatening ischemia.</p>

<p>Maurel et al 2009 (Ann Vasc Surg 2009; 23: 722-728)</p>	<p>Single center retrospective study; N=81</p>	<p>Indications:</p> <ul style="list-style-type: none"> • EIA • Claudication • Both focal and diffuse 	<p>SES, BES</p>	<p>Results: Primary patency rate was 97% (standard error [SE]2%) at 1 year, 90% (SE 4.6%) at 2 years, and 84% (SE 6.6%) at 3 years. Secondary patency rate was 98% (SE 1.5%) at 1 year, 93% (SE 3.9%) at 2 years, and 93% (SE 4.5%) at 3 years.</p>	<p>retroperitoneal hematoma, 10 restenosis</p>	<p>systematic stenting on the external iliac artery gives satisfying results in patients with claudication</p>
<p>Midulla et al 2010 (J ENDOVASC THER 2010;17:642–651)</p>	<p>Single center retrospective study; N=33</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac bifurcation • Included calcified, thrombotic, lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES - TAP (T And Protrude)-stenting technique</p>	<p>Results: At a mean 16.3-month follow-up (range 2–60), clinical and ABI (0.6 ± 0.2 at baseline versus 1.04 ± 0.1, $p < 0.01$) improvement was observed in all patients. All stents were patent (patency rate 100%).</p>	<p>None</p>	<p>The TAP-stenting technique adapted to the aortoiliac bifurcation appears to be feasible, with satisfactory early and midterm patency rates in patients with small abdominal aortas</p>

<p>Moon et al 2015 (Vasc Spec Int 2015;31(1):15-19)</p>	<p>Single center retrospective study; N=21</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Distal aorta, aortic bifurcation, iliac • Included CTO lesions • Claudication, CLI 	<p>SES</p>	<p>Results:</p> <p>Primary patency was 89.6% at 1 year, 74.7% at 3 years and 64.0% at 5 years. Secondary patency was 94.1% at 1 year, 88.2% at 3 years and 68.6% at 5 years</p>	<p>1 distal limb ischemia by emboli, 6 restenosis or reocclusion, 2 mortalities not associated with the procedure</p>	<p>Self-expandable kissing stents can be used successfully with comparable patency for endovascular treatment of symptomatic atherosclerotic occlusive lesions in the aortic bifurcation area.</p>
<p>Mouanoutou a et al 2003 (Catheter Cardiovasc Interv 2003;60:320–326.)</p>	<p>Single center retrospective study; N=50</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac bifurcation • Included calcified, CTO, thrombotic, lesions • Claudication, CLI 	<p>SES, BES</p>	<p>Results:</p> <p>Primary patency during follow-up of 20 ± 12.3 months was 92%, while secondary patency rate was 100%. Amputation-free survival was 100%.</p>	<p>distal embolization, 4 ISR</p>	<p>stent-supported angioplasty using the kissing stents technique in the aortoiliac bifurcation can be achieved with excellent technical and clinical success with minimal short- and intermediate-term complications.</p>

<p>Nawaz et al 1999 (Eur J Vasc Endovasc Surg 17, 351–359 (1999))</p>	<p>Single center retrospective study; N=140</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES</p>	<p>Results:</p> <p>The primary successful clinical outcome was 90% at 12 months and 84% at 36 months; the primary-assisted successful clinical outcome was 95% at 12 months and 91% at 36 months and the secondary successful clinical outcome was 92% at 12 months and 87% at 36 months.</p>	<p>30-day mortality was 5.5%, stent occlusion or restenosis</p>	<p>Stenting for aortoiliac occlusive disease has good short and long term clinical success, with low morbidity and mortality.</p>
<p>Onal et al 1998 (Cardiovasc Intervent Radiol (1998) 21:386-392)</p>	<p>Single center retrospective study; N=19</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Clinical and angiographic follow-up (3-46 months) revealed patency of all other stented segments.</p>	<p>1 subacute occlusion of the stented segments</p>	<p>Primary stenting is an effective and reliable approach for complex plaques in stenoses</p>

<p>Onder et al 2013 (Cardiovasc Intervent Radiol (2013) 36:56–61)</p>	<p>Single center retrospective study; N=40</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • Claudication • Both focal and diffuse 	<p>SES primarily or after balloon dilatation</p>	<p>Results: Technical, clinical, and hemodynamic success was achieved in all patients. None of the patients underwent reintervention during the follow-up period</p>	<p>distal thromboembolisms</p>	<p>Endovascular treatment of the obstructive aortic disease using self-expanding stents was safe and effective, with high technical success and long-term patency.</p>
<p>Ozkan et al 2009 (Cardiovasc Intervent Radiol (2009) 32:417–421)</p>	<p>Single center retrospective study; N=5</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, CIA, EIA • Claudication, CLI • Included thrombotic lesions • Both focal and diffuse 	<p>SES</p>	<p>Results: Primary patency rates at 6, 12, and 24 months were all 80%</p>	<p>bilateral rupture of the common iliac arteries, 1 had extension of intra-aortic thrombus into the iliac stent</p>	<p>endovascular treatment can be an alternative for aortoiliac occlusion in selected patients.</p>

<p>Ozkan et al 2010 (Cardiovasc Intervent Radiol (2010) 33:18–24)</p>	<p>Single center retrospective study; N=118</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Primary and secondary patency rates at 5 years were 63 and 93%, respectively</p>	<p>1 death secondary to iliac artery rupture, 8 stent thrombosis, stent occlusion</p>	<p>endovascular treatment of iliac artery occlusion has a high technical success rate with favorable long-term patency rate</p>
<p>Powell et al 2000 (J Vasc Surg 2000;32:564-9.)</p>	<p>Single center retrospective study; N=75</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>For patients with an external iliac score of 2 or less, the endovascular primary-assisted patency rates at 6, 12, and 24 months were 96%, 92%, and 89%, respectively. This was improved in comparison with the 90%, 63%, and 45% patency rates observed in patients with an external iliac score of 3 or more (P = .001).</p>	<p>Recurrence</p>	<p>Patients with extensive external iliac disease (score \geq 3) have poor results after angioplasty and selective stenting even with endovascular reintervention</p>

<p>Ramjas et al 2008 (Cardiovasc Intervent Radiol (2008) 31:650–654)</p>	<p>Single center retrospective study; N=8</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included calcified, CTO lesions • Claudication • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Technical success was assessed on the basis of dynamic and morphologic patterns observed on the angiogram at completion. A residual stenosis of <30% and good flow through the treated segment were achieved in all cases.</p>	<p>None</p>	<p>outback LTD catheter was recommended to be considered in cases of difficult re-entry into the true lumen of iliac vessels, including inflow occlusions.</p>
<p>Raza et al 1998 (Eur J Vasc Endovasc Surg 15, 439-443 (1998))</p>	<p>Single center retrospective study; N=22</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>Memotherm self-expanding stent</p>	<p>Results:</p> <p>At 6 and 12 months the stent patency remained at 95.5%,</p>	<p>1 post-procedure thrombosis distal to the stented site</p>	<p>The Memotherm self-expanding stent is a safe and effective device suitable for the majority of iliac occlusions</p>

<p>Riet et al 2008 (J Vasc Nurs 2008;26:82-85)</p>	<p>Single center retrospective study; N=25</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac bifurcation • Claudication, CLI, ALI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Primary patency was 87% after 1 year and 65% after 2 years. Secondary patency was 90% after 1 year and 72% after 2 years.</p>	<p>restenosis or occlusion</p>	<p>Endovascular treatment of symptomatic aortoiliac atherosclerosis at the aortoiliac bifurcation by means of a distal aortic stent or kissing stents can be used successfully with durable improvement in the majority of patients.</p>
<p>Sharafuddin et al 2008 (Ann Vasc Surg 2008; 22: 346-357)</p>	<p>Single center retrospective study; N=66</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Distal aorta, aortic bifurcation, iliac • Included CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>primary and assisted patency rates at 4 years of 81% and 94%, respectively.</p>	<p>Restenosis, Death from cardiac cause in eight, pulmonary cause in three, and malignancy in five.</p>	<p>Stent reconstruction of the aortoiliac bifurcation for occlusive disease is effective and durable, even with complex aortoiliac disease and long segment occlusions</p>

<p>Shen et al 2015 (Chin Med J 2015;128:303 5-42.)</p>	<p>Single center retrospective study; N=56</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, CIA, EIA • Included calcified, thrombotic lesions • Claudication, CLI 	<p>SES, covered stent</p>	<p>Results:</p> <p>Primary patency rates at 1-, 3-, 5-, and 7-year were 93.6%, 89.3%, 87.0%, and 70.3%, respectively</p>	<p>restenosis, stent occlusion</p>	<p>diabetes and femoropopliteal TASC II type C/D lesions are risk factors associated with restenosis after open and ET of TASC II D AIOLs</p>
<p>Steinkamp et al 2001 (Acta Radiologica 42 (2001) 508–514)</p>	<p>Single center retrospective study; N=90</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, Wallgraft</p>	<p>Results:</p> <p>The primary angiographic patency rate was 83.1%. The patency rate after 24 months was 90.0%.</p>	<p>3 thromboembolic events, Restenosis, perforations</p>	<p>Primary stent implantation is an effective treatment for short iliac obstructions and represents a true endovascular alternative to surgery.</p>

<p>Suh et al 2015 (J Vasc Surg 2015;62:68-74.)</p>	<p>Single center retrospective study; N=80</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>At 3 years, the single-stent and kissing-stents group had similar rates of primary patency (89% vs 87%; P = .916) and target lesion revascularization-free survival (93% vs 87%; P = .462).</p>	<p>One death related to retroperitoneal bleeding, one cardiac death, stent thrombosis, TLR</p>	<p>The single-stent technique in asymmetric complex aortoiliac bifurcation was safe and showed midterm outcomes comparable with those of kissing stents</p>
<p>Tapping et al 2013 (Cardiovasc Intervent Radiol (2013) 36:62–68)</p>	<p>Single center retrospective study; N=22</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, aortic bifurcation, CIA • Claudication, CLI 	<p>SES</p>	<p>Results:</p> <p>There was a significant difference in primary patency between isolated aortic stenosis (100 %) and aortoiliac stenosis (60 %) (p = 0.031)</p>	<p>Iliac dissection, pseudoaneurysms</p>	<p>There was a significant difference in primary patency between isolated aortic stenosis (100 %) and aortoiliac stenosis (60 %) (p = 0.031)</p>

<p>Timaran et al 2001 (J Vasc Surg 2001;34:440-6.)</p>	<p>Single center retrospective study; N=189</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Primary patency rates at 1, 3, and 5 years were 76%, 56%, and 56%, respectively, for patients with EIA stents and 92%, 85%, and 76%, respectively, for those with CIA stents</p>	<p>12 arterial dissections and four femoral pseudoaneurysms</p>	<p>Women undergoing EIA angioplasty with stent placement have significantly reduced primary patency rates. Conversely, men undergoing EIA stenting have a more favorable outcome than women</p>
<p>Timaran et al 2003 (J Vasc Surg 2003;38:272-8.)</p>	<p>Single center retrospective study; N=188</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Primary patency rates at 1, 3, and 5 years were 85%, 72%, and 64% after iliac stenting, and 89%, 86%, and 86% after surgical reconstruction, respectively</p>	<p>2 retroperitoneal hematomas, 18 arterial dissections, 4 femoral pseudoaneurysms, and 1 vessel perforation.</p>	<p>Poor infrainguinal runoff is the main risk factor for decreased primary patency after surgical reconstruction and iliac stenting to treat TASC type B and type C iliac lesions.</p>

<p>Uher et al 1999 (Eur J Vasc Endovasc Surg 18, 114–121 (1999))</p>	<p>Single center retrospective study; N=82</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, aortic bifurcation, CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Cumulative primary and secondary patency of stented Iliac atherosclerotic lesions at 1 and 3 years was 75 and 61%, and 83 and 75% respectively</p>	<p>3 amputation, 2 death, stent thrombosis, restenosis or occlusion</p>	<p>stenting of complex aortoiliac stenoses and chronic occlusions is a safe and effective treatment modality.</p>
<p>Varcoe et al 2011 (J Endovasc Ther. 2011;18:25–31)</p>	<p>Single center retrospective study; N=8</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, CIA, EIA • Claudication, CLI 	<p>Double barrel SES</p>	<p>Results:</p> <p>During a mean follow-up of 12.5 months (range 6–29), primary patency was 100% with no secondary interventions</p>	<p>femoral artery dissection, brachial artery thrombosis, and retroperitoneal hematoma</p>	<p>Total endovascular reconstruction of the occluded infrarenal aorta that extends into the iliac arteries is durable at midterm follow-up. Adjunctive use of the Outback LTD re-entry catheter can facilitate technical success.</p>

<p>Vertes et al 2018 (Journal of Endovascular Therapy 2018, Vol. 25(5) 632-639)</p>	<p>Single center retrospective study; N=105</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, aortic bifurcation, CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>The primary patency rates were 93%, 86%, and 77% at 12, 24, and 60 months, respectively.</p>	<p>ISR, 2 hematomas, 5 pseudoaneurysms</p>	<p>The kissing stent technique can be performed with good long-term patency</p>
<p>Vinogradova et al 2017 (Ann Vasc Surg 2017; 38: 184–189)</p>	<p>Single center retrospective study; N=77</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Kaplan-Meier analysis demonstrated a 37% patency in limbs where the stent covered the IIA orifice compared to 78% patency in uncovered arteries (P ¼ 0.04).</p>	<p>New-onset impotence, reduced patency</p>	<p>Placement of stents across the origin of the IIA may not result in immediate occlusion, but long-term patency of covered IIAs is decreased compared to uncovered IIAs.</p>

<p>Yilmaz et al 2004 (Cardiovasc Intervent Radiol. 2004 Mar-Apr;27(2):121-8.)</p>	<p>Single center retrospective study; N=13</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta • Claudication, CLI • Focal 	<p>SES</p>	<p>Results: During the 43 +/- 23 months (mean +/- SD) follow-up (range: 12-96 months), all stented aortic segments remained patent.</p>	<p>None</p>	<p>primary stenting should be considered the first line treatment in properly selected patients with focal atherosclerotic infrarenal stenoses of the abdominal aorta.</p>
<p>Yilmaz et al 2006 (J Endovasc Ther. 2006 Jun;13(3):291-301.)</p>	<p>Single center retrospective study; N=68</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac bifurcation, iliac • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results: Primary, assisted primary, and secondary patency rates, respectively, were 76%, 90%, and 94% at 1 year; 63%, 86%, and 92% at 3 years; and 63%, 64%, and 81% at 5 years.</p>	<p>7 died of cardiovascular or malignant disease, Restenosis</p>	<p>Implantation of kissing stents is a safe and effective alternative in the treatment of aortoiliac obstructions. However, overall primary and assisted primary patency rates are inferior to those reported for surgery.</p>

<p>Yuan et al 2014 (Eur J Vasc Endovasc Surg. 2014 Jul;48(1):46-52)</p>	<p>Single center retrospective study; N=11</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Flash infrarenal aorta • Included thrombotic lesions • Claudication, CLI 	<p>SES</p>	<p>Results:</p> <p>The ABI rose significantly between pre- and post-procedure (0.84 ± 0.18 vs. 0.44 ± 0.13 on the right leg, $p < .01$; 0.89 ± 0.23 vs. 0.48 ± 0.16 on the left, $p < .01$).</p>	<p>1 minor cerebral infarction</p>	<p>Transbrachial and femoral artery approach endovascular therapy for FIAO offers an alternative to surgical reconstruction with immediate outcomes.</p>
<p>Vries et al 2004 (J Vasc Surg 2004; 39:427-31.)</p>	<p>Single center retrospective study; N=69</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta • Included CTO lesions • Claudication, CLI 	<p>SES, BES</p>	<p>Results:</p> <p>At life table analysis, 5-year primary patency was 75%, and secondary patency was 97%</p>	<p>Adverse events:</p> <p>3 died - not related to the angioplasty procedure, recurrent stenoses</p>	<p>Early and long-term results of PTA (with additional stent placement) of isolated stenosis of the infrarenal aorta are good</p>

<p>AbuRahma et al 2007 (J Vasc Surg 2007;46:965-70.)</p>	<p>Single center retrospective study; N=110</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>The primary patency rates at 1, 2, 3, and 5 years were 98%, 94%, 87%, and 77% for the primary stent group vs 83%, 78%, 69%, and 69% for the selective stent group (P = .030).</p>	<p>Adverse events:</p> <p>1 DVT, 7 iliac artery thrombosis.</p>	<p>The early and late clinical success rates were comparable for short lesions (TASC - A and B lesions), but were inferior in selective stenting for longer lesions (TASC - C and D). Therefore, primary stenting should be offered to all TASC - C and D lesions</p>
<p>Dietrich et al 1993 (Eur J Vasc Surg 7, 228-236 (1993))</p>	<p>Single center retrospective study; N=29</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Distal aorta, aortic bifurcation, CIA, EIA • Included CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>BES</p>	<p>Results:</p> <p>Of 11 re-examined with aortography, IVUS imaging and pull-through pressure gradient measurements, no signs of restenosis have been seen on the arteriographic images.</p>	<p>Adverse events:</p> <p>distal embolization, haematomas</p>	<p>The specific intraluminal and transmural data offered by IVUS facilitates stent application and documents adequate deployment, two vitally important elements in the percutaneous treatment of abdominal aortic occlusive disease.</p> <p>Pulsed holmium YAG laser was used to clear a channel through the obstruction.</p>

<p>Javed et al 2013 (Catheter Cardiovasc Interv. 2013 Dec 1;82(7):1176-84.)</p>	<p>Single center retrospective study; N=24</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, ISR, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	<p>BMS, Covered stent</p>	<p>Results:</p> <p>The 6-and 12-month primary patency rates were 96% and 82%, respectively. The 12-month primary-assisted patency rate was 90% with clinically driven TLR in three patients.</p>	<p>Adverse events:</p> <p>distal embolization, ISR, 2nd deaths - 1 of sepsis and other from sudden cardiac death</p>	<p>Endovascular treatment of IA-ISR using an approach of balloon angioplasty followed by selective stenting is associated with high-patency rates and low rates of TLR at 1 year.</p>
<p>Kim et al 2011 (J Vasc Surg 2011;53:1542-9.)</p>	<p>Single center retrospective study; N=49</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, aortic bifurcation, iliac • Included calcified, CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>In patients treated successfully, the primary patency rate was 88.4% at 1 year and 80.1% at 3 years</p>	<p>Adverse events:</p> <p>1 death from pneumonia related sepsis, 1 spinal cord infarction with distal Embolization, 1 cerebral infarction</p>	<p>Endovascular therapy of infrarenal aortic occlusion was feasible in most cases, and midterm patency was favorable</p>

<p>McPherson et al 1999 (Australasian Radiology (1999) 43, 185–191)</p>	<p>Single center retrospective study; N=12</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, iliac • Included CTO, thrombotic lesions • Claudication, ALI • Both focal and diffuse 	<p>SES, BES</p>	<p>Results:</p> <p>Primary patency of 91% and secondary assisted patency of 100% has been achieved</p>	<p>Adverse events:</p> <p>iliac thrombosis complicating iliac dissection, distal embolism, 1 recurrent symptomatic aortic stenosis</p>	<p>Primary treatment of infrarenal aortic stenosis with endoluminal stenting results in high patency rates, with low morbidity and relatively low complication rates.</p>
<p>Moise et al 2009 (J Endovasc Ther. 2009 Feb;16(1):84-92.)</p>	<p>Single center retrospective study; N=31</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, CIA • Included calcified, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, Covered stent for calcified lesions</p>	<p>Results:</p> <p>At 1 and 3 years, the primary/secondary patency rates were 85%/100% and 66%/90%, respectively.</p>	<p>Adverse events:</p> <p>perioperative limb thromboses, acute renal dysfunction</p>	<p>Endovascular therapy for chronic infrarenal aortic occlusion has a high technical success rate, with good midterm primary and secondary patency rates.</p>

<p>Powell et al 2000 (J Vasc Surg 2000;31:1178-84.)</p>	<p>Single center retrospective study; N=87</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Included thrombotic lesions 	<p>SES, BES</p>	<p>Results:</p> <p>At 6, 12, and 36 months, the aortoiliac primary patency rates in patients without the presence of an external iliac artery stenosis were 88%, 78%, and 69%, respectively, compared with 68%, 47%, and 18%, respectively, in patients with external iliac artery lesions (P < .0001).</p>	<p>Adverse events:</p> <p>1 EIA rupture, one common femoral artery Thrombosis, 2 deaths - congestive heart failure and acute tubular necrosis in one patient and multiple system organ failure in the other patient</p>	<p>Endovascular therapy for multisegment aortoiliac occlusive disease has acceptable patency rates; however, reintervention is often needed</p>
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Suppl Table 5. RCTs, Nonrandomized Trials, Observational Studies, and/or Registries of Covered stents in Aorto-Iliac Arterial Interventions

Study Acronym; Author; Year Published	Aim of Study; Study Type; Design; Study Size (N)	Patient Population	Study Intervention (# pts)/Study Comparator (# pts)	Primary Endpoint; Endpoint Results; (include P value; OR or RR; & 95% CI)	Relevant 2° Endpoint (if any); Study Limitations; Adverse Events	Summary/ Conclusion Comment(s)
COBEST trial; Mwipatayi et al 2011 (J Vasc Surg 2011;54:1561-70.)	<p>Aim:</p> <ul style="list-style-type: none"> To determine if covered stents offer a patency advantage over bare-metal stents in the treatment of aortoiliac arterial occlusive disease. <p>• Study type: RCT, multicenter</p> <p>• Size: N=125</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> Men and women aged ≥ 18 years Evidence of TASC B, C, or D lesions Hemodynamically significant dissections and recurrent stenosis after angioplasty <p>Exclusion criteria:</p> <ul style="list-style-type: none"> Life expectancy <12 months TASC A lesion Pregnant women Extensive common femoral artery disease 	<p>Intervention: Advanta V12 covered stent (n=83)</p> <p>Comparator: BMS – BE or SE (n=85)</p>	<p>1° endpoint: Rate of binary restenosis and freedom from stent occlusion at 18 months.</p> <p>Results: Freedom from binary restenosis for CS compared with BMS (HR 0.35; 95% CI 0.15-0.82; P =.02). Freedom from binary restenosis for CS in TASC C and D lesions compared with BMS (HR, 0.136; 95% CI, 0.042-0.442).</p>	<p>Limitations: Different stent types used in the BMS group, the BMS group had fewer patients with TASC D lesion, DUS was the principal imaging tool used for follow-up</p> <p>Adverse events: 4 amputations – 2 in each group</p>	Covered and bare-metal stents produce similar and acceptable results for TASC B lesions. However, covered stents perform better for TASC C and D lesions than bare stents in longer-term patency and clinical outcome

<p>VBX FLEX trial; Bismuth et al 2017 (Journal of Endovascular Therapy 2017, Vol. 24(5) 629-637)</p>	<p>Aim:</p> <ul style="list-style-type: none"> To evaluate the safety and efficacy of a next-generation balloon-expandable stent-graft for the treatment of arterial occlusive disease in patients with de novo or restenotic lesions in the common and/or external iliac arteries. <p>• Study type: Prospective multicenter single arm</p> <p>• Size: N=134</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> RF 2–4 CIA or EIA de novo or restenotic target lesion(s) ≥50% stenosis Diameter between 5 and 13 mm Total lesion length ≤110 mm, Up to 2 discrete ipsilateral lesions or bilateral disease (1 lesion per limb) <p>Exclusion criteria:</p> <p>visible thrombus; Aneurysmal dilation; requiring atherectomy</p>	<p>Intervention: GORE VIABAHN VBX Balloon Expandable Endoprosthesis</p>	<p>1° endpoint: Composite of device- or procedure-related death within 30 days, myocardial infarction within 30 days, target lesion revascularization (TLR) within 9 months, and amputation above the metatarsals in the treated leg within 9 months</p> <p>Results: At 9 months, 3 major adverse event (3 TLRs)</p>	<p>2° endpoint: Patency and freedom from TLR and TVR measures ranged from 99.2% to 100.0% and 96.7% to 99.5% at 1 and 6 months respectively</p> <p>Limitations: The specific outcomes often differ slightly, along with definitions such as all-TLR vs clinically driven TLR, short follow up of 9 Months</p> <p>Adverse events: No device-related serious adverse events</p>	<p>The next-generation balloon-expandable stent-graft demonstrated notable 9-month safety and efficacy in treating iliac occlusive disease in patients reflecting common clinical practice.</p>
<p>Holden et al 2017 (J Endovasc Ther. 2017 Feb;24(1):11-18.)</p>	<p>Aim: To report the first-in-human iliac artery experience of a new balloon-expandable covered endoprosthesis</p> <p>Study type: Prospective single center</p> <p>Size: n=30</p>	<p>Indications: claudication or rest pain RF 2–4) de novo or restenotic occlusive lesions in CIAs or EIAs measuring between 5 and 13 mm in diameter Maximum length 110mm</p> <p>Excluded visible thrombus, aneurysm, lesion close to the iliac artery bifurcation, lesions requiring atherectomy or any ablative device to facilitate stent deliver</p>	<p>Gore BE covered endoprosthesis consists of a stainless steel stent and a fluoropolymer graft</p>	<p>Results: The primary 30-day safety endpoint was 0%. Per-subject estimates of primary patency, freedom from target lesion revascularization, and freedom from target vessel revascularization were 100% at 1 and 6 months and 96.6% at 12 months.</p>	<p>Adverse events: 1 patient expired at 6 months due to acute MI not deemed procedure- or device-related</p>	<p>This positive first-in-human experience with the Gore balloon-expandable covered endoprosthesis suggests this device will have an important role in the management of aortoiliac occlusive disease.</p>

<p>Kalmar et al 2014 (Eur J Radiol. 2014 Jul;83(7):1205-1208.)</p>	<p>Aim: to determine immediate results and mid-term outcome of the hemoparin-coated (HC)stainless-steel stent (camouflage coating) in the treatment of occlusive lesions of the iliac arteries.</p> <p>Study type: Prospective single center</p> <p>Size: n=28</p>	<p>Indications: TASC II A and B lesions of the iliac arteries Length 15-36mm</p>	<p>HC stent "EucaPWS-C Endovascular Stent System</p>	<p>Results: Significant decrease in translesional pressure gradient (>10 mmHg) was measured in 27 patients (96%). up. After 12 months, stent patency in CTA, MRA and ultrasound was 100%</p>	<p>Adverse events: In one patient, proximal dissection occurred without flow limitation</p>	<p>The use of HC stents in patients with iliac artery occlusive disease may lead to a lower rate of intimal hyperplasia and thus to increased patency rates even in heavily calcified vessels.</p>
<p>Grimme et al 2014 (Eur J Vasc Endovasc Surg (2014) 48, 545-550)</p>	<p>2 center retrospective study on prospective registry, n=36</p>	<p>Indications:</p> <ul style="list-style-type: none"> • RF 3-5 • isolated occlusive lesions of the infrarenal aorta • Length range 5-58mm 	<p>12-mm Advanta V12 LD balloon expandable ePTFE covered stent (Atrium Medical, Maquet Getinge Group, Hudson, NH, USA)</p>	<p>1° endpoint: primary patency</p> <p>Results: Primary patency rates were 100% at 1 and 2 Years ABI increased significantly from 0.73±0.18 to 1.01±0.14 (p < .01).</p>	<p>Limitations: Retrospective, small sample size</p> <p>Adverse events: One patent covered stent was removed surgically because of infection</p>	<p>The use of PTFE covered stents for the treatment of isolated infrarenal aortic occlusive disease is safe and very effective.</p>

<p>Grimme et al 2015 (Eur J Vasc Endovasc Surg (2015) 50, 638-647)</p>	<p>Aim: to present results are of a new endovascular technique using covered stents to reconstruct the aortic bifurcation in patients with aortoiliac occlusive disease.</p> <p>Study type: 2 center retrospective study on prospective registry</p> <p>Size: n=103</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Claudication, ischemic rest pain, focal tissue loss, diffuse gangrene • TASC II B to D • Stented length range 1-88mm 	<p>Covered Endovascular Reconstruction of the Aortic Bifurcation</p>	<p>1° endpoint: 1-year primary patency</p> <p>Results: Primary patency was 87.3% at 1 year and 82.3% at 2 years, while secondary patency was 95.0% at 1 year and 95.0% at 2 years. Mean ABI improved significantly from 0.64±0.21 before to 0.91±0.14, after the procedure (p < .001).</p>	<p>Limitations: Retrospective, follow up of 2 years was not completed for the entire cohort</p> <p>Adverse events: Six died of non-procedure related causes and in two deaths of unknown cause Dissection, rupture, stent dislocation, thrombus formation</p>	<p>The CERAB technique appears to be a safe and feasible alternative to open surgical reconstruction of the aortic bifurcation in complex occlusive disease. Comparative studies with the current gold standards are indicated</p>
<p>Inui et al 2018 (Ann Vasc Surg 2018; 53: 184–189)</p>	<p>2 center retrospective study on prospective registry, n=21</p>	<p>Indications:</p> <ul style="list-style-type: none"> • RF 3-5 TASC D • Average stent length range=50-250 mm 	<p>Atrium iCAST in the aorta and common iliac segments and/or Viabahn stents in the external iliac arteries</p>	<p>1° endpoint: survival</p> <p>Results: AI patency was 100%, AI bifurcation advancements primary patency 100%, EIA occlusion primary patency 88%, secondary patency 100%</p>	<p>2° endpoint: Secondary end points included primary patency, secondary patency</p> <p>Limitations: Small size, retrospective</p> <p>Adverse events: Two patients (15.4%) died of cardiovascular events.</p>	<p>Although uncovered stents are a common therapy for revascularization of this vascular bed, balloon expanding and self-expanding covered stents may be used to good effect with minimal complications in the intermediate term.</p>

<p>Pulli et al 2011 (J Vasc Surg 2011;53:92-8.)</p>	<p>Single center retrospective study on prospective data, n=212</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Occlusion or stenosis of CIA or EIA • TASC II A-D, RF 3-6 • Mean length 126.7±71 mm for iliac occlusion and 52.1±35.1mm for iliac stenosis 	<p>Nitinol steel, covered</p>	<p>Results:</p> <p>primary patency in iliac occlusion vs iliac stenosis was 97.3% Vs 98.7%, respectively at 30 days and, 82.4% vs 77.7% (P=.9) at 60 months</p>	<p>Adverse events:</p> <p>Four intraoperative iliac ruptures, 14 significant restenosis, 7 thrombosis</p>	<p>Endovascular treatment of iliac occlusions provides excellent early and long-term results, similar to those obtained in the treatment of stenotic lesions</p>
<p>Piazza et al 2015 (J Vasc Surg 2015;62:1210-8.)</p>	<p>Single center retrospective study on prospective data, n=128</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortic bifurcation, CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>covered stents, Self-expanding nitinol stents were used predominantly, except when the CIA orifice was occluded, in which case BES were used.</p>	<p>Results:</p> <p>At 24 months primary patency of CS vs BMS was similar (93% vs 80%; P= .14), and this finding was maintained after stratification by TASC II C (97% vs 93%; P =.59) and D (88% vs 61%; P =.07); secondary patency was 98% vs 92% (P=.22), and limb salvage was 99% and 95% (P =.35) respectively.</p>	<p>Adverse events:</p> <p>1 major cardiac event, 4 acute thrombosis and 7ISR in BMS group; 1 death, 1 stent thrombosis in CS group.</p>	<p>The use of CSs for severe iliac lesions has similar early and midterm outcomes compared with BMS. In a subcategory of TASC II D lesions with long-segment severe stenosis of both the common and external iliac arteries, CS should be considered as the primary line of treatment</p>

<p>Schwindt et al 2011 (J Vasc Surg 2011;53:1550-6.)</p>	<p>Single center retrospective study on prospective data, n=52</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal, Aortic bifurcation, iliac • Included CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES were preferred for long lesions, BES were used in lesions involving the aortic bifurcation, or when more radial force was needed, stent graft</p>	<p>Results:</p> <p>All patients had an improvement of ABI>0.10. The estimated assisted primary patency at 9 years was 96% and the mean survival time was 86.6 months.</p>	<p>Adverse events:</p> <p>1 death, 1 aortic rupture</p>	<p>Primary stenting offers safe and durable results and should be considered as the first line of treatment for focal aortic lesions.</p>
<p>Kokkinidis et al 2017 (Catheter Cardiovasc Interv. 2018 Sep 1;92(3):526-532)</p>	<p>2 center retrospective study, n=115</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included CTO, calcified lesions • Claudication, CLI, ALI • Both focal and diffuse 	<p>Covered stents and SES</p>	<p>Results:</p> <p>The 1- and 5-year TLR rates for lesions treated with re-entry device vs. standard approaches were 11% vs. 9%; P=0.8 and 29% vs. 29%; P=0.9 respectively. The 1 and 5-year major adverse limb event rates for lesions treated with re-entry device were 5% vs. 6%; P=0.8 and 11% vs. 11%; P=0.9 respectively.</p>	<p>Adverse events:</p> <p>3 perforations, 2 dissections</p>	<p>Recanalization of CIA occlusions using a RED is safe and is associated with long-term clinical outcomes similar to that of standard crossing techniques.</p>

<p>Dijkstra et al 2017 (Journal of Endovascular Therapy 2017, Vol. 24(1) 19–24)</p>	<p>Multicenter retrospective study, n=14</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Distal aorta, Aortic bifurcation, CIA, EIA, IIA • Included CTO, thrombotic lesions • Claudication, CLI 	<p>covered endovascular repair of the aortic bifurcation (CERAB) technique in conjunction with chimney grafts</p>	<p>Results:</p> <p>ABI significantly increased from 0.54 preoperatively to 0.97 in 11 patients examined at 12 months, and all patients had an improvement in the Rutherford category. All CERAB limbs, including the one recanalized, were patent at follow-up</p>	<p>Adverse events:</p> <p>5 unintended dissections, 1 vessel thrombosis, 1 occlusion of CERAB</p>	<p>Chimney-CERAB is technically feasible and may offer an alternative to open surgery for complex aortoiliac occlusive disease</p>
<p>Dorigo et al 2017 (J Vasc Surg 2017;65:99-107.)</p>	<p>3 center retrospective study on prospective registry, n=128</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal, Aortic bifurcation, CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES for lesions between 2 and 10 cm in length. BES were used preferentially for focal, ostial, and severely calcified lesions</p>	<p>Results:</p> <p>primary, assisted primary, and secondary patency rates were similar between aortobifemoral bypass and endovascular recanalization with the kissing stent technique; Univariate and multivariate analysis showed that only the presence of critical limb ischemia was independently associated with poorer primary patency during follow-up (hazard ratio, 2.4; 95% confidence interval, 0.9-6.4; P = .05).</p>	<p>Adverse events:</p> <p>13 deaths, 2 restenosis, 10 thrombosis</p>	<p>endovascular repair of aortoiliac complex lesions with the kissing stent technique provided similar satisfactory early and late results to those obtained with open surgery</p>

<p>Kokkinidis et al 2018 (Journal of Endovascular Therapy 2018, Vol. 25(2) 183–191)</p>	<p>2 center retrospective study, n=331</p>	<p>Indications:</p> <ul style="list-style-type: none"> • EIA • Included CTO, calcified, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	<p>Cutting balloon, Atherectomy, SES, BES, Covered stent, Drug coated balloons, atherectomy</p>	<p>Results: 1-year primary patency was 78% and secondary patency was 92%. One-year and 5-year TLR rates were 8.2% and 15.4%, respectively.</p>	<p>Adverse events: 63 deaths, 10 MI, 9 stroke, Dissections, vessel perforation, distal embolization</p>	<p>Intervention to EIA CTOs is associated with increased intraprocedural complexity but with similar midterm outcomes, including high patency and low rates of TLR to 5 years.</p>
<p>Maldonado et al 2016 (Eur J Vasc Endovasc Surg (2016) 52, 64-74)</p>	<p>Multicenter retrospective study, n=91</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortic bifurcation, iliac • Included CTO, calcified lesions • Claudication, CLI 	<p>AFX system consists of bifurcated unibodies with short, integrated iliac limbs, feature a cobalt chromium stent frame with a multilayer expanded PTFE material external to the stent.</p>	<p>Results: At all time points, primary patency rates were > 90%, assisted patency rates were > 98%, and secondary patency rates were 100%.</p>	<p>Adverse events: 1 death with extensive pelvic Thromboembolism, groin infection, groin hematoma, common iliac rupture, iliac dissection, and thromboembolic event</p>	<p>Use of the AFX stent-graft appears to be a safe and effective endovascular treatment for complex AIOD</p>

<p>Taeymans et al 2018 (J Vasc Surg 2018;67:1438-47.)</p>	<p>2 center retrospective study, n=130</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, Aortic bifurcation, Iliac • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>covered endovascular reconstruction of the aortic bifurcation (CERAB) technique using Advanta Atrium V12 stents</p>	<p>Results:</p> <p>Primary, primary assisted, and secondary patency was 86%, 91%, and 97% at 1 year; 84%, 89%, and 97% at 2 years; and 82%, 87%, and 97% at 3 years. Freedom from clinically driven TLR was 87% at 1-year follow-up and 86% at both 2-year and 3-year follow-up.</p>	<p>Adverse events:</p> <p>3 stent collapse, 2 early thrombosis, 1 death of unknown cause</p>	<p>The CERAB technique is a safe and feasible technique for the treatment of extensive AIOD with good 3-year results regarding patency and clinical improvement</p>
<p>Katsanos et al 2017 (Cardiovasc Intervent Radiol (2017) 40:351–359)</p>	<p>Single center retrospective study, n=256</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac • Included CTO, calcified, thrombotic lesions • Claudication, CLI • Diffuse 	<p>bare nitinol stent (BNS) or covered nitinol stent (CNS)</p>	<p>Results:</p> <p>Annualized stent thrombosis rates (per 100 person-years) were 12.5% in case of CNS and 1.4% in case of BNS (HR 6.3, 95% CI 2.4–17.9; p = 0.0002). Corresponding major amputations rates were 8.7 and 2.5%, respectively</p>	<p>Adverse events:</p> <p>Stent thrombosis</p>	<p>acute stent thrombosis and ensuing major amputation risks are significantly lower in the aortoiliac vessels and with use of bare nitinol stents compared to long femoropopliteal covered nitinol stents</p>

<p>Roach et al 2015 (J Vasc Surg 2015;62:645-53.)</p>	<p>Single center retrospective study, n=213</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, covered stent</p>	<p>Results: At 1 and 3 years PP was 86% and 53%, assisted PP 98% and 89%, and secondary patency 99% of 98%. PP at 1 year was 91% Caucasian vs 77% non-Caucasian (P = .001), 75% in patients aged <60 years, 86% in patients aged 60-70 years, and 96% in patients aged >70 years, (P <.001); 71% and 88% in patient with and without EIA occlusion respectively occlusion (P =.002),</p>	<p>Adverse events: Vessel perforation, dissection, distal emboli,</p>	<p>younger age, non-Caucasian race, and EIA occlusion were strong predictors for loss of PP.</p>
<p>Baker et al 2015 (Ann Vasc Surg 2015; 29: 55–62)</p>	<p>Single center retrospective study; N=20</p>	<ul style="list-style-type: none"> • lower extremity CTOs CLI, claudication 	<p>4 bare metal BE and 6 covered BE stents were used in CIA, 7 uncovered SE stents were used in EIAs and SFA. A single DES was used in EIA.</p>	<p>Results: ABIs significantly increased (0.5-0.9; P < 0.01) in the 13 patients with follow-up. Primary patency for the entire cohort was 62% at 12 months</p>	<p>Limitations: retrospective report, small sample size, relatively short follow-up</p> <p>Adverse events: 2 patients died unrelated to the procedure, 1 amputation, and 1 open revascularization.</p>	<p>Recanalization of CTO using IVUS-RED is safe and effective Acceptable safety and effectiveness</p>

<p>Balzer et al 2006 (Eur Radiol (2006) 16: 124–131)</p>	<p>Single center retrospective study; N=89</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included calcified, CTO lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, covered stent</p>	<p>Results:</p> <p>Eighty of 89 patients (89.9%) remained patent at 3-year follow-up. The secondary patency rate was 95.5%.</p>	<p>Restenosis, 1 perforation, 1 stroke</p>	<p>The patency rates were similar in selected TASC C and D patients to those so far published for TASC A and B, with low complication rates. Therefore, percutaneous intervention can be recommended for these patient</p>
<p>Bjorses et al 2008 (Eur J Vasc Endovasc Surg (2008) 36, 424-431)</p>	<p>Single center retrospective study; N=173</p>	<p>Indications:</p> <ul style="list-style-type: none"> • aortic bifurcation, distal aorta, CIA, EIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, Jostentgraft</p>	<p>Results:</p> <p>Primary, assisted primary and secondary patency was: 97%, 99% and 100%, and 83%, 90% and 95% at twelve and 36 months respectively. There was no significant difference in patency between the TASC groups. Patency was significantly worse for patients in Fontaine class III.</p>	<p>1 % 30 day mortality – most of them died of cardiovascular disease; restenosis, stent occlusion</p>	<p>Aortoiliac kissing stents is a valid alternative to open repair for TASC A-D lesions. The procedure has low mortality and morbidity and good patency at 3 years</p>

<p>Bruijnen et al 2012 (J Vasc Surg 2012;55:674-8.)</p>	<p>Single center retrospective study; N=12</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta • Included calcified, CTO, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>Balloon expanding PTFE covered stent</p>	<p>Results:</p> <p>During follow-up, all patients remained asymptomatic and ankle-brachial indexes had normalized. Duplex ultrasonography showed no re-stenosis, and there were no stent fractures on abdominal radiographs.</p>	<p>None</p>	<p>The primary use of PTFE-covered stents is a feasible, effective, and safe treatment for focal atherosclerotic lesions in the infrarenal aorta</p>
<p>Burke et al 2010 (Ann Vasc Surg 2010; 24: 4-13)</p>	<p>Single center retrospective study; N=174</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, aortic bifurcation • Claudication, CLI, ALI 	<p>aortofemoral bypass (AFB) group Vs aortoiliac angioplasty and stenting group with SES, BES, covered stent</p>	<p>Results:</p> <p>The difference between preprocedural and postprocedural ABI was greater for AFB than AS (R, 0.39 and 0.18, $p < 0.001$; L, 0.41 and 0.15, $p < 0.001$). This difference was maintained when patients were stratified by TASC category.</p>	<p>2 death, 2 MI, 2 stroke; revision or amputation</p>	<p>There were no differences between the AFB and AS groups with respect to longterm rates of mortality, amputation, or revision procedures. AFB continues to be performed safely, despite the case numbers in this series correlating with a lower-volume hospital. Morbidities associated with major open surgery in this series were counterbalanced by greater improvements in ABI.</p>

<p>Haren et al 2017 (J Vasc Surg 2017;65:398-405.)</p>	<p>Single center retrospective study; N=10</p>	<p>Indications:</p> <ul style="list-style-type: none"> • TASC D aortoiliac occlusive disease • Distal aorta, aortic bifurcation, CIA, EIA • Included calcified, CTO lesions • CLI 	<p>Endologix Powerlink unibody bifurcated endograft (Endologix, Irvine, Calif), SES, self-expanding covered stent</p>	<p>Results:</p> <p>The primary and secondary patency rates were 80% and 100%, respectively</p>	<p>1 death from unrelated cardiac cause, iliac artery thrombosis</p>	<p>endovascular repair using a unibody bifurcated endograft for TASC D aortoiliac occlusive disease is feasible, effective, and has excellent midterm patency. It should be considered an effective treatment option when the disease process involves the aorta, in particular if the patient is surgically unfit for a traditional aortobifemoral bypass.</p>
<p>Humphries et al 2014 (J Vasc Surg 2014;60:337-44.)</p>	<p>Single center retrospective study; N=162</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Claudication, CLI, ALI • Both focal and diffuse 	<p>BES, balloon-expanding covered stent</p>	<p>Results:</p> <p>Primary patency, assisted patency, and secondary patency were significantly better in the BMS group. CIAs treated with covered stents were more likely at 1 year or longer to require repeated intervention (hazard ratio, 2.5; 95% confidence interval, 1.2-5.3; P = .009).</p>	<p>Thrombosis, amputation</p>	<p>BMSs had significantly better patency compared with covered balloon-expandable stents for treatment of aortoiliac occlusive disease.</p>

<p>Kasemi et al 2016 (Ann Vasc Surg 2016; 30: 277–285)</p>	<p>Single center retrospective study; N=22</p>	<p>Indications:</p> <ul style="list-style-type: none"> • aorta, aortic bifurcation, CIA, EIA • Included calcified, thrombotic, lesions • Claudication, CLI • Diffuse 	<p>SES to EIA, Viabahn covered stent to aorta and CIA</p>	<p>Results:</p> <p>The primary patency rate was 95.2% at 1 year and 90.5% at 3 years, and the secondary patency rate was 95.2% at 1 year and 100% at 3 years.</p>	<p>Perioperative mortality rate was 4.5%, stent thrombosis</p>	<p>The Y-guidewire configuration technique for the aortic bifurcation reconstruction may render the procedure more feasible</p>
<p>Lacroix et al 1997 (Eur J Vasc Endovasc Surg 14, 204-207 (1997))</p>	<p>Single center retrospective study; N=16</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Claudication, CLI 	<p>BES, PTFE graft</p>	<p>Results:</p> <p>The primary patency of the 19 reconstructions was 100% at 1 month and 70% (CL 44-95%) at 1 year. The secondary patency was, respectively, 100% and 93% (CL 81-106%).</p>	<p>Two patients died, one of small bowel ischaemia and the other of a myocardial infarction; graft thrombosis/occlusion</p>	<p>Our experience shows that the reported technique is feasible. Whether the procedure is truly "less invasive" and the long-term results acceptable remains to be shown.</p>

<p>Marin et al 1994 (Am J Surg. 1994 Aug;168(2):156-62.)</p>	<p>Single center retrospective study; N=3</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • CLI 	<p>BES, EPTFE graft with BES sutured to each side</p>	<p>Results: Patency and limb salvage has been achieved to 1 year</p>	<p>1 repeat dilation, iliofemoral deep vein thrombosis</p>	<p>Endovascular stented grafts can be inserted to treat limb-threatening ischemia.</p>
<p>Psacharopulo et al 2015 (J Vasc Surg 2015;62:1219-26.)</p>	<p>Single center retrospective study; N=22</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac, CIA, EIA • Included CTO lesions • Claudication, CLI 	<p>Viabahn covered stent</p>	<p>Results: At the 2-year follow-up, primary patency did not differ significantly between the endovascular (91%) and surgical (95%) groups</p>	<p>2 occlusion, 2 acute renal failure</p>	<p>At 2 years of follow-up, the results of endoluminal bypass grafting with the Viabahn stent to treat complex aortoiliac disease are promising.</p>

<p>Shen et al 2015 (Chin Med J 2015;128:303 5-42.)</p>	<p>Single center retrospective study; N=56</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, CIA, EIA • Included calcified, thrombotic lesions • Claudication, CLI 	<p>SES, covered stent</p>	<p>Results:</p> <p>Primary patency rates at 1-, 3-, 5-, and 7-year were 93.6%, 89.3%, 87.0%, and 70.3%, respectively</p>	<p>restenosis, stent occlusion</p>	<p>diabetes and femoropopliteal TASC II type C/D lesions are risk factors associated with restenosis after open and ET of TASC II D AIOLs</p>
<p>Steinkamp et al 2001 (Acta Radiologica 42 (2001) 508–514)</p>	<p>Single center retrospective study; N=90</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA • Included calcified lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, Wallgraft</p>	<p>Results:</p> <p>The primary angiographic patency rate was 83.1%. The patency rate after 24 months was 90.0%.</p>	<p>3 thromboembolic events, Restenosis, perforations</p>	<p>Primary stent implantation is an effective treatment for short iliac obstructions and represents a true endovascular alternative to surgery.</p>

<p>Wain et al 1999 (Ann Surg. 1999 Aug; 230(2): 145.)</p>	<p>Single center retrospective study; N=46</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aortoiliac • Included calcified lesions • CLI 	<p>PTFE covered graft with BES BMS palmaz attached</p>	<p>Results:</p> <p>The 4-year primary and secondary patency rates for the endovascular grafts were 66.1% and 72.3% respectively.</p>	<p>6 amputations, 23 died during follow up, 15 failed - closed grafts</p>	<p>Endovascular grafts can often be used when conventional procedures are contraindicated or technically impractical.</p>
<p>Zander et al 2011 (J Vasc Interv Radiol 2011; 22:1124–1130)</p>	<p>Single center retrospective study; N=14</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Aorta, iliac • Included CTO lesions • Claudication, CLI 	<p>Bifurcated endograft</p>	<p>Results:</p> <p>At a mean follow-up of 62 months, primary patency was 85.7%, and secondary patency was 100%.</p>	<p>1 died of nonrelated cause, 2 prosthesis occlusion</p>	<p>Bifurcated aortic endograft is a good minimally invasive alternative to open surgery in high surgical risk patients</p>

<p>Javed et al 2013 (Catheter Cardiovasc Interv. 2013 Dec 1;82(7):1176-84.)</p>	<p>Single center retrospective study; N=24</p>	<p>Indications:</p> <ul style="list-style-type: none"> • CIA, EIA • Included CTO, ISR, thrombotic lesions • Claudication, CLI, ALI • Both focal and diffuse 	<p>BMA, Covered stent</p>	<p>Results:</p> <p>The 6-and 12-month primary patency rates were 96% and 82%, respectively. The 12-month primary-assisted patency rate was 90% with clinically driven TLR in three patients.</p>	<p>Adverse events:</p> <p>distal embolization, ISR, 2ndeaths - 1 of sepsis and other from sudden cardiac death</p>	<p>Endovascular treatment of IA-ISR using an approach of balloon angioplasty followed by selective stenting is associated with high-patency rates and low rates of TLR at 1 year.</p>
<p>Moise et al 2009 (J Endovasc Ther. 2009 Feb;16(1):84-92.)</p>	<p>Single center retrospective study; N=31</p>	<p>Indications:</p> <ul style="list-style-type: none"> • Infrarenal aorta, CIA • Included calcified, thrombotic lesions • Claudication, CLI • Both focal and diffuse 	<p>SES, BES, Covered stent for calcified lesions</p>	<p>Results:</p> <p>At 1 and 3 years, the primary/secondary patency rates were 85%/100% and 66%/90%, respectively.</p>	<p>Adverse events:</p> <p>perioperative limb thromboses, acute renal dysfunction</p>	<p>Endovascular therapy for chronic infrarenal aortic occlusion has a high technical success rate, with good midterm primary and secondary patency rates.</p>

Suppl Table 6. RCTs, Nonrandomized Trials, Observational Studies, and/or Registries of Drug eluting Stents in Aorto-Iliac Arterial Interventions

Study Acronym; Author; Year Published	Aim of Study; Study Type; Design; Study Size (N)	Patient Population	Study Intervention (# pts)/Study Comparator (# pts)	Primary Endpoint; Endpoint Results; (include P value; OR or RR; & 95% CI)	Relevant 2° Endpoint (if any); Study Limitations; Adverse Events	Summary/ Conclusion Comment(s)
<p>ESPRIT I trial; Lammer et al 2016 ((J Am Coll Cardiol Intv 2016;9:1178–87)</p>	<p>Aim:</p> <ul style="list-style-type: none"> • Safety and performance of a drug-eluting bioresorbable vascular scaffold (BVS) for treatment of PAD involving the EIA and SFA. <p>• Study type: Prospective, multicenter, single arm</p> <p>• Size: N= 35</p>	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> • symptomatic claudication (RB 1 to 3) • single de novo lesion of the SFA or iliac arteries • lesion length ≤50 mm • vessel diameter from ≥5.0 mm to ≤6.5 mm. <p>Exclusion criteria: inability to walk, presence of ulcers on either foot, previous amputation, occlusion, severe calcification.</p>	<p>Intervention: ESPRIT BVS</p>	<p>1° endpoint: Binary restenosis rate, TLR.</p> <ul style="list-style-type: none"> • At 1 and 2 years, the binary restenosis rates were 12.1% and 16.1%, respectively, and TLR was performed in 3 of 34 patients and 4 of 32 patients respectively. 	<p>2° endpoint: ABI improved from pre-procedure to 0.96 ± 0.16 at 2 years' follow-up.</p> <p>Limitations: Small size involving patients with short not-severely calcified lesions, single arm</p> <p>Adverse events: 1 death due to an unrelated stroke, 1 MI in a patient with known CAD, 1 flow-limiting dissection and 2 groin hematomas</p>	<p>The safety of the ESPRIT BVS was demonstrated with no procedure or device-related deaths or amputations within 2 years. The low occurrence of revascularizations was consistent with duplex-ultrasonography showing sustained patency at 2-years</p>
<p>Baker et al 2015 (Ann Vasc Surg 2015; 29: 55–62)</p>	<p>Single center retrospective study; N=20</p>	<ul style="list-style-type: none"> • lower extremity CTOs • CLI, claudication 	<p>4 bare metal BE and 6 covered BE stents were used in CIA, 7 uncovered SE stents were used in EIAs and SFA. A single DES was used in EIA.</p>	<p>Results: ABIs significantly increased (0.5-0.9; P < 0.01) in the 13 patients with follow-up. Primary patency for the entire cohort was 62% at 12 months</p>	<p>Limitations: retrospective report, small sample size, relatively short follow-up</p> <p>Adverse events: 2 patients died unrelated to the procedure, 1 amputation, and 1 open revascularization.</p>	<p>Recanalization of CTO using IVUS-RED is safe and effective Acceptable safety and effectiveness</p>

