Three-year outcome of the covered endovascular reconstruction of the aortic bifurcation technique for aortoiliac occlusive disease

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ABSTRACT

Objective: The objective of this study was to demonstrate the 3-year outcome of the covered endovascular reconstruction of the aortic bifurcation (CERAB) technique for the treatment of extensive aortoiliac occlusive disease (AIOD).

Methods: Between February 2009 and July 2016, all patients treated with the CERAB technique for AIOD were identified in the local databases of two centers and analyzed. Demographics and lesion characteristics were scored. Follow-up consisted of clinical assessment, duplex ultrasound, and ankle-brachial indices. Patency rates and clinically driven target lesion revascularization were calculated by Kaplan-Meier analysis.

Results: Of 130 patients (69 male and 61 female) treated, 68% were diagnosed with intermittent claudication and 32% suffered from critical limb ischemia. The majority (89%) were TransAtlantic Inter-Society Consensus II D lesions, and the remaining were B and C lesions (both 5%). Median follow-up was 24 months (range, 0-67 months). The technical success rate was 97%, and 67% of cases were performed completely percutaneously. The ankle-brachial index improved significantly from 0.65 ± 0.22 preoperatively to 0.88 ± 0.15 after the procedure. The 30-day minor and major complication rate was 33% and 7%. The median hospital stay was 2 days (range, 1-76 days). At 1 year and 3 years of follow-up, 94% and 96% of the patients clinically improved at least one Rutherford category (2% and 0% unchanged, 4% and 4% worsened). Limb salvage rate was 98% at 1 year and 97% at 3 years of follow-up. 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 target lesion revascularization was 87% at 1-year follow-up and 86% at both 2-year and 3-year follow-up.

Conclusions: 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. (J Vasc Surg 2018;67:1438-47.)

The last decades have shown a clear trend toward endovascular intervention as the first-line treatment strategy for aortoiliac occlusive disease (AIOD) and as a solution for complex lesions. Endovascular treatment of AIOD has been related to less morbidity and a shorter hospital stay compared with open surgery.[1] In addition, open reconstruction is related to late complications, including incisional hernia formation. The kissing stent (KS) technique, using two stents abutting or "kissing" in the central lumen of the distal aorta, is most commonly used when the aortic bifurcation is involved. A recent review showed that the primary patency of KS at 2-year follow-up is 79%, with 48% TransAtlantic Inter-Society Consensus II (TASC II) C or D lesions treated.[2] The geometry of the KS configuration was previously identified as a risk factor for restenosis and thrombosis.[3-5] The cross-configuration in KS influences the mismatch areas between the stent and vessel wall that in turn cause flow disturbances. This is thought to be the main cause of impaired patency, related to neointimal hyperplasia induced by low oscillating wall shear stress and stagnant blood flow.[6] To overcome these disadvantages and to achieve better long-term patency, our groups introduced a new technique in 2013 named the covered endovascular reconstruction of the aortic bifurcation (CERAB) technique.[7] We previously showed that this configuration is related to a superior flow geometry and more physiologic flow patterns in vitro.[8,9] In 2015, the early results of the CERAB technique were published with 1-year primary and secondary patency rates of 87% and 95%, respectively. These were considered to be promising, particularly because they included all treated patients from two sites including the first-in-man study.[10] In this study, we have evaluated 3-year outcomes of the same cohort and updated it with the more recently treated patients.

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METHODS

Patients. All patients treated with the CERAB technique between February 2009 and July 2016 in two hospitals, the Rijnstate Hospital Arnhem (The Netherlands) and the ZNA Vascular Clinic (Belgium), were identified and analyzed retrospectively. Human investigation review board approval was obtained for this study, and informed consent of the patient was not required because of the retrospective design. Patients treated for acute limb ischemia and patients with chimney configurations were excluded from the analysis.[11] Before endovascular treatment, all patients were treated with antiplatelet therapy, statins, and supervised walking exercise. Medical files were screened for demographic data, clinical status (using the Rutherford classification for chronic ischemia[12]), complications, and information on follow-up. Lesions were categorized according to the TASC II criteria by assessing the computed tomography angiography (CTA) scans.[13,14] Procedural reports were used to extract information on the procedure and the stent types used. The pretreatment runoff resistance score for the iliac outflow was calculated on the basis of the runoff grading scheme as proposed by Rutherford et al.[12] A 3-point degree of stenosis scale was used to gauge the resistance based on duplex ultrasound: <50% stenosis, 0; >50% stenosis, 1; and occlusion, 2. Weighting units are divided among the relative contribution to runoff: 2 for the external iliac artery and 1 for the internal iliac artery. The maximal combined runoff score for left and right was 12 (left + right = [2*2 + 2*1] + [2*2 + 2*1]). Follow-up was scheduled after 6 weeks and 6, 12, 24, 36, 48, and 60 months and consisted of clinical assessment and duplex ultrasound with ankle-brachial index (ABI) measurements. Because of the low number of patients with a completed follow-up of 48 and 60 months, follow-up to 36 months is reported in the Results section.

CERAB procedure. Suitability for the technique was evaluated on the basis of CTA imaging. Details of the CERAB technique have been described before.[7] Briefly, two introducer sheaths are placed in the common femoral arteries. The lesion is crossed either endoluminally or subintimally, depending on the lesion's characteristics (Fig 1, *A*, verifying re-entrance). After predilation, a 9F introducer sheath is inserted above the proximal margin of the aortic lesion. Thereafter, a 12-mm balloon-expandable expanded polytetrafluoroethylene covered stent (Atrium Advanta V12; Maquet Getinge, Hudson, NH) is deployed in the distal aorta. The distal end of the stent is placed approximately 15 to 20 mm above the bifurcation to facilitate canalization. This stent is flared proximally with a balloon adapted to the native diameter of the distal aorta, typically with a diameter of 16 mm, to ensure full apposition to the aortic wall. This creates a funnel-shaped stent with a distal segment that is still 12 mm in diameter. Subsequently, two iliac covered stents, typically 8 mm, are positioned in the conic segment and simultaneously inflated (Fig 1, *B*). As treatment planning is always from healthy to healthy tissue, in some cases distal extensions are required (Fig 1, *B*). In these cases, we try to preserve the internal iliac arteries, if patent, using a bare-metal stent at these locations to prevent buttock claudication and erectile dysfunction. After the procedure, patients receive statin treatment and dual antiplatelet therapy for at least 6 months, after which single antiplatelet and statin therapy is continued.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter retrospective cohort study
- **Take Home Message:** In 130 patients with aortoiliac occlusive disease treated by the covered endovascular reconstruction of the aortic bifurcation technique, 1-year, 2-year, and 3-year primary patency was 86%, 84%, 82%, respectively, with a 3-year limb salvage rate of 97%.
- **Recommendation:** This study suggests that the covered endovascular reconstruction of the aortic bifurcation technique is an effective option for patients with aortoiliac occlusive disease.

Definitions. Primary outcome of the study was the 3-year primary patency. Secondary outcome measures included assisted primary patency, secondary patency, freedom from clinically driven target lesion revascularization, technical success, clinical improvement, length of hospital stay, 30-day morbidity, mortality, and secondary interventions. Patency was determined by means of duplex ultrasound (peak systolic velocity [PSV] <2.5). Primary patency was defined as patency that is obtained without the need for additional or secondary surgical or endovascular procedures.[15] Assisted primary patency is defined as patency of the configuration achieved with the use of an additional or secondary surgical or endovascular procedure, as long as occlusion of the treated segment has not occurred.[15] Secondary patency was defined as the patency achieved by all procedures to recanalize an occluded CERAB configuration, preserving the configuration. Freedom from clinically driven target lesion revascularization was defined as the time between the procedure and any revascularization based on restenosis or occlusion and return or increase of symptoms. Technical success was achieved when blood flow was restored with <30% residual stenosis. Restenosis was defined as a PSV ratio >2.5, measured proximal to, in, or distal to the graft on duplex ultrasound. Major and minor complications were registered up until 30 days after the procedure. Complications leading to transient impairment were scored as minor. Complications leading to

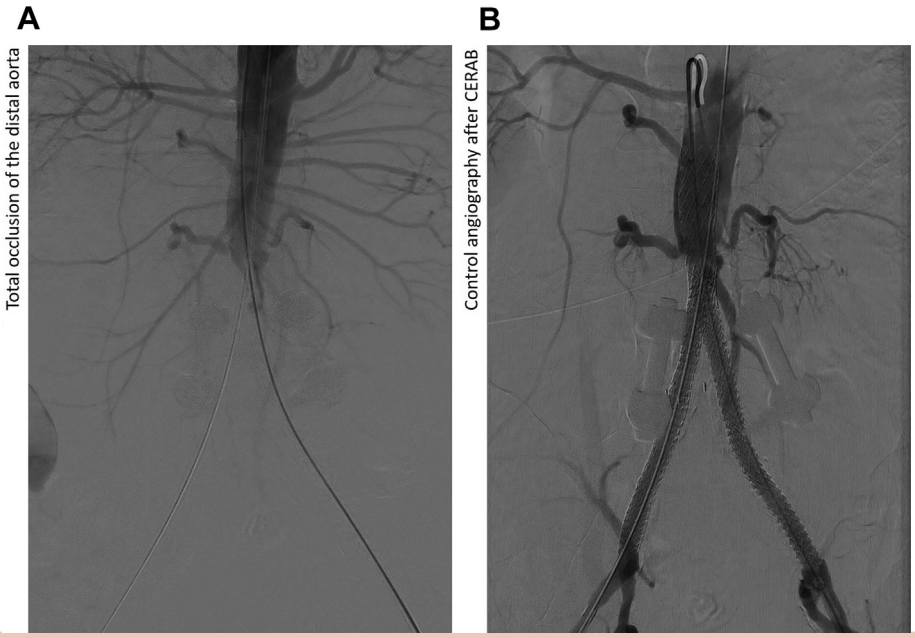


Fig 1. A, Angiography of a 54-year old man with intermittent claudication and an occlusion of the distal aorta. **B,** Control angiography after reconstruction with the covered endovascular reconstruction of the aortic bifurcation (CERAB) technique, with bilateral extensions, landing just above the iliac bifurcation. The aortic cuff is deployed 15 to 20 mm proximal to the anatomic bifurcation. On completion angiography, the caudal lumbar arteries are visible. Lumbar filling can occur because of three reasons: first, the artery can originate proximal to the aortic cuff; second, contrast material may flow between the aortic cuff and aortic wall in case of an incomplete apposition; and finally, contrast material may flow through the small gutters between the aortic cuff and the iliac limbs.

permanent damage or death were scored as major.[15] Limb salvage rate was defined as all patients without above-the-ankle amputations.

Statistics. Data are presented as mean ± standard variation unless stated otherwise. The Shapiro-Wilk test was used to test for normality. Statistical analysis was performed using SPSS 24 (IBM Corp, Armonk, NY). The nonparametric χ^2 test was used to test for differences in outcome with respect to previous vascular interventions, learning curve, intermittent claudication vs critical limb ischemia, and impaired runoff. The paired Student *t*-test was used to compare ABI preoperatively and postoperatively. An analysis of variance for repeated measures was used to test the difference in Rutherford category preoperatively and postoperatively. Univariate analysis was used to identify any correlation between smoking, diabetes, hypertension, renal status, cardiac status, and pulmonary status and patency. Kaplan-Meier survival analysis was used to calculate patency numbers. The log-rank test was used to compare the resulting survival curves. Statistical significance was defined as $P < .05$.

RESULTS

During the study period, a total of 130 patients (69 male and 61 female) were treated with the CERAB technique at the two sites. Characteristics of the patients are depicted in Table I and Fig 2. One patient was classified as Rutherford category 1 as he was preventively treated for an aortobifemoral prosthesis at risk for occlusion because of high-grade stenosis at the proximal anastomosis. The majority of lesions (n = 116 [89%]) were classified as TASC II D; the remaining were TASC II B and C (both n = 7 [5%]). Seven patients had previously undergone a surgical reconstruction of the aortoiliac segment: five aortobi-iliac bypasses, one iliofemoral, and one femorofemoral crossover bypass. Another 46 patients (35%) had previously undergone an endovascular intervention; 46% of these interventions were angioplasties of the common iliac artery (in 17%, kissing balloon), and 37% were angioplasties with stenting of the common iliac artery (31% KS). Table I provides details on the remaining interventions. Before the intervention, 35% (n = 44) had no stenosis in one of the outflow vessels, 35% (n = 44) had a stenosis, and 30% (n = 38) had an occlusion in one of the outflow vessels (either left or right). Further details per vessel segment are presented in Table I. Median follow-up was 23.5 months (range, 0-67 months). Follow-up at 24 and 36 months was available in 56 and 37 cases, respectively.

Procedural results. The technical success rate was 97%. In four cases, technical success was not obtained; in three patients, no re-entry could be obtained, and in one, the lesion could not be passed. All technical failures

Table I. Characteristics of the patients

Age, years, mean (range)		61 (36-81)
	No.	**%**
Men	69	53
Risk factors		
Current smoking	100	78
Diabetes mellitus	46	35
Hypertension	96	74
Hyperlipidemia	121	93
Cardiac disease	61	47
Pulmonary disease	51	39
Carotid disease	26	20
Renal disease	25	19
ASA category		
1	0	0
2	73	57
3	50	39
4	6	5
Rutherford category		
1	1	1
2	0	0
3	84	66
4	22	17
5	18	14
6	2	2
Outflow vessels (open; stenosis; occluded)	**Right, %**	**Left, %**
EIA	59; 30; 11	67; 22; 10
Internal iliac artery	66; 21; 14	61; 22; 17
Common femoral artery	71; 26; 3	76; 22; 2
SFA	67; 29; 5	66; 27; 7
Deep femoral artery	91; 8; 18	90; 10; 0
Preoperative runoff score	**No.**	**%**
0	53	43
1	3	2
2	11	9
3	5	4
4	19	15
5	5	4
6	10	8
7	3	2
8	5	4
9	3	2
10	4	3
12	3	2
Intervention history	**No.**	**%**
Previous aortoiliac intervention	53	41
PBA CIA	18	14
PBA CIA kissing	3	2
PBA EIA	3	2
PBA SFA	2	2
PBA + stent CIA	13	10
PBA + stent kissing	4	3
PBA + stent EIA	2	2
PBA + stent SFA	1	1
Surgical treatment of aortoiliac segment	7	5
Amputation	0	0

ASA, American Society of Anesthesiologists physical status classification system; *CIA*, common iliac artery; *EIA*, external iliac artery; *PBA*, plain balloon angioplasty; *SFA*, superficial femoral artery.

occurred within the first 40 treated patients (cases 20, 24, 37, and 39). Most procedures were performed by bilateral percutaneous access of the common femoral arteries (n = 87 [67%]). In 15% of cases (n = 20), a surgical cutdown of both femoral arteries was performed, combined with an endarterectomy of the common femoral artery in 65% of them (n = 13). In 18% of the procedures (n = 23), a percutaneous access technique was used on one side and surgical cutdown was performed on the contralateral side. At the location of the cutdown, this was combined with an endarterectomy in 52% of the procedures. Brachial access was used in two procedures.

Three covered stents were used in 55% (n = 67) of the cases, four in 19% (n = 23), five in 22% (n = 27), and more than six stents in 4% (n = 5). The aortic stent was predominantly used in the dimensions 12 × 41 mm (n = 77) or 12 × 61 mm (n = 34). Limbs (left and right) were deployed with a diameter × length of 8 × 59 mm (n = 190), 8 × 38 mm (n = 30), and 6 × 59 mm (n = 10). In a number of cases, the limb was extended into the external iliac artery to reach healthy tissue (14% to the right and 15% to the left side). The mean procedure time was 152.7 ± 88 minutes, and the mean amount of contrast material used was 122.5 ± 62.4 mL. Median hospital stay was 2 days (range, 1-76 days); 54% of the patients stayed in the hospital for 1 or 2 days; 29% of the patients stayed 3 to 5 days, and 6% were admitted for longer than 5 days.

In 11% of the cases, there were procedural complications, including unintentional dissection, arterial rupture, and thrombosis (Table II), and all of them were solved during the initial procedure. In one patient, extensive bleeding in the left common iliac artery led to a resuscitation after cardiac arrest and subsequent prolonged intensive care unit and hospital stay (76 days). The patient died, with an unknown cause of death, 3 months after discharge.

Clinical outcome. Postoperative complications are depicted in Table II. Minor complications occurred in

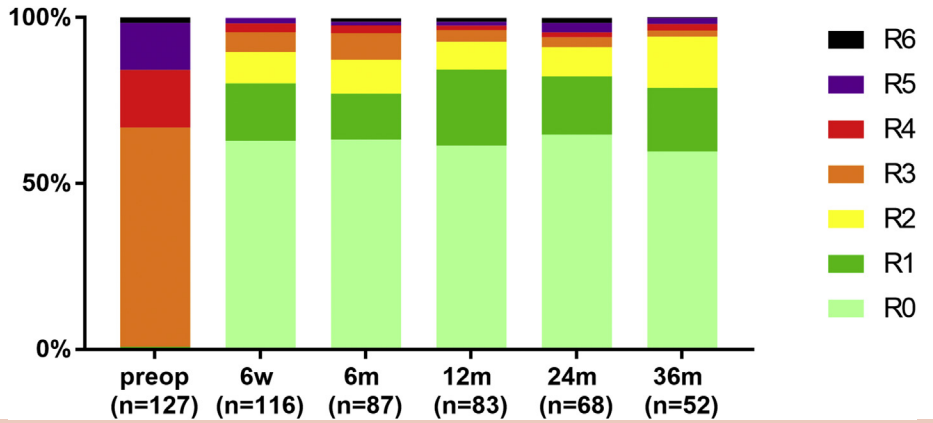


Fig 2. Distribution of Rutherford categories within the cohort during follow-up. The number at risk for each follow-up period is given in parentheses.

43 cases (33%); in 33 cases (77%), these were hematoma, ecchymosis, or leg edema. A reintervention was necessary in two cases with a minor complication, both requiring thrombin injection for a false aneurysm at the access site. In 8% of the treated patients, major postoperative complications occurred—in three cases, stent collapse in one of the limbs; in one case, the CERAB was explanted and replaced with an aortobifemoral graft, and in two cases, a kissing balloon technique was used to restore the flow lumen of the collapsed limb (Fig 3). Another patient was reoperated on for an occlusion of the femoral artery attributed to a misplaced closure device. In two cases, an early thrombosis of the CERAB occurred, both 3 weeks postoperatively. Both were successfully treated, one by thrombectomy and the other by thrombolysis. Postoperative deterioration of chronic renal insufficiency occurred in one patient without the need for dialysis. This patient, treated for Rutherford category 5, died 4 months postoperatively. The 30-day mortality rate was 0%.

Clinical improvement, expressed as an increase of at least one Rutherford category, at 6 weeks of follow-up was 87%. No improvement was observed in 11% of the patients, and in 3%, it worsened (maximum of one category). The median Rutherford category changed from 3 (minimum, 1; maximum, 6) preoperatively to a median of 0 (minimum, 0; maximum, 5) postoperatively ($P < .05$). At 24 and 36 months, the median Rutherford category was 0 (minimum, 0; maximum, 6) and 0 (minimum, 0; maximum, 6), both significantly different with respect to the preoperative staging; an overview is given in Fig 2. The ABI significantly improved from 0.65 ± 0.22 preoperatively to 0.88 ± 0.15 after the procedure ($P < .05$). At 24 and 36 months, the ABI was 0.97 ± 0.14 and 0.99 ± 0.14.

In total 3% of patients underwent toe amputations, three within 30 days and one during the procedure (unrelated to the procedure). The preoperative Rutherford classification was 5 in two cases and 6 in two cases. After 3-year follow-up, four (3%) major amputations (under or above the knee) were performed at 6 months (n = 1), 12 months (n = 1), and 24 months (n = 2) of follow-up, respectively. The initial Rutherford classification was 4 in three cases and 5 in one case. Limb salvage rate was 98% at 1-year and 97% at 3-year follow-up. The overall survival at 1-year and 3-year follow-up was 93% and 88%, respectively. In total, 12 patients died during the 3-year follow-up.

Patency. The patency rates are depicted in Fig 4. The primary patency was 86% after 12 months, 84% after 24 months, and 82% after 36 months. Univariate analyses showed no significant relation between primary patency and smoking, diabetes, hypertension, renal insufficiency, or coronary disease. No differences in outcome were observed between the first 20 treated in each clinic and the patients treated thereafter ($P = .54$ and $P = .28$), and as such, a clear learning curve effect could not be established.

Outcome between patients with and without a history of previous vascular interventions (either surgical or endovascular) was not significantly different ($P = .26$). More details are presented in Table III. There was no significant difference ($P = .24$) in primary patency for patients with an increased runoff score (score 1-12) before treatment and patients without (score 0). Furthermore, grouped initial Rutherford indication (intermittent claudication vs critical limb ischemia) did not influence the primary patency results ($P = .61$).

Reinterventions. During the follow-up period, CERAB-related reinterventions were performed in 18 patients (14%; Table IV); 72% of the patients received one or two reinterventions, and the majority of them were performed within the first 12 months after the initial procedure (88%). Apart from reinterventions, other endovascular interventions were performed in 27 patients (21%). In 67% of the cases, this was either a plain balloon angioplasty (PBA) or PBA and stenting of the outflow arteries.

Table II. Complications

	No.	Severity/comments
Procedural, major (no minor reported)		
Dissection	6	All resolved with endovascular repair in the same procedure (PBA or stenting), no influence on health
Bleeding	2	One led to resuscitation after cardiac arrest during the procedure
Rupture	2	All resolved in the same procedure with endovascular repair, no influence on health
Dislocation of stent	1	Migration of the CERAB body, correction unsuccessful; however, CERAB completed
Stent deformation	1	Treated with PBA
Thrombus formation	2	All treated in the same procedure (thrombectomy), no influence on health
Postprocedural, major		
Stent deformation	3	Recovery after reintervention; stent collapse (one limb crushing the other limb), PBA in two cases, aortobifemoral graft in one case
Pneumonia	2	Leading to death in one case; second case, same patient as MOF case
Thrombosis	2	Recovery after intervention; one thrombectomy and one thrombolysis treatment
CFA occlusion related to closure device	1	Recovery after intervention; removal of the closure device
MOF	1	ICU stay with complete recovery; patient died 6 months postoperatively
Acute renal insufficiency	1	Permanent impairment requiring dialysis; patient died 4 months postoperatively
Postprocedural, minor		
Groin hematoma	15	Temporary impairment in two patients
Edema, legs	18	Temporary impairment
Rebleed	2	Temporary impairment; conservative treatment with bandaging
Pseudoaneurysm of the CFA	3	Recovery after intervention; thrombin injection in two cases; other case, only temporary impairment
Fever of unknown cause	2	Temporary impairment; no focus found near the CERAB; no intervention
Atrial fibrillation	1	Temporary impairment; treated with medication
Wound infection	1	Temporary impairment; resolved after treatment with antibiotics
Wound dehiscence	1	Temporary impairment; no treatment

CERAB, Covered endovascular reconstruction of the aortic bifurcation; *CFA*, common femoral artery; *ICU*, intensive care unit; *MOF*, multiorgan failure; *PBA*, plain balloon angioplasty.

DISCUSSION

In this study, we have demonstrated that patency and clinical outcome of the CERAB technique for extensive AIOD are satisfying, with 3-year primary, primary assisted, and secondary patency rates of 82%, 87%, and 97%, respectively. The technical success rate was 100% in the last 90 procedures, and in many of them, open surgery would have been the only alternative treatment modality. Technically, there are no anatomic or morphologic lesion boundaries for indication of the CERAB technique. The amount of circular calcification is not considered to be an exclusion criterion for the technique. In cases presenting with lesions just distal to the renal arteries, the chimney CERAB technique of the inferior mesenteric artery was applied (not included in this study).[11] However, the overall health situation of the patient has to be taken into account, and in relatively fit patients, open surgical repair may be preferred to the use of chimneys in the visceral arteries. Eighty-eight percent of reinterventions were performed within the first year after treatment, which is reflected in the stable patency rates afterward. These results stand firm amid results that are obtained with the KS technique, with 2-year primary patency of 79% (range, 58%-92%), and also compared with aortobifemoral grafts, with a 2-year primary patency of 93% (range, 87%-98%).[2,16,17] However, more complex lesions were treated in this study compared with most results reported for KS and open repair, both 50% TASC C and D lesions, making the comparison less reliable.[2,16] Only the cohort of Dorigo et al[17] had a comparable distribution of the TASC categories. Flow and geometry seem to be important factors in view of stent patency. In previously published papers, we studied the influence of the KS and CERAB technique on radial mismatch and blood flow using in vitro modeling.[8,9] The effects of different stent configurations on flow perturbations

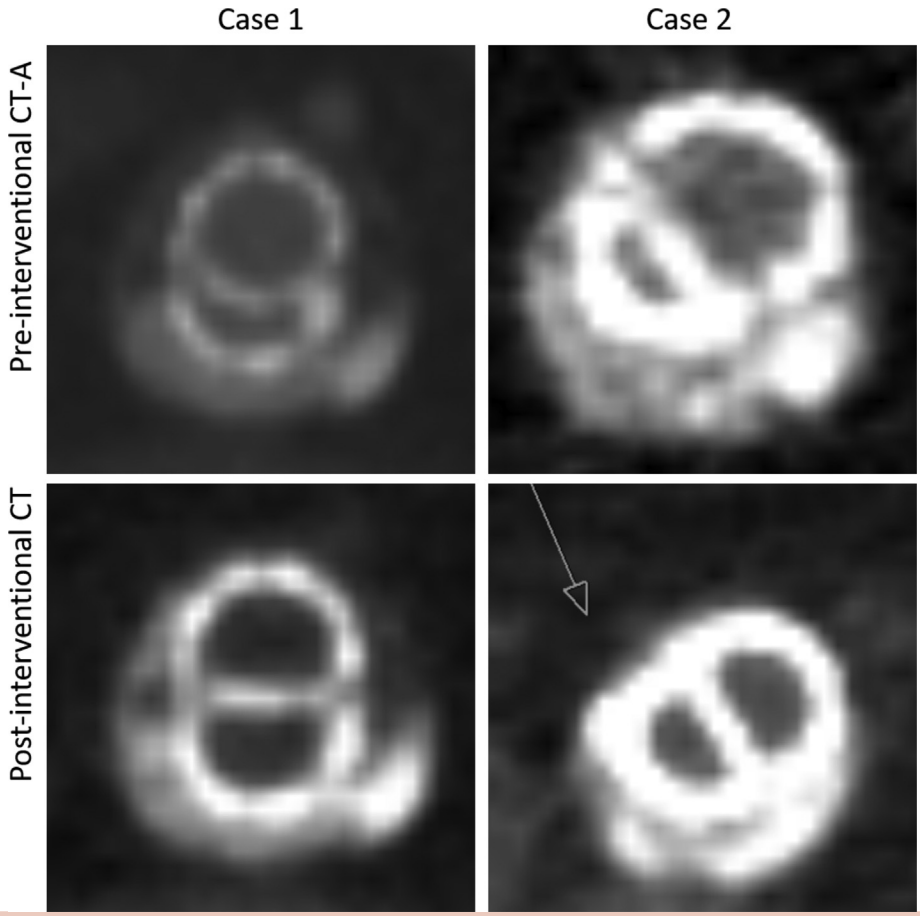


Fig 3. Limb crush examples as observed in two cases. Treatment was performed using a kissing balloon technique. Postoperative computed tomography (*CT*) shows restoration of the crushed lumen. *CT-A*, Computed tomography angiography.

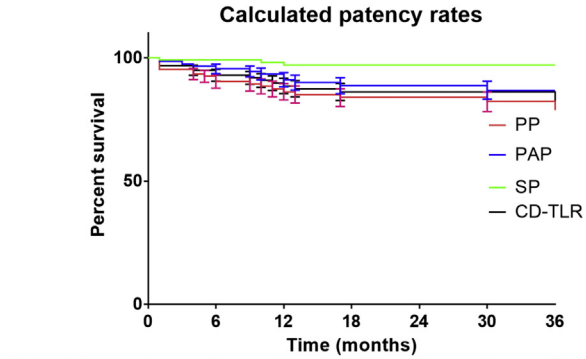
were investigated, and these studies showed that the CERAB configuration is the most unimpaired physiologic reconstruction, with only a few zones of recirculation and little fluid stasis. Lowering flow disturbances and radial mismatch (ie, mimicking a native bifurcation) could lower thrombus formation and thereby restenosis.[6]

The 30-day major complication rate of 8% is low in comparison to the 30-day major complication rate of 20% reported after aortobifemoral and aortobi-iliac bypass procedures[18] and in line with respect to those observed after KS treatment (5.8% ± 4.4%, TASC C and D in 50% of cases).[2] Therefore, the results of this study show that the technique is indeed a valuable alternative to these treatment options.

The relation between patency and outflow has previously been shown for KS by several studies,[4,16] whereas it was not observed by others.[19,20] Therefore, the impact of impaired runoff in aortoiliac stenting remains under debate. Studies that did observe the relation pointed out that the atherosclerotic process might be more virulent in patients with extensive peripheral arterial disease and impaired runoff. This underlines the importance of proper risk management using statins, antiplatelet drugs, and walking exercise. However, the optimal duration of double antiplatelet therapy has never been studied in this respect and should be the topic of further research.

First signs of patency loss are usually observed on duplex ultrasound. According to the study of Chong et al,[21] PSV values above average are commonly reported during duplex ultrasound follow-up in the CERAB configuration and could require CTA for further assessment. CTA data often report a patent configuration; therefore, Chong et al proposed a tool to predict the maximal PSV in the CERAB. In future studies, it would be interesting to incorporate such tools and to evaluate their predictive value.

Most reinterventions were performed within the first 12 months after treatment. This emphasizes that strict follow-up in the first 12 months is paramount to detect onset of restenosis, whereas follow-up afterward could be less frequent. With this follow-up schedule, a secondary patency rate of 97% can be achieved at 3-year follow-up.



Primary patency (PP)	**0**	**6**	**12**	**18**	**24**	**30**	**36**
No. At Risk	126	91	79	69	56	47	37
Patency (%)	100	90.4	86.2	83.9	83.9	82.1	82.1
SE (%)	0.0	2.8	3.3	3.6	3.6	4.0	4.0
Prim. Ass. Patency (PAP)							
No. At Risk	126	95	82	70	57	48	38
Patency (%)	100	95.5	91.1	88.7	88.7	86,8	86.8
SE (%)	0.0	2.0	2.9	3.3	3.3	3.7	3.7
Secondary patency (SP)							
No. At Risk	126	98	85	74	61	52	41
Patency (%)	100	99.2	97.0	97.0	97.0	97.0	97.0
SE (%)	0.0	0.8	1.7	1.7	1.7	1.7	1.7

Fig 4. Kaplan-Meier curve presenting the primary patency (*PP*), primary assisted patency (*PAP*), secondary patency (*SP*), and clinically driven target lesion revascularization (*CD-TLR*) for the follow-up moments, including number at risk and standard error (*SE*).

Table III. Patency results based on history of endovascular treatment

	Yes (n = 46), %	No (n = 80), %
One-year follow-up		
Primary patency	80	88
Primary assisted patency	91	97
Secondary patency	98	98
Three-year follow-up		
Primary patency	76	85
Primary assisted patency	83	88
Secondary patency	94	98

In this study, patency was defined according to the reporting standards as recently described by Stoner et al.[15] In other studies, including our first paper on the outcome after CERAB, another definition was used that includes the presence of a significant stenosis as loss of primary patency.[10] In the current cohort, there were only two cases with such a stenosis left untreated, and as such, the influence on the results is only minimal, with a 3-year primary patency of 81% vs 82%. Standardization of definitions and adherence to reporting standards are key and require attention in comparing data from different studies.

In the current cohort, four technical failures were reported, and in all cases, the lesion could not be passed from a retrograde direction. Brachial access was not attempted in these cases. Nowadays, brachial access is applied in our centers in challenging cases and is a viable option in case of a failed retrograde approach.[22] In comparing the major complication rate with the complications observed in our early series, a fourfold increase was noted (2% vs 8%). This could be related to the fact that over time, more complex lesions were considered to be suitable for the technique, and it also underlines frailty of this group of patients. Three of the complications were caused by a crushed iliac stent in the aortic cuff (two examples are shown in Fig 3). In one of them, this was likely to be a technical error where the aortic cuff was postdilated after positioning of the limbs, thereby crushing the contralateral limb. In the other two cases, no clear reason was observed, but it could have been related to the heavily calcified lesions. Improvement of stent design and additional knowledge on stent mechanics may also contribute to the prevention of this complication. In addition, a relining stent could be used to add radial force to the CERAB configuration. However, relining the CERAB configuration as a preventive measure would significantly increase cost. Furthermore, to our knowledge, no lesion morphology or geometry characteristics can predict stent crushing. In diagnosis of stent collapse, PBA in combination with relining could be beneficial because the original configuration might be weakened.

The choice of stents was based on studies that reported a superior patency of covered stents over bare-metal stents in treatment of TASC C and D lesions.[23-26] In 45% of the cases, we could not complete the procedure with three stents only, emphasizing the need for longer 8-mm-diameter limbs (currently limited to 58-mm length). In the current cohort, the CERAB was mostly constructed using Advanta Atrium V12 stents. Because of manufacturing problems since 2015, the large-diameter Atrium Maquet V12 stents are no longer available. In search of alternatives, the LifeStream (Bard Peripheral Vascular, Tempe, Ariz) and more recently the BeGraft and BeGraft Aortic (Bentley Innomed GmbH, Hechingen, Germany) were used for this indication. Future research should point out what the differences are between these three balloon-expandable stents with respect to placement accuracy, radial force, durability of the expanded polytetrafluoroethylene layer, and patency. Parallel to the introduction of the CERAB, the use of the AFX unibody bifurcation endograft (Endologix, Irvine, Calif) was described for treatment of AIOD.[27,28] The benefit of this stent is the fact that radial mismatch is completely prevented, but being a self-expanding stent, the AFX stent has less radial force.

This study is limited by the fact that it describes the first experience of a novel technique. With gaining experience, results were likely to improve, but broadening indication for the technique during time may also have affected results. Furthermore, the retrospective analyses of our registry limited us in drawing firm conclusions

Table IV. Reinterventions during follow-up

	No. of interventions
Reinterventions (related to the CERAB, in 18 patients)	
6 weeks	4
6 months	15
12 months	11
24 months	3
36 months	1
Total	34
No. of reinterventions per patient	
1	9
2	4
3	3
4	2
Type of reinterventions	
Embolectomy (iliac artery + aorta)	10
Kissing PBA, iliac artery limbs	7
PBA + stent iliac limbs (extension or in-stent)	6
Thrombolysis	5
Unilateral PBA, iliac limb	3
Surgery (aortobifemoral or axillofemoral bypass)	2
PBA + stent aorta	1
Other intervention (not related to the CERAB, in 27 patients)	
6 weeks	14
6 months	6
12 months	7
24 months	9
36 months	6
Total	42
No. of other interventions per patient	
1	18
2	5
3	2
4	2
Type of other intervention	
PBA	
CIA	1
EIA	5
SFA	3
PA	1
PBA + stent	
CIA	3
EIA	5
SFA	8
PA	2
Thrombolysis	2
Thrombectomy	2
Endarterectomy CFA	3
Surgical bypass (femoropopliteal or femorotibial)	4
Superior mesenteric artery stent	2
Unknown	1

CERAB, Covered endovascular reconstruction of the aortic bifurcation; *CFA*, common femoral artery; *CIA*, common iliac artery; *EIA*, external iliac artery; *PA*, popliteal artery; *PBA*, plain balloon angioplasty; *SFA*, superficial femoral artery.

on causation of failure of patency. Moreover, the 3-year follow-up was not completed for the entire cohort and reflects only early experience. Nevertheless, the standard error of the patency rate estimate was below 10%.

CONCLUSIONS

This study has shown that the CERAB technique is related to good 3-year results, with regard to patency and clinical outcome, in patients treated for mostly TASC II D lesions. Long-term studies should establish its role in these patients, and risk prediction tools need to be assessed.

AUTHOR CONTRIBUTIONS

Conception and design: PG, MR
Analysis and interpretation: KT, EGJ, SH, MV, MR
Data collection: KT, EGJ, JM
Writing the article: KT, EGJ, MR
Critical revision of the article: KT, EGJ, SH, JM, MV, PG, MR
Final approval of the article: KT, EGJ, SH, JM, MV, PG, MR
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KT and EGJ contributed equally to this article and share first authorship.

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