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Prospective Study of the Iliac Branch Device E-liac in Patients with Common Iliac Artery Aneurysms: 12 Month Results

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WHAT THIS PAPER ADDS

New dedicated iliac branch devices (IBDs) help to minimise ischaemic complications by preserving internal iliac artery (IIA) flow. There are currently three dedicated IBDs available on the market, including the E-liac Stent Graft System. The present study evaluates the safety and efficacy of this stent graft and is the first and largest prospective trial on this iliac side branch device. The favourable results demonstrate its promising performance and safe application.

Objectives: At 12 months follow up of the PLIANT study, clinical success and efficacy of the E-liac Stent Graft System (JOTEC GmbH, Hechingen, Germany) were evaluated. Clinical success was defined as aneurysm exclusion (no type I, III, IV endoleak) with primary patency of the internal iliac artery (IIA) and external iliac artery (EIA) on the E-liac implantation side.

Methods: In this prospective multicentre European observational study, clinical and morphological data of 45 patients (93% male, mean age 72 y) were prospectively collected in 11 European centres between July 2014 and June 2016. Forty patients underwent an aorto-iliac (three patients bilaterally) treatment and five an isolated iliac treatment.

Results: At 12 months follow up, data were available for 42 patients. Overall clinical success at 12 months was 90%, with a survival rate of 100%. Four patients (10%) did not achieve clinical success, one with an internal iliac artery (IIA) occlusion on the E-liac implantation side, one with an infrarenal type Ia endoleak, and two with type Ib endoleaks in IIA. At 12 months the primary patency rate in the internal iliac artery on the iliac side branch implantation side was 98%. Two patients (5%) received E-liac related re-interventions: one caused by an edge stenosis at the distal end of the graft limb in the external iliac artery (EIA) and one caused by thrombo-embolism in the external iliac artery. Thus, for the EIA, primary and secondary patency rates were 98% and 100%, respectively.

Conclusions: The low device related re-intervention rate of 5%, the high survival rate of 100%, and the high primary patency rates of 98% for the IIA and EIA at 12 month follow up demonstrate the safety and efficacy of the E-liac Stent Graft System. Long term 36 month results are awaited to confirm the efficacy and durability.

Keywords: Hypogastric artery, Iliac artery aneurysm, Iliac branch device, Endovascular iliac aneurysm repair, Stent graft
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INTRODUCTION

Endovascular treatment of aorto-iliac aneurysms used to be accomplished by planned occlusion of the internal iliac artery (IIA) and an endograft limb extension into the external iliac artery (EIA).[1] However, embolisation of the IIA can result in ischaemic manifestations, including sexual dysfunction, buttock or thigh claudication, and spinal cord and colonic ischaemia.[2,3] Therefore, it is recommended that bilateral interruption of the IIA should be avoided, at least in standard risk patients.[4]

In 2008 the Zenith Iliac branched device by Cook was introduced as the first dedicated device to preserve internal iliac artery flow in patients with aorto-iliac or iliac aneurysms. Currently, two additional iliac branch devices (IBDs) are commercially available in Europe: the GORE EXCLUDER Iliac Branch Endoprosthesis by Gore and the E-liac Stent Graft System by JOTEC GmbH, which received CE approval in 2013 and 2014, respectively. A first retrospective multicentre study of the E-liac Stent Graft System in 70 patients showed promising one year results.[5] The present PLIANT study prospectively evaluates the safety and efficacy of the E-liac Stent Graft System used in common iliac artery aneurysms in a unilateral or bilateral procedure. In this publication the 12 month results are evaluated.

METHODS

Study design and patient population

The PLIANT study is an observational, prospective, non-randomised, international, multicentre study, evaluating the safety and efficacy of the E-liac Stent Graft System.

The inclusion criteria were compliance with indication for use, which consists of the following points: unilateral or bilateral aorto-iliac or iliac aneurysm, suitable for endovascular repair, compliance with lifelong follow up investigation, age >18 y, iliac/femoral access vessel morphology compatible with the implantation procedure and the 18 F (6 mm OD) delivery system, a non-aneurysmal common iliac artery landing area in case of iliac artery aneurysm $\geq$ 20 mm, diameter of the common iliac artery in the proximal landing area: 12—17 mm, non-aneurysmal external and internal iliac artery segment distal to the aneurysm $\geq$ 15 mm, diameter of the external iliac artery in the distal landing area: 8—13 mm, angle between external iliac artery and internal iliac artery $\leq$ 50°, thrombus free iliac lumen in the area of iliac bifurcation to open the side branch and to implant covered stent $\geq$ 18 mm, sufficiently open internal iliac artery ostium. Further inclusion criteria were unilateral or bilateral common iliac aneurysm diameter $\geq$25 mm, unsuitable distal sealing site within the common iliac artery (CIA) for traditional EVAR, availability of the patient for appropriate follow up times for the duration of the study, and the signed informed consent by the patient. The exclusion criteria were: no compliance with the indication for use, internal iliac ostium diameter <4 mm, severe internal iliac atherosclerosis, no suitable landing area in the main stem of the IIA, pseudo-aneurysms, symptomatic and ruptured iliac aneurysms, contraindications as indicated in the instructions for use (IFU), patients pretreated with a bifurcated vascular graft, thrombocytopenia, creatinine > 2.4 mg/dL immediately before the intervention, malignancy requiring chemotherapy or radiation, enrolment in another clinical study, and life expectancy < 36 months.

A contrast enhanced spiral computed tomogram (CT) was performed for pre-operative planning, after the intervention prior to discharge and at 30 day (±15 days), at 12 months (±2 months), and 36 months (±2 months) follow up. The data in this article are referred to as 12 month follow up data. All CT scans and final angiograms were additionally subjected to analysis by a CoreLab.

Device description and implantation

A detailed description of the E-liac Stent Graft System and the implantation procedure have been given previously.[5] In brief, the E-liac Stent Graft System (JOTEC, Hechingen, Germany) is indicated for treatment of patients with uni- or bilateral, aorto-iliac or isolated iliac aneurysms. The E-liac Stent Graft consists of nitinol springs and a polyester cover (Fig. 1). The asymmetric stent design and configuration especially developed for this device result in high 3D flexibility and a good conformability to the iliac arteries. The moveable side branch, realised by an exceptional bifurcation stent, simplifies the bridging of the gap between the stent graft and the internal iliac artery. During positioning of the loaded graft in the delivery system and after its deployment, a JOTEC specific E-Marker indicates the position of the side branch. The E-Marker supports the correct

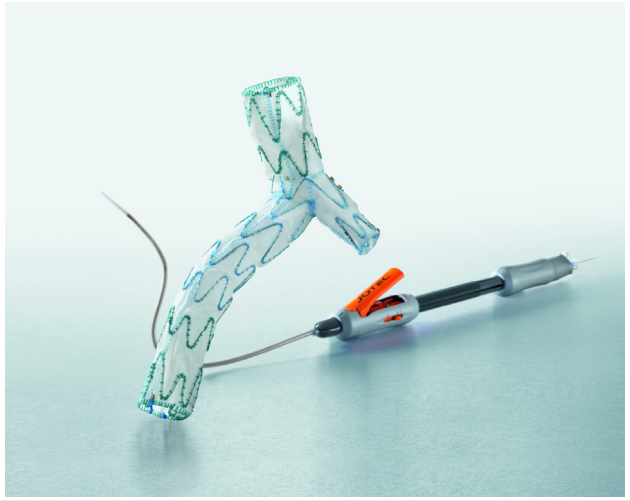

Figure 1. E-liac Stent Graft and delivery system. The stent graft consists of electropolished self expanding nitinol stents covered with woven polyester. The specially designed asymmetric spring configuration of the E-liac Stent Graft results in high 3D flexibility and provides good iliac artery conformability. The movable side branch supports smooth bridging to the internal iliac artery. The delivery system features a squeeze to release deployment mechanism, which allows stepwise release of the stent graft in the target position.

alignment of the side branch with the internal iliac artery and thereby facilitates easy cannulation. Technical specifications of the E-liac Stent Graft System have been published previously.[6]

Customised pre-operative planning based on contrast enhanced CT was performed for each patient to determine the diameters and lengths of the stent grafts. No specification was made for the type of peripheral stent graft and, after an amendment to the study protocol, to the type of abdominal stent graft to be used. Placement of the stent grafts was performed under fluoroscopic guidance. Local, regional, or general anaesthesia as well as medication was administered in accordance with the site's protocol. Follow up investigations were conducted at the physician's discretion, and contrast enhanced CT was obtained prior to discharge, at 30 days and 12 months follow up (Fig. 2A and B).

Study endpoints and definitions

The objective of the study was to evaluate clinical success as well as the safety and efficacy of the E-liac Stent Graft System. The following endpoints were analysed at 12 months follow up: clinical success, CIA aneurysm growth (>3 mm), primary and secondary patency rates, re-intervention rate, death, and adverse events.

The main study target was the clinical success defined as aneurysm exclusion (no type I, III, IV endoleak) with primary patency of the IIA and EIA on the iliac implantation side. Adjudication of adverse events as device related was performed by the individual clinical investigators at the study sites.

Data management and statistical analysis

Data from each patient were collected in an electronic case report form (MARVIN 2.5, XClinical GmbH) and analysed by an independent biostatistician. Data are reported descriptively and are presented as mean with standard deviation and/or range. Kaplan—Meier analyses were performed.They are presented with 95% confidence intervals (CI). The last documented patient contact was censored. Statistical analyses were performed using the SAS software version 9.4 (SAS Institute Inc.).

Ethics. The PLIANT registry was performed according to the Declaration of Helsinki. Where required, the study protocol and patient informed consent form were reviewed and approved by the ethics committee at the participating centres. Only patients who had given written informed consent to data collection prior to intervention were included.

The PLIANT study was registered under Clinical Trials.gov. Identifier no. NCT02209194 on 30 July 2014.

RESULTS

Between July 2014 and June 2016, of 97 patients treated with an IBD, 45 patients with uni- or bilateral aorto-iliac or isolated iliac aneurysms (93% male; mean age 72 years, range 53—90 years) met the inclusion criteria and were enrolled in the study by 11 centres in four European countries. Of the 52 patients not included in the study, three patients were treated with a comparable device and the rest (49 patients) did not comply with the inclusion criteria, or they met the exclusion criteria (Fig. 3). Clinical and morphological data of the initial 45 patients were collected prospectively. Demographic data, medical history, and iliac aneurysm morphology of these patients have already been described in detail.[6] The mean baseline diameter of the CIA aneurysm was 38 ± 11 mm (range 26—79 mm). Ten (21%) patients presented with an aneurysm in the IIA (diameter ≥ 12 mm). There were no patients with an EIA aneurysm. Twelve month follow up data were available for 42/45 (93%) patients. There was one study drop out according to the patient's wish, and two patients did not return to the 12 month follow up appointments. Because of the study design, the follow up was 12 ± 2 months, but the data in this article are referred to as 12 month follow up data.

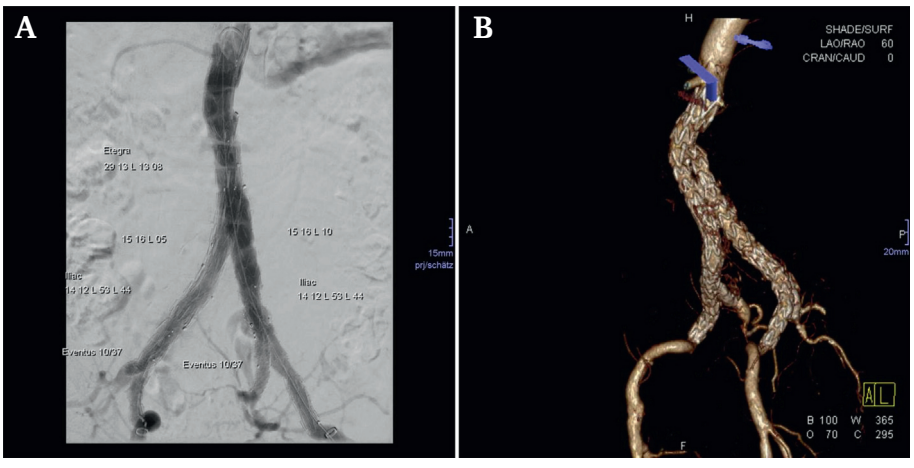

Figure 2. Patient treated bilaterally with E-liac Stent Grafts. (A) Final index procedure angiogram after deployment of bilateral E-liac grafts in 28° RAO projection plane. (B) Volume rendering technique (VRT) of 12 month follow up computed tomography indicating all devices in place and patent, with delineation of right E-liac in 60° LAO projection plane. LAO = left anterior oblique; RAO = right anterior oblique.

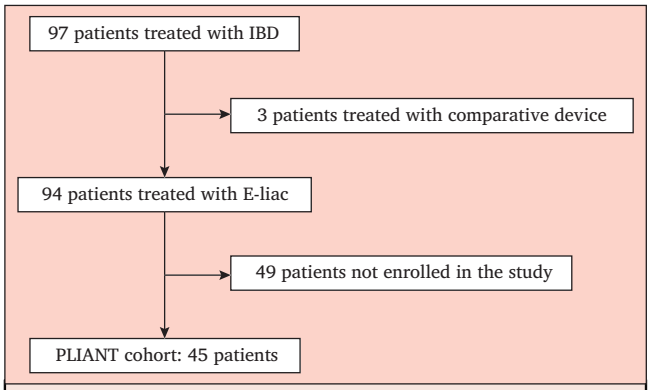

Figure 3. Flowchart showing patient enrollment in the PLIANT study. IBD = iliac branch device.

In 39/45 patients (87%) the E-liac Stent Graft was placed in combination with an abdominal stent graft. Three of these patients were treated bilaterally with the iliac side branch device. One patient (2%), who had already been treated with an abdominal stent graft, received iliac treatment for a type Ib endoleak of the abdominal graft. Five patients (11%) received an isolated E-liac Stent Graft. In total, 45 patients were treated with 48 IBDs. The gap between the side branch of the E-liac Stent Graft and the landing zone in the IIA was bridged by balloon expandable peripheral covered stents (E-ventus BX Stent Graft, JOTEC, [74%]; Advanta V12 Covered Stent, Maquet, [21%]; LifeStream Balloon Expandable Vascular Covered Stent, Bard, [3%]; BeGraft, Bentley, [2%]). In 46/48 (96%) of the IBD cases, the distal landing zone of the covered stent was in the main trunk of the IIA, and in the remaining two cases the landing zones were in the anterior IIA and posterior IIA respectively. Two peripheral covered stents were needed in 14 patients, six of whom had an IIA aneurysm.

According to analysis by CoreLab, 5/45 (11%) patients were treated outwith the IFU, as in three cases the angle between EIA and IIA was $>50^{\circ}$ and in two cases the thrombus free lumen above the iliac bifurcation was <18 mm.[6] Because of the register type, the data of these patients were not excluded from the analysis.

Twelve month clinical success and survival

At 12 months, clinical success was reported in 38/42-45 (84.4—90%) patients. Clinical success was not achieved in four patients, all of whom had been treated with an E-liac Stent Graft in combination with an abdominal stent graft. In two of these patients, a type Ib endoleak was diagnosed at the peripheral covered stent in the IIA caused by a diameter mismatch between the peripheral covered stent and the landing zone. One patient presented an infrarenal type Ia endoleak of the main body of the abdominal stent graft in a severely angulated, reverse tapered neck. All of these endoleaks were not causally related to the E-liac Stent Graft. In one patient, who suffered from right buttock claudication after walking a distance of 30 m, the peripheral covered stent in the right IIA thrombosed resulting in occlusion of the IIA on the E-liac implantation side. The left IIA showed retrograde perfusion. The occlusion on the right side was detected five months after the discontinuation of antiplatelet therapy with clopidogrel but continuation of 100 mg aspirin. There was no obvious technical reason for the occlusion, although the Advanta was deployed more proximally into the E-liac side branch than intended. The symptom was causally related to the procedure and the E-liac Stent Graft. The two type Ib endoleaks remain under observation. The aneurysm size and the increase in aneurysm size did not justify a re-intervention at that time. The type Ia endoleak had resolved one month after it was detected. No re-intervention was performed with respect to the IIA occlusion.

The 12 month survival rate was 42/42-45 (93—100%).

Re-interventions and complications

Of 42 patients, seven patients underwent a successful re-intervention. Three of the seven re-interventions were performed during the early post-procedural period within 30 days. The reasons for the three early post-procedural re-interventions were one type Ia endoleak in the common iliac artery, and one infrarenal type Ia endoleak both caused by mismatch between the stent graft size and the diameter of the landing area, and one patient with bilateral lower limb claudication on both sides caused by kinks that were caused by tortuous iliac arteries. The patient was treated with an unilateral E-liac and an abdominal aortic aneurysm (AAA) stent graft. The lower limb claudication was causally related to the E-liac.[6]

Between the 30 day and 12 month follow up, four re-interventions were performed in relation to the study target (Table 1):

- In one patient, who had been treated with an aorto-uni-iliac stent graft during the index procedure, a second procedure was planned to close the contralateral aneurysmal CIA, EIA, and IIA. Three AMPLATZER Vascular Plugs II were used. Additionally, an infrarenal type Ia endoleak was sealed using an aortic extension. Because of the treatment for the infrarenal type Ia endoleak, this intervention was classified as a re-intervention that is causally related to the study target.
- In one patient, an infrarenal type Ia endoleak of the abdominal stent graft was diagnosed at an unscheduled visit seven months after intervention. It was sealed with endoanchors (Aptus Heli-FX) two months after detection.
- One patient received a re-intervention because of an infrarenal type Ia endoleak combined with a type II endoleak, for the first time detected by CoreLab in the final angiogram. The type Ia endoleak was sealed using Onyx six months after intervention. During this re-intervention the coincidental finding of an edge stenosis in the EIA contralateral to the side of E-liac placement was treated by placement of a self expanding bare metal stent.
- In one patient, who complained about lower limb claudication on the E-liac placement side, thrombo-embolic occlusion of the EIA was observed. No technical

Table 1. Re-interventions and complications

Variable	0–30 days	30 days-12 months
	(n = 45)	(n = 42)
Re-intervention		
Endovascular to correct type Ia endoleak		
related to E-liac Stent Graft	0 (0%)	0 (0%)
mismatch of E-liac Stent Graft	1 (2%)	0 (0%)
related to AAA stent graft	1 (2%)	3 (7%)
Endovascular to correct type II endoleak	0 (0%)	1 (2%)*
Open surgery to correct thromboembolism/thrombosis		
related to E-liac Stent Graft	0 (0%)	1 (2%)
related to AAA stent graft	1 (2%)*	0 (0%)
Endovascular to correct stenosis		
related to E-liac Stent Graft	1 (2%)	0 (0%)
related to AAA stent graft	0 (0%)	1 (2%)*
Complications		
Renal insufficiency	2 (4%)	0 (0%)
Vascular access: wound complications	2 (4%)	0 (0%)
Bowel ischaemia	0 (0%)	0 (0%)
Transient buttock or thigh claudication	1 (2%)	1 (2%)
New buttock or thigh claudication	0 (0%)	1 (2%)
Buttock necrosis	0 (0%)	0 (0%)
Other complications	1 (2%)	2 (5%)

AAA = abdominal aortic aneurysm.
* Not related to study target (study target see "Study endpoints and definitions").

problems were detected with the E-liac Stent Graft, but a tentative explanation for the occlusion might be the scarring and stenosis in the groin. Thrombo-embolectomy was performed five months after the index procedure. Patency was restored and symptoms resolved without sequelae. Only this latter re-intervention was related to the E-liac Stent Graft.

In total, 2/42 (5%) patients had E-liac related re-interventions within the 12 month follow up period (Table 1). The probability of freedom from an E-liac related re-intervention within one year was 95.7% (95% CI: 79.8%, 98.9%) (Fig. 4). Additional re-interventions related to the study target occurred in 5/42 (12%) patients.

During the 12 month follow up, two cases of transient buttock or thigh claudication were observed (Table 1). One patient, who had been treated with an E-liac on the right side, presented with transient left buttock claudication because of embolisation of the left IIA. It was classified as causally related to the procedure, but not as causally related to the E-liac Stent Graft. The symptoms resolved without sequelae until the 12 month follow up visit, and no re-intervention was performed. One case of buttock or thigh claudication, already described above, was reported at 12 months follow up. Two additional complications were observed between the 30 day and 12 month follow ups. One patient reported buttock claudication, although both IIA were properly perfused. The symptoms were probably of neurogenic origin. Moreover, a neoplastic tumor in the colon was detected in a patient who presented with bowel obstruction. None of these complications was causally related to the E-liac Stent Graft. Two cases of renal

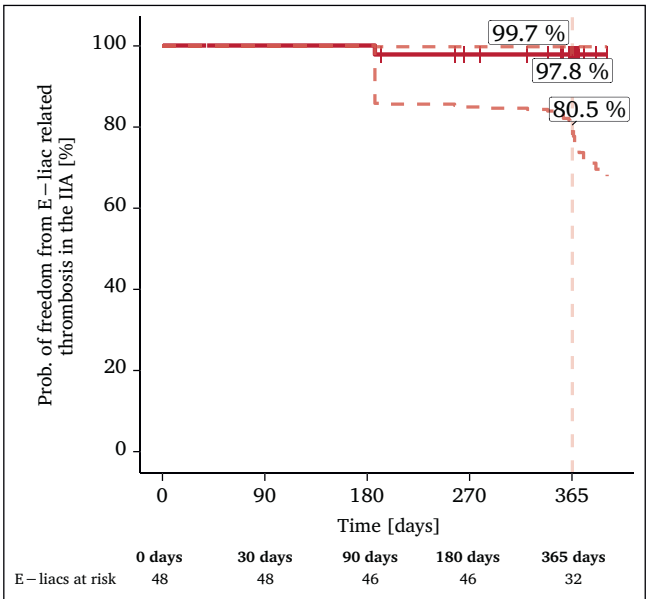

Figure 4. Kaplan–Meier estimates of the probability of freedom from E-liac related re-interventions with 95% confidence interval (hatched lines). IIA = internal iliac artery.

insufficiency, two cases of wound complication, and one renal infarction were reported during the early post-procedural period within 30 days. In the 12 month follow up period, no complications occurred in the three patients treated bilaterally with an E-liac Stent Graft (Table 1).

Patency

In total, only one occlusion each occurred in the IIA and EIA as an adverse event within the 12 month follow up period (see above). This resulted in a 12 month primary patency rate of 98% for the IIA and the EIA, and a secondary patency rate of 100% for the EIA. The probability of freedom from E-liac related thrombosis within one year was 97.8% (95% CI: 80.5%, 99.7%) in the IIA as well as in the EIA (Fig. 5).

Changes in CIA aneurysm diameter

Aneurysm growth >3 mm was reported in 3/42-5 (7%) CIA aneurysms. One of these patients had a combined type I/II, and the second a type II endoleak. In the third patient, who initially presented with an aorto-iliac aneurysm but had only been treated with an isolated E-liac Stent Graft (the patient refused further treatment with an abdominal stent graft), CIA aneurysm growth as well as an abdominal aneurysm growth was reported, although no endoleaks were detected in the CIA aneurysm. CIA aneurysm shrinkage >3 mm was observed in 15/42 (36%) of the CIA aneurysms. Thus, a stable or decreasing aneurysm size was reported in 93% of the CIA aneurysms treated.

DISCUSSION

The PLIANT registry is the first prospective study of the E-liac Stent Graft System and one of very few controlled studies on iliac branch devices with data acquisition across multiple centres. High data quality is provided by additional check ups

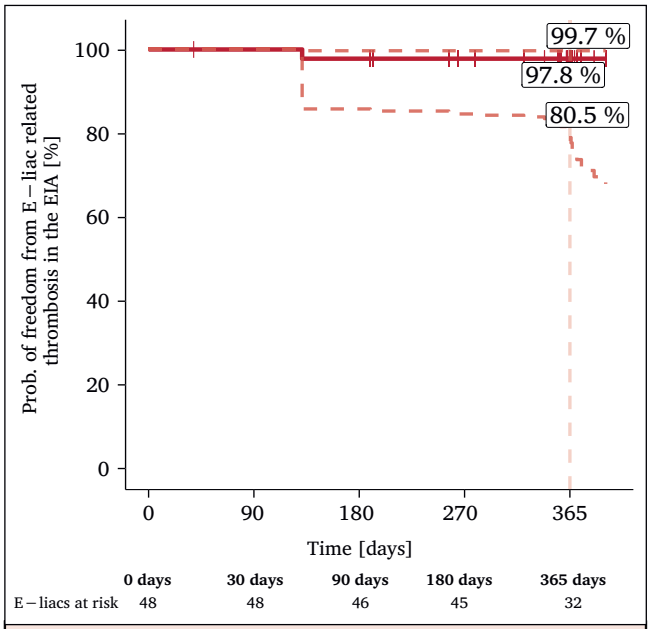

Figure 5. Kaplan–Meier estimates of the probability of freedom from E-liac related external iliac artery (EIA) thrombosis with 95% confidence interval (hatched lines).

by the CoreLab to ensure adequate and standardised reports on study outcomes. The results in the PLIANT study provide further evidence for the use of IBDs and demonstrate the excellent performance of the E-liac Stent Graft System and its safe application when used within its indications for use. Evaluation of the 12 month results shows that this novel IBD can be used as a standalone device or in combination with an abdominal stent graft for successful treatment of iliac or aorto-iliac aneurysms.

At the 12 month follow up, 84—90% of the patients achieved clinical success, which encompasses a high rate of exclusion of aneurysms without any type I, III, and IV endoleaks and with a high primary IIA and the EIA patency rate on the iliac implantation side.

Two of 42 patients received an E-liac related re-intervention (5%): one edge stenosis at the distal end of the graft limb in the EIA within 30 days; and, the other, thrombo-embolism in the EIA between 30 days and 12 months. The IBD related re-intervention rate of 5% in the PLIANT study compares well with those shown in other trials evaluating IBDs. In a previous retrospective study of the E-liac Stent Graft System, eight re-interventions were performed in 70 patients within a median follow up of 12 months.[5] In that study, three re-interventions resulted from type Ia or Ib endoleaks on the E-liac implantation side. The other five re-interventions were performed because of occlusion and/or kinking of the CIA segment of this device.[5]

In a retrospective study of the Zenith Iliac Branch System, with 140 patients, a total of 17 IBD related secondary interventions were reported (12.1%) with a longer follow up of two years; seven for type Ib endoleaks, two for type III endoleaks, seven for EIA occlusions, and one for a proximal stenosis.[7] In a more recent retrospective report of the same device, three IBD related re-interventions were described in 30 patients within a mean follow up of 15 months:[8] one for lower limb ischaemia caused by ipsilateral iliac limb occlusion and one for type III endoleak. In the third patient the re-intervention was caused by ischaemic colitis. All re-interventions were performed within the first 30 days.[8]

In a prospective study of the Gore IBD, none of the 61 evaluated patients received IBD related re-interventions through a follow up period of six months. However, one patient was treated for an external iliac artery dissection distal to the IBD and a second patient received a re-intervention for a type II endoleak.[9] Moreover, procedure related re-interventions following IBD treatment of iliac or aorto-iliac aneurysms were systematically analysed in a cohort of 575 patients treated by placement of 650 IBDs from Cook and Gore (75 bilateral).[10] Within 30 days, nine (1.6%) re-interventions were performed, six for occlusion of the treated EIA and three for IBD related type I endoleaks. During a mean clinical and radiological follow up of 33 $\pm$ 10 and 30 $\pm$ 21 months, respectively, 42 patients (7.3%) underwent additional re-interventions: seven patients for isolated ipsilateral EIA occlusion, 16 patients for combined ipsilateral EIA and CIA occlusion, and 19 patients for type I CIA endoleak. Accordingly, the overall post-operative IBD related re-intervention rate was 8.9%.[10]

More recently, IBDs have been used for the treatment of hypogastric artery aneurysms (HAA).[11] A study using the E-liac branch device for HAA treatment demonstrated an estimated freedom from re-intervention of 31% $\pm$ 23% at 2.7 years. The high rate of re-interventions can be explained by their use outwith the IFU, although the authors judge these results as good and the IBD implantation as a valuable option for HAA exclusion. Nevertheless, it is debatable to compare clinical outcomes from this exceptional study with HAA at a location that is normally used as a landing zone for IBDs, with the results of other studies like the present one using IBDs within their indications.[11]

Within 12 months follow up three patients in the PLIANT study presented with buttock or thigh claudication. However, in two patients the symptoms were transient and resolved without sequelae. In the third patient, buttock claudication was detected at the 12 month follow up visit. It was caused by a thrombosis in the IIA on E-liac implantation side and was therefore classified as causally related to the graft. These results are within the range of four retrospective studies using the Zenith Iliac Branch System, where the reported buttock claudication rates varied between 0% and 8.6%.[7,12–14] Moreover, in a prospective study of the Gore EXCLUDER IBD, buttock claudication was detected in six of 61 patients during a six month follow up. All cases developed symptoms contralateral to the IBD implantation side and these occurred in patients with bilateral CIA aneurysms who underwent staged procedures to embolise the contralateral IIA.[9]

Although the *a posteriori* analysis of the CoreLab revealed that 11% of the patients had been treated outside the IFU, only one IIA occlusion was recorded for a patient treated inside the IFU during the 12 month follow up. In the EIA, one thrombo-embolic occlusion on the E-liac placement side was reported. No IBD related occlusion or stenosis occurred in the patients who were treated outside the

IFU. The very low occlusion rate at 12 months, compares favourably with those reported for the two other IBD devices by Cook and Gore.

Tortuosity and kinking might be a reason for occlusion as reported by Verzini *et al.*, but this was not encountered in the present study.[15] Occlusion not only occurs in the short term but also may happen over a longer follow up as shown in previous studies.[8–10,12–14] Thus it is of importance to follow the present device's perfomance over a longer period of time.

The present results reveal CIA aneurysm growth in three of 42 patients (7%). In an earlier retrospective study of the E-liac Stent Graft System, CIA aneurysm growth occurred in one of 70 patients (1.4%). In that case the aneurysm enlargement was related to a type Ib endoleak.[5] In a prospective study analysing the Zenith Iliac Branch System, aneurysm enlargement in iliac arteries was reported in four of 100 patients (4%).[12] In a more recent retrospective study evaluating the same device, AAA or CIA aneurysm sac enlargement occurred in 14 patients (13.1%): in seven patients it was related to a type Ia endoleak and in one patient to a type II endoleak.[7] Thus, in this prospective study, the presented CIA aneurysm growth rate of 7% lies within the range of reported CIA aneurysm growth rates in the literature.

In this study, there were no deaths during the 12 month follow up, which compares well with the retrospective study of the device[5] and the very recent retrospective study of the Zenith Iliac Branch System including 30 patients, in which the overall survival was 96% at one year.[8] The results compare favourably with the outcomes in two studies (covering a mean of 17 and 26 months) using the Zenith Iliac Branch System,[7,12] with 100 and 140 patients, respectively. Three of the overall 34 deaths were procedure related. Studies on the Gore IBD are more scarce but no procedure related mortality was reported in a cohort of 61 patients during a follow up of six months.[9] However, it seems that re-intervention is a risk factor for death as reported by Donas *et al.*, with 14% mortality at a little less than three years.[10]

CONCLUSION

The low device related re-intervention rate of 5%, the high survival rate of 100%, and the high primary patency rates of 98% for the IIA and EIA at 12 month follow up demonstrate the safety and efficacy of the E-liac Stent Graft System. Long term 36 month results are awaited to confirm the efficacy and durability.

Limitations of the study

The present study is limited by the non-randomised setting and the lack of a control group. Further limitations include the subjective nature of the patient dependent evaluation of buttock or thigh claudication and the use of non-consistent anticoagulation protocols among the participating centres.

CONFLICT OF INTEREST

P. Szopiński, G. Mertikian, and J.P. Schäfer are consultants for JOTEC GmbH.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2019.06.020.

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COUP D'OEIL

Radial Artery Mycotic Aneurysm

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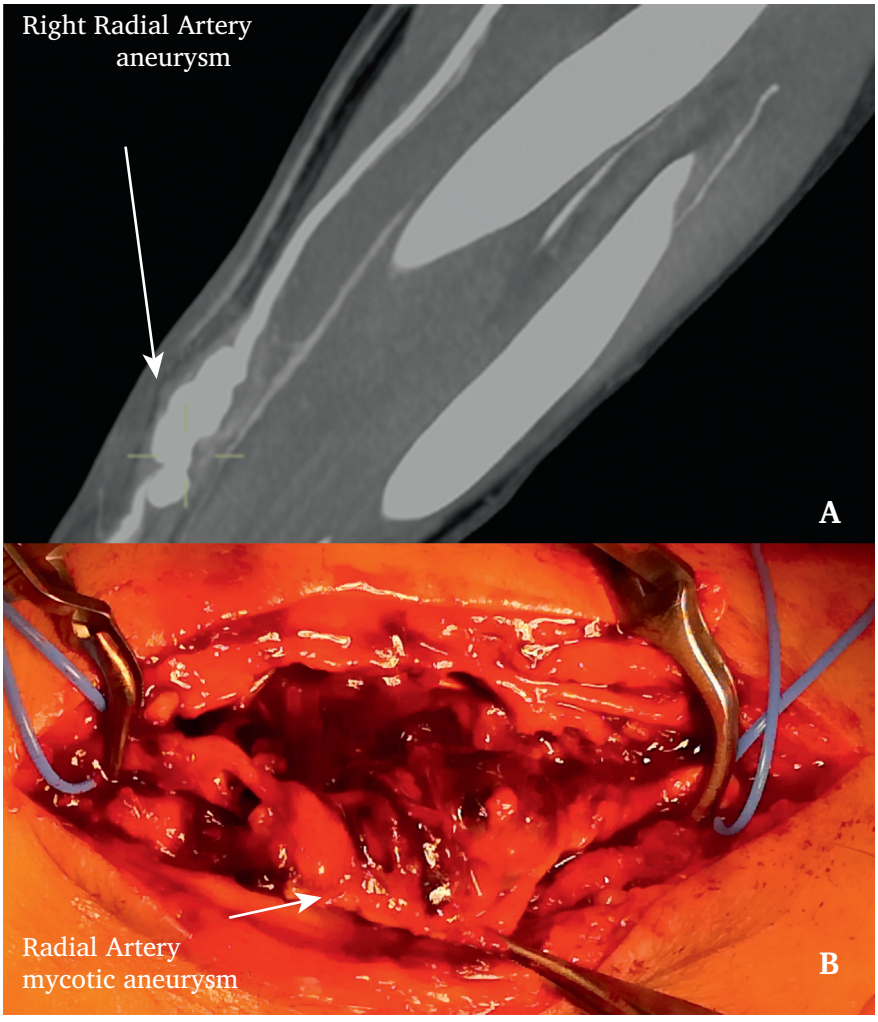

A 75-year-old male with diabetes type II and ischemic heart disease presented to the emergency department with a painful mass in the right wrist. He had a history of coronary angiogram performed 26 days earlier. A pulsatile reddened mass was identified on examination. His blood samples showed raised inflammatory parameters. CT scan revealed a distal right radial artery multilobular aneurysm (Panel A). Due to suspected mycotic aneurysm, the patient underwent surgical exploration (B), with ligature of the right radial artery after confirmation of a negative Barbeau test. Positive cultures for Pseudomonas aeruginosa in wound and blood were found.

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