Objective: This retrospective single-center study analyzed long-term results after LifePath (Edwards Lifesciences LLC, Irvine, Calif) endoprosthesis implantation for abdominal aortic aneurysm (AAA), primarily focusing on the wire form fracture issue and consecutive endoleak rate.

Methods: Between 1999 and 2004, all consecutive patients with LifePath AAA devices in our institution were included in the retrospective analysis. All patients had computed tomography angiography (CTA) imaging preoperatively and image postprocessing. The follow-up using CTA imaging specifically addressed material fatigue (wire form fractures) resulting in migrations and type I endoleaks.

Results: During the 6-year study period, which included the 1-year withdrawal and redesign of the device, 51 patients were treated with LifePath AAA endografts. The 30-day mortality was 0%. The perioperative 30-day morbidity was 9.8%. One patient required a primary conversion due to misdeployment of the iliac limbs within the graft main body. The primary endoleak rate was 20.56% (type I, 2%; type II, 19.6%). During the mean follow-up of 40.7 months, 12 patients died, six were lost to follow-up, and 32 underwent subsequent CTA imaging. Eight patients (25%) demonstrated a proximal type I endoleak, seven (22%) had a type II endoleak, and three had a type III endoleak (9%). In nine patients (28.1%), wire form fractures could be detected at image postprocessing. Four patients required a secondary conversion due to endoleak and aneurysm growth (2 type I endoleaks and 2 type III endoleaks).

Conclusion: Wire form fracture is the major structural problem in the LifePath balloon-expandable endograft device, resulting in a significant endoleak rate. We must caution those patients with a LifePath device in-situ that careful follow-up must be performed due to material fatigue and they should consider secondary conversion. (J Vasc Surg 2009;50:479-85.)
Furthermore, the high radial force and hoop strength of iliac limbs of BES dealing with calcified iliacs as deployed in the kissing balloon technique might be responsible for a near complete absence of iliac limb occlusions that are observed with SES. Complex infrarenal morphologies with angulated necks can also be treated with BES that straighten the angulation to protect against proximal endoleaks.

Two generations of LifePath endografts have been launched. After wire form fractures were observed at the level of the three top wires of the main body of generation I stents (1997 to June 2000; 42 months), the generation II device, with modified and strengthened wire forms was relaunched in September 2001 to June 2004 (34 months).

Short-term and midterm results for the LifePath system were published in a multicenter pivotal trial in 2004 by Carpenter et al. As a center with expertise in BES, with more than 50 implantations, we started this retrospective clinical study to obtain long-term results for the LifePath system, with a special focus on the development of secondary type I endoleaks and the occurrence of wire form fractures in the device.

METHODS

Patient characteristics. During the 62 months between March 1999 and May 2004, 182 patients underwent elective EVAR for AAA in our department using different endograft devices. Among those, 51 patients (28%) were treated with a LifePath AAA bifurcation device. Of the 51 LifePath devices implanted, 20 (39.2%) were from generation I and 31 (60.8%) were from generation II. All patients with LifePath devices were primary enrolled for a clinical trial. The trial-specific monitoring stopped after the LifePath system was withdrawn from the market in 2004. Afterwards, annual clinical investigation and imaging according to our institute-specific follow-up policy was performed.

One woman and 50 men were treated during the observation period. The mean age of the patients was 69.1 years (range 58-84 years), and the mean diameter of treated aneurysms was 5.3 cm (range, 4.0-6.5 cm). One patient had a symptomatic aneurysm with a 4.0-cm diameter. All of the analyzed demographic data are listed in Table I.

EVAR was done under general anesthesia in 49 patients (96.1%), and local anesthesia was used with two (3.9%). Patients that fulfilled clinical indication for aortic repair and morphological feasibility criteria for endovascular treatment (Heidelberg AAA Classification) were included in the retrospective study.

Patient selection. The inclusion criteria for EVAR were as follows: aneurysm diameter >50 mm, symptomatic or saccular aneurysm, aneurysm growing >5 mm/y, age <85 years, patient availability for future follow-up investigations, proximal neck diameter <28 mm, aortic neck length ≥15 mm, aortic neck angulation <60°, suitable iliac attachment zone, and suitable femoral access size ≥8 mm. If the femoral access site was ≤8 mm, an iliac conduit was performed.

The investigation excluded patients with rupture, paraaortic AAs, or bilateral hypogastric AAs.

Device selection. The anatomic suitability for EVAR was determined by computed tomographic angiography (CTA). Routine preoperative catheter angiography was not performed. Preoperative measurements of the aneurysm neck diameter were used for sizing the stent graft main body. Minimal oversizing of 5% to 8% was used. The implanting surgeon selected the graft, and graft length was chosen to avoid covering one hypogastric artery.

Deployment procedure. All procedures were performed in the operating room using a portable C-arm fluoroscopic device with digital imaging and road-mapping capacity. The device was inserted through a femoral cutdown or within a femoral artery <0.8 mm through retroperitoneal access with an iliac Dacron conduit.

Completion angiography at the end of the procedures confirmed successful deployment as well as adequate fixation and position of the endograft. If a type I endoleak was detected intraoperatively, further treatment (proximal cuff, iliac extensions) was performed during that operation. Type II endoleaks were primarily accepted without further treatment. Primary conversion to an open operation was indicated if safe placement of the endovascular device was difficult or impossible as a result of an anatomic peculiarity.

Image analysis. All patients underwent contrast-enhanced CTA before the intervention and postoperatively during the same hospital stay. Endoleaks were defined using the definition published by White et al.

The integrity of the wire form of the stent graft was analyzed using conventional radiographs and also by 3-dimensional volume rendering CTA (3D-CTA).

Follow-up. Patients underwent clinical examination, plain radiographs, and routine CTA checks before hospital discharge, after 6 months, and annually thereafter. Consecutive CT scans and radiographs were analyzed, and postoperative imaging and final imaging were compared.

Statistical analysis. Fisher exact two-tailed test (f test) and the log-rank (Mantel-Cox) were used to compare both generations of LifePath prosthesis using MedCalc (MedCalc Software, Mariakerke, Belgium).

<table>
<thead>
<tr>
<th>Variable</th>
<th>No (%)</th>
<th>Mean (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>Age, y</td>
<td>69.1 (58.84)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1 (1.96)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>50 (98.14)</td>
<td></td>
</tr>
<tr>
<td>Aneurysm size, cm</td>
<td>5.3 (4.0-6.5)</td>
<td></td>
</tr>
<tr>
<td>Symptomatic aneurysm</td>
<td>1 (1.96)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>45 (88.24)</td>
<td></td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>29 (56.87)</td>
<td></td>
</tr>
<tr>
<td>Pre-op renal insufficiency</td>
<td>8 (15.68)</td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>13 (25.5)</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>21 (41.18)</td>
<td></td>
</tr>
<tr>
<td>ASA I-II</td>
<td>17 (33.33)</td>
<td></td>
</tr>
<tr>
<td>ASA III-IV</td>
<td>34 (66.67)</td>
<td></td>
</tr>
</tbody>
</table>

ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease.

Table I. Demographics and comorbidities
RESULTS

Technically successful implantations were possible in 98% of the patients. One patient (1.96%) needed primary conversion caused by endograft limb misplacement, and another patient underwent an intraoperative corrective procedure (proximal cuff) for proximal sealing due to endoleak type I. The mean operation time was 135.2 minutes (range, 83-310 minutes).

Early outcome. No patients died during the 30-day observation period. One patient (1.96%) died during a hospital stay 68 days after the implantation procedure due to multiorgan failure after ischemic colon perforation.

The overall in-hospital morbidity including cardiac, pulmonary, renal, and neurologic events was at 9.8% (5 patients).

One patient underwent repeat intervention with implantation of a crossover bypass after iliac dissection. The patient with primary conversion showed severe complications with colon ischemia and additional peripheral embolization and required a colectomy and iliac bypasses.

Short-term imaging data. Before discharge, 92.2% of the patients underwent postoperative CTA. Primary endoleaks could be detected in 21.56%, consisting of one type I (1.96%) and 10 type II (19.6%) endoleaks. The patient with the proximal type I endoleak had a malignancy and refused a corrective procedure. The patient died 1 year after EVAR of causes not related to the procedure itself. Nine type II endoleaks were caused by lumbar arteries (17.65%) and one by an inferior mesenteric artery (1.96%). All were treated conservatively (Table II).

Late outcome. During the mean follow-up of 40.7 months, 12 of the 51 patients (23.5%) died. Their mean survival after endograft implantation was 22.8 months (range, 4-49.9 months). Six patients (11.8%) could not be located at the time of follow up. There was no difference in survival for the generation I and generation II patients (log-rank $P = .89$; Fisher exact test $P = .74$; Fig 1).

Four patients required reoperation during the follow-up period. One patient received thoracic endograft for a secondary thoracic aneurysm. One patient underwent femoral thromboendarterectomy for peripheral artery disease. Intervention was required for a chronic lymphatic fistula at the groin access site in one patient, and another patient required a toe amputation because of peripheral arterial occlusive disease that developed after primary conversion.

Long-term imaging data. A mean of four (range, 2-9) imaging controls by CT scan were performed. The 11 patients (21.5%) without further imaging after the hospital stay included one patient with primary conversion, one patient who died during the hospital stay, one patient with a type I endoleak who refused further treatment, and eight patients who died early after intervention or were lost to follow-up.

Endoleaks. The mean follow-up period of the patients was 40.7 months. Eight (25%) secondary proximal type I endoleaks (Table III) were observed, two of which were treated with interventional embolization, and two patients needed secondary conversion for treatment. Four patients with late contrast enhancement during CT analysis as a sign of proximal endoleak indicated relevant regression of the aneurysm sac and continue to be checked frequently. These patients were at high risk for a conversion operation or refused further treatment.

Two of the seven type II endoleaks were new in origin and required no further treatment. Compared with the 10 primary detected type II endoleaks, five occluded spontaneously without treatment.

Type III endoleaks developed in three patients (9.5%) at the leg docking area. One patient underwent successful endovascular repair, and the other two required a secondary conversion procedure during follow-up. A Kaplan-Meier analysis for freedom from endoleaks is provided in Fig 2. There was no significant difference between the occurrence in the two generations of stents for type I, II, and III endoleak.

A total of four (12.5%) secondary conversion procedures were necessary: two patients for type I and two patients for type III endoleaks (Table III).

Wire form fractures. We found nine patients (28.1%) with fractures in the wire form of the LifePath device. All were localized at the top of the main body, which is a well-known weakness of the device (Figs 3 and 4). Three of these nine patients with wire form fractures presented type I endoleaks. There was no difference in the occurrence of wire form fractures between the generation I and II devices (Fisher exact test, $P > .99$).

AAA sac regression. Sac regression during follow-up was documented in 27 of 37 patients (73%) with a follow-up imaging of more than 12 months. Seven patients (18.9%) demonstrated sac enlargement, including four patients presenting with type I endoleak and three with type II endoleak. Statistical analysis showed no significant difference in sac regression rate between the two LifePath generations (Fisher exact test, $P = .31$).
DISCUSSION

The study analyzed the long-term performance of Edwards LifePath AAA Endograft System. Compared with the encouraging midterm results, our long-term data for the LifePath system are poor, with a significant secondary type I endoleak rate of 25%, a type III endoleak rate of 9.5%, and a secondary conversion rate of 12.5%.

Long-term durability of EVAR is known to be highly dependent on the integrity of proximal fixation. Currently, most AAA endograft systems are based on SES systems, and it is generally accepted that they be oversized by 10% to 20%. The oversizing is needed to produce enough radial force to prevent proximal endoleak. As a result of oversizing, recent reports documented relevant neck dilatation rates of 28% and migration of the devices in 25% of cases for SES. Alternative implantation devices using a BES presented several advantages, such as exact deployment and good results in early-term and long-term follow-up. Malas et al presented data from the Montefiore Endografting System (MEGS), with an encouraging absence of neck dilatation and graft migration in their series. The MEGS System is Palmaz stent-based device with a polytetrafluoroethylene graft sutured to a metallic skeleton. It presents the only balloon-expandable alternative to the LifePath device. The MEGS system uses a different implantation principle (aortouniiliac with crossover bypass), and the construction provides the possibility of suprarenal stent graft fixation.

Taken together, BES-based prevention of proximal radial aortic neck stress occurs with minimal oversizing of only 5% to 10%. In this regard, a low rate of migration and endoleak occurrence after LifePath implantation was documented. The series by Dalainas et al reported a rate of aortic neck dilatation and migration for the LifePath device of only 7%. Remarkably, in two of these three patients, they also recognized type I endoleak development during follow-up.

Table III. Follow-up outcome

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. (%), or mean (range)</th>
</tr>
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<tbody>
<tr>
<td>Length of follow-up, mon</td>
<td>40.7 (1-91)</td>
</tr>
<tr>
<td>Follow-up mortality</td>
<td>12 (23.5)</td>
</tr>
<tr>
<td>Lost- to –follow-up</td>
<td>6 (11.8)</td>
</tr>
</tbody>
</table>

N = 32

Secondary endoleaks

Type I: 8
Type II: 2
Type III: 3

Secondary conversion

Type I: 2
Type II: 2
Type III: 2

Secondary correction

Endovascular

Type I: 2
Type II: 2
Type III: 1
Open: 3 (9.4)

Survival

Fig 1. Kaplan-Meier survival analysis for generation I (blue) and generation II (red) LifePath devices. For generation I, the standard error never exceeded 10%; for generation II, the standard error exceeded 10% after 24 months.
Harris et al\textsuperscript{14} also showed an absence of migration for the Lifepath system in their analysis based on the European Collaborators on Stent-Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) registry. In our series, the rate of primary endoleaks was remarkably high (20%), but mainly consisted of type II endoleaks. However, in contrast to the published data for midterm follow-up,\textsuperscript{4} we found a high rate of secondary endoleaks. Our oversizing rate was moderate at 5% to 8% and comparable with other authors\textsuperscript{3,5,8,10} and should not be the reason for the elevated complication rate. Nevertheless, eight patients (25%) from our series presented with proximal type I endoleaks, and four required treatment. It is notable that our institution-specific secondary type I endoleak rate for SES is 2\% to 3\%.

During long-term follow up, we saw three patients with late type III endoleaks, and they all required secondary intervention for treatment. One patient underwent an interventional correction procedure (endovascular limb implantation), and the other two required secondary conversion.

Wire form fractures are a well-known problem with the LifePath device.\textsuperscript{4,5} Although most fractures were without clinical consequence, migration or endoleaks were associated with these fractures in several cases. As result of early observations, the manufacturer strengthened the wire forms to reduce this complication.

Our series documented a high incidence of wire form fractures during long-term follow-up. Wire fractures were detected in both generations of the system without group-specific differences. Mostly the fractures were located at the three top wire forms, as previously reported. Association of type I endoleak and wire form fractures occurred in three patients.

Sac regression is an indicator for determining successful exclusion of the aneurysm from the blood flow. For the LifePath prosthesis, sac regression is reported to be higher than for all other devices, including self-expandable stents (84\% volume reduction in 1 year).\textsuperscript{4,5}

In our series, nearly 75\% of the patients showed a reduction in sac diameter, indicating successful aneurysm exclusion. Unfortunately, the CTA control showed seven patients had an enlargement of the sac. The enlargement was caused by secondary proximal type I endoleaks in four patients, and three patients showed type II endoleaks.

Some substantial limitations in our work need to be discussed. Our data demonstrates that only two-thirds of the patients regularly received a CTA check-up for detection of endovascular complications. All other patients ex-
ceeded intervals for CTA follow-up, so some patients with EVAR-associated complications may have been missed. Of the 18 patients (35.3%) who died or could not be located at the time of follow-up, no information was available in two-thirds about whether the death was aneurysm related.

CONCLUSIONS

In contrast to early reports on short-term and midterm results of the LifePath endoprosthesis, the long-term results in this series are poor. Clinical advanced outcome of the prosthesis on a wire form-based balloon-expandable system was not reproducible at long-term follow-up. The LifePath AAA Graft System was taken from the market in 2004 due to business decisions from Edwards. Our results underline that major construction problems are associated with both generations of the graft. Material fatigue (wire form fractures) of the Elgiloy stents (Elgiloy Limited Partnership, Elgin, Ill) provoked stent migration and an unacceptable rate of late type I endoleaks. Patients who underwent Lifepath endovascular aortic repair need regular and lifelong follow-up to prevent postprocedural complications.

AUTHOR CONTRIBUTIONS

Conception and design: SO, HS
Analysis and interpretation: DB, HV
Data collection: TK, SO, PK
Writing the article: SO, HS
Critical revision of the article: HE, DB
Final approval of the article: SO, HV, TK, PK, DB, HE, HS
Statistical analysis: SO
Obtained funding: SO
Overall responsibility: SO, HS

REFERENCES


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